COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 4.0 of the revised BSS, from Safety Standards Committees** **Page:** **Date: 5 November 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
General comments							
UK		1. In general, the drafting of version 4.0 of the BSS is good, and an improvement on previous drafts. In particular we welcome the improvements regarding Justification, notably paragraphs 3.18 and 3.20. We believe that there are now no major issues with the version 4.0 of the BSS, except the need to review the dose limit for the lens of the eye. There is evidence that a reduction in the dose limit is warranted, and hopefully the ICRP will be able to provide a more considered input to RASSC 29 in relation to this issue. 2. The UK commented on footnote 41 (to paragraph I-2 in Schedule I) in version 3.0 which said: "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 regulatory body". The resolution of this comment was to delete the footnote. Such a resolution, however, removes the idea that exemptions should normally be made on the basis of a safety assessment. Therefore it is requested that this idea is re-instated in the text of Schedule I of the BSS. A possible means of doing this would be to amend paragraph I-2 by including the following text in italics that is emboldened - so the 1st sentence of paragraph I-2 reads: "A practice or a source within a practice may be exempted under para. I-1(a) without further consideration provided that in all reasonably foreseeable situations, the effective dose expected to be incurred by any member of the public ***(normally evaluated on the basis of a safety assessment)*** due to the exempted practice or source is of the order of 10 mSv or less in a year." 3. We still believe that the exposure of air and space crew should be considered as planned exposure situations, but accept that version 4.0 of the BSS would provide equivalent protection.		X X X	1. ICRP report on dose to lens of the eye is still awaited. 2. Agree. Text to be modified. 3. Noted.		

	4. As a final point, it will be necessary in future to clarify and expand on the BSS text in one or more supporting Safety Guides, and we will look to a number of our comments on version 3.0 of the BSS being dealt with at that level of the safety standards.		X	4. Comments will be considered in the development of Safety Guides.		
Poland	The terms “radioactive material”, “exemption level” and “clearance level” have to be the same in all countries, taking into account numerical values presented in Schedule 1	National specification makes transboundary transport difficult and less secure.			X	It has been agreed that the basis for exemption and for clearance is dose criteria.
ENISS	We acknowledge the acceptance of some comments made by our group with respect to Draft 3.0, especially the acknowledgement of specificities of the transport of radioactive materials (e.g. foot note 10, page 35 regarding no need for authorization, foot note 20, page 58 regarding no need for radiation protection areas). We also welcome the high degree of stability between Draft 3.0 and Draft 4.0. However, as we pointed out time and again we are still concerned about the text on optimization. The optimization issue is not expressed properly and has not been modified according to our proposals. We noted that the Secretariat has commented our proposal for a change which is also supported by several Member States. In the Member States Resolution it reads: *This is a difficult issue – to subject something to a “process of optimization” will not necessarily result in optimization being achieved. Equally, when there is a requirement for something to “be optimized” it will never be possible 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.* That means the Secretariat accepts our position but puts again the emphasis on the result, reduced to the phrase “to ensure that protection is optimized”, whereas the emphasis should be put on the process. Optimization is a principle not directed to a definite result because the results are always specific to the circumstances and the process needs to be repeated on a continuous basis. We believe that this is still a crucial item for the implementation of radiation protection in practice. “To ensure that protection is optimized” is a very strong demand which simply cannot be demonstrated. It will with certainty create difficulties in practice as there are no clear criteria for the “optimized solution” (for further explanations of our concerns about the BSS version of optimization see attached annex). As a way to solve this difficult issue one may consider as an alternative the formulation already used in the Draft 4.0: “ensure the optimization of protection” (see para 3.127, page 70).				X	RASSC 26 (June-July 2009) agreed to use the term “is optimized” SF-1: Principle 5: “Protection must be optimized to provide the highest level of safety that can reasonable be achieved”. Passive form “is optimized” carries binding requirement that is needed for a shall statement. Current BSS uses “protection and safety shall be optimized” – para 2.24.

	Another point of concern is the new definition of environmental protection in the glossary and the corresponding enlargement of the text on environmental protection in Para 1.28. The demand for "*ensure the sustainability of agriculture, forestry, fisheries and tourism and of the use of natural resources, now and in the future"* goes far beyond the practice of radiation protection and compliance with these objectives is impossible to demonstrate. This text needs to be readjusted to the Draft 3.0 formulations. Detailed remarks and proposals for changes (in red letters) in the text see below.			X	In line with Safety Fundamentals, and UNEP position, the sustainability of *agriculture, forestry, fisheries and tourism and of the use of natural resources* is an issue to be considered together with protection and safety.
Hungary R & W	The whole draft is too extended. About half of the material should be moved to guides and other lower level standards.			X	Drafting was based on the agreed DPP.
India	The current version of new BSS is more or less final and is covering all the aspects that were covered in old BSS. However, a few suggestions and comments are given below. As per the draft BSS accidental exposure arises as a result of an accident or a malicious event. Does the accident include a 'Natural calamity' that may result into such exposure? The guidance on exposure of air crew is not very clear. Does this situation is not equivalent to planned exposure for crew members and regulatory limits for planned situation are applicable globally?	X	Accidents (a defined term) do not include natural events or deliberate acts. Aircrew exposure is dealt with in Section 5.		
ISSPA	We acknowledge the acceptance of some comments made by our group with respect to Draft 3.0, especially the acknowledgement of specificities of the transport of radioactive materials (e.g. foot note 10, page 35 regarding no need for authorization, foot note 20, page 58 regarding no need for radiation protection areas). We also welcome the high degree of stability between Draft 3.0 and Draft 4.0 as we believe the vast majority of the paragraphs have already reached a degree of consensus among the radiation protection community. However, we are still concerned about the text on optimization. The optimization issue is not expressed properly. We understand the issue of the Secretariat: *This is a difficult issue – to subject something to a "process of optimization" will not necessarily result in optimization being*			X	RASSC 26 (June-July 2009) agreed to use the term "is optimized" SF-1: Principle 5: "Protection must be optimized to provide the highest level of

	achieved. Equally, when there is a requirement for something to "be optimized" it will never be possible 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. That means the Secretariat accepts on the one hand the problem but puts again the emphasis on the result, reduced to the phrase "to ensure that protection is optimized", whereas we would like to put the emphasis on the process. Optimization is a principle. An optimum is a very ideal situation which in reality can only be converged. We believe that this is still a crucial item for the implementation of radiation protection in practice. "To ensure that protection is optimized" can become a very strong demand when transforming the BSS into national regulations which simply cannot be realized. This can lead to a lack of legal certainty at the operator's site. As we prefer to refer to the optimization as a process, we propose to put the text of the footnote 4 into the glossary Detailed remarks and proposals for changes (in red letters) in the text see below.					safety that can reasonable be achieved". Passive form "is optimized" carries binding requirement that is needed for a shall statement. Current BSS uses "protection and safety shall be optimized" – para 2.24.
USA	The United States appreciates the continuing opportunity to participate in the development of the Basic Safety Standards. The United States requests that a final version, including all technical edits suggested by the IAEA Editor, and the specific resolution of all comments, be provided for review to the Safety Committees for review and agreement. We further request that sufficient time be provided to review the final text. We do not believe it is appropriate to place the review of such an important document on the Chair's of the Committee's. The IAEA should not expect the RASSC, or other Safety Committees to reach a final recommendation at the fall set of meetings because insufficient time will be available to review and understand changes that have been suggested during the current committee comment period.	Standard procedural expectation is that the Safety Committee's agree on the final wording of requirements documents. The draft is currently undergoing editorial review, and thus a final text is not available with sufficient time for review and agreement for the Fall 2010 Safety Committee Meetings.	X	Procedure follows agreed procedures under SPESS manual. Technical edited Version 4.05 was posted for information on 2010-11-05.		

WNA	**Key messages from nuclear industry senior management -** The new draft (version 4.0, 9 September 2010) – as for the current BSS (1996) - continues to overemphasize the tiny public exposure to ionizing radiation received from nuclear energy, even though this dosage represents less than *0.01% (0.0002 mSv/y)* of overall exposure (2.8 mSv/y). ***Above all, this key issue revolves around (1) "imbalance in weighing public radiation exposure from all sources" and (2) "inordinate concern for negligible dose levels". The new draft thus fails to correct a basic flaw in the current BSS, which aims at limiting public exposure from nuclear energy to an extent that goes far beyond any possibility of genuine safety gain***. This unwarranted stress continues to adversely affect the public interest by creating a fundamental imbalance between cost and benefit that works to the detriment of efficient and widespread beneficial use of nuclear energy. ***Through WNA, industry senior management has notified IAEA senior management twice on this key issue*** (prior and after the issuance of BSS draft 3.0): see the attached ***two WNA letters*** dated on 28 October 2009 and more recently dated on 19 April 2010. A third WNA letter of 1 May 2010 (also attached) serves to clarify the direct connection between the two earlier WNA letters (and SENES" conclusions: see general comment No.4) and the IAEA BSS new draft (version 3.0). We trust that IAEA as well as the RP representatives from national governments will pay greater attention to this key issue and to its satisfactory resolution. ***General comment No. 2 provides evidences of the clear imbalance in the control of public exposure from all sources***. IAEA must seek a more sound and balanced international RP system for the control of public exposure. The related large discrepancies in the current BSS (1996) and in the BSS new draft (version 4.0) must be overcome. Resolving this becomes crucially important 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. These benefits should be a major consideration in the BSS revision. To prematurely conclude the BSS revision with the current text would result in a failure to achieve this objective and would instead prolong the essential flaws of the existing BSS for another decade. We hope that, on reflection, IAEA will conclude that this would be an unacceptable outcome. **Above all, the fact that the IAEA BSS draft 4.0 still needs fundamental improvement has been recently re- stated by industry senior management through WNA to IAEA DG Amano (see the WNA letter dated 18 October 2010 and the related information). The**		The application of the requirements requires the graded approach (see paras: 2.12, 2.31, Req. 6, para 3.6.) The detailed requirements apply to all practices and sources within practices as set out in the scope of sections 3, 4 and 5. The requirements for public exposure in planned exposure situations apply to all practices and sources within practices that are in the scope of		

	reader is invited to pay greater attention to this key info.		Section 3, and not only to NPPs.		
WNA	**Evidences on the imbalance in the control of public exposure** – In Section 2, key generic provisions (para.2.12, 2.14 and 2.18) set the general scene for the control of exposure: "…*shall be commensurate with the nature and extent of the radiation risks associated with the exposure*…" "…*shall ensure such protection without unduly limiting the operation of facilities or the conduct of activities*…" "…*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.*" ***The evidences described through General Comments No.5 to 7 and No.11 to 17 show that the more detailed provisions in Sections 3, 4 and 5 of the BSS new draft - which define the coverage of each main source of public exposure – clearly contradict the above key provisions of Section 2***. ***Evidences show that many of the detailed requirements in Sections 3, 4 and 5 are not commensurate to the actual risk. The detailed provisions of Sections 3, 4 and 5 are causing a significant imbalance in the control of public exposure, starting by putting greater stringency on the tiniest exposure***. ***The attached Table 1 is a summary of this imbalance in the requirements for the control of the main sources of public exposure.*** Moreover, the BSS new draft offers no rationale to overcome the key contradictions between Section 2 and Sections 3, 4 and 5. We emphasize that based on IAEA"s own data and analysis, over 99% of the overall public exposure (***2.8 mSv/y***) is from natural background radiation (85%) and from medical applications (14%). There are several key contradictions between the generic key provisions in Section 2 and the more detailed provisions in Sections 3, 4 and 5.		The revised BSS does not alter the approach to the control of public exposure. NORM industries within the scope of Section 3, are required to comply with the same requirements as for nuclear energy. The revised BSS follows recommendations of ICRP. For some sources of exposure, e.g. frequent fliers, provision of information is the only mechanism for control.		

WNA	**Evidences on the inordinate concern for negligible dose levels –** Public exposure from nuclear energy is so small that even at its highest values it is still much too little to alter the general background cancer risk from all causes in the population. Any protective measure at such a low level simply makes no contribution to real radiation safety. ***A new study performed by Japan's Central Research Institute of the Electric Power Industry (CRIEPI) has shown that Japan's general background cancer risk*** - which is among the world‟s lowest – ***corresponds in terms of equivalent health detriment to a public exposure of about 24 ± 1.5 mSv/y.*** ***The average annual radiation dose per individual from nuclear energy (0.0002 mSv/y or less than 0.01% of the overall public exposure) is 120,000 times smaller and it is 7,500 times smaller than this risk's natural variability (± 1.5 mSv/y).*** ***This means that no real radiation safety gain can be possibly made at very low public exposure (e.g. of a few mSv/y or lower).*** There is a compelling case for IAEA to review the grounds on which its radiation safety standards should be based. As no real radiation safety gain can be possibly made at very low dose (e.g. of a few mSv/y or lower), on which other grounds should the IAEA radiation safety standards at very low exposure be based on? Given this, would it be reasonable to seek the same extremely stringent level of protection than in the nuclear industry for the medical and other sectors? Without convincing evidence of genuine health benefit, why would regulators in sectors such as medicine, air transport and other non-nuclear industries move to impose the same extremely strict levels of exposure control as in nuclear energy?		Medical exposure is not public exposure. There is a direct benefit to the patient from a medical exposure. Patients receive a direct benefit from medical exposures. Medical exposures require justification (3 levels) and optimization of protection. The requirements on medical exposure require that the government ensure that diagnostic reference levels are established. Numerical values for diagnostic reference levels are not included in the revised BSS, but guidance on setting them will be provided in a		
WNA	**Independent review of the IAEA BSS new draft (version 3.0) – control of public exposure - by SENES Consultants Ltd (Dr Douglas Chambers): Through its review, SENES has confirmed the imbalance in the control of public exposure (as per General Comments 1 and 2). SENES' conclusions are also compatible with the inordinate concern for negligible dose levels (as per General Comment 3):** *"There is a great disparity in whether and how the exposures from various sources of radiation and radioactivity are controlled."* *"The risks of cancer from an exposure of 1mSv/y are small and well within the variability of the general background risk of cancer from all causes in population."* *"An annual exposure of the order of 1mSv/y might reasonably be considered as the lower bound for regulatory requirements for optimization of public exposure."* *"The annual exposures to the public from nuclear power generation are very low."* Unless otherwise demonstrated, SENES‟ independent review strengthens the key concerns				

	expressed by industry senior management to IAEA senior management: i.e. *(1) "imbalance in weighing public radiation exposure from all sources" and (2) "inordinate concern for negligible dose levels"*.		Safety Guide. The approach to control of public exposure from planned, emergency and existing exposure situations is different. Planned exposure situations require justification for introducing a new source of exposure, optimization of protection (including use of dose constraints), and dose limits for workers and the public. Existing exposure situations require justification of protective actions to reduce		
WNA	**The BSS revision should harmonize the requirements for the control of all sources of public exposures through planned, medical, emergency and existing exposures –** For comparable levels of public exposure, the requirements differ greatly between each main source of exposure: a) Exposure to natural background radiation: its four components - cosmic, terrestrial, internal and radon b) Medical exposure c) Nuclear energy exposure d) NORM industries exposure e) Air passengers (especially frequent fliers) exposure f) Exposure associated with the exemption and clearance of radioactive material g) Exposure associated with consumer products and commodities ***General comments No.11 to 17 highlight the differences in the coverage of each main source of public exposure.*** ***Irrespective of the breakdown of exposure situations between planned, medical, emergency and existing exposure, the coverage of each main source should be much clearer and more balanced***. ***At the beginning of Sections 3, 4 and 5, it is very difficult to have a clear picture of how each main source of public exposure are covered (or not), to which extend, and of whether or not it is thoroughly commensurate to the actual risk.*** The coverage of each main source (facility or activity) of public exposure is unclear. The detailed provisions of Sections 3, 4 and 5 reveal great disparities in the coverage of the public exposure as well as key contradictions with the generic provisions of Section 2 (see also General Comment No.2). This coverage needs to be harmonized. As part of the harmonization of the global safety regime -which is IAEA‟s main goal with integrated safety as a key driver - radiation safety requirements on public exposure should also be commensurate to the safety requirements in other safety fields – with safety requirements based on the actual risk.				

