COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Date: 9 September 2010 – LATE COMMENTS**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
General comments							
Italy (ISPRA)	There are no requirements or discussion on exclusion: in regard to that it should be noted that exclusion is a relevant regulatory tool. In the ICRP publications 103 and 104 it is stated that the main concepts associated with the scope of radiological protection regulations are termed "exclusion", "exemption" and "clearance". Regulators should consider application of the concept of exclusion to any exposure situation that is considered to be either uncontrollable or unamenable to control through regulation.				The concept of exclusion is covered in para. 1.31.		Comment: Issues deemed to be outside the scope do not need to be covered by the requirements
Italy (ISPRA)	Exemption and clearance requirements need more clarification in terms of criteria used (in particular in Schedule 1, which should therefore be revised). The concepts of exemption and clearance may be granted only if specified and clear conditions are met. In particular, the criteria for clearance should ensure that relinquishing control must, at least, not lead to an exposure situation that would fail to meet any of the conditions for exemption. Numerical values, which seem to be taken from Safety Guide RS-G-Í.7, before being established in the BSS, should be defiled through a broad and open international process.				Para 3.12 includes a requirement that cleared material does not again become subject to the requirements for notification, exemption or licensing. The numerical values in RS-G-1.7 were subject to 120 day comment period by Member States, and were approved by the IAAE Safety Standards Committees.		

Italy (ISPRA)	Chapter 4 concerning emergency exposure situation {Requirements 43 and 44). It is considered that (he optimization of protection strategy and the used reference levels, projected dose, residual dose and received dose should be further elaborated to provide a more effective guidance. This is a particular sensitive item in relation to the protection strategy to be embodied in emergency planning with the aim to reduce the risk of stochastic effects to the public in regard of that concepts included in the ICRP Publication n. 109 could be taken into account..			X	Guidance material in support of Chapter 4 is available in DS44
Italy (ISPRA)	Requirements for protection and safety (in particular for planned exposure situations) are structured mainly referring to registrants and licensees. It should be noted that, in many case, the same requirements apply also to any person or organization which submit a notification to the regulatory body (e.g. Requirements 9, 11, 12, 14, 24 etc.). For these cases, if could be adopted a formulation like "person or organization, registrants and licensees, or employers as appropriate, „...".		The text of para 2.40 has been modified to include “the person or organization responsible for facilities or activities for which notification only is required.”		
Italy (ISPRA)	With regard to protection of environment an effort to introduce indications on some instances would be useful.	X	Some additional explanatory information has been added to section 1		
Italy (ISPRA)	It is not clear if the exposure of aircrews should be treated as a planned exposure situation or an existing exposure situation- The treatment of this exposure needs to be clarified.		This is a decision for each Member State – see para 5.30.		
Kuwait ILO	The permanent mission is forwarding the reply from the general committee for the environment and that is after it revised the international standards set by the the IAEA.... 1. In what concerns the article (1), they find that the radiation from medical sources (which is the only source in Kuwait) is sent to the country of source (exporting country) according the the agreements signed between the Kuwait Ministry of Health (department of prevention and radiation) and the country to which the material is imported. And there are international agreements that it is the right of any country that doesnt want to deal with nuclear or radioactive waste resulting from nuclear activity (research based or for eneregy purposes or medical) to send these substances back to the exporting country to get rid of it or to recycle it either because the importing country is too small or if there is no appropriate storage or landfill		This comment is noted but no request is made for amendments to the text		

	for this type of waste in addition to the lack of experience and expertise in the handling of this kind of waste which can cause negative environmental and economic impact due to the hazardous nature of these substances and to ensure it's none-use for unhealthy purposes. 2. In reference to article (2) in that the government of Kuwait did not make a decision to develop a research centre and did not take a decision to develop an academic course in nuclear engineering, in this regard the countries of the cooperation council of the Gulf are in the process of studying the possibility to develop a project for a research center as part of the national center for the Arab Gulf Council for the prevention from hazardous resulting from radiation. The Kingdom of Saudi Arabia has presented a voluntary proposal for the development of such an initiative, and until today, this proposal has not yet been adopted noting that the Government of Kuwait is still studying this issue. 3. In reference to article (3), it was found that the BSS document does not address issues of safety and nuclear safety or safety of enterprises and nuclear and radioactive centers, the document only refers to the environmental safety (internal only, and workpalce environment and its surrounding which can be exposed to radioactivity) and this document refers to the quantity and amount of permitted exposure that workers can be exposed to in the workplace environment.		This comment is noted but no request is made for amendments to the text	X	The requirements in the BSS apply to all facilities and activities
Russia	Please be informed that Scientific and Engineering Center for Nuclear and Radiation Safety (SEC NRS) (a TSO of the Federal Environmental, Industrial and Nuclear Supervision Service of Russia) has reviewed the draft of DS379 and has no comments. Furthermore, the SEC NRS experts mentioned that the newly introduced concepts and approaches as compared with the previous revision of this document (1997) made no difficulties for understanding. They also pointed out that this very document completely depicted basic provisions of the "Code of Conduct on the Safety and Security of Radioactive Sources".		No action required.		

Trinidad & Tobago	**Comments on International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources.** 1) Relevance and Usefulness: are the stated objectives of the Standard appropriate, and are they met by the document? - This document is timely, appropriate and relevant in today's human activities and engagements. It is comprehensive and reflects the several inputs by the several related International Organizations, such as the IAEA, ILO, FAO, UNEP, etc. - With the proliferation of the use of radiation sources, it is imperative that proper guidelines and standards be established to guide the manner of usage. - The objectives of the document were achieved quite comprehensively and provide a clear framework for the safe use of radiation sources. 2) Scope and completeness: is the stated scope appropriate and is that scope adequately covered by the document? Re: 3.42: An emergency plan should also take into consideration the magnitude and extent of the consequences of the exposure. Re: 3.50(b): the effect of environmental impacts should be included. Apart from 3.42 and 3.50(b), the scope was sufficiently extensive to cater for the use of Radiation sources in all areas of human endeavors. 3) Quality and Clarity: do the requirements/guidance in the document represent the current consensus among specialists in the field, and are they expressed clearly and coherently? Re: 3(1), (d) and (e) - the line should read, "the use and handling of radiation…." The document was clearly written and provides a way forward on the use and handling of Radiation sources.	X X X	This comment is noted but no request is made for amendments to the text These issues are covered in more depth in chapter 4. Additional text has also been added to chapter 3 related to emergencies that do not need to addressed at a national level We feel that 'handling' is included within the term 'use'		

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Section 1: Introduction							
China Health Min (ILO)	1.4/line 10-12	"and that the detriment-adjusted nominal risk co-efficient, which includes all cancers and heritable effects, is approximately 5% per Sv1 "	"the detriment-adjusted nominal risk co-efficient" may be misapprehend.			X	We have used ICRP terminology
China Env.Min(ILO)	Para 1.6/6	So that radiation risks and health effects are reduced to the level as low as reasonably achievable.	To keep the consistent with the previous BSS and other international organizations.			X	Proposed wording change could cause some problems in relation to medical exposures. As this is introductory text, the BSS Secretariat agreed to make no further change
China Health Min (ILO)	1.9/8	"such as transnational emergency, the International Organization and" shall be followed "In some case".	In this case, the function of one government is exceeded.				Not clear what change is proposed

Italy (ISPRA)	1.18	After this paragraph the three categories of exposure should also be described.	The three categories of exposure are only quoted in the introduction. A text should be added to ensure completeness.			X	The structure of the BSS is based on exposure situations and not on categories of exposure. The categories of exposure covered by each of the three exposure situations are explained
Cuba	1.18. (i)	For the purpose of establishing practical requirements for protection and safety, these Standards distinguish between three types of exposure situations: planned exposure situations, emergency exposure situations and existing exposure situations [1]. Together, these cover all exposure situations to which these Standards apply: (i) A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source. Since provisions for protection and safety can be made before embarking on the activity concerned, the associated exposures and their probability of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations is by good design of installations,	The "appropriate capacitating and training of the personnel" results an important and basic role in the control of the exposures.	X	This is an important point that can be considered during technical editing		EDITORIAL REVIEW

		equipment and operating procedures and also by the appropriate capacitating and training of the personnel. In planned exposure situations, a certain level of exposure is reasonably expected to occur. If exposure is not expected to be delivered with certainty but may result from an accident or an event or sequence of events that are not certain to occur, it is referred to as 'potential exposure'.					
China Env.Min(ILO)	Para 1.18 (iii)	"Existing exposure situations include exposure to natural radiation and to residual radioactive material from past practices that were never subject to regulatory control or from a nuclear or radiological emergency after an emergency exposure has been declared ended" ***This paragraph does not describe clearly dose measurement for existing exposure situations, please re-consider the definition of existing.***	As the existing exposure situation, including natural background radiation, so there are two problems with the actual situation: First, how to measure existing exposure dose. Second, the public exposure and occupational exposure with the presence of cross, may make exaggerated existing exposure.				The detail requested is available in safety guides and is not appropriate for the BSS
China Env.Min(ILO)	Para 1.20	The dose constraint should be expressed according to the description to dose constraint in Para.230 of ICRP 2007 recommendations, "dose constraint is a level of dose above which it is unlikely that protection is optimized for a given source of exposure, and for which, therefore, action must almost always be taken.	A dose constraint, serving as an upper bound on the predicted dose in the optimization of protection, was set by the government or regulatory body, so registrants and licensees must comply with the dose constraint. In the IAEA IBSS (draft 3.0) publication, the implements for dose constraints have not fully been emphasized.	V	Para. has been significantly rewritten in line with other comments received.		Comment: This is explanatory text and not a strict definition. The definition in the glossary is consistent with ICRP 103

Italy (ISPRA)	1.20, 3.9 (d) and 3.30 (b)	in these paragraphs it is not used the concept of risk constraints for potential exposures. Some indications or advices should be added in the introduction and in the requirements. it should be clarified if, in the absence of risk constraints, a value between 20 and 100 mSv of projected effective dose should be adopted as reference level for potential exposures	Planned exposure situations give rise both to exposures that are anticipated to occur (normal exposures) and to exposures that are not anticipated to occur (potential exposures). It should be remembered that in the para. 6.1.3 of ICRP 103 a generic risk constraint of 2*1 C4 for year for workers and of 105 per year for the public are recommended.			X	This is guidance material that is not appropriate for the BSS
China Health Min (ILO)	1.22/17	"corresponding to approximately over 0.5% of stochastic effects according to the detriment referred to 1.4" shall inserted between "a year" and "would be".	"risk" is more visualized than "dose"	X	Too much detail for introductory text		
China Env.Min(ILO)	Para 1.23	Information provided on the risk of exposure to radon indicated that it should be highlighted the enhanced risk for smokers.		X	This has been added to the requirements in chapter 5		
Cuba	1.24/3	Dose constraints are also used in the optimization of protection of carers and persons exposed in biomedical research. Dose constraints are not applicable to **optimization of** the exposure of patients to radiation for diagnosis or treatment.	Dose constrain do not apply to the exposure to patients, but the exposure should be optimized (Requirement 38)	X	Editorial		Current text is correct
Cuba	1.26/4	In a global and long term perspective, protection of people and the environment against radiation risks associated with the operation of facilities and the conduct of activities — risks that may transcend national borders and may persist for long periods of time — is a key element to achieving	Protection of the environment against radiation risks is to be considered more than important to achieving equitable and sustainable development.	X	Text has been amended to increase emphasis on sustainability		

		equitable and sustainable development.					
China Env.Min(ILO)	Para 1.28	These Standards are aimed at governments, regulatory bodies, principal parties, other parties, and working groups, as specified in section 2, health authorities, professional bodies, and providers of specialized services such as technical support organizations.	To reach and keep the safety of a facility and an activity primarily rests with the sense of duty or working groups or teams and their initiative on the protection and safety, now just only having responsibility for safety on governments, regulatory bodies, principal parties, other parties in these standards, it is necessary to have the responsibility for safety on the working groups or teams within a licensee or registrant. And do in these standards, there may be a requirement on the working groups or teams.	X	Requirements for protection and safety also apply to workers – see 2.42 and Requirement 42		
Cuba	1.32	These Standards comprise basic requirements to be fulfilled in all activities involving radiation exposure. For certain facilities and activities, such as nuclear installations, radioactive waste management **activities and** facilities, **decommissioning** and the transport of radioactive material, other Safety Requirements, complementary to these Standards, also apply…	Decommissioning is missing and there are safety requirements that apply to it.		Editorial		List is not meant to be exhaustive
Cuba	1.38/	1.38. Section 3 sets out the requirements, in addition to those of Section 2, for planned exposure situations. Section 3 includes generic **and specific** requirements applicable to ~~**all categories of exposure**~~ **occupational exposure, public exposure and medical exposure**, and requirements for the safety of	Categories of exposure as defined in 1.33 include occupational exposure, public exposure and medical exposure.		Editorial		EDITORIAL REVIEW

		sources ~~and more specific~~ ~~requirements for occupational exposure, public exposure and medical exposure..~~					
Section 2: General Requirements for Protection and Safety							
Cuba	2.?? New para. In Req 1 or in Req 2	**The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals**.	This is a new and important requirement that appeared in the GS-R Part 1 and should be some how reflected in the BSS.	X	These issues are all covered in the BSS, but not in the same overarching requirement		
China SAWS (ILO)	2.6	The Standards shall come into force two years after the date of their adoption or acknowledgement, as appropriate, by the relevant Sponsoring Organization.				X	The current BSS states 'one year'.
Cuba	2.8 - 2.12	Requirement 1: Application of the principles of radiation protection Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied in all exposure situations.	From this requirement as well as the para 2.8 – 2.12 related to this requirement is not clear that the principle of limitation does not apply to medical exposure. Moreover when in the para 2.30 established that "The regulatory body shall establish appropriate requirements for the implementation of radiation protection principles specified in para. 2.8 to 2.11 for each exposure situation and adopt regulations and guides addressing protection and safety" there is not clarification on the non application of the dose limits for medical exposure..	X	The text of para 2.11 has been modified.		

China Health Min (ILO)	2.13	"Stochastic effects of radiation exposure" shall be alone as 2nd point of radiation risk (annotation 6, p23) to be added	Stochasic effects is the basic of health effects of "Dose Limits for Planned Exposure Situation (Schedule III, p126	X	The footnote has been deleted.		
Italy (ISPRA)	**2.14**	It is proposed to merge the two paragraphs-as following The government. shall ensure a system for adequate protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation. To this aim the Government shall establish and maintain an appropriate an effective regulatory and organizational framework for protection and safety and exposure situations. This framework shall encompass both the assignment and the discharge of governmental responsibilities and the regulatory control of facilities and activities that give rise to radiation risks. the national framework has to allow for the fulfilment of international obligations. The Government shall ensure such protection without unduly limiting the operation of facilities and the conduct of activities that give rise to radiation risk.]	There are some repetitions in the two paragraphs.	X	The text of 2.14 has been modified, and para 2.25 has been deleted.		
Cuba	2.2? New para. In Requirement 2	**The government shall establish responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities.**	The financial provisions for decommissioning and radioactive waste management are an essential safety requirement. According to the safety principles "Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally			X	The current text is the basic requirement for the management of waste. The more detailed requirements, including financial provisions are covered in the

			acceptable solutions for its long term management".				Waste Safety Standards.
China Env.Min(ILO)	Para 2.23	The government shall ensure that arrangements are in place for the provision of technical services related to protection and safety, such as personal dosimetry, environmental monitoring and ***quality assurance for them.***	Because "calibration of equipment" is only a part of "quality assurance". In addition, the suggested replacement is also consistent with the statement of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"			X	It is agreed that quality assurance is a very important aspect of providing a technical service, but the proposed additional text implies that the quality assurance for the technical services is itself a technical service. It is understood that the technical services must undertake quality assurance, and there is guidance provided on the quality assurance for such services (see).
Cuba	2.24	The government shall ensure that adequate arrangements are made for the safe decommissioning of facilities **[WS-R-5]** and safe management **[GS-R Part 5]** and disposal **[GS-R Part?]** of radioactive waste arising from	References should be made in these activities to the main requirements as it was done for transport requirements.	**X**	**editorial**		

		facilities and activities, and for the safe management of spent fuel.					
China SAWS (ILO)	Para 2.24	Suggest to replace “management and disposal” by “management”	“disposal” is included in “management”	**X**			
China Env.Min(ILO)	Para 2.24	Suggest to replace “management and disposal” by “management”	“disposal” is included in “management”	**X**			
Cuba	2.30.	The regulatory body shall establish ~~**appropriate**~~ requirements for the implementation of radiation protection principles specified in para. 2.8 to 2.11 for each exposure situation and adopt regulations and guides addressing protection and safety.	It is supposed that the regulatory body always should establish and enforce “appropriate” requirements. In other requirements the word “appropriate” should not be included, as for example in 3.70.		**Editorial**		
Cuba	2.31/8	The regulatory body shall establish a system for protection and safety that includes: (e) The regulatory functions relevant to emergency exposure situations and existing exposure situations, ~~**as necessary**~~ ;	Such functions should be established always and not “as necessary”.	**X**	**Editorial**		
Italy (ISPRA)	**2.36**	The regulatory body, in conjunction with other competent authorities, shall establish an appropriate system to establish,	The government regulatory body shall ensure the establishment of a system for [principal parties which have the prime responsibility for protection and safety (see Requirement 4)			**X**	**This is a clear responsibility for the regulatory body as it applies to facilities and activities**

Cuba	2.39	The regulatory body shall establish, implement, assess and strive to continually improve an effective ~~**protection and safety**~~ management system that ~~**is**~~ **should integrate safety, health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization.** ~~**aligned with its goals and contributes to the achievement of those goals**~~.	The use of terminology should consider other safety requirements. There is not "protection and safety management system". There is only one "management system" that should integrate safety, health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization [GS-R-3, para 1.8]	**X**	**Delete "protection and safety"**		
Section 3: Planned Exposure Situations								
China Env.Min(ILO)	Para 3.1 – 3.3	The planned exposure situations in Para 3.1 and 3.2, suggest: refer to BSS (1996) Para 201 such as 1 the use of radiation or radioactive substances for medical, industrial… 2 the generation of nuclear power… 3 the natural sources (NORM)…	The suggested arrangement is perhaps more reasonable			X		
China Env.Min(ILO)	Para 3.21		Here the descriptions should be consistent with the definition of constraints for the occupational exposure and public exposure in the glossary in these standards.	X	Editorial			
China Env.Min(ILO)	Para 3.4 (a)/5	To be deleted: or the activity concentration of the 40 K is greater than 10 Bq/g	Because 40 K is life element with the function of metabolism, it is unamenable to control it in human body. It should be directly excluded from these standards.			X	Text does not refer to K-40 in the human body. In waste residues, the concentration may exceed 10 Bq/g and in which case must	

							be treated as a planned exposure situation
Italy (ISPRA)	**3.4**	3.4. Exposure to natural sources shall be considered as an existing exposure situation and be subject to the requirements in Section 5, The requirements for planned exposure situations in Section 3 apply to the following exposures to natural sources: (a) any relevant activity where the concentration in the material of any radionuclide in the uranium and thorium decay chains is greater than 1 Bq/g or the activity concentration of ^K is greater than III Bq/g; in the application of the requirements for planned exposures situation a graded approach should be adopted in accordance with Requirement 6; (b) ……	The text of parag. 3.4 and sub-point (a) need to be reworded in order to make the formulation of the requirement more clear. Reference to activities quoted in para. 3.1 is also misleading. It should be observed that according the chapter 5 of RSG- Î .7 concerning the application of the values of activities concentrations for radionuclides of natural origin the graded approach as described in paras. 5.11-5.13 should be applied, it sbould be taken into account that scenarios were not used for calculating activity concentration values for radionuclides of natural origin rather, the values were based on consideration of the worldwide distribution of concentrations of radionuclides of natural origin Moreover, it should be taking in mind that three are cases where it is difficult to control industrial materials which exceed the concentration criteria.	**X**	Text has been modified based on all comments received.		
Cuba	3.5	No person or organization shall adopt, introduce, conduct, discontinue or cease a practice or shall, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, acquire,	According to the definition of "source" given in this document is still important to underline the exempted sources from these requirements. Otherwise all the sources should				Para 3.10 exempts practices and sources within practices from the

		import, export, distribute, loan, hire, receive, site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source within a practice except in accordance with the appropriate requirements of these Standards, **unless the source is exempted from the requirements of these Standards.**	comply with the present requirements.				requirements of the Standards. It is not necessary to include the proposed extra text in para 3.5.
China Env.Min(ILO	Para 3.7 /3	Notification alone is sufficient provided that the exposures associated with the practice or action are unlikely to exceed a small fraction, specified by the regulatory body, for example, the dose criteria of exemption level and clearance level, of the relevant limits, and that the likelihood and expected amount of potential exposure and any other detrimental consequence are negligible.	Only for easily understanding with the concept of a small fraction of the relevant limits.	X	This would be a regulatory decision and can be discussed further in guidance material		
China Health Min (ILO)	3.8	"no. 11" solely list and extensive content properly. Simultaneously, the differences between registration and licensing should be demonstrated unambiguously in the manage program instead of being juxtaposed completely.	4 typical practices that are amenable to registration are presented in footnote No11. It is recommended that these 4 typical practices be interpreted as a single item in DS379.			X	No substantive change has been requested
China Env.Min(ILO	Para 3.21 and Para 3.118	It is necessary to indicate the range of risk constraint	In order to apply the risk constraint in the optimization o protection and safety, definitude of the range of risk constraint is useful to practice.			X	Numerical values for constraints are not to be included in the BSS, but may be covered

							in Safety Guides.
Cuba	3.46 and 3.47	3.46 The registrant or licensee shall conduct an investigation as soon as possible after the event and prepare a written report on its cause, with a verification or determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events. **The registrant or licensee shall communicate to the regulatory body and to any other relevant parties as appropriate, this written report.** 3.47. ~~**The registrant or licensee shall communicate to the regulatory body and to any other relevant parties as appropriate, a written report of any formal investigation relating to events prescribed by the regulatory body, including exposures greater than a dose limit.**~~ Registrants and licensees ~~**also**~~ shall immediately **investigate and** report **to the regulatory body** any event where a dose limit is exceeded.	Para 3.46 should cover all the information related to the investigation and its written report. Para 3.47 should standing alone cover the information on any event where the dose limit is exceeded giving the importance that have such events.		**EDITORIAL REVIEW**		Comment: Proposed amendment could be problematic as reporting of doses above the dose limit should take place immediately and not await the outcome of an investigation. Current text covers all issues appropriately but the proposal, with some amendments, may be more elegant
Cuba	3.49	~~**Where applicable**~~ ~~r~~Registrants and licensees shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the regulatory body,	This is an important requirement. The use of the words “where applicable” gives the opportunity for an assessment and the justification for not		**EDITORIAL REVIEW**		

		and other relevant parties: (a) To obtain information on conditions of use and operating experience that may be important for protection and safety; (b) To provide feedback and information that may have implications for protection and safety affecting other users, or that may have implications for future improvements in protection and safety of radiation generators and radioactive sources.	comply with it. This requirement is very important for developing countries that use to import established technology and some how it establishes the obligation for asking and transmit the mentioned information.				
Cuba	3.54	Registrants and licensees shall **inform the regulatory body as part of the application for the authorization** ~~share~~ appropriate information from their radiation generator or radioactive source inventory records ~~with~~ **and maintain** the regulatory body **this information updated at intervals established by the regulatory body. Registrants and licensees shall share this information with** ~~or~~ other designated body when requested.	The statement "shall share" is too soft for this requirement. The regulatory body shall request this information as part of the application for the authorization. Without this information it is impossible to perform or review any safety assessment. In addition with the change of this information the conditions, limits and control impose in the authorization must change. This is why this information must be updated. Finally GS-R-Part 1 established in its "Requirement 35: Safety related records. The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities". 4.63 The regulatory body shall make	X	Change 'share' to 'provide' Para 2.36 of the revised BSS covers the text of GSR part 1: Req 35 and para 4.63.		

			provision for establishing and maintaining the following main registers and inventories: registers of sealed radioactive sources and radiation generators…				
Cuba	3.59	Registrants and licensees shall ensure that arrangements are made for the safe management and disposition of radioactive sources, including financial provisions ~~**where appropriate**~~, once they have become disused.	The statement "where appropriate" is doing this requirement not strong as necessary. In addition this statement contradict similar requirements in other IAEA Safety Requirements e.g.: GS-R- Part 5 Requirement 20: Shutdown and decommissioning of facilities…. In addition, assurance shall be provided that sufficient funds will be available to carry out shutdown and decommissioning. GS-R-1 Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel 2.33 Appropriate financial provision shall be made for: a) Decommissioning of facilities; b) Management of radioactive waste, including its storage and disposal; c) Management of disused radioactive sources and radiation generators; and d) Management of spent fuel.		EDITORIAL REVIEW		

Cuba	3.62	If it has been determined through the process specified in para. ~~3.60~~ **3.61** that a particular practice of human imaging is justified, then, such a practice shall be subject to regulatory control.	Should be reference to para. 3.61 instead of 3.60	**X**	All internal references will be cross-checked as part of the editorial review		
Cuba	3.71	The regulatory body shall establish and enforce ~~**appropriate**~~ requirements to ensure that occupational exposure from all authorized sources and facilities is limited as specified in Schedule III.	It is supposed that the regulatory body always should establish and enforce "appropriate" requirements. In other requirements the word "appropriate" should not be included, as for example in 3.70.	**X**	**editorial**		
Cuba	New para in Requirement 21	**Registrants and licensees and employers of workers shall establish monitoring programmes, which shall be sufficient to ensure that the requirements of these Standards regarding occupational exposure in planned exposure situations are satisfied. Registrants and licensees and employers of workers shall reports to the regulatory body in the established intervals on occupational exposure (including results of monitoring programmes and dose assessments).**	The "Requirement 20: Requirements for monitoring and recording of exposure" established that the regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposure in planned exposure situations. Nevertheless latter on in the "Requirement 21 on Responsibilities of employers, registrants and licensees for the protection of workers", there is not a world establishing such obligations for the Registrants and licensees and employers.			X	These are covered by Req. 24, and paras 3.95-3.101.
China Health Min (ILO)	3.87-3.91	1. Extend the description of controlled areas and supervised areas 2. Controlled areas should be given upper limit boundaries.	The classification of radiation work areas is determined by means of administrative procedures, and the interpretation about controlled areas and supervised areas should be				Interpretation of these requirements are covered by

			extended to put in practice conveniently rather than being described conceptive.				guidance material
Cuba	3.93	3.93 Employers, registrants and licensees shall, if appropriate in consultation with workers or through their representatives: (e) Designate**, ~~as appropriate,~~** a radiation protection officer according to criteria established by the regulatory body.	The use of the word and concepts "if appropriate", "as appropriate" is excessive. An example is the combination of the requirement 3.93 (e) with the requirement 3.95 which states "Registrants and licensees, in cooperation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace under the supervision of a radiation protection officer or other qualified experts as appropriate". The combination of these two requirements is not a well and straight forward requirement on a designation of a radiation protection officer and its responsibilities. In our opinion in the application of the requirements should be a graded approach and this is explained in the beginning of the standards. This means that is not necessary in each requirement the use of the word and concepts "if appropriate", "as appropriate" etc.	**X**	**editorial**		
Cuba	3.95	Registrants and licensees, in cooperation with employers **~~if appropriate~~**, shall establish, maintain and keep under review a programme for the monitoring of the	The same reason as in point 3.93, 3.100 and 3.101.	**X**	**editorial**		

		workplace under the supervision of a radiation protection officer or other qualified experts as appropriate.					
Cuba	3.97	Registrants and licensees, in cooperation with employers ~~**if appropriate,**~~ shall keep records, as appropriate, of the findings of the workplace monitoring programme which shall be made available to workers, where appropriate through their representatives.	The same reason as in point 3.93, 3.100 and 3.101.	**X**	**editorial**		
China Health Min (ILO)	3.100 / 1	"category A" instead of "any"	Using a clear word for remembrance easy			**X**	**The BSS does not categorize workers.**
Cuba	3.100 and 3.101	3.100 For any worker who is regularly employed in a supervised area or who enters a controlled area only occasionally, the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace or individual monitoring, ~~**as appropriate.**~~ 3.101 Employers shall ensure that workers who may be exposed to contamination, including workers who use protective respiratory equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed doses, ~~**as appropriate.**~~.	The same reason as above (in comment No 17). In addition the para 2.18 stated "The government shall ensure a graded approach to the control of radiation exposure, so that the stringency of regulatory requirements applied to any exposure situation is commensurate with the associated radiation risks". More over the para 2.32 established "The regulatory body shall employ a graded approach to the implementation of the system, applying requirements that are commensurate with the radiation risks associated with the exposure situation." And finally there is a specific	**X**	**editorial**		

			Requirement 6: Graded approach The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or source within a practice and with the magnitude and likelihood of the exposures.				
Cuba	Subtitle	***Health surveillance*** 3.107	Subtitle *Health surveillance* should be right before point 3.107 and not before the 3.106 as it is in the draft document.	**X**			
Cuba	3.120	The regulatory body shall establish and enforce ~~**appropriate**~~ requirements to ensure that public exposure from all authorized sources in planned exposure situations is limited as specified in Schedule III.	It is supposed that the regulatory body always should establish and enforce "appropriate" requirements. In other requirements the word "appropriate" should not be included, as for example in 3.70.		**editorial**		
Cuba	3.121.	Before authorization of a new or modified practice the regulatory body shall require, and review, the safety assessments (see paras 3.28-3.35) and other design documents from the responsible parties that address: the optimization of protection, the design criteria and the design features related to the ~~**normal**~~ **exposure** and potential exposure of the public.	The term "normal exposure" is not longer used in the BSS as it follows from the point 1.18 i) , therefore for coherence with point 3.109, it should be used 'exposure and potential exposure"	**X**			
Cuba	Requirement 31	Requirement 31: Radioactive waste and discharges The relevant parties shall ensure that radioactive waste and discharges of	In many countries there is already a specific regulation for the radioactive waste management that is more detailed than the BSS. Usually the authorization will not repeat			X	It was decided at a RASSC meeting that the phrase "of these Standards" would

		radioactive material to the environment are managed in accordance with **the requirements of these Standards and any other applicable IAEA standards and in accordance with** the authorization.	requirements established in the regulation in force and only will underline specific limits conditions and controls to be established by the licensee. This is actually stated in para. 3.130 a, but should be in the text of the requirement.				not be included in the overarching requirement. The phrase is used in para 3.130(a).
Cuba	3.130 b	Ensure, ~~**if appropriate,**~~ separate processing of different types of radioactive waste where warranted by differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste storage and disposal;	The segregation and classification of radioactive waste is a requirement from GS-R-part 5. Is not possible to say "if appropriate". Proper classification and segregation is one of the ways of minimization of radioactive waste.	X	editorial		
Cuba	3.130 c	~~**Ensure that radioactive waste predisposal and disposal activities are in accordance with applicable standards, and in accordance with their authorization;**~~	This is almost the same as the 3.130 a. If needed the 3.130 a could be complemented with the statement "radioactive waste predisposal and disposal activities are in accordance with applicable standards"	X	editorial		
Cuba	3.131	Registrants and licensees**,** ~~**in cooperation with suppliers**~~, in applying for an authorization for discharges, shall, as appropriate: …	In this point we do not see the need for the "cooperation with the supplier"			**X**	
China Env.Min(ILO	Para 3.132	The dose constraint should be the dose baseline to derive the authorized release limits.	The requirement should be coincident with the IAEA No. WH-G-2.3	X	Text has been modified.		

Italy (ISPRA)	**Req. 6**	Graded approach point	Essential provisions should be added to implement of graded approach principles; in establish such additional indications should be taking into account those relevant provisions contained in other IAEA Safely Guides (e.g. those provisions concerning the application of the values of activities. Concentrations of radionuclidcs of natural origin in paras. 5.11- 5T3 of RS-G-1.7.			X	This is appropriate for a Safety Guide, but not in a requirements document.
Italy (ISPRA)	3.48 line 1	…in cooperation with manufacturers and suppliers,...	Manufacturers and suppliers are in general two different parties, as also indicated in para. 2.41.	X	The text has been modified. The definition of suppliers include manufacturers. Where emphasis on the manufacturer is stated, the phrase "manufacturer and other supplier" is now used.		
Italy (ISPRA)	**3.69**	It is proposed to change the text as following. The regulatory body shall establish appropriate provisions for the application of requirements for occupational exposure in planned exposure situations by employers, registrants and licensees.	Responsibilities are established by the Government - The role of the Regulatory Body is to verify, through the authorization, the inspection and enforcement process that they are properly fulfilled.		**Editorial**		

Italy (ISPRA)	**3.118**	The government or the regulatory body Shall establish and enforce requirements that protection and safety are optimized for circumstances involving public exposure	In line with para, 3.70, it seems that the primary objective of government/regulatory body is that one to establish appropriate requirements on the optimization of protection and safety.	X	Text has been modified.		
Cuba	3.139	Suppliers of consumer products shall comply with the conditions of the authorization to supply such products, ensure that such products comply with the requirements of these Standards, and anticipate appropriate provisions for the service, maintenance and disposal of such products. The design and construction of these products, in relation to features that could affect the exposure of people during normal handling and use, as well as in the event of mishandling, misuse, accident or disposal, shall be subject to optimization of protection and safety. In this regard, designers, manufacturers and suppliers shall take into account:	This paragraph should be split in two. The first part related to the obligation of the suppliers to comply with the requirements of the present standard and the authorization for the distribution of the product. In other hand not all the suppliers need to be authorized considering that the product could be exempted. The second part is related to the obligations of designers, manufacturers and suppliers with the recommendation of this standard independent of having or not an authorization.		The text has been modified based on all comments received.		
Cuba	3.139	To add a new issue: **f) The way and form that the product should be dispose of.**	It is important that the designers and manufacturer since the design stage think and advise on the form and the way how these products should be disposed of.			X	Current text includes 'disposal' as a factor to be taken into account.

Cuba	3.148.	3.148. The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (including radiological medical practitioners, medical physicists, medical radiation technologists, and any other qualified experts with specific duties in patient protection) to take on the responsibilities specified in these Standards only if they: (a) are specialized in the appropriate area **as officially recognized by the relevant authority**; (b) meet the respective education, training and competence requirements in the radiation protection, in accordance with para. 2.33**, as recognized by the regulatory body;** (c) are named in an up-to-date list maintained by the registrant or licensee	The standards do not make a proposal on how should the regulatory body ensure the fulfilment of this requirement. One possible way to do that is the official recognition of competences or individual licensing by the relevant organizations.			X	Footnote 26 states this Para 2.33 makes the link to the regulatory body
Cuba	3.152	(d) For therapeutic uses of radiation, the calibration, dosimetry and ~~**quality assurance**~~ **management system** (including medical radiological equipment acceptance and commissioning) requirements of these Standards, specified in paras 3.165, 3.166(c), 3.168 and 3.169 are conducted by or under the supervision of a medical physicist; (e) For diagnostic and image-guided interventional uses of radiation, the	"quality assurance" is not more used. Should be changed by "management system". The same apply for 3.168 – 3.170			X	Management system is the umbrella. QA is used in the medical exposure part as a small component of the management system. To use management system would

		imaging, calibration, dosimetry and ~~**quality assurance**~~ **management system** (including medical radiological equipment acceptance and commissioning) requirements of these Standards…,					confuse.
Cuba	3.168	Registrants and licensees, as part of applying the relevant management system requirements of these Standards, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of the **radiological medical practitioners,** medical physicists, ~~**radiological medical practitioners,**~~ medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists, taking into account the principles established by the World Health Organization (WHO) the Pan American Health Organization (PAHO) and relevant professional bodies.	The "radiological medical practitioners" play the principal role in medical exposure as far as they are responsible for justifying the medical exposure to any specific individual.			X	3.168 lists the key players. The medical physicist is arguably the first of these.
Cuba	3.169/ new point	To inclue a new point: **(a) Prescription and follow up of the clinical aspects related to diagnosis or treatment.**	The "prescription and follow up of the clinical aspects related to diagnosis or treatment" is a specific task for the radiological medical practitioners			X	This is medical practice, not radiation protection specific, and outside the scope of the BSS.

Cuba	3.183 New para	**(f) Release of patient who has undergone a therapeutic procedure with sealed or unsealed sources and the radioactivity that they had incorporated.** **(g) Cases of the unintended or accidental medical exposure and includes the information specified in 3.179 (a) to (d).**	To add new records established in previous para or not considered before.	**X**	Text has been added	X	Include in a Safety Guide.
Cuba	3.183 d	3.183. Registrants and licensees shall keep for a period specified by the regulatory body and make available, as required, the following records: In radiation ~~**oncology**~~ **therapy**, a description of the planning target volume, the dose to the centre of the planning target volume and the maximum and minimum doses delivered to the planning target volume or alternative equivalent information on doses to the planning target volume, the doses to other relevant organs selected by the radiological medical practitioner, the dose fractionation, and the overall treatment time;	Radiation oncology is considered to be more restrictive that radiation "therapy", as far as the last includes the treatment of so called "not maligns diseases".	**X**			
Section 4: Emergency Exposure Situations							
Cuba	Requirement 43	Emergency management system The government shall ensure that an integrated and coordinated emergency management system is established and maintained **in the event of a nuclear or radiological emergency**.	Is out of the scope of the BSS to require the Governments to establish a "general" emergency management system". The BSS should be focused on radiological or nuclear emergency situations.			X	It was decided that the overarching requirement should be as short as possible. The detail is in the

							associated requirement – para 4.2 includes the proposed additional text.
Cuba	4.5 New para	The system shall provide for, inter alia, the following elements at the on-site, local, national and international levels, as appropriate **Error! Reference source not found.**:… **(k) Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation in a manner that allows their effective use under postulated emergency conditions. [GS-R-2 para 5.25]**	Somehow the system should identify and provide the resources needed for the emergency response.			X	The text includes "inter alia" – it was not meant to be complete - with a cross reference to GS-R-2.
China Env.Min(ILO	Para 4	Suggest to add one more Para about " optimization and rationalization principles of the emergency exposure" (refer to ICRP 109).			**??**		
China Env.Min(ILO	Para 4.8 (a), 4.8(b) and schedu le IV Table IV-I	a) Suggest to replace "……and dose that would be expected to be received, shall be developed" in Para 4.8 b) by "and residual dose, shall be developed." b) The expression –way for Table IV-I in Schedule IV needs further improvement.	The "Protective actions" given in the right side of Table IV-1 should be clarified more correct to avoid misunderstanding. Among the two "protective actions" given there, the second one (Immediate medical … …) depends on the internal exposure only indeed, but the first one (Precautionary urgent protective actions) depends on not only the external exposure, but also the internal exposure, that is the total	**X**	Text has been modified.	X	Table IV-1 refers to external and internal exposure, with clarification through footnotes.

			dose.				
Cuba	4.12	~~**The government shall establish a programme for managing, controlling and recording doses received by emergency workers.**~~	To be deleted considering that requires with the same wording the same as required by the Requirement 45.			x	Editorial. Repetition of text of overarching requirement in the associated requirements is permitted.
Cuba	4.15.	Response organizations and employers shall ensure that no emergency worker is exposed in excess of the maximum single year dose limit for occupational exposure specified in Schedule III except: (a) For the purpose of saving life or preventing serious injury; (b) If undertaking actions to prevent the development of catastrophic conditions; or (c) If undertaking actions intended to avert a large collective dose.	The use of the term "collective dose" should be clarify within the Standards in the light of the ICRP publication No. 103 that recommends: When the exposures occur over large populations, large geographic areas, o long time period, the total collective effective dose is not a useful tool for making decisions because it may aggregate information excessively and could be misleading for selecting protection actions.			X	This should be included in guidance material
Cuba	4.21	Following an emergency, workers undertaking remedial work, such as repairs to plant and buildings, **radioactive waste management,** ~~**waste disposal**~~, or decontamination of the site and surrounding areas, shall be subject to the relevant requirements for occupational exposure in planned exposure situations given in Section 3.	During emergency exposure situation as well as during existing exposure situation the radioactive waste are managed including disposal, when available.	**X**			

Section 5: Existing Exposure Situations							
Cuba	Requirement 47	Responsibilities of **the** government **and the regulatory body** specific to existing exposure situations	The para 5.4 and 5.5 under this requirement cover the responsibilities of the regulatory body			**X**	The title of the overarching requirement relates to the content of the overarching requirement, and the content does not include 'regulatory body".
Cuba	5.3 New points	The government shall include in the framework for protection and safety (see Section 2) provision for the management of existing exposure situations. The framework shall: **(e) Assign responsibilities for the identification and evaluation of existing exposure situations** **(f) Assign responsibilities for the establishment and implementation of appropriate financial provision (funding mechanism) for the implementation of remedial and protective actions in the case of past activities that were never subject to regulatory control or that were regulated, but not in accordance with these Standards**	To include a new item to comply with the Requirement 47 which establishes "The government shall ensure that a programme is established to identify and evaluate existing exposure situations…" To include a new item considering the needs for funding to implement the strategies for the management of existing exposures situations when past practices are identified.			X	(e) – the proposed text is not consistent with the change made to the overarching requirement. (f) this is covered by 5.10(a)

China Env.Min(ILO	Para 5.8	The annual effective dose to the representative person in the range 1~20mSv, the range is very roomy, Suggest: make detailed for the range.	In the Para 5, existing exposure situations, the annual effective dose to the representative person is in the range 1~20 mSv, and this range is very roomy. It needs to be divided into some sub-ranges.			X	This would be covered in Safety Guides.
Cuba	5.11	The government shall ensure that an appropriate waste management strategy**, as part of the national policy and strategy on radioactive waste management,** is established to deal with any waste arising from the remedial work and that provision for such a strategy is made in the framework for protection and safety.	It is important that such strategy will be coherent and consistent with the national policy and strategy on radioactive waste management.			X	National waste management policy and strategy is not mentioned in Section 2.
Cuba	5.12	(d) In the choice of the optimized remediation option: … (ii) The cost of transportation, ~~**handling, storage and disposal**~~ **management** of the waste, the radiation exposure of, and other risks to, the workers ~~**handling**~~ **managing** it and, subsequently, the exposure of the public associated with its disposal, are all taken into account;	"Radioactive waste management" is more than handling, storage and disposal.	**X**			
Italy (ISPRA)	5.22 and 5.23	Reference level of 1 mSv/y	A reference level of 1 mSv/y from each type of commodity seems too high. It is understood that it should be apportioned to each commodity. In regard to that the text needs therefore to be clarified. Furthermore, a contradiction seems to be present between para. 5.22 and 5.23 because,			X	The requirement states "generally not exceeding a value of around 1 mSv".

			for example, WHO for drinking water recommends a reference dose level of 0.1 mSv/y.				
Cuba	5.26	The employer shall ensure that the exposure of workers undertaking remedial work is controlled in accordance with the relevant requirements for occupational exposure in planned exposure situations given in section 3 **and para 5.14.**	The requirements reflected in the para 5.14 also concern to exposure of workers undertaking remedial work			**X**	
Schedule I – Exemption and Clearance							
Italy (ISPRA)	**1-1**	The general criteria for exemption are that: (a) the exempted practice has been determined to be justified; and (b) the radiological risks to individuals arising from the exempted practice or source within the practice are sufficiently low as to be of no regulatory concern (c) the exempted practice is inherently safe, with no appreciable likelihood of scenario that could lead to a failure to meet the criterion (b).	See comments on. I and 2. The text of para. I-l is very confused and need to be simplified and revised in order to clarify the worldwide well known general criteria for exemption. Moreover, the sentence "{b) Regulation of the practice or source would provide no net benefit, in that no reasonable control measures would achieve a worthwhile return in reduction of individual doses or risks/' is a rough application of the concept of exclusion			X	The text of (b) is consistent with the ICRP approach on the exemption of situations involving the exposure to NORMs. See paras 138 and 139 of ICRP Publication 104.
Italy (ISPRA)	**I-2 line 5**	Delete "To take account of low probability scenarios for which the above criterion fails, an additional criterion can be used, namely that the effective dose due to such low probability events does not exceed 1mSv in a year."	This sentence is in contras* with the general criterion that no appreciable likelihood of scenario could cause exposures that would fail the individual dose criterion.	X	The text has been modified.		

Italy (ISPRA)	1-4 and I-9 (b)	This paragraph should be revised in accordance with the revision of para. 3.4. letter (a).	The requirements contained in this paragraph are very confusing and in contrast with para. 3.4 letter (a). In the view on the application of graded approach for exposures arising from radionuclides of natural origin dose criteria could be introduced either for workers and for public. Dose criteria for clearance of Radionuclides of natural origin should also be adopted		The text of I-4 has been modified, and a footnote added referring to para 3.4(a).		
Cuba	I-6.	Exemptions may be granted subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form and to the use or disposal of the radioactive material. In particular, such an exemption may be granted for an apparatus containing radioactive material not otherwise exempted under para. I-3(a) provided that: (a) The equipment is of a type approved by the regulatory body; (b) The radioactive material ~~(i)~~ ~~I~~is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage~~, or~~ ~~(ii) Is an unsealed source of a small amount such as sources used for radioimmunoassay;~~ (c) In normal operating conditions it does not	It is not clear the intention and how to implement precept (b) (ii). What does amount mean and what does small amount means. If we understand as activity, then for instance the activity of a ^{125}I common source used in radioimmunoassay (370 kBq) complies with the paragraph I-3. (1000kBq). Notice that in the present BSS the point I-5 b) states that "the radioactive substances are in the form of sealed sources that effectively prevent any contact with radioactive substances or their leakage except that this should not prevent exemption of small quantities of unsealed sources such as those used for radioimmunoassay" ;				

		cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the apparatus; (d) Necessary conditions for disposal have been specified by the regulatory body.					
Italy (ISPRA)	**I-7**	Criteria for clearance should be revised	See comments on. 1, 2, 15, 16 and 17.				
Italy (ISPRA)	**I-10**	With reference to note 46 it has to be clarified if higher values than those defined in Table 1-2 could be adopted and more guidance on the development of clearance levels for specific type of materials should be provided.		X	Para I-10 has been re-written.		
Italy (ISPRA)	**III**	Equivalent dose limits to the lens of the eye	It should be taking into account that ICRP is currently being reviewed this limits.	X	RASSC agreed that the dose limit to the lens of the eye would be reviewed at the next RASSC meeting, when the ICRP report would be available.		
Italy (ISPRA)	III-6 - IITS	Values of the effective dose and absorbed dose organ or tissue per unit kerma ; dose coefficients and procedures for estimation of committed effective dose; conversion coefficients for radon and thoron	It should be taking into account that ICRP is currently being reviewed these data and procedures. Some provisions should be introduced in event that ICRP publication will be updated after the BSS publication	X	The values would be updated, subject to the approval of the IAEA Safety Standards Committees.		

Cuba	TABLE IV-2	GUIDANCE VALUES FOR RESTRICTING EXPOSURE OF EMERGENCY WORKERS Actions to avert a large collective dose	The use of the term "collective dose" should be clarify within the Standards in the light of the ICRP publication No. 103 that recommends: When the exposures occur over large populations, large geographic areas, o long time period, the total collective effective dose is not a useful tool for making decisions because it may aggregate information excessively and could be misleading for selecting protection actions..	X	Note added to definition of collective dose.		
Glossary							
Cuba		**contamination** *Radioactive material* on surfaces, or within solids, liquids or gases (including the human body), where its presence is unintended or undesirable, or the process giving rise to its presence in such places.	The establishment of values to define contamination, as the Transport regulations do, could be very useful in applying the Standards.	X	Para I-13 has been modified to allow clearance in terms of surface contamination, which would need to meet the dose criterion of I-11.		
Cuba		**effective dose, *E.*** Θ The unit of *effective dose* is the *sievert (Sv)*, equal to 1 J/kg. The *rem*, equal to 0.01 Sv, is sometimes used as a unit of *equivalent dose* and *effective dose*. ~~**This should not be used in *IAEA publications*, except when quoting directly from other publications, in which case the value in *sieverts* should be added in parentheses.**~~ Θ *Effective dose* is a measure of *dose* designed to reflect the amount of *radiation*	The sentence "This should not be used in *IAEA publications*, except when quoting directly from other publications, in which case the value in *sieverts* should be added in parentheses". Makes reference to and internal IAEA editorial requirement and it should not be included in a safety standard.	X	Text has been modified.		

		detriment likely to result from the *dose*.					
Cuba		**equivalent dose, *HT.*** Θ The unit of *equivalent dose* is the *sievert (Sv)*, equal to 1 J/kg. The *rem*, equal to 0.01 Sv, is sometimes used as a unit of *equivalent dose* and *effective dose*. ~~**This should not be used in *IAEA publications*, except when quoting directly from other publications, in which case the value in *sieverts* should be added in parentheses.**~~ Θ *Equivalent dose* is a measure of the *dose* to a tissue or organ designed to reflect the amount of harm caused.	The sentence "This should not be used in *IAEA publications*, except when quoting directly from other publications, in which case the value in *sieverts* should be added in parentheses". Makes reference to and internal IAEA editorial requirement and it should not be included in a safety standard.	X	Text has been modified		
Cuba		**exemption** The determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure (including potential exposure) due to the source or practice is too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks. ~~**Θ See also clearance.**~~	The sentence "See also *clearance*" should be removed. Exemption and Clearance are completely different concepts. Note that the definition of "Clearance" does not make reference to exemption.	X	Text has been modified		

Cuba		**remedial action** (modified) The removal of a *source* or the reduction of its magnitude **(activity and extend)** for the purposes of preventing or reducing *exposures* that might otherwise occur in an *existing exposure situation***.**	The magnitude of the source should be define for coherence.	**X**	To be reviewed during editorial review.		

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations **Page:** **Date: 9 September 2010**							
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
General comments							
EC		**There are many differences between the Euratom and international Standards, the resolution of which would benefit to harmonisation and better understanding of the different requirements. The Group of Experts will examine a draft document to that effect at their meeting on 3-4 June 2010 and the outcome of these discussions will promptly be forwarded to IAEA.**		X	noted		
Austria		IAEA issued a (draft) safety glossary policy on 17 March 2007 to which the attention of all IAEA safety standard committee members and Secretariat staff was directed (http://www-ns.iaea.org/committees/files/NUSSC/491/PolicyonSafetyGlossary13-03-2007.pdf). This policy explicitly prohibits the inclusion of a glossary in individual safety standard publications (such as DS379). Thus, the glossary in the DS379 draft should be deleted in accordance with this IAEA's policy and practice. In the case of terms that are used in a specific way in a particular standard, or for which new terms or modified definitions of existing terms are introduced in a particular standard, the specific definition is included in a footnote, not in a glossary (which is prohibited in individual publications).			EDITORIAL REVIEW	X	The IAEA has previously decided to include a glossary in the revised BSS
Austria		The use of the English language in several chapters or sections, most prominently in Chapter 1 and in parts of Chapter 3, is not sufficiently precise for an international standard document of such importance as the IAEA Basic Safety Standards, for which it is imperative that the wording is clear and unambiguous. For instance, the term "risk" seems to be used in three different meanings throughout the document (a) in general for any possible hazard to human health or safety, b) "risk" of harmful or injurious consequences due to exposure, as generally used by ICRP, and c) the product of the probability of an adverse event and the magnitude of the resulting consequences). This appears to be inconsistent with a clear definition of the term. The document will need to be reviewed carefully for this and similar imprecision in terminology and language. [It is to be noted that "risk" is defined in the IAEA Safety Glossary		X	This will be addressed the editorial review process		EDITORIAL REVIEW

	(2007).]					
Austria	In many cases, statements or requirements seem weak or imprecise. An International standard will not only be interpreted by radiation protection professionals, but also by legal practitioners, administrators and others who are not fully familiar with the scientific background. It is therefore imperative that the wording is clear and unambiguous. The current wording may, in parts, lead to misconception or misinterpretation.		X	This will be addressed during the editorial review process		EDITORIAL REVIEW
Austria	International standards, including those by the IAEA, generally use "shall" to denote requirements, while "should" indicates a recommendation. In this draft, the term "must" (e.g., in 1.7.) is used frequently to represent a requirement. This renders the document internally inconsistent. It is imperative that a standard document of such importance is clear and unambiguous.		X	This will be addressed during the editorial review process. The 'must' is para 1.7 is a direct quote from the Safety Fundamentals SF-1. Section 1 in the Introduction and does not contain any requirements.		EDITORIAL REVIEW
Austria	Use "activity concentration" rather than "concentration" throughout the document.		X	Where appropriate, this will be done		EDITORIAL REVIEW
Bahrain	In this regards, the Mission has the honour to inform you that the revised safety standard has been revised by the competent authorities in the Kingdom of Bahrain, and they not have any comments in this document,		X	Noted		
Belgium	Add a section on the applications of ionizing radiation in veterinary medicine (similar to the section on medical exposures).	The protection of the animals that are exposed is not dealt with. One should also think about the application of the justification principle to the practice of veterinary nuclear medicine and veterinary brachytherapy.			X	The protection of animals in veterinary medicine is outside the scoope of the BSS
Bulgaria	1, The revision of the IBSS takes account of all subsequent developments in radiation safety, including the 2007 Recommendations of the International Commission on Radiological Protection (ICRP Publication 103). The new IBSS makes allowance for the ICRP		X	Noted		

	recommendations, in particular the distinction between three exposure situations; planned, emergency and existing exposure situations. Thorough re-structuring of the BSS-1996 has been made. The IBSS offers appropriate levels of protection to workers and to members of the public against the dangers of ionizing radiation. The basic safety standards and principles of radiation protection (justification, optimisation and dose limitation), which also have been incorporated in the fundamental safety principles published in the IAHA Safety Standards, are laid down comprehensively, The IBSS maintains the classification of controlled and supervised areas and the categories of workers. The stated objectives and scope are appropriate and they are met and adequately covered by the document DS379 (draft 3.0). The requirements/guidance in the document are expressed clearly and coherently. There arc no objections among specialists in the radiation protection field. The new IBSS formal better differentiates the requirements so as to facilitate the various uses of the standards within the regulatory framework, These uses include their incorporation into or referencing in national regulations and as source material for review purposes.				
Bulgaria	7. The IBSS has developed the concept of a graded approach to regulatory control, so that it is commensurate with the risk and with the effectiveness of such controls. The system of regulation is based on the concepts of notification, registration and licensing. The graded approach and the harmonisation of national authorisation regimes are welcome (in the light of current national systems).	X	Noted		
Bulgaria	8. With regard to the management of emergency exposure situations, the former approach based on intervention levels has been replaced by a more comprehensive system comprising; - overall emergency management system; - preparedness and response to an emergency, protection strategy; arrangements for exposure of emergency workers; - criteria for use in emergency preparedness and response. In line with (CRP Publication 103 each strategy should aim at keeping doses below a reference level, optimising the available protective actions rather than jus tifying each action on the basis of intervention levels. The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.	X	Noted		
Bulgaria	9. The European Commission has undertaken the simplification of Community legislation in the area of radiation protection and has proposed the consolidation into a single text of the	X	Noted		

	following Directives: • Council Directive 96/29/ Euratom of 13 May 1996, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, • Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure. • Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency. • Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas, • Council Directive 2003/122/Euratom of 22 December 2003 on the control of high activity sealed radioactive sources and orphan sources. The Article 31 Group of Experts has revised and recast the Basic Safety Standards Directive 96/29/Euratoin taking into account the ICRP Publication 103 (2007) and the IAEA draft of the new IBSS (DS379). The work of this Group of Experts resulted in the draft Euratom Directive (Euratom Basic Safety Standards) laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (last version from 24 February 2010). A consolidation between the new IBSS and the new Euratom Basic Safety Standards (BBSS) should be achieved. Throughout the development of the revised International Basic Safety Standards (IBSS) and the revised and recast Euratom Basic Safety Standards (EBSS) there has been good cooperation in order to ensure their consistency to the largest possible extent. To a very large extent the Euratom and international standards are consistent. There are no essential points that are in contradiction. Numerical values are all the same, with the provisional exception of the definition of High Activity Sealed Sources, pending further consideration of the rationale of the two sets of values. Nevertheless, there are some differences between IBSS (draft 3,0) and EBSS (draft 24.02.2010). While both organisations (IAEA and EC) started from ICRP Publication 103, they have given a slightly different interpretation to the introduction of planned, existing and emergency exposure situations in structuring the requirements. This does not matter too much since the main message of ICRP was that throughout the exposure situations the principles of				

	radiation protection apply very much in the same way. Nevertheless, the allocation of responsibilities and the extent of regulatory control have been addressed in different ways for some situations, especially for exposure to natural radiation sources. The comparison between IBSS (draft 3.0) and EBSS (draft 24.02.2010) shows that their structure is different. EBSS (draft 24.02.2010) is structured along the categories of exposure, occupational, medical and public, within which the differences in management along the exposure situations are reflected. This inversion of the matrix has no implications on content, but makes the comparison of the two standards more difficult. The requirements included in IBSS (draft 3.0) and EBSS (draft 24.02.2010) use a different set of definitions. The concept of "facilities and activities" in IAEA is reflected in the definition of "Undertaking" in Euratom BSS. The latter definition incorporates better the concept of legal responsibility for the conduct of activities or the introduction of a radiation source. The term "radiation source" has a very general meaning in the Euratom BSS (including "facilities") and is further differentiated between radiation generators, radioactive sources, natural radiation sources. This allows a more precise formulation of the requirements where the term "source" may because of confusion. The terminology of the Euratom Standards has been adjusted to the international standards on one important point. The requirements for regulatory control arc now structured along the concepts of notification, registration and licensing (as opposed to reporting and prior authorisation in Directive 96/29). The more important differences between IBSS (draft 3.0) and EBSS (draft 24.02.2010) are related to the approaches to natural radiation sources and in the application of the concepts of exemption and clearance, especially for naturally occurring radionuclides.				
Bulgaria	As a whole, the NRA concludes that the objectives of the new IBSS (DS379 - draft 3.0) are achieved and that it will allow more coherent and more comprehensive radiation protection across all exposure situations and categories of exposure.		X	Noted		
Costa Rica	See file containing comments. These were submitted in Spanish and have therefore not been included in this Table.					
Czech	I have a problem with the headings used in whole text. There is main heading using bold letters, then we have a kind of inter heading not in bold and then we have requirements , which have a kind of title and than the requirements itself – it seems	Better understandability of the text.	??	EDITORIAL REVIEW		

	to me very confusing , moreover the title of requirement is very often not very well fitting. I recommend to delete the titles of requirements.					
Denmark	*Structure and format* There is a structural problem created by following the three ICRP exposure situations. This makes the Standards difficult to read and follow, as compared to the draft Euratom Basic Safety Standards which are structured basically on the categories occupational exposures, exposures of the patients and exposures of the general public.					Comment: There was a policy decision made to follow the format of ICRP 103
Denmark	*Balance:* Detailed requirements are given for some topics which could preferably be moved to guides or appendices (*e.g. occupational exposure* with details of designation of areas, protective aprons, etc.). At the same time, due reference to important standards and requirements for other topics are not given (*e.g. Emergency Exposure Situations: GS-R-2 is only referred to, without any comment on what it contains and how those requirements complement the BSS).* Some numerical values are given in Schedules and others are not (e.g. Schedule II, D-values)	The different chapters of the draft are still not balanced. Some of the problems are due to the objective to keep the standards as a "*stand-alone document*" while simultaneously following the IAEA Safety Standards scheme.				Comment: Unfortunately the document does have to be *stand alone*, and this does result in some compromises that might not otherwise be necessary
Denmark	*Glossary*	The draft 3.0 International BSS was sent out without a complete glossary. This, in fact makes it not possible to determine the exact scope and limitation of some statements.	X	This will be addressed during the editorial review process		EDITORIAL REVIEW
Denmark	*Three exposure situations*	The difficulties in applying the new process-based exposure situations to all types of activities involving ionising radiation unfortunately results in unclear requirements. The three exposure situations are not sufficient for categorization of exposures and the different				Comment: There was a policy decision made to follow the format of ICRP 103

		approaches to those concerning justification and optimisation gives unnecessary problems. One example is the protection of aircrew.				
Denmark	*Education and training:* More emphasis should be given to the important section in chapter 2 on education and training if the International BSS is expected to be a "*self standing*" document. More specific and detailed advice on the requirements on education and training and on competences and duties for the *qualified expert* and the radiation protection officer should be given, both for operators and authorities. Qualified expert, although defined, is little used in the document.			EDITORIAL REVIEW		
Denmark	*Security and safety of sources:* Security as complementary to safety should be highlighted and it should be reflected in the International BSS with appropriate security requirements included and not only in the parallel Security Standards series (chapter 3).		X	Noted		
Denmark	*References:* When a reference is given in the text to another section or paragraph it is helpful to give (in addition to the number) a short notice on the content of that section/paragraph.		X	This will be addressed during the editorial review process		EDITORIAL REVIEW
Denmark	*GS R-2:* It is proposed to either insert parts of the GS R-2 into the International BSS or to make more extensive reference to the requirements of GS R-2. This proposal is made especially in view of the completeness and "*stand alone*" of the document.	The concept of averted dose is used in emergency planning and still appears in the IAEA standards GS R- 2 on emergency preparedness. It is proposed to either insert parts of the GS R-2 into the International BSS or to make more extensive reference to the requirements of GS R-2. This proposal is made especially in view of the completeness and "*stand alone*" of the document.				
Denmark	The paragraphs on public exposure contain several "*as appropriate*"! The necessity of this frequent use should be further analysed.		X	This will be addressed during the editorial review process		EDITORIAL REVIEW
ENISS	We appreciate the improvement of Draft 3.0 in comparison to the former draft. Again, we acknowledge the acceptance of several comments made by our group with respect to Draft 2.5. e.g. the changes of the provisions on environmental protection and the extension of				X	This is a difficult issue – to subject something to a "process of

	the provisions on clearance with regard to other pathways for the cleared material as e.g. the use as construction material, reuse of metals or landfill of waste. However BSS draft 3.0 is still a very comprehensive document containing a lot of requirements which sometimes have more the character of a guidance rather than of a requirement. The use of footnotes may be reconsidered in that way that either its content could be incorporated in the main text or into the glossary. We believe that the proposed changes in the glossary are helpful for a better understanding. The treatment of the optimization issue has not been modified according to our proposals. We still believe that this is a crucial item for the implementation of radiation protection in practice. The principle of optimization based on ICRP 103 is correctly described in the introduction section as a process, see in particular para. 1.14. In the main text of the BSS optimization has often been reduced to the misleading phrase "to ensure that protection is optimized" (for instance para. 2.10). This could create difficulties in practice as there are no clear criteria for the "optimized solution". As we believe, there is no principal difference among the RP experts about the optimization principle. So, we suggest changing the corresponding formulations. Individual source-related restrictions (dose constraints) are given still too much emphasis within the system of protection and safety. Setting dose constraints is only one tool in the optimization process and dose constraints are not necessary in all cases and for all sources of radiation. Details for setting dose constraints should be addressed in safety guides and not as requirements in the BSS. Setting dose constraints for occupational exposure is the responsibility of the licensee or the employer and the current draft is not consistent in this aspect with the definition of dose constraint in the glossary (see para. 3.21). The Chapter 4: "EMERGENCY EXPOSURE SITUATIONS" is not clear. In particular, it should be defined more clearly the use of dose quantities (Residual Dose, Projected Dose, Averted Dose), reference levels and intervention levels. In particular, it is unclear whether the reference levels are to be used only after an emergency or in the preparation of emergency plan. Detailed remarks and proposals for changes (in red letters) in the text see below.				optimization" will not necessarily result in optimization being achieved. Equally, when there is a requirement for something to "be optimized" it will never be possiblr to show definitively that the strategy or solution is indeed the optimized outcome. This is why the definition in the glossary refers to optimization being a process. It may not be ideal, but there are arguments on both sides that can only be discussed and explained in a safety guide. The text has been amended to make it clear that dose constraints for occupational exposure are the responsibility of

					the operator. Other comments are addressed under the specific paragraphs to which they refer
FAO	• The document is thorough, comprehensive and logical. • Food irradiation is an important technology for the food industry as it is useful in ensuring quality and safety through control of organisms that cause food-borne diseases, as well as in reducing food losses due to spoilage and deterioration. The document on Basic Safety Standards is therefore of critical importance to the industry as it provides guidelines on the safe use and operation of radiation facilities and methods. It is important to underscore the need for competent authorities to take necessary and effective actions to ensure implementation of the guid	X	Noted		
Finland	*Structure and format* There is a structural problem created by following the three ICRP exposure situations. This makes the Standards difficult to read and follow, as compared to the draft Euratom Basic Safety Standards which are structured basically on the categories occupational exposures, exposures of the patients and exposures of the general public.				See comments to Denmark
Finland	*Balance* The different chapters of the draft are still not balanced. Some of the problems are due to the objective to keep the standards as a "*stand-alone document*" while simultaneously following the IAEA Safety Standards scheme. Detailed requirements are given for some topics which could preferably be moved to guides or appendices (*e.g. occupational exposure* with details of designation of areas, protective aprons, etc.). At the same time, due reference to important standards and requirements for other topics are not given (*e.g. Emergency Exposure Situations: GS-R-2 is only referred to, without any comment on what it contains and how those requirements complement the BSS).* Some numerical values are given in Schedules and others are not (e.g. Schedule II, D-values)				See comments to Denmark
Finland	*Glossary* The draft 3.0 International BSS was sent out without a complete glossary. This, in fact makes it				See comments to Denmark

	not possible to determine the exact scope and limitation of some statements.				
Finland	*Three exposure situations* The difficulties in applying the new process-based exposure situations to all types of activities involving ionising radiation unfortunately results in unclear requirements. The three exposure situations are not sufficient for categorization of exposures and the different approaches to those concerning justification and optimisation gives unnecessary problems. One example is the protection of aircrew.				See comments to Denmark
Finland	*Education and training* More emphasis must be given to the important section in chapter 2 on education and training if the International BSS is expected to be a "*self standing*" document. More specific and detailed advice on the requirements on education and training and on competences and duties for the *qualified expert* and the radiation protection officer should be given, both for operators and authorities. Qualified expert, although defined, is little used in the document.				See comments to Denmark
Finland	*Security and safety of sources* Security as complementary to safety should be highlighted and it should be reflected in the International BSS with appropriate security requirements included and not only in the parallel Security Standards series (chapter 3).				See comments to Denmark
Finland	*References* When a reference is given in the text to another section or paragraph it is helpful to give a short notice on the content of that section/paragraph.				See comments to Denmark
Finland	*GS R-2* The concept of averted dose is used in emergency planning and still appears in the IAEA standards GS R- 2 on emergency preparedness. It is proposed to either insert parts of the GS R-2 into the International BSS or to make more extensive reference to the requirements of GS R-2. This proposal is made especially in view of the completeness and "*stand alone*" of the document.				See comments to Denmark
Finland	The paragraphs on public exposure contain several "*as appropriate*"! The necessity of this frequent use should be further analysed.				See comments to Denmark
France	The BSS Structure The added value of some overarching items is not convincing. These overarching items extend the length of the text in adding 52 requirements: should we keep or delete the associated	X	Some associated requirements are indeed redundant		Comment: This is the agreed structure for IAEA

	requirements when they are redundant (sometimes redundant with the overarching: i.e. R.18 with 3.160). The overarching requirements shall not be taken out of context and become a specific document such as the one currently on IAEA web site			and can be deleted		requirement standards with which we must comply
Germany	The term "qualification" is used in different paragraphs related to education and training. This term needs to be defined in the glossary.					EDITORIAL REVIEW
Germany	According to Para. 1.14, it is important to stress that optimization is a **process,** which means that the requirement "is optimized" covers primarily the **process** of optimization which results in the optimized solution. Therefore further clarification concerning the use of the terms "optimisation" and "be optimised" is still needed to make sure, that the requirements for "be optimised" cover the **process of optimisation** and the result of **that** process.		X	Noted EDITORIAL REVIEW		Comment: see response to ENISS and glossary definition
ILO Finland (AKAVA)	Maximum occupational exposure to radiation quoted in the BSS draft, of 150 mSv and that for 16 to 18 years old of 50 mSv is too high. For members of the public, the maximum exposure should be 15 mSv a year.	STUK – the Radiation and Nuclear Saftey Authority, Finland has been applying this guideline since 2007.			X	Values are consistent with ICRP. Member States are free to adopt lower values if they so desire
ILO Finland (AKAVA)	The share of cataracts caused by ionising radiation in medical use is unknown Taking account of people's exposure of their own accord (flight journeys, alpine skiing), there is no reason to decrease exposure limits, although lower levels could still be striven for. However, in reducing occupational exposure, technical solutions play a key role and cannot be influenced through medical examinations.	In Finland, cataract surgery performed due to opacity of the lens of the eye is mainly due to the impacts of ageing, ultraviolet radiation (sunlight, welding at work, sunbeds) and certain medications (cortisone). The organization finds the national maximum exposure limit sufficient, because clinical radiology has moved on from radioscopic technology, where the person looks directly through a screen, to image transfer chains and radioscopy that do not cause exposure to the examiner. Likewise, mass inspectors for tuberculosis, based on film recording, have been abandoned.	X	Noted		Comment: Dose limit in revised BSS will be reviewed based on ICRP report due before end 2010
ILO Finland	Radon in most Nordic countries	(a) In Finland, examination of occupational exposure to radon forms part of the workplace	X	Noted		Comment: No argument with

(AKAVA)	(a) Uniform policies should be followed as regards exposure. (b) Stricter national policies would be justified. c) The measures should be targeted not only at the planning of premises and ventilation but also at decision-making procedures concerning the type of land areas on which workplaces and residences are built.	survey carried out by occupational health care, taking account of local conditions. The maximum acceptable exposure is 400Bq/cubic metre and 200 Bq in residential premises, but the aim is to lower this to 100 Bq. The instruction for new buildings is that, during the heating season, the radon content per cubic metre of air should not exceed 50 Bq. (b) Considering the connection between radon and lung cancer. Research indicates that lower exposure to radon among the population would result in a significant decrease in the occurrence of lung cancer. (c) The key issue is not to lower occupational exposure but to decrease total public exposure.				the points made; member States are expected to adopt more stringent requirements where this is necessary/justified
ILO Finland (Trade Union)	It would be better if the draft included instructions on how liabilities should be divided whenever impacts extend across borders.	Although the BSS is clearly outlined, the requirements applicable to certain radiation activity are given in different chapters, which means that operators must familiarise themselves carefully with the entire standard. Since the draft does not include any sanctions for failing to comply with the regulations, financial, insurance-related and penal issues and liabilities must be resolved at national level.				Comment: There was a policy decision made to follow the format of ICRP 103. Penalties are indeed a national issue, but the issue can of course be discussed in a safety guide
ILO Japan (business federatio	The revision of BSS should harmonize the requirements for the control of all public exposures related to planned exposures, medical exposures and existing exposures.	Public exposures to nuclear facilities: Dose limit (1mSv/y) > Dose constraint and Operational limit are required. Medical exposures: No dose limit. Public				Comment: The philosophical approach of the ICRP is to

n)		exposures to indoor radon: Reference level for dwellings is 300 Bq/m3 (equivalent to 10mSv/y), an annual average radon concentration.				differentiate between the different types of exposures and how they are dealt with. For example, it is not appropriate to restrict doses from medical exposures to the same level as public doses from planned exposure situations – this would result in no useful clinical information being obtained.
ILO Japan (business federation)	Requirements should be carefully screened according to priority and should be more concise.	There is an imbalance in the number and details of the requirements for occupational exposure, medical exposure, existing exposure situations. There are 75 requirements for the nuclear industry (occupational exposure plus public exposure), while there are 41 for medical exposures or 31 for existing exposures.	X	Noted		
ILO Mauritius (Min of Labour)	The draft BSS 3.0 is fully supported as it would help countries in improving and further consolidating radiation protection and radiation safety matters.		X	Noted		
ILO Mauritius (Min of Labour)	All important environmental aspects have been taken into account in the proposed draft BSS.		X	Noted		
ILO	The draft BSS 3.0 meets all necessary Safety Standards.		X	Noted		

Mauritius (Min of Labour)					
ILO Mauritius (employers)	The requirements for the implementation, monitoring, evaluation and control of the draft BSS 3.0 are too stringent for the country's present level of economic development.	X	Noted		Comment: The BSS allos sufficient flexibility to allow governments and regulatory bodies apply a graded approach and to prioritise those situations that represent the highest level of hazard and/or risk
ILO NZ (trade unions)	The NZCTU endorses actions to improve health and safety practices for all workers. The NZCTU notes that international evidence shows a positive association between effective employee participation in health and safety practices and reduced workplace injury rates. While the draft standard includes worker participation in the safety framework under *Section 2.51 Safety Culture*, this is not given sufficient prominence to ensure effective working arrangements. The NZCTU suggests that worker participation should be included with other safety principles in Introductory *Section 1.5*, in *Section 1.10* and subsequent sections. Worker participation in the safety operations should include: • Adequate training and information; • Opportunities to investigate and communicate with other workers; • Channels for dialogue with management on problems and on plans to address them; Opportunities to participate in decisions on health and safety systems. NZCTU recommends the explicit inclusion of worker participation in the safety framework to better ensure the successful vigilance at all levels of safety awareness in the industries and sectors using ionising radiation	X	There are a number of paragraphs dealing with these issues: See paras: 3.76(h), (j), 3.78, 3.79, 3.81, 3.82, 3.86, 3.109		

