Member State Comments on draft Safety Standards on
DS434 –Radiation Safety of Accelerator Radioisotope Production Facilities

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Romania	General	Very well structured according to the considered purpose		A			
Sweden	General	More reference to GSR Part 3 regarding training, monitoring etc., as is done for workplace monitoring and other sections, could be useful.		A			
Sweden	General	Many sections (for example 6. RP Programme and 16. EPR) are also very well written.		A			
Switzer-land	General	The IAEA document provides a good overview with regard to running a radionu-clide facility – or starting up a new radionuclide facility. There are no further sug-gestions for the document		A			
Tajiki-stan	General	Tajikistan supports the draft safety standard Radiation Safety of Accelerator Ra-dioisotope Production Facilities (DS434)		A			
UK	General	The requirements in this standard should complement not contradict require-ments in Directive 2013/59/Euratom (BSSD).				R	No specific instance cit-ed. This guidance doc-ument basis is primarily the GSR Part 3, 2014.
UK	General – through-out docu-ment	The terms “vault room” “cyclotron room” “target room” “radiation room” are all used in the document. Suggest using a defined term consistently.			A These are common termi-nologies used in practice, however, will be fixed by the technical editor.		
Sweden	1.2 Line 1-3	Any possibility to update the statistics given in the sentences?	The information is outdated – are there no newer estimates which could be used for the report (published 2018 or later)?	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	1.4 Line 1-2	This cannot be true, if the objective is as described in 1.5. The reason for this can be found at page 381 of the GSR Part 3: "*The following definitions apply for the purposes of these Standards. Further definitions are provided in the IAEA Safety Glossary*"	For GSR Part 3, MS and co-sponsoring organizations agreed that definitions used should be those of the section **Definitions**, included in the GSR Part 3 Standards. The reason for this was that no re-interpretation of the text should be possible by changing the definitions.	A Added GSR Part 3 and the updated web version of the glossary (2016)			
Indonesia	1.7. (b) (iv) page 2	The hanging is enlarged or equalled with points (iii) above it;		A			
Sweden	1.7 and 3.1	These two paragraphs are consistent and seems OK. However, when compared with the Technical Report 465 a different classification is used and some other literature uses other values.	Where in the document are these categories really used and what is the origin of the classification? Could a reference be given to the source, e.g. *low energy (<20 MeV/Nucleon)* etc. be given?			R	This is provided by the experts in the CS meeting and no reference is given. Low energy is in the context of comparison.
Sweden	1.12/ lines 1-2	The second part …*the benefits of radioisotopes that are produced…are outside the scope of this Safety Guide* seems categorical. Consider re-phrasing, adding *largely* or some other qualifier.	In Para 1.14 we are informed that justification of radioisotope production facilities are addressed in Section 2. This would at least purely theoretically contradict para 1.12 since the benefit should outweigh the detriment?			R	This para is on non-radiological risks and benefits. Can be fixed during final editing if needed.
Sweden	1.13	Consider moving this para to after 1.7	E.g. first to address what is included and then what is not included (1.8 – 1.12).			R	Nuclear security is not a focus in this guide.

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	2.4	The description is a bit short and one could get the impression that all sources included in the categorization system are dangerous if one does not read the reference [10]. Consider adding something like: *…the categorization compares the activity level (A) of the source with the dangerous quantity (D) and defines five categories of sources covering the scope from very dangerous (A/D>>1) to less dangerous sources (A/D <<1).*	Sources in cat. IV-V are less dangerous and perhaps not even dangerous in the way that they could result in death or permanent injury. Consider reformulating the text of paras 2.4 – 2.5 so that it is better understood that not all the sources categorized have activity levels equal or higher than the D-values (A/D > 1).		A Para 2.5 edited based on comments from others. When there is detailed guidance, it is better to give the reference.		
Brazil	2.5 last line	The categorization of finished products of radioisotope production should be considered on a case by case basis	Adequation to the Safety Guide RS-G-1.9	A			
Indonesia	para 1, page 5	At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled, and therefore these sources need to be kept under appropriate regulatory control	The word however followed by even breaks the whole meaning, and therefore, the word even should be deleted.	A			
Indonesia	Page 5, line 4	The finished products of radioisotope production fall into source categories 1-5.	This document should be reviewed to confirm whether this guidance covers radioactive material category 1 to 5, and to be adjusted according to accelerator category in para 3.1	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	Section 3.2	The Section titled "Irradiation of targets in accelerators" lacks information on how radioisotopes are generated by irradiating targets. Recommend a short description (at the beginning of this section) to provide context to this section. Recommend adding the following (or similar) text: "When an accelerated particle such as proton collides with the nucleus of a target atom a reaction occurs forming a radioisotope product. Many radionuclides produced in accelerators cannot be produced by neutron reactions. The principal advantage of accelerator radioisotope production is the higher specific activity (e.g.; more disintegrations per mass of the desired isotope) than is the case with reactor products.	Completeness		A Para 3.2 – 3.4 modified.		
Sweden	3.3 – 3.4	It is not clear to what extent these two paragraphs are separate or over-lapping. Needs clarification. What is meant by accelerators of type I-V?	One para (3.3) talks about accelerators that can be used for the activation of isotopes for research and radiopharmaceutical usage and the other para (3.4) about those which are used for activation of isotopes for research and radiopharmaceutical usage. Both paras take up the production of 18F. Furthermore, 3.4 talks about accelerator types I-V [Section 6 of reference 12], however in 3.1 we have just read that we have 4 different types of accelerators in this document?		A Para 3.2 – 3.4 modified.		