WNA	**Disproportion in the number and stringency of requirements between the three exposure situations (Part I)** – **Per type of exposure situations**, the approximate number of requirements related to public exposure is as follow: Section 3 - Planned : General (76 requirements) Section 3 – Planned: Public exposure (32 requirements) Section 3 - Medical exposure: (50 requirements) * Section 3–Planned: Occupational exposure (57 requirements)* Section 4 - Emergency: General (5 requirements) Section 4 – Emergency: Public exposure (6 requirements) Section 5 - Existing: General (5 requirements) Section 5 – Existing: Public exposure (30 requirements) ***As public exposure associated with planned situation is much smaller, it is therefore notably surprising to note a comparable number of requirements for existing public exposure and a much smaller number of requirements for emergency public exposure***. ***Moreover, planned public exposure is subject to more stringent requirements than for the much higher medical public exposure and existing public exposure.*** Planned public exposure is subject to a very stringent three-level control mechanism (dose limit from all sources of 1 mSv/y, constraints and operating limits) whereas: (1) the much higher medical public exposure is not subject to a public dose limit nor to a numerically-set criteria for diagnostic reference levels, and (2) the much higher existing public exposure is subject to reference levels which can range from 1 to 20 mSv/y, with options for excess. ***Is the above commensurate to the actual risk?*** There are clear evidences of disproportion in the number and stringency of the requirements for public exposure between planned, medical, emergency and existing exposure situations.		exposure, optimization of protection (including use of reference levels).		
WNA	**Disproportion in the number and stringency of requirements between the three exposure situations (Part II)** – **Per main source of public exposure**, the requirements" coverage is as follow for the seven main sources of public exposure: a) ***Exposure to natural background radiation***: its four components - cosmic, terrestrial, internal and radon. Only a dozen requirements apply to radon in homes with reference levels which can range from 1 to 20 mSv/y and an option for excess. The general average concentration should not lead to exceeding about 10 mSv/*y*. See General Comment 11. b) ***Medical exposure:*** No public dose limit and no numerically-set diagnostic reference levels are required. See General Comment 12. c) ***Nuclear energy exposur***e: The full Section 3 applies (including a dose limit of 1 mSv/y from all sources, constraints and operating limits) – See General Comment 13.				

	d) **NORM industries exposure**: If concentrations in input material are above a set level, the full Section 3 applies. Otherwise, the much less stringent Section 5 applies with reference levels which can range from 1 to 20 mSv/y and an option for excess. See General Comment 14. e) ***Air passengers (especially frequent fliers) exposure***: ***Neglected.*** See General Comment No. 15. f) ***Exposure associated with the exemption and clearance of radioactive material***: Only a few provisions of Section 3 apply. See General Comment 16. g) ***Exposure associated with consumer products and commodities***: Only a few provisions of Section 3 (consumer products) and of Section 5 (contaminated commodities) apply. See General comment No.17. ***Is the above commensurate to the actual risk?*** There are clear evidences of disproportion in the number and stringency of the requirements for public exposure between the main sources.				
WNA	**Potential considerations for the development of a more balanced policy in controlling public radiation exposure from all sources** – Further to General Comments No.1 to 7, ***adding a few key generic provisions on public exposure is needed in Chapter 2 in order to set a balanced framework for public exposure*** prior to its subsequent more detailed coverage by planned, medical, emergency and existing exposure situations. Such key generic provisions should include the following: *1. All routine public exposure to ionizing radiation should be included in the RP policy framework with emphasis on the sources of highest exposure and with action on exposure to be based on the real expected impact on public health and environmental radiation safety. Prescribed actions should take into account:* *• The general background cancer risk from all causes.* *• The fact that no real gain in radiation safety can be made for exposures that are very low (e.g. about 1 mSv/y or lower).* *• The public health and environmental benefits (individual or collective) of the activities that give rise to exposure* *• The need to tailor actions to the real exposure risk of any given source.* *2. Limitations on the use of a beneficial technology (such as nuclear energy and medical applications using ionizing radiation) should be based on a full analysis of costs and benefits.* 3. *Countries that wish to retain the current levels of excessive RP protection should not be*				

	allowed to impose that preference on others. The operative international standard should be justified by a sound, up-to-date and practical safety evaluation, and not by previous ill-based practice and simple inertia. A few key generic provisions on public exposure is needed in Chapter 2 in order to set a balanced framework for public exposure prior to its subsequent more detailed coverage by planned, medical, emergency and existing exposure situations in Sections 3, 4 and 5.				
WNA	**Potential considerations for the development of a more balanced policy in controlling public radiation exposure from all sources – extra considerations –** ***Given of all of the above, clearly, the emphasis for the control of public exposure should be put on the main sources which result in exposure higher than about 1 mSv/y or which have a significant probability to result in exposure significantly higher than a few mSv/y.*** [See General Comment 8 – Item 1.] ***Below this level of public exposure, requirements should be minimal***. A further reflection on the definition and applicability of the public dose limit from all sources of public exposure seems therefore warranted in order to seek more balance in the control of public exposure. As it stands in the BSS new draft (Schedule III, para.III-3) states that: *"For public exposure, the dose limits for members of the public are:* *(a) An effective dose of 1 mSv in a year;* *(b) In special circumstances, an effective dose up to 5 mSv in a single year provided that the average over five consecutive years does not exceed 1 mSv/y…"* ***In comparison to the overwhelming public exposure from natural background radiation*** (with reference levels from 1 to 20 mSv/y, and a option for excess) ***and to medical exposure*** (no dose limit and no numerical diagnostic reference levels are required), ***what are the best options to control other main sources of public exposure commensurate to the actual risk?*** Experience shows that a very stringent three-level control mechanism (a strict dose limit of 1 mSv/y from all sources, constraints and operating limits) has resulted in average public exposure from nuclear energy of only 0.0002 mSv/y. Everything being equal, should the excess severity in control be reduced by a factor of 10 (e.g. by an higher dose limit and by a simplified two-level control mechanism), the resulting average exposure would only be 0.002 mSv/y – which is still inconsequential in terms of both increased public exposure (relative to 2.8 mSv/y) and of associated health risk. Seeking a more balanced framework for public exposure from all sources.		See above		

WNA	**Potential considerations for the development of a more balanced policy in controlling public radiation exposure from all sources – extra considerations –** ***Confusion between the ability, with extra effort and cost, to possibly further reduce public exposure through improved technologies and practices, and real radiation safety, needs to be overcome***. As shown, the extreme stringency built in the current BSS (1996) and in BSS new draft for the control of public exposure from nuclear energy is incorrectly based on the assumption that such measures contribute to real public health and environmental protection. This extra stringency also reflects the fact that the public is involuntary exposed to an associated assumed increased tiny risk, and that there is an a consequential trade-off between health detriment and benefits that nuclear energy brings.. Fundamentally, the notion of trade-off does not stand simply because there is no real detriment in the first place. Therefore, on the grounds of real radiation safety, whether the tiny exposure is voluntary or not is irrelevant in this case. ***If public exposure can, with extra effort and cost, be further reduced through improved technologies and practices, this does not make a compelling case to impose ever lower requirements (beyond real safety) in international radiation safety standards with the undue consequence of challenging technologies and practices beyond real radiation safety gain***. The good functioning and maintenance of facilities and equipment of an industrial setting is generally required by law, irrespective of radiation safety. It is very important to not confuse the two domains – notably at the IAEA level. Confusion between the ability, with extra effort and cost, to possibly further reduce public exposure through improved technologies and practices, and real radiation safety needs to be overcome. This does not make a case compelling case to impose lower international radiation safety requirements that challenge technologies and practices beyond real radiation safety gain.		See above		
WNA	**Imbalance in the control of public exposure to natural background radiation – 85% of overall exposure** *(with its four components consisting of* cosmic, terrestrial, internal and radon): Radon 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 of 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. Cosmic, terrestrial and internal exposure – ***The new draft provisions essentially neglect***	X	See above		

	these three components of natural background radiation which altogether contributes to ***1.2 mSv/y*** (42.5% of overall exposure). It is also not clear if such public exposure is even partially covered in the case of contamination (para.5.1). And if so, reference levels ranging from ***1 to 20 mSv/y, with options for excess,*** *would apply.* [para.5.8]. ***Overall, there are very few requirements that are applicable to natural background radiation exposure which contributes 85% of overall public exposure.*** ***Is this commensurate to the actual risk?*** It would be very difficult to demonstrate how the control of public exposure in the BSS new draft is commensurate to the actual risk. For example, simply consider the reference levels for the control of radon in homes (which can range from 1 to 20 mSv/y) and a very stringent three-level control (dose limit of 1 mSv/y from all sources, constraints and operating limits) for the tiny exposure from nuclear energy – which averages 0.0002 mSv/y.				
WNA	**Imbalance in the control of medical public exposure – which contributes 14% of overall exposure**: ***There is no dose limit and no numerically-set dose criterion for diagnostic reference levels associated with medical exposure in medical imaging*** (such as X-rays) – para.3.145. 3.147 and 3.168 – ***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. ***Also, the dose limits are not applicable to medical exposure*** (para. 3.144). The average medical exposure per individual is ***0.4 mSv/y***. A single chest X-rays contributes to about ***0.14 mSv***. ***Overall, most of the detailed requirements for planned (public) exposure in Section 3 are also not applicable to medical exposur***e. Fundamentally, is there a real health concern for the very small public exposure associated with routine medical procedures like X-rays? If not, the notion of trade-off between detriment and benefit cannot be invoked because there is no detriment in the first place. Given this, why only the very small exposure from the medical sector should be subject to a special regime? Why should it be different for comparably small public exposure from other sectors? Because of the huge health and environmental benefits that nuclear energy brings, why it cannot also be subject to a special regime like for the medical sector?		See above		
WNA	**Imbalance in the control of nuclear energy's public exposure - <0.01% of overall exposure**: ***Exposure is subject to a public dose limit of 1 mSv/y from all sources*** – 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. ***Furthermore, a very***		See above		

	stringent three-level mechanism (dose limit, constraints and operating limits) is imposed. [para.3.22, 3.24, 3.26-3.28, 3.117-3.124.] ***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 much higher than nuclear energy exposure, ***the extreme stringency for nuclear energy is difficult to understand***. ***It is certainly not commensurate to the actual risk.*** ***Within the nuclear industry alone, the extreme stringency imposed through the very stringent three-level mechanism*** (dose limit, constraints and operating limits) ***for public exposure*** (of 0.0002 mSv/y) ***that is on average 1,000 times smaller than the average occupational exposure (1-2 mSv/y) – with the latter that is subject to a more flexible two-level mechanism*** (dose limit and constraints), ***is also difficult to understand***. This means that a two-level mechanism (dose limit and constraints) should also be sufficient for public exposure – with constraints that should *de facto* correspond to operating limits. Moreover, as operating limits like authorized discharges are set by regulators, the option to exceed such limits is not generally offered – and this would most certainly pose a challenge to site licence conditions. 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.				
WNA	**Imbalance in the control of public exposure associated with non-nuclear 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***. Examples of such NORM industries include: mining, coal-fired generation, offshore oil and gas production, titanium pigment manufacturing, phosphate fertilizer production, water treatment plants, etc. What is the rationale to require less stringent requirements for public exposure in the NORM industries which is comparable or much higher than those in the nuclear industry?		See above		

WNA	**Imbalance in the control of public exposure associated with air passengers' exposure**: ***This 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. 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?		See above		
WNA	**Imbalance in the control of public exposure associated with exemption and clearance**: Exemption - Some source of public exposure can be exempted from some or all requirements. [Requirement 8, para.3.10]. In order to apply this, concentrations have been derived from a dose criterion 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 226Ra or of 224Ra 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 Comment No.8). The risk-based consistency of the exemption and clearance requirements 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 or clearance dose criterion of 0.01 mSv/y, it is very difficult to understand the rationale (if any) that supports a very stringent three-level system for nuclear		See above		

	energy exposure.				
WNA	**Imbalance in the control of 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.3.138.] 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] The risk-based consistency of the exemption 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 very difficult to understand the rationale (if any) that supports a very stringent three-level system for nuclear energy exposure.		See above		

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 4.0 of the revised BSS, from Safety Standards Committees** **Page:** **Date: 5 November 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							
WNA	Section 1	**Section 1 –** This section needs a lot of re-alignment and streamlining. 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. 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? 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. Para.1.19: It overlooks **air passengers' exposure**! 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.		X	The purpose of Section 1 is to explain the context of the BSS, and provides basic information on the scientific basis and ICRP approaches. It explains objective, scope and structure of the Standard. It has been developed following discussion and resolution during drafting and review process. The BSS deals only with		

					controlling the risks. ICRP states that it is not necessary to treat the exposure of frequent flyer passengers as occupationally exposed for the purpose of control. Only air crew should be considered. ICRP makes no statement about air passengers' exposure.		
WNA	Section 1	Para.1.26-1.28**: 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 radioactive discharges at the level of the BSS (see para.3.123), 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	Clearly, IAEA must realize and account for the fact that nuclear energy plays a key positive role in the combat against climate change and in the planet wide environment and health. Generic provisions on the environment that fails to address this cannot be appropriate for IAEA.	X	This is a statement and does not suggest proposals to change the text.		