ILO NZ (Dept of Labour)	Having read the NZCTU comments on this document, the prospect of worker inclusion in safety systems is to be welcomed. However a *caveat*; in any highly technical area such as the amelioration of adverse effects of ionising radiation on workers, safety and safety protocols are best left with those sufficiently qualified to create them. Of course every attempt should be made to phrase protocols in language that is easily understood by the layman and where possible verbal explanations should be available to those who require them. Other NZCTU suggested alterations are semantic by nature and do not substantively change technical aspects of the document.		X	Noted		
ILO NZ (Dept of Labour)	Further work may later be required to harmonise IAEA Safety Standards with class 7 of the HSNO Act (1996)..	Currently radioactive substances (class 7) are exempt from HSNO and their utilisation is administered by the National Radiation Laboratory				Comment: This appears to be a national issue
IRPA Germany	The BSS draft 3.0 has further improved. Some of the comments of IRPA societies regarding Draft 2.5 have been accepted. The new structure with highlighted requirements is appreciated. The main issues of the BSS are well defined and documented. Especially the new provision I-10 in Schedule I and Footnote 46 take now account of a proven practice in a number of Member States to release contaminated materials for e.g. recycling, landfill or incineration. A 1 mSv criterion for low probability scenarios is now included. This reflects the existing and potential situation of clearance of materials and sites much better than the 1 PersSv criterion for the collective dose. The possibility of clearance under certain conditions is now included; specific clearance of metals, building rubble and waste for landfill is explicitly listed. The possibility of specific clearance solutions has a particular significance, as many materials mainly during the decommissioning of nuclear facilities are cleared in these specific ways. The additional parts to radiation protection of the environment also reflect now the fact that a general international framework about protection of the environment and Environmental Impact Assessments already exists and a framework on protection of non-human species will be developed under the leadership of the ICRP. There are still some points which have to be mentioned. We still believe that, according to 1.14., it is important to stress that optimization is a **process,** which means that the requirement “is optimized” covers primarily the **process** of optimization which results in the optimized solution. Therefore further clarification concerning the use of the terms “optimisation” and “ be optimised” are still needed to make sure ,that the requirements for “ be optimised” cover the		X X X	Noted Noted Noted		Comment: The definition in the glossary states that optimization is a process

	process of optimisation and the result of **that** process. Detailed remarks and proposals for changes (in red letters) in the text see below.				
Israel	Congratulations Congratulations to the BSS Secretariat for the impressive result of their work.	X	Noted		
Israel	Subheadings The addition of subheadings is of great assistance to the reader.	X	Noted		EDITORIAL – see contradictory comment from Czech Rep.
Israel	Compatibility of the BSS (GSR Part 3) with other parts of the GSR Since the BSS is now part of the General Safety Requirements, it would be useful if reference would be made in the relevant parts of the BSS to the more detailed requirements appearing in the other parts of the GSR, for instance reference under Requirement 13 to GSR Part 4 or reference under Requirements 2 and 3 to the soon to be published GSR Part 1. With regard to responsibilities of the government and the regulatory body, since GSR Part 1 and the BSS are on the same level, consideration should be given to the possibility of integrating part of the overarching requirements of GSR Part 1 under Requirements 2 and 3 of the BSS, for the sake of consistency. It seems that the requirement of para. 2.38 does not appear in GSR Part 1, but on the other hand, the requirements for inspection by the regulatory body are wider in GSR Part 1 than in DS379.	X			
Israel	Dose coefficients The concentration of dose coefficients in a single document (as was done with the tables included in Schedule II of SS-115) is useful to many members of the radiation protection community. It seems that there was an agreement at the RASSC/WASSC meeting in November 2008 to retain the tables in the BSS. If their inclusion is not practical, they could be published as a separate document, following the example of the Schedules of TS-R-1 (the Schedules were included in TS-R-1 until the 2003 Edition, were removed from the 2005 Edition and were recently published as TS-G-1.6).	X	Dose co-efficients will be included, probably as a CD attached to the BSS		
Israel	Correspondence between the Fundamental Safety Principles and the overarching requirements Following the example of Table 1, it would be useful to have a correspondence table between the 10 Fundamental Safety Principles and the overarching requirements, stating for each overarching requirement which Safety Principles it satisfies. Such a table would help the readers as well as the editors of the BSS. It could look like the following:	??			EDITORIAL REVIEW

	Req.	1	2	3	4	5	6	7	8	9	10	11	..	19	..		
	FSPs	4,5,6,10	2	2	1	3	3,5	2	2,4	1	2,4	2,5	..	2,5,6	..		
Israel	Facilities and activities vs. practices Since the term "facilities and activities" seems to encompass the terms "practices" and "sources within practices", "facilities and activities" should replace "practices" and "sources within practices" in some of the instances where the latter terms are still used. Alternatively, it would be useful to explain the difference between the terms. New publications in the General Safety Requirements, such as GSR Part 4, refer exclusively to "facilities and activities". The definitions of "facilities and activities" in footnote 1 (para. 1.7) and in the DS379 glossary are not identical.																EDITORIAL REVIEW
Israel	Occupational exposure subsection of section 3 For the sake of consistency the expression "employers, registrants and licensees" should be used in all paragraphs where it is relevant.															X	This will be checked during the editorial process
Israel	Interface with security Although para. 1.30 was added to make reference to publications in the Nuclear Security Series, very few changes were introduced to improve the linkage between safety and security and to upgrade the text concerning security, as recommended by the RASSC/WASSC meeting in November 2008. Safety requirements derived from security principles, requirements and considerations should be included in safety standards, either directly or by reference, after careful examination of their contents and of the improvement in safety contributed by adhering to them															X	Noted
Israel	Responsibility for protection and safety of patients in medical exposure A balance should be found to share responsibility between the radiological medical practitioner and the referring medical practitioner. The present draft puts the "primary responsibility for protection and safety of patients" on the radiological medical practitioner (para. 1.8), as well as the "responsibility for ensuring overall patient protection and safety, including the justification of the procedure … and the optimization of protection" (para. 3.152(a)). Although it is said that the radiological medical practitioner shall carry out the justification of medical exposure for an individual patient "in consultation with the referring medical practitioner when appropriate" (para. 3.155), it is felt															X	Agreed. Wording will be developed in consultation with WHO and PAHO

	that the responsibility of the latter in the present draft is not articulated well enough.				
Israel	Numerical values of dose constraints for carers and comforters It is useful to have numerical values as in the present BSS (Schedule II, para. II-9). Para. 3.171 of the draft requires the use of relevant dose constraints and refers to para. 3.147(a)(i) for their definition, but the latter paragraph (including footnote 25) is too general. It would be useful to mention a maximal dose constraint of 5 mSv for carers and comforters of patients in general and a maximal dose constraint of 1 mSv if they are pregnant women.				
Israel	Terms defined in the glossary It would be useful for the reader if terms defined in the glossary would appear differently in the text (e.g., italics or bold).		EDITORIAL REVIEW	X	This was previously considered but felt not to be realistic because of the frequency with which glossary terms appear in the main body of the text
Israel	1) We found that the proposed standard allows a higher radiation dose to the general public, compared to the present standard. We suggest to define more clearly in the proposed standard which is the total annual effective ionizing radiation dose acceptable for the general public, from all sources, i.e. natural soil with particular high radionuclide concentration (example, phosphate soil), building materials including NORM and TENORM, commodities, food, feed, drinking water, security screenings, radiation from the work place or from hospitals for visitors and employees which do not have the status of "radiation worker" and therefore are also members of the public, etc. In the present BSS this dose was limited to 1 mSv and the ICRP recommends dividing it into practices of 0.3 and 0.1 mSv each. The proposed standard allows 1 mSv from each of the above mentioned sources, such that, by adding all the sources together, the dose to the general public increases much beyond 1 mSv and there is no clear limitation. The relevant sections in the proposed standard are: 1-22, 5.8, 5.22, I-2, I-8 in contradiction to III-3 (a). We suggest deciding on a total dose for the public, from all sources, natural and artificial, in normal living conditions (excluding the emergency situation and "after" emergency situation), and dividing it into practices, as recommended by the ICRP.			X	The summed dose from al practices is 1 mSv, consistent with ICRP. This is in addition to natural background, which normally is not amenable to control, and can vary by several orders of magnitude from location to location
Israel	We found the proposed standard too general, practically leaving to the regulatory body to			X	A requirements

	decide on doses or specific action. We suggest including in each section more specific guidance and more bibliographic references to IAEA or other standards, or technical reports.				document with worldwide application needs a high degree of flexibility. Specific issues are discussed in detail in safety guides
Israel	**Missing tables**: As compared with BSS-115 1996, the following tables are missing: II-III till II-X. , III-I till III-VI, IV-I till IV-II, V-I. The info in these tables is important to provide a uniform reference of data for risk assessments. We suggest adding these tables to the standard.		Dose co-efficients will be included, probably as a CD attached to the BSS – see references to tables in paras III- 6 and III-7.		
ISSPA	The BSS draft 3.0 has improved in comparison to former drafts. We acknowledge the acceptance of comments made by ISSPA. The phrase **"protection and safety is optimized**" could create difficulties in practice. Further clarification concerning the use of the term "is optimized" is needed. Therefore we recommend to replace it by "**protection and safety is subject to an optimization process**" Other remarks and proposals for changes (in red letters) in the text see below.			X	See response to ENISS
India	The current draft of the new BSS is in excellent form and format. It takes care of the latest ICRP recommendations and all other aspects of radiation safety. It very clearly includes all radiation exposure situations in to three categories. It can be accepted as final with following suggested minor editorial and conceptual modifications.	X	Noted		
Mexico	In relation to the IAEA communication No: J5.03.1 about the document for review, entitled "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (DS379)" (guide and recommendations). I allow myself to inform that we do not have commentaries to this document.	X	Noted		

Norway	Structure and format Detailed requirements are given for some topics which could preferably be moved to guides or appendices (*e.g. occupational exposure with details of designation of areas, protective aprons, etc.*). At the same time, reference to important standards and requirements for other topics are not given (*e.g. Emergency Exposure Situations: GS-R-2 is only referred to, without any comment on what it contains and how those requirements complement the BSS).*	X			
Norway	Structure and format When a reference is given in the text to another section or paragraph it is helpful to give a short notice (key word) on the content of that section/paragraph.				
Norway	Structure and format A standard document should focus on <u>who shall do what.</u> There are however still paragraphs where it is unclear who this responsibility is assigned to. We propose that the Secretariat reviews the document with respect to this. We also suggest enhancing the readability by identifying the responsible party in the very beginning of the first sentence of every paragraph.	X	Noted		EDITORIAL REVIEW
Norway	Structure and format The BSS is written in such a way that it also may serve as a guidance document for licensees, registrants and workers. Throughout the document there are references made to "these standards". Providing adequate guidance to licensees, registrants and workers the BSS should make reference to the national legal framework. Not doing this, is a misguidance.			X	The BSS is not a guidance document – it is a requirements document. National legislation is required to be in compliance with the BSS
Norway	Balance in document The different chapters of the draft are still not balanced. Some of the problems are due to the objective to keep the BSS as a "*stand-alone document*" while simultaneously following the IAEA Safety Standards scheme.				See comments to Denmark
Norway	Balance in document Detailed requirements are given for some topics which could preferably be moved to guides or appendices (*e.g. occupational exposure with details of designation of areas, protective aprons, etc.*). At the same time, reference to important standards and requirements for other topics are not given (*e.g. Emergency Exposure Situations: GS-R-2 is only referred to, without any*				See comments to Denmark

	comment on what it contains and how those requirements complement the BSS).				
Norway	Balance in document Some numerical values are given in Schedules and others are not (e.g. Schedule II, D-values).	X	D-values form GS-R-1.9 are to be added		
Norway	Glossary The draft 3.0 International BSS was sent out for comments without a complete glossary. This, in fact makes it not possible to determine the exact scope and limitation of some statements.				See comments to Denmark
Norway	Unclear exposure situations, balance in document The difficulties in applying the new process-based exposure situations to all types of activities involving ionizing radiation unfortunately results in unclear requirements. The three exposure situations are not always sufficient for categorization of exposures and the different approaches to those concerning justification and optimization gives unnecessary problems. One example is the protection of aircrews. The aircrews should reasonably have the same level of protection as other occupationally exposed workers. This is not obvious in the existing draft, as the requirements for protection of aircrew are vague (5.30) and even less than for space crew (5.31). One should anticipate that aircrew is far more common than space crew among Member States and hence, the requirements should be more developed. This shows an example of the poor balance between the exposure situations in the BSS.				See comments to Denmark
Norway	Exposure situations and radon Public exposure to radon in dwellings is recognised as a significant risk to public health in many countries, especially in synergy with smoking. A basic principle of radiation protection is optimization. In the case of radon in buildings, caverns etc. we do however recognise that the result of the optimization process conducted in the planning/construction phase compared to the outcome post construction optimization are significantly different. It is far more efficient to conduct the mitigation actions as part of the construction than doing it afterwards. So optimizing the optimization process strongly demonstrates that where possible, mitigating actions should be conducted in the planning and construction phase. In the BSS, however, radon in houses is defined as existing exposure situations. These are as described in § 1.18 "situations of exposure which already exists when a decision on the need for control needs to be taken".	X	Noted – not clear what change is proposed		Comment: see 5.20(c) 5.20(d) which cover this point
Norway	Exposure situations and radon We welcome the new text on radon which implicitly now also includes Rn-220 as we read it. We suggest that the inclusion of Rn-220 should be more clearly stated in the document and that	X	Noted		Comment: In existing exposure situations, the requirements will

	better guidance should be provided to states implementing their radon strategy. We leave it to the Secretariat to formulate the text.					only refer to radon-222. In occupational exposure situations, they will apply to both radon-222 and radon-220
Poland	„radioactive material" and "exemption" need to be correlated and defined unequivocally in all Member states, and not by their regulatory authorities (see comments # 10 & 12 below)	National specification of "radioactive material" and "exemption" makes trans-boundary transport difficult and less secure.	X	This is covered in Schedule 1, but regulatory bodies have the flexibility to exempt at higher concentrations or regulate at lower concentrations		
Poland	Re-format the text of BSS to contain the overarching principles only, and place the remaining text into principle-related subsidiary text.	In its present form, BSS is far too long and has too much confusing detail – it is no longer "basic".			X	The BSS needs to be a stand-alone document. While every effort has been made to delete guidance material and transfer it to safety guides, the level of detail in the current draft is necessary
Slovakia	The current version of the BSS improve over previous drafts and is as generally acceptable. The document should put more emphasis on the integration of safety and security, in particular with respect to protection of sealed sources		X	Noted		
Spain	Quite frequently it is not easy to appreciate why certain requirements are catalogued as being either "overarching" or "supporting". Furthermore, quite a number of the "supporting requirements" do not appear to be sufficiently essential as to warrant consideration as requirements and would appear to be associated more with a recommendatory context (use of		X	Where overlap exisits or certain requirements are redundant, this will		

	terms such as “should”). Finally, there are certain overlaps between the texts relating to requirements that refer to one same area.		be addressed during the editorial review		
	Although possibly interesting and useful for certain readers, the contents of chapter I (Introduction), and particularly its “Background”, are excessively voluminous (14 pages). Overall it would be appropriate to reconsider the real need, orientation and added value of this extensive sub-chapter, and whether it might not be better to make it an “executive summary”.			X	Given the importance of the BSS as a stand alone document, it is important to have sufficient explanatoty text
	Specifically, paragraph 1.1 indicates that the contents of chapter 1 are not part of the requirements, despite which terms such as “shall” and “must”, which might cause confusion, are widely used.	X	The term “shall” has been removed from chapter 1		
	The publishing of these BSS and of the EC equivalents should desirably put an end for once and for all to the seemingly endless debate on exemption and clearance values, and also on transport values, and all the inconsistencies and examples of incoherence still existing in the latest available versions of the two texts should be cleared up.	X	Noted		
	There is a noteworthy degree of unbalance between the levels of detail used in the different sections of the standards. For example, it does not seem to be reasonable that a total fourteen pages should be dedicated to the requirements associated with medical exposures, while the requirements associated with the enormously transcendental issue of emergency exposures is dealt with in only five pages.			X	The imbabance does not relate to the importance or dose contribution of each area, but rather to its complexity
	Draft 3 continues to ignore the numerous comments made by some Member States and international organisations on the need to replace the requirement that “protection and safety are optimized” (which appears repeatedly throughout the draft) with “protection and safety are subject to a process of optimization”. In our opinion, the reply to these comments by the co-sponsoring organisations, consisting of including a footnote (number 4 on page 22) that explains that “Optimized means that optimization of protection and safety has been applied and the result of that process has been implemented” is inadequate and we still do not understand the reluctance of the co-sponsoring			X	Those requesting this change are in the minority. The definition in the glossary clearly indicates that optimization is a process. To simply state

	organisations to accept the numerous specific comments that have been made in this respect.				"subject to a process of optimization" does not require an optimized outcome
	Throughout the draft the term "Registrant and licensees shall…." is used on numerous occasions; for this reason it is particularly surprising that the term "Registration" is not explicitly reflected in "overarching requirement" number 7 (Notification and Authorization). It is true that the glossary clarifies this when it explains that "Registration" is a form of "Authorization" for moderate or low risk practices; however, in view of the numerous references to "Registrant and Licensees", it would appear to be more appropriate for the term "Registration" to be explicitly included in "overarching requirement" number 7. The use of the terms notification, registration and authorization is confusing throughout the document, giving rise to various inconsistencies. The introduction should clearly explain the new structure or model of the document, introducing the requirements and the sections on development. Otherwise there might be serious difficulties in application of the BSS.	X	Term to be added EDITORIAL REVIEW		Comment: "registration" and "licensing" are sub-sets of "authorization"
Ukraine	In BSS the clearance is defined as "The removal of radioactive material or radioactive objects within authorized practices from regulatory control by the regulatory body." In Para 3.12 it is stated that "The regulatory body shall approve which sources, including materials and objects… At the same time there is no definition in the document what "objects" mean. Its needs to be clarified whether the activity concentration levels in Tabl.I-2 are applicable for release of radioactive waste disposal sites from regulatory control or other sites on termination of practice.				Comment: "Objects" has the normal English meaning The values in Table I-2 apply to clearance of all materials, regardless of their origin or quantity, from regulatory control
Ukraine	It is desirable to identify the threshold value of probability in text of Schedule I (see paragraph I-1 "appreciable likelihood"; paragraph I-2 - "low probability scenarios", "reasonable foreseen				Comment: "appreciable

	situations").					likelihood" is directly linked with the dose criteria in I-2
UK	We agree with the IAEA that there is no major issue with the current 1996 version of the BSS, nevertheless we welcome the IAEA's revision as an opportunity to update and improve the BSS. In particular, we welcome the changes that will align the revised BSS with the IAEA's Fundamental Safety Principles, and the coverage of types of exposure situations (planned, emergency and existing) rather than the previous practices and interventions.		X	Noted		
UK	In general, the drafting of the document is good, and an improvement on previous drafts. However we have a major issue regarding Justification, notably Paras 3.18 and 3.20. Nevertheless we are encouraged that the revised BSS will recognise protection of the environment. We are similarly encouraged that the requirements on controlling radon in both planned and existing exposure situations have been revised in line with recent ICRP recommendations. This brings the IAEA BSS more into line with ICRP's current thinking on environmental protection.		X	Noted		Comment: the wording of 3.18 and 3.20 has been amended based on all comments received
UK	We encourage the IAEA to consider the overall financial impact of implementing the new BSS. A number of measures have the potential to create significant financial burden (notably on the nuclear industry) and the impact should be clearly understood and evaluated, to ensure that the costs of compliance will not unreasonable in relation to the risks being controlled.		X	No change to text proposed. Requires further discussion.		
USA	The United States is pleased to provide the following general and specific comments in response to the IAEA request for Member State review. These comments represent viewpoints from a wide variety of Federal and State regulatory organizations in radiation protection, health care, and occupational protection. These comments have also been informed by an opportunity for public stakeholder dialogue hosted by the U.S. Interagency Steering Committee on Radiation Standards.		X	Noted		
USA	Provide complete responses and resolutions to comments. We urge the IAEA and co-sponsor organizations to take sufficient time in developing a revised draft, based on Member State comments, to achieve a consensus of all organizations and produce a high quality report for the review of the	The United States strongly encourages the IAEA, and the international agency joint secretariat, to carefully consider all comments received, without prejudice of previous positions. We also strongly encourage the IAEA to provide a complete analysis of comments and resolutions on the web site.	X	Complete analysis of all comments will be made available by mid-September 2010		

	Safety Committees.					
USA	Update References	A review of all references should be made to ensure that the most recent documents are referenced by the BSS.				EDITORIAL REVIEW
USA	Glossary updates	The U.S. notes the ongoing revision of the IAEA safety glossary, and urges that decisions made regarding the BSS be incorporated into the IAEA safety glossary as the documents continue to move forward.				EDITORIAL REVIEW
USA	The requirements are well written and coherent, but it would be useful, perhaps in Chapter 1, to include a table that shows where this document sits in the IAEA safety and security and guidance document series.	Several places, to be noted in comments below, refer to other IAEA documents that need to be made more transparent.				EDITORIAL REVIEW
USA	Consider relationship of transportation exemptions and exemptions in BSS	During the U.S. review, a potential conflict was noted between the exemption of individual items, such as lamps, and the requirements for transportation. The U.S. understands that this is issue is being reviewed in the context of the transportation requirements, and urges that such considerations be continued. The U.S. government does not have sufficient information on the potential impacts of the proposal, and thus has no position at this time.	X	Noted. The IAEA Secretariat is aware of, and supports, the need for harmonization of the values in Table I-1 of the BSS and TS-R-1.		
USA	Provide for review process for any amendments or adjustments to the BSS that may be considered in the future.	Procedure issue. How will member states have the opportunity to review and comment on any addendum material in the Schedule I if there are updates from the European Commission, or other organizations? The U.S. requests that any modifications of the document utilize the same process of development and comment by stakeholders and member states as the original draft.				Comment: All changes to the BSS, including addendum material, will be submitted to all four Safety Standards Committees for approval and be

						subject to Member State comment in the same way as any requirements document
ICRP	ICRP provides these comments with the intention of facilitating the IAEA Board of Governors' direction to take ICRP recommendations into account to the extent possible. ICRP welcomes the full participation of all the co-sponsors, each representing an important set of stakeholders whose input is invaluable, and appreciates the opportunity to act as an observer in the BSS Secretariat. ICRP encourages the co-sponsors to continue to work together to use the recommendations of ICRP to promote harmonization of international radiological protection standards to the greatest possible extent. The scope of these comments is generally limited to those areas where the current draft BSS may not fully reflect the System of Radiological Protection embodied in ICRP Publication 103 and subsequent ICRP publications. However, these comments should not be taken to mean that ICRP necessarily fundamentally disagrees on every point with how the System of Radiological Protection is being taken into account in this draft. Likewise, lack of comment in a certain area does not imply that ICRP endorses that part of the draft.		X	Noted. Specific comments are individually addressed		
NEA	The EGIR welcomes the commitment of IAEA to post the resolution of all submitted comments on their website.		X	Noted		
NEA	The current version of the BSS was broadly seen as an improvement over previous drafts, and was seen as generally acceptable.		X	Noted		
NEA	(Overarching) Requirements need to reflect the structure and details of the associated requirements - this is not always the case, for example *Requirement 18 with para 3.60; Requirement 4 with para 2.42; Requirement 22; Requirement 24*.		X	Other similar comments have been received and redundant requirements will be deleted		
NEA	Some exposures were still seen as needing clarification of how they should be treated: a) Should aircrew be put into planned or existing exposure situations? b) How should new home construction be noted in terms of protection from radon, as an existing or planned exposure situation? *Note: Thoron (Rn-220) is not addressed yet and*		X	Location of aircrew to be reconsidered if strong arguments are made for doing		<u>Comment</u>: The outcome from the TM on radon is that the state of knowledge about thoron is not yet

	can be a problem. Need a clarification of where in the requirements situations such as "leaks from underground pipes" are addressed		so. New home construction is considered as an existing exposure situation. "leaks from underground pipes" would be covered by BSS, in particular, Req. 16 and paras 3.44-3.47.		sufficient to include requirements in existing exposure situations. Exposure to rs still not being addressed by several member States, is a greater priority
NEA	The document should put more emphasis on the integration of safety and security, in particular with respect to protection of sealed sources.	X	Noted		
NEA	Exemption and clearance were seen as needing some clarification, in terms of the criteria used in the schedules.	X	Noted. Based on other specific comments received, Schedule 1 will be redrafted		
NEA	There is no discussion of exclusion in the document. This is a relevant governmental / regulatory tool.			X	Covered in 1.31, which indicates which practices are excluded form consideration by the BSS
NEA	The BSS should not suggest that non-medical imaging is generally not justified.	X	Text has been rewritten in line with other comments received		
NEA	The use of the concept of "dose limits" for workers in the context of Emergency Exposure Situations (see paragraphs 4.15 and 4.17) seems to be inconsistent with the definition of dose limits. The wording in these paragraphs, and throughout the document, should be checked.	X	Noted. This will be addressed as part of the editorial		EDITORIAL REVIEW

			review		
NEA	*It should also be noted that the World Nuclear Association (WNA) participated in the NEA meeting as an observer, and suggested that:* 1. *The document is very unbalanced in that it addresses the smallest contributor to public exposure (the nuclear industry) with the largest number of requirements, while providing very few requirements for public protection against much more significant exposures, for example radon exposure or air travel.* 2. *The document expresses too much concern over extremely low doses, e.g. less than 1mSv/year.* 3. *The document tends to confuse "public safety" concerns and "dose reduction" concerns.*	X	Noted. Separate comments were submitted by WNA and these are addressed individually		

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 1: Introduction							
Country/ Org.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
UNEP	General	1. We note firstly the high-level principles related to protection of human health, and the associated detailed requirements for the protection of the public, workers and patients under various exposure situations. It is clear that these are very mature, being based on a long history of experience and feedback. We also note the high-level Fundamental Safety Principles (cosponsored by UNEP), which explicitly expound protection of the environment, and note that these are partially reflected in the draft IBSS. We note the 2008 Report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) that reviews the scientific basis for radiation effects on non-human species, and also acknowledge the efforts of the IAEA and the International Commission on Radiological Protection (ICRP) on studying possible frameworks for evaluating impacts on flora and fauna. However we have some concern that the radiation protection community may be interpreting protection of the environment in a narrow sense that is not fully		X	Text has been modified in various parts of Section to take account of the UNEP comments – see paras 1.14, 1.20, 1.26		

		consistent with that of a wider environmental science perspective. We note that the draft IBSS contains no specific definition for 'environment' and therefore presume that the common meanings of the term should apply, i.e the surroundings or conditions in which a person, animal or plant lives or operates; and the natural world, especially as affected by human activity. In particular, we have concerns with the expression in para. 1.26 that the sole aim of radiation protection of the environment is to protect ecosystems against radiation risks. From UNEP's perspective and indeed the more usual common perspective, this is too narrow a focus, since it does not explicitly address protecting the sustainable use of the goods and services that the natural environment provides. UNEP has in the past stated that in principle this would include: provisioning services such as food and water; regulating services such as flood and disease control; cultural services such as spiritual, recreational, and cultural benefits; and supporting services, such as nutrient cycling, that maintain the conditions for life on Earth. In practice, some of these services are less relevant for radiation hazards, nevertheless it would seem that impact of contamination on, for example, agriculture, forestry, fisheries and tourism, ought to be reflected in the IBSS. It is true that this aspect might have been taken into account to some degree by considering the protection of man directly. However, particularly for the long-term protection of these environmental services, a regulatory regime might in practice address limiting impacts at different levels, including soil, water, air and other environmental media, from which these goods and services derive, and not simply on avoiding health effects in plants and animals themselves. We understand that more work will be done to develop guidance on protection of the environment outside of the IBSS, and UNEP would welcome being consulted in the planning and conduct of future work in this area. However, we feel it important that the above broader and more usual interpretations of the term environment and the associated aim of its protection be explicitly made and clarified in the draft IBSS, presumably in para. 1.26, but possibly elsewhere. We kindly ask the IAEA to make proposals for wording changes in this regard (for example, we believe that the wider and more usual interpretation of environment would have some impact on the wording for Schedule I, exemption I.1.a).				

		Clarifying this basic issue would help to provide a much sounder basis for future development of radiological protection guidance that would be consistent with approaches for assessing other non-radiological drivers of environmental change, and therefore also with the more usual interpretations of Ministries of the Environment. 2. We note that paras. 1.14 and 1.20 related to optimization of protection and safety presently do not explicitly refer to the environment, and are therefore not fully consistent with para. 3.23 of the Fundamental Safety Principles, where environmental factors are included alongside economic and social factors. We kindly ask that this be amended as appropriate throughout the text. 3. The draft IBSS rightly recognizes the responsibilities of national bodies for protection of health, but we question whether the international issues have been addressed adequately, particularly in regard to the global environment. For example, the build-up of long-lived globally circulating radionuclides in the environment would appear to be an international issue, beyond solely national control. We would welcome a review of the existing draft to ensure that this issue is appropriately addressed. 4. Related to international commitments, we would also kindly request the IAEA to review the draft IBSS and confirm that the requirements consistently reflect the Stockholm declaration (1972), especially principles 1, 2, 4, 6, 7 and 14, and the Rio declaration (1992), especially principles 1, 2, 7, 10, 14, 15, 16, 17 and 19. We consider that some of these principles might usefully be cited in para. 1.26. Others may have bearing on the expression of requirements for protection of the public and discharge limitation. 5. We would value an explanation of how the present draft either covers or might be amended to cover protection of the environment from illicit dumping of waste at sea, and from the risk due to nuclear vessels (including abandoned ones) at sea.				

		6. We note that the present definitions of protection and safety appear circular. 7. As you know UNSCEAR is the body in the UN system charged with assessing the levels and effects of ionizing radiation, and that UNEP provides the Committee's secretariat. We note that the IAEA's General Conference in its resolution GC(53)/RES/10, para. 21 requested the IAEA Secretariat to take account of the scientific information provided by UNSCEAR when developing IAEA safety standards. We would kindly ask that this linkage be explicitly highlighted in any preface to the IBSS. We also note that version 3.0 cites the 2000 UNSCEAR Report, and the next version ought to be updated to cite the 2008 UNSCEAR Report (expected to be published in coming weeks).					
EC	Whole doc.	Aircrew is sometimes spelled aircrew, sometimes air crew		Y	Correct spelling is aircrew		
ILO Finland (Trade Union)	Introduction and General requirements for protection and safety		The SAK agrees with the basic principles presented in these chapters, and states that the importance of having a safety culture can never be overemphasised and that the consideration of human factors forms an essential part thereof.		No action required		
Sweden	Pages 16, 17, 127, 151 and 161	x-ray	The word "x-ray" occurs once (p. 151), "X ray" four times. One should choose between small/capital letter and with/without hyphen. It is suggested that "x-ray" is used in accordance with ICRU (Report 74, 2005).	Y	Correct term is X ray		
Sweden	References pp. 133-134	It is suggested that all references, where applicable, has an URL address to where it can be found, directly or indirectly.		Y	This will be addressed during the review by technical editors		EDITORIAL CHECK
Belgium	1. Introduction	Re-insert the deleted considerations on non-cancer diseases (cardiovascular,…) and on cataract (former paragraph 1.4).	Even if scientific uncertainty on the subject of non-cancer diseases and –to a lesser extent- on cataractogenesis still subsists, these issues should not be	Y	To wait for ICRP paper and to finalise at next		

			ignored or kept quiet. Explicitly mentioning these items may be seen as a demonstration of openness and scientific honesty.		RASSC meeting		
Spain	1. Introduction	The introduction should be shorter.	The introduction is too long for a document of this type			N	It is important in a 'stand-alone' document to provide as much explanation as possible in the introduction
Spain	1. Introduction	The introduction is not part of the requirements. It should not be using "shall"	The use of "shall" in a section where there are no requirements can be confusing	Y	Change has been made to paras. 1.11, 1.16 and 1.20		
Spain	1. Introduction	The introduction should explain the new structure and implications of the document with the introduction of overarching and supporting requirements. Otherwise doubts may arise in the implementation of the standards.	Clarity	Y	New text included under 'structure' by technical editor		EDITORIAL CHECK
WNA	Section 1	This section needs a lot of re-alignment and streamlining.			No specific action proposed, but all individual comments have been considered in developing next draft.		
Austria	1.2	*The radiation risks to people and the environment that may arise from the uses of radiation and radioactive material must be assessed and, ~~where necessary~~except where determined by assessment by the regulatory body to result in risks that are below regulatory*	Para. 1.2 of DS379 states in part, "*The radiation risks to people and the environment that may arise from the uses of radiation and radioactive material must be assessed and, where necessary, controlled through the application of standards of safety.*"			N	Editorial – the proposed change appears more restrictive than the current text and does not change the

		concern, controlled through the application of standards of safety."	The only aspect that is known of where some type of control of radiation risks is not necessary is where the uses result in doses or levels of contamination that are below regulatory concern – and in these cases, the lack of control is a deliberate one, resulting from an assessment. In all other cases (be they medical, industrial, power generation, or whatever), radiation risks are controlled. Thus, the quoted sentence apperas to make little sense.				meaning. When control is necessary and how such control is achieved is dealt with in the requirements.
India	7/1.2/1	Radioactivity is a ~~**natural**~~ **spontaneous** phenomenon and…	'Spontaneous' is more appropriate than 'natural'			N	Text from Safety Fundamentals
France	1.3	Remove "frequency" in the following sentence about deterministic effects: "certain threshold level of dose above witch their severity and frequency increase ".	The frequency of effects increases with dose for stochastic effects and not for deterministic effects	Y	Sentence redrafted to provide greater clarity		
WNA	1.3-1.4	Para.1.3-1.4: **Radiation-risk** needs to provide clear guidance for users. It is too complex, too scientific and lacks numerical benchmarks. See Specific Comment No. 27.			No action required. Response given under more specific comment		
India	1.3/4	…above which their severity and frequency ~~**increase**~~ **increases with dose.**	Correction for better clarity.	Y	Sentence redrafted to provide greater clarity		
Russia	1.3/line 4	Effects of this type are called 'deterministic' and they are clinically observable if the radiation dose reaches a certain threshold level of dose, above which their severity and frequency increase with the dose.	If we specify, that severity and frequency of deterministic effects will increase with the doze after threshold, the sentence will be more accurate.	Y	Sentence redrafted to provide greater clarity		
India	1.3/5	…Deterministic effects are also	Deletion in order to be consistent with		This term only	N	The term

		referred to as '~~harmful~~ tissue reactions'	ICRP nomenclature		appears in para. 1.3. It has been deleted from here but retained in the glossary		'harmful tissue reaction' appears in paras 28 and 46 of ICRP 103
Russia	1.3/line 5		The last sentence of the paragraph 1.3 ("Deterministic effects are also referred to as 'harmful tissue reactions'") should be removed. Introducing of term "harmful tissue reactions" is inexpedient, as it has more narrow meaning than "deterministic effect". Moreover, term "deterministic effect" is understandable term, which accepted and in use worldwide.	Y	This term only appears in para. 1.3. It has been deleted from here but retained in the glossary		
Austria	1.3	~~Deterministic effects are also referred to as 'harmful tissue reactions'~~.	To be moved to the glossary, if even appropriate (is the reaction by the tissue harmful, as this terminology might indicate; or is it the incidence if ionizing radiation which is harmful to the tissue?)	Y	This term only appears in para. 1.3. It has been deleted from here but retained in the glossary		
WNA	Specific 1.3, 1.4	**Radiation-Risk –** These two important two paragraphs on radiation-risk (including deterministic risk and stochastic risk) should primarily aim at guiding upfront the BSS users on radiation-risk and on its practical applicability. The latter requires the inclusion of practical numerical benchmarks. As it stands, the text is too complex, too scientific and lacks numerical benchmarks for a normal user. This is very important because it is fundamental to the good understanding of the applicability of the	The text on radiation-risk is too complex, too scientific and lacks numerical benchmarks for a normal BSS user.	Y	Changes have been made to paras. 1.3 and 1.4 based on all comments received	N	Adding the sentences "*Doses lower than a few mSv per year are very low to the point that it is unlikely to change the general background risk of cancer from all causes among the public. In other words, at very*

		subsequent requirements in Sections 2 to 5. We therefore highly suggest to replace the current text by a much more simpler text such as follow: "*For practical purposes, deterministic risk – meaning a health risk that can be directly attributed to the exposed individual - corresponds to doses that are above about 1,000 to 2,000 mSv. Stochastic risk – meaning a probable health risk to an exposed individual among an exposed population - has been only conclusively demonstrated for doses higher than about 100 to 200 mSv. For lower doses, a stochastic risk is theoretically assumed for protection purposes. Doses lower than a few mSv per year are very low to the point that it is unlikely to change the general background risk of cancer from all causes among the public. In other words, at very low doses of the order of 1 mSv/y or lower, no real radiation safety gain can be possibly made from extra protection measures.*"					*low doses of the order of 1 mSv/y or lower, no real radiation safety gain can be possibly made from extra protection measure"* is not consistent with the principle of optimization and therefore cannot be added
Austria	1.4	However, there remains **a certain** probability…..	A quantity is the product of a numerical value and a unit.	Y	Change made to improve clarity and accuracy		
Belgium	1.4	Replace "…// (the risk co-efficient) is approximately 5% per Sv" by "…is probably in between 5 and 10% per Sv"	The co-efficient of 5% per Sv is only valid if one assumes a DDREF of 2, which has recently been challenged at several occasions and by different organizations. A more prudent approach should therefore be favored.			N	The requirements in the BSS are based on DDREF of 2 and therefore the value of 5% needs to be retained

China	Para1.4	To be deleted: "and that the detriment-adjusted nominal risk co-efficient, which includes all cancers and heritable effects, is approximately 5% per Sv [1]"	Description about the detriment-adjusted nominal risk co-efficient here may be misapprehended, and lead to misuse of the value 5%.	Y	Changes have been made to paras. 1.3 and 1.4 based on all comments received		
USA	1.4, line 7	Recommend changing to: ".. called a 'stochastic' effect, is assumed to have no threshold."	Editorial. As written, saying that stochastic effects are independent of dose, the sentence is wrong. The following sentence gives the linear relationship to dose.	Y	Changes have been made to paras. 1.3 and 1.4 based on all comments received		
Germany	Para. 1.4	~~(i.e. a spermatozoon or an oocyte)~~	It is suggested to delete these words, because neither the term „spermatozoon" nor the term "oocyte" describes all the stages of spermatogenesis or oogenesis, respectively. The term "germ cell" preceding the parenthesis is sufficient.	Y	Changes have been made to paras. 1.3 and 1.4 based on all comments received		
Germany	Para.1.4	. . . For the purposes of these Standards, it is assumed that the probability of stochastic effects is proportional to the dose received, with no dose threshold, and that the detriment-adjusted nominal risk co-efficient, which includes all cancers and heritable effects, ~~is approximately 5% per Sv~~ is between 5% and 10% per Sv."	The current statement is based on a DDREF of 2 as used by ICRP 103. BEIR VII suggests a DDREF of about 1.5; the German Radiation Protection Commission (SSK) and the Federal Radiation Protection Authorities favor a value of 1. UNSCEAR will recommend that DDREF "may probably be at the level of 2". These uncertainties should be reflected.			N	The requirements in the BSS are based on DDREF of 2 and therefore the value of 5% needs to be retained
ISSPA	1.4	For the purpose of these Standards, ~~it is assumed that~~ the probability of stochastic effects is considered to be proportional to the dose received without a dose threshold, with an ~~approximate~~ overall lifetime fatal risk coefficient due to excess cancer and	The use of "assumed" is confusing. It can imply that the decision is arbitrary as is claimed by health physicists who disagree with the LNT dose-effect model. The use of "approximate", which	Y	Changes have been made to paras. 1.3 and 1.4 based on all comments received		

		heritable effects of ~~around~~ about ~~5%~~ 0.05 per Sv [1].”	means “close to”, is inappropriate given the inaccuracy of risk estimates over the full exposure range considered for this Standard. Risk coefficients are usually expressed as fractions rather than percentages.				
Germany	Para. 1.5	.. management of ~~*relative*~~ risks.	Risk management does not exclusively deal with relative risks without looking at absolute risks.	Y	Text amended		
WNA	Specific, 1.6, 1.7 , 1.14,1.203. 21,3.23 3.118, 3.122 and in all of the BSS	**Optimization-Constraints – *Based on the IAEA Fundamental Safety Principles, Optimization – as a Principle – is overarching the more detailed concept of constraints. A priori set constrained-optimization is incorrect and so is the definition of constraint “…which serves as a “boundary” in defining the range of options in optimization.” What is the difference between boundary and limit?*** ***Constraint can only be set as an integral part of Optimization, taking social and economic factors into account*** – as opposed to arbitrarily set constraint a priori. ***After setting a constraint, optimization is carried out iteratively below the dose level corresponding to the constraint. Many requirements confuse constraints as an integral part of Optimization and a priori set constrained-optimization – the former is correct and the latter not. All BSS requirements should be corrected accordingly***. “constraints are used for	The scope of constraint is within the Principle of Optimization. Optimization cannot be a priori constrained or bounded (limited!) by constraint. The related requirements need to be corrected throughout the BSS.	Y	The introductory text and the requirements on dose constraints have been rewritten to take account of all comments received		

		optimization…"should therefore be replaced by… constraints are used in the optimization… For public exposure, criteria and operating limits to establish or approve must be equivalent to constraints which are expressed in different forms such as exposure rates, concentrations and the likes. There is no need for a three-level control mechanism.					
Canada	1.6 5th and 6th line	Manage and control exposures to ionizing radiation so that radiation risks, health effects and effects on the environment are reduced……	Ensures alignment with Fundamental Safety Principles "fundamental safety objective is to protect people and the environment	Y	Text amended		
China	Para 1.6/6	… so that radiation risks and health effects are reduced to the level as low as reasonably achievable.	To keep the consistent with the previous BSS and other international organizations.	Y	Text amended		
India	8/1.6/5	…and safety aims to assess, ~~**manage**~~ and control exposures…	Delete 'manage' as aims of system protection and safety are only to assess and control exposures.			N	The system of protection and safety also 'manages'
India	9/1.7/ Safety principle 9	… response for nuclear or radiation incidents **and accidents**.	Add for completion as emergency preparedness is planned for both incidents and accidents.			N	In the IAEA safety glossary, "incident" is a broader term than "accident" and includes malicious acts
Austria	1.7	for facilities and activities1 that give rise to radiation risks […] unacceptable risk of harm.	The definition of risk seems to be inconsistent with other standards (e.g., risk as the product of dose x risk factor, risk as the product of incident probability x severity); in other paragraphs it seems to be used	Y	Radiation risks is defined in the Glossary.		

			differently (Safety Principle 6). A clear and unique definition would be necessary.				
Belgium	1.7/last sentence	The principles of radiation protection, which are justification of the practice, optimization of protection and individual dose and risk limits, are expressed in Safety Principles 4, 5, 6 and 10.	Coherence with requirements 10, 11 and 12.	A	The title sof the Safety Principles have been added to improve clarity		
India	9/1.7/last sentence	The **general** principles of radiation protection…	Justification, optimization and limitation are termed as general principle of radiation protection. Hence addition.	A	Text amended to improve clarity. Added word "three"		
Austria	1.8	Definition of "activity"	"Activity (Bq)" is the number of disintegrations in a source, while here it is also used for human actions. A clear and unique definition would be necessary.		Text has been amended. Comment: Many terms have a definition in the BSS and can also have a second, different, meaning in common speech. This is unfortunately unavoidable		
ICRP	pg 9, 1.8 line 10	Change "procedures for delivering exposure" to "radiological procedures".	Delivering exposure is not the objective of medical uses of radiation.	Y	Text amended		
Philippines	1.8-1.17	To remove explanatory paragraphs of Fundamental Safety Principles 1-10. Instead replace with *The above ten (10) fundamental safety principles are discussed in Ref. 2.*	The explanatory paragraphs 1.8-1.17 are more of repetition of the contents of Ref. 2. This will further promote reading Ref. 2. This will result in the reduction of number of pages and will save on ink			N	It is important to make the link with the Safety Fundamentals and this text needs to be retained.

			and paper when printed.				
Austria	1.8	bear responsibilities relating to the design, manufacture and operating instructions for the safe use of such devices	Some or all of these responsibilities might also be subject to authorization by the regulatory body.				Comment: Responsibilities of the regulatory body are not excluded by the current text
Austria	1.8	~~because of the medical~~ ~~setting in which such exposures occur, primary responsibility for protection and safety~~ ~~of patients lies with the physician responsible for administration of the radiation dose,~~ ~~referred to in these Standards as the 'radiological medical practitioner'~~	This paragraph is replaced by more detailed descriptions later-on in Chapter 3 (medical exposure).				Comment: Section 1 is explanatory material and not part of the requirements. For clarity, the text needs to be retained
UK	1.8/7	Modify to read: "… of patients lies with the physician **or other authorised health professional** responsible for administration of the radiation dose, …"	Throughout the document the concept of medical practitioner is used and is defined as being a physician. In the UK there is the concept that other health professionals with appropriate training can take on such roles. We suggest making the changes suggested in Para 1.8 to allow for this.	X	Text has been modified.		
IRPA	1.19/line 10	For the purposes of these Standards, controls on the exposure of air crew from cosmic radiation are considered within planned exposure situations in Section 3, Occupational Exposure.	It is more logical and appropriate to consider air crew exposures as occupational.			N	There is very little difference in the protection afforded by considering aircrew exposure as either a planned or existing exposure situation

Austria	1.10	such as the establishment of ~~the~~ standards and guidelines	Grammar.	Y	Text amended		
USA	1.10/Lines 7-10	Suggest removing the sentence.	The sentence could be inferred to suggest that the Gov't may have a responsibility to support private industry through education and training, technical services, and other functions. In some cases the U.S. Gov't played an active role in these programs in the development and expansion of the commercial nuclear power industry in the U.S. However, services of these types are available in the U.S. private sector and largely considered the responsibility of the industry benefiting from the use of radiation. In other governmental systems, the Gov't may take a more proactive role in supporting industry, but this is not consistent throughout most governments.			N	Text clearly limits responsibilities of Government to ensuring that "provisions are in place….". and is consistent with GSR-part 1
India	10/1.11/5-6	…, together with **social and** economic considerations.	The requirements of effective safety management should also take into account the 'social' factors along with other mentioned. Hence add.	Y	Text amended		
Czech	1.11	.. together with economic and societal considerations	Not only economic consideration are important , the same as for optimization (see also ICRP 103)			N	Not included in GS-R-3
Sweden	1.11.	It is suggested that not only "quality assurance", but also "quality control" and "quality management" are included in the Glossary		Y	This will be included in the review by technical editors		EDITORIAL CHECK
ILO NZ (trade unions)	Section 1.11	Leadership in safety matters shall be demonstrated at (*insert* **all levels including**) the highest levels in an				N	Text is taken directly from the safety

		organization and safety shall be achieved and maintained by means of an effective management system. The management system also shall ensure the promotion of a safety culture, the regular assessment of safety performance (*insert* **the active participation of workers in the safety framework**) and the application of lessons learned.					Fundamentals
UK	1.11/7	Consider cross-referencing to Para 2.51 and providing references	The term "safety culture" is a difficult concept and guidance would be welcome	Y	Guidance is provided in a number of publications: e.g. GS-G-3.1, GS-G-3.5, INSAG-15		
USA	1.11	Revise to avoid use of "shall"	Editorial. The text of paragraph 1.11 is written in shall statement format, and should be revised to be consistent with an explanation, rather than a requirement.	Y	Text amended in paras. 1.11, 1.16 and 1.20		
USA	1.12	Consider removal of parenthetical.	The parenthetical additions may not assist in clarity of the explanation.			N	Comment not clear – do you mean in para. 1.11?
USA	1.12	Suggest adding to end of paragraph: ".. social factors, and often goes well beyond protection and safety considerations."	Editorial and Clarity. The justification of an exposure involves many factors, and the reader should be given more explanation about what the economic and social statement means.	Y	Text amended		
UK	1.12	Replace 1st sentence with "Any new class or type of facility/activity that alters the radiation exposure situation by introducing a new source of radiation, or by changing existing	Draft 3's way of stating the "justification principle", i.e. "do more good than harm" is rather different and quite a bit looser than the words used by the ICRP or in the Euratom	Y	Text amended using different wording to that proposed.		

		exposure, must be justified, in the sense that the detriment that it may cause is outweighed by the associated individual or societal benefit."	Directive; these talk about radiological health detriments from a practice being weighed against its benefits. Also "the concept of balancing good and harm also involves...." is not quite right. Justification is not about "balancing", it is about "comparing" benefits and radiological health detriments and showing that the benefits outweigh the detriments.				
Israel	1.12	"The operation of facilities or the conduct of activities" instead of "The conduct of activities or the operation of facilities"	Consistency with other paragraphs, e.g. 1.26 and 2.14, and with the expression "facilities and activities"	Y	Text amended using different wording to that proposed.		
Germany	Para. 1.13	"… As an overarching justification of medical exposures, it is accepted that the use of radiation in medicine does more good than harm ~~to the patient~~."	Apart from patients, medical exposure also includes exposure of other individuals such as exposure of asymptomatic individuals as part of a health screening programme or of an individual health assessment, exposure of volunteers in medical research and exposure of people voluntarily helping in the support and comfort of patients. Either these different cases should be addressed or – as proposed – the words "to the patient" should be deleted.	Y	Text amended		
WNA	1.13, 1.14, 1.25	Para.1.13, 1.14, 1.25: **Medical sector**: Unclear why benefits are only recognized for the medical sector and that only the medical sector is subject to a special RP regime without international numerical dose criteria. Does IAEA recognize the huge health and environmental benefits of nuclear energy? And if so, how this is accounted for in the development of radiation safety standards?					Comment: In medical exposures, the benefit is to the individual. The principles of justification and optimization apply, but dose limits are

							inappropriate as the dose required to obtain the necessary clinical information or to treat the disease must be delivered
Germany	Para. 1.14	"… As in the case of justification, the application of the optimization principle to medical exposures ~~of patients and volunteers in biomedical research~~ requires a special approach."	See comment to Para. 1.13			N	Medical exposures include the exposure of comforters and carers, but these are not covered by this sentence.
USA	1.14/ line 2	Consider revision: . . . workers, members of the public and comforters and carers (caregiver) of patients and biomedical research subjects undergoing . . .	Dose restraints for biomedical research are associated with the controls under medical exposures, 3.147(a) (ii). Also, note comment 11 below, where we recommend the use of the term caregiver.				Volunteers in biomedical research are not covered by this statement – see lines 13 and 14.
Austria	1.14	Para. 1.14 of DS379 states in pertinent part, "*The optimization of protection and safety, when applied to the exposure of workers, members of the public and comforters and carers of patients undergoing radiological procedures, is a process for ensuring that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable, taking social and economic factors into account.*" This is not what SF-1 says, but rather this comes verbatim from ICRP 103. SF-1, principle 5, states it differently: "*Protection must be optimized to provide the highest level of safety that can reasonably be achieved.*" SF-1 further explicitly defines what it means by "safety", stating, "*For the purposes of this publication, 'safety' means the protection of people and the environment against radiation risks, and the safety of facilities and activities that give risk to radiation risks.*" In addition, Principle 6 states, "*Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.*" Explaining this, SF-1 continues:				N	This para. deals with optimization and so referring to ALARA seems to be appropriate

		3.25 Justification and optimization of protection do not in themselves guarantee that no individual bears an unacceptable risk of harm. Consequently, doses and radiation risks must be controlled within specified limits. *3.26 Conversely, because dose limits and risk limits represent a legal upper bound of acceptability, they are insufficient in themselves to ensure the best achievable protection under the circumstances, and they therefore have to be supplemented by the optimization of protection. Thus both the optimization of protection and the limitation of doses and risks to individuals are necessary to achieve the desired level of safety.* ALARA is not the safety standard recognized by SF-1 – safety as high as reasonably achievable (SAHARA) is the standard for optimization of safety (Principle 5). ALARA is the protection standard, not the safety standard. This was not an inadvertent choice of words – this wording was the subject of protracted debate during the development of SF-1. Indeed, Austria (among others) recommended the wording of safety as high as reasonably achievable (SAHARA) instead of ALARA for safety, and was successful in getting this outcome. IAEA can't now turn around in a requirements document and reverse SF-1. ALARA is subsidiary to SAHARA – SAHARA is the overall safety standard, and ALARA is the protection standard. ALARA may be found in ICRP documents (including ICRP 103), but it is not the international safety standard set forth in SF-1. ALARA has only to do with optimization of protection (see the Safety Glossary for this clarification on page 138). The reference to ALARA in Para. 1.14 of DS379 is wrong. Perhaps it is worth noting that ICRP 103 does not refer to SF-1 at all.					
Austria	1.14		DS379 ignores radiation risks from foreseeable events, and cuts short with economic and social factors (the words of ICRP 103), forgetting that SF-1 also identifies environmental factors to be considered. SF-1 should be either referred to, or cited verbatim. .		Should 'environmental' be added everywhere we use "social and economic….."?		
ISSPA	1.14	In some cases, ~~T~~too little radiation can be as bad as too much radiation, in that	In some diagnostic procedures, minimization of dose does not			N	Current wording is correct

		the cancer may not be cured or the images may not be of suitable diagnostic quality.	compromise the quality of the image or the diagnosis. See 3.163(b).				
UK	1.14, 2nd sentence		This sentence is intended to be an explanation of optimization, but is one more likely to confuse. Surely this should explain the ALARA principle, where you strive to reduce the level of dose/radiation detriment/risk to a level until to do so further would entail more "cost" than the additional risk reduction is worth.	Y	Sentence deleted for clarity		
UK	1.14/10		There is a reference to "individual source-related values of dose". Should these be referred to as constraints?	Y	Text amended to improve clarity		
ICRP	1.15 line 1		Limiting risk of accidents does not control occupational or public exposure. An exposure is matter of extant situation while accident risk involves unlikely events. Also in normal conditions exposures are controlled not only by individual dose limits but also by optimization (e.g. number of exposed persons).	Y	Text amended based on all comments received		Some rephrasing seems appropriate
ILO NZ (trade unions)	Personal Dosimetry Sections 1.15, 1.20-1.22	There are different options for the logistics of personal dosimetry. While an assessment of risk in the individual workplace can help influence the method used, it would be useful to have some recommendations for best practice included as part of the standards. The standards give general guidance but appear to be too much open to interpretation.				N	Specific guidance on how to implement the requirements in the BSS is published in separate safety guides

ILO NZ (Dept of labour)	Section 1.15, 1.20-1.22	(a) The NZCTU comments on personal dosimetry pertaining to Section 1.15, 1.20-1.22 are supported here. Some indication of best practice in this regard is essential as part of this standard or as an adjunct to it. (b) The document is rather verbose, which detracts from ease of reading. However the subject matter covers scenarios likely to be encountered in New Zealand, including use of radio nuclides in medical and commercial circumstances, as well as addressing radon in terms of occupational exposures. In this respect the document is relevant to local conditions.		Y	Para. 1.20 has been rewritten to clarify and simplify the text.	N	Specific guidance on how to implement the requirements in the BSS is published in separate safety guides
ILO NZ (trade unions)	Section 1.15	Occupational and public exposures are controlled by limiting the risk of accidental exposures and by assuring that, in normal conditions, doses received by individuals do not exceed specific dose limits. The emphasis appears to be on the quantum of the dose used, not the level of training, awareness or involvement of the workers concerned. The apparent top down nature of the development and application of safety systems and procedures leaves out the fundamental resource of the knowledge and experience of the workers in the industry.		Y	Text amended based on all comments received		Some rephrasing seems appropriate
Poland	1.15	ADD in the last line: „and all doses are kept as low as reasonably achievable taking economic and social factors into account".	To clarify and implement Safety Principle 5 (in 1.7).	Y	Text amended based on all comments received		Some rephrasing seems appropriate

Spain	1.15	This paragraph as it is now is only appropriate for "planned exposure situations". This is not clear in the text.	N/A	Y	Text amended based on all comments received		Some rephrasing seems appropriate
UK	1.16, 1st sentence	Revise to read "All reasonably practicable efforts…"	The sentence as drafted could be read as meaning anything practical must be done if it could contribute to accident prevention/mitigation irrespective of cost. In the UK the words "reasonably practicable" are used and have a legal meaning that includes the requirement for costs to be considered			R	The text is a direct quote from SF-1.
USA	1.17	Suggest text be elaborated.	In section 1.17, "nuclear" includes nuclear explosions. In such an event, there is no way to ensure that radiation risks would be minor. Fallout will create exposure problems up to miles away. There are ways to ensure the loss of life is minimized and protect people from long term effects. While a nuclear explosion is unlikely, it is not impossible. The document should mention this but does not need to be addressed in detail. Text which specifically refers to a nuclear explosion should also contain the appropriate level of detail so as to not mislead the reader as to the probability of the scenario. It would be inappropriate to point out this type of scenario without mentioning other, more likely, scenarios. That level of detail would be more appropriate for a document such as DS44, Criteria Used for Preparedness and Response for a Nuclear or Radiological Emergency.			N	The need for guidance material is accepted, but it is not appropriate to include this material in a requirements document such as the BSS

ICRP	pg 12, 1.17 line 2		When it is said "nuclear or radiation incidents", the scope of the incident is not clear. In addition, emergency planning and preparedness are, in general, not relevant for such an incident indicated in item (ii) of the article, i.e. a reasonably foreseeable incident whose risk would be minor.				Comment: In IAEA parlance, "incident" is a broader term than "accident" and includes malicious acts
USA	1.18	Suggest addition of the following sentences to end of 1.18i: Potential exposures are not planned to occur, although the situation (use of the source) is planned. The occurrence of an event or sequence of events considered as a potential exposure during the assessment of a planned exposure situation may be treated as an emergency exposure situation, depending upon the severity of the event.	The definition of "potential exposure" here and in the glossary is good, but there is a benefit to providing a clearer explanation of what is meant by 'planned exposure' vs 'potential exposure'. It is difficult to draw a very sharp distinction between emergency and potential exposure. The suggested addition is intended to clarify this explanation. However a separate consideration of the use of potential exposure, in the case of long term scenarios in waste disposal, is still troublesome. Potential exposure from sealed waste management facilities has its own IAEA safety standard, WS-R-4, which suggests it is a separate class of exposure (the document does not discuss its scenario-driven exposures as potential exposure, but that clearly is its subject). There needs to be emphasis in the text that the estimated exposures from a planned exposure situation represent possible, not real exposure.	Y	First proposed new sentence seems to duplicate existing text. Second sentence slightly modified and added.		
USA	1.18	Consider Elaboration	Elaboration to help understand the differentiation between planned and			N	This is material for a safety guide

			existing exposures could be helpful. During the U.S. review, a question was raised regarding where treatment of releases, such as tritium from a leak from underground piping in a facility, would be treated. It may be appropriate to make clear how this situation should be handled. Consideration should also be given to clarification of requirement paragraphs if necessary.				rather than a requirements document We cannot address particular examples in the Introduction.
ENISS	1.18		Comment: description of occupational exposure, public exposure and medical exposure should be added				Comment: Not fully clear – is the proposal for additional text? These terms are already defined in the glossary.
ENISS	1.18 (i)	Add a footnote "dose constraints and dose limits do not apply for potential exposure"	In paragraph 1.18 the definition of planned exposure situation includes "potential exposures". In section 1.20 in the optimization process it is introduced the planned dose constraints, but the dose constraints are valid only for the doses planned and not for potential exposures, for potential exposures have to use the risk constraints as defined in ICRP 103.	Y	Text has been changed in para 1.18 and makes the footnote unnecessary.		
Czech	1.18(i)	"potential exposure" – last sentence	Use the definition from glossary	Y	Amended in line with comment from USA		
Sweden	1.18. (i)	The last sentence should be explained further.	How can an "exposure (that) is not expected …" represent "a planned exposure situation"? The word "accident" is more likely to be	Y	Amended in line with comment from USA		

			associated with para 1.18. (ii).				
UK	1.18 (ii)	Replace last sentence with: "Although preventative and mitigation measures can be taken before an emergency exposure situation arises, once it actually occurs than exposures can be reduced only by protective and other actions."	It would be helpful to recognize that some actions should be taken before the onset of an emergency.	Y	Text amended in line with all comments received		
Austria	1.18(ii)		Please clarify "other actions" in the last sentence of that paragraph.	Y	Text amended in line with all comments received		
Germany	Para. 1.18 (ii)	Exposures can be reduced ~~only~~ by protective and other actions.	The meaning in this context and the relationship between "only" and "other actions" is not clear.	Y	Text amended in line with all comments received		
WNA	1.19	Para.1.19: It overlooks **air passengers' exposure**!					ICRP states that these exposures are unamenable to control.
Spain	1.19	The treatment for the air crews is different to that in the EU BSS. This is perhaps an issue for the "Inter Agencies Committee"	N/A			N	There is very little difference in the protection afforded by considering aircrew exposure as either a planned or existing exposure situation
UK	1.19/9 and 5.1 (c) (iii)		The viewing of aircrew exposure as an existing exposure is contrary to the draft EU BSS view, which considers it to be a planned exposure. The EU view ensures occupational exposure controls are applied. A consistent			N	There is very little difference in the protection afforded by considering aircrew exposure

			approach is desirable in view of the global nature of air travel.				as either a planned or existing exposure situation
Argentina	1.20	It is proposed to modify the second sentence as follows: "For occupational and public exposures in planned exposure situations, a dose or risk constraint serves as a boundary in defining the range of options in optimization..."	Planned exposures embrace both normal and potential exposures. Dose constraint applies only to the normal situation, while risk constraints apply when dealing with potential exposures.	Y	The introductory text and the requirements on dose constraints have been rewritten to take account of all comments received		
Austria	1.20		Para. 1.20 of DS379 restates the limited circumstances of considering social and economic factors, again forgetting environmental factors as well as specified in SF-1.	Y	The introductory text and the requirements on dose constraints have been rewritten to take account of all comments received		
Belgium	1.20	At the end, after the words "…and the available technology.", add the following sentence: In view of the current scientific uncertainties with regard to the health consequences of the exposure of certain organs or systems (in a footnote, cite the lens of the eye and the cardiovascular system as examples) and as a matter of precaution, the optimisation principle could also be applied to organ doses, where appropriate, to keep these doses as low as reasonably achievable.	The Group of Experts to art 31 of the Euratom treaty, in its conclusions of the EU Scientific Seminar in 2008 on emerging evidence for radiation induced circulatory diseases, indicated that epidemiological evidence is accumulating in favour of an increased risk in circulatory diseases for cumulative doses higher than 0.5 Gy low-LET radiation." There is also increasing evidence of cataract being generated at lower exposures than the thresholds previously presumed.			N	The IAEA will reconsider the dose limit for the lens of the eye once the ICRP has published its assessment of the available scientific evidence. The BSS requirements are based on existing accepted scientific data and it is not helpful to the user

							to suggest a different approach
Czech	1.20	first sentence – use societal instead social	ICRP 103	Y	Change made – also to para. 1.11, 1.12 and 1.14		
ICRP	Pg 14, 1.20	Indicate the relationship between "Operational limits and conditions", such as authorized discharge limits (see 3.31, 3.122), and the prospective quantities "constraints". Delete the text of para 1.20 after "…. regulatory infraction"	In order to avoid confusion	Y	The introductory text and the requirements on dose constraints have been rewritten to take account of all comments received		
India	14/1.20	Comment: For harmonization internationally dose limits for planned exposures are recommended. for harmonization of 'optimization' is it possible to recommend even 'dose constraints' facility and activity wise?	Query and suggestion.	Y	The introductory text and the requirements on dose constraints have been rewritten to take account of all comments received		
WNA	1.14, 1.20	Para.1.14, 1.20: **Optimization-constraint**: These paragraphs confuse constraints as an integral part of Optimization and a priori set constrained-optimization – the former is correct and the latter not. They need be corrected accordingly. See Specific Comment No.28.		Y	The introductory text and the requirements on dose constraints have been rewritten to take account of all comments received		
Czech	1.21	second sentence " The reference level represents the level of dose or risk above which it is judged to be inappropriate to plan to allow exposures to occur , and below	To express better that the optimization is continuing process , we optimize also above the reference level			N	ICRP 103 specifically refers to optimizing below the reference level

		which optimization of protection continue to be implemented.					
USA	1.22	Consider revision: Any situation resulting in a dose above 100 mSv incurred acutely or in a year would be considered unacceptable except under circumstances addressed specifically in this document.	Current text is too general considering that those circumstances are addressed later in the document and appropriate exposure limits are established, specifically in table IV-2	Y	Text amended		
Spain	1.22	The example given for the 1 to 20 mSv/y band as "dose constraints or reference levels", is only for occupational exposure in "planned exposure situations" and there will be useful to add other example representative of "existing exposure situations".	Clarity	Y	Text amended to cover reference levels in existing exposure situations		
UK	1.22, 1st sentence		Consider rewording this sentence to improve understanding; it is currently difficult to read/understand.			N	Editorial. No other requests to clarify text. Not clear what part of the sentence is confusing
Finland	1.22, second sentence	Please change "natural background radiation" to "radiation of natural origin".	The doses given in the footnote include doses caused by indoor radon WHICH IS NOT "background radiation". The UNSCEAR reference in the footnote "radiation of natural origin" is correct and should be followed also in the main text.	Y	Text amended for consistency with footnote		
Ireland	1.22 (iii)	What does the word "attribute" mean? It might be more appropriate to use the word "circumstances".		Y	Text amended		
WNA	1.22	Para1.22: **Dose constraints or reference levels lower that are lower than 1 mSv/y** are based on which grounds? See General Comments No.1 to 17.					Comment: The changes made to para. 1.20 address

							this point
Germany	Para. 1.23	a) Because of the synergistic effects of smoking and exposure to radon, the absolute risk of lung cancer from unit exposure to radon for smokers is more than twenty times greater than for those who ~~do not smoke~~ never smoked. b) The differences in risk should be taken into account……	a) This statement is only valid for smokers compared to "never-smokers" not for those who gave up smoking or who do not smoke in the moment. b) Consequences are not clear: For example, should smokers get better protection than never-smokers because of their higher risk? Clarification is necessary or the sentence should be deleted. At least an explanation/example should be given in a footnote.	Y Y	Text amended Best option is to delete sentence		Comment: The policy implications are not clear – do we set standards to protect the smoker or the non-smoker from radon? And is there any health benefit to restricting smoking in the workplace when individuals are free to smoke elsewhere?
ILO NZ (trade unions)	Section 1.23 Addressing risks of smoking	Workers should be involved in any plans to address and reduce risks from smoking including full support for quit smoking type programmes. Information provided on the risk of exposure to radon should highlight the enhanced risk for smokers. This difference in risk should be taken into account in designing radiation protection approaches in setting smoking policies for workplaces, in consultation with worker representatives.		Y	Text has been amended in line with comment from Germany		
India	15/1.23	Comment: Yes, there is higher risk for smokers but in case we are to mention specific factor of 20, it is proper to give a reference. In that situation only the last sentence will be meaningful. In the absence of this reference both these		Y	Text has been amended in line with comment from Germany. Reference will be added as also		Editorial review – add reference

		sentences may be deleted.			requested by NEA and Japan		
Israel	Footnote 2 (1.22)	"in any large population" could be understood as "in any country or region". Since it is not sure that the mentioned distribution of doses fits all countries or regions, it would be better to refer to it as the worldwide distribution.				N	Wording has been taken directly form UNSCEAR
ICRP	pg 16, 1.23 line 1		The Commission will not provide separate dose conversion coefficients for smokers. Hence the last sentence could cause confusions.	Y	Last sentence has been deleted		
Australia	Para 1.23	Delete this paragraph If the paragraph is to be retained, it is suggested that it be reworded as follows: *The system of protection and safety in these standards includes protection against exposure to radon which is based on the average level of risk to a population with typical but various smoking habits. Because of the synergistic effects of smoking and exposure to radon, radiation protection approaches should consider public and worker acceptable means to reduce the dominant contribution from smoking to radon risk.*	The ICRP position on radon and smoking is still not clear, and the paragraph makes recommendations that are more suited to a Safety Guide rather than an introduction to a Requirements document. Although it is admirable that the drafters of the document want to address the biggest cause of cancer (smoking) the means of controlling the much smaller radiological component is still under scientific debate and is not mature enough for inclusion in the BSS. The statement of twenty times risk could be taken out of context and result in either unwarranted public or worker concern and potentially give rise to future litigation risks. Until a well developed process for handling the difference between smokers and non-smokers is approved through appropriate bodies (ICRP) a statement like this should not be in the BSS.	Y	Last sentence has been deleted Comment: Scientific data supporting factor of 20 higher risk for smokers compared with never smokers has been reviewed and accepted by both UNSCEAR and ICRP. Agree that the policy implications of this have not been fully developed		
NEA	Para 1.23	**The system** of protection and safety…	EGIR felt there is a need to mention risk for different groups (children				Comment: request is not clear – this para.

			versus adults, pregnant women...). For completeness there is need to DRAFT additional sentence here showing value of reference level for dwellings (300 Bq/m3).				deals specifically with radon and smoking
NEA	Para 1.23	…than **twenty times** greater than…	EGIR felt there is a need for reference and/or justification/explanation for this number. Eventually further explanation may be inserted as footnote.	Y	Reference to be added		
Japan	1.23/4-5	(Following information which relates in the description "...20 times greater than ..." in paragraph 1.23 should be added in footnote or reference.) "Radon in homes and risk of lung cancer: collaborative analysis of individual data from 13 European case-control studies. Darby S et al", BMJ, 330, 223-227, 2005	All scientific values in Basic Safety Standards should have a significant mean. Therefore, information of reference paper for each scientific value should be added in footnote or references.	Y	Reference to be added		
Canada	1.24	Dose constraints are also used in the optimization of protection of caregivers and persons exposed in biomedical research.	Consider the term 'caregivers' instead of 'carers'			N	"Carer" is a more widely used and understood term. "Caregiver" is specifically used in USA and Canada and could cause translation problems into other IAEA languages
Germany	Para. 1.24	"Dose constraints are also used in the optimization of protection of carers and persons volunteers exposed in biomedical research, for whom no direct medical benefit is expected from	Biomedical research projects can include either healthy volunteers or volunteers with a clearly defined disease. For volunteers with a clearly defined disease, participating in a			N	Such additional text is not appropriate for the Introduction, or as a

		the exposure. In addition, for these volunteers, constraints with respect to age and mental state are established. Dose constraints are not applicable to the exposure of patients to radiation for individuals as part of their own diagnosis or treatment."	clinical study, it should be considered if dose constraints make sense. So, for example, for volunteers diseased with cancer, who participate in a radiotherapy study, dose constraints are meaningless. The same holds true for chemotherapy studies, in which an extensive therapy monitoring and follow-up is typically performed by use of CT. These volunteers usually have – at least – a potential benefit from participating in a clinical study. However, the key question here is, if the aims of the study are meaningful from a scientific point of view, if the study is well designed and if the expected benefit of the study for the further development of health care justifies the individual radiation-induced risks and harms potentially caused by participating in the study. Therefore, dose constraints should be restricted to healthy volunteers, for whom no direct medical benefit is expected from their exposure. For individuals, for whom no direct medical benefit is expected from their exposure due to a biomedical research project, further obligations are necessary; especially those individuals being younger than 18 years or being mentally handicapped should not take part in such a biomedical research project. In addition see comment to Para. 1.13				requirement. It would be covered in a future Safety Guide.