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	3.3 - 3.4	The first sentence in paragraphs 3.3 and 3.4 are the same. Recommend removing the redundancy, merging the two paragraphs, and re-ordering the three paragraphs as follows: 3.2 Accelerators can be used for the activation of isotopes for research and radiopharmaceutical usage. Examples of accelerator types I–V can be found in Section 6 of Ref. [12]. 3.3 Some accelerators are designed specifically for positron emission tomography (PET) radiopharmaceuticals, e.g. ^{18}F. Such accelerators are designed and sold to isotope production facilities or hospitals. 3.4 Accelerators for the production of radioisotopes are generally located in the same building as where the radioisotope containing products are synthesized. Consider deleting: "For the production of ^{18}F, the target is irradiated and the liquid mixture (^{18}O -water containing ^{18}F) is transferred in capillary pipes to a processing hot-cell."	Eliminate redundancy and improve readability		A Para 3.2 – 3.4 modified.		
Germany	3.4	Delete paragraph.	No significant difference to Para 3.3.		A Para 3.2 – 3.4 modified.		
Indonesia	para 2, page 5	which should weigh the tradeoff between the various benefits and risks associated with their operation in determining whether	Inserting the tradeoff between the benefits and risks to make the sentence		A "weigh" replaced with "consider". Further this may be fixed by the editor.		

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Indonesia	page 6	Verifying appropriate design and the adequate quality of facilities and activities and of their associated equipment	This section sounds contradictory with the section 1.8. where quality assurance procedures that pertain to its production are outside the scope of this document.			R	This is a direct quote from the Fundamental Safety Principles
Indonesia	Page 7	Specific duties ..... will, however, be assigned to all range of hierarchical level, including senior management, the radiation protection officer (RPO), workers who operate the facility and handle radioactive material, and qualified experts/radiation protection advisers (RPAs)	Worker, RPO, and RPA are position in a hierarchical level rather than just a people.		A Modified as Specific responsibilities for the design, operation and eventual decommissioning of the facility will, however, be assigned to all range of hierarchical level, including senior managements....		
Indonesia	Page 7	If this expertise is not available in house, an external qualified expert/RPA should be appointed to take responsibility, for radiation safety and regulatory compliance	Writing mistakes			R	Not clear. Editor to fix.
Iran	4.1	Providing security consideration should be added as one of the operating organization responsibilities				R	This is a direct quote from the Fundamental Safety Principles

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	4.1	This paragraph outlines the responsibility of the person or organization responsible for facilities and activities and a reference is made to the Safety Fundamentals (SF-1) for the bullets a) – f). Why is reference made to bullet point g) of GSR Part 7 in this context?	The list of SF-1 is very general and the bullet c) *Establishing procedures and arrangements to maintain safety under all conditions* also covers EPR activities (In SF-1 we have principles 8 and 9 about prevention of accidents and EPR measures.). If a further bullets should be given, in addition to the SF-1 list, one would expect the use of the requirements of GSR Part 3 since it is stated in 1.5 that the objective is *to provide recommendations on how to meet the requirements of GSR Part 3*??		A Para 3.6 of the Fundamental Safety Principle do not mention the item (g) and ref on GSR Part 3 included.		
USA	4.1, item (d)	Recommend addressing shielding as follows: "Verifying appropriate design, adequate shielding, and adequate quality of facilities…"	Completeness			R	This is a direct quote from the Fundamental Safety Principles
UK	4.2	Specific duties and the day to day responsibilities for the design, operation and eventual decommissioning of the facility will, however, lie with a range of people, including….	Paragraphs 4.1 and 4.2, seems to divide the duties between different parties. It would be more appropriate for paragraph 4.2 to just refer to 'specific responsibilities' and keep the 'duties' on the employer (person or organisation) in charge of the work. [HSE]	A			
Indonesia	before point 4.3. Page 7	At this point can be mentioned things related to security culture though it is not discussed but can be stated the document that discusses security in detail related to accelerator	Today, radioactive source security culture becomes an important issue.			R	Section 12 provides guidance on security related topics.

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Indonesia	4.2; 4.3; 4.15; 4.17 4.18	A qualified expert/RPA is an individual who is duly recognized, by virtue of certification by appropriate boards or societies, professional licenses or academic qualifications and experience, as having expertise in a relevant field of specialization	- The inclusion of the minimum competency for the RPA/qualified expert (apart from the specific expertise) is strongly recommended. - This has been referred in reference 18 (DS453). On the other hand, the minimum standard has not been implied in the DS453.			R	Para 4.19 provides details of the expected competency.
UK	4.3 line 3	If this expertize is not available in house, an external qualified expert/RPA should be appointed to ~~take responsibility, for~~ provide advice regarding radiation safety and regulatory compliance.	The second sentence suggests that responsibility may be assigned to an external" Qualified Expert" or RPA. While the advice and technical input of a QE should be sought, responsibility for safety lies with employer. This currently contradicts the final sentence of 4.18 which states that the operating organization can not delegate its responsibility for safety to a qualified expert. [PHE]	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	4.4	~~A senior manager should be designated as having overall responsibility for~~ Responsibility for overseeing radiation safety, and verifying that all activities involving radioactive material are carried out in accordance with regulatory requirements may be delegated to a senior manager. Responsibilities for radiation safety are required to be established, and they should be agreed to by all relevant parties and recorded in written form. ~~Managers should ensure that~~ Procedures should be put ~~are~~ in place for the protection of workers, the public and the environment, and for ensuring that doses are kept as low as reasonably achievable (the principle of optimization). All policies and procedures should be documented, and should be made available to all staff and the regulatory body as appropriate.	In paras 4.1 and 4.3 it is the employer that has overall responsibility. In para 4.4 this shifts to a senior manager. Suggest changing this paragraph to say that responsibility may be delegated to a senior manager, however ultimate responsibility (the 'duty') remains with the employer, i.e. the person or organization responsible for facilities and activities that give rise to radiation risks.) [HSE]	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	4.6	The formulation: *In cases where there is a potential conflict between operational responsibilities, such as responsibilities for meeting a production schedule and responsibilities for radiation safety, radiation safety requirements should always take priority.* This formulation needs clarification, perhaps even change, in order to be understandable - as it stands, it is too categorical. In case of safety culture we say: *as an overriding priority, protection and safety issues receive the attention warranted by their significance.*	This formulation is a bit too strict. Safety first is of course true (not in the BSS however!), on the other hand – when not referring to deterministic effects but rather small radiation doses, protection and safety shall be optimized and this implies that due account should be taken of other factors (societal, economic etc.). Para 2.18 of GSR Part 3 requires that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation. It cannot be a black and white situation perhaps the word *always* is wrong?	A			
UK	4.7		This paragraph contradicts itself by stating that it does not apply blame but disciplinary procedures.		A "do not assign blame" changed to "should consider the circumstances"		
Sweden	4.8	The last sentence: *The radiation protection programme should be integrated into the management system.* Requirement 24 of the International BSS requires the existence of a radiation protection programme for occupational exposure. Could one change it to read: *The radiation protection programme should be a part of the integrated management system*?	It is of course clear that relevant parts of the RP programme (objectives, authority and decision paths, staffing, resources, processes) are part of the integrated management system but this does not mean that there should be no RP programme.	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	4.9, 4.10, 4.11, 4.12, 5.42 etc	The use of "*should*" is difficult when referring to requirements (not quoted word by word) which are "*shall*" statements in Safety Requirements. A rigid approach would be preferable. At least it could be useful to explain the situation in a general paragraph in the beginning of the guide.	Could be seen as weakening safety requirements. Other issues not covered by GSR Part 3 and other Safety Requirements e.g. "radiation safety committee", "radiation awareness programme" are formulated as "should be established", "should be included" – this then becomes confusing.		A Editorial. Requirement statements will be checked during final technical editing.		