		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.*"					
WNA	Section 1	Para.1.26-1.28**: 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 CO2 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 CO2 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?			X	Out of scope of BSS.
WNA	Section 1	Para 1.36: **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				X	According to footnote 3, there are two sources listed as not

		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. Para 1.41: 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.					being amenable to control. Other sources are in principle within the scope of the Standards, however, the stringency and scope of application of the Standards is subject to a graded approach.
India	1.2/1	Radioactivity is a natural phenomenon…	Radioactivity is a ~~natural~~ spontaneous phenomenon…			X	Text from Safety Fundamentals
India	1.3/1	Exposure of tissues or organ to radiation can induce cell death,…	Exposure of tissues or organ to high level of radiation can induce cell death,…	X	Sentence is correct as it stands. Consider using "levels above threshold".		
India	1.3/2-3	Effects of this type are called 'deterministic' and…	Effects of this type are called 'deterministic' (also called 'tissue reaction') and…			X	ICRP uses both terms. The use of deterministic effects is adequate for the purposes of the Introduction, as it is a defined term. The term 'tissue reaction' is not used in the BSS text.
USA	1.3	Consider update of paragraph	The language of this paragraph reflects older ICRP terminology, and should be updated.			X	The language is consistent with ICRP.

WNA	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 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.*"	The text on radiation-risk is too complex, too scientific and lacks numerical benchmarks for a normal BSS user.				The purpose of Section 1 is to explain the context of the BSS, and provides basic information on the scientific basis and ICRP approaches. It explains objective, scope and structure of the Standard. It has been developed following discussion and resolution during drafting and review process.

USA	1.4, line 8	Amend the sentence starting on line 8 to read as follows: The current state of scientific knowledge does not allow us to know if there is ~~no~~ a threshold level …	The sentence is written as a declarative, when in fact it is a statement of assumption. The suggested edit clarifies the basis for the statement.	X	To be modified.		
India	1.6/4-7	…that radiation risks including possible health effects and impact on the environment, are reduced to the extent…	…that radiation risks ~~including possible health effects and impact on the environment,~~ are reduced to the extent…			X	The text has been included to be consistent with the Safety Fundamentals.
WNA	1.6, 1.7 , 1.14,1.2 03.22,3. 24 3.119, 3.123 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 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	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.				The current text covers the principle of Optimization, as recommended by ICRP. ICRP 103 para. 198 "optimization below the constraint .. is the most effective tool for protection".

		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. Also, it is also highly inappropriate to modify the Optimization Principle as per 1.14. Strict consistency is needed.					
Belgium WASSC	1.7/last sentence	The principles of radiation protection, which are justification of practices, optimization of protection and individual dose limits, are expressed in Safety Principles 4, 5, 6 and 10.	Coherence with requirements 10, 11 and 12 and with ICRP terminology.			X	The text is meant to be general, and not exact quotation. Principle 10 relates to the justification of protective actions and not to justification of a practice, so the term 'justification" only is used.
India	1.10/4-6	…coordination across govt depts. and agencies that have responsibilities for protection and safety, e.g. health, environment, labor, regulatory body, mining, science, agricultural, education.	…coordination across govt depts. and agencies that have responsibilities for protection and safety and security, e.g. health, environment, labor, regulatory body, mining, science, agricultural, education, **security**.			X	Interface with security is covered in para 1.30 and 1.31.
India	1.10/8	…that provisions are in place…	…that provisions (including finance) are in place…			X	Provisions would include "finance".
India	1.11/10	The term management system reflects and includes the initial concept of quality control, …	The term management system ~~reflects and~~ includes the ~~initial~~ concept of quality control, …			X	The current text is taken from the text in para 1.4 of the Safety Requirements GS-R-3 "Management System for

							Facilities and Activities".
ENISS	1.14	The optimization of protection and safety, when applied to the exposure of workers, members of the public and carers and comforters 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 economic~~,~~ and societal ~~and environmental~~ factors into account	Optimisation should be defined according to ICRP 103 which is correctly done in the IAEA BSS glossary (see also para 1.20)			X	In this part of the text, it is meant to be encompassing all possible factors. The Safety Fundamentals also includes environmental factors to be considered in the optimization process (para. 3.23) Where optimization is explicitly meant in the text, the precise formulation is used.
India	1.14/10-12	Too little radiation can be as bad as too much radiation, in that the cancer may not be cured or the images may not be of suitable diagnostic quality.	Comment: If too little radiation cannot cure cancer or provide images of suitable diagnostic quality, then it is as undesirable as too much radiation. Suggestion: Delete the complete sentence as it does not make any point or value addition to the text. Last			X	Deletion of the sentence would make the last sentence too cryptic – i.e. the message would be lost.

			sentence takes care of this as well.				
Japan	1.14/10	Change the following underlined expressions. "To little radiation can be as ~~bad~~ inappropriate as too much radiation, "	The originally expression "bad" sounds like a weak sense of morals, which does not fit in this context.			X	"Inappropriate" is too weak.
Japan	1.14/5, 1.20/3,	Modify according to the following underlined expressions. 1.20. Dose constraints and reference levels are used for optimization, the intended outcome of which is that all exposures reach levels that are as low as reasonably achievable, economic and societal ~~and environmental~~ factors being taken into account.	There is some understanding of needs for environmental factors in a conception of "ALARA". However, a definition of "environmental factor" within "ALARA" is not clearly and no considerations under the current radiation protection system. It prefers delete "environmental factors" at the present stage.			X	See ENISS comment above.
India	1.18 (i)/8-10	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.	If exposure that ~~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.			X	This expression is consistent with the ICRP definition of "potential exposure".
ENISS	1.18 (i)	…. The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. 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. In this case, dose limits do not apply.	We note the change of text between draft 3.0 & 4.0, but it misses the point that accidents studied at the design phase of a facility or an activity may lead to dose higher than the limits, for workers or the public, and still be acceptable.			X	This is not correct. According to the BSS dose limits do not apply to medical exposures (3.28) and to humans in space based activities (5.31).

ENISS	1.20	Dose constraints and reference levels are used for optimization,, the intended outcome of which is that all exposures reach levels that are as low as reasonably achievable, economic~~,~~ and societal ~~and environmental~~ factors being taken into account.	See comment 1 on 1.14			X	See comment above
USA	1.20	Amend the sentence on lines 12 – 15 to read as follows: For public exposure in planned exposure situations, the government or regulatory body becomes involved in the establishment or approval of ~~establishes or approves~~ dose constraints, taking …	The text is not an accurate reflection of the actual requirements.	X	Text to be modified: "For public exposure in planned exposure situations, the government or regulatory body ensures the establishment or approval of dose constraints, taking…". See e.g. 3.64(a), 3.65, Req. 34.		
India	1.22/9	…or reference levels of 1 - 20 mSv would be used when individuals usually receive…	…or reference levels ~~of 1-20~~ up to 20 mSv would be used when individuals usually receive…			X	Range 0–1 mSv is dealt with in 2nd sentence of 1.22.
India	1.22/13	Reference levels of 20- 100 mSv would be used…	Reference levels of 20-100 up to 100 mSv would be used…			X	Range 0–100 mSv is not meant here.
Australia	Para 1.23	1.23. Information provided on the risk of exposure to radon needs to highlight the enhanced risk for smokers. 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 substantially greater than for	The critical element of para 1.23 is that, notwithstanding the higher risk for smokers, the ICRP and BSS approach to radiation protection is based on 'average levels of risk to a population'. It is therefore suggested that the sentences in para 1.23 be reordered	X	The text will be modified to remove the reference to a factor of 20.		The text is quoted and referenc

		those who never smoked [4, 5, 6]. However, 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.	as suggested to make this point clearer. It is also suggested to change 'more than twenty times' to 'substantially' greater than. 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.				
Germany Wassc	1.23 (page 16)	2nd sentence: „…never smoked [4, 5, 6]. Information …"	Editorial (missing punctuation mark).	X			
India	1.24/1-2	Dose constraints are also used in the optimization of protection of carers and comforters and persons exposed…..	Dose constraints are also used in the optimization of protection of carers and comforters of patients subjected to radiation exposure and persons exposed…..	X	Agreed to the comment. However, leave text unchanged as the change has been effected through a modification of the definition of carer and comforter,. See tech edit draft 4.05.		
USA	1.25	Amend line 6 to replace the word "is" with the word "ought", so that it reads: "a local review ought to be initiated …	Consistency is needed with the actual requirements.			X	Section 1 is non-prescriptive introductory text.
India	1.27/10-11	The methods and criteria for these radiological assessments are being developed and will continue to evolve.	The methods and criteria for these radiological assessments for typical Reference Plants and marine life are being developed and will continue to			X	These points are too specific to include in the BSS.

			evolve. Comment: Consideration also needs to be given to the potential for build-up and accumulation of long-lived radionuclides released due to normal as well as anticipated accidental scenarios to the environment.				
ENISS	1.28	Radiological impacts within a particular environment constitute only one type of impact and in most cases, may not be the dominant impact of a particular facility or activity. Further, the assessment of impacts on the environment should be viewed in an integrated manner with the other features of the system of protection to establish the conditions applicable to a particular source. Because there are complex interrelations, the approach to the protection of people and the environment is not limited to the prevention of radiological effects on human health and on flora and fauna. ~~When establishing regulations, an integrated perspective has to be adopted to ensure the sustainability of agriculture, forestry, fisheries and tourism and of the use of natural resources, now and in the future.~~ Such an integrated perspective also has to take into account the need to prevent unauthorized acts with possible consequences for the environment, including, for example, the illicit dumping of radioactive material and the abandonment of sources of radiation. Consideration also needs to be given to the potential for build-up and accumulation of long-lived	This new text introduces very broad objectives that may be valid (e;g; sustainability of agriculture, fisheries…), but are of such nature that demonstration of compliance are impossible to achieve. Furthermore this article advocates a global approach but gives at the end examples that deals only with radioactivity.				See comment in General section.

		radionuclides released to the environment.					
Japan	1.34/1-2	Add “heavier ions” after “alpha particles.” “… includes gamma rays, X rays and particles such as protons, alpha particles and heavier ions, beta particles …”	There are some opportunities to encounter carbon ions in particle therapy and heavier ions in space activity.			X	The list does not need to be comprehensive. Using the word “includes” indicates that the list is not complete.
USA	1.35	Consider amendment to read as follows: These Standards do not deal with security measures. However, these standards do deal with source control, and other functions which are related to both safety and security. Nuclear security recommendations complementary to safety requirements are addressed in the IAEA Nuclear Security Series.	Amendment to clarify that some measures, particularly for control of sources, are both safety and security related.			X	These matters and synergies are dealt with in para. 1.30. Text has been agreed with Office of Nuclear Security of IAEA-NS.
Germany Wassc	1.36 (page 19)	Add 3rd sentence: „Guidance on amenability to control and appropriate exclusion is provided in RS-G-1.7.“	The concept of exclusion needs to be addressed here, as there is no other mention in the draft text. Although the BSS do not apply to excluded materials, it could be helpful to improve the clarity in relation to NORM. Because a suitable IAEA Safety Standard is already available (RS-G-1.7 „Application of the Concepts of Exclusion, Exemption and Clearance“), this should be referenced here.	X	A footnote to be added referring to RS-G-1.7.		

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 4.0 of the revised BSS, from Safety Standards Committees** **Page:** **Date: 5 November 2010**				RESOLUTION			
Country.	**Para/ Line No.**	**Comment/ Proposed new text**	**Justification/Reason**	**Accepted**	**Accepted, but modified as follows**	**Rej.**	**Reason for modification/ rejection**
Section 2							
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 ~~optimized~~ subject to an optimization process[4] Foot note 4. Subject to an optimization process means that a process of optimization has been applied and results have been implemented.	See general comment and annex. A good example how the problem can also be solved is Para 3.127 *(b) Measures for ensuring:* *(i) The optimization of protection;* i.e. using the phrase "ensure the optimization of protection" Another possibility would be to use "strive for optimized protection and safety", similar to the text of Para 2.38 where this was used in connection with the improvement of management systems. Para 3.140 also says: "shall be subject to optimization of protection and safety" which again is an example for an acceptable formulation.			**X**	RASSC 26 (June-July 2009) agreed to use the term "is optimized" SF-1: Principle 5: "Protection must be optimized to provide the highest level of safety that can reasonable be achieved". Passive form "is optimized" carries binding requirement that is needed for a shall statement. Current BSS uses "protection and safety shall be optimized" – para 2.24.

WNA	Specific 2.12,2.18 2.31,2.49	**Requirements commensurate to the actual risk** – 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 commensurate with the radiation risks associated with the exposure situation.*" "*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 commensurate with the associated radiation risks.*" "*2.31. 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.*" "*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 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….*"	Also, para. 2.11 does not belong to Chapter 2 which is about the general requirements that cover everything. The breakdown of the general requirements belongs to Chapters 3 to 5 and this breakdown must be commensurate to risk			X	The requirements in Section 2 apply to all exposure situations i.e. to Section 3, 4 and 5. These requirement is repeated in other Sections where necessary.