USA	1.24	Insert after "carers" the word "(caregivers)" This should be inserted in all instances were the term "carer" is used in the document, particularly the glossary since it is a new term.	There is no such word in the American English dictionary as "carers". Rather, the word is more typically English. Unsure how "carers" will translate into other languages.			N	"Carer" is a more widely used and understood term. "Caregiver" is specifically used in USA and Canada and could cause translation problems into other IAEA languages
USA	1.24	Remove reference to dose constraints being applied to persons exposed in biomedical research	Note: dose constraints are not applied to persons exposed in biomedical research (10 CFR Part 20.1002). Many persons included in biomedical research are in fact patients as well (e.g, clinical trials).			N	This is not the case for the BSS
ICRP	pg 16, 1.25	Add in 1.25, the following "In X ray diagnostic imaging, **interventional** and diagnostic nuclear medicine, diagnostic reference level (DRL) is …"	Diagnostic Reference Levels are not specifically addressed in the BSS for interventional procedures. ICRP has proposed the use of DRLs also for interventional.	Y			
ICRP	pg 16, 1.25	Make 1.25 more explicit by the following : "Periodic assessments of **incident radiation field quantities (for x-ray medical imaging) and of typical patient doses and/or administered activities (for diagnostic nuclear medicine)** are to be performed in …" Also 3.167 and the glossary should be modified accordingly	Dose reference levels for x-ray medical imaging are always quantities that relate to the incident x-ray fields and not the actual organ or tissue doses in a patient	Y	ICRP is correct, but existing text is retained for simplicity		
Germany	Para. 1.25	"In X ray medical imaging and diagnostic nuclear medicine, a diagnostic reference level (DRL) is	See comment to Para. 1.13	Y	Delete 'patient'	N	Proposed new text is redundant

		used as a trigger for investigation. Periodic assessments of typical ~~patient~~ doses and/or administered activities are to be performed in a medical facility and, if the comparison with established DRLs shows that the typical doses significantly exceed the DRLs and/or the typical administered activities are either too high or unusually low, a local review is to be initiated to ascertain whether protection has been adequately optimized and whether corrective action is required."	In X-ray diagnostics, DRLs serve as an upper bound.				
ICRP	Pg 16, 1.26	The inclusion of environmental protection is welcomed.			No action required		
ICRP	Pg 16, 1.26	The IAEA's 'aim', as stated here, is somewhat different from that set out in ICRP 103. It is more vague (and more restrictive) in that it refers only to protection of 'ecosystems' (which are not defined) against radiation risks (which are also not defined). Compare this with ICRP's (**103** (2.1 30)) aim of 'preventing or reducing the frequency of deleterious radiation effects to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems'. The term 'ecosystem' was apparently first used by A G Tansley in 1935 to describe a discrete unit that consists of living and nonliving parts, interacting to form a stable system. This could raise two issues for the IAEA. One is the problem of whether or not we are concerned with the non-living part of the environment (ie, simply contamination of soils etc.) More difficult, however, is the fact that the term ecosystem is usually used when referring to the environment on a large scale (eg as in 'the marine ecosystem'). It is hardly likely that a single authorization of anything is going to affect, adversely, the entire marine ecosystem, so aiming to protect it is not much of an objective. Perhaps it would be clearer if the IAEA stated that its aim was to protect the relevant natural habitats, and their fauna and flora, within the vicinity of the facilities being authorized.			Text under 'Protection of the environment' has been modified based on all comments received.		
ICRP	Pg 16, 1.26	There is a lack of clarity in this section. For example the fourth sentence is a non-sequitor relative to the third. It appears what the authors are trying to say, by way			Text under 'Protection of the		

		of these two sentences, is as follows. For the environment immediately occupied by humans, the concentrations of radionuclides permitted to obtain (because of the presence of humans) will result in doses so low to other fauna and flora that they would also be protected. But in other parts of the environment as a whole, where humans do not dwell (for example in mud – as in the bottom of estuaries or the sea) dose rates to humans (via the food chain) could be acceptable, but the dose rates to the fauna and flora that dwell there permanently could be very much higher. Or are they trying to say something else?			environment' has been modified based on all comments received		
ICRP	Pg 16, 1.26	The 5th sentence implies that there are now, new, international 'trends' that indicate that the environment is more susceptible to radiation than was previously thought – is there evidence that this is actually the case?			Text under 'Protection of the environment' has been modified based on all comments received		
ICRP	Pg 16, 1.26	The final sentence states that these standards are designed to clearly identify (split infinitive!) protection of the environment as an issue to be assessed. But it is difficult to see how they do so as it seems the environment is not mentioned again.			Text under 'Protection of the environment' has been modified based on all comments received		
ICRP	Pg 16, 1.26	Presumably all of this was written before ICRP 108 was published. This now spells out a framework based on RAPs, their relationships with 'representative organisms', and thus application to different exposure situations. There is sufficient information in ICRP 108 to estimate doses to a range of animals and plants, and tables of DCRLs to compare such estimated doses with in order to see if further effort is required. The 'environmental community' would now expect all of this information to be used. It is, after all, now (since 103) part of the ICRP's 'system of protection'.			Text under 'Protection of the environment' has been modified based on all comments received		
EC	1.26 4th line	Change to: "…- is important to achieve equitable and sustainable…"			Text under 'Protection of the environment' has been modified based on all comments received		

Spain	1.26 Fifth line.	The following text is proposed "Protection of the environment has the general aim of preventing or reducing the frequency of deleterious radiation effects in the environment to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities, and ecosystems"	The reason being that the aims of radiation protection of the environment are not yet well defined and those of the ICRP in Pub 103 and 108 are expressed in a broader manner than just protecting ecosystems		Text under 'Protection of the environment' has been modified based on all comments received		
India	16/1.26/14	…This is normally accomplished through an environment **impact** assessment, which…	Add for correct terminology that is used for environment safety.		Text under 'Protection of the environment' has been modified based on all comments received		
Canada	1.26 14th line 16th line Lines 22 and 23	This is normally accomplished through an environmental impact assessment, which identifies….. The methods and criteria for the radiological impact assessment Designed to clearly identify the requirement for protection of the environment while leaving flexibility on how to meet the requirement into the appropriate….	Need for consistency in the use of terms Proposed text is clearer and relates to the intent better		Text under 'Protection of the environment' has been modified based on all comments received		
UK	1.26		This paragraph seems to require use of an environmental risk assessment process. Overall, we would support this requirement.		No action required		
USA	1.26	No change necessary.	We commend the IAEA for the drafting of this paragraph, and strongly support the approach taken, and integrated view of environmental		No action required		

			assessment.				
UK	1.26/10	Modify to read: "..environment. Trends also indicate**, for example in research work carried out for the Framework for ASSessment of Environmental ImpacT (FASSET) and Environmental Risk from Ionising Contaminants: Assessment (ERICA) projects,** the need to be able to demonstrate (rather than to ….."	It might be helpful to reference research projects carried out in this area under EC 5th and 6th Framework Programmes as sources of further information on this topic.			N	It does not seem appropriate to refer to two European specific research projects, among many undertaken throughout the world
Bulgaria	General comment – environ-ment	6. The subject matter and general purpose of the IBSS is the health protection of the population and workers against the dangers of ionising radiation. This includes the protection of the human environment as a pathway from environmental sources to the exposure of man. In line with ICRP Publication 103 this should be complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole. The policies for the protection of man and the environment should be coherent; requirements on the protection of the environment are incorporated in the BSS. Environmental criteria and dose constraints should be considered for the authorisation of discharges of radioactive effluent. The application of the principles of radiation protection to non-human species and ecosystems needs to be further developed taking into account the recent publication by ICRP (Publication 108) of guidance on the definition of reference animals and plants, and on the assessment of the impact of radiation on non-human species. The protection of the environment should not warrant a high level of regulatory control, and the means for the demonstration of compliance should be proportionate to the expected relevance of the issue, in line with the graded approach. The experience with this new issue is limited.			No action required		Comment: While this is still an area undergoing development, because the BSS is likely to have a lifetime of 10 to 15 years, it is important to include requirements to protect the environment, now and in the future, in line with the Safety Fundamentals
WNA	1.26	Para.1.26**: Environment**: We obviously appreciate and support a global and long term perspective on protection of people and of the environment in order to achieve equitable and sustainable development. The main problem here is that such a perspective needs to be introduced at a much broader policy level within the IAEA and its safety standards. Correspondingly, the concept of Environmental Assessment, which can only be narrowly invoked in relation to			Text under 'Protection of the environment' has been modified based on all comments received		

		radioactive discharges at the level of the BSS (see para.3.122), is also much broader and generally involves public hearings which careful consider broader issues like social and economic factors. In comparison, para.1.26 is too detailed and too subjective. On the environment, as stated in the WNA letter of 19 April 2010 to IAEA, "*we urge you to consider our view that IAEA's essential purpose in the BSS revision should be to achieve standards geared to the key challenges of our time. We live in an era in which the generation of nuclear energy and also medical applications of ionizing radiation are both expanding significantly due to the considerable health and environmental benefits they bring.*" Para.1.26**: Environment (continued)**: Concerning energy and climate change, in its 2009 World Energy Outlook (WEO 2009), the OECD's International Energy Agency (IEA) puts this world challenge into perspective and shows how choices in energy mix (especially nuclear power) considerably influence public and environmental wellbeing. In short, an increase in world electricity generation of about 10,000 TeraWatt-hours per year (TWh/y) is needed with a simultaneous reduction in CO_2 emissions from about 18 to 12 billion tonnes per year, all by 2030. This is to improve health, wellbeing and quality of life for billions of the world's poorest people while avoiding atmospheric concentrations of CO_2 in excess of 1,000 ppm and a corresponding increase in global average temperature of 6°C. This shows the magnitude of today's challenge. The WEO 2009 press conference revealed that the substantial increase of 10,000 TWh in "Green Growth" electricity generation by 2030 relies on renewable energy, nuclear energy and in the shorter term, on natural gas. Moreover, WEO 2009's summary and conclusions state that the path "*towards 'Green Growth' would bring substantial benefits*", including "*much less air pollution and huge health benefits*". This demonstrates the widely understood key role nuclear energy plays in meeting the challenge of the present era. Is there any evidence that IAEA accounts for this key role of nuclear energy as part of safety standard development?				
Denmark	1.28	These standards are primarily aimed at governments and regulatory bodies for adoption and implementation within national legal frameworks. Where these	The text in the draft 3.0 seems incomplete and the suggested paragraph better describes the objective.	Y	Text has been rephrased to underline that the majority of		Comment: some specific requirements are placed on parties

		standards are not fully implemented within the national legal framework, other parties as specified in section 2, health authorities, professional bodies, providers of specialized services such as technical support organizations and workers may use these standards or parts of them as guidelines for their work, complementary to the national legal framework			requirements apply to governments and regulatory bodies		other than goverments and regulatory bodies and it is not correct to refer to these as "guidelines for their work"
Finland	1.28	These standards are primarily aimed at governments and regulatory bodies for adoption and implementation within national legal frameworks. Where these standards are not fully implemented within the national legal framework, other parties as specified in section 2, health authorities, professional bodies, providers of specialized services such as technical support organizations and workers may use these standards or parts of them as guidelines for their work, complementary to the national legal framework	The text in the draft 3.0 seems incomplete and the suggested paragraph better describes the objective.	Y	Text has been rephrased to underline that the majority of requirements apply to governments and regulatory bodies		Comment: some specific requirements are placed on parties other than goverments and regulatory bodies and it is not correct to refer to these as "guidelines for their work"
Norway	1.28	Proposed revision: *"These standards are primarily aimed at governments and regulatory bodies for adoption and implementation within national legal frameworks. Where these standards are not fully implemented within the national legal framework, other parties as specified in section 2, health authorities, professional bodies, providers of specialized services such as technical support organizations and workers may use these standards or parts of them as guidelines for their*	BSS should be aimed at governments and authorities more than at licensees and workers. That would mean less details and probably more clarity	Y	Text has been rephrased to underline that the majority of requirements apply to governments and regulatory bodies		Comment: some specific requirements are placed on parties other than goverments and regulatory bodies and it is not correct to refer to these as "guidelines for their work"

		work, complementary to the national legal framework."					
Sweden	1.28	These standards are primarily aimed at governments and regulatory bodies for adoption and implementation within national legal frameworks. Where these standards are not fully implemented within the national legal framework, other parties as specified in section 2, health authorities, professional bodies, providers of specialized services such as technical support organizations and workers may use this standards or parts of them as guidelines for their work, complementary to the national legal framework.	The text in the draft 3.0 seems incomplete and suggested paragraph better describes the objective.	Y	Text has been rephrased to underline that the majority of requirements apply to governments and regulatory bodies		Comment: some specific requirements are placed on parties other than goverments and regulatory bodies and it is not correct to refer to these as "guidelines for their work"
USA	1.29	Add citation	Nephrotoxicity associated with ingestion or inhalation of uranium should be cited as an example of a non-radiological aspect of health and safety that the draft safety guide addresses.			R	Outside scope of BSS.
ICRP	Pg 17, 1.29	Delete "which include …….".	"Ionizing radiation" is a defined term (see Glossary).			N	This is explanatory text and the clarification seems useful
Austria	1.31		The distinction between exposures "amenable to" and "unamenable to" control is unclear here.			R	This is a regulatory decision, and the word is used in its dictionary sense.
Israel	1.31	Footnote 3. Add to glossary the definition of "natural background"			Definition of natural background		

		including all natural sources. It is used several times in the text, without precise definition.			is defined in IAEA Glossary, and is to be added to BSS Glossary during editorial review.		
Spain	1.31	Instead of saying "amenable to control", it should be better to say "are considered as amenable to control"	There will almost always be a need to use judgement to decide.			R	Change opens up to "considered by whom?"
UAE	1.31	Refer to RS-G-1.7 in footnote 3	The brief reference to exclusion in para 1.31 appears to downplay the concept				It is policy not to include references to documents at the Safety Guide level.
UK	1.31	Add a new sentence at the end of this paragraph to read: "Guidance on amenability to control and appropriate exclusion is given in RS-G-1.7 *Application of the Concepts of Exclusion, Exemption and Clearance*."	There is no mention of exclusion in the text apart from in Para 1.31. Whilst it is not unreasonable to say that the BSS does not apply to excluded materials, it might be helpful to make it clearer particularly in relation to NORM. As the IAEA already has a suitable document (RS-G-1.7) either this should be referenced or Footnote 3 should be expanded to cover natural radionuclides at 1 Bq/g or less.				It is policy not to include references to documents at the Safety Guide level.
WNA	1.31	Para 1.31: **Amenable to control or not**: If this paragraph is kept, it must be clarified in the requirements (Sections 2 to 5). As shown in General Comments No. 1 to 18, there is a clear imbalance in the control of public exposure from the main sources of exposure, and a lot of it has to do with the lack of rationale on what is amenable to control or not (a key question that goes well beyond the RP community alone) and on what is the real radiation safety gain that can be achieved or not.					Comment: This is material for a safety guide but the ultimate decision on what is unamenable to control lies with the government or regulatory body in each

							Member State
Belgium	1.32/1	… in all facilities and activities…	Coherence with 2nd sentence.	X			
Israel	1.32	1. Add "They are part of General Safety Requirements (GSR) applicable with a graded approach to all facilities and activities and composed of a set of 7 publications addressing 7 different themes (these standards being Part 3 of the GSR)." after the first sentence. 2. "Specific Safety Requirements" instead of "other Safety Requirements".	Changes introduced to reflect the long term structure of safety requirements			N	Editorial. This will be explained in the front matter which will be added later.
Sweden	1.32.	Last sentence: …, specific Safety Guidelines ~~have been~~ **will be** developed and published.	If there are any Safety Guides, they should be referred to.	Y	Use "are developed and published"		Comment: some safety guides are already published, particularly to support other SR documents
USA	1.32	Delete new last sentence. These Standards comprise basic requirements to be fulfilled in all activities involving radiation exposure. For certain facilities and activities, such as nuclear installations, radioactive waste management facilities and the transport of radioactive material, other Safety Requirements, complementary to these Standards, also apply. ~~These Standards are supported by thematic safety standards.~~ To assist with implementation of these Standards, as well as other relevant Safety Requirements, specific Safety Guides have been developed and published.	It is not obvious why the sentence was added at the end. While true, the BSS is supported by other general safety requirements, and thus the reference would seem to be duplicative of material already present. The modified sentence also seems to be duplicative and unnecessary.			N	Text has been written in this manner to distinguish between safety requirements and safety guides

Czech	1.33	These standards apply to ~~exposure and potential exposure in~~ the following three categories…	It is not clear why it is stressed here potential exposure	Y	Text amended as proposed		
USA	1.33	Revise the sentence to read: These Standards apply to ~~exposure and potential exposure in~~ the following three categories of exposure: occupational exposure, public exposure and medical exposure.	Clarity.	Y	Text amended as proposed		
ICRP	pg 18, 1.33 line 1	"and potential exposure" should be deleted.	Classifying the person into three categories (occupational, public and medical) has no meaning for potential exposure. The purposes of categorization of exposed persons for the three exposure situations are to deal them separately to simplify the system of protection and to apply different control measures i.e. different values of dose limits, dose constraints or reference levels. Since potential exposure is not a real exposure (although it uses the word 'exposure' after tradition), only risk limits/constraints are considered, where we do not account what are the persons but accounts them as natural persons.	Y	Text amended as proposed		
UK	1.34		For completeness and clarity. Consider providing a list of acronyms within the document, eg for FAO, ILO, PAHO and WHO.				To be included in front matter.
ICRP	Pg 18, 1.35	Add a statement about the role of the ICRP in establishing of protection quantities. E.g. "effective dose" is a protection quantity, which is defined by	ICRP defines protection quantities			N	This is covered by para. 1.5 which states that the IAEA takes account of the

		the ICRP.					recommendations of the ICRP
WNA	1.36	Para 1.36: The **coverage by exposure situations** (planned, medical, emergency and existing) is not ideal but it is fine provided that the coverage of each main source of public exposure is clear and well balanced – i.e. commensurate to the actual risk. As viewed by General Comments No.1 to 17, this is far than been the case.					Comment: The decision to use "exposure situations" was at the request of MS
UAE	Paras 1.36-1.43	The document as a whole is very complex and there is much repetition following from the three 'exposure situations' and the three 'exposures' and the roles of the Government, the regulatory body and the licensees. The drafting of the paragraphs in this section should be carefully reviewed and more graphic techniques considered for use with the aim of making the structure of the document clearer and more user-friendly. The section could also be given more prominence – perhaps standing as a separate section as a guide to using the BSS .					Comment: This will be considered by the technical editors in conjunction with NSRW staff
India	19/1.41/1-4	…The ~~**locations**~~ **sections**, within these standards,…in Table 1. ~~**Thus for**~~ **For** any particular facility or activity, more than one section of these Standards ~~**must**~~ **may** be considered,….	Editorial corrections to replace a few words with more appropriate ones.			R	editorial
EC	1.41	Add a sentence after Table 1: "This is also the case for requirements to protect the environment. General requirements are given in Section 2 whereas specific requirements related to the different exposure situations are given in Sections 3 and 4. "	Considering the importance the international BSS gives in its Fundamental Safety Principles to the protection of the environment, it should be indicated in the part about Structure, where such requirements can be found in the following Sections.	Y	Text amended		
South Africa	1.41 (ii)	Include a list of the numbered Requirements and page numbers with Table 1	For easy reference			N	We do not want to specifically reference overarching requirements as this could lead to an assumption that only these are important.

							The contents page will include a list of an internal headings and page numbers for eacy reference
UK	Page 20 Table 1	**Section 3** should be inserted before "Paras 3.5 to 3.67" in all three columns of Table 1.	Omission.	Y	Text will be amended during editorial review		

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country/ Org.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 2: General Requirements for Protection and Safety							
Norway	Chapter 2	Long repetitions	There are long repetitive requirements on responsibility for different parties. This could possibly be written in a more general form.				
Norway	Chapter 2	More focus on education and training and detailed advices	More emphasis should be given to the important section in chapter 2 on education and training if the BSS is expected to be a "*self standing*" document. More specific and detailed advice on the requirements on education and training and on competences and duties for the *qualified expert* and the radiation protection officer should be given, both for operators and authorities. Qualified expert, although defined, is little used in the document.			R	Education and training is covered in paras. 2.21, 2.33 and 2.44. Specific requirements on E&T are addressed in other parts of the BSS.

UAE	2.1	Refer only to the IAEA Safety Glossary.	There are terms in the BSS not defined in the attached 'BSS' glossary. If there is a separate BSS glossary, inevitably over time there will be divergence with the overall IAEA Safety Glossary.			R	The BSS Glossary contains terms that are related to BSS, and is being updated for the revised BSS.
India	2.2/1	…~~**Except as**~~ **Unless** specifically authorized by …	Editorial			R	Use text of current BSS.
Ireland	2.2	This paragraph should be reworded for clarity.				R	Use text of current BSS.
Israel	2.4	Add "the" before "regulatory body"	Editorial	X			
Czech	Req. 1	Application of the principles of radiation protection – is it an intend to mention here only radiation protection and not safety – then it is not in compliance with the rest of the text where protection and safety is used. The rest of text in paras 2.8.-2.12. concerns justification, optimization and limitation – what about other principles named on p. 8? Is this an application or only a list of some general (or basic) principles for radiation protection?	It is confusing why only three principles are mentioned here. I recommend also to delete the title of requirement – see general comment.			X	BSS draft 3 includes requirements on the implementation of the other safety principles. The last sentence of para 1.7 states that there are three principle of radiation protection.
ILO NZ (trade unions)	Section 2.5	Rather than "*Nothing in these Standards shall be construed as restricting any actions that may otherwise be necessary for protection and safety"*, there should be a positive provision promoting the use of actions necessary for protection and safety.				X	Use text of current BSS. Clear legal statement.

ICRP	pg 22, 2.8 line 3		It is said that no practice is undertaken unless justified while ICRP Publication 103 says that changes in exposure situations should be justified. Justification of practice is the term used under the old practice-intervention based system.			X	2.8 only addresses planned exposure situations. The term "practice" is still used in the BSS in its normal meaning, Paras 2.8 and 2.9 together reflect ICRP recommendation
ICRP	pg 22, 2.9 line 3	"preventive," should be deleted.	It implies that preventive actions are justified in emergency and existing exposure situations. This is conceptually strange because emergency or existing situations are at the scene already so that preventive actions have no meaning.	X			
Ireland	2.9	Include the term "Protection Strategy" in the glossary. This is the first time that "Protection Strategy" is mentioned. There is no explanation and it is not included in the glossary.				X	The text has been modified to read strategy for protection. *It's used as plain language term*

Spain	2.8 and 2.9	Justification covers very often much more than just radiological protection considerations. Consequently it would be convenient to add a foot note recognising this fact, placing the emphasis on the "justification process" on radiological protection grounds and clearly stating that the responsibility to take the decision may well be aside the RP community.	Self explained			X	2.8 and 2.9 does not state who and how justification is to be made. See for example req 10, 37,
Spain	2.10	At the end of the phrase it could be convenient to add: "…optimised, considering the appropriate dose and/or risk constraints or reference levels".	Clarity			X	The use of dose constraint, reference levels is addressed in the respective exposure situation. In 2.10, such an amendment would lead to more confusion than clarity

ENISS	2.10	In all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety are <u>being</u> optimized[4] Foot note 4. <u>Being</u> optimized means <u>that optimization is being done and the results are being implemented in a continuous process.</u>	From the definition of optimization in the glossary and the explanatory remarks in 1.14 it is obvious that optimization is always a process. The formulation "is optimized" has to be understood therefore as the grammatical passive form of the verb optimize and not as the past tense. In our view, this understanding is crucial (see below) and the respective ambiguity due to English grammar has to be fixed, especially since most of the readers of the BSS are non-native English speakers. Past tense "be optimized" would mean a static status which is not intended by ICRP's optimization principle. It cannot put into practice as e.g. the optimized state today may no longer be optimized tomorrow as the conditions may change. The proposed change of the formulation aims at an understanding in line with ICRP 103 using the idiom "process of optimization".			X	Extensively discussed in the past. RASSC agreed to the phrase 'is optimized' Grammatical structure implies that the process has been carried out.
Spain	2.10 and footnote 4 in page 22	Here again it's highly convenient to recognize that radiological protection considerations are often just one component in the whole optimization process.	Clarity			X	This is addressed in subsequent requirements, e.g. req 11

India	21/2.8-2.11	Comment: The phrase 'when relevant requirements apply to that party' may be deleted from each of these para.	The requirements listed in these paras read better and clearer without this phrase.			X	It would be wrong to delete this part because the requirement would be misunderstood as being applicable to all mentioned parties The current wording provides flexibility to select requirements that apply to a particular case.
Austria	2.8 – 2.11	ensure, ~~when relevant requirements apply to that party~~, that	This qualifier is more misleading than helpful and weakens the standard requirements.			X	See India above
France	2.10	Replace foot note 4 by "optimized means that optimization of protection and safety ***is being*** applied and the result of that process has been implemented ***in a continuous way***"	Optimization is a continuous process			X	See ENISS 2.10.
ICRP	pg 22, 2.11 line 1	Insert "except for the case of medical exposures" after "situations".		X			

WNA	Specific 2.12,2.18 2.32,2.49	**<u>Requirements commensurate to the actual risk</u>** – These key generic requirements of Section 2 are overarching the subsequent more detailed requirements of Sections 3, 4 and 5. The latter must therefore be fully consistent with the former. "*2.12. The application of the requirements of the system of protection and safety shall be <u>commensurate</u> with the nature and extent of the radiation risks associated with the exposure situation and with the magnitude and likelihood of the exposures.*" "*2.18. The government shall ensure a graded approach to the control of radiation exposure, so that the stringency of regulatory requirements applied to any exposure situation is <u>commensurate</u> with the associated radiation risks.*" "*2.32. The regulatory body shall employ a graded approach to the implementation of the system, applying requirements that are <u>commensurate</u> with the radiation risks associated with the exposure situation.*" "*2.42. The relevant principal parties shall establish and implement a protection and safety programme appropriate for the exposure situation. The protection and safety programme shall:* *(a) Adopt protection and safety objectives in conformity with the requirements of these Standards;* *(b) Apply protection and safety measures <u>commensurate</u> with the nature and extent of the radiation risks associated with the exposure situation and sufficient to ensure compliance with the requirements of these Standards….*"		X	EDITORIAL Wording consistency needs to be ensured		
Argentina	Para. 2.12, line 3	The text: "and with the magnitude and likelihood ofthe exposures" should be deleted	The text to be deleted is redundant with the definition of "Risk" in the Glossary	X			
	Para 2.13 footnote 6	Footnote 6 should be deleted	Radiation Risk is defined in the Glossary,	X			
Israel	Heading before Req. 2	Add "THE" before "GOVERNMENT"	Editorial	X			

Czech	Req. 2	… organizational framework for protection against radiation risks	Is there a reason to use another words instead radiation and safety? This appears in whole text – there is radiation protection, protection and safety and protection against radiation risk – pls. reconsider to use only one relevant expression.	X	Use 'protection and safety'		
Israel	2.14	Delete the sentence "The legal, regulatory … radiation risks."	The same sentence appears in para. 2.13	X			
NEA	Para 2.14	MODIFY …shall ensure **a system for** adequate protection…	The EGIR felt that while the government cannot ensure safety, it can and should ensure the establishment of a system.	X	Modified: "The government shall ensure that adequate arrangements are in place for protecting people and the environment, both now and in the future, against harmful effects of ionizing radiation without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks"		
ICRP	pg 23, 2.14 line 4	"rise to radiation risks" may replaced by "benefits".	The intention of this sentence should be ensuring protection without unduly limiting beneficial activities.		Text has been modified.		
UK	2.14, 2nd sentence		This sentence does not read well. Modify to improve clarity.		EDITORIAL		

USA	2.14	Reword the paragraph to state "The government shall ~~ensure~~ provide a system for adequate protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation.'	Paragraph requires the government to 'ensure adequate protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation.' Governments cannot *ensure* the public from risk but they can and do provide a system that is designed to protect the public from radiation effects.	X	See NEA 2.14		
USA	2.15, 2.52, and 3.61	Replace "inter alia" with "among other things."	Clarity. This Latin phrase is not common in the U.S. and many other places. This may pose a translation difficulty.		EDITORIAL		
India	23/2.15	Add new clause after ' c ': The Government should establish a single regulatory body with jurisdiction over the whole country to regulate all practices involving radiation exposures.	This is must for harmonization of regulations.			X	(d) covers the establishment of a regulatory body. By definition, a regulatory body may be a single authority or a system of authorities

India	23/2.15	Add new clause after ' e': The Government should promote national associations of specialists in radiation safety and encourage innovations in regulation and control of radiation exposures.				X	This suggestion is too specific for a requirement type doc. There is a number of requirements related to the involvement of interested parties including the public and professional organizations. (e.g. 2.19, 2.31 (f),…)
India	23/2.15/e	…Provides for coordination between **governments and** governmental agencies with …	In some federal structures there are smaller states and respective state governments, hence the addition.	X	Text modified to make consistent with GSR Part 1.		
USA	2.16	Consider clarification	Conceptually, it may be seen as a logical conflict to have the regulatory body effectively independent, and at the same time encourage the involvement of non-governmental organizations and stakeholders in various points of the process. Is there a way to clarify this to avoid confusion?			X	2.16 and 2.19(b) together clarify this issue and encourage involvement of interested parties without affecting independece
USA	2.18	Consider incorporation as a sub-bullet item in paragraph 2.15.	This requirement would seem to be one of the things that would be done by the government through the legislation, as given in paragraph 2.15.			X	Legislation is not the only means for the government to ensure graded approach

UK	2.18		The risk-based graded approach suggested here is welcomed as a way of balancing risk and detriment. This should be implemented across both the non-nuclear and nuclear sectors as a useful way to balance the true risks. However, there is still a lack of risk based strategy and administrative arrangements that do not differentiate between high and low risks.				
ILO NZ (trade unions)	Section 2.19	Delete *where appropriate* from 2.19 and from 2.19(b) as follows: 2.19 The government shall establish mechanisms to ensure that, ~~where appropriate~~: (b) Interested parties are involved in decision making or decision aiding processes, ~~as appropriate~~.		X	- Remove where appropriate from the stem of 2.19 - Keep 'as appropriate in 2.19(b)		
USA	2.19 and 2.19(b)	Remove one of the "appropriate" clauses	Use of the term twice is redundant.	X	See ILO NZ above		
Austria	2.21		The relation between "qualified experts" and other radiation protection professionals (e.g., radiation protection officer, etc.) has to be clarified.			X	- Para 2.41 indicates that a RPO is different from qualified experts. - Contrary to qualified experts, no formal recognition of RPO is required according to BSS 3.0. See also 3.93(e)

Ireland	2.21 (b)	Should “radiation protection officers” also be included here? The difference between a qualified expert and a radiation protection officer is unclear.				X	Contrary to qualified experts, no formal recognition of RPO is required according to BSS 3.0. See also 3.93(e), definition of radiation protection officer
Israel	2.23	Add "radioanalytical measurements," before "environmental monitoring"	Radioanalytical measurements are important technical services related to protection and safety			X	The list in 2.23 is not exhaustive
Spain	2.24	The words “and disposal”, can be deleted because “disposal” is included in the “radioactive waste management”, according to the glossary	Glossary	X			
India	25/2.23/2	…, such as personal dosimetry, **availability of appropriate radiation monitoring and characterization systems**, environmental monitoring, ~~**and**~~ calibration of monitoring and measuring equipments **and timely response to nuclear and radiological emergencies.**	Apart from ensuring availability of various monitoring services, government has to ensure that capability to respond to emergencies exists.			X	This is covered in chapter 4
India	25/2.24/3	…from facilities and activities, and ~~**for the safe management of spent fuel**~~ **Safety and security of disposal sites.**	Management of spent fuel is altogether a different aspect and not fitting here properly.			X	- the BSS covers radiological aspects of spent fuel management - safety requirements for disposal sites covered in other requirements publications.

Iran	Article 2.25	2.25. The government… against radiation risk. Rest of the article should be deleted	The methods and criteria for the environmental radiological assessment have not been developed yet, so identifying values is not possible.	X	2.25 Deleted		
Slovakia	2.25	Delete this paragraph	This paragraph is redundant with para. 2.14	X	2.25 Deleted		
Spain	2.25	Nowadays it looks too detailed to say "… including identification of the values, goals, and objectives to be achieved". Considering the existing doctrine it could be better to just say: "… within the general context of the protection objectives to be achieved".	N/A	X	2.25 Deleted		
Belgium	2.25/3	Delete "goals".	Duplication of "objectives".	X	2.25 Deleted		
Israel	2.25	Delete "including identification of the values, goals and objectives to be achieved"	The sentence is too vague. It could be replaced by making reference to the work being conducted by the ICRP on protection of the environment.	X	2.25 Deleted		
Poland	2.25	DELETE all text	Redundant, already covered by para 2.14.	X	2.25 Deleted		
USA	2.25	Delete Paragraph	This paragraph would seem to be duplicative of the requirements in 2.14. Both deal with ensuring protection of the environment.	X	2.25 Deleted		
NEA	2.25	**The government** shall…	The EGIR felt that this paragraph is almost totally redundant with 2.14, so these paragraphs should be combined.	X	2.25 Deleted		

WNA	Specific 2.25, 3.122, 3.125, Req.31	**Environment –** Para.2.25 is unclear. What is met by values, goals, and objectives …to be achieved? Relevant generic provisions are covered by para.3.122 and 3.125, and requirement 31. Para. 2.25 should be re-aligned accordingly.	Specific 2.25, 3.122, 3.125, Req.31	X	2.25 Deleted		
USA	2.29	Revise to read as follows. The government shall ensure that adequate arrangements are in place to allow the government to fulfill the international obligations and arrangements to which it has subscribed, including, as appropriate, provisions for peer reviews and cooperation. ~~In establishing the legal and regulatory framework, the government shall~~ ~~(a) fulfil its respective international obligations;~~ ~~(b) allow for participation in relevant international arrangements, including international peer reviews;~~ ~~(c) promote international cooperation to enhance safety globally.~~	This is paragraph which would mandate every member state to fulfill international obligations. Such a requirement is inappropriate, and outside of the scope of the safety standards.			X	Paragraph is the same as R14 of GSR Part I (It was intensively discussed in CSS26)
Iran	Article 2.29a, Page 25	deleted	Surely if a state signs a convention or treaty it shall fulfill its obligations otherwise international obligations make no sense. also it is not related to protecting people and the environment against radiation risks.			X	Paragraph is the same as R14 of GSR Part I (It was intensively discussed in CSS26)

Iran	Article 2.29b, Page 25	Deleted	Although participating in international arrangements is very useful, but it should not be mandatory especially from safety point of view.			X	Safety standards are not mandatory
NEA	Para 2.29(a)	MODIFY: …fulfil its **relevant** ~~**respective**~~ international obligations **to which it has subscribed**;…	The EGIR noted that there are many international agreements, but that this is referring specifically to RP agreements. It was also strongly suggested that these requirements should hold governments to those obligations to which the government has agreed.			X	Paragraph is the same as R14 of GSR Part I (It was intensively discussed in CSS26) - 'obligations' implies that the government is party of the respective int. agreement
India	26/2.29/ c	…promote international cooperation to enhance safety **and security of sources** globally.	Add for completeness			X	Covered in 2.28 and 2.48(a) as security guidelines are not yet int. standards
Czech	Req. 3	General responsibilities of the regulatory body. – Do we have any specific responsibilities – again good example why would be better to delete the titles of requirements.	Illogical	X	'General' deleted		

Sweden	2.30	Add: 'adopt regulations ***stating regulatory requirements*** and guides ***indicating acceptable ways to meet regulatory requirements as appropriate*** addressing protection and safety	This paragraph and Requirement 3 are the only references to guides in the document. The role of guidance should be defined and may also be helpful to include reference to guidance in paragraphs referring to graded approach			X	Suggestions does not add value
Iran	Article 2.30, line 3	The regulatory….each exposure situation OR adopt….	Regulatory shall establish requirements or adopt requirements. "and" is not correct	X	'establish or' inserted before 'adopt regulations and guides…' (See also GSR Part I Req 32)		
Argentina	Para 2.31	Add a footnote to subparagraph a) as follows: *"Notißcaiion and authorization* *<*):* *{*) The system of notification and authorization may differ from country to couniry according wiih their history and nationai legal framework, but' usually two kinds of authorizations are given: a) for persons, ihat is a formal recognition ihat a person has the qualification and expertise required for the responsibilities he or she will bear in the conduci of an authorized activity and, b) to a facility or actmty ihat is a formal récognition that ihe regulatory body has satisfactorily evaluated the safety case presented by ihe applicant in suppori of such authorization. "*	It seems important to at least give an indication that the usual systems embrace these two kinds of authorizations.			X	only part (b) is included in the authorization as defined in the glossary

India	26/2.32	**Add after 2.32 or at the end of 2.32 following: Where the practice has potential to give rise to exposure to large number of the public, the regulatory body shall make it mandatory for the licensee to hold public hearing.**	This is important to allay fear from the mind of the public.			X	Several provisions address informing and consulting the public, e.g. 2.31 (f)
India	26/2.34/3-4	…lessons learned from ~~**authorization**~~ **operational experience** and inspection experience…	Authorization does not provide experience that should be shared. It is rather operation and regulatory inspection that give experience which should be shared.	X	Use the phrase '…from regulatory and operating experience…' GSR Part I Req 15		
IRPA	2.34/line 2	…dissemination of information to relevant parties, such as manufacturers, suppliers and users of sources, <u>and the public</u>…	The public should also be informed of this information for its understanding and benefit.			X	Public information is covered in 2.31(f)
IRPA Germany	2.34., 2.41(a), 3.139	Delete the term "manufacturers"	According to the definition of the term "suppliers" in the Glossary, supplier includes also manufacturer and designer. So "manufacturers" have to be deleted as it is included in "suppliers".	X			

UK	2.36/3		This paragraph refers to a register of radiation generators. Does this include all radiation generators, including medical equipment, static and mobile? Does Footnote 9 refer just to radioactive sources or to radiation generators also? Clarification is needed.				The paragraph is written in a quite general way to include all generators as specified by the RB. 'source' in footnote 9 refers to all sources, incl. radiation generators. Identical text to GSR-Part 1.
Iran	Article 2.36, Page 27, line 6	The regulatory…; and inventories of spent fuel	Radioactive waste has a broad definition and in many cases there is no need to have inventory for instance contaminated papers and syringes in nuclear medicine			X	
ILO UK (employers)	2.36	Incorporate footnote 9 into main body of text	Regulatory body to specify what included on registers taking into account associated risk. Footnote as written should be seen as part of regulatory responsibilities.			X	Editorial (2.36 is the same as para 4.63 of GSR Part I)
UK	2.36, Footnote 9	Incorporate Footnote 9 into the main body of the text.	It is the role of the regulatory body to specify which sources are to be included in the registers and inventories, taking into account the associated risk. The Footnote as written should be seen as part of regulatory responsibilities.			X	Editorial (2.36 is the same as para 4.63 of GSR Part I)

Spain	2.36	For consistency with the requirements of GS-R-1 the responsibility to establish, maintain and record "inventories of radioactive waste and spent fuel" should be assigned to the Government, not to the Regulatory Body.	This proposal is more consistent with paragraph 6.11 of GS-R-1 *(Government shall ensure that the regulations provide for establishing an inventory of existing and anticipated radioactive waste)*			X	2.36 is the same as para 4.63 of GSR Part I)
USA	2.36	Recognize that the information and records referenced in this requirement are first the responsibility of the licensee or registrant. It might be useful to clarify that the regulatory body may require this of the implementer, and the relationship of national data to that required of users.	Consistency with sections 3.53 and 3.54 which suggest this is also an implementer's responsibility.			X	2.36 does not specify who has to establish and maintain the records. See also 2.43 (e)
USA	2.36, line 3	Delete "records of occupational doses"	Section 2.43(e) requires relevant parties to keep records. Section 2.43(e) could be expanded to include the records described in section 2.36. The inclusion of this phrase in section 2.36 implies a national requirement to develop and maintain a national dose registry system.		Would the use of 'provisions for establishing….' instead of 'arrangements to establish' in line 1 of para 2.36 help?	X	The role of the RB is to ensure that such records are established and maintained.
ICRP	Pg 27, 2.36	Delete "non-routine".	Routine releases are also a subject for recording and reporting (see para 3.134 (e)).			X	Routine releases are not a radiation event
Denmark	2.38	Propose to move this paragraph to chapter on medical exposures.	Seems to be more appropriate location			X	It has been agreed that this is not always under the jurisdiction of a medical facility, and instead the regulatory body or public shall take appropriate measures to protect public.

Norway	2.38	Misplaced. *Suggested moved to chapter on medical exposures.*				X	It has been agreed that this is not always under the jurisdiction of a medical facility, and instead the regulatory body or public shall take appropriate measures to protect public.
ICRP	2.38	Delete "or as consequence of an emergency exposure situation"	Otherwise the Standards should establish a symmetrical requirement for a living person, who is contaminated as consequence of an emergency exposure situation. Such requirements should not be included into the BSS, but may be considered in the emergency-related documents of the IAEA. The accumulated experience demonstrates that in most cases of emergency contamination of people (even after in the Chernobyl accident) the provisions indicated in 2.38 are not required.			X	GS-R-2 includes requirements for arrangements for treatment of contaminated persons e.g. para 4.80.
Finland	2.38	Please this paragraph to the chapter on medical exposures	Too detailed issue to be addressed here.			X	It has been agreed that this is not always under the jurisdiction of a medical facility

Sweden	2.38	Move to chapter on medical exposures	*Deceased persons*				It has been agreed that this is not always under the jurisdiction of a medical facility
Iran	Req. 4,	The principal parties shall establish and implement a protection and safety programme appropriate for the exposure situation.	Current overarching requirement does not cover all types of the exposure situations, so it is not proper for the text and also it is true only for planned exposure situation because only in this situation activities give rise to radiation risk. For example in emergency exposure situation activities might decrease exposure.			X	It covers all exposure situations, and is line with GSR-Part 1.
Czech	Req. 4	2.41. is not a prime responsibility – if title will be deleted then would be OK.				X	The title of the overarching requirement relates only to the overarching requirements.
UK	Req. 4: 2.40 – 2.52	In the past 10 years, there has been a large increase in the use of contractors within the nuclear industry. Balancing the needs of the contractor and the site licensee can create challenges, particularly in balancing the legal obligations of the different parties, e.g. for overall dose management compared with control at the workface. This can result in long term dose management considerations taking precedence over the needs of nuclear risk reduction. For example, setting daily low dose constraints for contractor employees in a radiologically very challenging environment may appear to be good dose management, but can result in higher overall doses which are not ALARA and can extend the duration of the task and hence the overall nuclear risk. It is important that future regulation takes account of the high use of contractors within the industry and requires the site licensee to balance the obligations on the different employers with the needs for overall nuclear risk reduction. Therefore guidance on this would be welcome			No change requested to BSS. Safety Guide on Occupational Radiation Protection to be revised after revision of BSS is completed.		

India	2.40/ a and b	Comment: Delete 'and' after semicolon in a and b	Editorial	X			
Norway	2.40	Extend list of principal parties to also include persons/organisations responsible for notified practices which are not subject to licensing or registration i.e. exempted practices.	*Responsible for protection and safety of notified practices are missing.*	X	Text has been modified.		
Finland	2.40	Add a new subpoint under (a) Registrants, ~~or~~ licensees: **(b) any person or organization carrying out any action subject to the requirement of notification**	Without such an addition, activities and practices which are subject to notification only (see para 3.7) would have no "principle party". This would not be correct.	X	Text has been modified.		
Finland	2.40. (b), (c), (d)	(b) employers.	The principal parties should be in the position to be able to be responsible for the radiation protection independently. That is not the case when the radiological medical practitioner is employed by a licensee or a designated person or an organization is contracted by a licensee. See also 3.152 (a) of the responsibilities.			X	Even if a radiological medical practitioner is employed by the licencee, it is a principal party responsible for the radiation protection of the patient. *For comparison, RPO is not a principal party*
France	Requirement	Add a specific requirement (4bis) regarding the missions of the qualified expert and the RPO.	The description of tasks or responsibilities of the RPO/RPE should be defined more precisely in the main text.			X	
Austria	2.41		Please clarify what distinguishes a "worker" from professions c) to f).	X	'Text has been modified.		

Finland	2.41.	(i) radiological medical practitioners	The principal parties should be in the position to be able to be responsible for the radiation protection independently. That is not the case when the radiological medical practitioner is employed by a licensee or a designated person or an organization is contracted by a licensee. See also 3.152 (a) of the responsibilities.			X	Radiological medical practitioner is considered to be a principal party in the context of medical exposures.
ICRP	Pg 28, 2.41	a) needs editing b) move "Suppliers" to para. 2.40 ("principal party")	a) "Suppliers" is a defined term and manufactures are included into the term "Suppliers" (of source) – see Glossary. b) Parties, listed in the definition of term "Suppliers" (e.g. designers and manufactures) should have primary responsibilities for protection and safety. Most design features of the installation, which are important for protection and safety, cannot be (and should not be) changed by registrants and licensees during operational stage of the installation.	X	For (a)	X	For (b)

ILO NZ (trade unions)	Under section 2.42	*"Add to"* The protection and safety programme shall: (a) Adopt protection and safety objectives in conformity with the requirements of these Standards; (b) Apply protection and safety measures commensurate with the nature and extent of the radiation risks associated with the exposure situation and sufficient to ensure compliance with the requirements of these Standards. (c) **Include workers participation in the development of the programme.**				X	Too detailed for 2.42 Covered in 2.51 9(d)
USA	2.42	Consider deletion	This statement is now a repetition of the overarching requirement. This is an example of where the new format has not yet been clarified in terms of the role of the overarching requirements vs. the associated conditions. This must be resolved at a policy level, and the resulting decision consistently implemented. Logically, if the statement is in the overarching requirement, it need not be repeated in the associated conditional requirements.		The text of Req. 4 has been modified in view of comments.		
Slovakia	2.42	Delete :The protection and safety programme shall …	This sentence is the same like "Requirements 4"	X	The text of Req. 4 has been modified in view of comments.		
Poland	2.42	DELETE all text	Redundant, repetition of requirement 4	X	The text of Req. 4 has been modified in view of comments.		

Czech	2.42	(a) – adopt protection and safety objectives in conformity with the requirements of these standards – there is only hesitation if it is OK to require relevant parties to be in compliance with these standards – this is a responsibility of government or regulatory authority when establishing national legislation and then all parties shall be in compliance with national legislation (?). the same in (b)	Need of clarification.			X	BSS standards have to be complied with by registrants and licensee. This type of wording is often used in the BSS draft 3.0
NEA	Para 2.42	DELETE: ~~The relevant principal parties shall establish and implement a protection and safety programme appropriate for the exposure situation~~. The protection and	The EGIR felt that this sentence is redundant with Requirement 4 and as such has been deleted.		The text of Req. 4 has been modified in view of comments.		
Spain	2.42.a	It should be convenient to add text to say: "… these Standard as decided by the corresponding Governments and/or Regulatory Bodies".	Clarity			X	No added value
Australia	2.46, Req. 5 & 2.47-2.51	Change 'principal parties' to 'relevant principal parties'.	For consistency with other sections. Not all principal parties are responsible for each requirement.	X			
UAE	Requirement 5	Add '***applying to the organization responsible for the facilities and activities that give rise to radiation risks.'***	The wording 'the overall management system' leaves unclear as to what management system is referred to.	X	Text has been modified.		
Iran	Req. 5,	The principal parties shall foster and maintain safety culture and take into account human factors and support good performances and good practices.	The proposed text should be added to the overarching requirement because safety culture and human factors are very important and are not mentioned in the current overarching requirement.			X	Too detailed for an overarching req.

Israel	2.47	"organizations" instead of "organization"	Editorial	X			
Austria	2/48	Compromised	The wording “compromised” might be misinterpreted.				Editorial. The expression “safety is not compromised” is used in other IAEA Safety Standards e.g. GS-R-3: Management System for Facilities and Activities.
UK	2.48 (c)		This statement implies that safety should always take precedence over other requirements or demands. This appears to prioritise safety over all other factors and therefore goes beyond ALARA. It is also inconsistent with Para 2.48 (a). There should be reference to “reasonably practicable” in this statement.			X	No, it is consistent with GS-R-3 2.1 (3rd bullet) and 2.2, and SF-1
Israel	2.48(e) and 2.51	Delete "strong" before "safety culture"	The adjective is not needed. "Safety culture" means by itself a strong commitment to safety	X	Editorial		
Israel	2.48(a)	"with guidelines for security" instead of "complementary to guidelines for security"	Clarification	X	… and guidelines for security. (delete ‘complementary to’)		

Czech	2.51	Safety culture – this is very problematic part for implementation – in my opinion regulator can only promote and foster safety culture – not ensure.			No change to text requested. There is guidance on safety culture e.g. GS-G-3.1, GS-G-3.5, and GS-G-1.3, and INSAG has published a report on practical issues relating to safety culture INSAG-15.		
Israel	2.51(f)	Add ",with regard to protection and safety" after "as appropriate"	Clarification	X	EDITORIAL Text has been modified.		
NEA	Para 2.51	ADD (g1) Encouraging and protecting the reporting of safety concerns	The EGIR felt that this paragraph should ensure that "whistle-blowers", who report safety-related concerns to authorities, are specifically protected.			X	Neither INSAG safety culture nor GS-R-3 refer to protection of whistle-blowers
USA	2.51	Consider addition of bullet after (g) to read as: (g bis) encouraging and protecting the reporting of safety concerns;	Include a provision in this paragraph for reporting safety concerns and the protection of workers who report safety concerns (i.e., whistle blower protections).This significant issue is addressed later in the document, (section 3.79), but it should be included in this section.			X	Neither INSAG safety culture nor GS-R-3 refer to protection of whistle-blowers

USA	2.51	Consider Revision	Provisions for safety culture are good, but how do you go about enforcing a safety culture? As written, the requirement would be very difficult to enforce, as many of the subparagraphs are subjective.			X	There is guidance on safety culture e.g. GS-G-3.1, GS-G-3.5, and GS-G-1.3, and INSAG has published a report on practical issues relating to safety culture INSAG-15.
USA	2.52	Include a provision in this section for other human factors issues like fitness for duty, work/rest cycles, alcohol or other substance abuse, and others.	There are other areas that could properly be included within the general construct of Human Factors.			X	2.52 (a) is about promoting individual and collective commitment. The suggested text would be covered in a Safety Guide (see GS-G-3.1, para. 2.32)
Austria	2.52 a)	and to reduce the possibility of misinterpreting indications	The use of clear wording in this regard is imperative for this standard; please review it carefully for wording.	X	Text has been modified.		

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 3: Planned Exposure Situations							
China	Section 3, section 5 and Glossary	Suggest: to revise and indentify the definitions of "occupational exposure" respectively in Para. 3 and Para. 5, according to the associated definition of occupational exposure in ICRP No. 103 (2007).	The item of "occupational exposure" arises in the planned exposure situation in Para. 3 and in the existing exposure situations in Para. 5 respectively. It is easy to lead readers into confusion while implementing the standards.			X	Review agreed on current definition of 'occupational exposure'
WNA	Specific 3.1, 3.21, 3.23, 3.25-3.27 3.116-3.123	**Are requirements commensurate to the actual risk : Public exposure from nuclear energy?** – ***A very strict three-level control mechanism is imposed (dose limit of 1 mSv/y from all sources, and stricter constraint and operating limits) for the tiny public exposure from nuclear energy that contributes 0.01% (or 0.0002mSv/y) of the overall public exposure***. Though, the limit is not applicable to the two most important (over 99%) main sources of public exposure: i.e. natural background radiation and medical exposure. ***Overall, about 100 (planned public exposure) that apply to nuclear energy***	There is no compelling case to prolong a very strict control only for the tiny public exposure from nuclear energy. A BSS revision that would fail to remediate this basic flaw is certainly not helpful. The requirements for nuclear energy exposure cannot be commensurate to the actual risk.			X	The strict approach to nuclear energy is needed for reasons of safety (accident prevention) rather than radiation protection. Regarding natural background exposure and medical exposure, it is not logical to apply limits to these – for reasons of controllability rather than risk.

		exposure. Of this, about 30 are specific to nuclear energy. The rest are general requirements. ***Overall, nuclear energy is subject to the highest number of requirements and to the most stringent requirements of Section 3. In comparison to all other main sources of public exposure*** (see General Comment No 11-12 and 14-17) which are all comparable or <u>much higher</u> than nuclear energy exposure, ***the extreme stringency for nuclear energy is difficult to understand. It is certainly not commensurate to the actual risk.*** ***It is awkward to find clear evidences which show that the most stringent and the most numerous requirements are imposed on nuclear energy exposure, which is among the tiniest of all main sources of public exposure***. Moreover, we emphasize that nuclear energy exposure (which averages 0.0002 mSv/y, with a proven very low probability to exceed 1 mSv/y) is even much lower than the lowest dose criterion (0.01 mSv/y, with the option for up to 1 mSv/y for low probability event) for the exemption and clearance of radioactive material. See General Comments No. 2, 3 and 13. See attached Table 1.						
WNA	Specific, para.3.1-3.4, 4.1 and 5.1	**Integrated Safety -** ***As part of the harmonization of the global safety regim***e - which is IAEA's main goal with integrated safety as a key driver - ***radiation safety requirements on public***	It is unclear if the radiation safety requirements are commensurate to safety requirements in other safety fields covered by IAEA.			X	The strict approach to nuclear energy is needed for reasons of safety (accident prevention) rather

		exposure should be first commensurate to the safety requirements in other safety fields – with safety requirements based on the actual risk. Is this the case? Moreover, ***within the scope of radiation safety, the coverage of each main source (facility or activity) of public exposure should be clearer and more balanced*** – irrespective of the subsequent breakdown of the coverage by exposure situations: planned, medical, emergency and existing. The requirements on scope in Sections 3, 4 and 5 (e.g. para.3.1-3.4, 4.1 and 5.1) do not provide a clear picture of the coverage of each of the seven main sources of public exposure mentioned earlier. Some main sources of public exposure are simply not covered (like natural background radiation other than radon or air passengers' exposure). Also, the more detailed requirements for each main source of public exposure show that the requirements are not commensurate to the actual risk. ***Consistently with the concept of facility and activity of the overall IAEA safety standards, the coverage of each of the main source of public exposure should be clearer and more balanced***. To the extent possible, for greater harmonization***, a common set of requirements should apply to all main sources of public exposure, with a level***	The scope of Sections 2 to 5 should clearly define the applicability to each main source of public exposure. It is not currently the case.				than radiation protection. Regarding natural background exposure and medical exposure, it is not logical to apply limits to these – for reasons of controllability rather than risk.

		of applicability that is commensurate to the actual risk.					
WNA	Specific 3.2(a), 3.4(b) 5.1(c) 5.8	**Are requirements commensurate to the actual risk : Public exposure from industries involving naturally occurring radioactive material (NORM)?** – The entry level to coverage of public exposure for a wide industry depends on the radioactive content of the input material. ***If concentrations are higher than a set level*** (e.g. 1 Bq/g of any radionuclide in the uranium and thorium decay chains) ≈ **> 0.1-1 mSv/y**, ***the coverage is as for the nuclear industry with a dose limit of 1 mSv/y and the rest***. [para.3.4]. ***Alternatively, if concentrations are lower than the set level (≈ < 0.1 mSv/y), the full coverage of public exposure under Section 5*** (e.g. para.5.1, c) ***is unclear***. Possibly, illogically, higher dose criteria – called reference levels - which can range from ***1 to 20 mSv/y, with an option for excess,*** would also apply. [para.5.8]. ***Experience shows that public exposure from NORM industries is comparable or much higher than the one in the nuclear industry***. See General Comments No. 2, 3 and 14. See attached Table 1.	What is the rationale to require less stringent requirements for public exposure in the NORM industries which is comparable or much higher than the one in the nuclear industry. How these requirements can be commensurate to the actual risk?			X	Public exposure to NORM industries is <1 mSv and is controlled in much the same way as that from nuclear installations. The fact that even lower dose levels are achievable in nuclear installations is due to the characteristics of the facilities, not to any differences in radiation protection approach
Austria	3.1		a) to g) ordering should at least reflect roughly the order of importance			X	It is not possible to establish the level of importance unequivocally. The order should not matter and is not numbered in

							priority.
Austria	3.1	in~~to~~ which radionuclides are ~~incorporated~~ **contained**	The wording "incorporated" could be misinterpreted for incorporation of radionuclides in the human body.			X	The sense is clear from the context
Israel	3.1	Add exposure of the general public from sources which are amenable to control: NORM and TENORM in construction materials, from soil in regions with high NORM content in soil, day-to-day security screenings, and from drinking water.				X	With the exception of security screening, these exposures are all treated as existing exposure situations. Security screening is covered by (d)
China	Para 3.1 ~ 3.3	Suggest: refer to the classification method in BSS (1996) Para. 201, such as the use of radiation or radioactive substances for medical, industrial…;the generation of nuclear power…;the natural sources (NORM)…	The classification in BSS (1996) is easier to understand and more acceptable. The paragraphs in DS379 specialize each item concretely, which may cause to the lack of completeness of summary of the concept.			X	Para 3.1 is more exhaustive, and para 3.1(g) allows for the regulatory body to specify other activities not included in the scope.
UAE	3.1	Delete 'the following practices'	The use of the term 'practices' throughout the document confuses the concept of 'planned exposure situations' and 'facilities and activities'.			X	The term 'practice' is not synonymous with 'planned exposure situation', so a direct substitution is not possible. A 'practice' is a human activity from which an 'exposure situation' originates. For the purposes of a regulatory-style document such as the BSS, the continued use of the term 'practice' (with its definition

							remaining unchanged) is necessary in order to avoid very cumbersome text.
UAE	3.1(b)	Add 'and neutron generators'				X	The list is not meant to be (and can never be) exhaustive.
Canada	3.1 (b)	The production and supply of devices that generate radiation, including charged particle accelerators and …	There are other types of accelerators such as synchrotrons			X	The list is not meant to be (and can never be) exhaustive.
India	3.1(d)	…and devices where such use may ~~**affect**~~ **involve** exposure to radiation;	Editorial			X	This would change the meaning to something that was not intended. It is meant to apply to things like instrumentation and software which in themselves do not involve exposure
USA	3.1(f)	The text could include a footnote to note that aircraft and spacecraft crews are included in existing exposure situations.	The mining of raw materials is an existing exposure situation, but also a planned exposure situation under certain conditions. If this example is retained in the text, then consideration of aircraft and spacecraft crews should be addressed also, for clarity of locations of the requirements. This should be as a footnote for reference of the reader.		Such a footnote is not appropriate -- it doesn't make sense to add such a footnote without adding similar footnotes mentioning all other activities giving rise to existing exposure situations. 3.1(f) needs to be applied in conjunction with 3.4 to determine those facilities		

					mining and processing raw materials are included in the scope of planned exposure situations.		
Ireland	3.2 (a)	Should dental facilities be included in this list?				X	Covered by definition of 'medical radiation facilities'
Canada	3.3, 2nd line	Medical exposure, public or environmental exposure	Better alignment and consistency with overall Safety Principles			X	While protection of the environment is included in the scope, only 3 categories of exposure are defined by ICRP
Spain	3.3	The requirements for planned exposure situations apply to any occupational exposure, medical exposure (except dose limits) or public exposure …….	Dose limits do not apply to medical exposures			X	This is not the place to specifiy which requirements apply to which types of exposure. There are other requirements that also do not apply in all cases
Austria	3.4		Please explain the difference between "decay chains" and "radon and radon progeny".			X	'Decay chain' means the whole chain, while 'radon and radon progeny' refers to only a segment of the relevant decay chain
France	3.4	To avoid discrepancy with values given in TS-R-1 we propose to add at the end of 3.4- a :	Value of exemption for activity concentration for K40 is 10 times less than in TS-R-1. The meaning of the following sentence "in any relevant activity specified in			X	3.4(a) has nothing to do with exemption. The 1 Bq/g value is simply a criterion for treating as a planned

		"For purpose of transport of these material, only those exemption allowed in **Regulations for the Safe Transport of Radioactive Material (**TS-R-1) shall apply"	para 3.1 where the activity concentration in the material of any radionuclide in the uranium and thorium decay chains is greater than 1 Bq/g" is not clear. In TS-R-1 the values given for exemption for uranium and thorium is 1 Bq/g but **take into account some decay products**.				situation rather than as an existing exposure situation
Israel	3.4	We suggest adding sub- paragraph (f) for radon levels in public buildings and in dwellings. The radon level is amenable to control by building standards.				X	Public exposure to radon is treated as an existing exposure situation
Norway	3.4	Proposed amendment in new bullet e): *"Public exposure to radon where mitigating actions can be efficiently carried out in the construction phase. This applies to all new builds".*	In order to provide good guidance consistent with the basic principles of radiation protection.			X	Public exposure to radon is treated as an existing exposure situation
Germany	Para. 3.4	Add the following to 3.4 a): … or below these values where situations are identified by the regulatory body which necessitate regulatory control;	See Attachment below.			X	Following discussion by RASSC of this particular comment, it was decided that no change should be made (the 1 Bq/g criterion is not based on dose)
WNA	Specific 3.4	**Are requirements commensurate to the actual risk: Public exposure to natural background radiation?** – There are no requirements in Section 3 that apply to natural background exposure (85% of the overall public exposure). Moreover, of natural background radiation, only exposure to radon is covered in Section 5. There are no requirements in the BSS new draft	The requirements do not cover all components of natural background radiation and they are not commensurate to the actual risk. Radon exposure for radon in homes is a case in point/.			X	Natural background exposure is not amenable to control

		that apply to the other three forms of natural background radiation: cosmic, terrestrial and internal – which totals half of the exposure from natural radiation or 42.5% of the overall exposure. ***For radon in homes, reference levels can range from 1 to 20 mSv/y with an option for excess***. The general average concentration should not lead to an excess of about 10 mSv/y. [para.5.1(c), requirement 50, para.5.19-5.21]. **Only a dozen requirements apply**. Typically, radon exposure per individual averages at 1.2 mSv/y (42.5% of overall exposure) and ranges from 1 to 10 mSv/y, with occasional much higher values (e.g. up to 100 mSv/y). On average, the radon exposure is 6,000 times greater (1.2 ÷ 0.0002 mSv/y) than the one from nuclear energy. See General Comments No. 2, 3 and 11. See attached Table 1.					
Belgium	3.4.a)	Add, after "…1 Bq/g" or lower values that are specified by the regulatory authority	1 Bq/g does not offer sufficient guarantees for adequate protection in some specific circumstances			X	Following discussion by RASSC of this particular comment, it was decided that no change should be made (the 1 Bq/g criterion is not based on dose)
WHO Bulgaria	3.4 (a), end lines of the paragraph	"… activity concentration in the material of any radionuclide in the ^{238}U and ^{232}Th decay chains is greater than 1 Bq/g or the activity concentration of ^{40}K is	1. Radioactive decay is the phenomenon attributable to radionuclides, not to elements. 2. The overwhelming majority of			X	Review meeting decided to maintain "thorium and uranium decay

		greater than 10 Bq/g;"	radionuclides in natural uranium are ^{238}U and its decay product, not ^{235}U.				chains".
China	Para 3.4(a)	To be deleted: or the activity concentration of ^{40}K is greater than 10 Bq/g	The activity concentration of the radioisotopes ^{40}K is of several tens of Bq/g in human body. In the new publication of ICRP, the exposure caused by ^{40}K has not been regulated any more. It should be directly excluded from these standards.			X	Exclusion of ^{40}K applies only to its incorporation into the body. External exposure could, in theory at least, still be of radiological concern
ILO UK (employers)	3.4(a)		Need to ensure consistent approach between 3.4 and schedule 1 para 1-4. As an Existing exposure situation optimization will be required below 1Bq/g for NORM but not above 1Bq/g where an exemption allowed under1-4. Because doses would be less than 1mSv p.a.			X	This is an anomaly caused by strict application of ICRP recommendations. In practice, the possession or use of material below 1 Bq/g would be deemed to be optimized or, if it were a commodity such as building material, would be considered either as 'permitted' or 'controlled'. No change to the requirements can be suggested.
Japan	3.4 a	(3.4(a) should be replaced by) (a) Exposure due to the categories ofthe material designated by regulatory body, among the materials in which the average level of activity concentration in the material ofany radionuclide in the uranium and thorium decay chains is greater than 1 Bq/g or the activity concentration of 40K is greater than 10	There are cases where it is difficult to control industrial materials which exceed the criteria of concentration as planned exposure situation. For example, industries which use refined KCl (or KOH) reagent which concentration exceed 10 Bq/g. In those cases, people use the materials without awareness of their radioactivities and			X	In order to implement RS-G-1.7, it is necessary to retain the exact specification of materials in 3.4(a). The problem that has been highlighted is addressed by the

		Bq/g.	they cannot plan the measures for radiological protection in the design stage. Not every industrial material should be subject to regulation as planned exposure situation.				provision for exemption by the regulatory body. The proposed term "material designated by the regulatory body" is just another way of saying "material not exempted by the regulatory body"
UK	3.4 (a) and Sch. 1, I-4		There is a possible incoherence in the exposure situation approach recommended for NORM, whereby optimization will be required for all cases below 1 Bq/g (i.e. as an existing exposure situation), but will not be required above 1 Bq/g where an exemption is allowed under I-4 (i.e. because doses are below 1 mSv/y). Clarification is needed.			X	This is an anomaly caused by strict application of ICRP recommendations. In practice, the possession or use of material below 1 Bq/g would be deemed to be optimized or, if it were a commodity such as building material, would be considered either as 'permitted' or 'controlled'. No change to the requirements can be suggested.
Ireland	3.4 (a)	It is unclear what is meant by "soil amendments". Reword to improve clarity.				X	This is a recognized term in agriculture
NEA	Para 3.4 stem and (a)	…Section 5, except that the requirements for planned exposure situations in Section 3 apply to the following exposures to natural sources: (a) Exposure due to material other than	(1)The EGIR strongly felt that the "double-negative" text in paragraph 3.4 and in sub-point (a) is very confusing and needs to be simplified so that it can be correctly understood.		Text has been modified		

		food, feed, drinking water, agricultural fertilizer and soil amendments, construction material and existing residues in the environment, in any relevant activity specified in para. 3.1 where…					
Israel	3.4 (a)	We suggest rewriting this paragraph more clearly, for example by breaking the long sentences into shorter sentences.			Text has been modified		
NEA	Para 3.4(a)	(a) Exposure due to material	The EGIR felt that there is a possibility of contradiction with paragraph I-4 in Schedule I. Specifically; the numeric values cited here MAY result in conflict with exception criteria, and this should be followed up with specific consideration of these numeric values.			X	The numerical values in 3.4(a) are not exemption values. The only potential problem is the concern raised with respect to optimization -- this is dealt with above, under the comments on 3.4(a) by ILO UK (employers) and UK
NEA	Para 3.4(a)	ADD …than 10 Bq/g**, and the categories of the material designated by regulatory body**;	The EGIR noted that there are cases where it is difficult to control industrial materials which exceed the criteria of concentration for planned exposure situations. For example, industries which use refined KCl (or KOH) regent which concentration exceed 10 Bq/g. In those cases, people use materials without awareness of their radioactivity, and they cannot plan the measures for radiological protection in the design stage. Not all industrial materials should be subject to regulation as planned exposure			X	In order to implement RS-G-1.7, it is necessary to retain the exact specification of materials in 3.4(a). The problem that has been highlighted is addressed by the provision for exemption by the regulatory body. The proposed term "material designated by the regulatory

			situation.				body" is just another way of saying "material not exempted by the regulatory body"
Australia	3.4(a)	Change the first use of "activity" to "practice".	Activity is used twice in this paragraph with two different meanings. The paragraph refers to 3.1 which uses practices.	X			
ILO UK (workers)	3.4(a)	It is proposed to remove the exceptions for agricultural fertilizer, soil amendments, and construction material.	Why is agricultural fertilizer and soil amendments exempt? Why is construction material exempt? Some phosphate fertilizers in particular, can have significant radioactivity. This is not a material that pre-exists in the environment, it is a product manufactured and distributed for a particular use. The same can be said of certain gypsums, especially those that are byproducts of phosphate fertilizer production.		They have been removed from text of (a), but have been included in a new footnote to (a), stating that they are within the scope of existing exposure situations.	X	These materials are not exempt, because exemption applies only to planned exposure situations and these materials are specifically designated as being subject to the requirements for existing exposure situations. Under the latter requirements, these materials are potentially subject to control measures regardless of the activity concentration (in theory, all the way down to zero!). These materials are everyday commodities (many of which may be obtained by the user directly from the environment) for which it is not practicable to apply

							the regulatory approach for planned exposure situations (e.g. safety assessment, licensing, radiation protection programme, monitoring, health surveillance etc. etc.)
ILO UK (workers)	3.4(c)	Delete 'in the uranium and thorium decay chains';	This is not unnecessary as radon is a part of only these chains.	X			
Israel	Footnote 10 (3.4(c))	Delete "treatment"	Therapy already means treatment	X			
USA	3.4(c) Footnote #10	Insert definitions for the terms "balneotherapy" and "fangotherapy" into the appropriate sections of the glossary	These are not typically terms used in the US. Additionally, balneo-therapy and fangotherapy are not defined in the "Cambridge Dictionary of American English"; therefore, adding these terms to the glossary would be informative.	X	Footnote has been deleted, due to change of text of (c).		
Ireland	3.4(c) Footnote 10	This footnote is very specific. Should it not be made more general?		X	Footnote has been deleted, due to change of text of (c).		
EC	3.4	*(numbering to be updated)* "3.4. Exposure to natural sources shall in general be considered as an existing exposure situation and subject to the requirements in Section 5. This is the case for exposure to natural radioactive substances in food, feed, drinking water, construction materials and agricultural fertilizers or soil amendments. For other exposures to natural sources the	The existing text in 3.4 is not a true requirement, lacks clarity and may be misleading in that people would think that for fertilizers, building materials etc higher values apply (double negations should always be avoided). In addition reference to "residues in the environment" is out of place (it applies also to artificial radionuclides) and the reference to "radon progeny in the	X	Text has been modified		

		requirements for planned exposure situations in Section 3 apply to: (a) any relevant activity specified in para. 3.1 where the concentration in the material of any radionuclide in the uranium and thorium decay chains is greater than 1 Bq/g or the activity concentration of K-40 is greater than 10 Bq/g; (b) public exposure delivered by discharges or in the management of radioactive waste arising from a practice involving material specified in (a); The requirements in Section 3 shall also apply to occupational exposure to radon and radon progeny: (c) in workplaces in which radon arises in the uranium and thorium decay chains within an activity as specified in (a) (d) when the exposure to radon is required by or is directly related to the work; (e) in an existing exposure situation where the annual average activity concentration of radon in air in the workplace remains above the reference level established in accordance with para. 5.27 after implementation of remedial action in accordance with para.5.28."	uranium and thorium decay chain" is superfluous (it should be noted that now the term "uranium decay chain" is used which may be read as including a "U-235 decay chain" which in nature would constitute only 0.7% of the Uranium activity.)				
ICRP	Pg 33, 3.4		Transition from a type of exposure situation to another should not be only a matter of number (which sound like a magic number); it is also a matter of			X	The criterion is not just numerical. It is also a question of whether the material is an everyday

			judgment taking into account the characteristic of the situation and its perception by the exposed people.				commodity (food, drinking water, fertilizer etc.) or rather a material that tends to be used in some sort of industrial process. This distinction is exactly the result of "judgement" of the practicalities of the situation referred to in the comment
ICRP	Pg 33, 3.4	Specify the mass for averaging of the specific activity	A criterion in terms of specific activity without an associated averaging procedure is ambiguous and cannot be use as a quantitative criterion.			X	The question of averaging depends on whether the activity is reasonably homogeneous throughout the material or concentrated on the surface. This is a complex question and is being addressed in a lower level of document
ICRP	3.4(a) line 3		It is not clear to which "where" indicates: the commodities or the material other than the commodities listed.		Text has been modified		
ICRP	3.4(b) line 1		The source discharged to the environment is not a natural source.			X	It refers 3.4(a) that deals with natural sources.
Spain	3.4 (a)/2		The term "residue" is used and is not defined anywhere. In 3.4 (b) the term used is "waste".				Residue follows the normal English meaning.