Indonesia	4.12 after point "k" Page 8	At this point can be mentioned things related to Radioactive security program document though it is not discussed but can be stated the document that discusses security in detail related to accelerator	A radioactive security program document is important to support the existence of a security culture			R	This whole section is on safety aspects and separate section is provided for security related aspects.
Indonesia	Page 9	Characteristics of the particle accelerator, i.e. type (cyclotron, linear accelerator), energy, current, beam characteristics and size/geometry	Size or geometry is part of characteristics of the accelerator, rather than layout	A			
Indonesia	Page 9	Facility in which particle accelerators and/or radioactive material will be processed and stored with particular attention paid to associated safety systems and equipment layout, e.g., radiation shielding, interlock systems, fume hoods, remote handling tools, effluent exhaust systems, monitoring systems, and warning systems;	Safety systems and equipment should be arranged in a wright position in the facility layout	A			
UK	4.12		Is this list of information that is needed to be submitted for a license consistent with the Directive 2013/59/Euratom (BSSD)? [HSE]			R	Scope of the document is within the GSR Part 3, however, inconsistency of the items is not observed.

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Russia	4.12	Add new subparagraph (n) un article 4.12 (n): initial decommissioning plan	According to requirement 10 (article 7.4) of IEA document Decommissioning of Facilities, GSR part 6 the licensee shall prepare and submit to the regulatory body an initial decommissioning plan together with the application for authorization to operate the facility	A			
USA	4.12	There is no mention that documentary evidence should include verification that the recipient has a permit or authorization to receive the radioactive material being transferred. Recommend adding another listed item after item (f) to address this verification.	Completeness	A			
USA	4.12	There is no mention that documentary evidence should include a decommissioning and decontamination plan with financial assurance. Recommend adding another listed item after item (m) to address decommissioning plan and financial assurance.	Completeness	A			
USA	4.13, lines 2-5	It may be burdensome to notify the regulatory authority when there are changes to qualified experts. Recommend the following change: "The operating organization should notify the regulatory body of any changes to key personnel, in particular senior managers~~,~~ and the principal radiation protection officer ~~and qualified experts/radiation protection advisers~~."	Improve applicability	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	4.13	The operating organization should obtain the approval of the regulatory body before commencing a new facility or implementing modifications to the facility. The operating organization should notify the regulatory body of any changes to key personnel, in particular senior managers or the principal radiation protection officer. ~~and qualified experts/radiation protection advisers.~~	The regulator does not need to know every time a qualified expert or radiation protection adviser changes. [HSE]	A			
UK	4.15	Employers should have sufficient RPOs to cover periods of absence. ~~During times when the RPO is not available to provide oversight on radiation safety matters, such as during periods of absence from the facility, arrangements should be made for the prompt provision of authoritative advice concerning radiation safety matters. Such arrangements could include timely access to qualified experts/RPAs or the designation of deputy RPOs who are present at the facility during times of operation.~~	Employers should have sufficient RPOs to cover periods of absence so should not need to make special arrangements for cover. [HSE]			R	The para only reassures the availability of RPO.
Iran	4.16	In C item, Personal protective equipments should be considered in inspection and maintenance by RPO		A			
UK	4.16 line 1	The ~~duties~~ responsibilities of the RPO ~~should~~ may include the following, some of which may require consultation with, or assistance from, a qualified expert.	Clarification. This paragraphs includes a list of duties that may be delegated to the RPO other than compliance with local rules, however it should be clear that the 'duty' and ultimate responsibility still rests with the dutyholder. [HSE]	A editorial			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	4.16	The listed RPO duties do not address the shielding design. Recommend adding another listed item after item (a) as follows: "Oversight of the review of the shielding design and statements regarding occupancy and workload."	Completeness	A			
Indonesia	Pg 11, 4.17	The implementation of this RPA is better to be prepared, as once the draft established, it will be the reference. The implementation is not limited in the accelerator but also in a non power nuclear reactor and non-reactor nuclear installation facility. Therefore, the criteria for stipulation and the				R	No clear suggestion.
Indonesia	4.19	A thorough knowledge of the hazards associated with the radiation and other hazard resulted during proses present and the ways in which the hazards can be controlled and minimized	It can be resulted any changing of chemical or radiochemical because of interaction with ion	A			
Indonesia	4.21. page 13	IMHO, in this sentence it would be better if you add something related to the issue of radioisotope security, as if "…issues relating to radiation safety and radioisotop security, including:…"	This should be noted by performing an A/D ratio related assessment when the radioisotope is generated from the accelerator facility			R	Not appropriate in this section. Section 12 provides security guidance.