		"2.11. In planned exposure situations except for medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant requirements apply to that party, specified dose limits are not exceeded."					
India	2.13/2	…legal, regulatory and organizational framework for protection and safety…	…legal, regulatory and organizational framework for ensuring protection and safety…			X	The framework is for protection and safety
India	2.23/3	…such as personal dosimetry, environmental monitoring and calibration of monitoring and measuring equipment.	…such as radiation monitoring equipments, personal dosimetry, environmental monitoring, calibration of monitoring and measuring equipment, timely response to nuclear and radiological emergencies and shall promote research and developments in these areas of safety.			X	The details in relation to emergencies are covered in section 4 (#4.2). In general, the provision of radiation monitoring equipment is not a technical service. It is considered too detailed to include requirements on government in relation to research and development in the BSS. (e.g. GSR Part 1 includes requirements on government in relation to research and development)
Germany Wassc	2.24 (page 25)		Add reference to IAEA Safety Standards for safe management of spent fuel (e.g. Draft Specific Safety Guide DS371 „Storage of Spent Fuel").			X	It is Agency policy to include references only to Safety Requirement level documents in

							a requirement. Including reference to a Safety Guide in a requirement would mean upgrading guidance to requirement
India	2.24/3-4	…, and for the safe management of spent fuel.	…, and for the safe management of spent radioactive sources including spent fuel.			X	Spent fuel is a defined term. Spent radioactive source would be considered as radioactive waste.
India	2.30/		Add after ' f':(g) Development of safety Standards and fixing the limits of radiation exposure and environmental release of radioactive substances (h) Maintaining liaison with statutory bodies in the state as well as outside regarding safety matters			X	Para 2.29 covers development of regulations and guides, and req. 12 covers establishment of dose limits. Para 2.19(a) includes requirement on government regarding coordination with other authorities.
USA	2.35	Revise first line to read: "The regulatory body shall make provisions for establishing, maintaining, and making retrievable adequate records…"	Consistent with, and answering the question posed in the comment matrix, the suggested text would be more acceptable.	**X**	Text to be modified.		
India	2.43/(c)	Any failures or shortcomings in protection and safety are identified and rectified, and steps taken to prevent their recurrence;	Any failures or shortcomings in protection and safety are promptly identified, reported, investigated and			X	Detail provided in later section e.g. para 3.45 to 3.48.

			rectified, and steps taken to prevent their recurrence;				
India	2.48		Add after (e): (f) ensuring safety through modifications based on feedback from other similar facilities and research.			X	The proposed modification is not consistent with the stem of the paragraph. It is covered by other requirements e.g. 2.43(b)

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 4.0 of the revised BSS, from Safety Standards Committees** **Page:** **Date: 5 November 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							
India	3.1(a)/ 4	…radioactive properties or properties as chemical elements;	…radioactive properties or other properties ~~as chemical elements~~;	**X**	Text to be modified., by deleting: "for their radioactive properties or properties as chemical elements", as the definition of "consumer products into which radionuclides have been incorporated" has been modified.		
WNA	Specific, para.3.1-3.4, 4.1	**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 exposure***	It is unclear if the radiation safety requirements are commensurate to safety requirements in other safety fields covered by IAEA. The scope of Sections 2 to 5 should			X	The stringency and scope of the application of the requirements have to be

	and 5.1	***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 of applicability that is commensurate to the actual risk***.	clearly define the applicability to each main source of public exposure. It is not currently the case.				commensurate with the risk (see para. 2.12). For example, the requirements of Section 3 apply to all practices and sources listed in the scope of Section 3, consistent with the application of the graded approach (Req. 6), and para 3.6 that states that not all requirements for every practice or source. For example, a radiology centre in a hospital has to comply with applicable requirements in occupational exposure (protection of medical staff using radiation), for medical exposure (protection of patients) for

							public exposure (e.g. in the design of the hospital department and in releases from nuclear medicine), and in carrying out a safety assessment etc as part of the application for authorization.
WNA	Specific 3.1, 3.22, 3.24, 3.26-3.28 3.117-3.124	**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 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***	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 stringency and scope of the application of the requirements have to be commensurate with the risk (see para. 2.12).

		main sources of public exposure (see General Comment No 11-12 and 14-17) which are all comparable or much higher 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.					
India	3.2 (a)/ 6	…, and mineral extraction and mineral processing facilities that involve or could involve exposure to radiation or exposure due to radioactive material;	…, ~~and~~ mineral extraction and mineral processing facilities and research centres using radiation sources for R & D that involve or could involve exposure to radiation or exposure due to radioactive material;			**X**	The list does not need to be comprehensive. Using the word "including" indicates that the list is not complete.
WNA	Specific 3.2(a), 3.4(b)	**Are requirements commensurate to the actual risk : Public exposure from industries involving naturally occurring radioactive material (NORM)?** – The entry	What is the rationale to require less stringent requirements for public exposure in the NORM industries which is comparable or much higher	X	Para 3.1(f) and para 3.4(a) are within the scope of Section 3. This		

	5.1(c) 5.8	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.	than the one in the nuclear industry. How these requirements can be commensurate to the actual risk?		ensures that NORM industries fall within scope of Section 3. They therefore need to meet the same requirements as nuclear industries. In addition, para 5.1(c) (iii) ensure that the regulatory body can require control of NORM which is not covered by scope of section 3.		
USA	3.4	Consider amending (d) to read as follows: "Exposure to radon and radon progeny ~~in an existing exposure situation~~ where the annual …"	The limitation to an existing exposure situation would seem to preclude the application of the 1000 Bq level in planned situations where actions can not reduce the exposure below the level. This does not seem to be correct.	X	Text to be modified		
Germany	Para 3.4 in conjunction with Para 5.1 (c)	It is appreciates that the former inconsistency (no mention of NORM below 1 Bq/g in the scope of existing exposure situations) is now eliminated by introducing Para 5.1 (c) (iii). But still, it is not considered to be a reasonable solution to assign such NORM not to planned but to	See comments on previous drafts.	X	5.1(c)(iii) has been modified to provide flexibility see comment later in this Table on Section 5.		

	(iii)	existing exposure. At least, there should be flexibility to treat the issue either the one or the other way.					
Japan	3.4(a)(c),5.1(c)(i)(iii)	It should be unify the expression of "Uranium and thorium decay chains" (3.4 (a)) and "^{238}U and ^{232}Th decay chains"(5.1 (c) (i))	It should be unify these expressions in order to avoid unnecessary confusion, if there is no reason to use different expressions.	X	Use "uranium and thorium radionuclide decay chains" in paras 3.4 and 5.1.		
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 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	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**	The stringency and scope of the application of the requirements have to be commensurate with the risk (see para. 2.12).

		one from nuclear energy. See General Comments No. 2, 3 and 11. See attached Table 1.					
India	3.8/1-2	…actions specified in para 3.5 shall, unless notification alone is sufficient, apply to the regulatory…	…actions specified in para 3.5 shall, ~~unless notification alone is sufficient,~~ apply to the regulatory…			X	Some practices require only notification.
WNA	Specific 3.10-3.12, Req. 8, I-2,I-3(a) I-4, I-8	**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 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 226Ra or of 224Ra 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	***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 radioactive material***. As this is not the case (and notably for nuclear energy exposure), the requirements must be modified accordingly.			**X**	The stringency and scope of the application of the requirements have to be commensurate with the risk (see para. 2.12).

		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 Comment No.8). See General Comments No. 2, 3 and 16. See attached Table 1.					
India	3.13/5-6	… , but shall retain the prime responsibility themselves.	… , but shall ~~retain~~ have the prime responsibility with themselves.			X	According 2.40, registrant and licensee have the prime responsibility. In this paragraph, they are able to delegate responsibilities, but they retain the prime responsibility.
India	3.14/3	…modification could have significant implication for protection and safety…	…modification could have ~~significant~~ implication for protection and safety…			X	Regulatory body to decide what is significant. It is not practicable to require the licensee to notify the regulatory body of every

							modification.
Hungary R & W	3.16 (New first sentence)	*Each State shall define for the various types of practices what bodies/persons are authorized to decide whether a practice is justified or not.*	E.g. when a new NPP is being built the decision whether the benefit exceeds the risk/harm can be judged differently by various bodies. Justification can be made by all citizens (via referendum), by Parliament, or by the government. On the other extremity, in the case of a medical diagnostic irradiation the physician treating the patient alone can decide. Competences have to be clarified in advance!			**X**	Para 3.16 and footnote 12 already state that government is to ensure that provision is made for justification, and this provision would include allocation of responsibilities for types of practices. Footnote 5 to para 2.10 provides explanation on responsibility of State in relation to government.
PAHO	3.17/ footnote 15	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, such as in food irradiation.	For greater clarity; most people will not know what it is meant by the footnote.			X	There have been requests from Member States to include various examples, and these examples were deleted during the development of draft v4.0. Examples include:

							irradiation of gemstones, screening at ports using neutron activation, food irradiation. Regulatory body to elaborate on examples used in their country.
Belgium	3.19	Add the following sentence: *"Human imaging using radiation for the purpose of art or publicity shall equally be deemed not to be justified".*	Agreed upon at RASSC meeting in June (see the draft report p.17, point 19.2.5, 6th and 7th para).	X			
Hungary R & W	Req. 10, 11, or Glossary	Please, indicate that the results of justification and optimisation contain elements of subjectivity, they are bearing uncertainties	The present definite statements "is justified" and "is optimised" suggests that the results of the processes are independent of the evaluators. Which is not the case.			X	Para 1.12 and 1.14 indicate that they contain contain elements of subjectivity. This would be covered in a Safety Guide, on how justification and optimization are applied.
ENISS	**Requirement 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.			X	RASSC 26 (June-July 2009) agreed to use the term "is optimized" SF-1: Principle 5:

							"Protection must be optimized to provide the highest level of safety that can reasonable be achieved". Passive form "is optimized" carries binding requirement that is needed for a shall statement. Current BSS uses "protection and safety shall be optimized" – para 2.24.
Hungary R & W	3.22.	Add: *Guidance shall be given on how cases shall be handled when the three elements of the criteria "magnitude of individual doses and the number of people ... exposed, and the probability and magnitude of potential exposures being as low as reasonably achievable..." are contradictory to each other.*	E.g. in a maintenance work involvement of less workers can result in an increase of the individual doses.			X	Guidance is provided in Safety Guides.
WNA	3.22, 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"… "(3.22) *The regulatory body shall establish requirements for optimization of protection and safety, require documentation addressing optimization of protection and safety, and establish or approve*	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."* And 1.14. needs to be strictly consistent with the Optimization Principle.	X	Accept "to be used in the optimization of protection and safety"	X	The definition of optimization includes reference to "social and economic factors"., so we do not repeat in the text.

		constraints, as appropriate, for dose and risk, or the process for establishing constraints, that are used for optimization of protection and safety."					
ENISS	3.23	Registrants and licensees shall ensure that protection and safety is ~~optimized.~~ subject to an optimization process.	See general comment and annex.			X	RASSC 26 (June-July 2009) agreed to use the term "is optimized" SF-1: Principle 5: "Protection must be optimized to provide the highest level of safety that can reasonable be achieved". Passive form "is optimized" carries binding requirement that is needed for a shall statement. Current BSS uses "protection and safety shall be optimized" – para 2.24.
WNA	Specific 3.28, 3.145, 3.147	**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***	Because of the absence of numerical dose criteria for medical exposure, the requirements are not commensurate to the actual risk			**X**	The stringency and scope of the application of the requirements have to be

	3.168	***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.					commensurate with the risk (see para. 2.12).
Belgium WASSC	Req. 12	Title should read "Individual dose limits".	Coherence with text of the requirement. See also comment no. 1. The words 'limit' and 'limitation' are not synonyms.	X	Agree that limit and limitation are not synonyms. These paras are about dose limitation, including establishing dose limits.		
India	3.31/3	…decommissioning, as appropriate,…	…life extension and decommissioning of a facility, and closer and release of waste management site as appropriate,…	X	Add (or closure) after decommissioning. References to other Safety Requirements that address life extension and closure of waste		

					management facilities, will be added.		
ENISS	3.31 (b)	Determine the expected magnitudes ~~and likelihood~~ of exposures in normal operations; and, to the extent reasonable and practicable, make an assessment of potential exposures;	In normal condition the likelihood is equal one	X	Agree.		
Germany Wassc	3.31 (page 41)	"Safety assessment shall be … maintenance and decommissioning/closure, …"	Amendment. Disposal facilities will be closed not decommissioned.	X	Add (or closure) after decommissioning. References to other Safety Requirements that address life extension and closure of waste management facilities, will be added.		
ENISS	3.32 (b)	The ways in which structures, systems and components, and software and procedures related to protection and safety might fail, ~~singly or in combination,~~ or might otherwise give rise to exposures, and the consequences of such events;	This demand is not appropriate, not in accordance with requirements in existing safety standards and not relevant for a great number of situations and practices.			X	Consistency with SF-1, para 3.31. Apply graded approach for practices where it is not relevant. There are requirements for defence in depth that require separation and redundancy.

India	3.42/		Add after (i): (j) To report and investigate incidents and near misses. (k) To periodic review of O & M procedures (l) To ensure internal auditing/ inspection and correction			X	(j) is covered by Req. 16 and following paragraphs. (k) is covered by 3.15(f). (l) is covered b y 3.15(i)
ENISS	3.42 (a)	To prevent reasonably foreseeable accidents ~~(including very low probability accidents)~~ in connection with the facility or activity	This new demand in brackets is not in line with requirements in existing safety standards and needs to be deleted.			X	The term very low probability accidents/events has been used in GS-R-2 and para 4.3 in relation to emergency response.
ISSPA	3.42 (a)	To prevent reasonably foreseeable accidents ~~(including very low probability accidents)~~ in connection with the facility or activity	This new demand in brackets is unreasonable and needs to be deleted.			X	The term very low probability accidents/events has been used in GS-R-2 and para 4.3 in relation to emergency response.
ISSPA	3.42 (d)	To ensure that there are adequate procedures for the control of the facility and of any reasonably foreseeable accidents ~~(including very low probability accidents);~~	This new demand in brackets is unreasonable and needs to be deleted.			X	The term very low probability accidents/events has been used in GS-R-2 and para 4.3 in relation to emergency response.