			"Residue" should be defined. Although residue and waste are different in English, it may not be the same in other languages, so definition in the glossary is considered to be necessary.				
Japan	3.4 c	(3.4(c) should be replaced by) **(c) Occupational exposure to radon and radon progeny from materials of radionuclide in the uranium and decay chain specified in (a)**	In principle, every exposure from the progeny of a source under regulation as planned exposure situation should be controlled as planned exposure situation and the dose should be included into calculation for dose limit.	X	Text of (c) has been modified.		
Spain	3.4(c) (this was (d) in draft 3.0)	Occupational exposure to radon in workplaces in which exposure due to material containing radionuclides in the decay chains headed by 238U and 232Th is required to be controlled in accordance with para. 3.4 (a), irrespective of whether the radon concentration is higher or lower than 1000 Bq/m3.	Para 3.4 (c) was like this in draft 2.5 and it is clearer than the one in draft 3. Para. 3.4 (c) of draft 3 may be not understood, because it is not clear which are the workplaces in which the exposure is required by or is directly related to the work. This is not clarified by footnote 10 which means that the affected workplace could be any one where there is radon exposure.	X			
Spain	3.4(d) (this was (c) in draft 3.0)	Occupational exposure to radon in an existing exposure situation, where the activity concentration of radon in air in the workplace remains above 1000 Bq/m3 after the implementation of remedial action in accordance with para.5.28.	Due to the conversion coefficients for radon and thoron progeny of table II-1, doses from radon exposures are higher than it was expected before. An exposure situation due to material containing radionuclides in the decay chains headed by 238U and 232Th that is to be controlled means that the occupational doses exceed the value of 1mSv/year. In this case, it should be necessary to take into account all the other contributions to the occupational dose	X			

			(in this case due to radon exposure). As it is now in draft 3, it is not clear if doses due to radon exposure should be added to other occupational doses and, in this last situation, to add the doses only in case the radon concentrations are higher than 1000 Bq/m3 leaves out of consideration doses till the value of 6 mSv/year.				
Spain	3.4 (d)	The requirements relating to the consideration of exposure to radon as part of occupational exposure should be carefully re-analysed since the current text is extremely confusing and might lead to misinterpretation: From one hand, section 3.4 establishes that the requirements for occupational exposure in planned situations set out in Section 3 are applicable to exposures to radon in situations in which the average annual concentration in the working environment exceeds the reference level established by the regulatory authority (1000 Bq/m3). This requirement might be interpreted in terms that each and every one of the requirements of Section 3 (access controls, classification of zones, radiation symbol, individual surveillance, etc.) are applicable to these exposures, which is clearly not reasonable. On the other hand, section 5.29 establishes (more correctly) that exposures to radon in situations in which				X	The graded approach applies to all requirements in the BSS, as stated in Req. 6.

		the average annual concentration in the working environment exceeds the reference level established by the regulatory authority (1000 Bq/m3) shall be subject to the "relevant requirements" on occupational exposure of section 3, which clearly points to the fact that not all the requirements of section 3 are applicable, but only the most relevant. Consequently, the text of section 3.4 should be revised to make it more coherent with that of section 5.29, clearly establishing that only the most relevant requirements of section 3 relating to occupational exposure (not all) are applicable to the aforementioned exposures to radon.					
Norway	§ 3.4 d)	Exposure situations and radon	Occupational exposure to radon is categorized as planned and existing exposure situations dependant on the resulting activity concentrations. This looks odd to us.				This follows ICRP, and the advice of the Technical Meeting on radon. No change has been proposed to the text.
France	3.5	It should be a overarching requirement	It is a basic and strong requirement			X	This is not a stand-alone requirement and therefore cannot be made overarching.
USA	3.5	Consider moving.	The requirement in paragraph 3.5 is now an "orphan" in that it does not fall under any of the overarching requirements. This would not seem to			X	It does not fit under notification andauthorization because it is more

			be appropriate. It would seem that this could be under overarching requirement 3-2, Notification and Authorization.				general.
Israel	3.5	The requirement is orphan (not covered by an overarching requirement) and could belong to the scope subsection. In this case the heading "GENERIC REQUIREMENTS" should be moved after para. 3.5. On the other hand, para. 3.5 introduces some redundancy with paras. 3.1-3.2 and could therefore be deleted.				X	This is genuine requirement and not part of scope..
Czech	Req. 6	… with the magnitude and likelihood of exposure or risks.	To include also potential exposure.			X	The word "likelihood" takes this into account. The text is consistent with the Glossary definition of graded approach.
Iran	Req. 6, Page 34	Overarching requirement should be same as the article 3.6.	The length of overarching requirement is more than the requirement.			X	Original paragraph in draft 2.0 contained both the overarching requirement and para 3.6. It is important to retain both requirements.
Israel	Req. 6	Replace "these Standards" by "protection and safety"	It was agreed at RASSC 27 to delete reference to "these Standards" in overarching requirements. We recommend to adopt the expression used in Req. 23			X	"These Standards" needs to be retained for this particular requirement.
USA	R 6	Revise to read as: "The application of the requirements of the system of protection and safety in planned exposure situations shall be commensurate with…"	Logically the requirement should be the application of the system of protection and safety, not a reference to the standards.			X	"These Standards" needs to be retained for this particular requirement.

USA	R 6	Consider moving and consolidating material.	It is questionable whether this overarching requirement should be here, given that there is just a single paragraph under it, and even that paragraph is not entirely relevant. Note that a graded approach appears as a statement in Chapter 2 for the government, for the regulatory authority, and for principal parties. If a graded approach is an overarching requirement, should there be a combination?			X	This is an important requirement for practices.
NEA	Req. 6	**Graded approach**	The EGIR felt that paras 5.11-5.13 from RS-G-1.7 should be added to BSS following this Requirement. These paras contain essential information needed for enforcement of graded approach principles. It is not satisfactory to say (as in para 3.6) that *not all requirements apply*.			X	Para. 5.11 of RS-G-1.7 is covered by the Glossary definition of graded approach and should not be repeated. Para. 5.12 is not (and cannot be) a requirement. Para. 5.13 is already covered in other requirements.
NEA	Req. 6	MODIFY …**requirements of the system of protection and safety in planned exposure situations**…	The EGIR feels that this change gives this a sufficiently generic nature to merit being an overarching requirements.			X	"These Standards" needs to be retained for this particular requirement.
UAE	Requirement 6 and para 3.6	Replace 'practice' by 'facilities and activities'. Redraft para 3.6 to emphasise the magnitude and likelihood as being the major issues for the graded approach	The graded approach is poorly defined in para 3.6. It does not address the magnitude and likelihood of exposures as referred to in Req 6			X	The term 'practice' has a different meaning from 'facilities and activities'. The term 'graded approach' is defined in the Glossary and should

							not be repeated here
France	3.6	Replace "The application of ***these*** requirements shall…" by "The requirement of these standards shall…"	Not clear: what are "*these requirements*". This requirement needs to be clarified.	X	Text modified		
Israel	3.6, 3.7, 3.8 and 3.9(b)	Add "or activities" after "actions"	Para. 3.5 describes actions and activities			X	They are all actions. This is the term used in the current BSS and there is no justification for change
France	3.7	Add: "***transport before their sale to the end users"*** "Notification for consumer products is required only with respect to manufacture, assembly, maintenance, import, distribution, **transport before their sale to the end users** and, in some cases, disposal."	There is no reason to exclude the transport except after sale to the end user (according to paragraph 107 d of TS-R-1 edition 2009).			X	Transport is covered by the Transport Regulations – see para 2.26.
India	3.7	… and expected amount of potential exposure and any ~~**other**~~ detrimental consequence are negligible.	The 'other' may be deleted because "potential" exposure itself does not constitute detriment. Alternatively, "other" may be retained and "potentially" introduced before "detrimental". It would then read, "... any other potentially detrimental consequence."	X	The second alternative suggestion is the better of the two		
Ireland	3.7	The term "small fraction" is used in his paragraph. This is vague and needs clarification.				X	The fraction is specified by the regulatory body

Ireland	3.7	Should “storage” be included in this list?				**X**	Storage is part of distribution etc.
India	3.7	Comment: Add in the end: **Only regulatory Authority shall decide, whether any kind of authorization is required**	As per Requirement 8.			X	The requirement has nothing to do with authorization
Spain	Requirement 7	It appears convenient to explicitly say that the text apply to facilities and activities as far as they are the origin of planned exposure situations, or otherwise are included in para. 3.5, unless it is considered that the glossary is clear enough to interpret this text	Clarity		Comment unclear.		
Austria	3.8		The conditions for registration as opposed to licensing expressed in the footnote are important enough for authorities and licensees to appear in the main text.			X	Approaches vary from one country to another, so we should not be too prescriptive. The footnote is retained from the current BSS as guidance and there is no justification for change
Austria	3.9(d)	If there is a potential for an exposure to be **significantly** greater than a level as specified by the regulatory body	If there is a potential for an exposure to be **significantly** greater than a level as specified by the regulatory body			X	The regulatory body will decide on the level. Significantly will change meaning of requirement.
ENISS	3.9 (a) (new)	Transport of radioactive material is excluded from notification and authorization when conducted in accordance with the provisions of the Transport Regulations TS-R-1	This is the proven practice in many Member States. Transport of radioactive materials have successfully been regulated by TS-R-1 and its predecessors and does therefore not need further regulations. The		This is an important point, but should be addressed by addition of the following footnote to paras 3.7 and		

			understanding is that TS-R-1 corresponds with the objectives of the BSS with regard to protection and safety.		3.8: "For material being transported in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material [5], the requirements for notification and authorization are fulfilled by compliance with those regulations."		
Ireland	3.9 (c) and (d)	Paragraph 3.9(c) requires an assessment of nature, magnitude and likelihood of potential exposures. Paragraph 3.9(d) requires a safety assessment to be made. Clarify text to avoid confusion between the two "assessments".		X	Text has been modified.		
USA	3.9 d	Consider Modification: "Perform a safety assessment to address potential exposures and submit to the regulatory body as part of the application."	As written it suggests a safety assessment be done to ascertain exposure, but then only submit it if that exposure exceeds a regulatory limit. That seems to contradict Requirement 13 and especially 3.34/5. Furthermore, it is not obvious if the requirement is related to potential exposure or not.	X	Text has been modified.		
Canada	3.9 (e)	Have an appropriate assessment made of the potential radiological impacts on the environment, using a graded approach commensurate with the hazards	Better alignment with scope of requirements and purpose of Standards	X	Text has been modified		
Israel	Req. 8	Replace "these Standards" by "protection and safety"	It was agreed at RASSC 27 to delete reference to "these Standards" in overarching requirements. We recommend to adopt the expression			X	It has to be clear that the exemption is from the requirements of

			used in Req. 23				these Standards.
Sweden	Requirement 8	The regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, and shall approve which sources, including materials and objects, within notified or authorized practices may be ~~cleared~~ released from regulatory control	A common language should be used in all descriptions of clearance			X	The specific term relating to clearance must be used, to avoid confusion.
France	3.10	Add at the end of 3.10 : "**For transport, only those exemptions allowed in the Regulations for the Safe Transport of Radioactive Material (TS-R-1) shall apply**."	The application of this paragraph could lead to different values for exemption in different countries and raise difficulties in national and international transport. It is not consistent with TS-R-1. For transport, only those exemptions allowed in TS-R-1 shall apply.			X	This proposed addition would be in conflict with the new version of the Transport Regulations currently being drafted. The issue is being addressed by a joint TRANSSC/RASSC working group Para I-5 covers exemption from Transport Regulations.
India	3.10	…including the requirements for ~~**notification,**~~ registration or…	Notification should not be exempted for any practice or source within the practice.			X	Included in current BSS and no justification for change
WNA	Specific 3.10-3.12, Req. 8, I-2,I-3(a)	**Are requirements commensurate to the actual risk : Public exposure associated with the exemption and clearance of radioactive material?** Exemption - Some source of public exposure can be exempted from some or all requirements. The corresponding	***In making sure that requirements for the control of public exposure are commensurate to the actual risk, the requirements for each main source of public exposure must also make sense relative to the dose criteria for the exemption and clearance of***			X	Following discussion by RASSC, it was decided that no change should be made

	I-4, I-8	dose criterion is of the order of ***0.01 mSv/y*** with the option of using an additional criterion if the dose, due to such low probability events, does not exceed ***1 mSv/y***.[para.I-2] ***For radionuclides of natural origin***, the option (on a case-by-case basis) of using a dose criterion commensurate with natural background levels is included provided that it is unlikely to exceed ***about 1 mSv/y***. [para.I-4.] ***For moderated amount of radioactive material, some sources are automatically exempted without further considerations from the requirements, including those for notification, registration or licensing***. [para.I-3(a)] Interestingly, in this latter case, the corresponding concentrations for ^{226}Ra or of ^{224}Ra are set at 10 Bq/g – which is paradoxically 10 times higher than the concentration levels [para.3.4(a)] used to decide if natural sources are subject to Section 3 or 5 (see General Comment No.8). Clearance – The dose criterion of ***0.01 mSv/y*** and the option for an additional criterion if the dose is due to such low probability events that does not exceed ***1 mSv/y*** is also applicable to clearance [para.3.12 and I-8]. In the case of natural sources, the criterion is that each radionuclide of the uranium and thorium decay chains does not exceed 1 Bq/g – which is a similar criterion than para.3.4(a) to decide if natural sources are subject to Section 3 or 5 (General	***radioactive material***. As this is not the case (and notably for nuclear energy exposure), the requirements must be modified accordingly.				

		Comment No.8). See General Comments No. 2, 3 and 16. See attached Table 1.					
India	3.12	…or any clearance levels **which may be more stringent than those specified in Schedule I,** defined by the regulatory body on the basis of such criteria	The insertion of this clause would ensure that any deviation from the BSS values or criteria is on the safer side.			X	3.12 states that the regulatory body approves clearance levels based on the criteria in Schedule I.
Israel	3.12	Add "The government or" before "the regulatory body"	Consistency with Req. 8 and para. 3.10	X	Text of requirement 8 has been modified.		
Israel	3.12	"or licensing" instead of "and licensing"	Clarification	X			
Spain	3.12	The wording of this paragraph should be revised in order to avoid misinterpretations. We propose an alternative text: *The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from further regulatory control using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels defined by the regulatory body on the basis of such criteria, unless otherwise specified by the regulatory body. This approval shall ensure that sources that have been cleared do not again become subject to requirements for notification, registration and licensing.*	The last phrase of the paragraph (*unless otherwise specified by the regulatory authority*) is confusing and could give rise to misinterpretations. It is not clear whether that phrase refers to the first part of the sentence (*criteria for clearance specified in Schedule I*) or to the second part (*sources that have been cleared do not again become subject to requirements…..*). The proposed text has the following advantages: 1) Consistency with the existing BSS (the first part of the proposal virtually reproduces the wording of paragraph 2.19 of the existing BSS) 2) It establishes clearly that the phrase "*unless otherwise specified by the regulatory body*" only refers to the	X	Text has been modified to make clearer.		

			radiological criteria for clearance.				
Spain	3.12	How can requirement 9 be applied in those cases where only "notification" is required? (The text between 3.13 and 3.15 refers only to "registrants and licensees")	Clarity	X	Text of req. 9 has been modified. Notification is only for the benefit of the regulatory body. It is not intended as a means of imposing further responsibilities on the person concerned.		
Belgium	Req. 9	?	Duplication of req. 4.	X	Text has been modified.		
Finland	Req. 9, explanatory sentence	~~Registrants and licensees~~ **The relevant principle parties** shall bear the prime responsibility for ….	Otherwise it would remain unclear who bears responsibility in case of action which is subject to notification only (see also the comment made on par. 2.40)			X	Text of req. 9 has been modified. Text of para 2.40 was modified, and para 2.42 requires relevant principal parties to establish and implement a protection and safety programme …
USA	R 9	Consider "authorized users" or similar term	The requirement is for registrants and licensees. While this is true, it would also be true for an entity that was only required to notify the regulatory authority of activities. There needs to be consideration of the more global term, and then the conditions paragraph can remain as registrant or licensee.			X	See above

Australia	Req. 9 & 3.13 – 3.15	Change 'Registrants and licensees' to 'Relevant principal parties'	For consistency with Req. 4 & 2.40 – 2.46.			X	See above
Finland	Par 3.13 and 3.14 ; also 3.22 and elsewhere in the document	~~Registants and licensees~~ **The relevant principle parties**-shall ….	The same problem appears through out the document; in many cases where it is stated "registrants and licensees shall…." should actually cover also those who are subject to notification only. E.g. now notified activities are NOT subject to the requirement of opimization (see par. 3.22)!!			X	See above
Argentina	Para. 3.13, line 4	The explanation of "qualified person" should be included in the Glossary	"Qualified person" is not defined in the document	X	Text has been clarified.		
NEA	Requirement 9	**Registrants and licensees shall bear the prime responsibility for protection and safety in planned exposure situations.**	The EGIR suggests that those who simply notify authorities of their intention to implement a planned exposure situation are not necessarily assigned the prime responsibility for safety as per this requirement. The EGIR had no concrete suggestion to address this, but felt that it should be addressed and should be consistent with Requirement 4.	X	The text has been modified.		
UK	3.13 and 3.15 (b)		There appears to be some contradiction between these two paragraphs, in that Para 3.13 implies that responsibilities cannot be delegated and Para 3.15 (b) discusses delegated responsibilities. Clarification is needed.	X	The text has been modified.		
UK	3.13/2	Modify to read: "…implementing the necessary technical and organizational **and infrastructure** that are needed for …."	Consider making the suggested changes to cover material requirements that contribute to protection and safety practices.			X	Infrastructure is part of organizational

USA	3.15 e	Delete last few words about numbers of persons.	Unless this is expanded, it may suggest that even for very long term potential exposure calculations future populations and lifestyles must be estimated, which is not what WS-R-4 suggests. 3.30 b states this same requirement much clearer and is more consistent with international recommendations.			X	In the assessment of potential exposure, it is important to consider the size of the affected population. If there is a conflict with WS-R-4, specify more precisely.
Canada	3.15 (e) 2nd line	Potential radiological impacts	Better alignment with scope of requirements and purpose of Standards	X	Text has been modified		
NEA	Para 3.15(b)	**…delegation** of responsibilities by a principal party…	The EGIR notes that para 3.13 suggests that responsibility cannot be delegated, but here it is suggested that it can. The intent of the word responsibility used here, perhaps intended as authority, should be clarified.		The overall prime responsibility cannot be delegated. Other responsibilities can be delegated, but the licensee always retain the prime responsibility. Para 3.13 has been changed to emphasise that this is not transfer of responsibility, but delegation of responsibility with retention of prime responsibility by the licensee.		

Czech	Req. 10	….only justified practices are authorized. – is there any requirement for justification of notified practices?	Need for clarification.	**X**	Footnote added to para 3.16.		
USA	3.16	Consider revision as follows: ~~The government or regulatory body, as appropriate, shall ensure that measures are in place for determining the justification of any type of practice, the review of the justification, as necessary, and that only justified practices are authorized.~~ The government or regulatory body, as appropriate, shall ensure that: (1) measures are in place for determining the justification of any type of practice; (2) the review of the justification, as necessary; and (3) that practices are authorized only if they are justified	The sentence construction is still slightly awkward and could be improved. It is difficult to trace what the government or regulatory body has to do.	**X**	Text has been modified to improve clarity		
UK	3.16/2	Modify to read: "…measures[12] are in place for determining the justification of **classes and** types of practices, the …"	Changing the text as suggested provides more flexibility and avoids an overly prescriptive approach.			X	Class has no clear meaning. How is it different to type?
NEA	Para 3.16	MODIFY …of any **class or** type of practice…	The EGIR felt that justification is granted at a high-level, and as such proposes this change to assure that justification is seen as a high-level consideration.			X	Class has no clear meaning. How is it different to type?

Belgium	3.16/4	… authorized or exempted.	Only justified practices can be exempted.			X	This is covered by paragraph 3.11.
Belgium	3.17. (b)	Delete the word "frivolous"	Gives rise to confusion and opens a debate on which practices should be considered "frivolous" and which are not, For instance, in exposure of gemstones to neutron beams in order to "improve" their color and hence their market value, this practice may not be considered "frivolous" by the diamond sector, whereas the radiation protection authorities may think otherwise.			X	Text in current BSS. Regarding gemstones, it is a decision for each national regulatory body – see footnote 14.
USA	3.17(b)	Consider whether this section should state whether distribution and use of gemstones is prohibited.	Clarification is required because it is uncertain as to whether it prohibits the manufacture, sale, distribution and personal use of gemstones. This has been an ongoing issue in the United States, and other Member States.			X	Text in current BSS. Regarding gemstones, it is a decision for each national regulatory body- see footnote to para 3.17(b)..
USA	3.17 (footnote 14)	Consider adding irradiation to destroy organisms.	Some minor activation may occur from irradiation processes used for sterilization.	X	Text has been modified – see NEA comment.		
NEA	Para 3.17	**Except** for justified practices… MODIFY FOOTNOTE 14: This requirement is not intended to prohibit those practices that may involve the short term activation of commodities or products, and where there is no residual activity in the finally supplied commodity or product. DELETE ~~There may be some practices specifically authorized by the regulatory body e.g. neutron activation analysis systems to~~	The EGIR suggests that the footnote to this text be changed (see changed footnote) to reflect that short-term activation is not the target of this requirement.	X			

		~~examine consignments at ports, that could lead to the activation of food, feed, beverages, cosmetics or any other commodity or product.~~					
ILO Finalnd (Min of Employment)	3.17-3.2	Certain radiation usage practices that are not considered justified. However, they don't explicitly prohibit certain currently non-approved types of usage such as X-ray apparatus for the fitting of shoes, still in use as last as 1948. A new requirement has been added to the standard to cover certain forms of human imaging for purposes other than medical diagnosis or treatment. Examples of these include airport security scanners, or establishing the age of immigrants through imaging their skeletons. The principles to be adhered to in such cases, given in paragraph 3.60-3.67, may be of benefit to authorities in decision-making.			No change of text requested.		
Czech	3.18	Human imaging using radiation <u>and</u> performed	For better readability and understanding		New text was developed by a working group at RASSC		
UK	3.18	Modify to read: "Human imaging using radiation performed for occupational, legal or health insurance purposes, and undertaken without reference to clinical indication **shall only be justified by applying the requirements of paras 3.60 to 3.64.**"	These paragraphs are inconsistent with Paras 3.60 to 3.67, which indicate that human imaging without reference to clinical indication, and for security screening, can be justified. Consider redrafting this paragraph as suggested to improve consistency.		New text was developed by a working group at RASSC		

Austria	3.18-3.20		The wording "deemed to be not justified" denotes a weak statement for regulations or requirements.		New text was developed by a working group at RASSC		
Czech	3.18	If, in ~~exceptional~~ certain (or specific?) circumstances …	It seems that exceptional must be something like the war or so – but for example the control in jails – is this exceptional ?		New text was developed by a working group at RASSC		
India	3.18	…**~~If, in exceptional circumstances, the~~ The** justification …	As the trend of such imaging is increasing we should delete the 'exceptional' and let such imaging be justified prior to introduction.		New text was developed by a working group at RASSC		
NEA	Para 3.18	MODIFY: legal~~, or~~ health or insurance purposes,	The EGIR wanted to specifically ensure that imaging of self-referral patients without clinical indication is not justified, so made this change to specifically assure that both health and insurance imaging without clinical indication are seen as not justified.		New text was developed by a working group at RASSC		
ILO Finland (Trade Union)	3.18 concerns human imaging for other than medical purposes.	In the SAK's opinion, situations where such imaging is permitted should be specified in detail.	Imaging cannot be set as the precondition of insurance, for instance.		New text was developed by a working group at RASSC		
Spain	3.18	Some of the practices referred to in this paragraphs are regularly being carried out in many Member States. For this reason the implementation of such practices should not be regarded as "exceptional" and even less as "not justified".	The requirement in this respect in the new European BSS draft could serve as a reference for re-writing this paragraph: *Member States shall ensure that no practice involving medical imaging exposure for purposes other than*		New text was developed by a working group at RASSC		

		This requirement should be softened in order to provide more flexibility to Member States.	*medical diagnosis or treatment will be undertaken without reference to clinical indication, unless that appropriately justified in advance before being accepted.*				
UAE	Paras 3.18-3.20	Delete	Requirement 18 and paras 3.60 to 3.67 establish a comprehensive approach to the issue of justification of non-medical human imaging and allow for these matter to be subject to decisions by government. 'Deeming' provisions are not required.		New text was developed by a working group at RASSC		
Spain	3.19 – 3.20	See comment to paragraph 3.18			New text was developed by a working group at RASSC		
Norway	3.19	Merge with 3.20*: "Human imaging using radiation for theft detection or the detection of concealed objects for security or anti-smuggling purposes shall normally be deemed to be not justified".*	Generic rejection of theft detection as not justified, as in 3.19, should be classified as normally not justified like the examples in 3.20 on using radiation for detection of concealed objects for security and anti-smuggling. The difference between theft detection and anti-smuggling or security does not merit this absolute generic statement. Hence, the paras should be merged.			X	It is different. The use of human imaging technology for theft detection has been in some industries for screening of workers leaving workplaces e.g. diamond mines. The use for smuggling has been for persons visiting prisons, drug couriers, etc.
Sweden	3.19	…shall normally be deemed not justified..	In line with 3.20 (no strong principal difference between theft and smuggling)			X	See response to Norway

Finland	3.19	…shall *normally* be deemed to be not justified…	In line with 3.20; no strong principal difference between theft and smuggling.			X	See response to Norway
Denmark	3.19	… shall *normally* be deemed to be not justified.	Should be in line with 3.20. There is no strong principal difference between theft and smuggling.			X	See response to Norway
Ireland	3.19	There appears to be an inconsistency between 3.19 and 3.20. 3.19 absolutely prohibits the use of radiological imaging for detection of "theft" in all circumstances while 3.20 prohibits the use of radiological imaging for detection of "smuggling" except in exceptional circumstances. This seems inconsistent.				X	See response to Norway
Australia	3.20	Change "shall normally deemed" to "shall normally be deemed"	Word missing		New text was developed by a working group at RASSC		
ILO UK (workers)	3.20, 3.67	The term 'security' is used in a way which is inconsistent with the glossary.	Consistency.		New text was developed by a working group at RASSC		
UK	3.20	Modify to read: "Human imaging using radiation for the detection of concealed objects for security or anti-smuggling purposes **shall only be justified by applying the requirements of paras 3.60 to 3.63, and 3.65 to 3.67.**"	This statement on the non-justification of human imaging for security purposes is a hostage to fortune. Backscatter imaging systems have already been justified in many countries, including the UK and USA, and transmission systems are likely to be justified in the near future. Suggest either deleting Para 3.20 because Paras 3.60 to 3.67 already cover the important requirements, or alternatively reword as suggested.		New text was developed by a working group at RASSC		

USA	3.20	Clarification required	Additional clarification may be needed, since it may be considered that scanning is for theft or other purposes. Does this section prohibit the use of whole body scanning machines for the detection of explosives by transportation authorities? If not, what is an exceptional circumstance? Routine screening of all international airline passengers is not an exceptional circumstance. This is a rapidly evolving area, and further discussion is needed to reflect what may now be a changing consensus.		New text was developed by a working group at RASSC and agreed		
Belgium	Req. 11	Delete “establish requirements for optimization of protection and safety”.	Duplication of “require that protection and safety is optimized”.		Text has been modified		
Czech	Req. 11	The regulatory body shall establish requirements for optimization of protection and safety ~~and require that protection and safety is optimized.~~	Para 3.21. use better formulation for second part of sentence of req.11		Text has been modified		
ENISS	**Require ment 11**	**The regulatory body shall establish requirements for optimization of protection and safety ~~and require that protection and safety is optimized.~~**	The leading principle is that of optimization and the demand for having requirements for optimization is sufficient to follow this principle.		Text has been modified		
Israel	Req. 11 and 3.22	The concomitant requirements under Req.11 address the regulatory body as well as registrants and licensees. Req. 11 should therefore address both and include 2 sentences. The second sentence could be para. 3.22. We propose: "The regulatory body shall	Req. 11 and 3.22		Text has been modified		

		establish and enforce requirements for optimization of protection and safety. Registrants and licensees shall ensure that protection and safety are optimized."					
Iran	Req. 11, page 38	Registrant and licensee shall ensure that protection and safety is optimized.	Optimization is one of the most important responsibilities of licensee.		Text has been modified		
Australia	Req. 11	The regulatory body shall establish requirements for optimization of protection	The current wording says the same thing twice.		Text has been modified		
USA	Req. 11; Req. 38	The title for requirements 11 and 38 differ, but concern similar topics. Recommend using the same title for both requirements.	Editorial suggestion. The requirements will read better if things are referred to consistently.	X	Text has been modified		
Israel	Req. 11 and 3.22	"are optimized" instead of "is optimized"	Req. 11 and 3.22		"protection and safety" is a defined term, and is optimized as one.		
Australia	3.21	Change "safety, to require" to "safety, require"	Editorial correction	X			
France	3.21	Add "for dose and/**or** risk at the end of the sentence: "The regulatory body shall establish requirements for optimization of protection and safety, to require documentation addressing optimization of protection and safety, and establish or approve constraints, as appropriate, for dose and risk"	Risk constraints are generally used for potential exposure.				The use of "and" does not imply that both types of constraint need to be considered, while including "or" might imply that only one type of constraint is sufficient.
Czech	3.21	… for dose ~~and~~ or risk….	Not always for both dose and risk.				The use of "and" does not imply that both types of constraint need to

							be considered, while including "or" might imply that only one type of constraint is sufficient.
ILO Japan (business federation)	3.21	Add "taking social and economic factors into account" to the end of the following paragraph.3.21; *(3.21)* *The regulatory body shall establish requirements for optimization of protection and safety, to require documentation addressing optimization of protection and safety, and establish or approve constraints, as appropriate, for dose and risk, or the process for establishing constraints, that are used for optimization of protection and safety.*	To achieve consistency between the intent of Safety Principle 5 and para.1.14, and to avoid demands for unreasonable be achieved. *Safety Principle 5: Protection must be optimized to provide the highest level of safety that can reasonably be achieved.* *1.14. The optimization of protection and safety, when applied to the exposure of workers, members of the public and comforters and carers of patients undergoing radiological procedures, is a process for ensuring that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable, taking social and economic factors into account.*		The definition of optimization includes "taking societal and economic factors into account".		
Israel	3.21	Delete "to" before "require"	3.21	X			
Spain	3.21	The wording of this paragraph is somewhat confusing. It may be hard to understand for those who do not know enough in depth the new recommendations of ICRP-103. This paragraph should be re-written to put more emphasis on the facts that: 1) For public exposure, the regulatory body is responsible for establishing (or	Clarity			X	The extra detail for occupational and public exposure are covered in later parts of section 3: para 3.76bis deal with dose constraints in occupational

		approving) constraints. 2) For occupational exposure, the regulatory body is responsible for establishing (or approving) the process for which constraints are established (by the licensee).					exposure and 3.119 covers public expiosure.
ENISS	3.21	The regulatory body shall establish requirements for optimization of protection and safety, to require documentation addressing optimization of protection and safety, and implementation of ~~establish or approve constraints for dose and risk, or~~ the process for establishing constraints, that are used for optimization of protection and safety, as appropriate.	Dose constraints are only one tool in the optimization process and not each practice will need them. If dose constraints for occupational exposure are appropriate they shall be established by the licensee or the employer according to the ICRP 103.			X	Decision of RASSC.
WNA	Specific 3.21, 1.14	**Optimization** – In para 3.21, the expression "taking social and economic factors into account" should be added and the expression "that are used for optimization"… should be replaced by "that are used in the optimization"… "*(3.21)* *The regulatory body shall establish requirements for optimization of protection and safety, to require documentation addressing optimization of protection and safety, and establish or approve constraints, as appropriate, for dose and risk, or the process for establishing constraints, that are used for optimization of protection and safety.*"	Unduly low dose constraint requirements for optimization of protection should be avoided according to Safety Principle 5 and para.1.14. *"Safety Principle 5: Protection must be optimized to provide the highest level of safety that can reasonably be achieved."* "*1.14. The optimization of protection and safety, when applied to the exposure of workers, members of the public and comforters and carers of patients undergoing radiological procedures, is a process for ensuring that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable, taking social and economic factors into account.*"		The definition of optimization includes "taking societal and economic factors into account". Guidance on setting dose constraints is provided in Safety Guides.		

ENISS	3.22	Registrants and licensees shall ensure that protection and safety is being optimized.	See 2.10			X	Footnote 4 states what is meant by "is optimized".
Spain	3.22 – 3.24	Paragraphs 3.22 to 3.24 deal with responsibilities of Registrants and Licensees. These supporting requirements do not correspond to overarching requirement 3.11 (the regulatory body shall establish…..)	Consistency		Text of Requirement 11 has been modified.		
Israel	3.22	To be deleted				X	Editorial. This is an important requirement. Duplication of Req. 11 is intentional.
Germany	Para 3.22	Registrants and licensees shall ensure that protection and safety is subject to an optimization process.	See general comment 2 above.			X	Footnote 4 states what is meant by "is optimized".
UK	3.22	Modify to read: "Registrants and licensees shall ensure that protection and safety is optimized, **and that this is clearly documented.**"	This is an important general requirement. The optimization needs to be part of a coherent demonstration, which is auditable to the regulators. Note: Correction of the typo (i.e. {2.24} deleted).			X	This is covered by para 3.21.
USA	3.22	Consider adding: "Registrants and licensees shall ensure that protection and safety is optimized and comply with the requirements specified by the regulatory body"	With the introduction of paragraph 3.22, it is not clear that 3.23, which requires a licensee to optimize protection and safety, also means that the licensee has to comply with the requirements set by the regulatory body.			X	This is not to be stated throughout the BSS. See also para 2.3, that the BSS requirements are in addition to national regulations.

Czech	3.22	Consider adding: "Registrants and licensees shall ensure that protection and safety is optimized and comply with the requirements specified by the regulatory body"	With the introduction of paragraph 3.22, it is not clear that 3.23, which requires a licensee to optimize protection and safety, also means that the licensee has to comply with the requirements set by the regulatory body.			X	This is not to be stated throughout the BSS. See also para 2.3, that the BSS requirements are in addition to national regulations.
Belgium	3.22/1	Delete "{2.24}".	Editorial.	X			
Iran	Req. 12 page 39	Registrant and licensee shall ensure that the exposure of individual from the practice for which they are authorized is restricted to dose limits.	For implementing requirements of dose limits, the role of licensee is more important than the regulatory.	X	Text has been modified.		
Belgium	Req. 12	Title should read "Dose limits".	Coherence with requirement itself. See also comment no. 1.			X	Editorial. The paragraphs cover more than dose limits.
Israel	Req.12	"for occupational exposure and public exposure" instead of "for public exposure and occupational exposure"	Consistency with the order of the sub-sections in section 3	X			
Spain	Requirement 12	The text of requirement 12 should explicitly add that "Dose limits do not apply to medical exposures" (this is written now only at the end of para. 3.27).	Clarity			X	It is sufficient to state only in para 3.27.
Israel	3.25	"for occupational and public exposures" instead of "for public and occupational exposures"	Consistency with the order of the sub-sections in Schedule III	X			

ILO Finland (Trade Union)	3.25 on dose limits for occupational exposure refers to Table III	Fundamentally, it should be possible to introduce strictest limits in this context on the basis of new scientific data. Moreover, the applied safety culture should also involve the registration and examination of any exceptional or near miss incidents, even if no exceptional exposure to radiation occurred.			No change to text is required.		
ILO UK (workers)	3.26,3.27, 3.30(b), 3.87,3.88, 3.70,3.74, 3.109(a)	Add 'normal' in front of 'exposures';	Bring it in line with the definition of 'normal exposures' which needs to be re-instated.			X	It is better to clarify text than to depend on definition.
WNA	Specific 3.27, 3.144, 3.146 3.167	**Are requirements commensurate to the actual risk: Medical public exposure** – ***There is no dose limit and no numerically-set dose criteria for diagnostic reference levels associated with medical exposure in medical imaging*** (such as X-rays) ***which are routinely performed on many people all around the world***. This should not be confused with higher medical exposure such as CT scans and nuclear medicine. The average medical exposure per individual is ***0.4 mSv/y*** or 14% of the overall public exposure. A single chest X-rays contributes to about ***0.14 mSv***. ***Overall, about 120 requirements (planned public exposure) that apply to medical exposure. Of these, about 50 are specific to medical exposure. The rest are general requirements.*** See General Comments No. 2, 3 and 12. See attached Table 1.	Because of the absence of numerical dose criteria for medical exposure, the requirements are not commensurate to the actual risk.			X	

Spain	Requirement 13 and para 3.28 to 3.35	No mention is made to the impacts on the environment as such (non-human biota), which should be part of any new "safety assessment".	N/A			X	The current definition of "protection and safety" applies to protection of people. There are separate requirements for protection of the environment.
Spain	Req. 13 and para 3.28 to 3.35	The level of detail of supporting requirements 3.28 to 3.35 seems excessive in relation to other sections of the BSS.	Consistency			X	This is text from the current BSS. There is no proposal to delete some of the paragraphs.
Iran	Req. 13 page 40	Safety assessment shall be made at different stages, as appropriate by the person or organization responsible for facilities and activities that give rise to radiation risk.	For safety assessment the role of responsible person is more important than the regulatory.	X	Text has been modified.		
USA	R 13	Revise to read as follows: ~~**The regulatory body shall establish and enforce requirements that the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct a safety assessment of this facility or activity.**~~ "The person or organization responsible for facilities and activities that give rise to radiation risks shall conduct a safety assessment of the facilities and activities."	The overarching requirement is very long, and gives a focus on the regulatory body establishing requirements for safety assessment. Yet the condition paragraphs following talk about the regulator, the licensee, and the contents of the safety assessment. Thus it would seem more appropriate for the overarching requirement to be broader, requiring a safety assessment.	X	Text has been modified.		

Australia	3.28-3.34	These paragraphs sometimes refer to "persons or organizations" and elsewhere to "registrants and licensees". It should be made consistent.	Inconsistency			X	Often the safety assessment is carried out by a person or organization as part of the application for an authorization. A reassessment would be carried out after authorization is issued.
France	3.28	**Safety assessment** Add : "***commensurate to the magnitude of risk"*** "…the person or organization shall be required to submit a safety assessment ***commensurate to the magnitude of risk*** , which**…"**	It should be suitable that this requirement for a safety assessment take into account the magnitude of the risk which is different between a nuclear reactor and a dentist X ray device.			X	Covered by requirement for graded approach – see Req. 6 and para 3.6.
Czech	3.28	Delete first sentence.	Repeating Req.13 using another words – this could be misleading.			X	It is allowed to repeat the overarching requirement in the accompanying requirements.
Israel	3.30	Delete "related to protection and safety measures"	The requirement is not limited to safety assessments related to protection and safety measures		Text has been modified. It is noted that the definition of safety assessment is explicitly related to protection and safety – see Glossary.		

Israel	3.30	Add "in the lifetime of a facility or activity" after "stages"	Clarification			X	The following terms are used to delineate the lifetime of a source.
ICRP	pg 40, 3.30(a) line 1	Strike out “and potential exposures”.	Potential exposure is not an exposure which is incurred. It only underlies with a source.	X			
France	3.31	Add “according to the defense in depth principles after “ as appropriate”.	With reference to 3.38			X	Proposed change unclear. The safety assessment may assess defence in depth, but is not carried out according to defence in depth principles.
UK	3.31	Add a new bullet to read: “(g) Any uncertainties/ assumptions and their effects on safety.”	To establish the integrity of the Safety Assessment and understand the implications to safety from uncertainties and assumptions. Assessing sensitivities to assumptions and uncertainties is an important part of any Safety Assessment. Although it is noted that uncertainties in the assessment of exposures are specified in Para 3.125 (Page 68) under Requirement 30 applied to optimization of protection.	X	Text has been modified..		
ICRP	pg 41, 3.31(b) line 3		A failure of a source or a system does not lead to potential exposures, rather a source or a system itself simply has its potential exposure. Such a failure may lead to an accident exposure or an emergency exposure.	X			

UK	3.32	Additional point: (e) factors that could give rise to a loss of shielding, and the measures to prevent, identify and control such occurrences	Unplanned or uncontrolled movement of shielding can occur (eg during maintenance or decommissioning), this can include leak of liquid shielding, melting of lead in a fire, etc	X	Text of (c)has been modified		
UK	3.34	Add a new bullet to read: "(d) Deterioration of the performance of components is suspected."	The suggested changes cover for ageing, environmental effects on components, damage, etc.			X	Covered by (c) as part of operating experience. Could be included in a Safety Guide.
NEA	Para 3.34(a)	MODIFY: …envisaged, or significant changes in the understanding of the natural setting of the facility;…	The EGIR supports this change to account for new knowledge that may arise with regard to the geologic or environmental circumstances of the facility in question.	X	New (b) has been added to para 3.34.		
USA	3.34 a	Consider modification: Significant modifications to the facility or its operating and maintenance procedures are envisaged, or significant changes in the understanding of the natural setting of the system are uncovered;	Discovery of a new fault near a surface facility or an unexpected feature in an underground facility ought to trigger a new safety analysis.	X	New (b) has been added to para 3.34.		
India	3.34(c)	…Any significant changes in activities, or any relevant changes in guidelines or standards, are envisaged ~~**or have been made.**~~	Changes cannot be made without the necessary authorization. Any consequential modifications following a review of safety assessment have to be made cautiously keeping in view all the implications for protection and safety.	X	(c) has been split into two sub-paragraphs, and text modified.r4		
Czech	3.35	Last sentence – The implementation of all improvements shall be prioritized so as to optimize protection and safety. – I only hesitate if this is not against the use of BAT – for consideration to use instead of optimize – "improve".				X	Material for Safety Guide

Czech	Req. 14	The registrant or licensee shall conduct the monitoring and measurements to verify compliance with the requirements on protection and safety.	It sounds more logical to verify compliance with something.	X			
Iran	Req. 14, article 3.36 line2 and 3, article 3.37 part a	Measurements should be deleted	Monitoring means measurement and interpretation so measurements, is included in monitoring when they are mentioned separately it makes confusion.	X			
Israel	Req. 14	"Registrants and licensees" instead of "The registrant or licensee"	Consistency with other requirements	X			
Israel	Req. 14	Delete "the" before "monitoring"	Editorial	X			
Israel	Req. 14	Add "with the requirements of protection and safety" after "compliance"	Consistency with Req. 23	X			
ILO UK (workers)	Req. 14	Delete 'the'.		X			
Czech	3.36	Second sentence: The regulatory body shall be responsible for the review ~~and approval~~ of monitoring and ….	It is not a practice in all countries to approve monitoring program or any other documentation. The approval of documentation is sometimes understand from the side of licensee or registrants as the responsibility of regulatory body for the correctness of all processes described.	X			
Germany	Para. 3.37 (d)	According to the requirements set by the regulatory body, records are maintained of the results of monitoring and verification of compliance, including records of the tests and calibrations carried out in accordance with these	The requirements to be established by the regulatory body should contain requirements for records.	X	Text modified		

		Standards.					
Ukraine	3.37	It is suggested to complement this requirement by a point (f): The monitoring programs should be agreed with regulatory authority. Reports on monitoring results must be passed to the regulatory authority. Reports on the results of monitoring must be produced in accordance with requirements approved by regulatory authority. Quality assurance should be provided for monitoring program.	Clarification of responsibilities			X	Covered by other paras.
Czech	Req. 15	….take all <u>practicable</u> measures	Only for consideration – is "practicable" here really the best expression? What about "reasonable" ?			x	Practicable is used in the Safety Fundamentals – principle 8. Practicable implies reasonable, and practical.
Czech	Req. 15	…and mitigate the consequences of those that ~~do occur~~ already occurred.	For better understanding			X	This is taken from the Safety Fundamentals. It implies that you mitigate as soon as possible.
ICRP	pg 43, Req. 15		Prevention and mitigation of accidents. Accidents in this context do not belong to planned exposure situations and should not be included in section 3.			X	The situation is planned, and not the exposure.

UK	3.38	Include a footnote “INSAG 10 provides further information on defence in depth in nuclear safety”	The authors should refer to INSAG 10.			X	Safety Guide
Argentina	Para. 3.38, line 4	The text: "a subsequent independent level of protection would be available" should be replaced bv "a subsequent hierarchical level of protection would be available"	In order to assure compatibility with the meaning of "defense in depth " in the Glossary	X	Text has been modified to make it consistent with the Safety Fundamentals.		
Argentina	Para. 3.38, Item (a)	The text "that mav cause exposure" should be deleted	The text to be deleted is redundant with the definition of "Accident" in the Glossary	X			
Argentina	Para. 3,39	This paragraph should be part of a new Requirement named "Technical requirement" before Requirement 15	The text of para, exceeds overreaching Requirement 15	X	The text of req. 15 has been modified.		
France	3.39	*Add “* ***and the design, licensing, manufacture, testing, documentation, use and maintenance of transport packages or parts thereof “:*** “…that the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning of facilities or parts thereof, ***and the design, licensing, manufacture, testing, documentation, use and maintenance of transport packages or parts thereof****, …*”	Similar rules apply to transport packages. This is consistent with para. 306 of TS-R-1			X	Covered by the Transport regulations.
Czech	3.39	The term “sound engineering” is understandable for everybody?		X	Text has been modified		
UK	3.39	Add a new bullet to read: “(e) Make allowance for activation of materials used in proximity of the source.”	Omission. The chemical constituents of components should be checked for potential activation.			X	This is not appropriate for this paragraph – include in a safety related paragraph

							somewhere?
WHO Mauritius (Min of Labour)	Req. 15: para 3.40	To add words in bold: "…..maintained **in a sustainable manner** so as to prevent….."				X	This is more appropriate as detail for a Safety Guide.
USA	3.40	In accident prevention: 3.40: "registrants and licensee shall ensure that systems, including software…" Consider further elaboration or explanation.	Is this a human element that can truly be measured and factored in??? You can never totally eliminate the human element even when a system is entirely under a machine's control because a human designed the machine.			X	Software here refers to computer code.
UK	3.40 to 3.43		Two concepts – accident prevention and accident mitigation – are included under in the Section titled Accident Prevention. These should be separated.	X	New sub-heading has been added.		
UK	3.41, bullets (a) and (d)	Modify the bullets to read: "(a) To prevent reasonably foreseeable accidents in connection with the facility or activity;" (d) To ensure that there are adequate procedures for control of the facility and any reasonably foreseeable accidents;"	Use of "postulated" does not create the impression of being able to predict the type of accident.	X	Text has been modified		
UK	Para 3.41	Consider adding additional bullets to read: "(j) To develop a suitable, graded plan to deal with accidental events leading to doses to persons and/or contamination of areas, which would not require the initiation of a major emergency plan (see Section 4) unless necessary; (k) To make arrangements to monitor persons receiving doses through whatever pathways they are received	Requirement 15: The issue is that there seems to be no intermediate response to accidents that do not require the "government ... ensur[ed] ... integrated and coordinated emergency management systems" which seem to be referred to in Para 3.43. In effect, there is no sign of a graded approach to events that lead to exposures. For example, if the event is confined to workers and has only a local effect, there is no need to put into place a	X	Text of para 3.42 has been modified to take account of proposed additional bullets.		

		and to provide necessary medical treatment; (l) To provide reassurance monitoring where potential exposures have occurred; (m) To control areas where contamination may exist and make arrangements to clean these to a suitable standard; (n) The graded plan developed by the registrant or licensee should be compatible with the major emergency plan if the event so warrants or escalates, and clearly be capable of being extended in a consistent manner."	major emergency plan. There is however a need to treat persons affected and areas that have been affected (even the latter would not apply to a radiation shine from a criticality effect). Hence the requirement is on the registrants and licensees. This can be compared with Requirement 43 on a Government to have an emergency management system. In the UK on a licensed nuclear site following an event, the licensee initially invokes its on-site plan, which if radiation is detected at a defined high level at the site boundary is then escalated to a nuclear emergency, which brings in many off-site agencies. We propose that the additional bullets suggested should be included in Para 3.41, or in a separate paragraph.				
Israel	3.42	"the likelihood of an emergency … the public is not negligible" instead of "there is a reasonable likelihood of an emergency … the public". "not trivial" or "significant" could also be used instead of "not negligible".	Clarification. The expression "reasonable likelihood" is not clear.	X	Text has been modified		
ICRP	pg 45, 3.42 line 1		The current subsection provides requirements for *accident prevention* while an emergency plan is for a given accident. In other words, emergency plan does not go with the title of this subsection (accident prevention). The same problem is found in article 3.43.	X	A new sub-heading has been added.		

India	3.43	Comment: Add ' d ': **Regular drills shall be carried out to check the efficacy of the plan.**	Add for completion	X	Text has been modified		
India	3.43	Registrants, ~~**and**~~ licensees **and the Government, as appropriate,** shall be responsible for the implementation of their emergency plans and shall be prepared to take any necessary action for effective response.	In the case of emergencies with off-site consequences, the government would have the responsibility in many States.			X	The government responsibilites for emergencies are set out in Section 4.
WHO Mauritius (Min of Labour)	para 3.43 (a)	To add words in bold: "…..Develop, maintain and implement **approved** procedures….."				X	Approved by whom?
WHO Mauritius (Min of Labour)	para 3.43 (c)	To add words in bold: "…..Train personnel **and workers,** and periodically retrain them **and assess their competency** in the procedures to be followed."			???		
WHO Mauritius (Min of Labour)	Para 3.44:	To add words in bold: "…..Registrants and Licensees shall ensure **through regular management reviews** that information……"				X	Detail not needed.
Czech	Req. 16	Registrants and licensees shall conduct formal investigations of any abnormal circumstances arising ~~in the operation of~~ on facilities or ~~the conduct of~~ during activities <u>and shall disseminate information that is significant to protection and safety.</u>	The underlined text is necessary to reformulate – now it is not clear what kind of information they shall disseminate and to whom – it is necessary to express that these are results of required investigation.			X	Current text is ok. The information is in the following requirements.
Iran	Req. 16 line1,	Registrants…..formal investigations of abnormal circumstances that are significant to safety and protection …	Formal investigation is mandatory only for abnormal circumstances that are important.			X	The detail is provided in para 3.45. The overarching requirement has

							been kept.
UK	3.46/2	Modify to read: "….after the event and prepare a written report on its cause **(or suspected causation factors)**, with a verification or …"	It may not be possible to isolate a single cause.	X	Text has been modified.		
Israel	3.47	"The registrant or licensee" instead of "Registrants and licensees"	Consistency with the first sentence of the para.	X			
Iran	Req. 17, and its title	Registrant and licensee shall ensure the safety of sources.	Article 3.51 discusses about the facilities which are source but they are not radioactive source, so it seems "source" is more general.				The term "facility" in para 3.51 is a place where radioactive material is used, handled, stored etc.
Germany	Requirement 17	Modify … ensure the safety and security of radiation ….	The issue of security for generator and sources is a key point that should be highlighted here, in particular since it is mentioned in 3.50 (a). In the glossary, the term security should be defined.			X	Recommendations on security are covered in Nuclear Security Series
NEA	Requirement 17	MODIFY: ... **ensure the safety and security of radiation..**.	The EGIR feels that the issue of security for generators and sources is a key point that should be highlighted here, particularly in that it is mentioned in para 3.50(a). The glossary should be modified to appropriately define security. Note: another solution would be to remove the word security from paragraph 3.50.			X	Recommendations on security are covered in Nuclear Security Series

UK	Requirement 17: Radiation generators and radioactive sources	Modify to read: "Registrants and licensees shall ensure the safety **and security** of radiation generators and **sealed** sources."	Security is an important element in ensuring safety; loss of a sealed source can present a high hazard to people and the environment. Note: Security is mentioned in Para 3.50 (a).			X	Recommendations on security are covered in Nuclear Security Series
France	Req. 17 and 3.48	***Maintain R17 and 3.48 but add new requirements*** **to reinforce the manufacturer responsibility on safety, defence in depth, good engineering practice and training of users at commissioning**…(see comments)	Is it really under the responsibility of registrant and licensee to ensure the safety of radiation generators and radioactive sources? In the same way is it really under the responsibility of registrant and licensee …. that the manufacturer are discharged his responsibility (ie for the design of radiation generators…)? The responsibility of the manufacturer should be pointed out in the draft. Specific requirements should be useful (overarching + associated requirement). Taking into account the requirements defined in 3.30 (safety assessment), in 3.38 (defence in depth), in 3.39 (good engineering practice), in 3.48 and in 3.160 is needed.	X	Text has been modified		
Czech	3.48	(a) to delete " as applicable "	"If applicable" is already in the first sentence, to duplicate it has no sense		editorial		
Germany	Para. 3.48	Modify …with manufacturers and suppliers…	It should explicitly be required to coordinate with manufacturers with regard to safety and security.	**X**	Text has been modified		
UK	3.48 (a) (iv)	Modify to read: "Provide displays, dials and instructions on operating consoles **that enable a rapid response** in a language	It is important that operators can make a quick decision in some instances.	X	Text has been modified		

		understandable and acceptable to the user."					
UK	3.48	Include new (d) shielding and other protective measures are optimized including the provision of adequately shielded enclosures	Omission. This paragraph should include explicit reference to requirements for the safety of enclosures in which radiation generators operate.	X			
Austria	3.48		The term "user" is new in the context of this standard.			X	Normal dictionary meaning.
NEA	Para 3.48	MODIFY: … with **manufacturers and** suppliers,…	The EGIR recognised that the term "suppliers" is defined to include manufacturers, yet felt strongly that it must be explicitly required to co-ordinate with manufacturers with regard to safety and security.	**X**	Text has been modified		
Slovakia	3.48	Modify : Requirements and licensees in cooperation with manufacturers and suppliers….	Cooperation with manufactures is useful	**X**	Text has been modified		
Czech	3.50	(a) … safety and security….	Only for clarification if it is correct to mention here " security" because in preamble is stated that security is not covered in these Standards		It is correct to mention security here. Although security is nor covered by these Standards, para 3.50 requires that when choosing the location of a source, security matters need to be considered.		
Israel	3.51	"releases of significant amounts" instead of "releases of large amounts"	"large amount" is already used earlier in the sentence	X			
ISSPA	3.51	When selecting a site for a facility that will hold ~~a large amount~~ (insert a	There is no applicable definition of "large." While a regulator may specify			X	It is not possible to specify

		prescribed quantity or make reference to a quantity) of radioactive material and has the potential for releases of ~~large amounts~~ (insert a prescribed quantity or make reference to a quantity) of such radioactive material, registrants and licensees shall take into account any features that might affect protection and safety, features that might affect the integrity or function of the facility, and the feasibility of carrying out off-site protective actions ~~if~~ when they become necessary.	a quantity as a license condition, this section should also apply to operations where such specification is not included by license condition. Suggest prescribing a quantity, referring to an attached schedule or referring to a recognized standard such as ICRP.				quantity, and it is a decision that would require judgement by a regulatory body.
Israel	3.52	"protected" instead of "secure"	Consistency with 3.52(d)	X	Text has been modified		
Finland	3.52(d)	Delete word “movable”.	Why limit this requirement only to movable generators or sources? Periodic inventory is important for all generators and sources.	X			
Austria	3.53	Registrant**s** and licensees […]		X			
Austria	3.54	[…] inventory records with the regulatory body or ~~other designated body~~ when requested.	Please clarify who that “other designated body” may be, and who will designate that body.	X			
ILO UK (workers)	3.53	Add ‘s’ to the end of ‘Registrar’.		**X**			
Belgium	3.53/1	Registrants…	Editorial.	**X**			
Iran	Article 3.55,	Deleted	Categorization itself does not improve safety and this article just asks the licensee to categorize his sealed sources.			X	Categorization is an important part of the graded approach.
ILO UK (employer	3.55	Should this paragraph be incorporated in section 2 as a responsibility of the	Requirement 17 overarching statement relates to registrants and licencees.3.55	X	Text has been modified		

s)		regulatory body? Possibly after 2.36	is a regulatory body requirement.				
UK	3.55		The overarching statement of Requirement 17 relates to registrants and licencees. However Para 3.55 is a requirement of the regulatory body. Consider therefore whether this paragraph should be incorporated into Section 2 as a responsibility of the regulatory body; possibly after Para 2.36.	X	Text has been modified		
USA	3.55	Consider reference.	"The regulatory body shall require that sealed sources are categorized in accordance with the categorization scheme set out in Schedule II." Should this section also include a reference to IAEA Dangerous Quantities of Radioactive Material (D-values) 2006?	X	RASSC agreed to add D-values for a selected set of radionuclides to Schedule II.		
Germany	Para. 3.57	Registrants and licensees shall, in cooperation with manufacturers, ensure that, where practicable, sealed sources are identifiable and traceable by stamped or engraved numbers on the source. Where this is not practicable alternative processes for identifying and tracing those sources are to be put in place.	Consistency with the regulations of the Code of Conduct.			**X**	**The current text is consistent with the Code of Conduct.**
UK	3.58/2	Modify to read: "..in use they are stored in an appropriate manner such that protection, safety **and security are** maintained."	See Comment 40 with regard to security.			**X**	
Australia	3.59	Is disposition the right word here? Should it be disposal?	Meaning unclear			X	"Disposition" is a defined term in the IAEA Safety

							Glossary. It has been added to the BSS Glossary.
USA	3.59	Suggest revision of phrase "they have become disused" with the phrase "it has been decided to take them out of use."	Clarity. A decision is made to no longer use a source. This statement serves as a more positive statement for action, and better defines what is needed to ensure the continued control of sources.	X	Text has been modified		
Norway	3.59	Proposed amendment: *"Registrants and licensees shall ensure that arrangements are made for the safe management and disposition of radioactive materials, including financial provisions where appropriate, once it has been decided to take them out of use".*	Considering all the serious events over the years where "forgotten" radioactive sources have re-entered the arena, the BSS should better describe the process through which a radioactive source or radioactive materials become radioactive waste.	X	Text has been modified		
NEA	Requirement 18	MODIFY: …**than medical diagnosis, ~~or~~ treatment, or bio-medical research shall be** …	The EGIR felt that bio-medical research is an important area of medical use of ionizing radiation, and as such should be specifically called out in this overarching requirement.	X	Change Requirement 18 to read: Requirement 18: Human imaging for purposes other than medical diagnosis, treatment or biomedical reseach The government shall ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, treatment or biomedical research shall be subject to the system of protection and safety required by these Standards.		

Germany	Requirement 18	"Requirement 18: Human imaging for purposes other than medical diagnosis or treatment"	The scope of this requirement is not clear and needs to be refined. For example, does it apply to human imaging of volunteers in biomedical research? The purpose of this kind of imaging is surely not medical imaging and treatment	X	See above proposed change.		
USA	R 18 3.60	Revise to read as follows: Requirement 18: Human imaging for purposes other than medical diagnosis, ~~or~~ treatment, or biomedical research. The government shall ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, ~~or~~ treatment, or biomedical research shall be subject to the system of protection and safety.	Revision suggested to be clear that the non-medical imaging requirement and paragraph are not misinterpreted as applying to biomedical research. The requirements for biomedical research are found within the medical exposures section.	X	See above proposed change.		
USA	3.60	Consider if changes are needed to be clear about the relationship of these requirements to the requirements in 3.19 and 3.20.	This section is contradictory to sections 3.19 and 3.20. The previous sections stated that imaging for nonmedical purposes "shall normally be deemed to be not justified." How can human imaging for nonmedical purposes then be subject to the system of protection and safety required by the Standards? It might be assumed that this paragraph, and the others in the set, only comes into force if the imaging has been deemed to be justified by the government, but this is not stated.	X	Paragraph to be deleted. Link to earlier paragraphs added		
USA	3.60	Consider Deletion	Beyond comment 50 above, this is another example where a paragraph is essentially duplicative of the overarching requirement, and could therefore be considered for deletion as	X	Paragraph to be deleted.		

			duplicative.				
USA	3.60 – 3.62	Modify paragraph consistent with revision suggested above for addition of biomedical research.	Consistent with comment on requirement, changes should be made in paragraphs 3.60 and following to clearly avoid possibility that biomedical research would be misinterpreted.	X			
Belgium	3.60	Delete.	Identical to the requirement itself (except the last five words).	X	Paragraph to be deleted.		
Czech	3.60	Delete	Repetition of general requirement 18	X	Paragraph to be deleted.		
Israel	3.60	The requirement is not needed	Redundant (repetition of Req. 18)	X	Paragraph to be deleted.		
NEA	Para 3.60	**The government** shall…	The EGIR felt that this paragraph is completely redundant with the overarching requirement and should be considered for deletion.	X	Paragraph to be deleted.		
Spain	3.60	Delete or rewrite	The text is a mere repetition of the requirement 18	**X**	Paragraph to be deleted.		
Spain	3.61	The reference made to para. 3.16 should be extended up to 3.20.	Clarity		Text has been modified.		
Iran	Article 3.61(a)	Deleted	Appropriateness of radiation equipment is not part of justification it is part of regulatory control. The other part is related to justification.		Text has been modified.		
France	3.61 b	add the fact that the justification process shall consider the benefits and detriments of the use of alternative techniques considered.		**X**	RASSC agreed that 3.61(b) be deleted		
UK	3.61 (b)	Delete	This bullet should be deleted, as consideration of alternative procedures	**X**	RASSC agreed that 3.61(b) be deleted		

			is not a legitimate part of the justification procedure set out by ICRP. This could be a hostage to fortune for other justification exercises, such as nuclear electricity generation.				
Australia	3.61(f)	Delete "during the intended period of use"	Words do not appear to be relevant to the rest of the paragraph			X	The intent is to ensure the sustained viability of the activity i.e. to ensure that there are no radiation protection issues in the future arising through the lack of resources.
ILO UK (workers)	3.62	Should this refer to 3.61 rather than 3.60.		**X**			
Spain	3.62	The reference made to para. 3.60, should be to para. 3.61.	Type error	X			
Sweden	3.62., first line	… in para ~~3.60~~ **3.61** that …	Wrong para No.	X			
Belgium	3.62/1	… in para 3.61…	Editorial correction.	X			
NEA	Para 3.62	EDITORIAL: **…**specified in para **3.61** that a particular…	The EGIR changed this to refer to the correct paragraph.	X			
USA	3.62	Change referenced paragraph to 3.61	It would appear that the reference to 3.60 should actually be to 3.61, since it refers to the process, and the process for justification of a human imaging is given in 3.61, while 3.60 simply states that such exposures are to be subject to the system of protection and safety.	X			

ILO UK (workers)	3.62	Add ‘authorisation and’ before ‘regulatory control’.	To emphasise that the practice needs to be authorized as well as justified.			X	Authorization is part of regulatory control
ILO UK (workers)	3.63	Add ‘and authorisation’ at the end of the sentence.	Strengthen oversight.			X	Authorization is part of regulatory control
UK	3.63	Delete “periodic”	Governments or regulatory bodies may well wish to review only when new important information emerges rather than periodically.	**X**	.		
ILO UK (workers)	3.64	Propose the removal of the phrase "conducted by medical staff using medical radiological equipment".	All human imaging which exposes humans to radiation should be considered, not just that "conducted by medical staff using medical radiological equipment". There is now human imaging being conducted by non-medical staff, using equipment that was not designed primarily for medical purposes. In the setting of dose constraints for such equipment (3.64.(a)) Such dose constraints should normally be LOWER (stricter) than for medical imaging, as the potential for continual or repeated exposure is greater.			X	1. The comment misses the point that <u>all</u> human imaging is covered by 3.64 and 3.65, but the situations are divided into two – namely that 3.64 covers the pseudo medical exposures, while 3.65 covers the rest. 2. The expectation is that the dose constraint would be lower than any corresponding DRL.
Australia	3.64	Change “occupational” to “employment”	Causes confusion with occupational exposure			X	Decision by RASSC
Australia	3.64	Is this paragraph meant to be public exposure?	While paragraph 3.65 clearly states that it relates to public exposure, 3.64 does not. The system of protection is meant to encompass all types of exposure and it should be made clear where this type of exposure fits.			X	It is not public exposure. They are afforded the radiation protection sytem as if they were

							medical exposures.
Australia	3.64	Amend 'medical staff'	Should be consistent with terminology used in 3.143 – 3.183.	X	Change to medical personnel		
Australia	3.64	What are 'exceptional circumstances'?	It seems to be necessary to give further information on the type of 'exceptional circumstances' that are envisaged. A further option could be to remove 'exceptional circumstances' and just emphasise the need for justification.			X	Not mentioned in 3.64.
USA	3.64 footnote 19	Consider whether the phrase "detection of drugs concealed within the body" should be deleted.	This is inconsistent with section 3.19 that states that human imaging for theft detection purposes (or in this case smuggling) to be deemed not justified.		3.20 has been changed.		
NEA	Para 3.64(b)	EDITORIAL: … paras 3.160 to 3.~~176~~ 172 are…	The EGIR changed this to refer to the correct paragraph.	X	3.173 to 3.175 are also part of optimization of protection.		
Israel	Footnote 19 (para. 3.64)	Delete "detection of drugs concealed within the body,"	This purpose is covered in para. 3.65 as detection of contraband			X	Note 3.65 is specific to inspection imaging devices, while 3.64 is for medical radiological equipment. E.g. a CT could be used to detect concealed drugs, and this would be covered by 3.64 not 3.65
UK	3.65		There is perhaps a need to point out that holders of dosimeters (such as film badges) should be particularly wary about these devices being scanned by inspection imaging equipment. They could give the holder an inaccurate			**X**	Not relevant to the logic of 3.65.

			dose record, triggering unnecessary actions.				
Spain	3.65	In order to clarify that human imaging for purposes other than medical diagnosis or treatment are subject to dose limits, we propose an alternative text: *Inspection procedures, using inspection imaging devices, which intentionally expose humans for the purpose of detection of concealed weapons, contraband or other objects on or within the body shall be considered as giving rise to public exposure, and registrants and licensees shall ensure that the requirements for public exposure in planned exposure situations are met and, in particular, that optimization of protection and safety is subject to any dose constraints set by the government or regulatory body. <u>Such dose constraints shall be well below the dose limit for members of the public.</u>*	Paragraphs 3.60 to 3.65 clearly establish that non medical imaging procedures are subject to the principles of justification and optimization. The applicability of dose limits to such procedures is not so evident. Even though it is implicitly established in paragraph 3.65 (*registrants and licensees shall ensure that the requirements for public exposure in planned exposure situations are met*) we understand it is better to make this requirement more explicit.			X	Not necessary. A Safety Guide will elaborate further.
Spain	3.66	This requirement should be deeply reconsidered. It is not always feasible to provide prior information about the possibility of choosing alternative techniques that do not use ionizing radiation. More flexibility is necessary to allow for specific cases where enforcement bodies may proceed without informed consent of the individual	Depending on the particular circumstances this requirement may be difficult (or even impossible) to fulfil.			X	Practical issues should not be a problem. E.g. Informing persons may be achieved by signage with instructions.

Austria	3.66	[…] that does not use ionizing radiation, ~~where available~~.	Earlier, it was "deemed not to be justified" to employ inspection procedures using ionizing radiation, although according to 3.60 it might be justified on a case-by-case basis. Now, however, the qualifier "where available" leaves extra room for not providing alternative methods.			X	1. Paras 3.18-3.20 have been modified. 2. There may not always be an alternative.

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations **Page:** **Date: 9 September 2010**							
Section 3: Planned Exposure Situations: Occupational Exposure							
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
UK	3.68 to 3.115 Occupational Exposure		Throughout this draft there are a number of references to accidents and incidents. It would be beneficial to provide a distinction between planned exposure situations and accidents, incidents and emergencies, especially when used to exercise dose limitation.	X	Text checked.		
Israel	3.68	"and section 5" instead of "or section 5"	Clarification	X			
ENISS	**Requirement 19**	**The regulatory body shall establish and enforce requirements to ensure that protection and safety is being optimized, and that doses from occupational exposure comply with dose limits.**	See 2.10			**X**	Footnote 4 provides explanation of 'is optimized'.
UK	Req. 19	Reword to read: "The regulatory body shall establish and enforce requirements that provide for protection and safety being optimized, and doses from occupational exposure complying with	As written the duty for optimization and compliance with dose limits is on the regulator, rather than where is should be on the employer/registrant/licensee.			**X**	Consistent with Req. 29.

		dose limits."					
USA	R 19 3.69 – 3.72	Consider consolidation of requirements from occupational and public exposure for regulators into single more generic section to avoid repetition.	Paragraphs 3.69 to 3.72, and two overarching requirements, have been created to provide parallel construction for the section dealing with public exposure. This raises the substantial question of why these parallel sections are not combined and placed in the general requirements section of Chapter 3.			**X**	
IRPA	3.69, Req 21 3.74 3.76 3.77 3.78 3.79 Req 23 Req 24 3.86 3.92 3.93 3.106 Req 27 Req 28 3.113 3.114 3.115	registrants, licensees and employers,	Since the prime responsibility for protection and safety is that of the registrant or licensee, their name should precede the employer in all the paragraphs regarding occupational exposure. This is how it is done in medical exposures. There should be consistency. The alternative is to change the order in the medical exposure section and put there radiological medical practitioner before registrants and licensees.			**X**	According to para 2.41, all three parties have responsibilities.
Czech	3.70	… requirements that protection and safety are optimized <u>for circumstances involving occupational exposure.</u>	I don't understand this sentence – what is the purpose?	**X**	Text has been modified.		
ENISS	3.70	The regulatory body shall establish and enforce requirements that protection and safety ~~shall be~~ <u>are being</u> optimized…	See 2.10			X	See above

Czech	3.71	…from all authorized sources and facilities…..	Maybe it is more correct to use facilities and activities?	**X**	Text has been modified		
ILO UK (employers)	3.72	Requirement for regulators to authorise plans, designs etc. Definition of authorization in Glossary includes the terms 'for specified activities'.	The requirement will increase the regulatory burden and it is considered that it is inappropriate for all new or modified practices to require regulatory approval. Does not match the requirement for adopting a graded approach to regulation as outlined in 2.32. Authorization is not required for exempted activities.	X	Text hass been modified. Each regulatory body to decide on applying the graded approach to the regulations.		
UK	3.72		The requirement is for regulators to authorize plans, designs, etc. The definition of *authorization* in Glossary includes the term "specified activities". This requirement will increase the regulatory burden and it is considered excessive and inappropriate for all new or modified practices to require regulatory approval. This does not match the requirement for adopting a graded approach to regulation as outlined in Para 2.32. Authorization is not required for exempted activities.	X	Text has been modified. Each regulatory body to decide on applying the graded approach to the regulations.		
Czech	3.73.	(a) review and approval	It is not a practice in all countries to approve monitoring program or any other documentation. The approval of documentation is sometimes understand from the side of licensee or registrants as the responsibility of regulatory body for the correctness of all processes described.	**X**			
ENISS	3.73	The regulatory body has to be responsible, as appropriate, for: a) Review ~~and approval~~ of monitoring	Approval of monitoring programmes is not a common practice in all Members States	X			

		programmes of registrants and licensees, which has to be sufficient:					
ENISS	**Requirement 21**	**They shall ensure that protection and safety is being optimized and the dose limits for occupational exposure are not exceeded.**	See 2.10			X	See above
ENISS	3.74 (c) new	Establishing dose constraints if appropriate	For clarification and consistency			X	This is covered by para 3.86 in draft 3.0 (moved in draft 4.0)
ILO Finland (Trade Unions)	3.76 concerns the obligation of the operator to ensure the maximum dose limits are not exceeded	(a) Employers also include leased employees. For the sake of clarity, it would be important to emphasise the employer's obligations to leased employees as well. In shared workplaces, the employer exercising primary authority should supervise the compliance of other operators on the premises with protection and safety measures concerning radiation. (b) With respect to the monitoring of radiation data, movement within the EU should be taken into account by requiring that an employee's monitoring data travel with him/her and that employees have the possibility to check their register data when necessary. (c) In medical operations, it must be ensured that, with respect to occupational exposure, the does limits of employees participating in such operations are not exceeded. Concerning patients, exceptions are possible in the manner required to create the potential health benefits.					(b) and (c) are covered by 3.104(c), 3.108. Detailed guidance will be included in a future Safety Guide or Safety report

ENISS	3.76 (b)	Occupational protection and safety are being optimized in accordance with the relevant requirements of these Standards;	See 2.10			X	See above
USA	3.76(f)	Change "are provided" to "should be provided"	Not every country has a national healthcare system. In countries without a national healthcare system, small businesses may not be able to provide health surveillance or services themselves.			X	The employer has to see that the OEW receive regular health surveillance. This is is current BSS, (I.4) and there is no justification to change.
Spain	3.76.g	**Appropriate protective devices and monitoring equipment are provided and arrangements made for their proper use, maintenance, testing and calibration.**	Better understanding	X			
Germany	Para. 3.76 (h)	Suitable and adequate human resources and appropriate training in protection, and safety are provided, as well as periodic retraining and updating as required in order to ensure the necessary level of competence	The requirements related to education and training applicable to different types of planned exposures should have the same level of detail and use consistent wording when the meaning is intended to be the same.				No change proposed. See also Req. 26.
USA	3.76(h)	Provide additional clarification regarding what constitutes "suitable and adequate human resources.	The text does not clearly state what is meant by "suitable and adequate human resources." This may be an issue that would be left to a safety guide, and the specific answer will be very context dependent. Nevertheless, as stated, it would seem to be impossible to know if the requirement has been complied with.				This is very difficult to be precise within a requirements document, and is subject for elaboration in a Safety Guide. Se also Req. 26.
USA	3.76	Revise last portions of a) and b) to	Earlier, at paragraph 3.71, material was				See para 3.25 and

		read: "as specified by the regulatory body" (a) Occupational exposures are so controlled that the relevant dose limits for occupational exposure ~~specified in Schedule III~~ as specified by the regulatory body are not exceeded; (b) Occupational protection and safety are optimized in accordance with the relevant requirements ~~of these Standards~~ as specified by the regulatory body;	introduced which required the regulatory body to establish and enforce requirements for dose limits and for optimization. Presuming that this is retained, either in the occupational exposure section, or in the generic section, the references in sub-paragraphs a) and b) now cause confusion, because they refer to the standards, rather than to the requirements specified by the regulatory body. Therefore the ends of the two sub-paragraphs should be revised.				3.71.
India	3.76(f)	Comment: **'Necessary workers' is not a defined term. This needs to be defined. It should be called as 'classified workers' who receive more than 3/10 of annual dose limit for the occupational workers.**		X	Text has been modified		
India	3.77	Comment: **This para needs to be deleted as this may cause difficulty in implementation in a plant environment.**				X	This is an important paragraph. It is in current BSS.
ILO Finland (Min of Employment)	3.77	A more precise definition of the term "directly related" would be desirable in the BSS glossary.	Para 3.77 on occupational exposure requires employers to ensure that workers exposed to radiation from sources due to practices not required by, or not directly related to, their work receive the same level of protection s if they were members of the public. With respect to exposure to natural sources of radiation due to the location of the workplace, related to the radon in air inhaled into the lungs, it is unclear whether or not this is directly related to			X	Normal dictionary meaning.

			work. If this is not the case, the dose limits to be applied to workers under the instructions issued should be those for public exposure (population/residences), not occupational exposure. Paragraph 5.27-5.28 may give the impression that, in certain cases, radon in workplace air is not directly related to work.				
Finland	3.77	move to before or after 3.74 or include in 3.68	In order to highlight this important par; now it is like "hidden".			X	Agree that it is important para, but keep it in same place. Cannot combine with 3.68.
ICRP	pg 54, 3.77 line 1	Use "persons" instead of "workers"	'workers' usually refers radiation workers in these Standards.			X	If persons are not workers, they are protected as members of the public, and do not need to be included in para 3.77.
Denmark	3.77	Propose to move this paragraph to before or after 3.74 or include in 3.68	This paragraph should have a more prominent position.			X	See response to Finland
Norway	3.77	Not optimal placed.	The requirement in 3.77 concerning protection of workers not directly involved in the practice should be moved to a place where it is not hidden. Perhaps it could be placed directly after Requirement 21, before or after paragraph 3.74 or in paragraph 3.68 describing the scope of the section.			X	See response to Finland
Sweden	3.77	Move to before or after 3.74 or include in 3.68	Needs to be highlighted!			X	See response to Finland

Slovenia	Under Req. 21, new para. after 3.79	**Proposed additional text under Requirement 21** (new paragraph after 3.79): In case of contracted employers, prime responsibility for protection of workers remains with registrants and licensees, unless specified otherwise in a contract.			This is covered by para 3.74, 3.83, 3.84, 3.85.	X	
Czech	Req. 22	Workers shall be required to fulfill their obligations and duties for protection and safety.	I have a feeling that the requirements in these Standards couldn't be addressed directly to the workers – at least we don't use it in national legislation – all requirement are addressed to the authorized or notifying persons , employers			X	
NEA	Requirement 22	ADD: **Employers, registrants and licensees shall facilitate compliance by workers with the requirements of the Standards. Workers…**	The EGIR noted that the text reinstated here has been "accidentally" deleted without any justification. As such, the EGIR strongly suggests that this text be added. The missing text was the first sentence of para 3.82 (of BSS rev. 2.5), para 3.73 (of BSS rev. 2.0), para 3.69 (of BSS rev.1.), and it is para I.9 of BSS1996.	X			
Japan	Requirement22	(Following paragraph should be added.) Employers, registrants and licensees shall facilitate compliance by workers with the requirements of these Standards.	Necessary Requirement for employers, registrants and licensees	X			

Brazil	3.81	Workers shall **be responsible for**:	Emphasize that workers are also responsible for radiological protection and are the main responsible by their own acts.			R	Different level of obligation and will create confusion with the responsibilities of employers.
India	3.81	Comment: **Though it is covered under 3.112 yet at this place as a part of 'compliance by the workers', the *declaration of pregnancy to employer by a female worker* shall be included.**	Addition for completeness			R	Explanation is provided in footnote 22 to para 3.112.
Ireland	3.82	The requirement for the worker to report these circumstances is quite loose. "As soon as feasible" should be replaced with "promptly".				X	Continue to text of current BSS.
Israel	Req. 23	"Employers and registrants or licensees" instead of "Employers, registrants and licensees"	Consistency with the title of the requirement	X			
Spain	3.83 – 3.85	Independently of the necessary cooperation between employers and registrants or licensees, it should be clearly established that the primary responsibility on the protection of the workers lies on the employer.	Cooperation between employers and licensees is necessary, but it is also necessary clarify the allocation of responsibilities	X	Covered by para 2.40(b)		
Australia	3.85 & 3.105(c)	Should transfer of records be a regulatory requirement, rather than an obligation on employers etc?	Privacy Legislation makes such cooperation difficult to achieve unless it is a regulatory requirement				New text has not been proposed. Each State to decide on the regulatory requirements.