Indonesia	Page 13, section 4.21	Adding point (k). Radioactive waste management	Expert/RPA knowledge on radiation safety must be adequate enough, as well as on radioactive waste management.	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	4.21/ bullet (f)	It is not clear why this foot-note is needed? In the foot-note 3) the term emergency arrangements is explained as in GSR Part 7: "the integrated set of infrastructural elements, put in place at the preparedness stage, that are necessary to provide the capability for performing a specified function or task required in response to a nuclear or radiological emergency" and include….	In the GSR Part 3 emergency arrangements are defined as: "the integrated set of infrastructural elements necessary to provide the capability for performing a specified function or task required in response to a nuclear or radiological emergency. These elements may include authorities and responsibilities, organization, coordination, personnel, plans, procedures, facilities, equipment or training." If this is not used, GSR Part 7 should be added to para 1.5.			R	Not to miss the additional items such as exercises, quality management programme etc.
Indonesia	4.22. page 13	In this paragraph, it should be stated that radiation workers should be involved in building a safety culture	Fostering a safety culture for workers is important and should be written in this document to be a beacon to achieve it	A			
Indonesia	Page 13	Section 4.22. ….Workers include individuals whose work activities cause to be exposed to radiation	Propose alternative phrase that explain the risk of radiation exposure explicitly		A (editorial)		
UK	4.22 (b)	(b) Wear their individual dosimeters in the correct place at all times during radiation work and record their daily doses. If the dose exceeded the investigation level set by the local rules they should report it to the responsible (senior) manager or RPO (see Section 6);	Clarify that the dose referred to in the local rules is the dose investigation level. [HSE]			R	Not necessarily the investigation level always. This could be a value determined in the local rules.
Sweden	4.22 /bullet (f) (line 19)	Consider changing "*willful*" to "*wilful*"	3.83 of GSR Part 3 uses the British spelling		A (editorial)		
Sweden	4.23/ First line	Add "*adversely affect protection and safety,*" after …*incident or circumstances that could…* and before…*result in higher than usual radiation doses to themselves or to other persons.*	This is in line with para 3.84 of GSR Part 3 and makes it more general	A (see UK comment)			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	4.23	Workers should promptly inform the RPO of any incident or circumstances that have or could result in ~~higher than usual radiation~~ doses that exceed the organisation's dose investigation levels to ~~themselves or to other~~ any persons. ~~This~~ These incidents could include failures or observed deficiencies in safety systems and warning systems, errors in following procedures, or inappropriate behaviour. A written report should be made to the RPO as soon as practicable after the incident or observation.	A written report would only be required where a dose exceeds the dose investigation level. As written, the paragraph could require a written report for doses only a few microSieverts above normal in any reporting period. [HSE]		A Workers should promptly inform the RPO of any event or circumstances that could adversely affect protection and safety and/or result in radiation doses that exceeds the organization's dose investigation level to any persons. These events could include failures or observed deficiencies in safety systems and warning systems, errors in following procedures, or inappropriate behaviour. A written report should be made to the RPO as soon as practicable after the event or observation.		
Sweden	4.26/first line	Add "*for protection and safety*" after local rules and procedures in the first line of 4.26	Consistency with the requirements of GSR Part 3	A			
Sweden	4.26 (b)/sixth line		The words "*their respective duties*" refers to whom (the operating organization, workers?)?		A Editorial (Refers to all those in the emergency plan)		
Sweden	4.26 (c)/first and second line of p.15	*…duties and responsibilities with regard to radiation safety of key individuals within the operating organization…* Consider rephrasing: *…duties and responsibilities of key individuals within the operating organization with regard to radiation safety …*	language suggestion Is it the radiation safety of key individuals…or the duties and responsibilities of key individuals (regarding radiation safety)	A			
UK	4.26 (h)	Written instructions describing the wearing of suitable personal protective clothing in s~~u~~ ~~pervisory~~ supervised and controlled areas;	Clarification on area Designation [HSE]	A			

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USA	4.26, item (i)	Using the term "plant" has the connotation that it is a nuclear power plant. Recommend replacing "plant' with "facility."	Reduce ambiguity	A			
UK	4.26 (i)	Written instructions to require that the workers check with the RPO that the plant is safe before entrance.	A check with the RPO every time an entry is made seems rather unworkable, unless by "plant" this means the actual area containing the accelerator? [HSE]		A "plant" changed to "facility"(see USA comment)		
Germany	FIG. 1; 5.25; 5.26; 5.29; 6.28; 7.4; 7.8; 9.6(a); 9.8; 9.19; 13.4(c); 14.2; 14.8;	Replace "Cyclotron" by "Radioisotope Production Facility" in the diagrams.	Linear accelerators should not be excluded.		A Modified as "Radioisotope production facility (Cyclotron/linear accelerators)"		
USA	Page 17, Figure 1	Recommend adding "Access Control" as a listed item under the "Radiation Protection" category (on the left side of the schematic).	Completeness	A			
USA	Page 17, Figure 2	Recommend adding "Verify Authorization to Receive" to the right of "Vial Filling" (at the bottom of the schematic).	Completeness	A			
Brazil	Fig 2, p.17	Change Figure 2	The relation between P1, P2 and P3 is not evident/clear enough	A			
Sweden	5.7/7-8 lines	The sentence: "*The relevant requirements for performing the appropriate risk assessments are provided in 5.1*" can be deleted.	This sentence refers to 5.1 which in turn refers to GSR Part 4. This has already been mentioned and is not needed in para 5.7 (only confusing).	A			
USA	5.8 and Figure 2	Recommend adding explanatory text to Figure 2 to explain abbreviations such as: GMP, P1, P2, P3	Completeness and illustration of the Figure and abbreviations	A			

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Belgium	Page 18 §5.9 & 5.10	Add a sentence (or §) about the contamination risks during the maintenance of the accelerator.	There is also a risk during the maintenance of the accelerator. Moreover the physico chemical nature of the contaminants is different (longer half-life, activated products coming from the targets, the plating, melted piece of equipment, ...)	A			
USA	Page 18	Before paragraph 5.12; recommend adding a paragraph addressing the need for the facility to verify that the recipient has a permit or authorization to receive the radioactive material being transferred.	Completeness	A			
UK	5.13	Direct radiation exposure of workers and members of the public due to the operation of radioisotope production facilities should be attenuated to optimized levels by the use of appropriate shielding. Concrete is often used to construct the radiation room shield, but other materials such as earth fill, steel and lead may also be used in its construction. The shielding properties of particular materials are well established [21–28], but experience deriving from existing radioisotope production facilities should be taken into account. The shielding should provide adequate reductions in radiation levels to keep doses within the dose limits and constraints established or agreed to by the regulatory body.	clarification			R	Shielding designs are always preferred to dose constraints rather than to the limits.