ENISS	3.42 (d)	To ensure that there are adequate procedures for the control of the facility and of any reasonably foreseeable accidents ~~(including very low probability accidents);~~	This new demand in brackets is not in line with requirements in existing safety standards and needs to be deleted.			X	The term very low probability accidents/events has been used in GS-R-2 and para 4.3 in relation to emergency response.
India	3.43		Add after (b): (c) provisions for carrying out drills at regular intervals to assess efficacy of the plan and upgrade it based on feedbacks from these drills.	X	Add text		
India	3.48		Add at the end of the para: The event shall be treated as closed based on the acceptance of the report on the event and its investigation by the regulatory body.			X	It is not clear what is meant by “closed event”.
India	Req 17	Registrants and licensees shall ensure the safety of radiation generators and radioactive sources.	Registrants and licensees shall ensure the safety, security and management of radiation generators and radioactive sources as per Authorization.			X	Security is outside scope of BSS – see para 1.30, 1.31.
Germany Wassc	3.51 (a) (page 49)	„Factors that could affect the safety ~~and security~~ of the radiation generator or radioactive source;“	Consistency with the wording in Requirement 17 („Registrants and licensees shall Ensure the safety of radiation generators andradioactive sources.“). According to Para 1.35, the BSS do not deal with security meas-ures. Recommendationson security are addressed in the IAEA Nuclear SecuritySeries.			X	This text is not a security measure, but that security needs to be considered in relation to choosing location for use or storage of the source.
USA	3.53(d)	Consider elimination of duplication with 3.53(d). One possible solution is to reword 3.53(d) to state:	Paragraph 3.53 (d) requires a periodic inventory of radiation generators or radioactive sources. Paragraph 3.54	X	Accept proposed modification to 3.53(d)		

		(d) A periodic inventory, as required by 3.54, of...	also requires that registrants and licensees maintain an inventory of each radiation generators or radioactive source for which they are responsible. This seems to be a duplication of requirements.				
USA	Req. 18	Delete the second "shall" in the text of Requirement 18, just preceding paragraph 3.61. The phrase "shall be" in the third line could be replaced with "is".	The text of Requirement 18 contains two "shall" statements within the single sentence. Removal of the second "shall" statement, in line three, will clarify the requirement, and does not alter the use of "shall" for the requirement.	**X**	Agree to replace second "shall" by "is"		
Belgium	3.61	Modify the current point (d) to make it sound like: "The effectiveness and suitability of the proposed type of imaging procedure*, including the active search for alternative procedures that expose to less ionizing radiation or to none at all,* including*, where applicable,* the appropriateness of the radiation equipment for the proposed use;	Any decent justification procedure cannot go without considering alternative techniques, including techniques not based on the use of ionizing radiation. For the moment, the subject is treated as if the radiation doses concerned are so "trivial" that there is no need to go to these standard steps in the justification procedure.			X	See explanation under 19.2.3 of the report for the RASSC meeting held in June 2010.
Germany Wassc	3.61 (e) (p 51)	„…period of the practice~~;~~.“	Editorial (punctuation mark).	**X**	Editorial		
Belgium WASSC	3.64/8-9	Delete "(see footnote 16)".	The reading of footnote 16 has no added value.	**X**	Agreed – parenthetic reference to footnote 16 **needs to be deleted**.		
PAHO	3.66	Registrants and licensees shall ensure that all persons that are about to be exposed to radiation for inspection procedures, are	Not needed; there is always the possibility of manual pat downs.			**X**	There may not always be an alternative. E.g.

		informed about the possibility of choosing an alternative technique that does not use ionizing radiation					Manual pat downs are not appropriate for swallowed objects.
India	3.66/ 3	**… choosing an alternate technique that does use ionizing radiation,**	**Comment:** **This presupposes that the registrants should know about the alternative techniques.**			**X**	The requirement is for the licensee to inform the person if they (the licensee) have a non-radiation alternative available at the site.
ENISS	**Requirement 19**	**The regulatory body shall establish and enforce requirements to ensure that protection and safety is ~~optimized~~ subject to an optimization process., and that doses from occupational exposure comply with dose limits.**	See general comment and annex.			X	RASSC 26 (June-July 2009) agreed to use the term "is optimized" SF-1: Principle 5: "Protection must be optimized to provide the highest level of safety that can reasonable be achieved". Passive form "is optimized" carries binding requirement that is needed for a shall statement.

							Current BSS uses "protection and safety shall be optimized" – para 2.24.
ENISS	3.70	The regulatory body shall establish and enforce requirements that protection and safety shall be ~~optimized~~ subject to an optimization process.	See general comment and annex.			X	See above
Belgium WASSC	3.71/2	Replace "is limited as" by "complies with the dose limits".	See comment no. 2.			X	"Complies" means to meet requirement, while in para 3.71 exposure is to be limited.
India	3.73/ (d)	Provisions for maintaining records and results of assessment of occupational exposures;	Provisions for maintaining records and results of assessment of occupational exposures for a specified time period;			X	The proposed new text is covered in para. 3.104
ENISS	**Requirement 21**	**They shall ensure that protection and safety is ~~optimized~~ subject to an optimization process and the dose limits for occupational exposure are not exceeded.**	See general comment and annex.			X	RASSC 26 (June-July 2009) agreed to use the term "is optimized" SF-1: Principle 5: "Protection must be optimized to provide the highest level of safety that can reasonable be achieved". Passive form "is optimized" carries binding

							requirement that is needed for a shall statement. Current BSS uses "protection and safety shall be optimized" – para 2.24.
ENISS	3.76 (b)	Occupational protection and safety are ~~optimized~~ subject to an optimization process in accordance with the relevant requirements of these Standards;	See general comment and annex.				See above
India	3.77 (a)/1	Involve workers, through their representatives if appropriate, …	Involve workers, either directly or through their representatives if appropriate,…			X	Current text is clear. Involvement of workers through their representative is an option, if appropriate.
India	3.83		Add after (f): (g) In case an occupational worker undergoes a medical exposure, for e.g. a nuclear medicine or a radiological procedure, he or she should ensure that the dosimeters meant for monitoring occupational exposure are not used during his/her medical exposure. Especially, in nuclear medicine, he or she should resume occupational work and use dosimeters, only when the radioactivity levels in the body have come down to negligible levels.			X	It is not a basic requirement, and it is suited a guidance document.

India	3.84/2	, the workers shall, as soon as feasible,	, the workers shall, as soon as ~~feasible~~ possible,	X	Editorial change		
India	3.86(a)/3	…for such workers are at least as good as those provided for employees of the registrant licensee;	…for such temporary workers are ~~at least as good as~~ better than those provided for employees of the registrant or licensee;			X	The workers may not be 'temporary".
India	3.87(b)/2	…information relevant for compliance with these standards that…	…information relevant for compliance with the requirements of these standards that…	X	Editorial change		
Belgium WASSC	3.88/1 and footnote 20	Delete footnote 20.	The designation of controlled areas is not dealt with in TSR-1, although 'transport' comprises all operations and conditions associated with, and involved in, the movement of radioactive material; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, unloading and receipt at the final destination.			X	TS-R-1 incorporates a requirement to separate public and workers from radioactive material. The terminology is historically different (transport uses the term segregation) and the practical application is different (there is a reliance on the occupancy factor for the source), but the effect is to designate areas within which controls are required. Footnote 30 is intended to

							explain this.
PAHO	3.105 (b)	Information on exposures (doses and intakes)	To be consistent with definition of exposure			X	Information includes qualitative and quantitative information on e.g. duration of exposure, nature of exposure
India	3.106 (c)/ 1-2	…. To new employers, when workers change employment.	…. To new employers or the regulatory agency, when workers change employment.			X	Requirement states – facilitate provision. 3.106(b) covers access to exposure records by the regulatory body.
PAHO	3.109	If one or more workers are to be engaged in work that involves or could involve exposure from a source that is not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition for such engagement, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the regulatory body.	Requirement is not clear.	X	Text to be modified.		
PAHO	Req 27:	Employers shall not offer benefits as substitutes for protection and safety measures.	Registrants and licensees are not be empowered to make such offers	X	Current paras 3.111 and 3.112 do not include registrants and licensees, but it is considered that it		

					is appropriate to assign responsibility to all three parties. Modify para 3.112 to add "in cooperation with registrants and licensees"		
Belgium WASSC	Req. 29	Replace "dose limitation" by 'individual dose limits".	See comment no. 1.			x	"dose limitation" includes all associated requirements and such a formulation is broader that 'individual dose limits'
ENISS	3.120	The government or the regulatory body shall, as appropriate, establish or approve constraints for dose and risk to be used for optimization of the protection of the public.	The corresponding Para 3.118 of Draft 3.0 contained "as appropriate". Dose or risk constraints are not always necessary. Consumer products e.g. containing radioactive material have been used for decades without any dose constraint. In many Member States discharges are regulated by discharge limits, not by dose constraints.			x	The absence of generic (for a type of facility of activity) or site-specific constraints may cause a situation when the total annual dose to members of the public from all authorized practices exceeds 1 mSv.

							The dose constraint is a design parameter which should be used prospectively. After the start of operation of a source the "operational limits and conditions" should be used – see para 3.123
ISSPA	3.120	The government or the regulatory body shall, as appropriate, establish or approve constraints for dose and risk to be used for optimization of the protection of the public.	The corresponding Para 3.118 of Draft 3.0 contained "as appropriate". Dose or risk constraints are not always necessary and meaningful.				See above.
Belgium WASSC	3.121/ 3	Replace "is limited as" by "complies with the dose limits".	See comment no. 4.			X	"Complies" means to meet requirement, while in para 3.71 exposure is to be limited.
India	3.126(c)/ 1-2	… discharged radioactive material during the operational life time of a source;	… discharged radioactive material ~~during the operational life time of a source~~;	x	Proposed alternative text : Possible build-up and accumulation in the environment of radioactive material from discharges during the lifetime of the source;		

ENISS	3.127. (h)	Registrants and licensees shall, with respect to the sources under their responsibility, establish, implement and maintain: (h) Emergency plans if necessary, procedures and arrangements, commensurate with the nature and magnitude of the risk involved.	Not all activities and facilities need an emergency plan. See also para. 3.43			x	The issue is covered by "commensurate with the nature and magnitude of the risk involved" See also para 3.6
Japan	3.129	Modify according to the following underlined expressions. "if a source ~~of external exposure~~ can cause external exposure to the public: "		x	Proposed alternative text : Registrants and licensees shall ensure that if a source can give rise to external exposure of members of the public:		
WNA	3.131 (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.		x	Para to be split into two parts. Proposed new text first part: (a) Shall ensure, in the optimization of protection and safety, that any radioactive waste generated is kept to the minimum practicable in terms of both activity and		

					volume;		
Japan	3.131(b)/4	Modify according to the following underlined expressions. "… taking into account the available options for waste storage and disposal~~, without precluding the mixing of waste for purposes of protection and safety~~;"	This may be true, however relevant Safety Requirement DS354 (SSR-5) and GSR Part 5 do not mention this issue. To keep consistency between BSS (Revised) and waste safety standards, this issue should not be emphasized here but may be appropriate to mention in the relevant Safety Guide	x	Proposed new text: Shall ensure that there is, separate processing of radioactive waste of different types, where warranted by differences in factors such as radionuclide content, half-life, activity concentration, volume, and physical and chemical properties; taking into account the available options for waste storage and disposal, without precluding the mixing of waste for purposes of protection and safety, if warranted;		
PAHO	3.131 (c)	***Define predisposal in the glossary***	Predisposal is not a common word	x	See (a) Glossary in draft BSS v.4.05		

					(b) Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).		
India	3.135(e)/2	… and results of assessments of public exposure;	… and results of assessments of public exposure and their periodic review;			x	See 3.135(b), 3.136, 3.137 All up-to-date information related to the public exposure will be reported to the regulatory body and (e) requires that an appropriate records shall be maintained
India	3.137/		Add after 3rd bullet: • Committed internal dose assessment from intake			x	3.137(a) covers the measurable quantities and 3.137(b) covers assessments
USA	3.138	Revise to read as follows: "… unless the justification of their use by members of the public has been approved or accepted by the regulatory body, and …	As drafted, the requirement was on the regulatory body to justify the consumer product. In many cases, the regulatory body will require that a justification analysis be developed and provided,	x	Text to be modified. To use "approved" and not "approved or accepted".		

			and the regulatory body will be acting to approve or accept that analysis, rather than conducting a de novo justification decision.				
WNA	Specific 3.138 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.3.138.] 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 exemption 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 very difficult to understand the rationale (if any) that supports a very stringent three-level system for nuclear energy exposure.			x	The editor's version of 3.138 (a): Providers of consumer products into which radionuclides have been incorporated shall ensure that such products are not made available to the public unless the justification of their use by members of the public has been approved or accepted by the regulatory body, and either their use has been exempted on the basis of the criteria specified in Schedule I or their provision to the public has

							been authorized. a) see definition of Consumer products; b) Commodities from contaminated areas are not subject of Requirement 33 (planned exposure situation):
USA	3.139	Revise initial sentence to read as follows: "Upon receipt of a request for authorization to provide to the public ~~of providing to the public~~ a consumer product capable of causing public exposure, the regulatory body shall:"	Awkward sentence construction. Proposed editorial intended to clarify the requirement.	x	Proposed revised text: Upon receipt of a request for authorization to provide to the public a consumer product into which radionuclides have been incorporated, the regulatory body:		
Belgium WASSC	3.139/ 4	Replace "requirements" by "provisions".	Editorial. Reserve the term "requirement" for the text in bold.			x	Text in bold and all paragraphs containing shall statement are requirements.
PAHO	3.140 (a)	The various radionuclides that could be used, their decay scheme and activities;	Radiation types is an odd expression			x	"Radiation type" is used by ICRP-