NEA	Requirement 24	**Employers, registrants and licensees…**	The EGIR felt that this requirement to "maintain a radiation protection programme" does not well describe the subsequent requirements, which deal with definition of areas, protective equipment and area monitoring, but do not cover all the aspects of an occupational exposure programme. This text needs to be rewritten to better reflect the subsequent requirements.		Text has been modified.		
UAE	Requirement 24	Review placement. Add 'as a part of and consistent with their management system'.	Requirement 24 – as a principal means of achieving optimization of protection and safety should be linked with Requirement 21. The RPP should be a part of the licensee's management system.		Text has been modified. The management system is covered by Req. 5 and does not to be repeated here.		
Belgium	Req. 24/2	exposure, commensurate with the magnitude and likelihood of the expected exposures.	Application of the graded approach principle.		Graded approach is covered by Req. 6 and does not be repeated in the overarching requirements.		
Czech	3.86	b) establish and use, as appropriate, dose constraints as part of optimization …	It is necessary to say who is going to establish a dose constraints for occupational exposure (but maybe I have overlooked some paras related to this?)		RASSC agreed that dose constraints set by licensee – see para 19.2.2 of RASSC report for RASSC28 meeting.		
ENISS	3.86	Employers, registrants and licensees shall, ~~as part of their responsibility for ensuring that occupational protection and safety are optimized~~ in accordance with the relevant requirements of these Standards:	Deletion because this text is unnecessary.	X	Text has been further modified, to renove all words after shall:		

Israel	3.86	Move the paragraph under Req. 21, for instance after para. 3.76.	The requirement deals with optimization and does not deal with the radiation protection programme	X	Text is moved to after 3.76..		
USA	3.86	Delete paragraph. Move a) to become a new requirement following 3.79. Move b) to within paragraph 3.76, as a new point after b).	Paragraph 3.86 deals with the fundamental aspects of communication with workers, and with establishing constraints. As such, these points should be addressed in other places, rather than separately here in radiation protection programs. It is suggested that the points be moved.	X	Text has been kept together, and moved to after 3.76.		
ISSPA	3.86 (b)	Use, as appropriate, constraints and reference levels as part of optimisation of protection and safety.	To be consistent with recommendations in ICRP 103.			X	Constraints are for planned situations, reference levels for emergency exposure situations and existing exposure situations
Ireland	3.86-3.91	The more general designation of controlled areas is welcome (versus annual occupational liability to receive a threshold dose in excess of 6mSv). However, it is important to ensure that it doesn't result in excessive regulation for scenarios that do not warrant it from a risk perspective. The reference (3.90) 'even though specific protective measures and safety provisions are not normally needed' is ambiguous as all areas where exposure could occur have protective measures so this could give rise to all areas being					This is an issue for a Safety Guide. The current Safety Guide RS-G-1.1, which is about to be revised, provides some guidance on the controlled and supervised areas.

		classified as “controlled areas”. Need to clarify the difference between specific and “other” protective measures.					
IRPA	3.87 following (b)	The requirements of controlled and supervised areas are not applied to the transport of radioactive materials. However, compliance with appropriate requirements of TS-R-1 is deemed to establish equivalent safety level.	As mentioned in paragraph 8.8 to 8.12 in TS-G-1.3 (RADIATION PROTECTION PROGRAMMES FOR THE TRANSPORT OF RADIOACTIVE MATERIAL SAFETY GUIDE), the requirements of controlled and supervised areas are not applied to the transport of radioactive materials.		Footnote added to para 3.87.		
Israel	3.87-3.90	We suggest adding dose limits for controlled, supervised and, if possible, public areas.					Appropriate for a Safety Guide.
China	Para 3.87-3.91 3.88	Extend and make more detailed description of controlled areas and supervised areas. Controlled areas should be given a upper limit boundaries.	The classification of radiation work areas is determined according to administrative procedures. The interpretation about controlled areas and supervised areas should be extended in practice conveniently rather than being described conceptually.				Appropriate for a Safety Guide.
Japan	3.87	(Following sentence should be added in footnote or in end of paragraph 3.87.) The requirements of controlled and supervised areas are not applied to the transport of radioactive materials. However, compliance with appropriate requirements of TS-R-l is deemed to establish equivalent safety level.	As mentioned in paragraph 8.8 to 8.12 in TS-G-1.3 (RADIATION PROTECTION PROGRAMMES FOR THE TRANSPORT OF RADIOACTIVE MATERIAL SAFETY GUIDE), the requirements of controlled and supervised areas are not applied to the transport of radioactive materials.		Footnote added to para 3.87.		

NEA	Para 3.87	ADD: …required for (ADD FOOTNOTE: "The requirements of controlled and supervised areas are not applied ~~to~~ during the transport of radioactive materials. However, compliance with appropriate requirements of TS-R-1 is deemed to establish equivalent safety level."):	The EGIR felt that this suggested addition, as a footnote, is necessary because as mentioned in paragraph 8.8 to 8.12 in TS-G-1.3 (RADIATION PROTECTION PROGRAMMES FOR THE TRANSPORT OF RADIOACTIVE MATERIAL SAFETY GUIDE), the requirements of controlled and supervised areas are not applied to the transport of radioactive materials.		Footnote added to para 3.87.		
NEA	Para 3.89	ADD **(i)Provide appropriate information and training for persons working in controlled areas.**	The EGIR felt that this requirement, regarding information, was not listed yet is very important.		Text has been added		
Austria	3.89	Where a source is brought into operation or energized only intermittently or is moved from place to place	Two alternative interpretations of this sentence are possible and will therefore lead to confusion in a legal context.		Text has been modified.		
UK	3.89		It is suggested that there should also be a requirement for appropriate training for persons in controlled areas.		Text has been added		
Canada	3.89	Add: "Provide adequate training of employees'			Text has been added		
ISSPA	3.89. (b)	Delete: "**and appropriate instructions**"	Instructions may be too complex , only trained and supervised personal has access				Appropriate instructions will mean specific for area. A new bullet has been added for training.
Australia	3.89 (a) & (e)	Suggest delete (a)	Para (a) allows delineation by physical or other suitable means, which is inconsistent with (e) which requires access to be restricted by admin.				Both actions are necessary. Text is unchanged

			procedures **AND** physical barriers. So delineation does not require barriers but restricting access does. Given (e), para. (a) appears to be unnecessary. If (a) and (e) are to remain in modified form they should follow each other on the list.				from current BSS.
UK	3.89 (g)	Add a new bullet to read: "(v) Decontamination facilities appropriate for the removal of any contaminants found on monitoring."	For completeness. Sites feature wash stations (using special cleansers) and other facilities to remove contaminants from workers.		Text modified.		
France	3.89 i	Add item (i) Shall ensure that access is restricted to individuals who have received appropriate instructions,			Text has been added.		
France	3.89 j	Add item (j) Shall ensure that working instructions appropriate to radiological risk are laid down.			Text has been added.		
UK	3.92 (1.)	Modify to read: "Engineering controls **(including design features, safety features, and warning devices)**,"	The suggested text provides a better link with SS115. Also consider whether engineering controls should be listed as "passive" and "active". Reliance on active controls requires instrumentation/interlocks, etc to maintain low dose limits.			R	Include in Safety Guide.
ILO Finland (Min of Employm net)	Introductio n of a hierarchy for control measures	Consistency with the principles of the EU's industrial safety legislation on occupational exposure, in paragraph 3.92.			No action required.		
Spain	3.94	Include a paragraph indicating that the process of delivery of personal	The written record of the delivery of personal protective equipment is a basic			**X**	Too detailed – include in a Safety

		protective equipment will include the written record of the terms of use, cleaning and maintenance. Also, the employee must sign the receipt of such equipment	rule in all scopes				Guide.
UK	3.94 (a) (ii)	Consider replacing "protective respiratory equipment" with "respiratory protective equipment (RPE)"	Majority of users refer to RPE.	**X**	The technique is called respiratory protection and uses respiratory protection devices or equipment		
Ireland	3.94 (c)	Rewrite as "Tasks requiring the use of some specified personal protective equipment are not assigned to workers who on the basis of medical advice are not capable of safely sustaining the extra effort necessary". As currently written all workers must receive medical certification" before they can use any PPE. This seems excessive.			Text has been modified, but is to remain consistent with para 3.107.		
Austria	3.96	[…] depend on ambient dose rate	Why specifically on "ambient dose rate"; a more general term might suffice.		Text has been modified		
Slovakia	3.96(b)	Modify : Depend on ambient dose …in air and on surfaces, inducing …	The surface contamination is relevant for workplace monitoring		Text has been modified		
NEA	Para 3.96(b)	MODIFY: …in air and on surfaces,…	The EGIR felt that surface contamination may be relevant for workplace monitoring, and as such should be mentioned here.		Text has been modified		
UK	3.96 (b)	Modify to read: "….ambient dose rate and activity concentration in air **and on surfaces**, including their…"	Workplace monitoring should consider surface and air contamination.		Text has been modified		

ILO UK (employers)	3.97	Add… 'and to the Regulatory Body as required'	Records of monitoring should be available for inspection			R	Covered by para 2.45
Spain	3.97	It should be specified the minimum period of time for which records of workplace monitoring must be retained	The lack of definition on the period time for which records of workplace monitoring must be retained could lead to misinterpretations with 3.103			X	The period should be established by the regulatory authority. Guidance is provided in a Safety Guide.
IRPA	3.97/line 4	… representatives, and be available for inspection by the regulatory authority.	It seems reasonable that the regulatory authority should have access to these records.			R	Covered by para 2.45
UK	3.97/4	Modify to read: "..representatives **and to the regulatory body as required**."	Records of monitoring should also be available for inspection by the regulatory body.			R	Covered by para 2.45
Austria	3.98	as well as self-employed individuals	These have not been considered in earlier paragraphs; should they be mentioned in a more general description also?				Covered by definition of employer and worker, and are considered as both employers and workers.
Austria	3.98		Is it sufficient for an individual monitoring service to only have an appropriate QA system? Would not technical competence (e.g., as specified in ISO 17025), accreditation or kind of authorization be desirable also?				Desirable, but in the majority of cases not possible. There is a Safety Guide.
Canada	3.98	… shall ensure that adequate arrangements are made with appropriate dosimetry services that "are approved by the regulatory authority"	Assures accepted procedures and quality processes	X	Text modified and also included in para 3.73.		

Spain	Requirement 25	Employers, registrants and licensees shall be responsible for making arrangements for assessment of the occupational exposure of workers, for their health surveillance and for maintaining adequate exposure records.	Exposure records are part of the requirements below.	X	Text modified		
Austria	3.99	normally employed in a controlled area	Consideration of students at a university who are not generally "employed"?	X	Text has been modified.		
Austria	3.99		Consideration of short-term access to the controlled area by persons not occupationally exposed (e.g., students, general service staff, etc.)	X	Text has been modified		
Austria	3.99		Monitoring for occupational exposure potentially > 6 mSv should always be on an individual basis.			X	This is the European approach.
Canada	3.99	Define: 'significant occupational exposure'				X	To be covered by a Safety Guide.
Israel	3.99	We suggest including in the new standard 3 maximal dose levels for exposure in the work place for: visitors, workers exposed occasionally to radiation, workers exposed continuously to radiation (as in the European Union Legislation).				R	This would be covered in a Safety Guide.
UAE	3.99-3.100	The drafting should be reviewed to make more clear who is not required to have individual monitoring.				R	Requires judgement by the regulatory body on a case by case basis.
Brazil	Req. 25	Designation of Classified Persons With the object of control and monitoring, two categories of occupational workers will be distinguished: category A and category	Include item under requirement 25			X	The BSS does not classify workers, but classifies work areas.

		B workers. Category A worker - All employees aged 18 or over who are likely to receive an annual effective dose greater than 6 mSv or an equivalent dose greater than 45 mSv (eye), 150 mSv (skin) or 150 mSv (hands, forearms, feet and ankles) must be designated as classified persons in a Category A worker and informed of such. Category B worker – Those workers who are not classified in a Category A worker.					
India	Req. 25	…for assessment of the occupational exposure, **maintain exposure records** of workers and for their health surveillance.	Add for completeness		Text has been modified		
UK	3.100		Does this mean that it will become compulsory to assess dose in supervised areas? At present, the requirement to assess dose is based on the dose likely to be received (> 1 mSv). This works well. The need to assess dose based on the person working regularly in a supervised area does not appear necessary or justified by risk.			**R**	Guidance will be provided in a Safety Guide. Requires application of the graded approach,.
UK	3.100		This requirement applies for any worker in a supervised area, who occasionally enters a controlled area but does not necessarily work. It is pragmatic in allowing either dose assessment by workplace monitoring or individual monitoring. Omission: There is no			**R**	Guidance to be provided in a Safety Guide. Regarding maintenance of records, it is not clear what is meant

			guidance/requirements regarding the adequacy for maintanence of dose assessment records.				by the comment.
Austria	3.101	[…] to assess the intake of radioactive substances ~~or~~ **and** the committed effective doses, […].	It is not obvious when it would be sufficient to only assess the intake of radioactive substances.	X			
ICRP	pg 61, 3.101 line 4	Use "radionuclides" instead of "radioactive substances".		X			
Slovenia	3.101	**Proposed additional text under Requirement 25** (new paragraph after 3.101) 3.102: In case of contracted employers, prime responsibility for exposure assessment remains with registrants and licensees, unless specified otherwise in a contract.				X	Covered by para 3.84.
UK	3.103		This requirement specifies that exposure records are required for each worker during employment, and further states that these shall be preserved for 30 years since work termination and age 75 years. Para 3.106 supplements this requirement. Footnote 21 (page 62) also mentions dose records; these apply only to category A workers, there is no requirement to keep dose records for category B workers or lower. Dose histories may be retained up to 2 years since exposure. This is not a realistic requirement for many reasons including: pragmatism; cost; value compared to risk and probabilistic death causation; detail of actual work is overburdening. Better information would perhaps be obtained if the focus were on			**X**	This text is in the current BSS, and there is no justification to change.

			radiation workers above a threshold (e.g. > 1 mSv/a or lifetime > 25 mSv).				
Ireland	3.103	The requirement for exposure records to be kept for the working life and up to the age of 75 years for potentially <u>all</u> workers seems excessive as it seems that 'workers' (as defined in the glossary) are not sub-classified (Currently in the EU records are only required for this time period for category A workers.				**X**	This text is in the current BSS, and there is no justification to change.
ICRP	3.103 line 2	Use "he/she" instead of "the worker".	'worker' means he/she is still working.	**X**	Text has been modified		
Canada	3.104	Add a clause: 'The information should be sufficient for an independent dosimetrist to reconstruct the dose from the raw data				**X**	Guidance to be provided in a Safety Guide..
ICRP	Pg 62, 3.104	3.104. The exposure records shall include: ... (b) Information on dose of record, parameters of exposure, and the data upon which the dose assessments have been based. (c) When a worker is or has been occupationally exposed while in the employ of more than one employer, information on the dates of employment with each employer and the indicated in (a) and (b) data for each such employment. The exposure records which are associated with actions taken in an emergency or due to accidents shall be distinguished from the exposure records which are associated with normal work,	Using of word "doses" may cause an ambiguity and incompatibility of dose records, which are made by different employers (or in different countries). The exposure records always should contain "dose of record" and parameters of exposure, but the estimation of the intake value in many countries is optional because of regulatory criteria in terms of dose. The ICRP proposed the dose coefficients "dose per unit measurement", which permit assessments of the dose of records without indication of the intake value (see ICRP 103).			**X**	The term "dose of record" as defined in ICRP 103 has not been widely accepted in the RP community. It is considered not helpful to non-fluent English speakers to exchange words such as in "dose record" and "dose of record", which mean the same thing. Continue calling it a dose record. Details will be provided in a Safety Guide.

		shall additionally include, as appropriate, the results of assessments of absorbed doses in organs and tissues, information about contamination and injuries, medical treatment (e.g. with DTPA) and references to reports of any relevant investigations.					
IRPA	3.104 (b) /line	Information on exposures (doses and intakes) at…	To be consistent with definition of exposure			X	To be consistent with definition of
UK	3.104		This paragraph states that exposure records shall include (a) information on the general nature of the work. The other bullets (b) to (d) are relevant but should be focused above a specified value or level. In addition there would be no exposure records for **all** intakes for internal exposures and definitely not for **all** workers. The requirement at (a) is unrealistic and overburdening. Surely this information can be obtained (if and when required) by investigation of other sources of information. What is the basis and need? Would this only be required for 0.5% of all workers?			**X**	This text is in current BSS. There is no justification for change. This information is not overburdening… most individual monitoring services and national data bases ask at least what is the profession of the person.. doctor… nurse..radiographer … researcher… More detailed information on the nature of the work is also kept in the employee's personal file, which can be used in the exposure record.

Austria	3.103	for not less than 30 years after the termination of the work involving occupational exposure	Even though this is probably very useful for possible legal proceedings in the future, the effort for storing and maintaining the data is most likely very large.			X	This text is in the current BSS, and there is no justification to change. The data storage is getting easier
India	3.105	When ~~**a worker**~~ **an individual** ceases to **be a worker**, make arrangements for the retention of the workers' exposure records by the **state registry,** employer, registrant or licensee, as appropriate.	Worker is defined whereas work is not. Add 'state registry' because the responsibility for maintenance of records should be with a State Registry and the registrant / licensee.		Text modified		
Czech	3.105(a)	a)provide ~~for access by~~ workers with access to information on….	Editorial	X			
Czech	3.105 (c)	c) only question if it is correct that the dose history is passed to another employer without consent of worker?				X	Facilitate provides flexibility.
Canada	3.105 (c)	Employers, registrants and licensees shall: (c) Facilitate the provision of copies of workers' exposure records to new employers (with workers consent)	Ensure privacy laws are respected			X	Facilitate provides flexibility.
Czech	3.105 (e)	e) confidentiality of dose record is in my opinion a matter of another specific legislation and it is maintained by very different ways in individual MS, it is not relevant to these Standards				X	In current BSS.
Belgium	3.106	Move this paragraph upwards.	This paragraph belongs to the section 'Exposure records' and not to the section 'Health surveillance'.	X			
Czech	3.106	These requirement is primarily addressed to the regulatory body or government – the company in bankruptcy will for sure not a make any arrangements for the retention of workers dose records. The regulatory body shall first establish a				X	The regulatory body's responsibilities in relation to

		system for maintenance of such records – e.g. State register					occupational dose records are set out in para 2.36.
Austria	3.106		Section heading “Health Surveillance” seems to be out of place; move before 3.107	X			
ILO Finland (Min of Employment)	3.106-3.108	The first paragraph concerns the retention of the exposure records of employees who have ceased activities involving occupational exposure. It would be more logical for this paragraph to be handled as the final paragraph of the section		X			
Finland	3.106	Move the title “Health surveillance” after this paragraph.	This paragraph is still discussing dose records not heath surveillance.	X			
Israel	Heading before 3.106	The heading "Health surveillance" should be moved before 3.107	3.106 does not deal with health surveillance	X			
IRPA	3.106	This paragraph should be moved to before the ***Health surveillance*** heading.		**X**			
Spain	3.106	This paragraph belongs to “Exposure assessment”, instead of “Health surveillance”.	Type error	**X**			
Spain	3.106	It should be included an additional requirement on the need that, when a worker ceases to work, the employer must provide to him with a copy of his exposure records.	Workers have the right to know their own exposures and moreover to have a copy of his exposure records in case of new employment			**X**	The dose records should be provided on request. Covered by 3.105(a).
ILO UK (workers)	3.106	Move the title ‘Health surveillance’ after 3.106		**X**			
UK	3.106	Move the title ***Health Surveillance*** to after Para 3.106 and before Para 3.107.	Editorial correction.	**X**			

USA	3.106	Move header “Health Surveillance” from before section 3.106 to after 3.106.	The header is misplaced by one paragraph.	**X**			
ILO UK (employers)	3.106/ 3.107	Move Title ‘Health Surveillance’ to after 3.106 and before 3.107	Editorial	**X**			
ILO UK (workers)	3.107	Propose adding item c): "Programs of health surveillance of workers shall be designed and implemented in consultation with the trade union or unions representing the affected workers, or where no such organization exists, other representatives chosen by the workers themselves."	To strengthen the definition of such programmes.			X	Responsibility of occupational health specialist.
UK	3.107	Modify to read: “Workers’ health surveillance shall be based on an assessment of risk.”	The majority of medicals done at present are unnecessary.			X	Apply Req 6 – graded approach.
USA	3.109 R 26	Needs to acknowledge the IAEA work in Knowledge Management (mention and reference). Propose adding a new subparagraph (d) to read as: (d) Provide for knowledge management of information related to radiation protection and safety.	Education and training of the top levels of complex nuclear, multi-generational projects requires more than just education and training in the classic sense, it requires implementing the basics of Knowledge Management as defined by the IAEA in several documents.			X	It may be appropriate to include in a generic requirement, but it is not relevant to para 3.109.
Czech	3.109	a) provide to all workers <u>by the verifiable way all</u> adequate information ….	It is better to have any evidence of provided information			X	Covered by (c)
Slovenia	3.109	**Proposed additional text under Requirement 26**, paragraph 3.109 (new item after c) d: In case of contracted employers, prime responsibility for training remains with registrants and licensees, unless specified otherwise in a contract.					X
Spain	3.109	Add: “Workers and their representatives shall be informed about the accidents that occur as a result of the use of ionizing	The right of information of workers and their representatives is one of the most important in the EU			X	Too detailed – appropriate for a Safety Guide

		radiation as well as the circumstances giving rise to an increase of radiological risk					
UK	3.109		It would be useful to stress that appropriate refresher training should also be provided.	X	Text has been modified		
Israel	3.109(a)	Add "actual" after "whether"	Clarification (actual vs. potential)	X	Text has been modified		
Germany	Para. 3.109 (a)	Provide to all workers adequate information on the health risks due to their occupational exposure, whether normal exposure or potential exposure, adequate instruction and training on protection and safety and adequate information on the significance for protection and safety of their actions; Modify …Provide periodically to all workers…	The requirements related to education and training applicable to different types of planned exposures should have the same level of detail and use consistent wording when the meaning is intended to be the same. Information should be periodically given to assure that all persons remain up-to-date with their knowledge as to their role and responsibility	X			
Germany	Para 3.109 (b)	Modify …and safety periodically to those workers…	Emergency training should be periodically given to assure that all persons remain up-to-date with their knowledge as to their role and responsibility.	X			
NEA	Para 3.109(b)	MODIFY: … and safety periodically to those workers..	The EGIR felt that emergency training should be periodically given to assure that all personnel remain up-to-date with their knowledge as to their roles and responsibilities.	X	Text has been modified		

Japan	3.109(b)/2	(Following sentence in 3.109(b) should be replaced by) ".... protection and safety to those workers " ".... protection and safety periodically to those workers "	Periodically education, training, and providing information are fundamental factor to prevent nuclear / radiation hazards.	X	Text has been modified		
Slovakia	3.109(b)	Modify: Provide appropriate information …on protection and safety periodically to those …	This is important from point of view emergency training	X			
ILO	3.109 (c) 3.109 (d)_	All workers will be given sufficient training to ensure they understand: • the management system in their workplace regarding radiation safety; e.g. rules and procedures, • the radiation hazards present in their workplace; e.g. the types of ionizing radiation, the sources of the radiation, routes of entry, harmful effects, methods of preventing or reducing the exposure, etc., • how their exposure is to be controlled; e.g. time, distance, shielding, protective equipment or clothing, exposure limits, etc., • how radiation hazards are monitored/measured in the workplace, • How their dose is tracked and recorded. The depth of the training in 3.109 (c) will depend on the radiation risks in the	To ensure all Workers understand the hazards and how they are being protected from those hazards.			X	Too detailed for the BSS. Covered by Safety Guides.

		workplace and the degree of oversight provided by Radiation Protection Officers. All Workers will be given the basic training outlined in 3.109 (c) and additional training will be be given depending on the type of protection model used. This can Rnge from Workers that are under the direct supervision of a Radiation Safety Officer to Workers providing their own self protection.					
WHO Mauritius (Min of Labour)	Para 3.109 (c)	To add words in bold: "…..Keep records of the training provided to individual workers**, and assess the effectiveness of the training delivered.**"				X	Detail for a Safety Guide.
Spain	Requirement 26	Rewrite: "Information, education and training"	The right of information of workers and their representatives is one of the most important in the EU	X	Text has been modified		
Israel	Req. 27	Delete "required by these Standards"	It was agreed at RASSC 27 to delete reference to "these Standards" in overarching requirements	X			
Israel	Req. 28	Add "for female workers," before "as necessary"	The special arrangements are intended for female workers	X			
Israel	Req. 28	"embryos and foetuses" instead of "the embryo and foetus"	Consistency with the plural form of breast-feeding infants	X			
India	Req. 28	…, breast feeding **mothers and their** infants,…	Feeding is by mother, hence the addition.	X	Text has been modified		
Spain	3.111	Alternative text: Employers shall make every reasonable effort to provide workers with suitable alternative employment in circumstances where it has been determined, either by the regulatory body or in the framework	Better understanding			X	No justification for the change. The text is from the current BSS, and there is no justification to

		of the workers' health surveillance programme required by these Standards, that the worker, for health reasons resulting from the exposure to ionizing radiation, may no longer continue in employment involving occupational exposure					change it.
Spain	3.113	Alternative text: The notification of pregnancy or breast feeding shall not be considered a reason to exclude a female worker from work; the employer of a female worker who has notified pregnancy or breast feeding shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo, foetus or infant is afforded the same broad level of protection as that required for members of the public during at least the remainder of the pregnancy	Better understanding			X	The requirement also includes protection of infant, so additional text is not appropriate. Detail to be covered in a Safety Guide.
Canada	3.113, 3rd line	Has been notified of pregnancy	editorial	X			
India	3.114	…no person under the age of ~~16~~ **18** years is subjected to occupational exposure.	The regulatory age limit for occupational exposure is 18 years.			X	This text is in the current BSS. Occupational exposure for 16 and 17 year old is permitted – see para 3.115 and the dose limts are found in III-2.

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 3: Planned Exposure Situations: Public Exposure							
Czech	General	Only reflection – it is not very comprehensive chapter, a lot of things is repeated and individual paras have no very logical sequence				x	Repetitions and problems with the sequence of paras are not indicated in the comment.
Denmark	General	The paragraphs on public exposure contain several "*as appropriate*"! The necessity of this frequent use should be further analysed.		x	The necessity of "*as appropriate*" is analysed. In most cases it is unavoidable because not all requirements are universally appropriate for all types of facilities or activities, technologies, etc. Several "*as appropriate*" have been deleted.		
Norway	From 3.116 to 3.142	Unnecessary use of "as appropriate"	The paragraphs on public exposure (from § 3.116) contain several "*as appropriate*". These might be unnecessary and leaves too much	x	See reposnse to Denmark		

			freedom to the implementing countries/authorities. The necessity of this frequent use should be further analysed.				
Israel	3.116	We suggest adding public exposure from natural sources such as NORM and TENORM in construction materials and from radon in public places and dwellings. These radiation levels are amenable to control by building standards.				X	The comment is related to para 3.4: Public exposure from natural sources such as NORM in construction materials and from radon in public places and dwellings is existing exposure situation (see para 3.4)
Czech	Req. 29	The government or the regulatory body , ~~as appropriate~~, shall establish and enforce requirements to ensure that protection and safety is optimized, that doses from public exposure are limited and shall establish the responsibilities of ~~registrants, licensees, suppliers, and suppliers of consumer products. r~~elevant parties.	To be in compliance with other text – we don´t use "as appropriate" after gov or reg body in many other places in these Standards Relevant parties are used in Req 30 and this is more appropriate than to name some of them	X	Text has been modified.		
ENISS	**Require ment 29**	**The government or the regulatory body, as appropriate, shall establish and enforce requirements to ensure that protection and safety is being optimized, that doses from public exposure are limited, and shall establish the responsibilities of registrants, licensees, suppliers and suppliers of consumer products for their implementation.**	See 2.10			X	Footnote 4 provides meaning of 'is optimized'.

Ireland	Req. 29	Should manufacturers be included in this list?		x	Text of R29 has been modified.		
Israel	Req. 29 and 3.117	"and suppliers of sources and of consumer products" instead of ", suppliers and suppliers of consumer products"	Clarification	x	Text of R29 has been modified. Para 3.117: "Supplier" is a defined term. Replace "suppliers of consumer products" with "providers of consumer products.", as suppliers cannot include providers of consumer products according to definition,		
Israel	3.117	Move after para. 3.123	Consistency with the order of requirements in Req. 29	x	Text of R29 has been modified.	x	The order of paras 3.117 – 3.122 represent the following logic: (a) establishing of responsibilities (3.117), and (b) requirements and specific responsibilities in the following paragraphs.
USA	3.117	Consider deletion.	This paragraph is largely a repeat of the bold R-29 and is not necessary.	x	R29 is an "overarching" requirement and paras 3.117-3.122 specify details.		

USA	3.118	Consider Revision. "The government or the regulatory body shall establish and enforce requirements that protection and safety are optimized for circumstances involving public exposure."	The section on public exposure goes directly to constraints, without the initial requirement for optimization of protection, as was the case in the occupational exposure section, paragraph 70. This change is suggested to put the primary emphasis on optimization of protection, not on the setting of constraints, as constraints are a tool in optimization. The requirement for constraints in paragraph 118 is suggested to be combined with the material already in paragraph 119, see comment below.	x	Paras 3.118 and 3.119 are modified as proposed by US and NEA		
NEA	Para 3.118	MODIFY: The government or the regulatory body shall establish **and enforce requirements that protection and safety are optimized for circumstances involving public exposure ~~or approve constraints for dose and risk, as appropriate, to be used for optimization of the protection of the public.~~** .	The EGIR felt that the section on public exposure goes directly to constraints, without the initial requirement for optimization of protection, as was the case in the occupational exposure section, paragraph 70. This change is suggested to put the primary emphasis on optimization of protection, not on the setting of constraints, as constraints are a tool in optimization.	x	Paras 3.118 and 3.119 are modified as proposed by US and NEA		
ENISS	3.118	~~The government or the regulatory body shall establish or approve constraints for dose and risk, as appropriate, to be used for optimization of the protection of the public.~~		x	Paras 3.118 and 3.119 are modified as proposed by US and NEA		
ENISS	3.119	Delete				x	

USA	3.119	Revise lead in paragraph to read as follows: "The government or the regulatory body shall, as part of the requirements for optimization of protection of the public, establish or approve constraints for dose and risk, or the process for establishing such constraints, taking into account, as appropriate:"	This revision is suggested to combine the requirement for establishing constraints to be used in optimization with the items that are to be taken into account. This revision, taken in conjunction with the revision of paragraph 118 above, provides a more coherent approach to requirements for optimization.	x	Paras 3.118 and 3.119 are modified as proposed by US and NEA		
NEA	Para 3.119(b)	MODIFY FOOTNOTE 23: … authorized or anticipated[23] practices so FOOTNOTE 23: ~~**Realistically**~~ assessed possible future sources and practices.	The EGIR felt that the word "realistically" should be removed from footnote because it is impossible to ensure that future doses are realistic.			x	"Realistically assessed possible future sources and practices" is the text of current BSS (see III.3 a), which was not commented at the review stage. The qualifier "Realistically" excludes from the consideration sources and practices which would be very unlikely
ICRP	Pg 66, 3.119		Setting dose constraints for public exposure is not exclusively the domain of government or regulatory bodies.		The text has been modified.	X	The comment is not clear: para. 3.119 uses the phraseology "When establishing or approving constraints…", not "setting".
ICRP	Pg 66, 3.119	Add "(c) characteristics of the exposure situation"	according to ICRP Publication 103 Table 5	A	Text has been modified		
IRPA	3.120, 3.121,	The government or the regulatory body	To be consistent with 3.117 to 3.119	x	Included in 3.120 and 3.123	x	3.121, 3.122 are responsibilities of

	3.122, 3.123						the regulatory body
Finland	3.122	Some discussion on the relation and difference between dose constraints and operational limits (including authorized discharge limits) should be added.	Because there is no discussion on this relation, it could be concluded that operational limits are derived directly from dose constraints which is NOT the case. So the actual sequence of events should be spelled out: 1) Setting of a dose constraint, 2) optimization, 3) Setting of operational limits at some optimized level (which might be well lower level than the dose constraint).			x	Such guidance materials are given in the Safety Guide WS-G-2.3 and will be extended in DS442.
ICRP	3.122 line 3	Delete “and limits on the exposure due to direct radiation from a source”.	Limits are not set for particular pathway of exposure.		Text modified	x	The text in 3.122 is related to the example of “operational limits and conditions” (see the IAEA Safety Glossary) and should not be confused with dose limits (3.120 and Schedule III).
ILO Finland (Min of Employers)	3.122-3.113 concern protection of pregnant women		These instructions require employers to modify their working conditions so as to prevent the exposure of the foetus to radiation. In practice, however, this is not always possible. For instance, at a workplace with two employees only, where radioisotopes are handled, it is not possible to arrange alternative work that avoids exposure for the duration of a pregnancy. In such situations, Finland employs a system whereby, as a last resort, a pregnant worker exposed to ionising radiation at work can, if the modification of the working conditions		No change to text required.		

			and reduction of other exposure has proven insufficient, take leave of absence in return for a special maternity allowance from the social insurance system, compensating for lost earned income.				
ILO UK (workers)	3.122(b)	Delete the word 'the' after 'correspond to'.		x			
ILO NZ (Dept of Labour)	Page 67 section 3.122 (c)	"good practice" - it is suggested the term "best practice" be made applicable to New Zealand.		x	No modifications are proposed. Good practice is not a defined term and if a national regulation uses the term "best practice", it would be a more restrictive requirement.		
Belgium	3.122/7	Correspond to the dose constraints and…	Clarification. '… to the doses below the dose limits' is not clear at all.			x	See the comment of Finland: "Setting of operational limits at some optimized level (which might be well lower level than the dose constraint)." The guidance materials on setting of authorised discharge limits (operational limits and conditions) are given in the Safety

							Guide WS-G-2.3 and will be extended in DS442.
Czech	3.122	d) allow margin …	I don't understand		Text modified		
ENISS	3.122	The regulatory body shall establish or approve dose constraints or operational limits and conditions related to public exposure, including authorized discharge limits and limits on the exposure due to direct radiation from a source. The dose constraints or these operational limits and conditions shall:	Member States have been using for many years either dose constraints or authorized discharge limits since they achieve the same purpose.			x	See the IAEA Safety Glossary: definitions of constraint and operational limits and conditions. **constraint** A prospective and source related value of individual dose (dose constraint) or risk (risk constraint) used as a tool in the optimization of protection and safety of the source, which serves as a boundary in defining the range of options in optimization. **operational limits and conditions** A set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel approved by the regulatory body for safe operation of an

							authorized facility
Israel	3.122	Mention dose limits or indicate bibliography.				x	Dose limits are in 3.120 and Schedule III
NEA	Para 3.122	MODIFY: … body shall ~~**establish or**~~ **approve, or establish if appropriate, …**	The EGIR felt that the need "*to establish"* operational limits and conditions is ONLY necessary in the case if there is a need. In countries having extensive regulatory system and many activities and facilities, it is impossible to establish (duty by law) operational limits for each single activity or facility. This should be done only for those which do not have adequate expertise or capacity.			x	3.122 states "The regulatory body shall establish OR approve…": both options are included. The priority of options in not specified.
Austria	3.122. b)	Correspond to ~~the~~ doses below […]		x			
Israel	3.122(b)	Delete "the" before "doses"	Editorial	x			
Ireland	3.122 (e)	This is the first time that "national requirements" has been included. Should this not be the case throughout the document?		x	Generic comments to the draft. Para 2.3 states that BSS in addition to national regulations.		
Canada	3.122(e)	Account for the results of an assessment of radiological environmental impacts undertaken ….	Better alignment with scope of requirements and purpose of Standards	X	Text has been modified		
Australia	3.123	Separate into (a), (b) & (c) format	Sentence too long and difficult to understand	x			

Brazil	3.123	When a source within a practice could cause public exposure in a country other than the country where the source is located, the regulatory body shall ensure that the assessment of the radiological impact includes those impacts outside the country, to the extent possible, **and** establish commensurate requirements for control of discharges. **The government of the country where the source is located shall arrange with the affected country the means for exchange of information and consultations, as appropriate**	it is not usual and it is generally inappropriate that regulatory bodies assume the competence of exchanging information with other States	x	The issue is resolved by the modification proposed by IRPA		
Israel	3.124	"and suppliers of sources and of consumer products" instead of ", suppliers and suppliers of consumer products"	Clarification	X	Text modified – see comment to para 3.117.		
India	3.124	…demonstrate compliance with the requirements ~~**of these Standards as**~~ specified by the regulatory body…	Compliance is more appropriate with regulatory requirements than with Standards.			x	These Standards (BSS) is a set of regulatory requirements
France	3.125	Remove text "or for post closure .facilities"	It is only noted when optimization is developed and not into the previous sections.	x	Text has been modified		
Spain	3.125	According to the glossary it appears better to delete the explicit mention made to the "post-closure period", and to use instead a somehow more generic term, like: "… operation and decommissioning or closure of a source, shall take…".	Glossary	x	Text has been modified.		
ICRP	3.125(c) line 1	Use "radionuclides" instead of "radioactive material".				x	"Radioactive material" is a defined term (see the IAEA Safety glossary) and it is extensively used in

							BSS and ICRP publications (e.g. see the ICRP-103 Glossary). "Radioactive material" is broader than radionuclides, and also indicates the importance of the chemical speciation in the environment.
USA	3.125 d	No change necessary.	A good statement on the need for uncertainty analysis and evaluation. Consideration should be given to mentioning it in the beginning of section 1.11 where quality assurance is also mentioned as a generally applicable principle.	x	Positive comments.		
USA	3.125	Suggest Addition.	Manufacturing of and evaluation for the quality assurance of a source or device should be added.				This issue covered by Req. 5. This is a generic requirement for earlier part of BSS - There is a specific requirement for radioactive sources, covered by para 3.48.
Austria	3.125	[…] (or for the post-closure period of ~~the~~ waste disposal facilities) […]		X			

Canada	3.125 (c) 2nd line	Build up and accumulation of discharged radioactive materials in the environment during the operational life time of a source that could result in exposure to the public or a significant radiological impact to the environment	Better alignment with scope of requirements and purpose of Standards			x	Redundancy in the text: Item (c) is explicitly associated with the introductory phrase of 3.125 "…ïn applying the principle of optimization of protection and safety…"
Austria	3.126. b)	(i) The optimization of ~~the~~ protection (ii) The limitation of the exposure of ~~the~~ members of **the** public […]		x			
Germany	Para. 3.126 (e)	Appropriate training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating as necessarily required, in order to ensure the necessary level of competence;	The requirements related to education and training applicable to different types of planned exposures should have the same level of detail and use consistent wording when the meaning is intended to be the same.	X	Editorial		
Austria	3.126. g)	Adequate records of ~~the~~ surveillance and monitoring		x			
Israel	3.127	We suggest adding the annual dose to visitors.				x	Para 3.127 requires "…Apply the relevant requirements of these Standards regarding public exposure to visitors to a controlled area or supervised area", annual dose to visitors are part of the relevant requirements

							regarding public exposure This is covered by (a) and Schedule III.
UK	3.127	Add a new bullet to read: "(e) Visitors will be provided with suitable dosimetry."	This requirement needs to be made clear, although it may already be covered by bullet (a).				This is covered by (a).
USA	3.127	Consider appropriate use of headers	The headers for "visitors" and then further down for "areas" have been retained from previous draft. But other headers have not been. Is it intended that the overarching requirement applies to all of these requirements?	x	Additional sub-heading at the beginning of the set of requirement under R30 compliments the existing heading "visitors" and "areas" and should clarify the structure R30.		
France	3.127-c	Add ***supervised areas*** : "Provide adequate information and instruction to visitors before they enter a controlled area ***or a supervised area*** …"	The information and instruction to visitors should be extended to entrance in supervised areas	x			
ICRP	3.127(d) line 2		Signs are posted outside of controlled areas, not in such areas.	x	…including the appropriate use of signs for such areas.		
UK	3.128	Modify to read: "Registrants, licensees and suppliers, shall ensure, as appropriate, that, if a source of external exposure can cause **significant** exposure to the public:"	The text requires that any building plans are approved by the regulator (as appropriate). This would have considerable financial consequences for healthcare and, as discussed in relation to the EU document, does not appear to provide a significant benefit (at least within the UK). It is also likely that			x	It is the requirement III.6 (a) of the current BSS; it should be implemented since 1996. The proposed

			regulators would need significantly more resources in order to do it.				modification will cause an ambiguity. The regulatory body shall apply graded approach.
NEA	Para 3.128	MODIFY: … can cause **significant** exposure to the public…	The EGIR felt that the wording "can cause exposure" was very broad, and as such, to make this wording more reasonable, added the term "significant".			x	It is the requirement III.6 (a) of the current BSS; it should be implemented since 1996. The proposed modification will cause an ambiguity. The regulatory body shall apply graded approach
Slovakia	3.128	Modify: Registrants licensees and …can cause significant exposure of the public.	Specification "can cause exposure" is very general			x	It is the requirement III.6 (a) of the current BSS; it should be implemented since 1996. The regulatory body shall apply graded approach
Argentina	Requirement 31	Should be split in two: one requirement for waste and another one for discharges	To avoid confusion between the two diiferent issues	x	Appropriate sub-headings are added.		
Austria	3.129. b)		In which cases would areas accessible to the public in a facility be subject to contamination?				See BSS III.7 and the comment to the definition of "contamination" in the IAEA Safety

							Glossary: The term "contamination" refers only to the presence of radioactivity, and gives no indication of the magnitude of the hazard involved. Examples includes public areas of a nuclear installation, public areas of a radiopharmaceutical department of a hospital, etc.
Czech	Req 31	question – is it correct to put radwaste and discharges together?	clarification	x	Appropriate sub-headings are added.		
ICRP	Req. 31 line 3	Use "radionuclides" instead of "radioactive material".				x	See above.
WNA	Specific 3.130 (a)	**Waste –** Activity and volume cannot be simultaneously minimized. In optimizing waste, all three key parameters (i.e. activity, volume and dose) are interconnected. **In optimizing dose**, if volume is reduced, activity increases and vice versa. Para. 130(a) should be changed as follow: Ensure that the **activity and volume of any radioactive waste** generated from the sources **are optimized** for protection and safety, and that waste is managed.	Specific 3.130 (a)	x	(a) is modified as proposed by US	x	Any optimisation problem in radiation protection has multiple parameters of optimisation (see definition). The subject of BSS is the optimization of protection and safety. Neither the optimization of dose nor

							optimization of activity and volume of radioactive waste are appropriate.
France	3.130	Replace "predisposal" by storage	It seems to be similar and it was not mentioned before			x	The IAEA Safety Glossary defines storage as a type of predisposal management (see term Waste Management).
UK	3.130	Add a new bullet to read: "(e) Produce and maintain a radioactive waste strategy and include appropriate evidence that this has been optimized."	This is good practice. As part of the responsibility for management of radioactive waste to the environment, the Licensee should produce and maintain a strategy in consultation with regulators, which has been shown to be the result of some optimization process and covers a complete lifecycle of the process/facility.	x	Produce and maintain a radioactive waste strategy and include appropriate evidence that protection and safety are optimized.		
ISSPA	3.130. (a)	…are kept to the minimum **reasonable**	A practicable reduction of activity and volume may not comply with the protection and safety optimization process.			x	The issue is addressed by the phrase "… are kept to the minimum practicable, when optimizing protection and safety, …"
NEA	Para 3.130(b)	MODIFY: … disposal**, without unnecessarily preventing the intentional mixing of waste for the purposes of improving worker or public safety;**	The EGIR felt that it is important to not unnecessarily limit good protection practice in waste management.	x			
USA	3.130	Consider revision: Registrants, licensees and suppliers, as appropriate, shall:	It is conflicting to impart a requirement to minimize both activity concentration	x	Para (a) has been modified to make		

		(a) Ensure that the activity and/or volume of any radioactive waste generated from the sources are kept to the minimum practicable, when optimizing protection and safety, and that the waste is managed in accordance with the requirements of these Standards and any other applicable IAEA standards, and in accordance with their authorization; (b) Ensure, if appropriate, separate processing of different types of radioactive waste where warranted by differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste storage and disposal without unnecessarily preventing the intentional mixing of waste for purposes of improving worker or public safety;	and volume simultaneously. As stated, part (b) ignores the scenarios in which intentional mixing or blending of waste could be beneficial to health and safety and improve waste management. Consider revision or deletion.		consistent with para 4.7 of GSR part 5 that requires "Careful planning has to be applied to the siting, design, construction, commissioning, operation, shutdown and decommissioning of facilities in which waste is generated, to keep the volume and the radioactive content of the waste arisings to the minimum practicable" Accept comment on (b)		
USA	3.131 (d)	(d) Consider the potential environmental impact, as required by the regulatory body in an integrated manner with other features of the system of protection to establish the conditions applicable to a particular source;	Similar comment on paragraph 1.26 was accepted, so this paragraph should be revised for consistency.	X	(d) Consider the potential environmental impact in an integrated manner with other features of the system of protection and safety, as required by the regulatory body		
Aregntina	Para, 130, Item d	The word "discharged" should be deleted	Discharge refers to radioactive effluents	X			

Canada	3.131 (b) (d)	Pathways by which discharged radionuclides can deliver public or environmental exposure Consider the results of an assessment of radiological impact to the environment as required by the regulatory body	Better alignment with scope of requirements and purpose of Standards	x	(d) para is modified in accordance with the US proposal	x	(b) environmental exposure is not a defined term
Australia	3.131	….(a) Determine the characteristics and activity of the material to be discharged, and, **for activities or activity concentrations exceeding exemption levels,** the potential points and methods of discharge; (b) Determine, **for activities or activity concentrations exceeding exemption levels,** by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides can deliver public exposure; (c) Assess, **for activities or activity concentrations exceeding exemption levels,** the doses to the representative person due to the planned discharges;……	Activities or concentrations that could be exempted from regulations should a priori be acceptable for discharge, so the addition of phrase ", for activities or activity concentrations exceeding exemption values," is proposed.			x	A practice or a source could be exempted from some or all requirements of BSS related to radioactive releases to the environment (see R8). The values of activity concentration provided in Schedule I are not intended to be applied to the control of radioactive discharges (see para 1.9 of RS-G-1.7). The clarification para I-14 is added to Schedule I
NEA	Para 3.131(d)	MODIFY: … regulatory **body in an integrated manner with other features of the system of protection to establish the conditions applicable to a particular source**;…	The EGIR strongly felt that RP of the environment needs to be regarded in an integrated fashion, and as such these words try to address this need.	x	(d) Consider the potential environmental impact in an integrated manner with other features of the system of protection and		

					safety, as required by the regulatory body		
Israel	3.132	Delete "and the exposure due to direct radiation from a source, as appropriate,"	Para. 3.134 deals with discharges only (as paras. 3.131-3.133 do). The location to treat direct radiation from a source might be under Req. 30.	X	Text modified.		
Israel	3.132	We suggest adding the radiation dose for discharges in public areas, or indicate bibliography.				x	Operational limits and conditions related to public exposure always consider all appropriate pathways/location of representative person (see definition of public). Guidance materials are given in the Safety Guide WS-G-2.3 and will be extended in DS442.
Argentina	Para. 3.132, line 1	The reason to include the text: "and the exposure due to direct radiation from a source, as appropriate" should be clarified in this paragraph	The paragraph refers to discharges	X	Text modified.		
Argentina	Para. 3.132, line 2	The word "within the authorized limits" should be replaced by the text "as below ths authorized limits as is reasonably achievable"	Licensees and registrants should optimize the protection			x	The issue is covered by R1 (2.10), R11, R29, 3.125. 3.126, 3.133

Czech	Req 32	….and that the results are recorded and made available .to whom?. to the public?	clarification			X	Para 3.136 (c) requires results to be made available to the regulatory body. The results are to be made available to the public, as indicated in 3.135 and 3.136(i)
Canada	3.134 (a) (i)	To ensure that the requirement of these Standards regarding public and environmental exposure in planned…	Better alignment with scope of requirements and purpose of Standards			x	(d) Ambiguity: environmental exposure is not a defined term
Austria	3.134. d)	Assessment of the total exposure of **the** public from […]		x			
Brazil	3.136	(c) Report, or make available~~,~~ the results of the monitoring programme to the regulatory body at approved intervals, including, as applicable, the levels, composition **and rates** of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring, results of retrospective assessments of doses to the representative person;	Relevant information to be included in reports and databases.			x	"The levels …of discharges" include volume, activity and rate discharges, as appropriate.
India	3.136	Add after 3rd bullet: • **ommitted internal dose from intake**	For completeness of monitoring programme			x	Bullets list the measurable input parameters. Assessment of the total dose (incl. internal and external doses) is included in (c)

Austria	3.136. c)	[…] dose rates at the site boundary and ~~in~~ **on** premises open to members of the public […]			Editorial		
Austria	3.136. f)		Any significant increase should be reported in the first place; an assessment or investigation will then determine the possible source.			x	The proposal is not clear
USA	3.136(f)	Include an explanation of what constitutes a "significant increase" in dose rate or content of radionuclides in the environment.	This section should explain (or provide a cross reference to another section) that quantifies a "significant increase" in dose rate or content of radionuclides in the environment.			x	(f) refers to reporting criteria established by the regulatory body. Guidance materials will be provided in DS 442. It is not feasible to specify the numerical criteria body
Israel	3.136(i)	It seems that the requirement is not needed	It seems that the same requirement appears in 3.136(c)			x	3.136(c) is about reporting to the regulatory body 3.136(i) is about public access to the information
France	Req. 33 and 3.137	1- Add ***planned*** before ***exposure*** : Suppliers of consumer products capable of causing ***planned*** exposures …" 2- delete "***unless either their use has been exempted***" 3- Re write article 3.137 : ***Before granting or refusing an authorization on the basis of justification principle, regulatory body as to take into***	Natural radioactive substances present in consumer products should not be covered by R.33 The introduction of consumer products capable of causing planned exposures (due to artificial or natural radionuclide) should have to be authorized by regulatory body on the basis of justification principle.		Text has been modified based on all comments received on R33 and para 3.137. However, it is noted that sub-somment 3 is covered in principle of justification, and		

		account the benefit for the society, the existence of alternative products and radiation protection issues including the exemption requirement as specified in schedule 1.			in Safety Guide.		
Israel	Req. 33 and 3.137	Para. 3.137 is not needed, since it is more or less a repetition of Req. 33. Alternatively, Req. 33 could be shortened to read: "Suppliers of consumer products capable of causing exposure shall not make them available to the public unless their use has been exempted or authorized." and para. 3.137 retained.		x	Text has been modified based on all comments received on R33 and para 3.137.		
NEA	Para 3.137	MODIFY: … products **whose use has been justified** shall…	The EGIR felt that it should be explicitly clear that only consumer products whose use has been justified shall be made available to the public, and as such proposes this additional text.		Text has been modified based on all comments received on R33 and para 3.137.		
Poland	3.137	MODIFY to read: „Suppliers of consumer products capable of causing exposure shall ensure that the use of such products is justified and that such products are not made available to members of the general public unless:" ……	Clarification of text		Text has been modified based on all comments received on R33 and para 3.137.		
Belgium	3.137	Insert a subparagraph: (.) the use of such products is a justified practice;	If the practice is not justified, it can not be exempted.		Text has been modified based on all comments received on R33 and para 3.137		
Slovakia	3.137	Modify: … product whose use has been justified shall …	Each consumer product whose use to the public, has to be justified.		Text has been modified based on all comments received on R33 and para 3.137		
ILO UK (workers)	3.137	Add 'by the regulatory body' after 'authorised';	To avoid confusion on who authorizes this.			X	See definition of authorization.

WNA	Specific 3.137 Req.33	**Are requirements commensurate to the actual risk : Public exposure associated with consumer products and with commodities (the latter from contaminated areas)?** – Consumer products: Generally speaking, consumer products must meet the exemption requirements (see General Comment 10). [Requirement 33, para.3.137.] As for exemption and clearance, the dose criterion is of the order of ***0.01 mSv/y*** with the option of using an additional criterion if the dose, due to such low probability events, does not exceed ***1 mSv/y***.[para.I-2] Commodities (from contaminated areas): Radionuclides in commodities including food, feed, drinking water, agricultural fertilizer and soil amendments, and construction material – coming from contaminated areas are covered by Section 5 [para.5.1(b), 5.1(c)ii]. **Reference levels are less than about 1 mSv/y**. The guideline levels in the joint FAO/WHO Codex Alimentarius is to be considered.[para. 5.22, 5.23] See General Comments No. 2, 3 and 17. See attached Table 1.	The risk-based consistency of the exemptery difficult to understand the rationale (ifion requirements for consumer products and of the requirements for commodities coming from contaminated areas with those for the control of other public exposure (Sections 3, 4 and 5) is not self-evident. Given than public exposure from nuclear energy is on average (0.0002 mSv/y) even lower than the lowest of the exemption dose criterion of 0.01 mSv/y, it is v any) that supports a very stringent three-level system for nuclear energy exposure.			x	R33: "Consumer product" is a defined term – see the Glossary Commodities from contaminated areas are out of the scope of Chapter 3 (planned exposure situation).
Belgium	3.137 (a)	the use of such products meets the exemption criteria specified…	There are no exemption requirements for products specified in schedule I.		Text has been modified based on all comments received on R33 and para 3.137.		

Finland	3.137 (b)	Add a footnote to clarify "otherwise authorized" .	Some indication should be given that what is meant by this. By whom and on what basis such an authorization could be granted?		Text has been modified based on all comments received on R33 and para 3.137.		
USA	3.137(b)	Revise to read: "Such products are deemed justified by the regulatory body and usage of such products are otherwise authorized for use by members of the public."	To avoid potential confusion with section 3.17 that discusses the justification of commodities or products that are radioactive, and to ensure that such consumer products are justified before authorization.		Text has been modified based on all comments received on R33 and para 3.137.		
Austria	3.138. a)	[…] documents that demonstrate ~~the~~ compliance with **the** requirements of […]		X			
France	3.139.	Why only for maintenance and disposal	Does maintenance include storage.? In 3140 recycling is also mentioned for provision	x	Recycling is added. The service, maintenance and disposal are listed additionally to "supply", which highlight the these issues, which could be omitted after the "supply" The storage is part of "supply".		
France	3.139	*4*- Add ***transport****:* "…in relation to features that could affect the exposure of people during normal handling**,** ***transport*** and use,…"	According to 107 d) of TS-R-1, the exemption for consumer product **only apply** to "radioactive material in consumer products which has received regulatory approval, following to their sale to the end user". The other transports performed before the sale to the end user have to comply	x			

			with the regulation.				
IRPA Germany	3.139.	Delete the term “designers”	In analogy to the subject given before also "designers" have to be deleted in 3.139 as it is included in "suppliers".			x	The term “Suppliers” does not includes of suppliers of consumer products – see Glossary. Suppliers has been replaced by “providers of consumer products”, and therefore it is appropriate to include designers and manufacturers in 3.139.
NEA	Para 3.139	ADD **(f) The justification for the waste created, its disposal and impact**	The EGIR feels that it is important to consider waste issues from the beginning, so this addition is needed to elaborate on the reference to disposal in the stem of this paragraph, above.		Justification has been included in R 33 and para 3.137, and the justification decision must take account of all benefits and all detriments, which would include consideration of waste.		
Argentina	Para. 3.139, line 2	The text: "the design and operation ofa source" should be replaced by "the design, construction, operation and decommissioning of a source"	Specific confinement provisions should be also taken during construction and decommissioning			X	Para 3.139 is related to consumer products – see BSS definition of the term. Construction and decommissioning would be inappropriate for

							devices, produced for sale to the general public, such as a smoke detector or luminous dial.
UK	3.140 and Glossary definition for **consumer product** (page 137)		This paragraph seems fine provided the definition makes it clear that consumer products do not include commodities or construction materials. There is potential confusion as these are addressed by different EU and national regulations (although unusually smoke detectors, one of the examples given, can be considered as both construction products or consumer products).			x	The definition states that consumer products are devices, so that rules out commodities and construction materials.
UK	3.140 (a)	Modify to read: "(a) Where practicable, a legible label is firmly affixed **to each consumer product**:…"	Some consumer items (such as fire alarms) have labels which are visible when opened and the source exposed, rather than on the surface of the product. It is believed that this provides adequate protection.			x	A label at a visible surface is a requirement of the current BSS A justification of the proposed change is not clear.
Israel	3.140(a)(i)	"radioactive source" instead of "source of ionizing radiation or radioactive material"	Clarification	x			
Austria	3.140. b)	[…] on the retail packaging in which ~~a~~ **the** consumer product is supplied.		x			
Finland	3.141	recommended *or required* disposal options	Usually there is legal requirements on this i.e. not only recommendeations.	x			
Spain	3.141	Although the requirement for the suppliers to include information on the "recommended disposal options" is considered very appropriate, it is considered useful to also add that such information should be "in accordance with	Clarity			x	3.139: Suppliers of consumer products shall comply with conditions of authorisation There are no needs

		the provisions they shall anticipate" (as clearly required in para. 3.139).					to repeat requirements of 3.139 in 3.141.
Sweden	3.141(b)	..recommended or required disposal options…	3.141(b)	x			
IRPA	3.141 (d)	Delete "during normal operation and…"	Dose rates during normal operation of consumer products should be so low as to not require any special precautions. Thus information on dose rates should be of no value to the user.			x	Dose rates during normal operation could be important parameters for service and repair. Moreover, there are no reasons to hide this information from an end-user.
UK	3.141 (d)	Delele "during normal operation and" to read: "(d) Radiation dose rates during servicing and repair operations;"	Dose rates during normal operation of consumer products should be so low as to not require any special precautions. Thus information on dose rates should be of no value to the user.			x	Dose rates during normal operation could be important parameters for service and repair. Moreove, there are no reasons to hide this information from an end-user.
Belgium	3.141 (e)	recommended recycling and disposal options		**x**			
Denmark	3.141(e)	Recommended *or required* disposal options.		**x**			
UK	3.141	Add a new bullet to read: "(f) The product shall state disposal options on the rear of the product."	This is to ensure that, should something like a smoke detector be thrown away after several years (after the packaging is long gone), the owner has access on the product to the safe method of disposal.			x	The issue is covered by 3.140 (a) (iii)

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 3: Planned Exposure Situations: Medical Exposures							
Israel	3.143	We suggest mentioning dose limits for exposure for: visitors, comforters, volunteers, medical personnel exposed occasionally, public, or suggest bibliography.				X	1. Requirement 3.143 is setting the scope for medical exposure, and clearly must be interpreted using the definition of medical exposure as given in the Glossary. 2. Further, the question of applicability of DLs is addressed in 3.144. 3. Moreover, dose limits are not applicable to carers and comforters & to volunteers. Req 3.147 refers to establishment of dose constraints for them. 4. Dose limits for the

							public are addressed in the section on public exposures.
ICRP	3.143 line 2	Delete “including….accidental exposure”.	Unintended or accidental exposures are neither planned exposures nor medical exposures.			X	The definition of medical exposure in the BSS 3.0 differs slightly, but importantly, from that in ICRP 103 and BSS 115. There is a deliberate de-coupling of the exposure and the patient, so that when the wrong part of the patient is exposed, or the wrong patient is exposed etc, then these situations are still covered by the requirements for medical exposure. The reasons for this are as follows: If, for example, the patient being given the wrong procedure is not part of medical exposure then it must be considered as public exposure (as it is clearly not occupational exposure). But public exposure protection is primarily afforded thru design and the prospective application of dose constraints, and of course the dose limits.

							The types of unintended and accidental exposures being considered cannot be dealt with in this way – there is no or limited scope for design requirements, prospective DCs cannot be specified, and finally the public DLs can easily be exceeded. Similarly there is no logic to consider the unintended or accidental exposures as occurring in an emergency exposure situation – there is no synergy with the attributes of these situations. You are not preparing or responding to a radiological emergency. Hence it was considered better to keep these unintended and accidental exposures within the scope of medical exposure and stipulate value-adding requirements to minimize their occurrence. Hence the change to the definition, and the

							words used in the scope requirement.
Sweden	3.143.	… including intended and unintended exposures. Alternatively: … including intended and accidental exposures.	The expression "unintended and/or accidental" occur ten times on pp. 76-88 and here for the first time. According to the glossary, "accident" is "any unintended event …", so it should be sufficient to use only one of the words, "unintended" or "accidental", not both together. Otherwise, the difference between "unintended" and "accidental" should be explained.			X	There was much debate over whether the use of the word "accident", alone, was sufficient. In the end, the consensus was: 1. The definition of accident in the Glossary is about an unintended event, the consequences of which are not negligible. 2. It was felt this was not suitable for the day-to-day practice in medical uses of radiation, where unintended events can occur but often with negligible or minor consequences, but there is no way of knowing *a priori*. 3. These minor events still needed to be captured by the requirements, and hence it was decided to use a combined expression, based on common English, without definition. 4. Requirement 3.178 clarifies the expression "unintended and

							accidental medical exposures", stating quite clearly what situations need to be investigated.
Canada	3.143-3.183	No specific mention is made of dental exposures, except in footnote 27 and in the definition on page 145	3.143-3.183			X	The comment is correct, but this is not considered a problem. Dental exposures are included in the definition of medical exposure (i.e. "…for the purpose of medical or **dental** …".)
Iran	Medical exposure in general	Too emphasize on the role of medical physicists	There is too much detail in comparison with the other part, In developing countries there is not enough physicist to undertake all responsibilities and in some cases really it is not necessary that physicist implement requirements, educated individual who had passed a short training course can do the tasks like dosimetry and measurement.			X	The medical physicist has a key role in radiation protection in medical exposures. Implementation difficulties in developing countries are recognized, and to this end the information/comment paragraphs attached to the definition of a medical physicist should help in the practicalities of implementing the requirements with respect to medical physicists.
USA	3.144/ line 1	Consider revision: Dose limits are not to be applied to patient medical exposures.	Medical exposures as defined on page 145 also includes those received by carers (caregivers), comforters and volunteers in biomedical research programs			X	1. The text in 3.144 is correct since dose limits are not applied to any of the 3 components of medical exposure – i.e they do not apply to patients,

							carers and comforters, or volunteers in biomedical research. 2. 3.147 refers to the establishment of dose constraints for carers and comforters, and volunteers in biomedical research.
Czech	Req. 34	… dose constraints for carers, comforters and volunteers in….	To specify for what dose constraints are used in medical exposure where dose limits don´t apply			X	The comment arises because of the need to limit repetition in the overarching requirement of the details that are in the associated requirements. Given that Requirement 3.147 gives the details, no change is considered needed.
Israel	Req. 34	Add "after radionuclide therapy" after "patients"	Clarification			X	The comment arises because of the need to limit repetition in the overarching requirement of the details that are in the associated requirements. Given that Requirement 3.147(b) gives the details, no change is considered needed.
Israel	Req. 34	Add "the" before "government"	Editorial			X	Not needed.

UAE	Requirement 34	Re-word the second part of the Requirement as 'and support the establishment of diagnostic reference levels, dose constraints and criteria and guidelines for the release of patients.'	Given the involvement of independent health professionals in these processes it is not possible for Governments to **ensure** that DRLs etc are established.			X	Requirement 34 is consistent with its associated requirements. Namely, Requirements 3.145 – 3.147 all say that "the Government shall ensure that…", but each elaborates on the facilitating or overseeing role of the Government in this process.
Belgium	3.146.	Add the underlined parts: "The government shall ensure, as part of the responsibilities given in § 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a) referral guidelines, containing generic recommendations on good medical practice in imaging, are available to the referring practitioners and radiological medical practitioners b) a set of diagnostic reference levels for medical exposures incurred in medical imaging is established, taking into account the need for adequate image quality, to enable the requirements of para. 3.167 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values appropriate to the local circumstances, c) all medical exposures are submitted to audits, in which both the application of the justification principle - by verifying the conformity to referral criteria- and the optimization principle –by confronting the	The government should see to it that adequate tools are in place to stimulate awareness on the well-identified issues of both justification and optimization. The appropriateness and the application of the ALARA principle should be audited.			X	1. The important role of referral guidelines is recognized and, as such, Requirement 3.156 invokes their use. 2. However, the prevalence of such guidelines at the national level currently is not common, and to have a mandated requirement to this effect in the Basic Safety Standards is unrealistic at this stage. 3. Moreover, the involvement of the regulatory body through consultation as mentioned in this requirement refers to the establishment of DRLs but is not so applicable for the

		local patient doses or administered activities to the diagnostic reference levels- shall be taken into account."					development of referral guidelines. 4. The concept of the "radiological review" is introduced into the BSS 3.0, in Requirement 3.180, and this already addresses the main issue raised in the proposed text in part (c).
Israel	3.146	Add at the end of the paragraph: "and shall refer to a few typical patients, as a function of the body surface area."	Diagnostic reference levels should be adapted to different typical patients			X	This is detail that will be discussed and elaborated in the Safety Guide.
Germany	Para. 3.146	"The government shall ensure, as part of the responsibilities given in para. 2.15, that as a res ult of consultation between the health authority, relevant professional bodies and the regulatory body, a) a set of diagnostic reference levels for medical exposures incurred in medical imaging is established, taking into account the need for adequate image quality, to enable the requirements of para. 3.167 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on widescale surveys or on published values appropriate to the local circumstances, b) recommendations concerning *referral criteria* for medical exposure are available to the referring practitioners and c) *radiological audits* are applied to medical procedures involving medical exposures, whereby the *principle of justification* of medical exposure as well as the implemented set of *diagnostic reference*	The added points b) and c) address issues specific and important to medical exposures, which should be ensured by the government. Concerning point c) the *principle of justification* of medical exposure as well as the implemented set of *diagnostic reference levels* are pivotal means for radiation protection in medical exposures that should be addresses by a clinical audit.			X	As above for Belgium, namely: 1. The important role of referral guidelines is recognized and, as such, Requirement 3.156 invokes their use. 2. However, the prevalence of such guidelines at the national level currently is not common, and to have a mandated requirement to this effect in the Basic Safety Standards is unrealistic at this stage. 3. Moreover, the involvement of the regulatory body

		levels shall be taken into account."					through consultation as mentioned in this requirement refers to the establishment of DRLs but is not so applicable for the development of referral guidelines. 4. The concept of the "radiological review" is introduced into the BSS 3.0, in Requirement 3.180, and this already addresses the main issue raised in the proposed text in part (c).
Spain	3.146	….a set of diagnostic reference levels for Medical exposures incurred in medical imaging, including interventional procedures is established, taking into account……	Diagnostic Reference Levels are not specifically addressed in the BSS for interventional procedures. ICRP has proposed the use of DRLs also for interventional and the same has been made for the draft European BSS.	X	Change 3.146 to include high-lighted text: "…incurred in medical imaging, including image-guided interventional procedures, is established, taking…."		
Germany	Para. 3.147	"The government shall ensure, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the establishment of: (a) (i) Exposures of carers and comforters of patients undergoing radiological procedures;	See comment to Para. 1.24			X	1. The presence or not of direct medical benefit is not germane to the requirement. 2. Details on how constraints may be established, and what attributes may need to be considered will be

		(ii) Exposures from diagnostic investigations of volunteers participating in biomedical research projects, for whom no direct medical benefit is expected from their exposure. In addition, for these volunteers, constraints with respect to age and mental state are established;"					in the Safety Guide. 3. Para 3.159 requires that the exposure of volunteers shall be in accordance to the provisions of the Declaration of Helsinki which explicitly mentions in its Article 9 that some research populations are particularly vulnerable and need special protection, and that this includes those who cannot give or refuse consent. Further, Articles 27 to 29 specifically refer to research subjects who are deemed to be incompetent. 4. Para 3.159 also requires accordance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2002), where the topics "research involving vulnerable populations" and "research involving children" are explicitely addressed.
USA	3.147(a)(ii)	Delete this section.	Human research subjects participating in clinical trials should not necessarily be subject to dose limits or constraints assuming that the clinical trial is subject to			X	1. Human research subjects participating in clinical trials are NOT subject to dose

			review by an institutional review board. Consider if the term “human research subject” needs to be defined in the glossary.				limits. 2. The role of the dose constraint is different to a dose limit – it is a prospective guide to the level of dose likely to be needed to conduct the radiological procedure. 3. Para. 3.147 is a requirement for the government to ensure that generic dose constraints are established as a result of consultation between health authorities, professional bodies and regulatory bodies. Then the use of these constraints is subject to the final review and approval by the ethics committee (or equivalent institutional review board) for a particular trial as established in 3.172. 4. The term “human research subject” is not used in the BSS 3.0 – hence no need to define it.