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Indonesia	5.14	Where practical, all tubes, pipes and conduits include skyshine, when above facility will not be used for certain purpose, should take a curved or stepped path through the shielding material to reduce external radiation levels or should be embedded in the concrete slab using pits and trenches	Skyshine should be calculated in order to optimize to the environment/ vicinity		A Considerations should also be given on the possible skyshine effect while designing the shielding of the facility.		
Sweden	5.17/5th and 6th line	The word "no" is missing: *The surface should have no? unnecessary protruded parts for easy decontamination of the surface."*	Typo ?	A			
USA	5.17, lines 5-6	The second sentence, as written, is not correct. Recommend adding the word "not" between "should" and "have." "The surface should not have unnecessary protruded parts for easy decontamination of the surface."	Accuracy and editorial	A			
Sweden	5.17 /9th to 10th line	Suggest changing the text within parentheses to: (*e.g. demands for a laminar flow when "filling machines"/dispensing systems are used for handling open radiopharmaceuticals*).	The text within parentheses: within parentheses to: (*e.g. demands for a laminar flow when "filling machines"/dispensing systems are used for handling open radiopharmaceuticals*).	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Korea	5.18	Fume hoods are appropriate for the handling of hazardous and radioactive materials when the potential for contamination control is low and when external dose rates are low. Partial-enclosure fume hoods allow high accessibility by chemists and manipulation of special equipment while affording protection from chemical fumes and radioactive aerosols. The sash height should be adjusted to maintain the face velocity (vapour : 0.5 0.4 to 0.75 m s-1) of air entering the hood opening, which should be greater than the capture velocity of contaminants likely to be released into the fume hood work area to prevent releases into the general laboratory area.	Typically, the hood face velocity of 0.4 to 0.6 m/s is recommended in many standards as below. *ANSI/AIHA Z9.5-1992 Section 5.7* "Each hood shall maintain average face velocity of 80 to 120 fpm (0.41 to 0.61 m/s) with no face velocity measurement more than plus or minus 20% of average" *ACGIH, Industrial ventilation Manual, 6.15* "for low-activity radioactive laboratory work, a laboratory fume hood may be acceptable. For such hood, an average face velocity of 80 to 100 fpm is recommended"	A	Value changed to 0.4-0.6m/s		
Sweden	5.18/ 2nd line	The text: *…when the potential for contamination control is low…*	Is this what is meant (the possibility to control the contamination is limited?) or should this read: *…when the need for contamination control is low…* or *when the potential for contamination is low…*?		Yes (the possibility to control the contamination is limited)		
Sweden	5.20	Consider integrating the footnote into the text of the paragraph.	This information seems important enough to be part of the main text.			R	Foot notes gives additional explanation and are part of the guide. Key point here is to ensure face velocity required.
USA	5.21, line 1	Remove the first sentence "The exhaust air should be routed through an appropriate filtration system." Because this sentence is repeated at the end of the paragraph.	Eliminate redundancy	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	5.23	Glove boxes are constructed using mild steel, stainless steel, or aluminium coated on the interior surfaces with chemical-resistant epoxy paint, laminated safety glass panels for viewing work activities inside the box, and heavy neoprene gloves (glove port) that allow the operator to handle materials safely inside the glove box. Glove boxes should be equipped with adequate lighting. At appropriate intervals glove boxes should be maintained and checks made on their integrity (for leaks, damage etc).	Add maintenance and safety checks requirement [HSE]		A Glove boxes should be maintained periodically and checks made on their integrity (for leaks, damage etc).		
Sweden	5.25	This para does not really fit under the subtitle **Clean environment considerations**. Recommend a new subtitle: **Neutron activation**. Also consider giving references to relevant publications on the issue.	Apart from the text already given one could also refer to relevant reports/references (should be checked by some expert for usefulness, select some of them): [see list at the end of this document]		A Para moved. (See also Brazil comment). Varying information is available and would not like to be prescriptive on any individual reference here.		
Brazil	5.25 p.21	Remove the entire item to p.18 'shielding"	It does not make sense to talk about neutron generation in a 'clean' environment considerations topic	A			
Belgium	Page 21 §5.25 and page 23 §5.41	Add a sentence (or §) about the activation of the shielding self-shielded cyclotrons which could pose other problems during decommissioning			A In the moved para 5.17: Activation of the shielding material may pose additional risks while decommissioning the facility.		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Belgium	Page 22	Some additional considerations about ventilation could be given	special ventilation designs arrangements have to be taken in order to fulfil pharmaceutical regulation e.g.: under-pressure for personal safety reasons versus overpressure for product safety reasons.			R	No specific references provided on the pharmaceutical regulation.