							103 (e.g. see Table B.4)
India	3.142 (e)/1	.. options for recycling or disposal.	.. options for recycling or disposal and the necessary precautions**.**			x	Covered by stem and (a)-(d)
USA	3.146	Check reference paragraphs in line 4. It would appear that the references should actually be to paragraphs 2.50 and 2.41.	Cross reference validation.	**X**	Agree. Reference should be to paragraphs 2.40 and 2.41.		
USA	3.147	In line 2, it would appear that the reference to paragraph 2.15 should be more specifically 2.15(e).	Cross reference validation, and clarification.			**X**	It could be more than just 2.15(e).
PAHO	3.150	The medical exposure has been justified (see paras 3.151, 3.153 and 3.159) or is part of an approved health screening programme;	The issue of justification is dealt with in the following paragraphs in more detail; to put it here in slightly different terms as it appears afterwards is confusing and may seem contradictory			**X**	1. 3.150 is specific to patient exposure. The proposed text to link in 3.151 (which is specific to biomedical research), 3.153 (which is on more general responsibilities) and 3.159 (which is the special case of asymptomatic individuals) would seem wrong. 2. Noting the resolution of the comment below about 3.159, there are no contradictions.
Germany	Para 3.150(b) page 79	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	In Para's. 3.150 (b) and 3.156, a significant change from the previous drafts has to be noticed which results in the conclusion that the responsibility for individual justification is not anymore clearly assigned to the medical radiological practitioner, as it was in the drafts before (see Para's. 3.149 (b)			**X**	The text in 4.0 is the result of the large number of comments received on draft 3.0, which included

	Para 3.156 page 81	practitioner when appropriate, or is part of an approved health screening programme; The justification of medical exposure for an individual patient shall be carried out by the radiological medical practitioner, in consultation with the referring medical practitioner when appropriate,	and 3.155 there). As a consequence, both the radiological medical practitioner and the referring medical practitioner share the responsibility for individual justification – at best. By the term "as appropriate", even this is not for sure, since it could also be concluded that justification can be carried out only by the referring medical practitioner, if it is appropriate. Justification is pivotal in the effort to restrict unnecessary medical exposures, and requires a high level of training and education in medical radiation protection to be effective. This high level of training and education cannot be considered as guaranteed in referring medical practitioners. It is highly recommended to reconsider these modifications, since responsibility for justification has to be clearly assigned to the health professional with the highest level of training and education in medical radiation protection, i.e. the radiological medical practitioner. The use of Referral Criteria etc. can provide important information to the referring medical practitioner, but cannot serve as a substitute for proper justification by a well-trained radiological medical practitioner. It is proposed to return to the original statements in Para's. 3.150 (b) and 3.156. To take into account special situations, e.g. in resource poor countries typically lacking of radiologists, it should be discussed to add a respective statement in both Para's. which facilitates more flexibility in justification under special situations.				comments such as the ones from Germany here. Reference should be made to the extensive discussion of those comments given in the Table of Comments to draft 3.0, available on the web.

Germany Wassc	3.151 (p 79)	4th line: „…as required in para. 3.160(b), and …“	Precision of reference.			X	All of 3.160 is relevant.
India	3.153(f)/1	Any delegation of responsibilities by a principal party is documented.	Any delegation of responsibilities by a principal party **is** approved by the competent authority and the same is documented.			X	The RB would not normally formally approve such delegations, but would want to view/discuss such delegation documentation during an inspection.
India	3.156/ 3	**…, taking in to account, particularly when the patient is….**	**…, taking in to account the condition of the patient, particularly when the patient is….**			X	The change by technical editor has made the text of 3.156 clearer (see draft 4.05).
PAHO	3.159	Any radiological procedure on an asymptomatic individual, intended to be performed for early detection of disease but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, when appropriate, following guidelines from relevant professional bodies or the health authority.	To be consistent with paragraph 3.150 and 3.153 which states that the justification is the responsibility of the radiological medical practitioner. In fact, even the suggested change may not be appropriate, as it means that an x-ray tech or a nurse can fight with the radiologist for an asymptomatic patient to undergo an x-ray exam.	X	1. Agree, but text to be changed (as indicated by bold text) to: Any radiological procedure on an asymptomatic individual, intended to be performed for early detection of disease but not as part of an approved health screening programme, shall require specific justification for that		

					individual **through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate,** following guidelines from relevant professional bodies or the health authority. As part of that process the individual shall have been informed …. 2. This brings the text in line with 3.150.		
PAHO	3.162	***Define radiochemist in the glossary***	It is a different profession than radiopharmacist.	**X**	Agreed. New term to be added to the Glossary, with information note: **Radiochemist**: A qualified expert who is duly recognized as having expertise in the chemistry of		

					radioactive substances. *Info Note:* For these Standards, this means expertise in the chemistry of radioactive substances used for medical applications.		
Japan	Subtitle (p.84), 3.167/1, 3.183(b	Change the term “clinical dosimetry” to “clinical radiation dosimetry”	It will be need to avoid confusion about the meaning of “dose” which is often used for medicine.			X	Point is noted, but given the scope of the BSS and the professionals involved any confusion should not arise.
Germany Wassc	3.174(a (p 86)	„She is or might be pregnant.“	Editorial (missing punctuation mark).	X	Add punctuation.		
India	3.177		**Comment:** **This section should also include that a patient who has undergone a therapeutic procedure is instructed about timeframe during which he or she should avoid fathering or conceiving a child.**			X	Too detailed for the BSS (as is covered implicitly by 3.177(b)(ii) which refers to information on the radiation risks), and will be elaborated in the companion Safety Guide.
PAHO	3.179 (a)	or using the wrong radiopharmaceutical, or with an activity, dose or dose fractionation	The wrong activity may be administered	X	Agree. It could be an activity that is prescribed. Change 3.179 to include the text		

					"an activity".		
PAHO	3.180 (e)	***Delete from 3.180 and add a new paragraph:*** The radiological medical practitioner shall inform the referring medical practitioner and the patient or a legal authorized representative about the unintended or accidental medical exposure.	This requirement cannot be the responsibility of the registrant or licensee but of the medical practitioner; it is a medical act.	**X**	**Change to read:** (e) Ensure that the appropriate radiological medical practitioner informs the …. Note: The responsibility is being assigned under a RP framework, and hence the licensee is appropriate, but the radiological medical practitioner needs to be responsible for the informing.		
Sweden	3.181	Clinical audit Registrants and licensees shall ensure that clinical audits are performed regularly. Clinical audits are systematic examinations or reviews of medical radiological procedures which seek 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.	The proposed "radiological review" is restricted to the implementation of optimization and justification. These are, however, not the only factors which matter, even from a radiation protection point of view. The outcome for the individual patient will depend on the organization in the department, the competence of the staff, resources and how they are used. It is crucial to widen the scope of review to comprise also these factors. Another observation: the reviews should not, as indicated in the present draft, be			**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

			restricted to internal reviews. Deficiencies can easily be overlooked because one gets used to them				the radiological review is quite clearly stated in 3.181. 3. Further, Chapter 2 and the generic section of Chapter 3 already have requirements on the broader facility/staff/resources issues. 4. External reviews are arguably better, but for the Basic SSs, the internal review is a step forward.

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 4.0 of the revised BSS, from Safety Standards Committees** **Page:** **Date: 5 November 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							
Hungary R & W	Requirement 43.	Change "management" to "response". *Requirement 43.: Emergency response system*	This requirement uses the term "emergency management system", but according to the content of the requirement it would be more correct to refer to "emergency response system" which is defined and used in other IAEA documents (e.g.: GS-R-2) and is in more concert with the content of the requirement.		For consistency, keep term emergency management system. A footnote (to the title) to be added: "Emergency management system covers emergency preparedness and emergency response."		
ENISS	4.5 (f)	The system shall provide for, inter alia, the following elements at the scene, local, national and international levels, as appropriate[15]: (f) Optimized protection strategies for the implementation and termination of measures to protect members of the public	The optimized protection strategies are based on reference levels defined in effective dose for people	X	Modify text to state: "including relevant considerations for protection of the environment"		

		who may be exposed in an emergency~~, including considerations for protection of the environment;~~					
WNA	4.8 (a)	**Emergency** – "*A reference level, expressed in terms of residual dose, shall be set, typically between 20 mSv and 100 mSv 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 and 100 mSv are received to many citizens of most countries in the world due to natural background radiation (mainly Radon) **per year**. 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 issue even worse.			X	Reference levels are recommended by ICRP Publication 103, and it has been decided to follow ICRP recommendations in the BSS, to the extent possible.
Japan	4.8(a)/ 2	Modify according to the following underlined expressions. "between 20 mSv and 100 mSv in effective dose "		X	Text has been modified by editor.		
WNA	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			X	Justification is done both during planning and response. Justification does not need to be

			should also be restricted to the planning stage, as correctly limited in Requirement 44.				subject of lengthy administrative process.
Belgium WASSC	4.12	Delete.	Duplication of the text in bold above.	X	Modify overarching requirement to following: The government shall establish a programme for managing, controlling and recording doses received in an emergency by emergency workers. Modify para 4.12 to the following: The government shall establish a programme for managing, controlling and recording doses received by emergency workers, which shall be implemented by response organizations and employers.		

Poland	4.15	Replace numerical value “50 mSv” by value “100 mSv”	ICRP No 103 publication recommends a maximum value 100 mSv as a reference level for emergency workers			X	The value of 50 mSv represents previously agreed text of “single maximum dose limit”
Poland	4.15(c)	Delete all text	The term “Large collective dose” is still undefined			X	This task represents the important part of emergency workers possible activities in an emergency. Specificity of the meaning large collective dose could be further defined at the national level.
WNA	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 that may be required.*” See also Specific Comment No.33 as a potential option.	Persons responsible to enforce any protective actions must be able to count on designated workforce. That doesn‟t work on a voluntary basis.	X	Add a footnote to para 4.17: “The voluntary basis for response actions by emergency workers is usually covered in the emergency response arrangements.”		

WNA	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.*				X	This is covered by the current and proposed modification to the text of 4.17.
Japan	4.19/4	… if a worker has received a dose exceeding ~~200 mSv~~ 500 mSv or if the worker requests it.	See Resolution Table – MSComments.pdf (page 318)			X	200 mSv is 10 times the single year dose limit, as it was written in previous drafts. 500 mSv is 10 times the maximum single year dose limit, which was not written in previous drafts. The MS comment resolution table (page 318) accepted the comment from Canada, but modified the text to state 200 mSv.

India	4.19/1	Workers shall not normally be precluded from incurring further occupational exposure,…..	Comment: This needs more clarifications. Can it be beyond 500 mSv as well for occupational exposure (not for life saving)? Is it ethical to have such a statement in BSS? Can it be misused by employers without violating regulatory norms stated by this statement?			X	Table IV-2 clearly states that doses beyond 500 mSv may be possible only for life-saving actions, and under the circumstances where the benefit to others clearly outweighs the emergency workers own risk. It cannot be legally mis-used by employers. Para 4.15 prevents such mis-use.

COMMENTS BY REVIEWER **Reviewer: Collated comments on draft 4.0 of the revised BSS, from Safety Standards Committees** **Page:** **Date: 5 November 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							
Japan	5.1 (c) (iii)	It prefers to delete the 5.1 (c) (iii).	This modification might be the results of reflection of Japanese comments in 3.4 (a) and 5.1(c) (ii) of BSS draft 3.0. However, this term is not necessary because this term does not reflect our intention precisely. In the new context of 5.1(iii) of BSS draft 4.0, it seems that all materials, in which the activity concentration of any radionuclide in ^{238}U and ^{232}Th decay chains (< 1 Bq/g) and ^{40}K (< 10 Bq/g), will be categorized to existing exposure situation. Currently radiation protection system does not include such materials into existing exposure situation and such consideration will cause some difficulty of implementation in regulatory control. Therefore, it prefers that materials in existing exposure situation should be limited in the types of materials described in 5.1 (c) (ii).	X	Text is modified, to add "as designated by the regulatory body", at the end of para. 5.1 (c) (iii). This will avoid the necessity to include material containing radionuclides in the uranium and thorium decay chains with activity concentration below 1 Bq/g within the scope of Section 5.		

			Most important point of Japanese comments in 3.4 (a) of BSS draft 3.0 is whether that materials are under the regulatory control or not. In general, all materials, in which the activity concentration of any radionuclide in ^{238}U and ^{232}Th decay chains (>1 Bq/g) and ^{40}K (> 10 Bq/g), can not be managed in planned exposure situation as long as the relevant regulatory body identifies such materials should be subjects in regulatory control at least. (Japanese comments for BSS3.0) (3.4(a) should be replaced by) (a) Exposure due to the categories of the material **designated by regulatory body**, among the materials in which the average level of activity concentration in the material of any radionuclide in the uranium and thorium decay chains is greater than 1Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g. (5.1(c)(ii) should be replaced by) (ii) Radionuclides of natural origin in commodities except the categories often material **designated by regulatory body** in planned exposure situation (see para 3.4(a))				
Japan	5.1(c)	Modify according to the following underlined expressions.	5.1(c)	X			