NEA	Para 3.147(a)(ii)	DELETE: (a)(ii);	The EGIR feels that the ethics committee is charged with the role of fixing constraints for such research, and this is correctly noted in paragraph 3.172. As such, this sub-point is incorrect and should be deleted.			X	1. The Ethics Committee in Requirement 3.172 is charged with invoking appropriate dose constraints for a particular clinical trial. 2. While para. 3.147 is a requirement **for the government** to ensure that dose constraints are established, the para 3.172 is a requirement **for registrants and licensees** regarding optimization of protection and safety. Therefore, the two requirements are complementary. 3. The dose constraints set by the ethics committee would be based on the generic values set thru 3.147(a)(ii).
Finland	3.147. (b)	…using unsealed or implanted sealed sources.	Brachytherapy with afterloading techniques using sealed sources should not be included.	X	Change to include high-lighted text: (b) Criteria and guidelines for the release of patients who have undergone therapeutic procedures using unsealed sources or who still retain implanted sealed sources.		

Israel	Req. 35	"exposure" instead of "exposures" in the title	Consistency with Req. 34	X	.		
Ukraine	Req. 35	It is suggested the following wording: Responsibilities of the regulatory body specific to medical exposures The regulatory body shall require that health professional with responsibilities for medical exposure are specialized in the appropriate area and meet the requirements for education, training and competence in the relevant specialty, *and requirement for assurance of safety culture and good practices.*	Comprehensiveness			X	The suggested text is not in line with the focus of the requirement. Further, safety culture requirements are given in 2.51.
Germany	Require ment 35	Responsibilities of the regulatory body specific to medical exposures The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and meet the requirements for education, training and competence in the relevant specialty.	The requirements related to education and training applicable to different types of planned exposures should have the same level of detail and use consistent wording when the meaning is intended to be the same. In Requirement 35 and also in Para. 3.148 it is not clear whether the requirements for education, training and competence refer only to the relevant specialty or include also radiation protection for patients. This should be clarified.			X	The comment arises because of the need to limit repetition in the overarching requirement of the details that are in the associated requirements. 1. The education, training and competence apply to both the specialty and the radiation protection. 2. For the former, to be acknowledged as being specialized (as in footnote 26 to 3.148) implies that that person has education, training and competence in that specialty from the medical, physics or radiography perspective, as relevant.

							3. For the latter, the radiation protection aspects are specifically stated in 3.148(b).
Sweden	Req 35, last line	… the relevant ~~specialty~~ **speciality**.	Typing error			X	Original spelling is correct.
Denmark	3.148	… and any other *health professionals* with specific duties in patient protection …	The use of the term qualified expert seems not appropriate	X	Replace "qualified experts" with "health professionals". Reason: 1. The others being considered here could include the radiopharmacist, radiochemists, and maybe nurses, etc. 2. The definition of the "qualified expert" is skewed towards radiation protection expertise, whereas the other persons are most likely to be health professionals of some sort.		
Norway	3.148	Proposed revision: *".. and any other health professionals with specific duties…"*	The *qualified experts* should be changed to other *health professionals*.	X	As above for Denmark on 3.148.		
Finland	3.148	change qualified experts to other health professionals	Patient protection includes also many other aspects and here it should be limited to radiation protection. For example a dentist's assistant is not a qualified expert, but is a medical professional.	X	As above for Denmark on 3.148.		
Israel	Footnote 27 (para. 3.148(a	"with regard to" instead of "in the case of" before "the radiological medical practitioner"	Editorial: "in the case of" is used twice later in the footnote.	X	Change 2nd sentence of Footnote 27 as indicated:		

	))				"…, particularly with regard ~~in the case of~~ to the radiological medical practitioner, …."		
Germany	Para. 3.148	(b) meet the respective education, training and competence requirements in the relevant specialty, …	The requirements related to education and training applicable to different types of planned exposures should have the same level of detail and use consistent wording when the meaning is intended to be the same. In Requirement 35 and in Para. 3.148 it is not clear whether the requirements for education, training and competence refer only to the relevant specialty or include also radiation protection for patients. This should be clarified.			X	As above for Requirement 35.
Finland	3.148. (c)	(c) continuously fulfil the requirements in (b) proved by the licensee or registrant as regulated.	Name on a list is not any indication of competence. It should be regulated if there is a need for example for a register of continuous professional development of radiation protection.			X	1.The point of part (c) is not to establish the competence of the named individuals or to ensure continuing professional development, but to simply ensure that the licensee maintains a record of who is who in their facility. This then enables the regulator to perform checks to see if only appropriate persons are indeed performing particular roles.
Sweden	3.148 and 3.152(b)	Change qualified experts to other health professionals	QE misleading to the radiation physics expert	X	1. For 3.148, as above for Denmark. 2. Also see change for 3.152(b) below.		

Israel	Req. 36	"exposure" instead of "exposures" in the title	Consistency with Req. 34	X			
France	Requirement 36 and 3.149 - d	Replace ***as appropriate*** by ***properly***: "…and the person to be exposed has been informed as appropriate" by "…and the person to be exposed has been informed ***properly"***	Patient information must not be optional.				The current wording reflects the consensus of various previous comments and discussions on informing patients, ranging from comments, such as from France, suggesting all patients are properly informed to comments that any requirement to inform will be impractical and impact negatively on the day-to-day practice. The Safety Guide will elaborate on this point and give guidance on when and how the patient can be informed.
Finland	3.149.	(b) The medical exposure has been justified by the referring medical practitioner as well as the radiological medical practitioner who should be involved as specified by the regulatory body in the justification process at the appropriate level, or is part of an approved health screening programme.	The referring medical practitioner should be also responsible. In some cases in practice there are not enough radiological medical practitioners available to do the individual justification for the most common radiography (like chest imaging).	X	Accepted with modification See comments below re USA on 3.149, 3.155, 3.156, 3.158.		
USA	3.149	It is suggested to add another bullet to read as follows: "Radiological medical practitioner shall document and sign any dose or activity changes to the original prescription."	This will reduce the chances of misadministration.			X	This comment is relevant but this is not the appropriate placement for the suggested text. It may be better included in a safety

							guide. Note: changes to the original prescription shouldn't be discouraged, since they may be needed during the justification process, as a result of the interaction between the radiological medical practitioner and the referring medical practitioner.
USA	3.149 3.155 3.156 3.158	Revise to read as: "the referring medical practitioner in consultation with the radiological medical practitioner when appropriate."	The current text gives responsibility for justification to the radiological medical practitioner, rather than the referring medical practitioner. In most cases, this relationship is exactly the opposite, at least in the United States. Consultation and agreement is the key.	X	Accepted with modifications: Noting all the Member State comments above and below on these requirements, plus the discussion in the right hand column, it is proposed that: Change "the radiological medical practitioner, in consultation with the referring medical practitioner when appropriate" to: 3.149(b): The medical exposure has been justified by consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or is		1. The issue of the respective responsibilities of the referring medical practitioner and the radiological medical practitioner were discussed at length at previous RASSC meetings with the wording in draft 3.0 reflecting the final recommendation of RASSC. 2. The issues are: a. The referring medical practitioner has the specialist knowledge about the patient and their medical history and context. b. The radiological medical practitioner has the specialist knowledge about the

					part…. 3.155 The justification of medical exposure for an individual patient shall be carried out by consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, taking into…. 3.156 Relevant national or international referral guidelines shall be taken into account for the justification of the exposure of an individual patient for diagnostic, image-guided interventional or therapeutical purposes. 3.158 Any radiological procedure on an asymptomatic individual, …, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, following guidelines		radiological procedure, including the benefits, risks and limitations. c. The development of referral criteria and appropriateness criteria is helping to bridge the gap between the referrer and the practitioner. d. It may be difficult to make referrers accountable under a radiation protection framework - radiological medical practitioners can easily be accountable under the authorization, but not so for the referrers. e. In some Member States, the radiological medical practitioner may have a financial interest in performing the radiological procedure. f. In some Member States, the referring medical practitioner may be practising defensive medicine, from fear of litigation, and hence over-order radiological procedures. g. In some Member States, the request for a radiological procedure

					….		from a referring medical practitioner is viewed as a request for a consultation by the radiological medical practitioner. h. In some Member States, the request for a radiological procedure from a referring medical practitioner is viewed as an order or instruction to the radiological medical practitioner to perform the procedure. i. In some Member States, where there is a high level of litigation, various professional groups are keen to avoid having to take responsibility. I.e. they would prefer to "pass the buck". Good radiation protection practice should not be compromised by such attitudes. j. Practicalities in a busy imaging facility make it unrealistic for the radiological medical practitioner to individually justify each and every radiological procedure. Some form of "standing orders" or standard procedures

							are needed for dealing with the majority of clinical conditions. In this context, referral guidelines can provide support to referring medical practitioners for determining the appropriateness of their referral, with special scrutiny (by the radiological medical practitioner) reserved for the higher dose/higher risk procedures and/or for particular clinical conditions that need specialist's advice . 3. ICRP makes several statements on this topic, which may be interpreted as supporting the radiological medical practitioner as the major player in level 3 justification. Namely: a. In ICRP 103, para 330, the ICRP simply says that the responsibility for level 3 justification falls on the relevant medical practitioners. However, in another paragraph (para 209) the sentence continues, "…, who need to have special training in

							radiological protection". This would seem to point towards the radiological medical practitioner. c. In ICRP 103, para 328, the last sentence states that "The final responsibility for the medical exposure of patients lies with the physician, who therefore should be aware of the risks and benefits of the procedures involved". Presumably the "physician" in this sentence is the same as the "physicians" in the first sentence of the same paragraph, where it states "the physicians and other health professionals involved in the procedures that irradiate patients should always be trained in the principles of radiological protection, including the basic principles of physics and biology". 4. It is useful to note what the draft re-cast EU BSS states re the respective roles of the

							referrer and the practitioner in justification: a. Art 82.1 states that the referrer as well as the practitioner shall be involved as specified by Member States. This would seem to imply that the referrer is in addition to the practitioner. b. Art 82.2 states that any medical exposure is effected under the clinical responsibility of the practitioner. The definition of "clinical responsibility" includes justification. c. Further, with respect to asymptomatic individuals, the EU in Art 80.3 states the practitioner has the major role, with the referrer in support through consultation. d. Together these would suggest that the practitioner has the stronger or final role. 5. Finally, it is worth noting that the actual implementation of the principle of justification in medical exposure is very poor throughout the world.

							This is receiving increased attention now, and strategies are being promoted, including the IAEA's 3 A's (Appropriateness, Awareness, and Audit), and the Referral Guidelines project within the WHO GI. The revised BSS needs to provide the appropriate platform to assist such initiatives.
UK	3.149 (a)	Modify to read: "(a) The examination or treatment has been requested by a referring medical practitioner **(or other health professional entitled by the employer)** and information on the clinical context has been provided, or is part of an approved health screening programme;"	Health Professionals who are appropriately trained and entitled by the employer may also refer patients for medical exposure.			X	No change is needed as the definition of radiological medical practitioner, together with that of a health professional, includes the possibility of other appropriate health professionals, as determined by national regulations. This point would be elaborated in the Safety Guide.
UK	3.149 (b)	Modify to read: "(b) The medical exposure has been justified by the radiological medical practitioner **or medical radiation technologist entitled by the employer** in consultation with the referring medical practitioner/**health professional** when appropriate, or is part of an approved health screening programme;"	Medical radiation technologists who are appropriately trained and entitled by the employer may also undertake justification.			X	As above, for UK comment on 3.149(a). Similarly with respect to the referring medical practitioner.

UK	3.149 (c)	Modify to read: "A radiological medical practitioner **or medical radiation technologist** has taken responsibility as specified in Para 3.152 (a);"	See the reason given for Comment 72.			X	As above, for UK comment on 3.149(a).
UK	3.149 (d) and 3.158/6		These paragraphs require that the patient be informed of the benefits and risks of medical exposure. This is not part of a national screening programme for either standard exposures or asymptomatic individuals.			X	It is not clear what the comment is proposing.
NEA	Para 3.149(a)	…by a **referring medical practitioner** and…	The EGIR noted that there is no definition of this term, or of radiological medical practitioner in the BSS glossary, and as such suggests that these terms be added.			X	This is not correct. Both the radiological medical practitioner and the referring medical practitioner are defined in the Glossary.
NEA	Para 3.149	ADD: (e**) The radiological medical practitioner documents any changes made to the original prescription**	The EGIR feels strongly that this addition is needed because changes in prescription have been at the origin of several medical exposure accidents.			X	This comment is relevant but this is not the appropriate placement for the suggested text. It may be better included in a safety guide. Note: changes to the original prescription shouldn't be discouraged, since they may be needed during the justification process, as a result of the interaction between the radiological medical practitioner and the referring medical practitioner.

ICRP	pg 78, 3.149	3.149. Registrants and licensees shall ensure that no patient, whether symptomatic or not, receives a medical exposure unless: … (b) The medical exposure **has been justified by the radiological medical practitioner, in consultation with the referring medical practitioner when appropriate,** or is part of an approved health screening programme;	Conflict between paragraph 333 of ICRP 103 and sections 3.149 (b), 3.155, 3.156 and 3.158 on justification of medical exposure. From ICRP Publication 103: "(330) ... The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners." Justification should be the responsibility of the referring medical practitioner, in consultation with the radiological medical practitioner as appropriate For interventional procedures and radiation oncology procedures, the interventionalist or radiation oncologist is responsible for both justification and optimization of the individual medical exposure.			X	1. There is no conflict with ICRP 103, para 330. As is quoted, the ICRP simply says that the responsibility for level 3 justification falls on the relevant medical practitioners. However, in another paragraph (para 209) the sentence continues, "…, who need to have special training in radiological protection". This would seem to point towards the radiological medical practitioner. Requirement 3.149, 3.155, etc, are not in contradiction to the underlined text. The additional text accompanying the comment in column 3 is simply an opinion, not an ICRP recommendation. 2. There is no issue with the referring medical practitioner and the radiological medical practitioner being the same person. The roles are separate, but this does not mean there needs to be two persons. In addition to the

							examples given, there is also the much more common case of the dentist.
Germany	Para 3.149	"Registrants and licensees shall ensure that no ~~patient~~ individual, whether symptomatic or not, receives a medical exposure unless:" (a)… (b)… (c)… (d) The patient has been informed, as appropriate, of the potential benefit of the radiological procedure as well as the radiation risks and – for those *radiological procedures* that have the potential for deterministic effects – of the potential radiation injuries; and (e) there is *informed consent* by the patient and (f) the radiological medical practitioner documents any change made to the original prescription	A patient can hardly be denoted as asymptomatic (see also comment to Para. 1.13). Concerning (d) and (e): From a medical point of view, the adequate information of an individual going to receive a *medical exposure* should include both radiation risk and – where necessary – radiation injury. By the *informed consent* the individual confirms that he has got all the necessary information to make that decision. Concerning (f): Addition is needed because changes in the prescription have been at the origin of several medical exposure accidents.	X	In light of the discussion in the righthand column: 1. Change 3.149(d) to be: (d) The patient or a legal authorized representative has been informed, as appropriate, of the potential benefit of the radiological procedure as well as the radiation risks. 2. Add to the glossary definition for Medical exposure the following footnote to the word "patient": **medical exposure**. (modified) Exposure incurred by patients[1] for the purpose of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers in a programme of biomedical research involving their exposure. [1]. A patient is a person who is		1. The suggestion is inconsistent – no change is suggested for the use of patient in 3.149(d) and, in the suggested additional text part (e), the word "patient" is again used. 2. The pros and cons of patient vs individual have been discussed before, but to summarize: a. The term "patient" also includes the asymptomatic individual – e.g. women presenting for exams in a mammography screening programme are commonly referred to as patients. b. A "radiological procedure" is a medical procedure, and hence the recipient is a patient. Asymptomatic individuals that undergo a radiological procedure are therefore patients. c. The term "individual" is used in

					recipient of services of health care professionals and/or their agents that are addressed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring of health; (4) maintenance of health; and (5) treatment of diseases, disorders, and injuries in order to obtain cure or, failing that, optimum comfort and function. Therefore, asymptomatic individuals are included in the definition of this term. For the purpose of these Standards, the term patient refers only to those undergoing radiological procedures.		3.151 (carers & comforters) because they are not patients. d. The term "individual" is used in 3.150 (volunteers in biomed research) to emphasize that the route to their being exposed is different to that for the standard patient exposures. e. Finally, the ICRP (Pub 103, para 195) defines the patient as an individual who receives an exposure associated with a diagnostic, interventional, or therapeutic procedure. The use of the term patient in 3.149 is consistent with this definition. f. WHO developed an International Classification for Patient Safety (ICPS) that includes a glossary .For the ICPS : PATIENT is a person who is recipient of healthcare. And: HEALTHCARE is

							1. Care provided to individuals or communities by agents of the health services or professions for the purpose of promoting, maintaining, monitoring, or restoring health. Health care is broader than, and not limited to, medical care, which implies therapeutic action by or under the supervision of a physician. 2. Services of health care professionals and their agents that are addressed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring of health; (4) maintenance of health; and (5) treatment of diseases, disorders, and injuries in order to obtain cure or, failing that, optimum comfort and function (quality of life). Therefore, it is clear that asymptomatic indiduals are included

							in this term. 3. “Radiation risks” does not refer to stochastic effects only, but also include deterministic effects or tissue reactions – therefore a potential radiation injury is a radiation risk. For example, in discussing a forthcoming image-guided interventional procedure, the patient will be told that depending on how the exam proceeds there may be a risk of deterministic effects. There is no certainty at that point in time – the likelihood being dependent on the actual dose that a particular tissue receives and the susceptibility of the individual to radiation effects. 4. Informed consent is a step too far for the Basic Safety Standards, but a comment to 3.179(e) is also relevant to 3.149(d). 5. Suggestion (f) is relevant but this is not the appropriate

							placement for the text. It may be better included in a safety guide. Note: changes to the original prescription shouldn't be discouraged, since they may be needed during the justification process, as a result of the interaction between the radiological medical practitioner and the referring medical practitioner.
Germany	Para 3.150	"Registrants and licensees shall ensure that no individual receives a medical exposure as part of a biomedical research programme unless it has been approved by an ethics committee (or other institutional body assigned similar functions by the relevant authority) as required in para. 3.159, and the individual has received relevant information on radiation risks and – where necessary – on radiation injuries prior to participating in the *biomedical research* project, and the individual has given informed consent, and a radiological medical practitioner has taken responsibility as specified in para. 3.152(a), and that the requirements specified in para. 3.172 are applied."	In particular in *biomedical research* projects, the information of the individual and his/her *informed consent* are of pivotal importance.			X	1. There is no argument with the importance of the provision of information and informed consent for biomedical research, but this is simply "business as usual" for any biomedical research – nothing special because radiation is being used. The key point is that requirement 3.150 is about it being approved biomedical research. 2. "Radiation risks" does not refer to stochastic effects only, but also include deterministic effects or

							tissue reactions – therefore a potential radiation injury is a radiation risk. 3. Para 3.159 requires that the exposure of volunteers shall be in accordance to the provisions of the Declaration of Helsinki (2008) as well as with the the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2002). Information on potential risks is addressed in Article 24 Declaration of Helsinki and mentioned in others. The CIOMS 2002 specifically addresses the information for research subjects as well as the obligations for sponsors and investigators regarding this topic (pages 32 to 45).
Israel	3.150	Add "for optimization of protection and safety" after "requirements"	Clarification			X	Unnecessary.
Israel	3.151	Add "for optimization of protection" after "requirements"	Clarification			X	Unnecessary.
Israel	3.152	We suggest requiring from the public health system to keep personal records of the radiation				X	1. Suggestion is not appropriate for this

		doses received by each person from all tests and treatments with radiation.					requirement, which is addressed to licensees, not the public health system. In any case, requirement 3.183 specified dose records. 2. Both 3.152 and 3.183 are requirements for registrants and licensees. 3. There are some projects and initaives to introduce personal records of the radiation dose accumulated by one individual (e.g. SmartCard), but to include this proposed requirement for PUBLIC HEALTH SYSTEMS would be unrealistic at this stage.
India	3.152	…by, or under the ~~**oversight**~~ **supervision** of or with the documented advice of,…	Editorial. The similar replacement is needed in 3.169-a/1			X	1. Oversight is a term commonly used in medical practice. Oversight is a broader term than supervision, and is considered appropriate for diagnostic procedures.
Finland	3.152. (a)	… in cooperation with the medical physicist, the medical radiation technologist and the radiation protection officer, as required in paras 3.160 to 3.176;	The radiation protection officer has the relevant knowledge of radiation protection, like personal doses of the staff.			X	1. This is the Medical Exposure section, and is not concerned with staff doses etc – that is covered elsewhere.
Israel	3.152(a)	Add ", in consultation with the referring medical practitioner" after "the justification of	Important to mention. Consistency with 3.155, 3.156 and 3.158			X	1. Not needed as the specific requirements

		the procedure"					are referenced.
UK	3.152 (a)	Modify to read: "(a) The radiological medical practitioner **or medical radiation technologist** performing or overseeing the radiological procedure has assumed responsibility for ensuring overall patient protection and safety during the planning and delivery of the medical exposure, including justification of the procedure as required in paras 3.153 to 3.159 and the optimization of protection, in cooperation with the medical physicist, as required in paras 3.160 to 3.176;"	Appropriately trained medical radiation technologists may be entitled to perform/oversee radiological procedures.			X	1. No change is needed as the definition of radiological medical practitioner, together with that of a health professional, provides the flexibility to accommodate different national regulations.
Norway	3.152 (a)	Update cross reference. 6.160 to ~~3.176~~ 3.172	The cross reference in the last line is to the paragraph 3.176, which should be 3.172 since this is the last paragraph under the optimization requirement.	X	Change cross reference to be: 3.160 to 3.175. Note: While 3.173 – 3.175 are not under the heading of Optimization, they are still an aspect of the application of this principle. However 3.176 is not, hence the change.		
USA	3.152 (a)	Update cross reference. 6.160 to 3.172	The cross reference in the last line is to the paragraph 3.176, which should be 3.172 since this is the last paragraph under the optimization requirement.	X	As above.		
Denmark	3.152(b)	… and any other *health professionals* with specific duties in patient protection ….	The use of the term qualified expert seems not appropriate	X	Replace "qualified experts" with "health professionals". This is then consistent with change to 3.148.		

Norway	3.152 (b)	Proposed revision: *".. and other health professionals with specific duties…."*	The *qualified experts* should be changed to other *health professionals.*	X	As for comment from Denmark above.		
Finland	3.152 (b)	change qualified experts to other health professionals	Same as in 3.148	X	As for comment from Denmark above.		
Argentina	Para. 3.152, Item (c) line 2	The following text should be added at the end of the paragraph: "in consultation with the repulatorv bodv as appropriate"	Safety aspects of medical exposure as specified by the regulatory body are relevant for this issue			X	1. This is a requirement re medical personnel and hence would seem to be the domain of the health authority.
USA	3.152(d) 3.152(e)	Consider reinstatement of deleted text. This also applies in paragraphs 3.165 and 3.166.	It is not at all obvious why the text stating that "specialized in the relevant field" has been deleted. In previous discussions, there had been a strong argument that the medical physicists need to have the appropriate specialization for the areas in which they are providing services.			X	1. This point has been discussed many times and the need for being specialized in the relevant field is not being disputed – it is crucial. 2. However, with the evolution of the definition of a medical physicist and with the specific paragraph 3.148, there is no longer the need to keep adding the qualifier "specuialized in the relevant field" – it is always implicit. 3. Further the need for appropriate specialization is not just for the medical physicist – it also applies to the radiological medical practitioner and the MRT.

Iran	Article 3.152 (d) line 2, page 79	The text inside the parenthesis (including medical radiological….) should be deleted	because the article just talks about therapeutic uses of radiation and surely medical radiological equipment cannot be included.			X	1. Medical radiological equipment is a defined term in the Glossary, and includes linacs etc.
Ireland	3.152 (d)	Rewrite the last part of the sentence as "under the supervision of an appropriately qualified medical physicist"				X	1. As above for USA comment on 3.152(d) & (e).
Argentina	Para. 3.152, Item (d) line 2	The text "including medical radiological equipment acceptance and commissioning": should be replaced by "including medical radiological equipment and associated software acceptance and commissioning	Medical equipment and the associated software are both relevant for radiological safety			X	1. It is agreed that software has a crucial role in radiation protection, but specific acceptance and commissioning of software, per se, is a highly specialized task. 2. The current wording re medical radiological equipment will in any case involve the use of the accompanying software. 3. Note, requirement 3.160 includes software.
Ireland	3.152 (e)	Rewrite "under the oversight of" as "overseen by".				X	1. Oversight is a term commonly used in medical practice.
Poland	3.152(e)	After the words: „medical physicist" ADD: „or qualified expert…"	more flexibility			X	1. The medical physicist is the required expert. 2. There is flexibility in how Member States recognize persons that may act in the role of a medical physicist.

NEA	Para 3.152(e)	MODIFY: … physicist **or qualified expert**, where…	The EGIR noted that the BSS speaks about qualified experts, but does not use this term much in the requirements text. Here, to assure that the experts involved at this level are appropriately qualified to give the advice they are providing, the EGIR suggests explicitly adding this text.			X	1. As above for comment from Poland on 3.152(e).
Spain	3.153	Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure. Account shall also be taken of the radiation detriment from the exposure of the medical radiological staff and of other individuals.	For justification, ICRP recommends to also have into account the doses to staff (subsidiary). This has not been included in the IAEA BSS. The European BSS has included the consideration of these doses for justification and optimization.			X	1. The proposed text has relevance only for generic justification (level 2), which is the only appropriate place for consideration of staff doses. E.g. if a new proposed procedure can be performed only with staff doses that exceed the occupational dose limits, it would likely be not justified even if patient benefits outweigh patient radiation risks. 2. ICRP 105 states that the exposures to staff should be considered on Level 2 justification in paragraph 65. Elsewhere, in ICRP 103, only general statements are made (paragraphs 209 and 330), with no further elaboration on this point. 3. The proposed text to 3.153 is likely to lead to potential mis-use in the context of level 3

							justification. 4. Elaboration of level 2 justification will occur in the Safety Guide.
UK	3.153		Omission. There should be a requirement to record the basis for the decision.			X	1. Requirement 3.153 is an umbrella philosophical statement, providing the principle of justification (for both generic and individual justification). The operational requirements regarding justification are elaborated in the succeeding requirements. 2. The suggestion is part of good medical practice. Individual justification involves, inter alia, clinical judgement and ethical considerations in addition to radiation protection and safety aspects. This includes consultation/dialogue between the referring medical practitioner and the radiological medical practitioner. The basis for medical decisions regarding diagnosis or treatment of a patient should be included in the patient's medical

							records as well as in the referrer's prescription. 3. However, to add a new requirement to keep records of the rationale behind individual justification would go beyond the scope of basic safety requirements.
ICRP	pg 79, 3.153	Also consider the detriment from occupational exposure when weighing benefits and risks for the purpose of justification in requirement 3.153.	ICRP has included the detriment to staff in the medical justification process, which is not considered in the draft BSS. From ICRP Publication 103: "(330) ... The principal aim of medical exposures is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals."			X	As for comment from Spain on 3.153, above.
Finland	3.154.	Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with **the regulatory body** and appropriate professional bodies,	New radiological procedures may need new regulation before justification for example if previously unused type of radiation is going to be used for medical purposes in the country.			X	The comment is correct in that there may well be many interactions with the radiation protection regulatory body on radiation protection aspects to do with the new radiological procedure, but the actual decision on justification (once all the other pieces are in place, including possible new regulations) is for the health authority and the appropriate

							professional bodies. I.e., the regulatory body has a supporting role, but it does not perform the justification.
Argentina	Para. 3.154, line 2	The text "health authoritv in conjunction with appropriate professional bodies, and shall be" should be replaced by "health authoritv in conjunction with appropriate professional bodies and regulatory bodv as necessary. and shall be"	According to the circumstance, regulatory bodies might be reievant to the generic justification process			X	1. As above for Finland. The radiation protection regulatory body is relevant, but not as a final decision maker.
India	3.155(c)	**Comment: Word 'characteristic' need to be qualified as to what it means in case of exposure.**				X	1. Common meaning of the word is being used. Further detail will be elaborated in the Safety Guide.
Finland	3.155.	The justification of medical exposure for an individual patient shall be carried out **by the referring medical practitioner as well as the radiological medical practitioner**, taking into account…	The referring medical practitioner should be also responsible. In some cases in practice there are not enough radiological medical practitioners available to do the individual justification for the most common radiography (like chest imaging).			X	As above for comment from USA on 3.149, 3.155, 3.156, 3.158.
UK	3.155	Modify to read: "The justification of medical exposure for an individual patient shall be carried out by the radiological medical practitioner **or medical radiation technologist so entitled**, in consultation with the referring medical practitioner **or healthcare professional** when appropriate, taking into account, particularly when the patient is pregnant, breast feeding or paediatric:"	See the reason given for Comment 72.			X	1. No change is needed as the definition of radiological medical practitioner, together with that of a health professional, provides the flexibility to accommodate different national regulations. 2. No change is needed as the definition of referring medical practitioner, together with that of a health professional, includes

							the possibility of other appropriate health professionals, as determined by national regulations.
Sweden	3.156., last line	… or international guidelines. **The radiological medical practitioner and the medical physicist has a responsibility to continuously update the referring medical practitioner about new imaging technologies, current doses and risk estimates and current referral criteria.**	The knowledge among referring medical practitioners is limited. There is a need for a basic level of knowledge to make a consultation (discussion) meaningful.			X	1. The idea behind the comment is worthy, but this is not a practicable requirement, nor would the proposed placement be correct.
Finland	3.156.	…purposes, the referring medical practitioner and the radiological medical practitioner, shall take into account…	Both practitioners need to take into account relevant national or international guidelines.	X	3.156 has been modified (see above in response to comment from USA on 3.149, etc).		
UK	3.156	Replace *radiological medical practitioner* with *radiological medical practitioner or other healthcare professional*	See the reason given for Comment 72.			X	1. No change is needed as the definition of radiological medical practitioner, together with that of a health professional, provides the flexibility to accommodate different national regulations.
Finland	3.157.	…shall be carried out by the health authority in conjunction with the regulatory body and appropriate professional bodies.	New radiological screening procedures may need new regulation before justification.			X	As above for Finland comment on 3.154.
ILO UK (workers)	3.157	Propose adding, "In the case of health screening of workers, the justification and design of the screening program shall be carried out in consultation with the trade union or unions representing the affected workers, or where no such organization exists, other representatives chosen by the workers themselves."	To strengthen the definition and protection of such screening programmes.			X	Requirement 3.157 is generic for all health screening programmes of asymptomatic populations, and is addressing justification only – not the design

							of the program.
Israel	3.157	"Generic" instead of "Specific"	Justification of a procedure in the framework of a screening programme is generic	X	Delete the word "Specific".		
Finland	3.158.	-	This justifies radiological procedures for individuals in opportunistic screening purposes. The radiological procedure should be either for diagnosis or for screening.			X	1. It is unclear what is being proposed.
India	3.158	…the individual shall have been informed about the estimated benefits, risks and limitation of the procedure	**Comment: It is an important aspect. Shall this information be given orally or in writing?**			X	1. This point will be elaborated in the Safety Guide.
Austria	3.159	The exposure of humans~~-~~ volunteers […]		X	Text modified by deleting humans		
Austria	3.159. a)	[…] and takes into account the guidelines for its application prepared by **the** Council for […]		X	Insert the word "the" as indicated: …and takes into account the guidelines for its application prepared by the Council for…		
WHO	3.159. a)	[…] of the Helsinki Declaration [12] and takes into account **the guidelines published** by **the** Council for […]	Comment: this is a request that arrived this week from the WHO Department on Ethics, Trade and Human Rights. The declaration and the guidelines are two different documents, one published by the World Medical Association (WMA) and the other by CIOMS. The guidelines were not published for application of the declaration of Helsinki (although it is included in the guidelines as Appendix 2).	X	Change 3.159(a) as proposed. (a) In accordance with the provisions of the Helsinki Declaration [12] and takes into account the guidelines ~~for its application prepared~~ published by the		

					Council for International Organizations of Medical Sciences (CIOMS) [13], together with the recommendations of the International Commission on Radiological Protection (ICRP) [14];		
Israel	Req.38	"are only delivered after protection has been optimized" instead of "are optimized"	The expression "optimized medical exposure" is not clear. Protection should be optimized:	X	1. Agreed. It is the protection rather than the exposure that should be optimized. (The word "optimized" is used and mis-used in many ways in various publications on medical uses of radiation.) 2. Consistency with Requirement 11. Change Requirement 38 to read: Requirement 38: Optimization of protection and safety Registrants and licensees and radiological medical practitioners shall ensure that for each medical exposure~~s~~ ~~are~~ the protection and safety is optimized.		

UK	Req. 38:	Modify to read: "Registrants and licensees, radiological medical practitioners **and medical radiation technologists** shall ensure that medical exposures are optimized."	Omission.			X	1. No change is needed as the definition of radiological medical practitioner, together with that of a health professional, provides the flexibility to accommodate different national regulations..
USA	Req. 11; Req. 38	The title for requirements 11 and 38 differ, but concern similar topics. Recommend using the same title for both requirements.	Editorial suggestion. The requirements will read better if things are referred to consistently.	X	See change above, in response to comment from Israel on Req 38.		
Austria	3.160	[…] can influence the delivery of ~~the~~ radiation				X	1. The definite article establishes a link between the equipment and the radiation from that equipment.
Austria	3.161	For diagnostic radiological procedures and image-guided interventional procedures, the radiological medical practitioner shall, in cooperation with the medical radiation technologist, the medical physicist, and the radiopharmacist, if appropriate, ensure that the following are used: (a) Appropriate medical radiological equipment and software and, for nuclear medicine, also appropriate radiopharmaceuticals	Radiology and nuclear medicine should be considered in two separate paragraphs in order to avoid confusion.			X	1. No confusion has been identified. 2. The definition of radiological procedure provided in the glossary (page 158) is such that the use of the term "diagnostic radiological procedures" means both diagnostic radiology and diagnostic nuclear medicine. 3. Requirements 3.161, 3.162 & 3.163, collectively, cover all radiological procedures, but each particular addresses subsets of radiological

							procedures that have commonality in terms of the approach to optimization.
Austria	3.161. b)	[…] taking into account relevant ~~norms~~ standards of […]				X	1. "Norms" was the word used in BSS 115.
Finland	3.161.	…and the radiochemist or radiopharmacist…	This is country specific which professionals are available.	X	Change the stem of 3.161 to be: 3.161. For diagnostic radiological procedures and image-guided interventional procedures, the radiological medical practitioner shall, in cooperation with the medical radiation technologist, the medical physicist, and the radiopharmacist or radiochemist, if appropriate, ensure that the following are used: Change the Glossary entry for radiopharmacist to: **radiopharmacist** (new term) A health professional, with education and specialist training in radiopharmacy and/or radiochemistry, who is competent to prepare and dispense		

					radiopharmaceuticals used for the purposes of medical diagnosis and therapy. Θ Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of radiopharmacists. States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee to act as a radiopharmacist and decide, based either on international standards or standards of a State where such a system exists, whether such an individual can undertake the functions of a radiopharmacist. Θ Some Member States may use different terms, such as radiochemist, but regardless of terminology the necessary		

					competence in the preparation and dispensing of radiopharmaceuticals for the purpose of medical diagnosis or therapy remains the same.		
Norway	3.161		We welcome this paragraph since it put focus on multidisciplinary cooperation in the process of optimization.	X	No change.		
ICRP	3.161		The occupation medical physicist is introduced. Although not an ICRP issue, this might create problems to several countries in the implementation of the BSS recommendations.			X	1. This isa generic comment, no changes are proposed. 2. The definition of medical physicist and its explanatory note provided in the glossary give flexibility for the implementation of the BSS requirements in Member States (e.g. .mechanisms for registration, accreditation or certification).
USA	3.161	No change necessary.	We like section 3.161 since it calls for optimization of medical exposures, i.e. striking the balance between image quality and dose.	X	No change.		
USA	3.161 (3.162)	Consider to delete “operational considerations”	Should the header from the old draft “operational considerations” be deleted, as the earlier header was?			X	1. The sub-headings originate from BSS 115. It is felt that they add clarity to the requirements.

USA	3.161	Consider revision.	Operational considerations: 3.161 would the word "as appropriate" be better than "if appropriate"			X	1. The "if appropriate" is qualifying the radiopharmacist (and radiochemist from new change) only.
Australia	3.163	Delete "while the activity in the rest of the body is kept as low as reasonably achievable."	Once administration of the prescribed activity of the chemical/physical form of the radionuclides has occurred the *in vivo* distribution of the radionuclide is, in most cases, outside the control of the radiological medical practitioner, medical physicist, medical radiation technologist, or radiopharmacist. Whilst localisation primarily in the organ(s) of interest, and low activity in the rest of the body are the desiderata, these two factors are functions of the chemical/physical nature of the radiopharmaceutical and in many cases will not be able to be manipulated separately			X	1. The comment is correct once administration occurs, but the purpose of the text is to influence the ensuing distribution before the administration occurs (i.e. the choice of radiopharmaceutical). The selection of one radiopharmaceutical over another can influence the resulting dose distribution in non-target organs, and this is part of optimization.
Finland	3.163.	…and the radiochemist or radiopharmacist…	This is country specific which professionals are available.	X	Change 3.163 (in line with 3.161) to: 3.163. For therapeutic radiological procedures involving administered radiopharmaceuticals, the radiological medical practitioner shall, in cooperation with the medical physicist, the medical radiation technologist, and the radiopharmacist or radiochemist, if		

					appropriate, ensure that for each patient the appropriate radiopharmaceutical and activity are selected and administered so that the activity is primarily localised in the organ(s) of interest, while the activity in the rest of the body is kept as low as reasonably achievable.		
India	3.163	**Comment: In this entire para there is no mention of RSO / RPO and the nursing staff though the dose optimization is a team effort, specially so in nuclear medicines.**				X	1. 3.163 is a requirement for optimization in medical exposures – i.e. looking after the patient. Radiation protection most certainly is a team effort, and the RPO has responsibilities for occupational radiation protection, etc.
Sweden	3.163., first line	administered ~~radionuclides~~ **radiopharmaceuticals**	"radiopharmaceuticals" is the proper word in medical applications.	X	Noting the discussion in the right-hand column, change to the use of "radiopharmaceuticals" in 3.163, 3.164, 3.173, 3.175, as indicated above and below.		1. "Administered radionuclides" is the terminology used in BSS 115. 2. The ICRP in Pub 94 uses the term "unsealed radionuclides" in the title. In the document itself both "unsealed radionuclides" and "radiopharmaceuticals" are used, with no

							obvious logic for when one term is used in preference to the other. 3. Further, it is noted that the current text in 3.163 uses both "administered radionuclides", in line 1, and "radiopharmaceutical" in line 4. 4. Other relevant requirements are 3.164, 3.173, 3.175, where the combined terminology of "unsealed radionuclides or radiopharmaceuticals" is used.
Sweden	3.164., 3.173., 3.175.	… ~~unsealed radionuclides or~~ radiopharmaceuticals …	No other unsealed radionuclides than radiopharmaceuticals are used in medical applications.	X	Change 3.164(f) to: (f) Exposure of a child as a result of a breast-feeding female undergoing a radiological procedure with ~~unsealed radionuclides or~~ radiopharmaceuticals.		
Austria	3.164	Considerations with regard to dose for a specific procedure should already be included in the justification process.				X	1. This requirement is about ensuring that the process of the optimization of protection considers, inter alia, the particular features of exposures involving higher doses that are amenable to

							being optimized. Optimization is about tailoring the actual exposure to actual patient.
Ireland	3.164 & 3.174	It would be useful to put 'significant dose' in context e.g. 'in relation to dose limits or constraints relating to members of the public'?				X	1. While the term "significant dose" may seem vague, in practical usage it is seldom a problem. Such phrases are very common in legislation and regulations around the world. 2. Assigning a value or a fraction of a dose limit or constraint introduces an artificial line. Just above the value is significant, while just below is not; and of course this is nonsense. 3. Elaboration would be done in the Safety Guide.
Ukraine	3.164	It is suggested the following wording: registrants and licensees shall ensure that the optimization process considers the unique aspects of medical exposures involving: (a) Pediatric patients; (b) Individuals as part of a heath screening program (c) Volunteers as part of a biomedical research project (d) Relatively high doses to the patients	Clarification			X	1. The purpose of 3.164(e) is to ensure appropriate optimization for those cases when pregnancy is known, and the embryo/foetus will be exposed. 2. Requirement 3.173 and 3.174 (in particular) address the issue around maybe

		(e) Exposure of an embryo or fetus, particularly for radiological procedures where the abdomen or pelvis of the women who is *or might be pregnant* is in the useful beam or may receive a significant dose.					being pregnant.
Austria	3.164. Footnote 29	Please clarify the last sentence in the footnote.		X.	Text of footnote has been modified:		
Sweden	Footnote 29, p. 82, bottom line.	… dose procedures in nuclear medicine**, first of all therapeutic, but also diagnostic**.	Nuclear medicine should be specified.	X	Text of footnote has been modified:		
USA	3.164d, Footnote 29, Lines 3-4	Revise the sentence "Similarly for image-guided interventional procedures …" It is a sentence fragment.	This sentence is incomplete,	X	Text of footnote has been modified:		
France	3.164 And Foot note 29	Replace unique by ***specific*** : "… that the optimization process considers the unique aspect…" By "… that the optimization process considers the ***specific*** aspect"	The use of the word "***unique***" in the first sentence is not clear.			X	1. The word "unique" was chosen to indicate the special and particular aspects of each of the situations. I.e. those aspects over and above those common to other situations.
France	3.164-d	Delete ***3.164-d***: **relatively high doses to the patient** and the **foot note 29.**	The 3.164-d and the associated foot note are very ambiguous: the comparison between scanography and conventional radiology and comparison between radiation oncology and nuclear medicine are not relevant as far as medical practices have been justified.			X	1. See change above in response to comment from Austria.

Iran	Article 3.165 line1	Registrant and licensee, in therapeutic use of radiation, shall ensure that:	Ensuring of Calibration is the responsibility of licensee, but calibration should be done by physicist or under his supervision. Also calibration is important in therapeutic uses not for all application of radiation in medicine.	X	1. The comment re the licensee responsibility is correct, and this gives greater consistency with 3.166 – 3.169, all of which link back to 3.152. Change the stem of 3.165 to: In accordance with para. 3.152 (d) & (e), the medical physicist shall ensure that:		
Finland	3.165.	Registrants and licensees shall ensure that:	It should be required that a medical physicist is involved in radiation therapy for calibration and consulted in nuclear medicine and diagnostic radiology.	X	1. As above for comment from Iran for 3.165.		
UK	3.165		Calibration for dosemeters used in patient dosimetry must be traceable to national standards. This requirement does not appear to have been stated anywhere in the past. Although any Medical Physics Expert (MEP) would do this, the requirement for the calibration of measurement equipment to be traceable to national standards should be included in this document.			X	1. Not all Member States have national standards. Instead 3.165(d) makes the required traceability to a standards dosimetry laboratory (which may be in another Member State). 2. Standards dosimetry laboratory is defined in the Glossary.

NEA	Para 3.165	ADD: …(e)**The calibration is reflected in the treatment programming software**…	The EGIR feels strongly that this addition is necessary to assure that new source installation, requiring calibration, are appropriately implemented in the software to avoid accidents.			X	1. This point is implicitly covered by 3.165(c) referring to "prior clinical use", since calibration includes everything (equipment and software) .This will be elaborated in the Safety Guide.
Austria	3.165. b)		Calibration and maintenance intervals could also be subject to national and / or international standards.			X	The registrant or licensee must follow standard set by the regulatory body.
ICRP	pg 83, 3.165(a) line 1	An appropriate expression for this purpose would be "Radioactive materials and doses used in medical prescriptions are calibrated….".	Radiation sources are not used "for medical exposure". Medical exposures are byproduct of radiological procedures. Note that diagnostic x-rays are not calibrated.			X	1. Source is a defined term in the glossary, and includes radiation generators, radioactive sources, etc. 2. Medical exposure versus the radiological procedure that leads to medical exposure is a moot point. The current wording is not wrong. 3. Diagnostic X-ray units are calibrated, in the sense that their output, linearity, reproducibility, etc are assessed.
USA	3.165	Include a provision that addresses the acquisition or modification of diagnostic or therapeutic equipment software.	Hundreds of over exposures have been attributed to misuse, or modification, of equipment software.			X	1. Comment is sound, but is better placed in QA (3.169). See below.

USA	3.165c	Revision for clarity of requirement is needed. Calibration: 3.165 (c): "prior to clinical use….. are independently verified (by a different medical physicist)".	What if the facility only has one? How can this be achieved? It is not clear what independent verification would entail			X	1. The footnote 30 elaborates on independent verification. It does not say that a 2nd medical physicist will always be needed.
Sweden	3.165., (d)	…, is traceable to a **primary or secondary** standards dosimetry laboratory.	It may be good to clearly point out that a secondary standards laboratory is OK.			X	1. Standards dosimetry laboratory is defined in the Glossary, and includes both primary and secondary standards.
UAE	3.165(d)	Add 'and that records of relevant procedures and results are maintained.'				X	1. Requirements for records are given elsewhere (3.169(d), 3.182). 2. See also changes to 3.181-3.183.
Sweden	3.166., (c)	… by the radiological medical practitioner **or the medical physicist**.	The expert in dosimetry shall have an influence on what is measured!			X	1. The radiological medical practitioner has overall responsibility for patient protection and is the one who defines the organs/tissues of interest based on clinical conditions.
USA	3.166	Add another bullet to read as follows: "The dose information for the patient shall be kept as specified by the regulatory body."	This type of information must be kept for a long time for legal and medical reasons.			X	1. A requirement for records is in the stem of 3.166. 2. Further requirements for records of patient exposures are made elsewhere (3.183). 3. See also changes to

							3.181-3.183.
Finland	3.168.	…radiochemists or radiopharmacists…	This is country specific which professionals are available.	X	Change 3.168 to: 3.168. Registrants and licensees, as part of applying the relevant management system requirements of these Standards, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of the medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization (WHO) the Pan American Health Organization (PAHO) and relevant professional bodies shall be taken into		

					account.		
USA	3.168	No change necessary.	Section 3.168 calls for quality assurance for medical X-ray applications. We think this is a good idea and recommend that it be retained.	X	. No change.		
USA	3.168	Consider reinserting phrase Registrants and licensees, as part of applying the relevant management system requirements of these Standards, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of the medical physicists, radiological medical practitioners, and in conjunction with other health professionals as appropriate, including medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists, taking into account the principles established by the World Health Organization (WHO) the Pan American Health Organization (PAHO) and relevant professional bodies.	It is not clear why the phrase "and in conjunction with other health professionals as appropriate," has been deleted from the text of this requirement.	X	1. The current wording states explicitly who must be involved - medical physicists, radiological medical practitioners and MRTs, plus radiopharmacists in some case. 2. However, other health professionals might conceivably include nurses, dental assistants. 3. The proposed text puts the others in the wrong place – MRTs must be involved. Change as indicated above for comment from Finland.		
NEA	Para 3.168	MODIFY: … technologists**, and other health professionals as appropriate,** and,…	The EGIR feels that; the purpose of this list of various types of professionals is to provide examples of those whose active participation is required. However, this short list can be taken as a limit to the range of health professionals that should participate in the programme of quality assurance. The professionals not contained in the list include nurses, midwives, and so on. It is almost impossible to cover the all	X	See change in response to USA comments on 3.168, above.		

			relevant professionals because job titles and scopes of their works vary among nations. The proposed text would address this issue.				
Japan	3.168	3.168 (3.168 should be replaced by) ... with the active participation of relevant heaith professionals including the medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists.	The purpose of this listing is to provide examples whose active participations required, but taken as it range of professionals participate programme it are can be limits the to of health can the quality assurance. The professionals not contained in the list include nurses, midwives, and so on. It is almost impossible to cover the all relevant professionals because job titles and scopes of their works vary among nations. Thus we have two options; putting some words indicating the list is just providing examples or putting comprehensive words like "relevant health professionals".	X	See change in response to Finland & USA comments on 3.168, above.		
IRPA	3.168/line 3	…medical exposure under the primary responsibility of the medical physicists, with the active participation of the radiological medical practitioners, radiation protection experts, medical radiation technologists and, for …	The medical physicist should be specifically given the primary responsibility for this programme, and a radiation protection expert should be an active participant.			X	1. Previous drafts had the medical physicist with prime responsibility, but the decision was made that the most important aspect ws that all professionals are involved in the QA programme, and that there should be flexibility to suit local conditions. Hence the current wording.
Austria	3.169	that could affect ~~patient protection~~ **relevant parameters**				X	1. "Relevant parameters" is too vague – the issue is impact on patient protection.

Brazil	3.169	**in nuclear medicine there shall be in place a quality control programme for all radiopharmaceuticals produced or in use at the facility.**	To include in quality assurance for medical exposures			X	1. "Medical radiological equipment" includes imaging devices used in nuclear medicine. 2. The requirements for calibration 3.165(a) include unsealed sources (radiopharmaceuticals) used in nuclear medicine. 3. A quality assurance programme for the production of radiopharmaceuticals is outside the scope of this requirement. 4. Generic requirements 3.48(a) & (b) include radiopharmaceuticals, but maybe this could be improved.
France	3.169	Add : ***f- Registration and analysis system of events involving or potentially involving accidental or unintended exposure;*** ***g- For radiotherapeutic practices, a study of risks of accidental or unintended medical exposure.***	The findings of the Versailles conference organized by ASN "Modern radiotherapy: Advances and challenges in radiation protection of patients" in December 2009 shown the importance of events registration and analysis. This requirement is also relevant in interventional radiology. It is really an important part of the quality assurance program. At this conference it was also demonstrated the interest of risk analysis in radiotherapy.			X	1. Investigation of unintended and accidental medical exposures is covered in requirements 3.178 & 3.179. 2. It is noted that the proposal in (f) goes further, requiring a registration and analysis system. 3. The radiological review in requirement 3.180 implicitly

							addresses point (f), and this would be elaborated in the Safety Guide. 4. A requirement for a study of risks of unintended and accidental medical exposures in radiotherapy is beyond the scope of the Basic Safety Standards.
Iran	Article 3.169 (a) line 1	Measurements of the physical parameters of medical radiological equipment:	In all parts of medical exposure there is too emphasis on the role of medical physicist. For measuring physical parameters it is too details to say by who it should be done and in this case qualified expert is more proper.			X	1. The medical physicist is the qualified expert in this case.
UK	3.169		This paragraph states that measurements by, or under the oversight of, a medical physicist after any major maintenance that affects patient radiation protection shall be included in a programme of quality assurance for medical exposures. We are not sure that a medical physicist always does these measurements. We often advise that they (registrants) do their own in-house quality control and if there are no changes, they don't need to involve medical physicists.			X	1. The medical physicist may be providing only oversight. Note, requirements 3.152(d) & (e) also give context on the role of the medical physicist in quality assurance.
USA	3.169(a)	Include a provision that addresses the acquisition or modification of diagnostic or therapeutic equipment software.	Hundreds of over exposures have been attributed to misuse, or modification, of equipment software. See also comment number 82.	X	Add the following to 3.169(a): (iv) After any installation of new or modification of existing software that could affect patient protection;		

Ireland	3.169 (a)	Rewrite "under the oversight of" as "overseen by".				X	See previous comment above.
UK	3.170		It is a good idea to include equipment in the regular and independent audits of the programme of quality assurance for medical exposures. However, we don't remember seeing this requirement previously.			X	1. The audit is of the whole programme (as in 3.169) and hence includes equipment.
Austria	3.172	[…] part of the proposal for ~~the~~ biomedical research […]				X	1. The definite article is needed because a particular given research programme is the focus of the requirement.
UK	3.173		While we agree that it is good practice to display signs prominently for pregnant and breastfeeding female patients scheduled to undergo a radiological procedure, we have never before seen it as a requirement.			X	1. It is not clear whether it is being proposed to delete this requirement. 2. This is a practicable measure to prevent unintended exposures of embryo, fetus and/or breastfed infants and needs to be retained.
Austria	3.173	External and potential internal exposure are used in the same sentence and might cause confusion. Two separate paragraphs would be necessary.		X	Change 3.173 to: 3.173. Registrants and licensees shall ensure that there are signs in appropriate languages in public places, patient waiting rooms, cubicles and other appropriate places, and other communication methods as		

					appropriate, requesting a female patient to notify the radiological medical practitioner, medical radiation technologist or other personnel if: (a) she is or might be pregnant; (b) she is breast-feeding and the scheduled radiological procedure involves the administration of ~~an unsealed radionuclide or~~ radiopharmaceutical. Also change 3.175 (to be consistent with 3.163, 3.164, 3.173) to: 3.175. Registrants and licensees shall ensure that there are arrangements in place to establish that a female is not breast-feeding before the performance of any radiological procedure involving the administration of ~~an unsealed radionuclide or~~ a radiopharmaceutical that may give a significant dose to an infant being breast-		

					fed, so that this information can be considered in the justification for the radiological procedure (see para. 3.153) and in its optimization (see para. 3.164). Also change 3.174 so that: 3.174. Registrants and licensees shall ensure that there are procedures in place to ascertain the pregnancy status of a female of reproductive capacity before the performance of any radiological procedure that may give a significant dose to the embryo or foetus, so that this information can be considered in the justification for the radiological procedure (see para. 3.153) and in its optimization (see para. 3.164).		
Ireland	3.173	In the first sentence include the word "relevant" before "personnel"		X	See above change for Austria comment on 3.173.		
Austria	3.173	in all languages ~~appropriate for~~ **expected to be understood by** the ethnicities of persons		X	See above change for Austria comment on		

		normally served			3.173.		
Spain	3.174	Registrants and licensees shall ensure that there are procedures in place to ascertain, <u>if necessary</u> the pregnancy status of a female of reproductive capacity before performing any radiological procedure that may give a significant dose to the embryo or foetus	Ascertain the pregnancy status of a female of reproductive capacity before performing any radiological procedure is a measure that would make the radiological procedures slower and more expensive than now.			X	1. Requirement 3.174 already contains the qualifier "… before performing any radiological procedure that may give a significant dose to the embryo or foetus." 2. These are the situations when it is necessary.
ICRP	pg 86, Req. 40	This topic may be moved to the public exposure section.	Release of patients after radionuclide therapy is mainly related to public exposures (although it also is related to medical exposure of carers at home).			X	1. The comment re public exposure is correct, but the topic's location in the medical exposure section has synergy with the rest of the section. 2. Further, any ensuing public exposure is arising from the patient having had (or in fact is still receiving) a medical exposure. 3. And as noted, it is related to medical exposure of carers and comforters at home. 4. ICRP 103 paragraph 353 in the Medical Exposures Chapter 7 addresses, inter alia, the release of patients. Presumably for the same reasons of synergy.

Austria	3.176		The “radiation protection officer” is new terminology here. Earlier, “qualified experts” where introduced. Please explain or define.			X	The radiation protection officer is a defined term in the Glossary.
Israel	3.176	We suggest adding dose limits or indicate bibliography for the permitted doses for: release of the patient from hospital, to family members, to comforters, to public.				X	1. Early drafts did include dose limits, but ensuing discussions led to the decision that application of dose limits was seen as being understood, and that the levels set by the authorities in 3.147(b), and implemented in 3.176, would be based on ensuring compliance with the dose limits. 2. The Safety Guide will contain technical details and discussions.
Iran	Article 3.176 line3, page 86	Medical physicists should be deleted	Establishing criteria for releasing patients should be the responsibility of RPO not physicists			X	1. The requirement is for ensuring criteria are met, not establishing the criteria. Both the medical physicist and the radiation protection officer have the requisite expertise to do this.
USA	3.176(a)	Consider dose based performance criteria.	No guidance, neither a dose limit to members of the public or a limit on the amount of radio-isotope administered, is provided for patient release. Is there a specific release criteria, for example, 1 or 5 mSv in a year, that could be included?			X	1. As noted above in response to Israel on 3.176. 2. Examples would be developed in the Safety Guide.

USA	3.176	Consider modification or elaboration	Unlike some other sections, it is not obvious how exposures from a released patient are to be treated. The exposure of the patient, and subsequent release, is a planned exposure situation. But how would any response to the contamination or exposure to the patient be handled, since it must be assumed that the release is the equivalent to an exemption or clearance action.			X	1. As noted above in response to ICRP comment to 3.176, there are difficulties in where best to place requirements addressing the release of patients. 2. Two categories of persons may be exposed by a released patient – carers and comforters, and members of the public. 3. Radiation protection for the former category are afforded through dose constraints (Requirements 3.171, and 3.147(a)(i)). Exposure of the public from planned situations is covered extensively in paras 3.116-3.142. 4. On release of a patient, a member of the public can be exposed through external irradiation or through contamination. 5. The criteria for release must be such that scenarios for either or both of these pathways cannot lead to a member of the public being exposed to a level exceeding

							the public dose limits.
France	Req. 41	Add at the end of the requirement: ***Accidental or unintended medical exposures shall be notified to regulatory body.***	The notification of events to regulatory body is important to organize as appropriate the feed back experience.			X	1. Requirement 41, and its associated requirements 3.177-3.179, addresses all unintended and accidental medical exposures. These can range from minor to lethal – all need appropriate investigation and follow up by the licensee, but not all warrant mandatory notification to the regulatory body. 2. Requirement 3.179(d) includes requirements for when the regulatory body must be notified. 3. Universal mandated reporting to the regulatory body can be counter-productive, leading to the suppression of unintended or accidental exposures. It is more helpful to have an open learning culture, whereby the incident is used to improve the situation for the future. 4. The regulatory body will always have access to the

							investigation reports in the course of their routine inspections, and the perusal of such reports is an important activity of the regulatory body. 5. The conclusion not to change is consistent with the guidance given by RASSC 28.
ICRP	pg 86, Req. 41	This section may be moved to the section deals with the potential exposure. Use of a term 'accidental medical exposure' should be avoided.	Unintended or accidental exposures in medicine are not medical exposures because a medical exposure is an exposure incurred by patients *as part of* their own diagnosis or treatment by the definition. Note that accidental exposures are not a part of medical procedures but depart from the procedures. Most of all, these exposures are *uncontrolled* exposure and hence belong to accidents. Prevention of such an accident is matter of potential exposure in medicine.			X	1. As noted above in the response to the ICRP comment on 3.143, the definition of medical exposure in the BSS 3.0 differs slightly, but importantly, from that in ICRP 103 and BSS 115. There is a deliberate de-coupling of the exposure and the patient, so that when the wrong part of the patient is exposed, or the wrong patient is exposed etc, then these situations are still covered by the requirements for medical exposure. The reasons for this are explained above (see 3.143).
Israel	3.177	"Registrants" instead of "Registrant"	Editorial	X			

IRPA	3.178(a) /Line 2	…or with a dose, quantity or dose fractionation…	The incorrect quantity of radiopharmaceutical may be administered.			X	If an incorrect quantity of radiopharmaceutical is administered, then an incorrect activity will be administered and the **dose** will differ (above or below) from the prescription. Therefore quantity and activity is covered by the word "DOSE".
UK	3.178 (c)		Clarification is needed. The phrase "substantially greater than intended" needs to be defined, using another schedule or in a separate, referenced document.			X	1. Expressions such as "substantially greater than intended" are quite common in legislation and regulations in many countries in many spheres of activity. They generally do not pose problems in implementation – common sense prevails. 2. As soon as you assign a number, then you have created an artificial divide – being just above the value is treated differently to being just below the threshold. 3. The UK in its IRM(ME)Regs 2000, Art 4.5, uses the expression "much greater than intended".

UK	3.178 (d)		There is a requirement to investigate any inadvertent exposure of the fetus in the course of performing a radiological procedure. We have just stopped doing this for everything but doses likely to be greater than 10 mGy or if the procedure broke down requiring formal notification. The reason for this was that we were just getting too many requests, usually via clinicians. The advice give to them was always the same, i.e. that the risks to the fetus from the radiation were very small in comparison to other naturally occurring risks.			X	This comment seems to be on 3.178 (e). 1. Practicalities are an issue, but a standard operating procedure to streamline confirmed low dose situations would still satisfy the requirement. 2. Indeed, according to the comments, they confirm whether the dose to the embryo or fetus is below that level (which is at least an estimation/confirmation).
UK	3.179		It would also be useful to consider whether the doses could result in any health effects for which treatment may be required.			X	1. This is implicit in determining the doses and distributions. Further elaboration would be given in the Safety Guide.
UK	3.179 (e)	Modify to read: "Inform the referring medical practitioner and the patient**, or the patient's guardian/ representative** about the unintended…"	The patient may be a child or other person unable to understand the concept or consequences of an accidental exposure, therefore his/her parent or some other representative would be more appropriate. In some cases, informing the patient may cause unnecessary anguish and the patient's consultant may view it as in the patient's interest to not inform the patient.	X	Change 3.179(e) to include high-lighted text: (e) Inform the referring medical practitioner and the patient or a legal authorized representative about the unintended or accidental medical exposure, as appropriate. Same change also		

					made to 3.149(d), above. Note: "the patient or a legal authorized representative" is the wording used in the Declaration of Helsinki.		
Israel	3.179(e)	Add "or the legal guardian of the patient" after "patient"	To account for patients who cannot be informed, as in para. 3.176(b)	X	As above for the UK comment on 3.179(e).		
IRPA	3.179 (e)	Inform the referring medical practitioner and the patient (or patient's representative) about the unintended or accidental medical exposure, as appropriate.	The patient may be a child or other person unable to understand the concept or consequences of an accidental exposure, therefore his/her parent or some other representative would more appropriate. In some cases, it may not be in the patient's interest to inform the patient.	X	As above for the UK comment on 3.179(e).		
Germany	Para. 3.179 (e)	Modify …medical practitioner, the patient and the carer or comforter …	To cover the case where the patient is a child	X	As above for the UK comment on 3.179(e). 1. Carers and comforters are not always the legal authorized representatives for a child patient.		
ILO UK (employers)	3.179 e	Inform the referring medical practitioner and the patient, or the patients guardian (representative??),….	Patient may not be able to understand the implications because of age etc.	X	As above for the UK comment on 3.179(e).		

NEA	3.179(e)	MODIFY: … the patient**, or the patient`s guardian/representative,** about…	The EGIR felt that it is very important to assure that those legally acting on behalf of those not in a position to act on their own behalf are required to be informed.	X	As above for the UK comment on 3.179(e).		
Israel	Req. 42	"medical radiation facilities" instead of "a medical radiation facility"	Editorial	X	Change Req 42 to: Registrants and licensees shall ensure that periodic radiological reviews are performed at medical radiation facilities and that records are kept.		
ICRP	pg 88, Req. 42 line 3	"and records are kept"		X	See above change.		
Finland	3.180	broaden the radiological review to clinical audit	Clinical and radiological audits should not be separated			X	1. A true clinical audit has a medical brief, and hence is much wider than the scope of the BSS with its set of basic requirements for radiation protection. 2. The radiation protection focus of the radiological review is quite clearly stated in 3.180. 3. It is noted that the definition of the previous term "radiological audit" was inadvertently left in the Glossary and this may have been confusing.

Norway	3.180	The concept of radiological review should be broadened to clinical audit.	In the section on medical exposures the concept of clinical audit is missing which is a requirement in the draft Euratom BSS Directive.			X	As for response to comment from Finland on 3.180.
Israel	3.180	"medical radiation facility" instead of "medical facility"	Term defined in the glossary	X			
Denmark	3.180 (+ heading above)	*Clinical audit* (instead of "radiological review")	Clinical and radiological audits should not be separated			X	As for response to comment from Finland on 3.180.
Sweden	3.180	Broaden the radiological review to clinical audit	Clinical and radiological should not be separated			X	As for response to comment from Finland on 3.180.
USA	3.183	Include a provision for maintaining records concerning the installation and testing of new equipment/software and repairs/modifications of equipment/software and their certification/acceptance.	Completeness.	X	1. There are various requirements for records and documentation in the Medical Exposures section, so perhaps 3.181 to 3.183 could be better focused and comprehensive. 2. Namely: 3.181 becomes personnel focused; 3.182, calibration, dosimetry, QA and investigations focused; and 3.183 retains its patient focus. 3. The comment is addressed by the new 3.182 which would include equipment/software testing implicitly. Details would be		

					elaborated in the Safety Guide. Change stem of 3.181 to: 3.181. Registrants and licensees shall keep for a period specified by the regulatory body and shall make available, as required, the following records for personnel responsibilities and radiation protection training: Change 3.182 to: 3.182. Registrants and licensees shall keep for a period specified by the regulatory body and shall make available, as required, the following calibration, dosimetry, and quality assurance records: (a) Results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments; (b) Records of clinical dosimetry (see para 3.166);		

					(c) Records of local assessments and reviews made with respect to diagnostic reference levels (see para 3.167); (d) Records associated with the programme of quality assurance (see 3.169(d)); Change stem of 3.183 to: 3.183. Registrants and licensees shall keep for a period specified by the regulatory body and shall make available, as required, the following records of medical exposure: And add: (f) Reports on investigations of unintended and accidental medical exposures (see para 3.179(d)).		
USA	3.183/ line 2	Consider modification: . . . the following records of patient exposures:	If patient exposure information is to be retained, the requirements should be clearly stated, as specified by the regulatory body.	X	As above.		
UK	3.183 (b)		There is a requirement to keep a record of the screening time and the number of images acquired in image-guided interventional procedures. We would			X	1. The key aspect of the requirement is "necessary information to allow retrospective

			prefer dose area product and entrance surface dose index as being more related to dose. Recording the number of images can be difficult as it is necessary to add up the images in runs.				dose assessment". This qualifier should be sufficient in itself, but there are many ways for such assessments, with varying degrees of uncertainty. For this reason, the fluoroscopy time and number of images were added to represent the bare minimum. Other equivalent (or better solutions) would be acceptable. Elaboration will be given in the Safety Guide.
Brazil	3.183.c)	In nuclear medicine, types of radiopharmaceuticals administered and their activities, specific examination, **reference on supplier and production batch, as applicable**	These are also relevant information to be recorded.			X	1. The requirements for patient exposure records represent the acceptable minimum. Clearly more detail is better, but the suggestion is probably far from being basic requirements.
Israel	3.183(d)	Add "and isodose distribution charts" before "or alternative equivalent information"	The information provided by isodode distribution charts is important			X	1. The requirements for patient exposure records in therapy represent the acceptable minimum. Additional information can also be recorded.

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 4: Emergency Exposure Situations							
Norway	Chapter 4	Concept of averted dose	The concept of averted dose is used in emergency planning and still appears in the IAEA standards GS R- 2 on emergency preparedness, but is no longer mentioned in the BSS. It is proposed to either insert parts of the GS R-2 into the International BSS or to make more extensive reference to the requirements of GS R-2. This proposal is made especially in view of the completeness and "stand alone" of the document.			**v**	The detailed information is provided in the DS-44 (Safety Guide)
Spain	Chapter 4 General.	There are several important ideas in publications ICRP-109 and 111 which have not been sufficiently considered in this chapter as it is now.	N/A			**v**	Fundamental ideas of ICRP 103 and 109 were considered and included (e.g. para 4.8)
China	Section 4	Suggest to add one more Paragraph about "optimization and rationalization principles of the emergency exposure" .	Refer to the relevant content in ICRP publication No.109.			**v**	Included already in paragraphs 4.5, 4.7, 4.8.