UK	5.26	~~An~~ robust interlock that cannot easily be defeated should be installed at the access door to controlled areas such as cyclotron rooms and target rooms to protect the workers from ionizing radiation. Specialist advice on the suitability of interlocks should be sought.	More detail about the robustness/type of interlock system would be useful. [HSE]	A			
Sweden	5.27/1st line	Consider changing the text to read…*to the elevated radiation fields following an irradiation*,…		A			
UK	5.27		What is meant by "radiation field"? Is this the residual field due to activation? If so, is it the intent that the system only allows access after the field had fallen to some pre-set value after the beam has been turned off? The text reads as if a "search-and-lock-up" system is being described. We would agree with this, but it should be explicit. [PHE]	A (see comment from Sweden)			
USA	Page 22, Ventilation section	Recommend adding a paragraph: "Determine if air sampling is needed for radiological effluents."	Completeness			R	Already covered in different paragraphs in the section.
USA	5.33, line 4	For consistency throughout the safety guide, revise "radiation safety officer" to "RPO."	Consistency	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	5.33	For facilities within larger organizations (for example production sites within a hospital environment) systems/procedures should be put in place to ensure that no ~~technical~~ personnel can access the ventilation system or power distribution cabinet of the facility without prior information and consent of the facility management and the radiation safety officer. The operating organisation needs to enforce appropriate standard operating procedures (SOPs) for the maintenance of all shared and interfacing infrastructure.	Access restriction applies to all personnel. [HSE]	A			
UK	5.35	Redundancy of critical ~~ventilators~~ ventilation systems should be in place to:	'Ventilation systems' is a more commonly used term.	A			
Sweden	5.38/2nd line	Change to read: *steel/mild steel which is epoxy lined or galvanized:*	Should be galvanized?	A			
Sweden	5.39/last line	Consider adding *[See Section 10]* at the end of 5.39.	The last sentence is a reminder of monitoring the exhaust air. This is of course a possibility to detect problems in the facility but I guess mostly in order to fulfil the requirements of effluent discharge.	A			
Indonesia	5.40. page 23	In the site selection paragraph should also be considered concerning potential unsecure				R	Security aspects are given in Section 12.
Sweden	5.40	Consider adding: *The hazard analysis should also consider nearby chemical or other industrial installations, which could constitute potential external hazards*.	Not all external hazards are of non-anthropogenic nature. Chemical releases, fires etc. could perhaps be a problem.	A			
USA	5.41	"(i) Potentially radioactive liquid waste handling system with liquid waste decay tank and chemical waste from quality control (QC) operation or target processing (solid target dissolution);"	QC was not declared before.	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	5.41(i) / 2nd line	What does *chemical waste from QC operation* stand for?	*Quality Control Operation*? Radio-active chemical wastes?	A See USA comment			
Sweden	5.42, 2nd line	Suggest changing to: *This information should be provided in the form of a documented safety assessment report describing and evaluating the predicted response of the plant of the facility, including structures, systems and components but also software and procedures, to incidents (…) and external events of natural origin and human induced origin that could lead to accident conditions.*	Not only technical systems but also procedures, software etc. as described in GSR Part 3, requirement 13, para 3.32. The suggested text is perhaps too long but "*of the plant*" could be seen as being restricted to passive safety systems but we do want to cover human factors (interaction, procedures, software, safety culture etc.) as well when assessing the safety.			R	Current paragraph is sufficient to provide all those suggested items.
USA	5.42, line 6	Using the term "plant" has the connotation that it is a nuclear power plant. Recommend replacing "plant' with "organization" or "facility."	Reduce ambiguity	A			
UK	6.1, line 1	The general objective of a radiation protection programme is to discharge the ~~management's~~ dutyholder's responsibility for radiation protection and safety through the adoption of management structures, policies, procedures and organizational arrangements that are commensurate with the nature and extent of the radiation risks.	Management is not the correct term. *Dutyholder* or *employer* is more suitable. [HSE]			R	Overall responsibility lies with the management.
Sweden	6.1, 4th sentence	Change: "*The operating organization should always strive to minimize doses to workers and members of the public*" to read: "*The operating organisation should strive to keep exposures and the likelihood of exposures as low as reasonably achievable*".	In radiation protection we do not talk about minimising radiation doses.		A		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	6.3 1st sentence and 6.4	In 6.3 it is written: "*…including in many cases measures to prevent or reduce potential exposures and to mitigate the consequences of accidents if they were to occur*". Could this be seen as contradictory to 6.4?	This could be seen to be contradicted in 6.4 where it is stated: "*The programme should be based on the operating organization's safety assessment and it should address planned exposure situations*. Should 6.4 be rephrased a bit? …"*The RP programme should mainly address planned exposure situations*"?			R	This is on application of optimization principle.
UK	6.4	The programme should be based on the operating organisation's safety assessment, and it should address planned exposure situations as well as reasonably foreseeable radiation accidents.	Consideration of accidents is also necessary. [HSE]	A			
UK	6.7, line 1	The radiation protection programme should include a description of the management structure as it relates to radiation safety. This structure, which may be presented in the form of an organizational chart, should show the names of the senior managers responsible for radiation safety and of the various ~~duty holders~~ responsible employees (e.g. the RPO).	Corrects terminology. Duty holder relates to the employer who has overall responsibility. Employees however may have delegated responsibilities. [HSE]	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	6.10	Greater emphasis should be provided to develop procedures for target change-outs, maintenance and repairs. Recommend that this section address the need for a pre-survey, development of radiation work permit that would include requirements for additional surveys, dosimetry, PPE, dosimetry, and a maximum stay time while working with the targets based on radiation levels that is countersigned by the Radiation Protection Officer and the workers.	Completeness	A Para 6.10 modified.			
UK	6.12, line 1	In larger organizations, it ~~might be appropriate to have several sets of specific local rules.~~ would normally be appropriate for each area or use of radiation to have its own specific local rules, rather than one document for the whole organisation. ~~A f~~Facility specific procedures should be established.	Clarification [HSE]		A In larger organizations, it might be appropriate to have several sets of site specific local rules depending upon the nature, magnitude and likelihood of exposures. A facility specific procedure should also be established.		