		"~~(iii)~~ (iv) Exposure of …"					
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, according to ICRP Publication 103, para. 189: "It is not necessary to treat the exposure of frequent flyer passengers as occupationally exposed" This was also discussed at RASSC 25.
PAHO	Req 48	The government, through the regulatory body or other relevant authority, shall ensure that remedial actions and protective actions are justified, and radiation protection is optimized ***Alternative:*** The government shall ensure that remedial actions and protective actions are justified, and radiation protection is optimized	The government is above the regulatory body and any "other relevant authority".			X	The current wording allows flexibility in the approach taken by countries.
Belgium WASSC	5.12/17	Replace "transportation" by "transport".	Editorial. Coherence with TS-R-1.	**X**			
Belgium WASSC	Req. 50	?	Does this requirement apply only to Rn-222? Specific requirements for Rn-220 are missing. See also comments nos. 17 and 18.			**X**	The outcome from theTM on radon is that the state of knowledge about thoron is not yet

							sufficient to include requirements in existing exposure situations.
Germany	Para 5.20(a) Page 104	The establishment of an appropriate reference level for 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 300 Bq/m^3	WHO proposes an annual average radon concentration of 100 Bq/m³ and 300 Bq/m³ only under consideration of the prevailing social and economic circumstances. It is suggested to revisit this issue when the final position of the ICRP is available			**X**	The WHO handbook proposes a reference level of 100 Bq/m3, however, if such level cannot be reached, the chosen reference level should not exceed 300 Bq/m3,…". The BSS adopts the position of adopting a level not higher than 300 Bq/m3, in line with the ICRP statement on radon.
Germany Wassc	5.20 (a) (page 104)	amend theFootnote 40 to the following sentence: „A reference level of 100 Bq/m3 isrecommended to minimize healthhazards due to indoor radon exposure."	This recommendation corresponds to the WHO Handbook on Indoor Radon (Ref. [6]).			**X**	The WHO handbook proposes a reference level of 100 Bq/m3, however, if such level cannot be

							reached, the chosen reference level should not exceed 300 Bq/m3,…". The BSS adopts the position of adopting a level not higher than 300 Bq/m3, in line with the ICRP statement on radon.
Japan	5.20 (a) and 5.27	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 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 in general exceed an annual average radon	It has obviously stated in the BSS 4.0 that the regulatory body in any member states can establish higher clearance values provided that the dose criteria in para. I-11 are met. This is a significant approach to be applied to reference level for radon exposure as well. There should be flexibility so that the regulatory body in any member states can establish country-specific reference level for radon concentration provided that the dose criteria (10mSv) are met. Moreover, there is no justified evidence in the reason for rejection against this proposal. It should be clarified how many member states agree reference level for only radon concentration or alternative reference level for individual dose. (Ref.)			X	Para 5.20 specifies the maximum value for the reference level so countries are able to select their own level. The Technical Meeting in December 2009 agreed that the reference level should be set in terms of activity concentration with a footnote to explain the corresponding

		concentration of 1000 Bq/m^3, or an annual effective dose of 10 mSv as a residual dose[39];	*Reason for rejection: 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.* 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, 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				dose. Activity concentration is used because of practicality. Consistency with other organizations e.g. WHO, ICRP. Dose conversion factors are currently being revised.

			gas concentration, which leads to make more scientific and rational regulation for radon in member states.				
WNA	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 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,39 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 (40);*" (40) "*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.*"	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 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 [4, 5, 6] Information provided on the risk of exposure to radon needs to highlight the enhanced risk for smokers."*			**X**	The policy implications of the higher risk factor for smokers have not been fully developed.
WNA	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	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			X	Para 5.20 specifies the maximum value

		(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 40; 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;	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 (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.				for the reference level so countries are able to select their own level. The Technical Meeting in December 2009 agreed that the reference level should be set in terms of activity concentration with a footnote to explain the corresponding dose. Activity concentration is used because of practicality. Consistency with other organizations e.g. WHO, ICRP. Dose conversion factors are currently being revised.
Germany	Para's 5.22 and	Para 5.22: Delete "drinking water" or make amendment for clarification	Para 5.22 allowing for reference levels up to values around 1 mSv/a does not agree with Para 5.23 where it is			X	Para 5.22 states "not exceeding a

	5.23		claimed to consider the WHO drinking water guidelines (reference dose level: 0.1 mSv/a).				value of around 1 mSv". Para. 5.22 also covers other commodities.
India	5.27		Comment: At all places in the BSS except in Table-III-I, there no mention of Thoron. As if BSS means Radon only as Rn-222. It is felt that appropriate guidance shall be provided even for Thoron (Rn-220) for Thorium fuel cycle based facilities.			X	Para 3.4(c) includes thoron in workplaces in which occupational exposure due to other radionuclides in the U238 and Th235 decay chains is controlled as a planned exposure situation. Thoron in thorium fuel cycle facilities would be covered by this paragraph.
Japan	5.27	Add the following underlined expressions. 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 in general does not exceed an annual average radon concentration of 1000 Bq/m^3, or an annual	In order to ensure consistency with para 5.20 (a) which is the requirement of "public exposure to radon indoors".			X	While "in general" is appropriate for dwellings, it is not appropriate for a workplace. Para 5.20 specifies the

		effective dose of 10 mSv as a residual dose[39];					maximum value for the reference level so countries are able to select their own level. The Technical Meeting in December 2009 agreed that the reference level should be set in terms of activity concentration with a footnote to explain the corresponding dose. Activity concentration is used because of practicality. Consistency with other organizations e.g. WHO, ICRP. Dose conversion factors are currently being revised.

EC	5.30	For draft by the Secretariat	Keeping aircrew exposure as an existing exposure situation (see 1.19, 1.45 and 5.1) rather than as a planned situation as is the case in the draft Euratom BSS is not regarded as a major issue; however, it is important that there is a uniform and binding approach to the assessment and control or aircrew exposure across the world. The latest CSS meeting urged IAEA and EC to resolve this point.	X	New text proposed – see following box – to replace 5.30. Footnote 43 to be deleted, as it is explanatory text to existing text.		
Sweden	5.30	The regulatory body or other relevant authority shall assess the exposure of aircrew to cosmic radiation and determine whether parts of the requirements for occupational exposure in planned exposure situations given in section 3 should be applied[34]. In particular, the regulatory body or the relevant authority should ensure, as appropriate, that for pregnant aircrew, the requirements of paragraphs 3.113 and 3.114 are being considered. FOOT-NOTE 43: The exposure of aircrew to cosmic radiation cannot be controlled for a specific flight, as it is determined by the sun-cycle variations, altitude, latitude and duration of the flight. However, the accumulated effective dose from several flights can be well estimated and restrictions in flight hours and schedules can be introduced. For commercial flights, radiation dose estimates may be carried out in advance using a computer program and internationally agreed information.	Although radiation doses to aircrew and “frequent flyers” are not classified as a planned exposure situation but an existing exposure situation, the occupationally exposed staff should be given the same right as other occupationally exposed workers to a reasonable level of radiation protection. Sweden does not think this is the case with the present formulation of paragraph 5.30 in draft 4.0 of the IAEA BSS. This is the reason for our suggested reformulation of paragraph and foot-note. The changed requirement does not necessitate, if applying a graded approach that all air-crew should be subject to individual dose assessments or would need extensive radiation training. Rather, it should/could be managed by appropriate and simple information to the concerned worker category and rescheduling of work tasks for pregnant aircrew, after they	X	New text proposed – see following box – to replace 5.30. Footnote 43 to be deleted, as it is explanatory text to existing text.		

			declared their pregnancy. Only if the incurred radiation doses are well above 6 mSv per year would individual assessments be proper. The radiation dose can be estimated in advance by available computer codes (with an error of no more than 50 %) which would be sufficient taking all other uncertainties into account. This would, by most radiation protection standards, be seen as reasonable actions to ensure an acceptable level of radiation protection for exposed air crews (under existing exposure situations).				
	<u>Aircrew</u> Proposed text to replace para 5.30: 5.xx The regulatory body or other relevant authority shall establish a framework and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation. 5.yy Employers of aircrew shall: (1) assess doses and keep records for individual aircrew in accordance with para. 5.xx; (2) make available to individual aircrew the records of their assessed doses; (3) inform female aircrew of the risk to the embryo or foetus due to exposure to cosmic radiation and of the need for early notification of pregnancy; (4) apply the requirements of para. 3.114 in respect of notification of pregnancy.						

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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**
Schedules							
Germany Wassc	Schedule I: I-2, I-11		The term 'low probability' should be defined in the glossary to improve clarity. In case that it is being considered as a matter of interpretation for the regulatory body to decide, please indicate an approximate order of magnitude.			X	It was agreed to use the term "low probability" event during RASSC25 to provide flexibility to regulators. Examples of low probability scenarios can be found in the Safety Report 44, which sets out the methodology for deriving the levels in Table I-2.
Sweden	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	As it is written, this paragraph means that ALL sources that occur within justified practices and that fulfill the conditions in I-3 a or I-3 b are			X	Para I-3 and I-12 complement each other to cover all possible

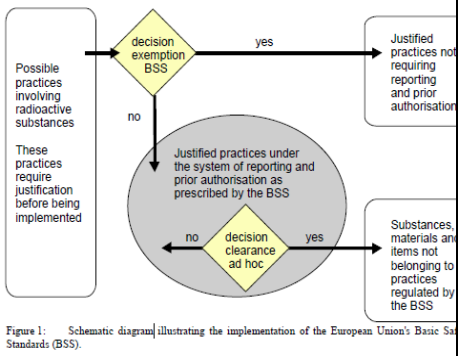
		exempted without further consideration from the requirements of these Standards, including those for notification, registration or licensing.	**exempted** from the requirements of the BSS. However, as the figure below indicates, sources within practices that are subject to notification or authorization shall be kept under regulatory control, as long as they cannot be cleared. Para I-3 should be changed accordingly.  Figure 1: Schematic diagram illustrating the implementation of the European Union's Basic Safety Standards (BSS).				scenarios mentioned in the comment. Para 3.10 states that the government or regulatory body determines which practices or sources within practices are exempted …. Para 3.12 states that the government or regulatory body determines which practices or sources within practices are cleared ….
Japan	I-4, footnote46, Table I-3	footnote 46 Material containing radionuclides of natural origin at an activity concentration of less than 1 Bq/g of any radionuclide in the uranium and thorium decay chains and less than 10 Bq/g of 40K is outside the scope of planned exposure situations, outside the scope of radiological protection (see Table I-3), so the concept of exemption for these activity concentrations does not apply. #####Table I - 3	Material containing radionuclides at an activity concentration of less than 1 Bq/g of any radionuclide in the uranium and thorium decay chains and less than 10 Bq/g of ^{40}K is a subject of clearance as shown in Table I-3. Therefore the concept of exemption should be also applied to such a material for these activity concentrations.			**X**	These levels define the scope of Planned Exposure Situations in Section 3 – see para. 3.4 (a). The regulatory body can also include levels below these

		Table I-3 Levels for EXCLUSION* and clearance of material: Activity concentrations of radionuclides of natural origin footnote for Table I-3(exclusion) * Exclusion is a concept to determine exposure situations out of the scope of radiological protection on the basis that they are not amenable to control with regulatory instruments					values within scope of Existing Exposure Situations (Section 5).
Hungary R & W	Schedule I, I-5. (new text)	*I-5. (a) The Regulations for the Safe Transport of Radioactive Material [12] (the Transport Regulations) do not apply to exempt material or exempt consignments — that is, material in moderate amount 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 Regulations [47]. 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.* *(b) The Transport Regulations do not apply to exempt material— that is, material in bulk amount in transport for which the activity concentration of the material in the consignment, does not exceed the relevant 'basic radionuclide value' for exemption given in Table I-2 of Schedule I.* *(c) The Transport Regulations do not apply to natural material and ores in bulk amount*	The Transport Regulations (according to 107. (e) in [12]) do not apply to natural material and ores in bulk amount containing naturally occurring radionuclides which are either in their natural state, or have only been processed for purposes other than for extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table 2 of [12], which are numerically equal to the corresponding exempt activity concentrations for radioactive material in moderate amount given in Table I-1 of Schedule I. The drafting of I-5. of Schedule I. shall be modified to resolve this issue.			X	The intention of I-5 is not to repeat TS-R-1 but to give an overview. It is not 100% inclusive (hence the term "in general", or "usually" in the edited version - Draft 4.05).

		containing naturally occurring radionuclides which are either in their natural state, or have only been processed for purposes other than for extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the activity concentration values specified in I-12 (b) of Schedule I.					
Germany Wassc	Schedule I: I-8		Checking the use of the term "residual radioactive material". The term "residual radioactive material" is used in other Para's (e.g. 1.18(iii), 5.1) with other regard (existing exposure: coming from past practices or from an emergency). Normally "discharge" is a planned exposure situation.	X	The term is used to indicate material that has come from a practice. Clarity is served by removing the word "residual".		
WNA	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 material46. 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 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 regulatory framework so allows) that the optimum regulatory option is not to apply regulatory requirements to the legal person responsible for the material.*			**X**	The "graded approach" is included in the BSS - see Requirement 6. The regulatory is able to clear at higher levels as set out in the criteria in Schedule I. The proposed modification would limit such values to a factor of 10, and this

			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.				limitation has not been justified.
Belgium WASSC	I-12/3	… of artificial origin <u>in solid form</u> does…	The clearance levels have been derived for solid material (see SR-44, para 1.1).			**X**	Safety Report 44 states that discharge of liquids and gases are not covered by the values in the Table, but para. 3.123 requires the regulatory body to establish authorized limits on discharges. Sections 4.4 and 4.5 of Safety

							Report 44 show application to liquids and gases.
Japan	I-12/ footnote 48	Modify according to the following underlined expressions. "These values may also be applied to clearance criteria in ~~I-8~~ I-11 , pending …."	I-12/ footnote 48	**X**			
Japan	I-13	Modify according to the following underlined expressions. "on the basis of criteria of ~~I-7 and I-8~~ I-10 and I-11, taking into …"	I-13	**X**			
Germany	Schedule I, I-13	…criteria of I-10 and I-11…	Editorial, wrong reference	**X**			
ENISS	Schedule I, I-13	Clearance may be granted by the regulatory body for specific situations, on the basis of criteria of I-~~7~~ 10 and I-~~8~~11, taking into account the physical or chemical form of the material, use or disposal of the material50.	Editorial, wrong reference.	**X**			
ISSPA	Schedule I, I-13	Clearance may be granted by the regulatory body for specific situations, on the basis of criteria of I-~~7~~ 10 and I-~~8~~11, taking into account the physical or chemical form of the material, use or disposal of the material50.	Editorial, wrong reference.	**X**			
Hungary R & W	Schedule I, Table I-1.	Modify the title of Table I-1: *Levels for clearance and for exemption…*	To make it consistent with text in I-14, and title of Table I-2.			X	The title is correct.
Hungary R & W	Schedule I,.	Put the data of U-nat and Th-nat back into the table and put them among parent radio-	These values are practical in some applications, e.g. are referred to in			X	To be checked.