Denmark	General comment	*GS R-2:* It is proposed to either insert parts of the GS R-2 into the International BSS or to make more extensive reference to the requirements of GS R-2. This proposal is made especially in view of the completeness and "*stand alone*" of the document.	The concept of averted dose is used in emergency planning and still appears in the IAEA standards GS R- 2 on emergency preparedness. It is proposed to either insert parts of the GS R-2 into the International BSS or to make more extensive reference to the requirements of GS R-2. This proposal is made especially in view of the completeness and "*stand alone*" of the document.			**x**	The section along lines of the DPP as agreed by CSS. The detailed information is provided in the Safety Guide DS-44.
ILO Finland (Trade Union)	Emergency exposure situations	It would be useful to know in advance who is obliged to take action.	The SAK agrees with the draft version, where it provided that any exceptional exposure of emergency workers to radiation must be taken into account and that, whenever it is possible that the radiation dose received will exceed the single year dose limit for occupational exposure (4.17), participation in emergency work is voluntary.			**x**	The definition of emergency worker (see Glossary) describes who is covered under this category. Further detailed guidance is provided in Agency documents and training material.
Poland	General comment	Re-consider the use of guidance levels for emergency workers, deleting Table IV-2 and by referring to the requirement that the emergency radiation worker consciously accepts the radiation risk generated by his/her working conditions, and that clear evidence of his/her sufficient and continuous training is provided and documented.	Guidance levels, as set out in Table IV-2 for emergency workers, will tend to be interpreted as dose limits, prohibiting emergency interventions. By analogy, any "constraint" which would limit the fireman from entering the fire is useless – it is the qualifications and training which makes his emergency work reasonable and socially acceptable.			**x**	Table IV-2 represents the important information for emergency workers efficient actions and protection in an emergency.
ICRP	pg 90, 4.1 line 2	Delete "in preparedness for and".	Emergency preparedness is not a task performed in emergency exposure situations. Rather, it is a task carried			**x**	Efficient emergency response is a result of the adequate emergency

			out before an emergency arises. The right place where the emergency planning and preparedness should appear is in the section deals with potential exposure. Problems in the same context are found in the subsequent subsections titled "general requirements" and "public exposure".				preparedness. These are two parts if one area and should be described and presented together.
Denmark	4.2	…protect human life *and the society* in the event of …				**x**	The current text in 4.2 is in line with the fundamental safety objective (SF-1, para 2.1 and 3.34.)
Norway	4.2	Proposed amendment: *"The government shall ensure that an emergency management system is established and maintained on its territories and within its jurisdiction for an emergency response to protect human life, health, the environment and the society in the event of a nuclear or radiological emergency."*	It seems self-evident that the function of the society at large is of prime importance in connection with large nuclear or radiological accidents.			**x**	The current text in 4.2 is in line with the fundamental safety objective (SF-1, para 2.1 and 3.34.)
Sweden	4.2	Protect human life and society…				**x**	The current text in 4.2 is in line with the fundamental safety objective (SF-1, para 2.1 and 3.34.)
UK	4.3/2	Modify to read: "...assessment [15] and to be able to respond effectively to **reasonably foreseeable accidents** in …"	Use of "postulated" does not create the impression of being able to predict the type of accident.		**x**		The text is modified as "…to reasonably foreseeable events (including very low

NEA	Para 4.3	MODIFY: … **to ~~postulated~~ all reasonably foreseeable** events…	The EGIR felt that the term "*postulated*" may be subject of misinterpretation. The suggested replacement, "all reasonably foreseeable " is already used in SF-1, para 3.37.		**x**		probability events)…" to address explicitly experience of Chernobyl accident, which was not "reasonably forseeable".
Japan	**4.3**	(4.3 should be replaced by) ... to be able to respond effectively to all reasonably foreseeable events in connection with facilities or activities.	As "postulated" is subject to misinterpretation, we suggest "all reasonably foreseeable events" from the expression in SF-1 paragraph 3.37. The scope on "a nuclear or radiological emergency" should be treated in the broad sense that including malicious act, dirty bomb and so on.		**x**		
UAE	Para 4.3	Replace 'threat assessment' by 'an assessment of the events and associated areas that may require protective actions to be taken and the actions that would be effective in mitigating the consequences of such events'. Para 4.5 (a) can refer to 'the assessment required by para 4.3.	The term 'threat assessment' is very misleading and should be replaced in the text by its definition.	X	"threat assessment" has been replaced by "hazard assessment"		
NEA	Para 4.5	ADD: (ei) **Provision for monitoring and dose assessment**	The EGIR felt that this element was also essential and merited listing independently to assure that this list is explicitly complete.	**x**			
Japan	4.5	(4.5 should be replaced by) These system shall provide for, inter alia, the following elements at the scene. ...	Scene on emergency in IAEA generally applies to "facility and activity", "on-site" is a restrictive expression for "facility". So, "at the scene", which is used in SF-1, is considered a prefer expression.	**x**			
Japan	4.5	A following item should be in 4.5 (k) involvement of relevant interest parties	"involvement of relevant interest parties" is also a specific important element in emergency exposure	**x**			

			situations as well as in existing exposure situations: - 5.3(d) Provide for the involvement of interested parties in decisions..., - It is essential that all aspects of the plan are consulted with relevant stakeholders, otherwise it will be more difficult to implement them during the response. (ICRP 109)				
Spain	4.5	Add a paragraph taking into account the consultation and participation of stakeholders	Clarity The active participation of the relevant stakeholders is one of the most relevant considerations when building the "emergency management system", more even in the "emergency preparedness" phase. This is not sufficiently clear in the existing text.	**x**			
Austria	4.5		In the listing there should also be the stakeholders in the early phase and late phase	**x**			
Austria	4.5		Information of the public should be more worked out	**x**			
Austria	4.5. e)	Reliable communications, […]		X			
NEA	Para 4.5(f)	MODIFY: (f)…exposed **in an emergency**, including…	The EGIR felt that this text should be added to assure clarity.	**x**			
Germany	Para. 4.5 (h)	Education and training, specifically in radiation protection, of all persons involved in response and exercising of emergency plans and procedures	To make clear that education and training in radiation protection is important for these persons and should be explicitly included.	**x**	Text modified		

NEA	Para 4.5(j)	MODIFY: … public health response to an emergency….	The EGIR felt that, as for item (f) above, this text should be added to assure clarity.	**x**			
NEA	Para 4.5	ADD**: (k) involvement of relevant parties**.	The EGIR felt that it is very important to secure involvement of all interested parties, and as such explicitly added this text.	**x**			
Slovenia	4.5	**Proposed additional text under Requirement 43**, paragraph 4.5 (new item after a): - Monitoring and dose assessment arrangements		**x**			
USA	4.5 f Line 1-3	Consider revision: Optimized protection strategies for the implementation and termination of measures to protect members of the public who may be exposed in an emergency, including considerations for protection of the environment;	Add wording "in an emergency" to clarify the conditions under which the system will apply	**x**			
USA	4.5 j Line 1	Consider revision: Arrangements for the medical and public health response to an emergency.	Add wording "to an emergency" to further clarify conditions under which the system applies.	**x**			
Ukraine	4.5	A list of system elements is left not completed - it is stated that presented elements are "inter alias". For example, "threat assessment" is included to the list but the equally essential element "emergency classification" is not. A complete list of main elements of the system shall be developed.	To clarify system's composition			**x**	For the purpose of providing complete information in ref. to [15] is added.
Iran	Article 4.6 page 91	Deleted	Surely if a state signs a convention or treaty, it shall fulfill its obligations otherwise international obligations make no sense.			**x**	It's not only obligations under Conventions, but also harmonization of arrangements and

							capabilities.
Ukraine	4.6	The following wording of the par. 4.6 is suggested: the government and relevant international organisations shall ensure coordination of emergency arrangements at national and international levels	To allocate responsibilities between stakeholders			**x**	Current text is more precise.
ILO UK (employers)	4.7	The Government shall…in order to avoid deterministic effects, *as far as practicable*, and reduce the risk of stochastic effects to the public.	In some emergency situations it may not be possible to avoid the likelihood of deterministic events	**X**	Text has been modified.		
Spain	4.7	The global strategy for protection must be justified, not only in the "planning phase", but also in the "response phase", as the same time than specific protective actions must also be individually justified as is clearly indicated in para. 4.9.	Clarity			**x**	Justification during response is explained in 4.8-4.11.
USA	4.7	Consider Elaboration.	Emergency exposure situations: 4.7: "…shall ensure that protection strategies are developed….. to avoid deterministic effects and reduce the risk of stochastic effects to the public" For example, is there a timeliness factor involved, or out to what about the distance from an incident, i.e. 10 miles out, etc.. ?	**X**	Text has been modified		
IRPA	4.7/line 3	Insert, "<u>whenever possible</u>" after "deterministic effects"	There are some emergency scenarios where planning cannot reduce the likelihood of deterministic effects to zero.	**X**	Text has been modified		

UK	4.7/3	Consider adding the following text to read; "…assessment in order to avoid deterministic effects, **as far as practicable,** and reduce the risk of stochastic…"	There are some emergency scenarios where planning cannot reduce the likelihood of deterministic effects to zero.	**X**	Text has been modified		
Germany	Para. 4.8	The following modified wording is proposed: "The response to an emergency requires careful preparedness to keep the exposure as low as reasonable achievable. (a) A reference level has to be set. The reference level indicates a level of dose above which it is inappropriate to allow exposure to occur. The reference level is typically set to be 100 mSv effective dose projected for the first year which includes dose contribution from all exposure pathways. (b) As soon as the projected dose indicates that the reference levels will be exceeded appropriate prepared countermeasures have immediately to be introduced to lower the residual dose below the reference levels. (c) Although when the dose value are projected to be below the reference levels, further efforts have to be considered to come to a residual dose as low as reasonable achievable. A protection strategy should be developed to optimise countermeasures with respect to	The meaning and function of the terms "residual dose", "projected dose" and "dose to be expected" are not clear in the current text. Therefore an alternative text is proposed. In addition, a reference level needs to be set for a time period (the first year), below the reference level, the optimization process should be emphasized; above the reference level, appropriate measures have to be taken.			**x**	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.**

		dose reduction, costs, sustainability, applicability and acceptability. (d) Derived operational intervention levels or emergency action levels are helpful for the evaluation of the radiological situation by field measurements before and after the introduction of countermeasures."					
Belgium	4.8.(a)	Replace the last sentence by: <u>The protection strategy shall be optimized so that residual doses be kept as low as reasonably achievable, even below the reference level.</u>	The reference level is a kind of predefined limit, beyond which exposure would be considered "unacceptably high", even in accidental conditions. In less unfavourable –yet accidental- conditions, efforts should be made to keep residual doses ALARA, even if already below the reference level.			**x**	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.** **The current wording does not prevent reducing doses below the reference level**
France	4.8-a	1- Replace : "The protection strategy shall be optimized to reduce residual doses below the reference level" by "***The protection strategy shall be optimized going on reducing doses below the reference level***"	The glossary definition in accordance with ICRP 103 publication state that optimization should continue to be implemented below reference level.			**x**	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.** **The current wording does not prevent reducing doses below the**

							reference level
ILO UK (employers)	4.8 a	Last sentence to read: The protection strategy shall be optimized to ensure that residual doses are as low as reasonably achievable below the reference level.	As currently written there could be seen to be no need to reduce doses other than just below the reference level.			**x**	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.** **The current wording does not prevent reducing doses below the reference level**
UK	4.8 (a), 2nd sentence	Modify to read: "The protection strategy shall be optimized to **ensure that doses are as low as reasonably achievable** below the reference level."	The current wording suggests that getting just below the reference level is sufficient.			**x**	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.** **The current wording does not prevent reducing doses below the reference level**

IRPA	4.8a	Change last sentence to "…*shall be optimized to ensure that doses <u>are as low as reasonably achievable</u> below the reference level."*	The current wording suggests that getting just below the reference level is sufficient.			x	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.** **The current wording does not prevent reducing doses below the reference level**
WNA	Specific 4.8 (a)	**Emergency** – "*A reference level, expressed in terms of residual dose, shall be set, typically between 20 mSv and 100Sv effective dose, which includes ...*" Replace '…20 mSv and 100 mSv…' with '…100 mSv and 500 mSv effective dose *(depending on the probability of occurrence, which includes…)'*	Doses between 20 und 100 mSv are received to many citizens of most countries in the world due to natural background radiation (mainly Radon) **<u>per year</u>**. The proposed reference level (20 – 100 mSv) which applies to incidences with a (very) low probability of occurrence is therefore too stringent. In populous regions such a stringent reference level (especially towards the lower end) often can't be achieved by standard designed reactors discriminating them against other production technologies, which might be less effective in protecting the environment against climate change. Exceptions for extreme situations in compliance with ICRP 103 (Para 236) are not foreseen in the current BSS draft. This makes the set of the			x	**The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109.**

			issue even worse.				
Spain	4.8.b	When applying specific protective actions it must be ensured that the optimised global strategy already decided is not disturbed. The existing text does not fully reflect this important idea.	Clarity	X	Text has been modified		
Spain	4.8.b	Based on the outcome of the optimization of the protection strategy, using the reference level, generic criteria for particular protective and other actions, expressed in terms of projected dose ~~and~~ or dose that would be expected to be received, shall be developed.	Clarity	x			
Ireland	4.8 (b)	The first sentence is difficult to understand and should be reworded.		X	Text has been modified		
UAE	Para 4.8 (b)	Restore the reference and Table IV-1 from earlier drafts.	The concepts are new and difficult and MS would benefit from this assistance.	**X**	Restored in Annex		.
UK	4.8 (b) and (c)		The terms "generic criteria" and "default triggers" should be defined in the glossary to improve the understanding of the requirements of a protection strategy, or make reference to DS44.	**x**	The definition for 'trigger' has been added to Glossary. It is considered that a definition for 'generic criteria' is not needed – dictionary meaning.		

NEA	Para 4.8(a)	MODIFY: … The protection strategy shall be optimized to **assure that residual doses are as low as reasonably achievable** ~~**reduce residual doses**~~ below the reference level.	The EGIR felt that this addition was necessary to assure that optimisation achieves doses that are ALARA.			**x**	The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109. The current wording does not prevent reducing doses below the reference level
USA	4.8a	Consider elaboration.	The reference level range is from 2 rem to 10 rem for emergency responders for their exposure from ALL pathways: does this include background and naturally occurring materials? It is implied that it is so….			**x**	This paragraph is for protection strategy for the public.
China	Para 4.8 (a), 4.8(b) and Schedule IV Table IV-1	a) Suggest to replace "…….and dose that would be expected to be received, shall be developed." in Para. 4.8 b) by "and residual dose, shall be developed.". b) The expression-way for Table IV-1 in Schedule IV needs further improvement.	The "protective actions" given in the right side of Table Ⅳ-1 should be clarified to avoid misunderstanding. The situation could not be excluded: when the external exposure and the internal exposure both exist and are just under the criteria level respectively, however the sum of two exposures are actually high enough to take protective actions. A footnote may be added to explain the measures in this situation.			**X**	Guidance is provided in the Safety Guide DS-44

ICRP	4.8(a)	Replace "optimised to reduce residual doses below the reference level" by "optimised to ensure that residual doses are ALARA below the reference level"	optimisation also applies below the RL			x	The current text is developed jointly with the ICRP and in line with the recommendations in the ICRP recommendations 103 and 109. The current wording does not prevent reducing doses below the reference level
ICRP	4.8(c) line 5	Use of the term "operational intervention level (OIL)" is questionable.	The term intervention level is no longer used in ICRP Publication 103			x	The term "operational intervention level" is different from "intervention level". It is defined in the Glossary.
France	4.8-c	2- Delete 4.8-c	All the tools for the preparedness and response of an emergency situation should be defined in a safety guide.			x	4.8c explains important step in planning and response, directly connected to steps explained in 4.8a and 4.8b.
USA	4.8(c)	Revise last sentence to read: Arrangements shall be established in advance to modify the response, as appropriate, during an emergency exposure situation, taking into account the prevailing conditions as these evolve.	The sentence stated that the triggers should be revised. This is not correct. It is not the trigger values themselves that may be subject to revision during the response, but the response actions themselves, based on the actual conditions. This modification reflects more clearly the			x	Both triggers and response actions need to be revised and modified taking into account the real conditions. However 4.8(c) describes revision of triggers

			balance between the emergency planning required to be in place and the flexibility that is necessary for an effective emergency response.				only, as a step in developing protection strategy.
Israel	4.8 (a)	We suggest mentioning specific dose limits of the public for: sheltering, hospitalization, relocation, or indicate bibliography.				x	The value in the table IV-1 for urgent protective actions is applicable for all those urgent protective actions, which are listed.
Japan	4.8(c)/7-9	(4.8 should be replaced by) **Arrangements shall be established in advance to modify the response.** during an emergency exposure situation, taking into account the prevailing conditions as these evolve	Arrangements to "revise the triggers" during an emergency situation are neither practicable nor necessary. The protection strategy should include triggers that can be used immediately and directly to initiate appropriate protective actions. Once an emergency is occurring, decision makers should first implement urgent actions indicated by the triggers, and then may . take additional actions, taking int account the prevailing conditions. However to revise the triggers during an emergency is not necessary.			x	Both triggers and response actions need to be revised and modified taking into account the real conditions. However 4.8(c) describes revision of triggers only, as a step in developing protection strategy.
WNA	Specific 4.9	**Emergency - *At the planning stage***, each protective action ….	During an emergency, protective actions must sometimes be taken immediately without adequate information. A justification of each of the actions may miss the point in respect of the urgency. Para 4.9 should also be restricted to the planning stage, as correctly limited in Requirement 44.			x	Requirement 44 does not cover planning stage only, but also response..

Spain	4.11	The text does not say that doses already received when a decision is to be taken must be considered in the optimization process.	Clarity			**X**	Details are provided in the Safety Guide DS44.
Belarus	4.11 (a)	Promptly implementing protective actions to avoid severe detenninistic effects based on observed conditions and, if possible, before any exposure occurs. Dose levels to be used as generic criteria to prevent severe deterministic effects are given in Schedule IV, Table IV-l; Implementing protective actions to avoid stochastic health effects that based on generic criteria expressed in terms of the projected dose based on a reference levels as given in Schedule ГУ, Table rV-2.	Experience from response to the accident at Cheraobyl NPP clearly demonstrated the need ofa single value for a specific protective action to reduce the risk of stochastic healih effects. According to tiie IAEA Draft General Safety Guide №GSG-x DS44 □Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency□, Vieima 2010, we propose to add the Generic criteria for protective actions and other response actions in emergency exposure situations to reduce the risk of stochastic heaitb effects (Table 3 p. 10)	x	Table reinstated in Annex		
UK	4.11 (d)	Modify to read: "Implementing further protection strategies **to optimize residual doses** as necessary …"	The modified text stresses the need for optimization below the reference level.			X	The details of optimization are described in para 4.8.
IRPA	4.11(d)/ line 1	Implementing further protection strategies *to optimize residual doses as necessary…*	To stress the need for optimization below reference levels.			X	The details of optimization are described in para 4.8.
Belgium	4.12	Delete.	Duplication of the requirement above.			**x**	Requirement 45 is overarching requirement.

USA	4.12	Consider modification: "The government shall" to "Local governments and agencies shall"	The requirement for establishing a program for managing, controlling, and recording doses should be delegated to the lowest level of emergency response and not managed or controlled at the highest level of government. Authority should be consistent with the other portions of the planning, which will most often be at the local level.			x	Requirements in the BSS are aimed at the government.
ICRP	4.14 line 1	Those requirements are applied "in an emergency exposure situation", not "in response to an emergency exposure situation".		x			
Poland	4.15 (c)	DELETE all text	the term „a large collective dose" is meaningless, e.g. in case of minimal doses to a large population			x	Averting a large collective dose is one of the actions to make in an emergency.
France	4.15	Replace: "… emergency worker is exposed in excess of the maximum single year dose limit …" by a numerical value : 100 mSv ***"… emergency worker is exposed in excess of 100 mSv …"***	There is no valid reason not to take into account ICRP 103 publication which recommends a maximum value of 100 mSv as reference level for emergency workers. If a lower value of the reference level is taken it could be difficult to employ emergency workers for accidental situations which are not necessarily considered as exceptional circumstances.		Text has been modified**.**	**X**	Numerical value of 50 mSv is inserted. Reference to maximum single dose limit for occupational exposure is deleted. The change to 100 mSv in para 4.15 would cause a conflict with Table IV.2.
IRPA	4.15	Delete 4.15(c)	"Large collective dose" is undefined and too vague in this context. An excessive dose to a large number of people would be included under			x	Averting a large collective dose is one of the actions to make in an

			4.15(b), “catastrophic conditions”.				emergency.
ILO Japan (business federation)	4.15(b)	Revise to "If undertaking actions to prevent the development of catastrophic conditions or to prevent severe deterministic health effect; or...”	See Schedule IV, Table IV-2.	**x**			
Poland	4.15 (b)	REPLACE “catastrophic conditions” by: “conditions severely impairing social stability”	avoids the use of „catastrophic” without specifying that term			**x**	This term is widely used in associated documents.
Japan	4.15 (b)	(Editorial comments) **In undertaken actions to prevent severe deterministic health effect** and to prevent the development of catastrophic conditions;	See Table 1V-2.	**x**			
UK	4.15/1	It may be helpful to define emergency worker here.	This would have implications for the employer and what dose limits apply. It would also help to identify dose limits for emergency workers for **all** exposure situations (see Glossary page 145). It may need government input to also exercise Para 4.16 requirements and not leave this to the licensee.			**x**	Definitions are presented in the glossary.
ICRP	pg 93, 4.15 line 2		Referring to a dose limit is confusing as far as emergency exposure situations are concerned. Further, the notion of "maximum single year dose limit" is not clear. Schedule III shows that the referred value be 50 mSv; this value seems to be low as far as responders are concerned; Pub 103 Table 5 introduces the value of 100 mSv as the maximum reference level (which may be exceeded in exceptional		**Text has been modified** Numerical value of 50 mSv is inserted. Reference to maximum single dose limit for occupational exposure is		

			circumstances), if we don't use it for responders, does it means that the maximum value is reserved to public exposure (see §4.8.A)?		deleted.		
Slovenia	4.15	**Proposed replacement of the text under Requirement 45**, paragraph 4.15; third line: or in excess of the maximum dose in 5 years specified in Schedule III except					Numerical value of 50 mSv is inserted. Reference to maximum single dose limit for occupational exposure is deleted.
Slovenia	4.15	**Proposed replacement of the text under Requirement 45**, paragraph 4.15; (old text in the last item c: …"to avert a large collective dose."): - … to avert a large exposure to the public.				**x**	Averting a large collective dose is one of the actions to make in an emergency.
Spain	4.16	It's not clearly stated who can approve that the values in Schedule IV, Table IV-2, can be exceeded by "emergency workers".	Clarity			**x**	The overall responsibility rests with the government (para 4.12). within this system further allocation of responsibilities is made.
WNA	Specific 4.17	**Emergency** – "*Response organizations and employers shall ensure that emergency workers who undertake actions in which the dose received might exceed the single year dose limit for occupational exposure specified in Schedule III ~~do so voluntarily, and have been clearly and comprehensively informed in advance of the associated health risk, as well as of available protection measures, and~~ are, to the extent feasible, trained in the actions*	Persons responsible to enforce any protective actions must be able to count on designated workforce. That doesn't work on a voluntary basis.			**x**	Provision of information and protective equipment is an integral part of arrangements. Operational implementation of the "voluntary basis" could be done at the preparedness stage.

		that may be required." See also Specific Comment No.33 as a potential option.					
WNA	Specific 4.17	**Emergency** –NRC regulations include the following: *Emergency workers receiving exposure in excess of the normal occupational exposure limits (emergency exposure)* *1) should be informed of the anticipated emergency dose before the emergency exposure and* *2) should give their consent prior to receiving the emergency exposure.* *This would help avoid emergency exposure which could result in more serious somatic effects for someone who was at risk, e.g., pregnant or immunosuppressed.*	Specific 4.17			**x**	Provision of information and protective equipment is an integral part of arrangements. Operational implementation of the "voluntary basis" could be done at the preparedness stage.
Switzerland – Fed Energy Office	4.17	Delete *.....to do so voluntarily, and ….*				**x**	Provision of information and protective equipment is an integral part of arrangements. Operational implementation of the "voluntary basis" could be done at the preparedness stage.

Canada	4.19	However, qualified medical advice shall be obtained before any further exposure, either if a worker has received an exposure exceeding 500 mSv or if the worker requests it	Schedule III provides the single year dose limit, 50 mSv, the use of the phrase "ten times the single year dose limit" over complicates the issue.	X	Accepted, but text modified.		
Spain	Requirement 46 para. 4.20 and 4.21.	These two paragraphs are just specific examples where publications ICRP 109 and 111 should be more exhaustively used	N/A	**x**			These paragraphs are developed based on ICRP 109.
UK	4.20		It would be helpful to provide guidance to those responsible for making the decision on when to make the transition from emergency to an existing exposure situation.			**X**	Provided in a Safety Guide. This paragraph should be applied in conjunction with Section 5.
Israel	4.20	We suggest mentioning dose limits for the transition period and for the next existing situation and decontamination levels, or suggest bibliography.				**X**	This paragraph should be applied in conjunction with Section 5.
USA	4.20	Consider elaboration, or additional requirement	The current text does not make it clear that the reference levels that would be expected in a longer term existing exposure situation should be lower than those accepted in an emergency exposure situation, and should strive to be within the criteria normally accepted for public exposure in planned exposure situations when possible.			**x**	This paragraph should be applied in conjunction with Section 5.
Ukraine	4.20	It is suggested to complement subsection "*Transition from an emergency exposure situation to an existing exposure situation*" (after paragraph 4.20) with paragraph which determine completion of emergency	Basis for making decisions is needed			**x**	This paragraph should be applied in conjunction with Section 5.

		exposure situation and transition to theof existing exposure situation. It is suggested to add that "*Regulatory authority must set transition criteria from the situation of emergency exposure to the situation of existing exposure in terms of projected annual effective dose which should not exceed 5 mSv. The recommended value is 1 mSv*".					
Denmark	4.21	Workers undertaking remedial work … ("Following an emergency, " should be deleted)		**x**			
Finland	4.21	~~Following an accident, w~~Workers undertaking remedial….	These words are not needed and might be misunderstood. The fact is that any such remedial work - irrespectively whether it is conducted during the accident or following it - should always be conducted in planned manner i.e. the workers shall be subject to requirements for occupational exposure in planned exposure situations.	**x**			
Norway	4.21	Proposed deleted: "~~*Following an emergency*~~*"*. Proposed revision: *"Workers undertaking remedial work, such as repairs to plant and buildings…"*	Workers should follow the requirements for occupational exposure in all planned exposure situations, both during and after the emergency.	**x**			
Sweden	4.21	Delete first three words ..*following an emergency..*		**x**			

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 5: Existing Exposure Situations							
Bulgaria	General comment - Radon	4. Recent epidemiological findings from residential studies demonstrate a lung cancer risk from indoor radon exposure at levels of the order of 100 Bq nf3. ICRP is currently re-considering its earlier guidance on the dose conversion factors relating to concentrations of radon gas and its progeny in the decay chain. The ICRP Main Commission has issued a statement in November 2009 now proposing a maximum value for the reference level in dwellings of 300 Bq m^{-3}, in line also with the WHO handbook on indoor radon published in 2009. The new BSS has incorporated this value for existing and future dwellings and other buildings with high occupancy factors. According to article 5,20 (DS379, page 103) the reference level for dwellings is set at maximum 300 Bq m^{-3} (an annual average radon concentration). This value corresponds to an annual effective dose of the order of 10 mSv. The value 100 Bq m^{-3} for the lower reference level proposed by WHO is suitable as a long-term goal but that currently the value of 200 Bq m^{-3} for new dwellings should be maintained. According to article 5.27 (DS379, page 105) a maximum value for the reference level for radon in workplaces has been set at 1000 Bq m^{-3} (an annual average radon concentration), in line with the most recent JCRP Statement published in November 2009, This value of a radon concentration of 1000 Bq m^{-3} corresponds to around 10 mSv per year, which is a high threshold for managing radon at work as planned occupational exposure and well above 6 mSv per year, used in the				X	It is not clear what the precise proposal is, but the requirements concerning radon are in line with the conclusions of an Agency meeting on radon in December 2009 and have been agreed by RASSC. The requirements are also fully in line with the ICRP Statement on Radon (Nov 2009) Member States are expected to set reference levels based on the distribution of radon in their country. Bulgaria may therefore choose a reference level for workplaces that is lower than the 1000 Bq/m3 maximum

		definition of Category A workers.					value
Bulgaria	General comment – natural sources	5. Along the lines of ICRP Publication 103, the protection against natural radiation sources and cosmic radiation is integrated in the BSS. Requirements for regulatory control and radiation protection related to industries processing materials containing naturally occurring radionuclides (NORM), to commodities and to aircrew/space crew/ are included. The review of the current basic safety standards led to the conclusion that requirements on natural radiation sources needed to be harmonised and strengthened. Further guidance should be issued for the implementation of these new requirements by regulatory authorities and by the industries.				X	The BSS is not the right place for guidance. This should be implemented through Safety Guides
Israel	5.1	We suggest adding dose limits for the public for establishing new settlements: at high altitude with particularly high cosmic radiation and in areas with particularly high radiation from the soil, or suggest bibliography.				X	Such exposures are unamenable to control and are therefore excluded
Israel	5.1 (b)	We suggest adding specific dose limits for increasing the radionuclide content in building materials due to NORM and TENORM.				X	Dose limits do not apply to existing exposure situations
Israel	5.1 (c)	We suggest adding <u>public</u> exposure to cosmic radiation in airplanes.				X	In line with ICRP recommendations, such exposures are regarded as unamenable to control and therefore excluded
USA	5.1	Consider deletion of the header “Generic Requirements” at the end of paragraph 5.1	It is not obvious how the headers now provide any value in the new format. Following the scope, it seems that the headers for “generic requirements” and “public exposure” are no longer needed.			X	The headers are needed for the structure.
Japan	5.1(c)(ii)	(5.1 (c) (ii) should be replaced by) (ii) Radionuclides of natural origin in	Existing exposure situation should be clearly separated from exposure to the	X	The text has been modified.		

		commodities except the categories ofthe material designated by regulatory body in planned exposure situation (see para 3.4(a))	materials under planned exposure situation, such as exposure due to the categories of the material designated by regulatory body, among the materials in which in which the average level of activity concentration in the material of any radionuclide in the uranium and thorium decay chains is greater than 1 Bq/g or the activity concentration of 40K is greater than 10 Bq/g.				
WNA	Specific 5.1.(c) (iii)	**Are requirements commensurate to the actual risk : Public exposure associated with air passengers?** – ***This significant public exposure has been omitted in the BSS new draft.*** [This should not be confused with aircrew – para.5.1.(c).(iii).] A single return trip between Europe-Asia results in an exposure of about ***0.1 mSv/y***. ***With only one trip per month, the exposure of a frequent international flier is above 1 mSv/y!*** Public exposure of frequent international fliers is comparable to aircrew. See General Comments No. 2, 3 and 15. See attached Table 1.	What is the rationale to omit the control of public exposure from air passengers, especially for frequent international fliers which receive a public exposure (above 1 mSv/y) comparable to aircrew? Is public health risk real or not also in this case of small public exposure? How these requirements can be commensurate to the actual risk?			X	Exposure of airline passengers is unamenable to control, and in line with ICRP recommendations
IRPA	5.1(c)(iii)	Delete	Include under Planned Exposure, Occupational			X	Exposure has characteristics of both planned and existing exposure situations. Discussed in RASSC and decided to keep as is

Iran	Req. 47	The government shall ensure that a programme is established to manage the existing exposure situation and to determine….	In concomitant requirements there are no requirements regarding identifying existing exposure situation. Also identifying this situation is not clear		Text has been modified		
USA	R 47	Suggest revision as follows: ~~**The government shall ensure that a programme is established to identify and evaluate existing exposure situations and to determine which occupational and public exposures are of concern for radiation protection.**~~ The government shall ensure that identified existing exposure situations~~**s**~~ are evaluated to determine which occupational and public exposures are of concern for radiation protection.	As currently written, the requirement puts an obligation on the government to go out and attempt to identify any and all existing exposure situations. This is unrealistic. While it is appropriate for programs to be established, as found in paragraph 5.3, it is not appropriate to fundamentally require the government to identify the situations. It is suggested that the overarching requirement be modified to provide the responsibilities when a situation is identified. The proposed revision sets the appropriate stage for the associated requirements that follow.	X	Text has been modified		
Czech	Req 47	The government shall ensure that a national ? programme is established…	clarification		Text has been modified	X	The programme could also be established at a sub-national level, especially for federal systems
Israel	Req. 47	Add "the" before "government"	Editorial	X			
ILO Japan (business federation)	5.2	Either reconsider the radon concentration reference lever or, in the footnote 37, clarify that the level has been calculated with consideration for the effects of smoking. *5.20. Where significant radon levels are identified from the information gathered as required by para. 5.19 (a), the government shall ensure that an action plan comprising coordinated actions to*	While background information on calculation of the radon concentration reference level is included in para.1.23, the absolute risk stated here is not contained in the ICRP statement on radon, and inconsistent with the ICRP document. Therefore, to keep consistency within the BSS, an indication that the effects of smoking have been factored in should be			R	Comment: The full implications of the synergy between radon exposure and smoking need further consideration, particularly in relation to exposure in workplaces.

		reduce such levels in both existing and future buildings is established,36 which include: *(a) The establishment of an appropriate reference level for dwellings, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 300 Bq/m3 (37);* *(37)* *Using an equilibrium factor of 0.4 and an annual occupancy rate of 7000 hours, the value of 300Bq/m3 corresponds to an annual effective dose of the order of 10 mSv.*	included in para. 5.20 the footnote 37, which details conditions for calculating the radon concentration reference levels. *1.23. The system of protection and safety in these standards includes protection against exposure to radon which is based on the average level of risk to a population with typical but various smoking habits. Because of the synergistic effects of smoking and exposure to radon, the absolute risk of lung cancer from unit exposure to radon for smokers is more than twenty times greater than for those who do not smoke.*				Several comments have been received to amend or delete the last sentence of 1.23. However, the footnote only refers to the relationship between radon concentration and dose, which is not affected by smoking habits.
Ukraine	5.2	It is suggested to complement 5.2. by a statement about necessity to define responsible authority for of radiation safety at the object (territory) with existing exposure situation.	Clarification of responsibilities			X	The text already says that responsibilities must be assigned
Canada	5.2 and 5.3	These clauses do not address multi-jurisdictions adequately. This is a general problem in the document where it assumes that one government has responsibilities for everything. It is more difficult to apply for multi-layer systems like Canada and USA.				X	Covered by footnote 6.
Denmark	5.3.(c)	… registrants, licensees*, employers* and other parties …				X	Covered by "registrants, licensees" or, if the employer is not the registrant or licensee, by "other

							parties". It is not necessary to be more specific
Norway	5.3 (c)	Proposed amendment: *"Assigned responsibilities for the establishment and implementation of strategies for the management of exposure to the regulatory body and other relevant authorities and, as appropriate, to registrants, licensees, employer and other parties involved in the implementation of remedial and protection actions;"*	*Employer* should be inserted after licensees			X	Covered by "registrants, licensees" or, if the employer is not the registrant or licensee, by "other parties". It is not necessary to be more specific
Finland	5.3 (c)	…and, as appropriate, to **employers,** registrants, licensees and other parties involved…	Employers of the workers involved would be the most important and most likely affected "prinicple party" and should thus be explicitly mentioned, if any.			X	Covered by "registrants, licensees" or, if the employer is not the registrant or licensee, by "other parties". It is not necessary to be more specific
Sweden	5.3(c)	Insert employers after licensees	5.3(c)			X	Covered by "registrants, licensees" or, if the employer is not the registrant or licensee, by "other parties". It is not necessary to be more specific
India	5.5	Ensuring that information **as determined by the regulatory body** is available to exposed individuals…	This will ensure that radiation safety-related information is handled by a single authority.			X	The information is defined in the requirement. The stem defines who is responsible.

Spain	5.5-a. Second line	Perhaps the word "planned" should be replaced by "programmed" to avoid any potential confusion.	Clarity			X	No suitable alternative to planned.
UK	5.5 (b)	Modify to read: "**Where determined to be appropriate,** ensuring that information is available…"	The appropriateness of this will depend on the specific exposure situation.			X	Weakens requirement.
Ireland	5.5 (b)	Change the last part of the sentence to "...reducing their own exposure and risk".		X			
IRPA	5.5 (b)	Insert at the start "Where determined to be appropriate…"	The appropriateness of this will depend on the specific exposure situation.			X	Weakens requirement.
USA	5.6	Consider deletion of the paragraph	In view of the new format, and the organization of the condition paragraphs under the overarching requirements, this second little paragraph of scope adds nothing to the text. It is suggested that this could be deleted.			X	Technical Meeting recommended the structure, which has been applied throughout the whole BSS.
ENISS	**Require ment 48**	**The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified, and radiation protection is being optimized.**	See 2.10			X	The term 'optimized' is used consistently throughout the BSS.
Spain	Requirem ent 48 y para. 5.7 to 5.9	Perhaps it would be convenient to explicitly say that the doses incurred by the workers involved in the protective actions to be taken must be considered in the process of their justification and optimization.	Clarity			X	This is under the heading "Public Exposure", so it is not relevant to mention worker exposures here

Iran	Article 5.8 line 8, page 98	…to the representative person, the actual value depending…	Putting number1-20 mSv makes the implementation for some states very difficult especially for developing countries. I would suggest taking decision regarding reference levels for public exposure in existing exposure situation is totally the responsibility of the government. This reference level cannot be implemented in cities like Ramsar.			X	The 1-20 mSv dose range is consistent with ICRP recommendations. The word "typically" makes provision for cases where levels outside this range may be appropriate. Furthermore, doses due to high natural background (the Ramsar situation) should be considered for exclusion
ENISS	5.8	The regulatory body or other relevant authority and other parties responsible for remedial or protective actions shall ensure that the form, scale and duration of such actions are being optimized.	See 2.10			X	The phrase 'is optimized' is used consistently throughout the BSS.
Israel	5.8	Based on the radiation sources mentioned in para. 5.1, we suggest to lower the dose limit for the public of 20 mSv (equal to that for a radiation worker!). The only source which may produce such a high dose is the emergency situation in 5.1 (a) (ii). We suggest lowering this high dose or suggesting time limits. In addition, this high dose is in contradiction with the total dose to the public of 1 mSv mentioned in para. III-3 (a).				X	Dose limits do not apply in existing exposure situations. Reference levels are not dose limits.
Australia	Req. 49 & 5.10 – 5.18	This is confusing, as it is not consistent with the definition of existing exposure used earlier.	If a member of the public receives an additional exposure as a result of a planned remedial activity, should this not be considered as a planned exposure, or subject to the same			X	Public exposure to contaminated areas is clearly identified in 5.1(a) as an existing exposure situation. The

			controls as would be considered for a planned exposure, as is required for workers (paragraph 5.26)?				remedial work is also treated as an existing exposure situation, notwithstanding the requirement for workers to be protected in accordance with the relevant requirements for planned exposure situations (see para. 5.26)
UK	Req. 49: 5.10 to 5.18		It is unclear how these requirements will interface with decommissioning strategies and requirements for power reactors and other facilities. Clarification is needed.			X	Decommissioning is part of a planned exposure situation
India	5.10	…nature and extent of contamination, **the actual remediation measures carried out,** the decision made,…	For completeness			X	Covered by 5.12(g) and 5.14(e)
ILO Finland (Trade Union)	5.10	It should emphasise the financial responsibilities of parties responsible for causing damage prior to granting an operating licence, as well as the definition of financial responsibility in eventual cases of emergency.	The protection workers must be ensured both as concerns cosmic radiation and radon. In the future, there may be good reason to lower the limits on the basis of the action taken.			X	The comment seems to be more about planned and emergency exposure situations. Exposure of workers to cosmic radiation and radon are covered in paras 5.27 to 5.31
UK	5.10		In this paragraph, it must be conceded that there will be circumstances where the responsible persons or organizations no longer exist.	X	Text has been modified		
Israel	5.10-5.18	We suggest mentioning reference dose levels for decontamination or suggest bibliography.				X	Reference levels in such cases will be situation-specific

Australia	5.12(c)	Need to add a requirement to this section to say who is responsible if the original organization no longer exists or cannot be identified.	It is not always possible to determine who is responsible, as the relevant organisations may no longer exist.		5.10 requires the government to address this issue in the framework.		
Canada	5.13 (d) 2nd line	May have a radiological environmental impact	5.13 (d) 2nd line	X			
France	5.17	Delete ***"that can be considered as normal"***: "… with the aim of establishing living conditions ***"that can be considered as normal***, including ***:"***	Tchernobyl accident, 25 years after, has demonstrated that in contaminated area it is difficult to consider "that living conditions can be considered as normal".			X	Adopt wording proposed by ICRP (below)
ICRP	Pg 102, 5.17	Replace "with the aim of establishing living conditions that can be considered as normal" with "with the aim to establish sustainable living conditions"	In line with ICRP Publication 111.	X	Text amended as indicated		
Ireland	Req. 50	Remove "if appropriate" from the requirement. When is it not appropriate to have an action plan?				X	An action plan may not be necessary in some countries where radon levels are consistently very low
UK	Req. 50		Clarification is requested (perhaps domestic discussion not for IAEA): The text on Radon levels for dwellings and workplaces refers to 7000 and 2000 hours exposure respectively (page 103, Footnote b). There are 8760 hours in a normal year. Is there an overly cautious assumption that someone living and working in a Radon area spends (less than) no time outdoors?				Comment: This is based on a cautious approach and habit survey data indicate that individuals spend an average of 7000 hours indoors, which includes time spent in the home and time spent at work. There has been some discussion about

							setting a reference level based on the time spent indoors, which would imply the same reference level for all indoor environments, but there is no international consensus on such an approach.
USA	5.19	Suggest revision of stem to read: As part of its responsibilities under ~~in terms of~~ para. 5.3, the government …	Editorial. The sentence construction can be simplified. One suggestion is provided. A simple cross reference could also be used.	X			
UK	5.19 (a) and Table III-1	Revise Table III-1 for workers and members of the public	There is ambiguity concerning dosimetry of the public in high occupancy workplaces such as schools. Requirement 50 covers indoor radon levels and Para 5.19 (a) (and Footnote 35) refers to "radon levels in dwellings and other buildings with high occupancy factors for members of the public" and "such buildings include kindergartens, schools and hospitals". The conversion coefficients for radon and thoron progeny given in Table III-1, however, list values for annual dose per unit radon concentration at home and at work, not for members of the public or workers. In situations such as members of the public in schools, where there are arguments both ways, it is unclear which dosimetry should be used.	X	A footnote has been added to Table III-1 to indicate that the dosimetry for homes should also apply to other buildings with high occupancy by the public		

Brazil	5.19		To move to a Safety guide			X	The requirements in 5.19 would seem to be the minimum actions that all countries could (and should) carry out. The requirements are worded so as to provide considerable flexiblity
Japan	5.19 (b)	(5.19(b) should be replaced by) **... including the associated risk factors such as tobacco smoking**	The association between radon exposure and smoking status is epidemiologically significant, and the risk of smokers is much higher (10 times or more) than non-smokers. In this context, tobacco smoking should be explicitly stated as an associated risk factor. Exemplification also prevents over interpretation of "associated risks" to be hypothetical, scientifically unconfirmed factors.	X	Text has been modified.		
IRPA	5.20(a)/line 3	"…concentration of 300 Bq/m^3 <u>or an annual effective dose of 10 mSv as a residual dose</u> [37]";	Reference level is originally defined as an individual dose as shown in Table 5 in ICRP Publication 103. Exposure to radon, however, depends on inhalation of radon progeny and various environmental and physical parameters. For these reasons, the reference level should be given also in terms of the individual dose (10mSv) as an option in addition to radon gas concentration.			X	Member States have expressed a strong wish to have the reference level set in terms of activity concentration rather than dose and the proposed change would result in a loss of clarity. This point is covered in the associated footnote.
Japan	5.20(a) and	The following sentence should be added in the ends of the paragraph 5.20(a) and 5.27.	Reference level is originally defined as an individual dose as shown in Table 5 in ICRP Publication 103. The main			X	Member States have expressed a strong wish to have the

	5.27	5.20 (a) The establishment of an appropriate reference level for dwellings, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 300 Bq/m3 or an annual effective dose of 10 mSv as a residual dose 37; 5.27 The regulatory body or other relevant authority shall establish a radon protection strategy for workplaces, including the establishment of an appropriate reference level, the value of which takes into account the prevailing social and economic circumstances but which does not exceed an annual average radon concentration of 1000 Bq/m3 or an annual effective dose of 10 mSv as a residual dose39:	reason why radon gas concentration is given as a reference level is due to its easily measurable property. Exposure to radon, however, depends on inhalation of decay products from radon gas, namely radon progeny. Even if indoor air is fulfilled with high concentration of radon gas corresponding to the reference level, the individual dose could be considerably reduced using some remedial actions, e.g. to make ventilation rate higher with fine filter, to reduce aerosol concentration lower and so on. In addition, exposure to radon can be reduced by controlling residence time in the indoor room. Therefore, if the residence time is so short, there must be a possibility to result in the case that the individual dose is significantly low although radon gas concentration is considerably high. From the above reasons, reference level should be given in terms of the individual dose (lOmSv) as a selectable option in addition to radon gas concentration, which leads to make more scientific and rational regulation for radon in member states.				reference level set in terms of activity concentration rather than dose and the proposed change would result in a loss of clarity. This point is covered in the associated footnote.
WNA	Specific 5.20, 1.23	**Radon** - Regarding reference level for radon concentration, it should be revised or described in the note37 as being calculated from the epidemiological studies including the effects of smoking. "*5.20. Where significant radon levels are*	Para.1.23 describes how the reference level for radon was induced. However, the ICRP statement on radon doesn't mention the absolute risk of lung cancer for smokers from unit exposure to radon described in para1.23. So, the description in para1.23 is not consistent with the ICRP statement. Therefore to			X	Para. 1.23 is being amended based on specific comments received Footnote 37 gives the relationship between activity

		identified from the information gathered as required by para. 5.19 (a), the government shall ensure that an action plan comprising coordinated actions to reduce such levels in both existing and future buildings is established,[36] which include: *(a) The establishment of an appropriate reference level for dwellings, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 300 Bq/m3 [(37)];*" (37) "*Using an equilibrium factor of 0.4 and an annual occupancy rate of 7000 hours, the value of 300 Bq/m3 corresponds to an annual effective dose of the order of 10 mSv.*"	keep consistency in the BSS, at the very least, the note37 should include a description on the effects of smoking on the calculated reference levels. "1.23. The system of protection and safety in these standards includes protection against exposure to radon which is based on the average level of risk to a population with typical but various smoking habits. Because of the synergistic effects of smoking and exposure to radon, the absolute risk of lung cancer from unit exposure to radon for smokers is more than twenty times greater than for those who do not smoke."				concentration and dose, which is not dependent on smoking habits
WNA	Specific 5.20(a) and 5.27	**Radon** - The following sentence should be added in the ends of the paragraph 5.20(a) and 5.27. 5.20 (a) The establishment of an appropriate reference level for dwellings, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 300 Bq/m^3 <u>or an annual effective dose of 10 mSv as a residual dose</u> [37]; [37]	Reference level is originally defined as an individual dose as shown in Table 5 in ICRP Publication 103. The main reason why radon gas concentration is given as a reference level is due to its easily measurable property. Exposure to radon, however, depends on inhalation of decay products from radon gas, namely radon progeny. Even if indoor air is fulfilled with high concentration of radon gas corresponding to the reference level, the individual dose could be considerably reduced using some remedial actions, e.g. to make ventilation rate higher with fine filter,			X	Member States have expressed a strong wish to have the reference level set in terms of activity concentration rather than dose and the proposed change would result in a loss of clarity. This point is covered in the associated footnote.

		5.27 The regulatory body or other relevant authority shall establish a radon protection strategy for workplaces, including the establishment of an appropriate reference level, the value of which takes into account the prevailing social and economic circumstances but which does not exceed an annual average radon concentration of 1000 Bq/m^3 <u>or an annual effective dose of 10 mSv as a residual dose</u>[39];	to reduce aerosol concentration lower and so on. In addition, exposure to radon can be reduced by controlling residence time in the indoor room. Therefore, if the residence time is so short, there must be a possibility to result in the case that the individual dose is significantly low although radon gas concentration is considerably high. From the above reasons, reference level should be given in terms of the individual dose (10mSv) as a selectable option in addition to radon gas concentration, which leads to make more scientific and rational regulation for radon in member states.				
Brazil	5.20	**The government shall establish an appropriate reference level for dwellings, taking into account the prevailing social and economic circumstances, and, in general, not exceeding an annual average radon concentration of 300 Bq/m3 37**	Other items are to be removed to a Safety Guide			X	The wording of (b) and (c) are general principles of radiological protection – they could be removed but their retention does not place any additional responsibilities on the government or regulatory body. Indent (d) includes the phrase 'whenever necessary' which provides flexibility and is helpful for those MS with an advanced rafdon programme

Iran	Article 5.20 line 2	… as required by para. 5.19 (a), if appropriate, the government…	Action plan will be established only if it is appropriate	X	Text has been modified.		
Belgium	5.20.	Include a "target level" of 100 Bq/m^3 in order to minimize impact on health of inhabitants/occupants. This could be achieved by formulating this idea as a footnote referring to 5.20.(b)	Corresponds to WHO recommendations			X	It is not appropriate to include as a requirement. Consideration of such a proposal should be reserved for a Safety Guide
Germany	Par. 5.20 (a)	The establishment of an appropriate reference level for dwellings, which … does not exceed an annual average radon concentration of 300 Bq/m³. Add at least the following footnote to the above sentence: "A reference level of 100 Bq/m³ is recommended to minimize health hazards due to indoor radon exposure. However, if this level cannot be reached under the prevailing country-specific conditions, the chosen reference level should not exceed 300 Bq/m³."	The requirement should be as close as possible to the WHO Radon Handbook, 2009.			X	It is not appropriate to include as a requirement. Consideration of such a proposal should be reserved for a Safety Guide
Belgium	Footnote 53, referring to 5.20.c)	Add to the list of examples for prioritization: (e) Buildings with a high occupancy by sensitive population subgroups, such as nurseries, kindergartens, schools.	As the impact on health will increase with decreasing age at exposure, effectiveness will be higher when interventions give priority to reducing the exposure of children			X	(Refers to footnote 38, not 53). Such buildings are already mentioned in 5.19(a) and footnote 35.
France	5.20 And delete footnote 38	Add the **points a- b and d** of the footnote 38 in 5.20 : 5.20. Where significant radon levels … is established [36] which include as appropriate: ***(a) specifying levels of radon***	It needs to add more detail on the content of the action plan.			X	Information of guidance material does not belong in a requirement

		concentration in dwellings and other buildings with high occupancy factors at which protection against radon can be considered optimized; (footnote 38 a) ***(b) identifying radon-prone areas; (footnote 38 b)*** (c) The establishment of an appropriate reference level for dwellings, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 300 Bq/m^3 [37]; (d) Making all reasonable efforts to reduce radon concentrations and exposures to a level where protection can be considered optimized; (e) Giving priority to reducing radon concentrations in those situations where such action is likely to be most effective[38]; ***(f) identifying and enforcing preventive measures for future buildings which can be introduced at relatively low cost; (footnote 38 d)*** *(g)* Inclusion of appropriate radon prevention and mitigation measures in building codes to prevent radon ingress and to facilitate potential remediation actions wherever necessary.					

EC	5.20	New paragraph after 5.20 (a): 5.20 (a) bis "The establishment of an appropriate reference level for new dwellings and other buildings with high occupancy factors for members of the public, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 200 Bq/m3;"	One of the most cost-efficient ways of reducing levels of radon concentration in indoor air is to construct buildings accordingly (also acknowledged in footnote 38). IAEA should introducing an upper boundary more in line with WHO guidelines and the Euratom approach, that is a value lower than 300 Bq/m3.			X	It is not appropriate to include as a requirement. Consideration of such a proposal should be reserved for a Safety Guide
EC	5.20 (a)	Modify to: "…appropriate level for dwellings and other buildings with high occupancy factors for members of the public, which take into…"	Earlier drafts mention that the reference levels would be set not only for "dwellings" but also for "…other buildings with high occupancy factors for members of the public.", see list in footnote 35. It's important that what went missing is re-introduced in order to have a credible approach to radon and exposure to members of the public.	X			
Israel	5.20 (a)	Footnote 37: the dose 10 mSv seems to be calculated with the new conversion factor recommended by the WHO. Using the conversion factor in Table III-1 (based on ICRP-65) the result is 5.15 mSv. We suggest adding the reference in footnote 37 and in Table III-1.			Retain until new dose coefficients are available, at which time Table III-1 will be reviewed..		
Israel	5.20(a)	Delete "in general"	If a maximal reference level of 300 Bq/m^3 is to be adopted, it should be clearly stated. A footnote could be added to indicate that in some areas this level would not be feasible.			X	Flexiblity is needed
WHO Bulgaria	5.20 (a), beginning of the paragraph	"The establishment of an appropriate reference level for dwellings and other buildings with high occupancy factors for members of the public, …"	To be in line with 5.19 (a).	X			

WHO Bulgaria	5.20 (a), footnote 37	"…the value of 300 Bq/m^3 corresponds to an annual effective dose of the order of 10 mSv" is not in line with values from Table III-I; e.g., for the value of *Annual dose per unit radon concentration 0.0172 mSv per (Bq/m^3) at home* 300 Bq/m^3 corresponds to an annual effective dose 5 mSv.			Retain until new dose coefficients are available, at which time Table III-1 will be reviewed.		
Israel	5.20(d)	Add "or mitigate" after "prevent"	Clarification			X	It does not means entirely prevent all ingress.
Israel	5.20(d)	Add "into dwellings" after "ingress"	Clarification			X	Not necessary
UK	Footnote 38/4 (5.20(c)) (page 103)	Modify to read: "… give rise to elevated radon concentrations; and (d) identifying and **requiring preventative** measures for …"	It is more appropriate to use "requiring" in place of "enforcing". These two words have quite precise and different meanings for our Building Control System; enforcement is what happens when something has gone wrong; and, requiring covers a range of actions including self certification by installers and building inspections, which reduce the need for enforcement.	X			
France	Req. 51	Add at the end of Requirement 51 the following sentence : ***"…coming from contaminated areas."***	R. 5.22 and 5.23 must be limited to consumer products coming from 5.1-b.			X	Para. 5.22 and the drinking water part of para. 5.23 apply also to commodities containing radionuclides of natural origin that have not come from contaminated areas
Brazil	5.21	**The government shall assign responsibility to:**	Governments responsibilities are to be generic to be applicable worldwide.	X			

		(a) establish and implement an action plan for controlling public exposure to indoor radon; and, **(b) determine the circumstances under which remedial action is to be mandatory or voluntary, taking into account the prevailing legal and social circumstances.**	Specific actions are to be moved to Safety Guides.				
Israel	5.22	By adding 1 mSv for <u>each</u> of the radiation sources mentioned (and we may add to the list security screenings, indirect radiation from work, hospitals, industrial radiography, etc), we exceed several times the public dose of 1 mSv mentioned in para. III-3. We suggest deciding on a total dose for the public, from all sources, natural and artificial, under the normal living situation (excluding emergency and "after" emergency) and dividing it into practices, as recommended by the ICRP).				X	The proposal is not in accordance with ICRP recommendations. In particular, we do not add doses from existing and planned exposure situations. The words "not exceeding" in the current text give enough flexibility to allow reference levels below 1 mSv
UK	5.22		Comment only – no change proposed here. The wording is very general and sets a very broad recommendation to *establish specific reference levels for exposure to radionuclides in commodities such as construction material* with little detail of how this should be put into practice. It is unlikely that this can be achieved in the same way as for other commodities such as food. Further information needed for clarification.	X	Will be done in a Safety Guide		

ICRP	pg 104, 5.22		It is true that reference levels should be established by each country because models and parameters used in the dose assessments can vary from country to country. However, considering that such calculations (for many materials and for large number of radionuclides) are not simple tasks at all and relevant dose level is low(~1mSv/y), the Standards may provide *generic reference levels* for internationally shared use.	X	Will be done in a Safety Guide		
Austria	5.27		If the annual occupancy rate is less than 2000 h/a, the annual average radon activity concentration could be higher than 1000 Bq/m³. In any case the annual average exposition in the workplace due to radon should not exceed 10 mSv.			X	RASSC considered the arguments and decided to stay with the activity concentration criteria. Further guidance could be given in a Safety Guide
IRPA	5.27/line 5	"…concentration of 1000 Bq/m^3 <u>or an annual effective dose of 10 mSv as a residual dose</u>[39]";	See reason above.			X	RASSC considered the arguments and decided to stay with the activity concentration criteria. Further guidance could be given in a Safety Guide
USA	5.27	Recommend placing the recommended average concentration be placed in terms of WL, or providing other conversions.	Progeny working levels are more directly related to risks than radon concentrations. Thus, it may be important to specify WL, or equilibrium factors with progeny, to facilitate national authorities establishing or continuing their activities. It is well known that the assumed degree of equilibrium strongly			X	RASSC considered the arguments and decided to stay with the activity concentration criteria. Further guidance could be given in a Safety Guide

			influences the values.				
France	5.28-b	Replace : "…related to the work are reduced to below the reference level…" by "…related to the work are ***optimized going on reducing doses below the reference level…***"	The glossary definition in accordance with ICRP 103 publication state that optimization should continue to be implemented below reference level.			X	The definition of reference level includes optimizing below
Spain	5.28 (b)	To the extent possible, radon concentrations in workplaces are reduced to below the reference level determined by the relevant authority.	The same as in comment 1, in spite of the footnote 10, it is not clear which are the workplaces affected by this para.			X	The definition of reference level includes optimizing below
Spain	5.29	The term "relevant requirement" and could give rise to problems in interpretation, for example as regards whether or not the dose limits (which are evidently one of the most relevant requirements of the standards) are applicable to these exposures. In order to avoid these problems it would be advisable to clearly establish what is meant by the term "relevant requirement"; in this respect, it is proposed that the term "relevant requirement" be replaced with "relevant requirement, monitoring and dose record-keeping as a minimum."	Better understanding			X	Relevant needs to be retained.
ICRP	Pg 105, 5.29		The ICRP Statement on Radon does not refer to occupational exposure (line 4). This word should be deleted: to manage a secretary in an office, a sailor in a store or a teacher in a school using the occupational dose limit is not ethical.			X	The ICRP Statement **does** refer to occupational exposure in para. (5): The Commission now recommends 1000

							Bq m^{-3} as the entry point for applying occupational exposure requirements….
Denmark	5.30	Paragraph should be rewritten.	Aircrew shall have the right to the same level of protection as for occupational exposures in planned exposure situations. (No artificial difference between different occupational exposures)			X	The current text does not necessarily imply a different level of protection. The circumstances are different from those in normal workplaces and the mechanism for control needs to be tailored accordingly. It is questionable whether any real controls are necessary, because the dose is inherently limited by limitations on flying hours. Monitoring is not carried out. Doses are merely assigned on the basis of computer codes.
Denmark	5.30	Change last line to : "… section 3 are to be applied, …"		X	Text has been modified		
Finland	5.30	rewrite: the aircrew shall have the right to the same level of protection as for occupational exposures in planned exposure situations.	There should be no difference between different occupational exposures.			X	The current text does not necessarily imply a different level of protection. The circumstances are different from those in normal workplaces and the mechanism for control needs to be tailored accordingly. It is questionable

							whether any real controls are necessary, because the dose is inherently limited by limitations on flying hours. Monitoring is not carried out. Doses are merely assigned on the basis of computer codes.
Sweden	5.30	Rewrite: the aircrew shall have the right to the same level of protection as for occupational exposures in planned exposure situations				X	The current text does not necessarily imply a different level of protection. The circumstances are different from those in normal workplaces and the mechanism for control needs to be tailored accordingly. It is questionable whether any real controls are necessary, because the dose is inherently limited by limitations on flying hours. Monitoring is not carried out. Doses are merely assigned on the basis of computer codes.
China	Para 5.30/4	For pregnant aircrew, the regulatory body or other relevant authority shall make sure proper measures are taken, as in paras. 3.112 and 3.113	The assessment of the exposure of pregnant aircrew to cosmic radiation, and the application of relevant requirements for occupational exposure in planned exposure for pregnant aircrew should be regulated deterministically.			X	RASSC decided that air crew to be kept as an existing exposure situation. It is a government decision on how to protect pregnant air crew.

Norway	5.30 and 5.31	Consider to rewrite the paragraphs.	The paragraphs 5.30/5.31 should be rewritten in accordance with the discussion above of protection of occupationally exposed workers (see comment 9 under general comments)			X	The current text does not necessarily imply a different level of protection. The circumstances are different from those in normal workplaces and the mechanism for control needs to be tailored accordingly. It is questionable whether any real controls are necessary, because the dose is inherently limited by limitations on flying hours.
Canada	5.31	The Canadian Space Agency has considered the draft text of paragraph 5.31 and concludes that it recognizes the special nature of space activities and is in strong agreement that the text remain unchanged in any subsequent revisions to the document.		X			

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Schedule I: Exemption and Clearance							
ICRP	Schedule I	Specify the mass for averaging of the specific activity	A criterion in terms of specific activity without an associated averaging procedure is ambiguous and cannot be use as a quantitative criterion.			X	The question of averaging depends on whether the activity is reasonably homogenous throughout the material or concentrated on the surface. This is a complex question and the IAEA is preparing separate guidance on this
Belgium	Schedule I	Add a paragraph on exemption levels in terms of surface contamination.	Coherence with TS-R-1, para. 107.	X	A paragraph has been modified that allows clearance of material in terms of surface contamination (para I-13).		

Belgium	Schedule I	Add footnote to schedule, with regard to the decay chains of U and Th, stating that "In specific circumstances, lower values can be specified by the regulatory authority"	1 Bq/g does not offer sufficient guarantees for adequate protection in some specific circumstances (see also above, remark on 3.4.a)	X	Para I-12(c) has been added regarding dose criteria for clearance of material containing radionuclides of natural origin.		
China	Schedule I	NORM will be managed at exposures approximately one hundred times higher than man-made sources. This presents a major difficulty in developing a system to regulate exposures from NORM and explaining it to members of the public. Suggest to introduce the definition of "NORM" in DS379, referring to the ICRP publication No.104. Extend the content with relevant requirements or recommendations for NORM management.	The industries invovling in NORM could play an important role in economic development especially in developing countries. The attention to the radiation safety in such industries will help to provide protection to a large population. The technical guidance or safety management guidance for exposure in NORM industry is expected.			X	NORM is defined already in the Safety Glossary but is not repeated in the BSS Glossary because the term is not used. RASSC discussed the criteria for regulation of NORM and decided thst no change should be made. Any material that is not subject to control according to draft 3.0 is of similar activity concentrations to those of normal rocks and soil
China	Schedule I	Make further improvement to reduce certain confusion in the paragraph	a) The nuclides given by table I-1 (moderate amounts of material) include the nuclides of ^{235}U, ^{232}Th. Does it mean that if the quantities involved are at the most of the order of a tonne, these radionuclide are deal with as artificial origin(10μSv/a) ? I-9 b) Said : "In the case of naturally occurring radionuclides, the activity concentration of each radionuclide in		The text has been clarified. Replace "naturally occurring radionuclides" with "radionuclides of natural origin". It is applicable to radionuclides of natural origin		

			the uranium and thorium decay does not exceed 1Bq/g……". Does it mean that this principle is also correct for the material containing these natural radionuclides from nuclear facilities (nuclear fuel cycle)?		from nuclear facilities, but any material being cleared may also contain radionuclides of artificial origin which have to be taken into account.		
EC	Sched I	It should be made clear what values to use as exemption levels for natural radionuclides (3.4 not consistent with I-4). For clearance of natural radionuclides a dose criterion should also be introduced, as well as indication that if drinking water supplies might be affected this would call for special attention. Basically the whole Schedule I needs rewriting. See also comments 7 and 8 below. At least delete the paragraphs that cause confusion (I-4 and I-9 (b)) pending a more thorough revision.	The 1 and 10 Bq/g criteria for natural radionuclides are not enough. In some situations, in particular when rest-products are recycled into building materials or when drinking water supplies are affected, doses to members of the public may be considerable.	x	An additional paragraph has been added with dose criterion for clearance of material containing natural radionuclides (para I-12(c))	X	Para 3.4 defines the scope of Section 3, and these values are not the same as exemption values. Building materials are outside of the scope of Section 3, and are controlled separately under existing exposure situations (i.e. Section 5).
France	Schedule I		Table I.1 apply to transport Table I.2 apply to bulk amounts of material for other practices. For some radionuclides the factor between the values for activity concentration is 10^4. Some material consignments will be exempted for transport and not for other practices. This should lead to errors for instance for recycling of radioactive material in			X	Higher values apply to transport because the exposure scenarios are more limited. Transport of material in accordance with the Transport Regulations ensures compliance with the BSS

			decommissioning activities				
ILO UK (employers)	Schedule 1	Comment	There are some items that contain small quantities of radioactive materials that are less than the exemption values, but are none-the- less required to be labelled when transported in bulk under the IAEA TS-R-1 requirements. There needs to be a consistency of approach. Such items include lamps containing krypton or thorium and igniter units used in such as aero engines which contain krypton or tritium.		Accept comment, but this is an issue for TS-R-1 and not for the BSS.		
ILO Finland (Min of Employers)	Table I-1 in Appendix I	Ca-41	In comparison with the previous BSS, several radionuclides have been added to Table I-1 in Appendix I, alongside details of activity concentrations. Radionuclide C-41 is probably incorrect, the intended one being Ca-41	A			
WNA	Specific Schedule I I-10	**Exemption and clearance** - Add the following underlined expressions. I-10. Clearance may be granted to subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form of the material, or to the use or disposal of the material[46]. <u>In addition, the relevant level given in Table I-2 of Schedule I can be allowed to be higher by up to ten times according to the nature of the national regulatory</u>	In RS-G-1.7, there is a comprehensive paragraph describing essential approach to radiological protection on clearance and exemption for bulk solid materials as follows: *GRADED APPROACH* *5.12. For activity concentrations that exceed the relevant values in Table 1 or Table 2 by several times (e.g. up to ten times), the regulatory body may decide (where the national regulatory*	X	The text of I-10 has been modified to remove the "granted subject to conditions." The "graded approach" is included in the BSS. The text of para 5.12 of RS-G-1.7 applies to		

		infrastructure.	*framework so allows) that the optimum regulatory option is not to apply regulatory requirements to the legal person responsible for the material. The mechanism for giving effect to such a decision will depend on the nature of the national regulatory infrastructure. In many cases, a decision will be made by the regulatory body on a case by case basis, following notification, and will take the form of exemption. In some cases, the regulatory body may specify that exposure arising from certain human activities involving activity concentrations of this magnitude need not be regulated.* The grade approach in this paragraph is a significant part of consensus when the agreement of publication of RS-G-1.7 was achieved in 2004. This graded approach should be surely included in the text of Schedule I in the BSS, if the revised BSS finally takes the relevant values of RS-G-1.7 into the Schedule I.		exemption and not to clearance. Para. I-4 of revised BSS allows exemption of bulk amounts of material containing radionuclides of natural origin, on a case-by-case basis, and providing dose criterion of around 1 mSv/y is met.		
UK	Schedule I, Footnote 41 (to I-2)		The wording states that a safety assessment on whether a practice or source within a practice is exempted would be done by, or on behalf of, the regulatory body. Currently, a safety assessment on whether a practice is exempt or not can be done by the licensee, which is entirely appropriate for some practices. We suspect that the wording refers to high-level policy rather than implementation of the	X	The footnote has been deleted.		

			policy by the licensee, but this should be made clear.				
Brazil	Table I.1 Schedule 1	Table I.1 - …Exemption **and clearance** ….	This table applies to small to moderate quantities and should address both exemption and clearance. There is no sense in changing the classification of some material because of its location inside or outside a regulated practice.			X	Table I-1 values are not necessarily valid for clearance scenarios
Germany	Schedule I, Table I-1	Replace C-41 by Ca-41 Replace Oc-182 by Os-18 For Th-229, replace 1x10° by $1x10^0$.	Typing errors	**X**			
Australia	Sched. I-1.	In I-1(a) delete the phrase "and the exempted practice or source is inherently safe".	The concept of 'inherently safe' is more clearly captured in the existing phrase 'with no appreciable likelihood of scenarios that could lead to a failure to meet this criterion'. The inclusion of the deleted phrase may confuse as it is not clear what 'inherently safe' means.	X			
ILO UK (employers)	Schedule I, I-2	Delete words 'of the order of' replace with "is unlikely to be greater than" 10 micro Sv.in a year.	How is 'of the order of' defined? Recognise that current wording is as previous BSS.			X	No justification for deviating from current BSS. The present wording is consistent with the approach taken for other exemption criteria, which are also not stated more precisely than an order of magnitude
UK	I-2, Footno	Modify to read: "…of a safety assessment undertaken by,	In the UK, Government is responsible for justification decisions. Modifying	X	Footnote 41 has been deleted.		

	te 41/2	on behalf of, the Member State or the regulatory body."	the text as suggestion also provides more flexibility for Member States to decide whether Government or the regulatory body makes the decision.				
Israel	I-2	The "low" probability is a matter of interpretation. We suggest mentioning the probability or the practice, or suggesting bibliography. By allowing to increase the low probability dose, as much as 100 times (!), from 10 μSv to 1 mSv, the standard adds new planned or existing radiation sources, which may never be removed. We suggest restricting the dose for exception and clearance, as in the present standard.			The text of the comment is not clear. "low probability" is a matter of interpretation for each regulatory body to decide. Some changes to the text have been made to improve clarity.		
Slovenia	I-2	**Proposed replacement of the text under Schedule I**, paragraph I-2; (old text in the last line: …"to such low probability events does not exceed 1 mSv in a year."): … to such low probability events does not exceed dose limit for public exposure in special circumstances specified in Schedule III				X	The value of 1 mSv is in accordance with RS-G-1.7 and was used in the derivation of the values
Japan	Schedule I, Table 1-2	In the table of bulk amount (Table I- 2), the target should not be only artificial nuclides, but also U-234, U-235, and U-238 without their progeny nuclides. Information of induced specific activity for each pure U-234, U-235, and U-238 is needed in Table 1-2.	Formula in 1-11 would be used for exemption and clearance ofradioactive material containing more than one radionuclide. However, in the cases for naturally occurring radioactive nuclides with their decay chains, their progeny nuclides shows equilibrium condition with their parents; this means the related concentrations of all nuclides are same. When using the formula I-11 for these, specific activity levels of U-234, U-235, and U-238 for exemption and clearance would be extremely smaller. As a result ofthis, exemption and clearance of naturally occurring radioactive nuclides		The text of I-11 has been modified to improve clarity.	X	The formula does not apply to radionuclides of natural origin. See paragraphs 4.6-4.8 of RS-G-1.7 on how to treat mixtures. For these radionuclides, the criterion for clearance is that each radionuclide must be at 1 Bq/g or less.

			with their decay chains would be impossible actually. In order to overcome this puzzling situation, a concept fo "exclusion" was applied to naturally occurring radioactive nuclides with their decay chains in RS-G- 1.7. For example, an induced value of IBq/g is applied to the criteria of exemption and clearance for each nuclide in U-series in RS-G-1.7. On the other hand, some nuclear-fuel relating facilities, for example, own solid materials contaminated with only U-234, U-235, and U-235 (without their progeny).For these nuclides, exemption and clearance are possible using the formula 1-11. Because they do not satisfy the necessary condition to apply the concept of exclusion, they should be considered and treated as same as artificial nuclides. In addition, exemption activities for moderate (small) amount of nuclides of one ton order or less are shown in Table 1-1. The table shows induced specific activity for exemption of U-234, U-235, and U-238 as the value of lOBq/g. Induced specific activity for exemption and clearance of U-234, U- 235, and U-238 should be calculated and shown in Table 1-2 with applying the above concept of Table 1-1. The value of them might be calculated as a level of around 1-10 Bq/g for Table 1-2. This could realize more reasonable exemption and clearance procedure comparing a situation based on the exclusion concept which uses 1 Bq/g.			

NEA	I-2	MODIFY FOOTNOTE 41: … or less in a year[41] … FOOTNOTE 41: A decision on whether or not to exempt a practice or a source within a practice is normally made on the basis of a safety assessment undertaken by, or on behalf of, the **government or** regulatory body.	The EGIR explicitly added '"government or" to the footnote because in some countries the responsibility for this is held by the government, not the regulatory body		As stated under the preceding comment "UK: Schedule I, Footnote 41 (to I-2)", footnote 41 has been deleted.		
Germany	Schedule I, Table I-2	It is recommended to reconsider the values for C-14 and I-129.	The consistent application of the RS-G-1.7-values for artificial radionuclides is very much supported and has first priority. But the "Comparative Study of EC and IAEA Guidance on Exemption and Clearance Levels"(RP Nr. 157) revealed that for C-14 and I-129 the assumptions and models used by RS-G-1.7 and Safety Report 44 concerning the water pathway may be too restrictive. Therefore the derived clearance levels for these radionuclides may be too low and even practically not manageable (routine measurements in clearance procedures). Therefore it is proposed to consider whether for the above radionuclides - instead of the RS-G-1.7-values - the EC-guidance values from RP122, which are 10 times higher, might be preferable.			X	It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.
UK	Schedule I, I-2, I-8 & I-13		The terms "low probability" and 'residual radioactivity' should be defined in the glossary to improve clarity.		"low probability" is a matter of interpretation for each regulatory body to decide. Some changes to the text have been		

					made to improve clarity.		
Japan	Schedule I-3	(Add the following underlined expressions.) (a) Radioactive material in a moderate amount, that is at most of the order of one tonne, for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration used in the practice, does not exceed the applicable exemption level given in Table I-I of Schedule I; except that for radionuclides of natural origin these conditions for exemption apply only to their incorporation into consumer products, or for their use either as a radioactive source (e.g. 226Ra, 210Po) or for their properties as chemical elements (e.g. thorium, uranium): (b) Radioactive material in a bulk amount, that is considerably greater than one tonne, for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table 1-2 of Schedule I;	The term "moderate" or "bulk" is ambiguous to understand and unclear. It should be clarified the scope ofthe application.			X	Footnote 46 provides guidance on moderate and bulk quantities.
IRPA	Schedule I I-3(a) Schedule I I-3(b)	"Radioactive material in a moderate amount, that is at most of the order of one tonne, …" "Radioactive material in a bulk amount, that is considerably greater than one tonne, …"	The term "moderate" or "bulk" is ambiguous to understand and unclear. Although the characterization "moderate" is implied in Footnote 43, the term "bulk" is not defined. The characterizations should be made clear in the text.			R	See footnote 42 (footnote 48 in draft 3.5).
Canada	Schedule I	According to I-2 and I-8, the same criteria should apply to both exemption and clearance.	This inconsistency should be clarified or changed			X	Table I-1 applies only to exemption relating to moderate quantities,

	I-3(a) and I-9(b)	Schedule-I gives 100 Bq/g and 10^6 Bq total for exemption of K-40, yet I-9(b) gives 10 Bq/g for clearance of K-40, with no mention of total activity. Likewise, Schedule-I gives 10 Bq/g and 10^4 Bq total for exemption of U and Th, yet I-9(b) gives 1 Bq/g, for clearance of U and Th with no mention of total activity.					which involves a much more restricted range of exposure scenarios than those for exemption in bulk quantities and clearance
ICRP	pg 106, I-3(a) line 1		The sentence is very complicated to comprehend. It will be helpful to give in the footnote examples for which the exemption does not apply. Could the counter-weight of airplane be an example?		The text has been modified.		
Sweden	Schedule I I-3	Under the criteria in paras I-1 and I-2, unless the practice is subject to notification or authorization, the following sources within practices are automatically exempted without further consideration from the requirements of these Standards, including those for notification, registration or licensing.	It should be stated that the exemption criteria in I-3 a and b are not applicable for sources within notified or authorized practices, for which the concept of clearance apply instead.			R	Covered by para 3.10.
Sweden	I-3 a	I-3 (a) Radioactive material in a moderate amount for which either the total activity of an individual radionuclide in the practice at any one time or the activity concentration of any radioactive material in the practice, does not exceed the applicable exemption level given in Table I-I of Schedule I	Substitution of the unclear wording "on the premises" by "in the practice". Clarification of which material the activity concentration should be determined for.			R	No clear justification to change text in current BSS.
Sweden	I-3a		The sub sentence "except that for…" should be clarified		Text has been deleted..		
Canada	I-3 (b)	The text should clarify whether the values of Table I-2 apply to all materials including non-effluent liquids.	IAEA-RS-G-1.7 (2004) states that these values apply to solids only. If they are intended to apply to non-effluent liquids as well in this			X	RS-G-1.7 does not state that the values apply to solids only.

			document, this should be stated, and the reference to the basis for extending their applicability to non-effluent liquids should be provided.				However, according to RS-G-1.7, Table I-2 does not apply to discharge of liquids.
Poland	I-3 (b) and footnote 42	INSERT in footnote 42 after the words: „(see Ref. [2.0]): „Amounts greater than 1 tonne are considered to be bulk quantities.”	Bulk amount is not described in footnote 42			X	Footnote 42 states that moderate quantities are of the order of one tonne. It is implied that larger quantities are bulk.
Ukraine	Schedule I Para I-3	It is suggested to complement paragraph I-3 with obvious statement (but not as a foot-note, status of which is not obvious), that Table I-1 can be applied only for the amounts of radioactive materials with mass up to 1000 kg.	Clarification			X	Member States have requested flexibility for moderate quantity. Footnote 42 allows regulatory body to specify the quantity.
Ukraine	Sch. I, Para I-3,	In Table I-1….	There is no Table I-I in Schedule I	X			
Ukraine	Sch. I, F’tnote 43	It is suggested the following wording: «The exemption levels set out in Table I-1 and the exemption and clearance levels set out in Table I-2…»	To be in coherence with a content of each Table.	X			
EC	Sched I Para. I-4	I-4 should be deleted or at least be revised in connection with modifications of 3.4 and I-9 (b). See comment below on I-9 (b).	This paragraph is still very confusing. The intention is probably to provide for exemption of bulk amounts. There is no need for such exemption since the scope of "planned exposure situations" is already defined in 3.4. A case by case assessment in relation to doses to individuals (workers?) of about 1 mSv per year would only apply for		The paragraph is necessary, as it provides the only mechanism for exempting material containing radionuclides of natural origin. Text has been modified to improve		RS-G-1.7 allows for exemption on a case-by-case basis at values greater than 1 Bq/g.– see para 5.11-5.13.

			the application for instance of requirements for occupational exposure (after assessment of doses when the concentration exceeds the levels defined in 3.4, so on a retrospective basis, not for prospective exemption).		clarity.		
Australia	Sch. I I-4	I-4. radionuclides of natural origin, other than when incorporated into consumer products, or used either as a radioactive source or for their properties as chemical elements, shall be exempted be if: (a) The activity concentration of each radionuclide in the uranium and thorium decay does not exceed 1 Bq/g and the activity concentration of ^{40}K does not exceed 10 Bq/g[45]; and (b) An assessment of the doses to individuals, if required by the regulatory body, demonstrates that doses as a consequence of these activity concentrations are commensurate with natural background levels, or unlikely to exceed 1 mSv in a year.	The current I-4 means that there would have to be a case-by-case assessment for exemption of every natural material, even the trivial. It also means there is an inconsistency with the clearance requirements. For example a material may not be exempt under I-4, but could still be cleared under I-9(b). It is proposed to re-word to make it more consistent with the criterion from paragraph I-9(b) for clearance in a new point (a) and some re-wording of I-4 in a new point (b) to give the regulatory body power to require an assessment but not to require it in cases where doses are clesarly trivial. Also remove 'about' in last phrase, similar to I-8.		Exposure to material with activity concentrations not exceeding 1 and 10 Bq/g is outside the scope of planned exposure situations, so exemption would not be relevant to such material. To say that this material is exempt would therefore seem to be stating the obvious. For clearance, the situation is different, because materials below 1 or 10 Bq/g may be generated in a practice and a mechanism is therefore needed to remove them from further regulatory control (I-9(b)). A footnote has been added to para I-4 for clarity.		