UK	6.13	~~A short version of the local rules should be approved for visitors to review and understand.~~ Visitors should be provided with safety information that is tailored to the purpose of their visit. If visitors are to be escorted at all times, a short briefing on arrival may be sufficient.	The information provided to a visitor should depend on what the visitor is intending to do at the facility. If visitors are to be escorted at all times, it may be suitable to give them a briefing on arrival. If they are expected to carry out work, it would be more suitable to get them to work under existing local arrangements, or hand over to their employer so that they are working under their own local rules. [HSE]	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	6.14	Visiting workers should be made aware and trained in relevant sections of the local rules, or alternatively, responsibility for a controlled area should be handed over to the visiting worker's organisation which will have its own local rules. In this case, the transfer of the controlled area should be formalised.	It would be normal to expect contractors taking over responsibility of a controlled area to have their own local rules and risk assessment and transfer of area should be formalised. [HSE]		A Itinerant workers should be made aware and trained in relevant sections of the local rules. Detailed guidance on itinerant workers is provided in the safety guide Ref.[18]		
UK	6.16	Operating organizations should ensure that female employees who enter controlled or supervised areas are provided with information regarding the risks to an embryo or foetus from exposure to radiation and the importance of notifying their employer as soon as pregnancy is suspected. Following declaration of pregnancy restricted radiation doses will apply. Breast feeding mothers will need to be considered by the dutyholder for potential contamination / ingestion / inhalation risks if working with unsealed radioactive materials.	Expand details about restricted doses and breast feeding mothers [HSE]		A Following declaration of pregnancy restricted radiation doses will apply. Considerations on potential internal contamination should be given for breast feeding female workers if working with unsealed radioactive materials (see also section 6 of Ref.[18]).		
UK	6.18, 6.19, 6.20 and 6.21	Add "Normally the..." to the start of each paragraph.	This section is very prescriptive. Consider adding "Normally the ..." at the start of each paragraph. Requirements should be based upon a safety assessment as described in paragraph 6.17. [HSE]	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Belgium	Page 28 § 6.21	Replace supervised are by controlled area	In case of the failure of a target (windows foil rupture) the risks associated with the removal of the radioactive products (through vacuum system into the bunker, ...) are not negligible.		A Normally in the accelerator room there should be low probability of contamination and radiation, however, considering the risks associated with the failure of a target the accelerator room can be operated as a controlled area		
Indonesia	6.22. page 28	Reviews and audits of the performance of the radiation protection programme can be reported in the form of a safety verification report periodically	Potential hazard and unsecure issues should not be separated		A Already mentioned in the next para (6.23)		
USA	6.24	Recommend adding to the end of the paragraph: "Good medical practices (GMP) shall always be executed when preparing pharmaceutical materials for human or animal use."	Completeness			R	Out of scope to explain more on medical practices
Sweden	6.27, 4th sentence	It is not so easy to understand what is meant by: "No special medical/health surveillance programme is necessary relating to routine work at an isotope production facility." Perhaps the sentence is not needed? Para 6.27 already states the requirements for health surveillance programme (as appropriate and consistent with regulatory requirements)	GSR Part 3, paras 3.108 and 3.109 does not refer to special health surveillance programmes but merely to special arrangements for workers' health surveillance.	A			

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Indonesia	Pg 29, 6.28	A radiation safety committee should be established for the purpose of regularly reviewing the performance of the radiation protection programme A radiation safety committee should be established for the purpose of regularly reviewing the performance of the radiation protection programme and emergency preparedness and response	The scope of the safety committee is not limited to radiation protection programme but also emergency preparedness and response.		A Added (f) Reviews of the emergency preparedness and response plan		
Sweden	7.1, First sentence	The sentence: "*Persons performing work in controlled areas within an isotope production facility are responsible for ensuring that their work is carried out safely and in compliance with all relevant regulations and safety standards*" is in general not correct (exceptionally the worker could be self-employed). An alternative sentence could be: "*Persons performing work in controlled areas within an isotope production facility should be able to fulfil their obligations and carry out their duties for protection and safety*. [3]"	This statement is not reflected in GSR Part 3. The responsibility described in the sentence rests with the person or organisation that is responsible for the facility (GSR Part 1, req. 4) and cannot be delegated to the workers. This does of course not mean that education is not needed. Workers are not among the principal parties responsible for safety. Worker responsibilities are given in requirement 22 and can be summarised as: …fulfil their obligations and carry out their duties for protection and safety (follow rules, procedures, use monitoring equipment, cooperate with principal parties, abstain from wilful actions, accept information, instructions etc.)			R	Workers too are responsible to carry out their work safely and in accordance with local rules and procedures. The para is ensuring training of the workers.