	Table I-1.	nuclides back.	transport regulations.				
Belgium WASSC	Table I-2, title	… bulk amounts of solid material …	The clearance levels have been derived for solid material (see SR-44, para 1.1).			X	See comment on I-12/3
Japan	Table II-1	Change " Table II – I " to " Table II – 1 "	Table II-1	X			
PAHO	Table II-2	***Replace "D" by "Dangerous Activity (D)" as the column header***	It is unfortunate that the IAEA chose D to represent a "Dangerous quantity of radioactive material" when D is actually the symbol for Absorbed Dose. In Table II-1, that refers to the ratio (A/D), this is not a problem; but in table II-2, where the column headers are D and underneath Bq, it is very confusing; hence the suggestion to spell out what D stands for there.	X	Discuss with Technical Editor.		
Germany	Schedule III	Review of the dose limit for the lens of the eye: There is evidence that a reduction in the dose limit is warranted, and hopefully the ICRP will be able to provide an input soon (e.g. to RASSC 29).		X	Awaiting report from ICRP.		
Belgium WASSC	III-6 and 7	?	Table III-X is missing.	X	The text to be modified.		
Japan	Table III-1	Change " Table III – I " to " Table III – 1 "	Table III-1	X			
Japan	Annex to Schedule VI /Table A-1 /3rd low	Add the following underlined expressions. 50 mSv in the first 7 days for adults.	Thyroid dose from radioactive iodine for members of public varies considerably with age. The target group to assess thyroid dose should be described to clarify whether the criteria refers only adults, or any groups of public members.			**X**	The criteria is applicable for all age groups. The status of Annex is to provide guidance for appropriate application by Member States. As such, it may be modified

							locally.
Japan	Table A-1	Remove the colons following the symbols.	Table A-1	**X**	Discuss with Technical Editor.		

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Glossary							
Hungary R & W	Glossary	'accident' and 'incident'	It would be useful to modify these terms. The wording is similar and there is no significant distinction for the consequences. See the same 'not negligible' wording.			×	Terms are used in other standards and will not be modified, but definitions of 'accident', 'incident' and 'event' will be included with explanations
PAHO	Glossary	***Revise and make consistent the definitions of:*** ***Accident, event and incident***	As they are, they are confusing			X	See above.
Belgium WASSC	glossary	disposal	There are two different meanings for the term "disposal". It is not always clear which definition applies in the text. This has to be clarified in order to avoid mis-interpretations. Also note that in SSR-5, the term has the first meaning.	×	Yes, the second meaning is a narrow, specialized meaning relating to disposal at sea, and should not have been included. It has been deleted.		

PAHO	Glossary : effective dose	***Rewrite: Effective dose should not be used to quantify higher doses or to make decisions on the need for any treatment related to deterministic effects.***	It is not clear. Higher doses than what?	×	Text will be modified according to IRP 103 para. 105**.**		
PAHO	Glossary : equivalent dose	***Rewrite: Equivalent dose should not be used to quantify higher doses or to make decisions on the need for any treatment related to deterministic effects.***	Same as above.	×	Text will be modified according to IRP 103 para. 105.		
Hungary R & W	Glossary	'equilibrium equivalent concentration'	Give definition of '*potential alpha energy*'	×			Definition can be included from IAEA Safety Glossary
Japan	Glossary P165	Modify according to the following underlined expressions. "The ~~short lived~~ radioactive decay products of radon-222. This includes the decay chain up to …….thallium-210 (radium C'') and ~~lead-209~~ lead -210. Lead-210…"	Glossary P165	x	Delete 'short lived'. Delete the explanatory note.		
Hungary R & W	Glossary	'radon progeny, 'thoron progeny' It would be better to summarize the features of the radon and thoron progenies in a table, making clear distinction between the short and long lived daughters.	The current wording is too complicated.			×	The explanatory note will be deleted – see comment above.
Germany	Glossary page 152	**exposure, categories of** **medical exposure:** 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.	In line with ICRP (Pub 103, Para. 195), asymptomatic individuals taking part in a health screening program or in an individual health assessment should be considered as patients. In the medical area, it is widely accepted to distinguish between patients providing clinical symptoms of a disease or at least severe concerns of being diseased and asymptomatic individuals with low prevalence of	x	The argument is correct. However, the concerns are addressed through the addition of a definition of "patient" that explicitly includes asymptomatic individuals taking part in a health		

			being diseased, such as individuals taking part in a health screening program or in individual health assessments		screening programme or in an individual health assessment (See technical edited draft 4.05).		
Belgium WASSC	glossary	exemption level: add 'surface contamination'	There are exemption levels in terms of surface contamination in TS-R-1.			X	There are no 'exemption levels' in terms of surface contamination in Rev. IBSS.
Belgium WASSC	glossary	Delete the entry "radon".	In order to avoid confusion, the term "radon" should be used only as the name of the chemical element. In the BSS, the term "radon" should therefore be replaced by "Rn-222", unless the element is alluded to.			×	This would change the defined usage of 'radon' and 'thoron'
Belgium WASSC	glossary	Delete the entry "thoron".	In the BSS, the term "thoron" should be replaced by "Rn-220".			×	This would change the defined usage of 'radon' and 'thoron'
ENISS	Glossary	Monitoring The measurement of *dose* or *contamination* for reasons related to the *assessment* or *control* of *exposure* to *radiation* or *radioactive substances*, and the interpretation of the results.	Take the definition from the IAEA glossary	×	Definition of monitoring from the IAEA Safety Glossary will be added.		
ENISS	Glossary	Θ protection of the environment includes the protection of: non-human species, both animal and plant; environmental goods and services such as the production of food and feed; ~~resources used in agriculture, forestry, fisheries and tourism; amenities~~	see general comments not in line with 1-28			×	No inconsistency with 1.28. In line with Safety Fundamentals, and UNEP position, the

		~~used in spiritual, cultural and recreational activities; media such as soil, water and air; and natural processes such as carbon, nitrogen and water cycles.~~					sustainability of *agriculture, forestry, fisheries and tourism and of the use of natural resources* is an issue to be considered together with protection and safety.
Germany Wassc	Glossary		Amendment of the term "nuclear material" as "other radioactive material". In the draft there are used terms like "nuclear or radiological emergency" or "nuclear and radiation safety".			×	Term 'nuclear material' is used only in definition of 'nuclear security'. "Nuclear or radiological emergency" is a defined term, and 'nuclear and radiation safety' is not used.
ISSPA	Glossary	**Is optimized** means that optimization of protection and safety has been applied and the result of that process has been implemented	See general comment		Text to be modified.	×	See comments on Section 2.
PAHO	Glossary : inspection imaging devices	Other types of inspection imaging devices instead may utilize: electrical and magnetic sources, ultrasound and sonar, nuclear magnetic resonance, microwaves, terahertz rays, mm-wave, infrared radiation or visible light.	The mm wave machines (passive and active) are the only ones developed commercially for screening purposes	X	Agreed. Insert the text "mm-wave".		
PAHO	Glossary : source	A sterilization gamma irradiation unit is a source for the practice of radiation preservation of food or other products,	Not to give the impression that it is used only for food preservation…	×	Text to be modified.		

Japan	Glossary (p. 151)	Additional precaution is needed like the underlined expression. “protection of the environment… and water cycle. It is noted that this term is used in the Safety Standards in the context of incurring radiological impact.”	In general, this definition of this term is true. However, IAEA Safety Standards concern with **radiological** effect or impact. To avoid confusion, some precaution is needed.	×	This will be clarified in each relevant place in the text.		
Japan	Glossary	Add the definition of “remediation” in the glossary “remedial action”	See Resolution Table – MSComments.pdf (page 400). The resolution table indicates that this comment is accepted. However, our intent is not reflected in BSS draft 4.0. (Japanese comments for BSS3.0) IAEA Safety Glossary defines "remediation" and mentions relevant information such as some synonyms of "remediation", such as "cleanup" and "rehabilitation". This information is useful.	×	Definitions of ‘remediation’ and ‘remedial action’ and relevant notes will be included.		

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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**
Additional comments							
ENISS		**ANNEX to the ENISS Comments on the IAEA BSS 4.0** **"To ensure that protection and safety is optimized":** **An unrealistic and inadequate requirement for radiation protection** The new ICRP Publication 103 speaks repeatedly of continuity and stability in the ICRP's system of radiation protection. In particular in para 12 ICRP states: "Thus, these recommendations should not be interpreted as suggesting major changes to radiological protection regulations that are appropriately based on its previous Recommendations in Publication 60 and subsequent policy guidance." The IAEA BSS should follow ICRP 103 according to a resolution of RASSC as much as possible. There is a general understanding in the RP community that indeed there are no reasons for fundamental changes in the RP system and this includes definitely no changes regarding the application of the optimisation principle. The RP practice has been proven to be effective in minimizing exposures. Evidently, there is a clear trend towards lower occupational doses for nearly all industries using ionizing radiation. In addition the number of workers exposed close to the dose limit exposure has been continually decreasing. This is demonstrated in detail by data recently published by UNSCEAR. According to the ICRP recommendations optimization is a process: "The principle of optimisation is defined by the Commission as the source-related process" (para 212 ICRP 103). And "Optimisation is always aimed at achieving the best level of protection under the prevailing circumstances through an ongoing, iterative process that involves: - evaluation of the exposure situation, including any potential exposures (the framing of the process); - selection of an appropriate value for the constraint or reference level; - identification of the possible protection options; - selection of the best option under the prevailing circumstances; and implementation of the selected option. "(para 213 ICRP 103)		×	See comments under Section 2.		

	The process as described above corresponds to the reality of the situation in the nuclear installations. This process is repeated on a continuous basis for all operations that could lead to significant exposure to the workers. This process has proven to be very successful. The formulation in the IAEA BSS implies that the current radiation protection practice as described above needs to be changed. The BSS convert the process into a requirement for a definite result. This would be a complete new philosophy, which is by no means justified. One may object that the expression "be optimized" is just an abbreviation for that continuing process of optimisation and the application of the (current) result, as it is described in footnote 4 (para 2.10) on page 22 of the Draft of BSS. In our view, this is not sufficient since - it is just one footnote on one single page in an extensive volume, - the expression "be optimized" or "ensure to be optimized" can be found at several places within the BSS, - the abbreviation accentuates unduly the result, it underemphasizes the aspect of the continuous process, - "nomen est omen", that is, there is high probability of taking the expression literally and ignoring the long description given by the footnote, - that expression misleadingly and against IAEA's intention supports the opinion that the principle of optimisation has been changed. Summing up, we urgently recommend emphasizing the aspect of the continuous process by using the term "ensure that protection and safety are subject to an optimization process", for example, and specifying the demand of implementation of the results of that optimization process via a footnote or in the glossary.					
Germany Wassc	Ref. [8] (page 138)	… IAEA Safety Standards Series No. GSR Part 1, IAEA, Vienna ~~(2011)~~(2010)	published in October 2010	×	References will be updated.		
Germany Wassc	Ref. [9] (page 138)	… IAEA Safety Standards Series No. WS-R-5, IAEA, Vienna (2006)(under revision, DS450 will supersede)	DS450 will supersede WS-R-5 (Link: http://www-ns.iaea.org/committees/files/draftcomments/993/DS450-draft_DPP_for_the_revision_of_the_Safety_Requirement_on_Decommissioning_and_Termination_of_Activities..pdf	×	References will be updated.		
Germany Wassc	Ref. [12]	… IAEA Safety Standards Series No. TS-R-1, IAEA, Vienna (2009)(under revision,	DS437 will supersede the 2009 Edition of TS-R-1	×	References will be updated.		

	(page 138)	DS437 will supersede)	(Link: http://www-ns.iaea.org/downloads/standards/drafts/ds437.pdf).				

WNA comments

Table 1: Summary of the imbalance in the control of main sources of public exposure to ionizing radiation

Public Exposures		Administrative Control	Dose criterion
Background Natural Radiation			
- Radon**:** Average **1.2 mSv/y (6,000 x nuclear)** Range 1-10, up to 100 mSv/y	Indoor dwellings Comic, terrestrial & internal	No dose control per individual Control per concentration level. ≈ **12 R**[1] No control. **0 R**	Reference levels **1-20 mSv/y**, with option for excess, and equivalent average concentration <10mSv/y
- Others**:** Average **1.2 mSv/y (6,000 x nuclear)**			**No criterion**
Medical Sector			
Average **0.4 mSv/y** (**2,000 x nuclear**)	Medical diagnostics (x-rays)	No dose control per individual. Control per equipment. **≈70 general R+≈50 specific R**	**No dose limit and no numerically-set dose criterion** for diagnostic reference levels
0.04 mSv (**200 x nuclear**)	A single chest x-rays		
10 mSv (**50,000 x nuclear**)	1 CT scan		
Nuclear Industry			
Average **0.0002 mSv/y** Range 0.00001-0.001 mSv/y	Most exposed persons living near to nuclear sites over the entire year – assuming very prudent assumptions	**Strictly controlled three-level mechanism dose limit**, **constraints**, **operating limits**, with ≈70 **general R + ≈30 specific R**	A dose limit of **1 mSv/y** from all sources, **with lower constraints and operating limits**
Industries involving naturally occurring radioactive materials (NORM)			
Range **0.001-1mSv/y** (**5-5,000 x nuclear**)	Examples of industries: (1) Fossil fuels (coal-fired power plants and offshore oil and gas platforms), (2) phosphate fertilizer manufacturing, (3) titanium pigment production, (4) mineral sands production, (5) water treatment.	As per nuclear industry but generally not yet imposed or implemented **≈70 general R + ≈30 specific R** No dose control per individual but generally not yet imposed or implemented: **≈30 R** .	If dose ≈ 0.1-1 mSv/y (If material content > 1 Bq/g U or Th), same as for nuclear : **1 mSv/y** Otherwise (dose **≈** <0.1 mSv/y), Reference levels from **1-20 mSv/y**, with option for excess
Air Transport			
0.1 mSv (**500 x nuclear**)	A single Europe-Asia return trip	No control: **0 R**	**No criterion**
Above 1 mSv/y (**5,000 x nuclear**)	An international frequent flier	No control: **0 R**	**No criterion**
Exemption and clearance of radioactive material			
Diverse	Diverse	No dose control per individual: ≈5R	**<0.01 mSv/**y (**1mSv/y** low probability
Consumer products, and Commodities (from contaminated areas)			
Consumer products	Diverse	No dose control per individual: ≈5R	**<0.01mSv/**y (**1mSv/y** low probability)
Commodities (from contaminated areas)	Diverse	No dose control per individual: ≈3R	Reference levels **<1 mSv/y**

[1] R: Number of requirements in BSS Draft (DS379 Version 4.0 - 9 September 2010) – WNA comments (5 November 2010) to IAEA .