Israel	I-4	This section does not offer precise guidance. We suggest defining the natural background in the Glossary, including gamma radiation from soil, radon outdoors, cosmic radiation, radiation from food, drinking water, etc. Is the reader supposed to understand that 1 mSv is allowed from consumer products only? And which are the consumer products?			Definition to be added to Glossary	X	Natural background is defined in the Safety Glossary, so the definition should automatically be included in the BSS Glossary. Changes have been made to I-4 based on all comments received.
ILO UK (employers)	Schedule 1, I-4	Delete 'about' 1mSv in a year. To read: "Doses to individuals as a consequence of these activity concentrations should be unlikely to exceed 1mSv in a year".	How is 'about' defined?		Text has been modified based on all comments.	X	The 1 mSv is not meant to be an exact figure. Some flexibility is required
Sweden	I-4	Deletion of "typically by using a dose criterion that is commensurate with natural background levels"	The sub sentence "typically by using a dose criterion that is commensurate with natural background levels" should be deleted or modified. Lower criteria may be warranted in some cases, with optimization of protection.		Text has been modified based on all comments.	X	For practices, it does not make sense to regulate exposure to radionuclides of natural origin when the doses are in the same range as those received from the natural background. This is part of optimization of protection (appropriate uses of regulatory resources)
UK	Schedule 1, I-4/3	Modify to read: "… exemption shall be considered on a case by case basis. Doses to individuals …"	Exemptions for activities "commensurate with natural background levels" might be difficult to interpret, consider deleting. Our current thinking is along the lines of public dose limits of 300 μSv/yr or 1 mSv/yr for low probability events in particular in relation to disposal/landfill. The modified text suggested, with		Text has been modified based on all comments.	X	It is important to make reference to natural background exposures, since the normal "trivial" dose criterion of 10 μSv is clearly not appropriate

			removal of reference to natural background levels, is consistent with this.				
Brazil	I.5	The Regulations for the Safe Transport of Radioactive Material [5] (the Transport Regulations) do not apply to exempt material or exempt consignments — that is, material in transport for which either the activity concentration of the material or the total activity of an individual radionuclide in the consignment, does not exceed the relevant 'basic radionuclide value' for exemption given in the Transport Regulations44. **The basic radionuclide values in the Transport Regulations are not necessarily equal to the exempt activity concentrations or exempt activities in Table I-1 of Schedule I, since they are derived from specific transport scenarios.**	To provide clarification as to why exempt activities and exempt activity concentrations may vary between the BSS and the TS-R-1.			X	The values in the BSS are the same as those in TS-R-1, even though they relate to different exposure scenarios
France	Schedule I.5	1- Replace : "The regulations for the safe transport of Radioactive material [5] (the transport regulations) do not apply to exempt material or exempt consignments-that is … In general, such basic radionuclide values are numerically equal to the corresponding exempt activity concentrations or exempt activities given in table I.1 of schedule I" by ***"For purposes of material (natural origin or artificial) in transport, exemption means exemption from the requirements of***	The proposal is more obvious and solves points 3.139 *and schedule I.5*			X	The proposed new text is not as explicit

		Regulations for the Safe Transport of Radioactive Material [5].”					
France	Schedule I.5	In footnote a) of table I.1, the list of decay product per isotope is given. This list is the same as the list given in TSR1.	All the values in TS-R-1 are currently under review by HPA. It could be good to wait for the result of their work before validating the footnote a) of table I.1.			X	It was agreed by RASSC to keep Tables I-1 and I-2 unchanged for now
Argentina	Schedule I - Para I-5	Delete the second sentence.	Leads to confusion of concepts.			X	This sentence is necessary to clarify that there are in principle two sets of numbers (with quite different applications) but that the numerical values happen to be the same
Australia	I-6	In (a) change ‘equipment’ to ‘apparatus’	For consistency with the rest of the para.	**X**	‘apparatus’ has been changed to ‘equipment’ for consistency.		
Belgium	I-6/4		Contradiction with I-3(a)? I-3(a) talks about total activity in a premise; I-6 talks about a single apparatus.			X	No clear justification to change current BSS approach.
USA	I-7 to I-10	The set of paragraphs needs to be restructured to first state that clearance may be granted subject to the conditions specified by the regulatory body (existing paragraph 10). The remaining paragraphs, I-7 through I-9 then need to be reorganized and restructured to provide the general criteria that can be used by the regulatory body in considering the	The current order of paragraphs is very confusing, and leads to difficulties for many regulatory organizations, including the United States, which will continue to reserve such decisions. The proposed restructure provided the fundamental position first, that is the		Para. I-10 has been modified in response to another comment, and rfeers to the criteria in I-7 and I-8. Paras I-7 to I-9 are already in a logical		The fundamental “role of the regulatory body” is covered in the main text in para. 3.12 and does not need to be repeated here

		granting of clearance, and then making to specific numerical criteria which could be used by a regulatory body, when the set of underlying conditions and modeling are deemed to be appropriate.	role of the regulatory body, and then provide for criteria that can be used.		sequence (I-7 = general, qualitative; I-8 = dose criterion; I-9 = activity concentration criteria). – and follows same approach for exemption.		
ILO UK (employers)	Schedule 1, I-8	Delete words 'of the order of' replace with "is unlikely to be greater than" 10 micro Sv.in a year.	How is 'of the order of' defined? Recognise that current wording is as previous BSS.			X	No justification for deviating from current BSS. The present wording is consistent with the approach taken for other exemption criteria, which are also not stated more precisely than an order of magnitude
Sweden	I-9 a	Clearance levels for naturally occurring nuclides are missing in Table I-2!	The definition of natural source EXCLUDES radioactive material for use in a nuclear installation and radioactive waste generated in such an installation. Thus radioactive material or waste emerging from a nuclear installation (ie according to the definition A nuclear fuel fabrication plant, research reactor (including subcritical and critical assemblies), nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility) MAY NOT, without further consideration, be released from regulatory control using I-9 b. This is in fairly good correspondence				The term natural source is not used. The values in para I-9(b) are applicable to radionuclides of natural origin from nuclear facilities, but any material being cleared may also contain radionuclides of artificial origin which have to be taken into account.

			with the European BSS (with more stringent criteria for material containing naturally occurring radionuclides that have been processed in view of its radioactive, fissile or fertile properties). However, it means that the current proposal for BSS DOES NOT contain any proposed clearance levels for materials containing naturally occurring nuclides from nuclear installations				
Australia	I-9(b)	Include a table to present the 1 Bq/g and 10 Bq/g (^{40}K) levels for natural materials.	It would be helpful if this information could also be provided in a table, as occurs in various guidance documents, e.g. RS-G-1.7.	X	Table has been added to Schedule I.		
Germany	Schedule I, I-9 (b)	Clearance value of 1 Bq/g for naturally occurring radionuclides in the uranium and thorium decay is not suitable as a generic criterion.	Value not compatible with the dose criteria in I-7 and I-8. Concerning the reasons, compare comment to Para. 3.4 and belonging attachment.	X	I-9 (c) has been added to cover specific situations		
NEA	Schedule I; CRITERIA FOR CLEARANCE	CRITERIA FOR CLEARANCE	The EGIR felt that the text on Clearance is not well though-out and needs to be revisited, although it should remain separate from, the text on Exemption. For example, para I-8 talks about clearance "without further consideration", and para I-10 talks about clearance "subject to conditions", but no distinction or requirements regarding numerical criteria is provided. The specific use of numerical criteria (Tables I1 and I2) as part of		Para. I-10 has been re-written to delete 'subject to conditions'. RASSC agreed to keep Tables unchanged and not to move to an Annex		

			the BSS requirements should be revisited. These may be better off as annex materials. Numerical values should be selected on a unified basis (i.e. exemption and clearance), through a broad and open process, and should be as internationally consistent as possible.				
Argentina	Schedule I - Para I-10	Delete 'to" in between "granted" and "subject".	Improve wording		Para. I-10 has been modified in response to all comments		
Australia	I-10	Change 'granted to subject' to 'granted subject'	Typographical error		Para. I-10 has been modified in response to all comments		
ILO UK (employers)	Schedule 1' I-10	Delete first 'to'	Editorial		Para. I-10 has been modified in response to all comments		
Japan	Schedule I 1-10	Add the following underlined expressions. **I-10. Clearance may be granted to subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form of the material, or to the use or disposal ofthe material46.** **In addition, the relevant level given in Table 1-2 of Schedule I can be allowed to be higher by up to ten times according to the nature of the national regulatorv infrastructure.**	In RS-G-1.7, there is a comprehensive paragraph describing essential approach to radiological protection on clearance and exemption for bulk solid materials as follows: *GRADED APPROACH* *5.12. For activity concentrations that* *exceed the relevant values in Table 1 or Table 2 by several times (e.g. up to ten times), the regulatory body may decide (where the national*				Para. I-10 has been modified in response to all comments. The regulatory body is able to establish higher clearance values provided that the dose criteria in para I-8 are met. It is noted that para 5.12 of RS-G-1.7 refers to exemption

			regulatory framework so allows) that the optimum regulatory option is not to apply regulatory requirements to the legal person responsible for the material. The mechanism for giving effect to such a decision will depend on the nature ofthe national regulatory infrastructure. In many cases, a decision will be made by the regulatory body on a case by case basis, following notification, and will take the form of exemption. In some cases, the regulatory body may specify that exposure arising from certain human activities involving activity concentrations of this magnitude need not be regulated. The grade approach in this paragraph is a significant part of consensus when the agreement of publication of RS-G-1.7 was achieved in 2004. This graded approach should be surely included in the text of Schedule I in the BSS, if the revised BSS finally takes the relevant values of RS-G-1.7 into the Schedule I.				and not to clearance.
IRPA	Schedule I I-10	Add: In addition, the national regulatory framework may allow the relevant level given in Table I-2 of Schedule I to be exceeded by up to ten times (RS-G-1.7).	In RS-G-1.7, there is a comprehensive paragraph describing essential approach to radiological protection on clearance and exemption for bulk solid materials. This graded approach is a significant part of the consensus reached when the agreement to publish RS-G-1.7				Para. I-10 has been modified in response to all comments. The regulatory body is able to establish higher clearance values provided that

			was achieved in 2004. This graded approach should be included in the text of Schedule I in the BSS, if the revised BSS takes the relevant values of RS-G-1.7 into Schedule I.				the dose criteria in para I-8 are met. It is noted that para 5.12 of RS-G-1.7 refers to exemption and not to clearance..
ENISS	Sch. 1, I-10, f'tnote 46	For example, specific clearance levels may be developed for metals, building rubble, and waste for landfill. (see ref 23 and 24)	For clarification		Editorial		
ENISS	Schedule 1, Table I-2	We recommend harmonizing the values of Table I-2 with the corresponding values of the EC recommendations (RP 122/I).	RP 122/I is deemed to be scientifically better justified. (see EC report: "EU policy and legislation requirements on exemption of practices from notification and authorisation and on clearance of materials arising from authorised practices », Wiesbaden 2009)			X	It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.
Argentina	Schedule I - Para 1-11	The text "For exempion and clearance of radioactive material containing more than one radionuclide" should be replaced bv "For exemption radioactive material containing more than one radionuclide (natural or artificial) and for clearance of material containing more than one artificial radionuclide'*...	To clarify than the formula applies for artificial and natural in exemption and only for artificial radionuclides for clearance.	X	Text has been modified – separate paragraphs for exemption and for clearance.		
Belgium	~~I-11~~ **I-10**	Clearance may be granted ~~to~~ subject…	Editorial correction.		Para. I-10 has been modified in response to all comments		
ENISS	Schedule 1, I-11	Where *f(i)* is the fraction of activity ~~or activity concentration~~, as appropriate, of radionuclide *I* in the mixture, *X(i)* is the applicable level for radionuclide *i* as given in Table I-1 or	For clarification	X	Text has been modified.		

		Table I-2, and *n* is the number of radionuclides present.					
Belgium	Table I-1	Th-232sec 1 10^3	This entry is missing.			X	Not included in current BSS. It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.
Israel	I-8	Same comment as for para. I-2 above.			The text of the comment is not clear. "low probability" is a matter of interpretation for each regulatory body to decide. Some changes to the text have been made to improve clarity.		
EC	Sched I Para. I-9 (b)	Footnote 45 should be modified to: "These activity concentration values are not valid when the material is intended for construction of buildings. Control of…".	Footnote 45 still does not make sufficiently clear that these values must not be applied to building materials or to situations where the residues of NORM industries would contaminate groundwater. In addition, there is no clearance criterion (in dose) for natural radionuclides. The criterion in I-4 (which should be deleted for exemption) is more useful in the context of clearance (case-by-case assessment on the basis of a dose criterion which should not exceed 1	X	Text has been modified by adding sub-para (c) to I-9.		

			mSv per year for workers (and for instance 0.3 mSv per year for members of the public). However this would require a full restructuring of the requirements or of Schedule I.				
Philippines	I-9	add “chains” … uranium and thorium decay *chains*	For completeness	X			
USA	I-9a	Revise reference to reflect recommendation to move the Table I-2 of Schedule to be an Annex.	See comment below for rationale for making the Table an Annex, rather than a Schedule.			X	Discussed by RASSC and agreed to keep in the Schedule
USA	I-9b	Reconsider implications of values.	Note: It is not obvious that the criterion specified for naturally occurring radionuclides actually provides protection with a public exposure of less that 1 mSv.	X	Text has been modified by adding sub-para (c) to I-9.		
USA	I-10	Delete the first “to” in that sentence. “Clearance may be granted to subject to…”	Editorial. The sentence will read more appropriately.	X	I-10 has been modified response to all comments. ‘subject to’ has been deleted.		
Israel	Schedule I, I-10	Delete "to" before "subject"	Editorial	X	I-10 has been modified response to all comments.		
UK	Schedule I, I-10	Delete “to” to read: “Clearance may be granted subject to conditions…”	Typo	X	I-10 has been modified response to all comments.		
Ukraine	Schedule I, page 110, Other consid	It is suggested to add new paragraphs: 1. The derived clearance and exemption levels of bulk amounts of material set out in Table I-2 are applicable for homogeneous materials. For practical applications of derived levels the Regulatory body shall define the averaging	To clarify the scope of activity concentration levels applicability	X	The question of averaging depends on whether the activity is reasonably homogenous throughout the		

	eration	mass and limit values of the non-uniformity within that mass. 2. The derived clearance and exemption levels in Table I-2 are not applicable for materials with surface contamination. For clearance of materials with surface contamination Regulatory Body may establish for specific sites materials and situation the radionuclide specific levels for total surface activity (in Bq/cm^2) and/or for fixed surface activity (in Bq/cm^2) basing on the general criteria for clearance in paragraph I-7, as well as the averaging areas for measurements.			material or concentrated on the surface. This is a complex question and the IAEA is preparing separate guidance on this Text of I-10 has been modified to include clearance levels expressed in activity concentration per unit surface area.		
Israel	I-11-I-12	There are human settlements built in areas with high NORM in soil, and industries producing TENORM by- products, exceeding the exception limit of 1 Bq/g. Is the regulating body supposed to impose regulations on the use of the natural soil and of such industry by-products?				X	High natural background situations are not subject to the requirements for planned exposure situations. It is up to the relevant national authority to decide whether such situations are amenable to control – experience suggests that they are not, and are therefore excluded. NORM by-products exceeding 1 Bq/g are subject to the requirements for planned exposure situations and regulated accordingly.
Sweden	I-11	For clarity, the summation formula, as for exemption values, should be used instead				X	To avoid confusion, the same formula as used in the Transport Regs. Is used. It is

							recognised that both formulae are valid.
NEA	Paras I-11 and I-12	**JOINT TO PARAS I-11 and I-12:** The EGIR felt strongly that the nuclides: U234, U235 and U238 should be added to Table I-2. Mixture may contain also nuclides U235 and U238, which are not included in Table I-2, and as such there is a need to amend Table I-2 by adding these two nuclides. Formula in para I-11 would be used for exemption and clearance of radioactive material containing more than one radionuclide. However, in the case of naturally occurring radioactive nuclides with their decay chains, their progeny nuclides are in an equilibrium condition with their parents; meaning that the concentrations of all nuclides in the decay chain are the same. When using the formula I-11 for these, specific activity levels of U-234, U-235, and U-238 for exemption and clearance would be extremely small. As a result of this, exemption and clearance of naturally occurring radionuclides in equilibrium with their decay chains would be practically impossible. In order to overcome this puzzling situation, a concept for "exclusion" was applied to naturally occurring radionuclides and their decay chains in RS-G-1.7. For example, a derived value of 1Bq/g is applied to the criteria of exemption and clearance for each nuclide in U-series in RS-G-1.7. On the other hand, some nuclear-fuel related facilities do have solid materials contaminated with only U-234, U-235, and U-235 (without their progeny). For these situations, exemption and clearance are possible using the formula I-11. Because they do not satisfy the necessary condition to apply the concept of exclusion, they should be considered and treated the same as artificial nuclides. In addition, exemption activities for moderate (small) amount of nuclides of one ton order or less are shown in Table I-1. The table shows derived specific activity for exemption of U-234, U-235, and U-238 as the value of 10Bq/g. Derived specific activity for exemption and clearance of U-234, U-235, and U-238 should be calculated and shown in Table I-2, applying the above concept of Table I-1. The value of them might be calculated as a level of around 1-10 Bq/g for Table I-2. This would result in more reasonable exemption and clearance procedure compared with a situation based on the exclusion concept which uses 1 Bq/g. Note: (Table I-2 is copy from RS-G-1.7, however its change is needed in upcoming revision, since RS-G-1.7 refers back to the BSS 1996.)				It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage. The formula does not apply to radionuclides of natural origin. For these radionuclides, the criterion for clearance is that each radionuclide must be at 1 Bq/g or less.

ICRP	I-13 line 1	Use “Residual material with radioactivity” instead of “Residual radioactive material”.				X	The use of this term is consistent with other IAEA safety standards
Philippines	Table I-1	Heading of column, use *Total Activity* instead of Activity Perhaps an explanation should be added on when to apply activity concentration and total activity for exemption. Suggestion: *When the activity concentration of the radionuclide is exceeded, the total activity of the radionuclide is limiting, when not exceeded the total mass in one location not to exceed one (1) tonne is limiting.*	To be consistent with I-3 under Criteria for Exemption. For clarity when reader directly refers to Table I-1.			X	Text of current BSS is considered clear. Guidance could be considered in a future Safety Guide.
UK	Schedule I Table I-1 (page 123)	Addition of consideration of secular equilibrium between Mg-28+⇔ Al-28 and T-44 ⇔ Sc-44 within this Table under Footnote[a]	These isotopes are in secular equilibrium and to ensure consistency with the other isotopes in secular equilibrium detailed, they should be included within the table.			X	It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.
UK	Schedule I, Table I-1	The values given in Schedule I are based on RS-G-1.7. Some in the UK have concern over some of the proposed values, particularly for U, Pu & Cs-137. These values are all significantly lower than the current exemption limits. They will be very difficult to comply with and are likely to have associated costs, which may be disproportionate to the risk. There is also concern that some employers may stop trying to classify waste as exempt, because the limits are so low that there will be difficulty in both measuring and demonstrating compliance. Consequently, material that could be exempted may well be sent unnecessarily to Low Level Waste Repositories. Greater realism and recognition of the real risks is necessary to avoid excessive pessimism in these values.				X	It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.

USA	Table I-1	We recommend moving values listed in Table I-1Schedule I (Exemption and Clearance) , in an Annex	The listed values may be established as required default values and may be inconsistent with specific country requirements. The requirement is for the regulatory body to establish appropriate values based on the criteria. As such, the numerical values are not a requirement, but supporting material for the requirement, and therefore more appropriately can be an Annex, rather than a schedule. This will remove some of the potential difficulties of having the numerical values themselves be the requirement.			X	Discussed by RASSC and agreed to keep in the Schedule
NEA	Table I-2	The EGIR felt strongly that the nuclides: U234, U235 and U238 should be added to Table I-2 See comment to paras I-11 and I-12				X	It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.
Ukraine	Table I -2 Para 124	Para I-9(a) clearly defines, that for the aims *of "clearance*" Table I-2 must be applied. To avoid possible improper interpretations, it is suggested to change the sequence of words in the name of Table I-2 thus: "*Levels <u>for exemption of bulk amounts of material</u> and <u>for clearance</u>* ..." (further after a text).	Clarification	X			
Bulgaria	Sch. I Table I-1 and I-2	3. The tables of exemption and clearance values in Schedule 1 should be updated through addendum if it is needed, after the revised BSS is published. The review of the current basic safety standards led to the conclusion that requirements on exemption and clearance needed to be updated and incorporated in a graded approach to regulatory control.		X	(No change to text at this stage)		

USA	Note on page 111	Note indicates that Schedule I may need to be updated after the BSS is published. In general, we believe the BSS should not be published until the final values in Schedule I are determined. Recommend inclusion of representatives from various Member States, to include the United States in the updating of existing values of any new values for Schedule I. The United States does not feel the development of the values listed in Schedule I has been transparent throughout the process, nor are we confident that there has been adequate peer review of the values in Tables I-1 and I-2. In addition, nuclides, such as Kr-85, have appeared and disappeared in various drafts of the BSS. For these reasons we believe serious consideration should be given to holding final approval of the BSS until these changes have been adequately explained and peer reviewed.	It is noted that the ICRP dose conversion factors are currently under revision and that there may be a need to update the values listed in Table I-1 before there is a need to update the BSS in its entirety, however, there is concern about how this addendum will be developed. The values in Table I-1 have been considered in the development of a variety of Member State regulations and protocols. Earlier versions of the BSS indicated a desire of some Member States to modify values that could have a significant impact on other Member States. Any modification of Table I-1 values merits a thorough peer review and the involvement of the affected Member States.			X	It was agreed by RASSC that the radionuclide values should remain for now, pending possible reassessment at a later stage.

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Schedule II							
Austria	Sch. II	Nominal or actual activity of the source?			The decision to use nominal or actual activity is a national decision on a case-by-case basis. No change made to text..		
Denmark	Schedule II	The D-values to be used included in the International BSS		X	RASSC agreed that the sub-set of 'D-values' published in RS-G-1.9 would be included in the revised BSS.		
Finland	Schedule II	The D-values to be used should be included in the International BSS.	Not appropriate to refer to values published in a much lower level document	X	RASSC agreed that the sub-set of 'D-values' published in RS-G-1.9 would be included in the		

					revised BSS.		
Ireland	Sch. II	Appreciate that the categories are in relation to ref. 10 but the examples of some of the medical sources (bone densitometers and PET check sources) seems unusual and in note ii, 'factors other than A/D….' could be usefully referenced or listed.		X	Reference [10] has been added to to end of note ii. Annex I of reference 10 provide further details on the factors other A/D that have taken into consideration.		
Norway	Schedule II	The D-values to be used should be included in the BSS.		X	RASSC agreed that the sub-set of 'D-values' published in RS-G-1.9 would be included in the revised BSS.		
Sweden	Schedule II	The D-values should be included in the BSS		X	RASSC agreed that the sub-set of 'D-values' published in RS-G-1.9 would be included in the revised BSS.		

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Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Schedule III							
USA	Page 128, Sections III-1, III-2	Replace "… *over* the age of 18 years" with "age of 18 years and older".	Text excludes persons that are 18 years old.			X	'over the age of 18 years' means that the person has reach ed the age of 18 years..
ICRP	pg 128, III-2	ICRP 103 does not mention exposure to apprentices. The IAEA should justify the limits that are proposed. It is questionable that specifying these special dose limits is needed. Instead, an article could be added in the section dealing with the dose constraints to say that the constraints for sources used in training of apprentices should be lower than 1/3 of the annual dose limits for occupational exposures.	Special limits for this minor group (apprentices) were removed since Pub. 60 on the ground perhaps that the dose constraints will play the role and actual doses received by the apprentices might be far lower than the special dose limits e.g. 6 mSv of effective dose.		.	X	No justification to change the current BSS
Japan	Schedule III	(Paragraph relating to dose limitation for female worker who has notified pregnancy or breast feeding should be added in end of III-l or inserted paragraph as III-3. Similarly, the dose limitation for embryo / fetus should be treated as public exposure.	Dose limits for the employer of a female worker who has notified pregnancy or breast feeding should be indicated in Schedule III. It is very important for some regulatory	X	Text modified.		

		) For example, workers who has notified pregnancy; "III-1(d) Additional restrictions apply to the occupational exposure of pregnant woman." For example, the embryo / fetus; "III-3 (e) Additional dose to the embryo / fetus of less than 1 mSv."	body to incorporate the dose limits into domestic regulations				
Bulgaria	Sch. III	2. The annual dose limit for the lens of the eye (equivalent dose of 150 mSv for occupational exposure of workers, 50 mSv for occupational exposure of apprentices of 16 to 18 years of age and 15 mSv for public exposure - Schedule III) should be changed in the light of new scientific evidence and operational experience, taking into account the ICRP advice to reduce this dose limit.			This issue should be discussed at the RASSC 29 meeting in December 2010, at which time the ICRP report can be reviewed and a final decision taken.		

Chile	Para III-3 literal b)	For public exposure, the DS379 allows that in special circumstances a member of the public may reach, in a single year, an effective dose equal to the implicit five-year limit. Actually para III-3 literal (b) settles down two copulative conditions to be fulfilled, i.e.: In 1 year: $E_{1an} \leq 5[mSv/a]$ (1) In 5 years: $\overline{E}_{5an} \leq 1[mSv/a]$ (2) Since the mean effective dose in 5 years is: $\overline{E}_{5an} = \frac{\sum_i^5 E_i[mSv]}{5[a]}$ (3) Equalizing (2) and (3) turns out that, $\frac{\sum_i^5 E_i[mSv]}{5[a]} \leq 1[mSv/a]$ (4) Simplifying, $\sum_i^5 E_i \leq 5[mSv]$ (5) That is, $E_1 + E_2 + E_3 + E_4 + E_5 \leq 5[mSv]$ (6) According to (1), the first term of this addition should, at the limit, reach 5 [mSv]; i.e. $E_1 = 5[mSv]$ (7) So, replacing (7) in (6) implies that the remaining terms would be null, that is, $E_2 = E_3 = E_4 = E_5 = 0$ (8) In fact, this is a condition/goal impossible to carry out. Apparent mathematical inconsistency	X	Text has been modified to overcome the mathematical inconsistency.		

ENISS	Schedule III	DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS Add a footnote stating that this schedule does not apply in case of accident (potential exposure)	For clarification			X	It does apply in the case of accidents.
NEA	III-1	MODIFY: …workers of ~~over the~~ **age** ~~of 18~~ **years** and over**,** the dose…	The EGIR felt that simply stating "18 years of age" was ambiguous, and as such suggested to be perfectly clear by saying "of age 18 years and over".			X	'over the age of 18 years' means that the person has reach ed the age of 18 years..
UK	Schedule III (page 128)	The limits for doses for the lens of the eye may need to be reduced.	A Task Group of ICRP is currently reviewing the non-cancer effects of radiation exposure. Without prejudging their conclusions it is likely, based on recent publications in the peer-reviewed literature, that the limits for doses to the lens of the eye will be reduced. Consequently, even if it is not possible at present to give new values for these dose limits, the fact that they are likely to change in the relatively near future and that ICRP will be advising on this matter should be highlighted.		This issue should be discussed at the RASSC 29 meeting in December 2010, at which time the ICRP report can be reviewed and a final decision taken.		
Germany	Schedule III, Dose Limits for Planned Exposure Situations, Occup	It is suggested to reconsider the dose limits for the skin.	These limits seem to be set too high when taking into account the latest results from the Japanese A-bomb survivors in Preston et al (2007). On page 31 one reads "Among persons exposed to 1 Gy or more, over 50% of the skin cancers were related to their radiation exposure" In a linear mode the ERR/Gy is 0.58 for non-melanoma skin cancer (ICD10: C44). However the gender averaged ERR/Gy for doses above 1 Gy is high at 1.2 with an			**X**	**The IAEA follows recommendations of ICRP.**

	ational Exposure		upper 99% confidence interval of 2.3 – where this value is even higher for females and for persons exposed at under 30 years of age. There is a very strong age at exposure effect modification to the ERR/Gy centered at an age-at-exposure of 30 years, i.e. a decrease in risk of 73% per decade increase in age-at-exposure. REFERENCE Preston D.L, Ron E, Tokuoka S, Funamoto S, Nishi N, Soda M, Mabuchi K and Kodama K (2007) Solid cancer incidence in atomic bomb survivors: 1958-1998. Radiat. Res. 168, 1-64.				
Germany	Sch.III, Table III-1	Reference	Please add footnote with reference	X	Reference to be added when available.		
Belgium	III-1 (a)	Replace 'per year' by 'per any consecutive twelve months'.	To have a better averaging of the dose.			x	Text is from current BSS, and there is no justification toi change. From the point of view of the doses received, there will be no real difference. From the point of view of bookkeeping, defining the interval as 12 consecutive months is a bit better. Each country

							can choose as they think appropriate.
Belgium	III-1 (b)	Lower the value of 150 mSv by a factor of 3 at least	An increasing amount of evidence shows that this dose limit is definitely set too high. The magnitude of the required change can be discussed in RASSC once the ICRP recommendations on the subject become available. This could be explicitly mentioned, for instance in a footnote or right away in the draft text on the subject (as was previously done for radon).		This issue should be discussed at the RASSC 29 meeting in December 2010, at which time the ICRP report can be reviewed and a final decision taken.		
UK	Schedule III, III-2/1	Modify to read: "For occupational exposure of **young persons** of 16 to 18 years of age who are being trained for employment…"	Schedule III-2 still refers to the term "apprentice". Why can't this paragraph refer to young persons 16 to 18 years of age? Is there some legal issue surrounding apprentices and students? The terms apprentice and student do not capture the whole population of persons 16-18 years who may work with or handle ionising radiation. Some may be young persons starting work, undergoing training but not apprentices or students.			**X**	
ILO UK (employers)	Sch III, III-2	Replace terms apprentice and student with generic term of young person (16-18)	The current wording does not capture all categories of 16 to 18 year olds.			X	
Ireland	Schedule III, III-3 b	The 'special circumstances' for a 5mSv dose should be referenced or stated.			Text has been modified		
Australia	Table III-1	Delete this Table	The dose coefficients are to be changed within the next 2 years by ICRP, and they are not needed to implement the BSS. Other dose conversion factors			X	RASSC was agreeable to the proposal that, once revised and approved, new DCFs

			have been removed on the basis that this is a requirements document and dose conversion factors will be republished in a safety guide.				could be issued on a CD, provided this procedure maintained their status as an integral part of the BSS.
Australia	III-8	Delete	As Table III-1 is proposed to be deleted			X	RASSC was agreeable to the proposal that, once revised and approved, new DCFs could be issued on a CD, provided this procedure maintained their status as an integral part of the BSS..
Israel	Table III-1	We suggest adding the reference ICRP-65.		X	Reference to be added when available.		
USA	Page 130 Table III-I	Insert error bars or ranges with the single values reported in Table III-L	Radon dose assessment can be difficult. The dose per working- hour varies with measurements conditions. But Table III-L provides a single-value method that could result in a gap between real exposure and model predictions. Use of error-bars or ranges would help express uncertainties and prove useful for risk communication purposes.			X	Introducing error bars would weaken the requirement.
ICRP	III-1		occupational exposure of workers: In ICRP publication 103 there are additional recommendations for: - pregnant women, remainder of pregnancy: 1mSv to the embryo/fetus - skin doses: provision for high LET	X	Text has been modified.		

ICRP	Schedule III	Explicit reference will need to be made to tables of conversion coefficients, committed effective dose per unit intake, etc. While some of these values will be published soon it is very likely that the full set will not be available prior to publication of the revised BSS. Nonetheless, some type of reference is necessary. Meanwhile, the use of values already published by ICRP is recommended (e.g. as stated explicitly for radon and progeny in the ICRP Statement on Radon).	The existing BSS includes Tables II-II, through II-X, necessary information for a workable, efficient, and harmonized implementation of the system of radiological protection. Corresponding tables do not appear in this draft. ICRP is currently developing revised dose conversion factors etc. based on ICRP Publication 103 and subsequent work (in particular note the recent ICRP Statement on Radon re: Table II-II).		RASSC was agreeable to the proposal that, once revised and approved, new DCFs could be issued on a CD, provided this procedure maintained their status as an integral part of the BSS..		
Russia	Sch III, footnote		Footnote 49 should have number 47, as footnotes 47 and 48 were missed in the document.	X			
Russia	Sch III, footnote		Footnote 50 should have number 48, as footnotes 47 and 48 were missed in the document.	X			
Russia	Sch III, footnote		Footnote 51 should have number 49, as footnotes 47 and 48 were missed in the document.	X			
Sweden	Footnote 37, p. 103 and TABLE III-I, p. 130		It seems to be an inconsistency in the calculation of annual effective dose (10 mSv and 5 mSv, respectively) from 300 Bq/m^3 of radon concentration at home.		RASSC agreed to a proposal that, once revised and approved, new DCFs could be issued on a CD, provided this procedure maintained their status as an integral part of the BSS.		

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Schedule IV							
Denmark	Schedule IV	The schedule is difficult to read and should be redrafted.				X	The Schedule IV went through numerous technical discussions and is developed in line with the ICRP 103 and 109 and IAEA Safety Guide DS 44
Finland	Schedule IV	The schedule IV is difficult to read and must be re-drafted.				X	
Norway	Schedule IV	Should be re-drafted	Difficult to read.			X	
Sweden	Schedule IV	Difficult to read, must be redrafted				X	
Japan	Schedule IV	"Precautionary urgent protective actions" in Table IV-1 should be in glossary.		X			
Israel	Schedule IV	Although it was decided at RASSC 26 not to include Table IV-1 of Draft 2.0 (generic criteria for protective actions in emergency exposure situations), it still seems that this table is of value in the BSS and should be included in a Safety Requirements document and not just in a Safety Guide (DS44).		X			Table is included as an Annex
ICRP	pg 131, Schedule IV,	Show what AD means in the table caption: ….ACUTE DOSES (AD)…	The notation "$AD_{Bone\ marrow}$" used for external exposure could cause confusion. Note that for internal		X		The notation "$AD_{Bone\ marrow}$" is not used in the

	Table IV-1		exposure it means dose to the red marrow. Proposed one is AD_{major} or $AD_{critical}$. Then footnote (a) may read: $AD_{critical}$ represents dose to the critical tissue (e.g. red marrow, lung, intestine, gonads, thyroid, lens of eye, etc.) for which deterministic effects are highly concerned at high doses.				table. AD is a symbol used by the IAEA for RBE-weighted absorbed dose and introduced in the SG DS44. Definition of RBE-weighted absorbed dose will be added to the Glossary.
ICRP	pg 131, Schedule IV, Table IV-1	The qualification clause "in a uniform field of strongly penetrating radiation" seems to be not important.				**X**	AD corresponds to average absorbed dose in organ or tissue and only in case of uniform irradiation of the body the limitation of red marrow exposure leads to sufficient protection of other organs
ICRP	pg 131, Schedule IV, Table IV-1	In footnote (d), use 50% instead of 5%.				**X**	Generic criteria in Table IV-I are related to threshold dose or intake and correspond to development of effect in 5% of exposed persons.
ICRP	Schedule IV, Table IV-1	A reference to the method of assessment of AD(delta) should be included.	The dose coefficients/methods for assessment of AD(delta) are not available from ICRP and are not anticipated yet in the forthcoming ICRP publications.	**X**			Concept of RBE-weighted absorbed dose introduced in the SG DS44. Dose coefficients for AD(delta) are

							available from a number of the IAEA publications (e.g. EPR-MEDICAL (2005) and EPR-D-VALUES (2005))
ICRP	Schedule IV, Table IV-1	A criteria "Z≥90" and "Z ≤ 89" should be replaced with "for alpha-emitters" "for others", respectively.				X	Criteria address differences in radionuclide biokinetics of different bone-seeking radionuclides, but not decay mode. Relevant footnote is added
Germany	Schedule IV, Table IV-2	Modifications to footnote a: "These values apply only to exposure from external penetrating radiation. The ~~dose~~ exposure from non-penetrating external radiation and from intake or skin contamination needs to be prevented by ~~all possible~~ appropriate means.	The requirement of "all possible means" is too strong.			X	Dose is the correct term in this context. Current wording is consistent with SG DS 44 and reflects the need to apply possible efforts to protect from these pathways of dose formation

<table>
<tr>
<td>Belarus</td>
<td>Schedule IV
Table IV-2</td>
<td>Schedule IV
Table IV-2 GENERIC CRITERIA FOR PROTECTIVE ACTIONS AND OTHER RESPONSE ACTIONS IN EMERGENCY EXPOSURE SITUATIONS TO REDUCE THE RISK OF STOCHASTIC HEALTH EFFECTS
<table>
<tr><th colspan="2">Generic criteria</th><th>Example protective actions and other response actions</th></tr>
<tr><td colspan="3">Projected dose that exceeds the following generic criteria: Take urgent protective actions and other response actions</td></tr>
<tr><td>H Thyroid:</td><td>50 mSv in the first 7 days</td><td>Iodine thyroid blocking</td></tr>
<tr><td>E:</td><td>100 mSv in the first 7 days</td><td rowspan="2">Sheltering, evacuation, decontamination, restriction of food, milk and water consumption, contamination control, public reassurance</td></tr>
<tr><td>H Fetus:</td><td>100 mSv in the first 7 days</td></tr>
<tr><td colspan="3">Projected dose that exceeds the following generic criteria: Take protective actions and other response actions early in the response.</td></tr>
<tr><td>E:</td><td>100 mSv per annum</td><td rowspan="2">Temporary relocation, decontamination, replacement of food, milk and water, public reassurance</td></tr>
<tr><td>H Fetus:</td><td>100 mSv per period of in utero development</td></tr>
<tr><td colspan="3">Dose that exceeds the following generic criteria: Take longer term medical actions to detect and to effectively treat radiation induced health effects</td></tr>
<tr><td>E:</td><td>100 mSv in a month</td><td>Screening based on equivalent doses to specific radiosensitive organs (as a basis for medical follow-up), basic counseling</td></tr>
<tr><td>H Fetus:</td><td>100 mSv per period of in utero development</td><td>Counseling to allow informed decisions to be made in individual circumstances</td></tr>
</table>
Taking protective actions at level of dose that indicated in this table will allow reduce the risk of stochastic health effects.</td>
<td></td>
<td></td>
<td>X</td>
<td>Table is included as an Annex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>Schedule IV-1</td>
<td>Delete schedule IV-1</td>
<td>All the tools for the preparedness and response of an emergency situation should be defined in a safety guide.</td>
<td></td>
<td></td>
<td>X</td>
<td>The Schedule IV presents not tools, but criteria for decision making in emergency exposure situations, which needs to be established in advance. They</td>
</tr>
</table>

							represent the vital part of the emergency planning and response arrangements in a country
Sweden	TABLE IV-II, footnote a, second line	… by all possible means**, i.e. the emergency worker should use a protective suit and a protective mask, when appropriate**.	The expression "all possible means" could be misunderstood.			**X**	Current wording is consistent with SG DS 44 and reflects the need to apply possible efforts to protect from these pathways of dose formation
IRPA	Table IV-2	Actions to avert an excessive dose to a large number of people.	See reason for Comment #15			**X**	Averting collective dose is an important action in an emergency
ICRP	pg 131	AD and AD (Δ) should be explained: the concept should be explained and the chosen values of AD and AD (Δ) for the different tissues should also be explained.	Those values are different from the ones recently developed by the NCRP, for example. The NCRP Report 161, Management of Persons Contaminated with Radionuclides: Handbook, 2008/2009 has introduced a new operational quantity, the CDG (Clinical Decision Guide) to provide a measure that physicians can use when considering the need for medical treatment for internally deposited radionuclides or as a screening level indicating the need for a more detailed investigation of tissue-specific absorbed doses over different time periods. For radionuclides other than isotopes of iodine, the CDG is the maximum,			**X**	AD is a symbol used by the IAEA for RBE-weighted absorbed dose and AD (Δ) – for committed RBE-weighted absorbed dose. Theses concepts are explained in the SG DS44 and were discussed with the ICRP prior to finalization. Definition of RBE-weighted absorbed dose will be added to the Glossary.

			once-in-a lifetime intake of a radionuclide that represents: (1) a stochastic risk, as judged by the calculated effective dose over 50 y for intake by adults and to age 70 y for intake by children, that is in the range of risks associated with guidance on dose limits for emergency situations and (2) avoidance of deterministic effects as judged by the calculated 30 d RBE-weighted absorbed doses to red marrow and lungs. The ICRP has judged that no tissues are expected to express clinically relevant functional impairment from internally deposited radionuclides at absorbed doses up to around 100 mGy (10 rad), low-LET or high-LET, with threshold doses for deterministic effects in most tissues in the 1 Gy or higher range (ICRP 103, 2007). Based upon the recommendations and limits for emergency situations and knowledge of deterministic effects, the numerical values of dose used for computing the CDG intake values for different radionuclides, excluding isotopes of iodine, in adults are 0.25 Sv (25 rem) (50 y effective dose) for consideration of stochastic effects [this represents about a 1.3% lifetime risk of fatal cancer attributable to the radiation dose (ICRP,2007)]; **a 30 d RBE-weighted absorbed dose value of 0.25 Gy-eq. (25 rad-eq.) for consideration of deterministic effects to bone marrow; and a 30 d**				The CDG from are levels for planning decorporation procedures. The objective of this planning is reduction of risk of stochastic effects (See Chapter 11 of NCRP-161). Such procedure is one of actions to effectively treat radiation induced health effects. Generic criteria for taking longer term medical actions of 100 mSv of effective dose received in a month is defined in Table 3 of the SG DS44. Table 3 from the SG DS44 is added to as an Annex to the revised BSS.

			RBE-weighted absorbed dose value of 1 Gy-eq (100 rad-eq.) for consideration of deterministic effects to the lungs.				
Russia	TABLE IV-1, footnote(g)		The "decorporation" term is unclear, it should be replaced with more understandable word, or explained in the document.	**X**	Footnote (g) now includes definition of 'decorporation'.		
USA	Table IV-1, Footnote (a)	Change "red marrow" to "red bone marrow"	Consistency with DS44, "Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency."			**X**	Term "red marrow" is used in the SG DS44. For consistency purposes the term red marrow will be used
USA	Table IV-1, Footnote (b)	Change "from contact (e.g. source…" to "from contact with a radioactive source (e.g. source…"	Consistent with DS44, "Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency."	**X**			
Ukraine	Schedule IV Table IV-1	BSS contains the table IV-1 "*Generic criteria for acute doses at which protective and other actions are expected to be undertaken under any circumstances to avoid or minimize severe deterministic health effects*". The same table is in the draft of document "*Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency*" (GSG-*x* DS44 Draft 3) - Table 2. The last document contains also Table 3 "*Generic criteria for protective actions and other response actions in emergency exposure situations to reduce the risk of stochastic health effects*", which is absent in BSS. - It is suggested to complement BSS with the	Need in comprehensive criteria for making decisions	**X**			Table is added as an Annex

		analogical table which sets criteria of introduction of protective measures to minimize the risk of stochastic effects. - Taking into account experience, gained from ChNPP accident in 1986, it is offered to produce the table which sets criteria of introduction of protective measures to minimize the risk of stochastic effects in the following way* (see footnote below table)					
Philippines	Table IV-2	Use *Criteria* instead of Guidance Values, hence *Criteria* for Restricting Exposure of Emergency Workers	To be consistent with Table IV-1 that uses the term Criteria			**X**	Term is equal to that from DS44 [**Error! Bookmark not defined.**]
Hungary	Table IV-2 on p.132, line 1	In the first row re. "Life saving actions" the Guidance value should be elevated: "**Twenty** times the single year occupational dose limit Hp(10)<**1000 mSv**." In this case the note to be deleted. Or: preserving the Hp(10)<500 mSv value, the note below this value should be modified as follows: "This value may be exceeded **twice** under the circumstances…."	1 Sv (most often 1 Gy in acute exposure) is the threshold of appearance of deterministic clinical effects following whole body exposure. Appearance of vomiting in a few percent of exposed persons (2-3 hrs after the acute exposure to 1 Gy) causes no detectable damage to the health of the rescue team member. By significance it is not comparable with the importance of life saving following a severe accidental exposure! (Ref.: Turai, I., Veress, K., Günalp, B., Souchkevitch, G.: Medical response to radiation incidents and radionuclear threats. *British Medical Journal,* 328(7439): 568-572, 2004)			**X**	The content was discussed and agreed with the ILO

ICRP	Schedule IV, Table IV-2	Last row: specify "a large collective dose"	Non-quantitative criterion is ambiguous.			X	Was specified in the previous version based on the NEA proposal as "A collective dose that has been deemed to be large", but then deleted.
ICRP	pg 132, Table IV-2	Therefore, for 500 mSv, we may use "approximate threshold dose for a significant deterministic effect" and for 100 mSv, "the maximum level of dose constraint" to explain the meaning of given numerical values.	"ten (or two) times the dose limit" is used in old days (Pub. 26). The term "maximum single year occupational dose limit" is not used in Pub. 103. The decimal number 10 or 2 does not have any meaning in relation to biological effects of radiation.			**X**	The content was discussed and agreed with the ILO
ICRP	pg 132, Table IV-2	Footnote (a) may be revised to "…from external radiation. The dose from intake or skin contamination…".	In footnote (a), qualification of radiation may not be needed because $H_p(10)$ itself discriminates weakly penetrating radiation.			**X**	The content was discussed and agreed with the ILO
ICRP	pg 132, Table IV-2	TABLE IV-2: GUIDANCE VALUES FOR RESTRICTING EXPOSURE OF EMERGENCY WORKERS The values are different from the ones recommended in ICRP publication103, 2007, table 8, page 117.				X	The content was discussed and agreed with the ILO. There are no significant differences between those values and values from ICRP publication103, 2007, table 8, page 117.

UK	Table IV-2 (page 132)		We question the inclusion of the task "Actions to avert a large collective dose". Would we really expect occupational exposure limits to be relaxed to avert "collective" doses?			X	The content was discussed and agreed with the ILO. Same content was formulated in para. V.27 of the current BSS

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 3.0 of the revised BSS, from Member States and cosponsoring organizations** **Page:** **Date: 9 September 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Glossary							
Argentina	Glossary	Dose magnitudes (quantities and units) should be defined as in ICRP 103 publication.	The definitions in the glossary are not rigorous, use of old units (rem) is not correct and explanations should not be part ofa standard.		Sentences related to old units in the notes have been deleted. The explanations are information notes, like footnotes. They are not part of the definition.		
Australia	Glossary Optimization	Amend last para of **optimization** definition to read 'For medical exposures of patients, optimization of protection and safety is the management of the radiation dose to the patient taking into account that the primary purpose of a medical exposure is to achieve an effective diagnosis or treatment.'	The definition of optimization does not make sufficient distinction between the meaning in the context of protection and safety and optimization in the medical context (where there is a clear benefit to the patient being exposed), i.e. 'commensurate with the medical purpose' is too vague.				1. Not clear that the suggested text is any better. 2. Is vagueness an issue – the requirements specify what needs to be done and by whom.
Belgium	glossary	Clearance level = a value established by a regulatory body and expressed in terms of activity concentration ~~and/or total activity~~, at or below which ~~a source of radiation~~ material may be released from regulatory control.	There are no clearance levels in terms of total activity. Clearance applies to material and not to any source of radiation.	X	Definition has been modified		

Belgium	glossary	exemption level: replace 'dose rate or radiation energy' by 'surface contamination'	There are no exemption levels in terms of dose rate or radiation energy. There are exemption levels in terms of surface contamination in TS-R-1.			X	I-3 includes exemption of radiation generators that are type approved and meet dose rate and radiation energy criteria.
Belgium	glossary	Replace 'medical physicist' by 'medical radiation physicist'; introduce radiation protection (of patients) in the explanation.	Coherence with other terms, e.g. medical radiation technologist.			X	1. Medical physicist is a defined term in the BSS, based on definition of the IOMP. 2. Within the BSS, the medical physicist is focusing on radiation applications in medicine, with responsibilities in the area of patient protection. Therefore, the word radiation is not needed.
Belgium	glossary	sealed source: Add: 'such that radioactive contamination is averted in normal conditions of use (minor mishaps included).	According to the ISO-standard 2919 a se aled source must be categorized according their capacity to withstand certain tests.			X	Explanatory detail not appropriate for definition.
China	Glossary/ exposure categories of…	Refer to the definition of public exposure in ICRP recommendation No.103.	According to the definition of "public exposure" in DS379, for the planned exposure situation, the normal local nature background radiation is excluded, while for the existing exposure situation, the background radiation is included. So there is	X	Definition has been modified.		

			paradox for the two definitions.				
China	Glossary	Suggest to introduce the definition of radioactive material as the "whose activity concentration is more than 0.01Bq/g for alpha radionuclides, and more than 01.Bq/g for gamma and beta radionuclides" referring to the publication of ICRP. Or make the illustration as the reference for regulating scope.	The regulatory body usually comes across some questions from public or stakeholders about the identificaiton of radioactive material. Therefore the definition of the radioactive material will help to make explanation to the public, and facilitate to ensure the regulating scope.			X	The clearance level for some radionuclides that undergo alpha decay is greater than 0.01 Bq/y, so if 0.01 Bq/g was used as definition of radioactive material, it would conflict with the definition of clearance.
Denmark	*Glossary*	The draft 3.0 International BSS was sent out without a complete glossary. This, in fact makes it not possible to determine the exact scope and limitation of some statements.			Check will ne made that all key terms are in the BSS. It is not intended to include a Glossary of all terms used in the BSS.		
ENISS	**Glossary:** **radiation protection officer (p.156)**	A person technically competent in *radiation protection* matters relevant for a given type of *practice* who is designated by the *registrant*, ~~*or licensee*~~ *or the employer* to oversee the application of relevant *requirements* ~~established in international *safety standards*.~~ Θ Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of radiation protection officers for the various types of facilities and activities. States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee or the employer to act as a radiation protection officer and decide, based	In many Member States radiation protection officers are also designated by the employer. Relevant requirements are not primarily those in international safety standards.	X	Definition has been modified.		

		either on international standards or standards of a State where such a system exists, whether such an individual could undertake the functions of a radiation protection officer, for the required facility or activity.					
Germany	Glossary, page 145	"**exposure, categories of** **medical exposure**. (modified) *Exposure* incurred by patients for the purpose of medical or dental diagnosis or treatment; by asymptomatic individuals as part of a health screening programme or of an individual health assessment; by *carers and comforters*; and by volunteers in a programme of biomedical research involving their *exposure*."	Glossary, page 145	X	In response to the comment here and Germany on 3.149, the following footnote to the word "patient" has been added to the definition of 'medical exposure': **medical exposure**. (modified) Exposure incurred by patients[1] for the purpose of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers in a programme of biomedical research involving their exposure. [1]. A patient is a person who is recipient of services of health care professionals and/or their agents that are addressed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring of health; (4) maintenance of health; and (5) treatment of diseases, disorders, and injuries in order to obtain cure or, failing that, optimum comfort and function. Therefore, asymptomatic individuals are included in the definition of this term. For the purpose of these Standards, the term patient		

					refers only to those undergoing radiological procedures.		
Germany	Glossary, page 157	Replace "~~Radiological audit~~" by "Clinical audit" and use the following definition: Clinical audit: A systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary.	Glossary, page 157			X	The term "radiological audit" has been deleted from the Glossary. Note: Radiological audit should have already been deleted. It has been replaced by the term "radiological review". The latter term does not need defining as the requirement as self-explanantory.
ILO Finland (Min of Employers)	Glossary		New terms have been introduced to the extensive glossary while former ones have been changed and others removed. After each term, new or modified terms are indicated in brackets. However, these indications are missing from some new and some modified terms. Moreover, in some cases, a term has been indicated as new, even though it was included in the glossary of BSS 1996 ("planning target volume").	X			
Ireland	*Glossary,* *2.9*	Include the term "Protection Strategy" in the glossary. This is the first time that "Protection Strategy" is mentioned. There is no explanation and it is not included in the glossary.		X	Wording in para 2.9 has been modified. The terms to have normal dictionary meaning.		

Ireland	Glossary: Reference Level	As well as dose and risk, include activity concentration in this definition.		X			
IRPA	Glossary: **radiation protection officer**	Delete: Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of radiation protection officers for the various types of facilities and activities. States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee to act as a radiation protection officer and decide, based either on international standards or standards of a State where such a system exists, whether such an individual could undertake the functions of a radiation protection officer, for the required facility or activity.	Many States have a legislative requirement for the assessment of the competence of QEs or RPEs, but few assess RPO competence. This confusion is illustrative of the variation in understanding associated with the QE/RPO roles.	**X**			
IRPA Germany	Glossary	Insert after optimization of protection: **Optimized protection and safety:** Optimization of protection and safety has been applied and the result of that process has been implemented	Foot note 4 should be repeated in the glossary to indicate that stressing the optimization **process** it is not only valid with respect to 2.10.	**X**			
ILO NZ (trade union)	Text and Glossary	The draft standard refers to **interested parties** in a number of sections. The Glossary says *"the term interested party is used in a broad sense to mean a person or group having an interest in the performance of an organization. Those who can influence events **may** effectively become interested parties".* Trade unions and employees are			The note states that interested parties have typically included trade unions and employees.		

		included in the list of possible interested parties. They should however be explicitly recognised as interested parties.					
IRPA Germany	Glossary	In the definition of "suppliers" include the term "exporters"	The term "exporters" has to be included in analogy to the term "importers" listed in the definition.	X	Definition has been modified		
Japan	Glossary	Add the definition of "remediation" in the glossary "remedial action".	Clarification. IAEA Safety Glossary defines "remediation" and mentions relevant information such as some synonyms of "remediation", such as "cleanup" and "rehabilitation". This information is useful.	X			
NEA	Glossary	ADD ENTRIES: **remediation** (definition as in IAEA Glossary) precautionary urgent protective action (term, which used in Table IV-1)	The EGIR felt that these entries shall be added for completeness.	X			
Poland	Glossary, Defence in depth	Repeat the definition of „defense in depth" presented in IAEA BSS 1996.	No reason to change the good old IAEA definition.			X	Definition changed to be consistent with the Safety Fundamentals and other Safety Requirement Publications.
Poland	Glossary Radioactive material	REPLACE the definition of „Radioactive material" by: "material containing radionuclides of activity or activity concentration exceeding their respective exemption levels listed in Table I, Schedule I, or exceeding dose rates or radiation energy specified in Schedule I, par. I-3, c)."	The term should be understood uniquely in all Member countries.			X	The criteria for exemption is primarily based on dose. The exemption levels given in Table I-1 apply to moderate quantities, while the values in Table I-2 apply to bulk

							quantities of material. Including levels listed in a Table in the definition would cause contradictions.
Poland	Glossary, Committed dose	The term „committed dose" should be replaced by "lifetime dose", throughout the text of BSS	Since "committed dose" now is integrated over a lifetime only, by analogy with "annual dose", above.			X	Definition is consistent with ICRP.
Poland	Glossary, exemption level	The definition of „exemption level" has to be changed, by referring to respective values in Schedule I (see specific comment # 10);	Exemption from consideration by international Basic safety standards levels should be the same in all countries. Exemption levels should not be decided by national regulatory bodies.			X	See above
Russia	Glossary: **committed equivalent dose**		Misprint in formula, wrong equivalent dose rate symbol - $H_T(t)$	X			
Israel	Glossary, suppliers	"to whom" instead of "to who"	Editorial	X			
Sweden	GLOSSARY Clearance and clearance level	Clearance The release of radioactive material or radioactive objects within notified or authorized practices from regulatory control by the regulatory body. Clearance level. A value, established by the regulatory body and expressed in terms of activity concentration and/or total activity, at or below which radioactive material or radioactive objects within notified or authorized practices may be released from regulatory control.	A common language should be used in all descriptions of clearance.	X	Definitions of clearance and clearance level have been modified.		

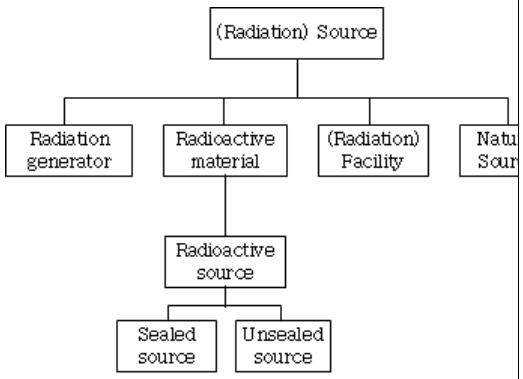
Sweden	Glossary	**radiopharmaceutical** **Pharmaceutical consisting of a radioactive compound used in diagnostic and/or therapeutic nuclear medicine.**	It is proposed that the word "radiopharmaceutical" is included in the Glossary, cf. "radiopharmacist".			X	Not required.
Ukraine	Clearance	It is suggested to complement definition with the following statement: *After decision about clearance material or objects are not subject of regulatory control.*				X	This is covered by para. 3.12
Ukraine	Exemption	It is suggested to complement definition with the following statement: *After decision about exemption source or practice are not subject to are or all aspects of regulatory control.*				X	The definition states this.
Ukraine	Source	It is suggested to add *'Object' in the definition of 'source'*				X	"Anything" is completely general.
Ukraine	Glossary Radiation protection	It is suggested the following wording: Radiological protection (also Radiation protection) principles Protection (against radiation): Radiological protection (also Radiation protection). The protection of people from the effects of exposure to ionizing radiation, and the means for achieving this. Radiological protection (radiation protection) See protection Radiological protection officer (radiation protection officer)	Glossary Radiation protection	X	Text has been modified		

		See protection					
UK	Glossary	Modify the definition to read: "**carers and comforters** (new term) Persons who willingly and voluntarily help (other than in their occupation) **and incur an exposure to ionizing radiation** in the care, support and comfort of patients undergoing medical diagnosis or treatment."	The suggested modification makes it clear that this term applies specifically to individuals exposed to ionizing radiation.			X	1. Carers and comforters are an identifiable group of people, irrespective of whether they incur an exposure. 2. The incurring of an exposure is in the definition of medical exposure. 3. Also, the suggestion would cause problems with the definition of medical exposure.
UK	Glossary	Add a new definition: "**local rules** Working instructions intended to restrict exposure in controlled and supervised areas."	Omission. There is no definition for Local Rules, although they do have a specific role in radiation protection.			X	The text sets out the content of local rules. Further guidance can be provided in a Safety Guide.
UK	Glossary		The EC has identified the need for clarity in the definition of **qualified expert** (several EC projects identified considerable variation in interpretation of the QE definition). It is recommended that the IAEA take account of this work, and consider introducing the new EC concept of the Radiation Protection Expert (RPE). Note: The IAEA was involved in the EUTERP project that developed the RPE concept and definition.		The term 'radiation protection expert' is not used in the BSS. The term 'qualified expert' includes 'radiation protection expert'.		
UK		Modify the definition to read:	The definition is difficult to	X	Definition has been modified.		

		"**optimization of protection (and safety)** (modified) The *process* of determining what level of *protection and safety* makes *exposure*s "as low as reasonably achievable, economic and social factors being taken into account" (*ALARA*), as required by the *System of Radiological Protection*. **(Exposures include the magnitude of individual doses and the number of people (workers and the public) exposed, and the probability and magnitude of potential exposures.)**"	understand in its current presentation. Modify to improve clarity.				
UK	Glossary	The requirement for Radiation Protection Officer competence to be assessed should be deleted.	The additional paragraph under the definition of **radiation protection officer** that says the competence of RPOs is assessed by the State is misleading. Many States have a legislative requirement for the assessment of the competence of QEs or RPEs, but few assess RPO competence. This confusion is illustrative of the variation in understanding associated with the QE/RPO roles and reinforces the need for the IAEA to follow the EC initiatives in this area.	**X**			
UK	Glossary	Consider adding a new definition: "**radiation worker** A monitored worker for dose and health record maintenance requirements."	Consider defining ***radiation worker*** as a monitored worker for dose and health record maintenance requirements rather than all workers.			X	The term 'radiation worker' is not used in the BSS. There is a definition for "worker" in the Glossary.

UK	3.140 and Glossary definition for **consumer product** (page 137)		This paragraph seems fine provided the definition makes it clear that consumer products do not include commodities or construction materials. There is potential confusion as these are addressed by different EU and national regulations (although unusually smoke detectors, one of the examples given, can be considered as both construction products or consumer products).			X	BSS does not use the term "construction product". Consumer product is defined as a 'device ….. '
UK	Glossary	Highlight in the main text all the terms *(for example, by using italics)* that are included in the Glossary.	Improve clarity. Some indication in the text of which terms are defined in the glossary would improve continuity and therefore understanding.		Under consideration by Technical editors		
USA	Page 135	Consider modification: "accident": insert definition # 2 from IAEA 2007 safety glossary pertaining to differences between the IAEA and INES definitions.	To keep consistency in both documents with respect to the IAEA and INES definitions.			X	INES is not referred to in the BSS.
USA	Page 135	Consider modification: "area and "controlled area": remove the term "(modified)" from the definition.	Definition indicates that it was "(modified)" from IAEA 2007 safety glossary; however, the definition is verbatim from the IAEA glossary with the exception of the clarifying notes.			X	"normal" was deleted from "normal exposure" from the IAEA Safety Glossary definition.
USA	Page 136	Consider modification: "carers" and "comforter": insert after "carers" the word "(caregivers)".	The form 'carer" is found in "Cambridge Advance Learner's Dictionary" and is indicated as the UK version with "caregiver" as the US version of the noun.			X	1. Noted, but as "carer and comforter" is a defined term, this addition is not necessary.

USA	Page 141	Correct Formula	In the Glossary – It references committed equivalent dose. The H in the formula parts of Ht(t) has an overstrike that makes the formula unreadable.	X			
USA	Page 145	Consider modification: "medical exposure" (modified): insert the term "caregiver" to the definition.	The form 'carer" is found in "Cambridge Advance Learner's Dictionary" and is indicated as the UK version with "caregiver" as the US version of the noun.			X	As above
USA	Page 161	Consider modification: "radioactive source" (new term): insert the term "(modified)" vice "(new term)".	To maintain consistency of clarifying statement on page 135 since the definition of "radioactive source" is in the IAEA 2007 safety glossary.	X	Definition has been modified.		
USA	Glossary	Consider if additional terms are needed to facilitate the relationship between safety and security.	As the Nuclear Security Series is being developed, there are certain definitions, such as "nuclear material", and "other radioactive material" which have very specific meanings. The connection between safety and security now being examined suggests that the implications of the definitions be considered, both in the BSS glossary, and in the IAEA glossary.			X	"nuclear material" and "other radioactive material" are not used in the BSS. They are defined in the Nuclear Security Glossary.
ICRP	pg 161, Source		Radioactive source should be a sub-category of radioactive material. Hence the hierarchy would look like the figure below where 'natural source' is added to include cosmic or terrestrial sources as defined in the draft. This version still does not include the source in the environment resulting from a practice. To include the latter, 'environmental source' may be used in place of 'natural source'.		Figure has been deleted.		

							
ICRP	Glossary	The following terms should be included - Protection quantity - Dose of records - Operational quantity - Fluence - Kerma - Dose coefficient - Bioassay - Direct radiation	The listed terms are important for the content of BSS. Most of these terms are used in the current draft; some are included into proposed modifications of the draft. Most of the listed terms are defined in ICRP 103.		Definitions for “kerma”, “fluence”, “bioassay” and “dose coefficient” to be added to the Glossary.		“dose of record”, and “direct radiation”, are not used in the BSS. “protection quantity” and “operational quantity” are not used in the BSS, although they are used in Safety Guides that provide guidance on implementing the BSS.
ICRP	Glossary	Absorbed dose. (a) simplify formulation as given in ICRP 103 (b)Replace the last explanation after the definition with the phrase “The SI unit for absorbed dose is joule per kilogram (J kg^{-1}) and its special name is gray (Gy).”	See definition in ICRP 103	X			

ICRP	Glossary	Direct radiation [New term]. The direct emission of radiation from the source, which is capable to cause the external exposure of members of the public. Explanation: For purposes of these Standards the direct radiation includes the scattered radiation from the source and is distinguished from external radiation due to radioactive releases from the source.	The term is used in 3.122, 3.132			X	The term "direct radiation" is no longer used in these paragraphs.
ICRP	Glossary	Dose Equivalent Quantities. (a) Use the formulation of ICRP 103 (b) Add explanation about the SI unit and the name (sievert)	See definitions in ICRP 103	X			
ICRP	Glossary	Effective dose. (a) add a reference to the ICRP 103 Annex B. (b) Replace all explanations (comments) after the definition with the phrase "The unit for the effective dose is the same as for absorbed dose, J kg^{-1}, and its special name is sievert (Sv)."	The reference to ICRP 103 should eliminate an ambiguity in the definition. Values of w_R, w_T, organ masses, sex averaging, "remainder tissues", reference person, etc. are specified in ICRP 103. The proposed comments are confusing, but a proper explanation of the quantity is given in ICRP 103 Annex B	X			
ICRP	Glossary	Equivalent dose. (a) Add a reference to the ICRP 103 Annex B. (b) Replace all explanations (comments) with the phrase "The unit for the equivalent dose is the same as for absorbed dose, J kg^{-1}, and its special name	The reference to ICRP 103 should eliminate an ambiguity in the proposed definition. Values of w_R, sex-averaging, organ masses, reference person, etc. are specified in ICRP 103.	X			

		is sievert (Sv).”	The proposed comments are confusing, but a proper explanation of the quantity is given in ICRP 103 Annex B				
ICRP	Glossary	All definitions of quantities: Add or correct the explanation about the SI unit and the name as indicated above	See definitions in ICRP 103	X			
ICRP	Glossary	Monitoring Keep the current definition in the IAEA Safety Glossary.	The proposed modification in the term is not correct: - “Derived operational quantities” is not a defined term. - term “Operational quantities” is defined by ICRP 103 for external exposure only (See ICRP 103 and ICRU publications)	X	Definition to be modified.		
ICRP	Glossary	Replace term “discharge” with the group term definitions: **release** The act or process of releasing of radioactive materials to the environment; also used to describe the material released (usually gaseous or liquid). **abnormal releases.** Releases that occur as the result of an accident or other unusual condition within a nuclear facility. **airborne releases**. Release to the atmosphere of gases and aerosols. **liquid releases**. Release to the aquatic environment: river, lake, sea or ocean. **discharge.** Authorized release; also used	The current definition of the term “discharge” uses phraseology “planned and controlled release” as disfiguring features of “discharge”. In practical applications a release would be considered as a “discharge” if it was authorized. The degree of the controllability (and planning) of a release cannot be describes as “controlled” or “not controlled”, but in most cases it is associated with the “gray scale”.			X	

		to describe the activity of discharged material. **discharge rate.** Activity of discharged material per a unit time.	For example, release of tritium during normal operation should a part of the discharge authorization, but the degree of the controllability of this component of the authorized discharge is not absolute. Same statement is true for effluents due to rainwater washout from a site.				
ICRP	Glossary	Dose limit Use the definition of ICRP 103.	The planned exposure situation should be included in the definition	X	Definition has been modified		
ICRP	Glossary	D value of radioactive sources	Since the category of radioactive source is very important, it would be useful to give the definition of D value of a radioactive source			X	The footnote to the table in Annex provides an explanation of "D value".
ICRP	Glossary	Air kerma kerma or air kerma is absent	It is a fundamental quantity	X			
ICRP	Glossary	collective effective dose	There are on the term "collective effective dose" and related terms, considering consistency with the current situation of use, it will be better to add these terms.	X	"collective dose" to be added.		
ICRP	Glossary	committed dose – remove definition under "dose"	This is already better defined under "dose concepts", and there is no need for two definitions of the same term.			X	The entry under dose is not a definition, but an explanation under the term "dose".
ICRP	Glossary	**personal dose equivalent, *H*p(*d*).** the *dose equivalent* in soft tissue (commonly interpreted as the 'ICRU sphere') at an appropriate depth d.	As an operational quantity, Hp(d) is defined on the ICRU sphere, it is better to point out that in the definition.	X	Add as an information note.		

ICRP	Glossary	In the notes after Effective Dose, add "Effective dose should not be used to quantify higher radiation doses or to make decisions on the need for any treatment related to tissue reactions."	From P 103, para 105	X			
ICRP	Glossary	In the notes after Equivalent Dose, add "Equivalent dose should not be used to quantify higher radiation doses or to make decisions on the need for any treatment related to tissue reactions."	From P 103, para 105	X			
ICRP	Glossary	**Occupational Exposure** All exposure incurred by workers in the course of their work, with the exception of: 1) excluded exposures and exposures from exempt activities involving radiation or exempt sources; 2) any medical exposure; and, 3) the normal local natural background radiation.	Inconsistent with P 103. See P 103 Glossary, and futher elaboration in P 103 para 178			X	It was agreed by review meeting not to change definition in draft 3.0.
ICRP	Glossary	**reference level**. (modified) In an *emergency exposure situation* or an *existing exposure situation*, the ~~a~~ level of *dose* or *risk* above which in an optimized protection strategy it is inappropriate to plan to allow *exposures* to occur and below which optimization of protection should continue to be implemented.	Typo	X	Definition has been modified		
Spain	Glossary Decommissioning	Contrary to what is said in the "note", "decommissioning" is also applicable for RW repositories as well as for other nuclear facilities used for the disposal of radioactive residues, because such facilities contain several buildings and structures besides those only devoted to "dispose" the waste. "Closure" is only specifically applicable to the "disposal" structures. Perhaps the text of the "note" needs a clarification.		X	Note modified.		

Spain	Dose concepts. Projected dose	Perhaps the word “planned” should be replaced by “programmed” to avoid potential confusion.	X	Definition changed back to that in IAEA Glossary.		
Spain	Exposure situations. Existing exposures situations	The text in the “note” does not fully reflect the different cases described in para. 5.1. Two aspects of 5.1 are not well reflected in the definition: a) Para. 5.1 says that only certain exposure to natural radionuclides are considered “existing”; and b) Para.5.1 includes exposures to residual materials from past practices that were regulated but not in agreement with current standards.	X	Text has been added to the note.		
Spain	Level. Clearance level	In accordance with the definition of “clearance” in page 137, here it should be added “within authorised practices”, right after “source of radiation”.	X			
Spain	Level Operational intermediation level (OIL)	The real need for this concept is not at all clear nowadays.			X	The term “operational intervention level” is used in para. 4.8(c).
Spain	Nuclear installation	The “spent fuel disposal facilities” are not included. Is there any reason for this?			X	“nuclear installation’ not included in the BSS Glossary. It is nnoted that in the Safety Guide GSG-1, spent fule can be classified as high level waste.