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	7.1	Persons performing work in controlled areas within an isotope production facility are responsible for ensuring that their work is carried out safely and in compliance with all relevant regulations and safety standards. Operating organizations should, therefore, ensure that radiation work is carried out only by workers who are trained, and who are competent and trained in radiation protection and safety. Trainees shall work under direct supervision of a suitably trained person.	Consider trainees in this opening paragraph. [HSE]	A			
UK	7.3	Designated emergency workers should be qualified and trained…	Make clear that 'emergency workers' refers to designated staff at the facility (as referred to in 16.17), and not off-site emergency services personnel. [LB]	A			
USA	7.7, line 2	For completeness in describing the training program, recommend the following change in the first sentence "…knowledge for operating the facility and accelerator."	Completeness	A			
Indonesia	Pg 31, 7.8	Addition of "Waste operator" on the worker group	There have been plenty of explanation of radioactive waste management in the 13th chapter. However, the operator from those activities has not been explained before.	A	Added the item - Operators handling radioactive waste		

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	7.10	Modify paragraph 7.10 to read: 7.10. Each training course should be structured around specific aims and objectives and should be customized to the needs of the target audience. ~~Fundamental concepts and measurements include:~~ The training may include the following topics: **Fundamental concepts ~~and measurements include~~** - Basic ionizing radiation concepts; - **....**	Editorial, and consistency in presentation of the training topics.	A			
Sweden	Header before Para 7.10		The word *the training course* is introduced in the header. Is this the same as *a training programme* used in the earlier paragraphs? This could be confusing. Para 7.10 goes on to talk about *each training course.*	A editorial	RPP • Training programme • Targeted training courses		
Sweden	7.10	6th bullet: *Regulatory requirements.* Suggest changing to Overall Regulatory Requirements or something similar	Some of the further bullets: Designation of controlled and supervised areas, Dose limits, dose constraints etc. are also	editorial			
Sweden	7.10 under the Header **Practical Radiation Protection**	Change h and i to capital letters (H,I): **Handling of RM...** **I**mplementation of emergency...	Typo	A			
Sweden	7.10 Under the header **Research Scientists**	"*Specific training on radiation protection without standard working procedures*"	Does this mean that research scientists are not involved in carrying out standard procedures – is this always so?		A Specific training on radiation protection and working procedures tailored to their nature of work		

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	7.10 **Waste operators**		Is it enough to mention instructions for radioactive waste? What about management procedures and task related, practical issues? Storage of radioactive materials and some of the items mentioned for the shipping clerks might be important for waste operators?		A Waste management procedures; Task related practical information; Storage and shipment of radioactive material; Local rules and procedures		
Sweden	7.15, 1st sentence	It reads…*given at intervals less than two years but not exceeding five years*?	Probably meant to read between two and maximum five years?	editorial			
Belgium	Page 34 (Individual monitoring) or page 39 (workplace monitoring)	Consideration should be given also to hand-foot monitors that are often find at the exit of the controlled area			A Para 9.10 modified: Depending up on the potential for personal contamination, appropriate hand and foot monitors may be installed at the exit of the controlled areas.		
Sweden	8.1, 1st sentence	Change to: *Production of radioisotopes increases the potential for direct exposure to ionizing, radiation, and indirectly, via exposure to radioactive substances and aerosols.*	Since contamination and inhalation also gives rise to exposure to ionizing radiation it is a bit unclear what is meant – the suggested wording is only a proposal	editorial			
Sweden	8.2	Suggest adding a qualifier *as appropriate* or something like that for *internal radiation dose*	The sentence, as it stands would indicate that all workers are subject to monitoring of internal radiation dose? This does not seem to be the case when we continue in the text. In that case, also the visitors (para 8.5) should be monitored for intakes.	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	8.6 last sentence	It is stated that the personal exposure and dosimetry records should be *permanently maintained in retrievable form*.	Unsure of the language here – they should be kept and GSR Part 3, para 3.104 gives some limits for how long they shall be maintained (75 years age of worker, 30 years after cessation of work). Nothing wrong to keep them longer but who has then the responsibility for that?		A Personal exposure and dosimetry records should be maintained in retrievable forms as specified in paragraph 3.104 of the GSR Part 3		
Sweden	8.8 1st sentence	It is stated that individual monitoring…*demonstrates the current level of the occupational radiation safety at a radioisotope production facility*. Suggests deleting or rephrasing in a more neutral way, perhaps: "*gives input to optimisation process and the assessment of exposures in the radioisotope production facility*"	This is a problematic statement which needs explanation. If the source term is high even good radiation safety could lead to higher individual doses compared to facilities with a lower source term (which might have worse radiation safety!). Merely the radiation doses cannot say whether the radiation protection is good or bad.	A			
USA	8.10, line 4	Since neutrons are addressed in paragraph 5.25 and the annex, recommend the following revision: Guidance on determining the type of radiation field (e.g., photon, beta, neutron or other high energy particles) present in the environs, establishing monitoring programmes…"	Completeness	A			
Indonesia	Pg 35, 8.12	Hot cell operator, RPOs, pharmacists, decontamination worker, laboratory technicians, researcher and maintanance staff who routinely enter….	The inclusion of "researcher" as the worker classification in 7.8	A			
Sweden	8.12 1st sentence	It is written at the end…*should be subject to individual dose monitoring*.	This is correct but also 8.11 is about individual dose monitoring (paras 8.11 and 8.12 has to be harmonised otherwise is it difficult to understand.)	editorial			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	8.14	~~Finger rings~~ Appropriate extremity personal dosemeters should be worn for situations requiring the monitoring of exposure to the hands.	So as to not restrict to only ring type dosemeters, e.g. finger stalls [HSE]	A			
UK	8.15	Appropriate eye dosemeters should be worn ~~on forehead~~ for situations requiring the monitoring of the eye doses. ~~In some cases, it might not be possible to wear eye dosimeters on the forehead.~~	Allows for future developments in this area of personal dosimetry. May be a forehead based dosemeter or other systems may be attached directly to the inside of spectacles.	A			
Sweden	8.15 2nd sentence	*"In some cases it might not be possible to wear eye dosimeters on the forehead [30]"*	Further information is needed about what then should be done. (Other measurements, calculations etc.) If this is explained in [30], statet this explicitly *Further advice on these situations are given in reference [30]?*	A See UK comment			
Sweden	8.16		Since beta dosimetry will not work if dosimeters are put under lab coat, aprons etc. this could be an issue. Should something be said about this?		A Modified with the addition However, in the case of beta exposures, dosimeters should be positioned appropriately to avoid shielding by protective clothing.		
UK	8.16	should ~~wear the dosimeters under the lab coat, apron, or overalls~~ position dosimeters under any protective clothing worn	for clarity [PHE]	A			
USA	8.16, line 1	Recommend revising as follows: "…wear the dosimeter under ~~the~~ personal protective equipment (e.g., lab coat, apron or overalls) in order to…"	Improve applicability	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	8.17, line 1	Remove "(evaluated or read)." This language was added in response to a previous comment. It was not Member State's intent to include this language, but rather for the technical officer to select the operative term.	Editorial		A Changed to read		
Sweden	8.17	Insert *the* in front of *technical specification*	Missing article	editorial			
Sweden	8.19		I would think the consultation should be with a qualified expert or RPA, not necessarily merely the RPO – this would of course depend on their individual qualification	Enough flexibility available in the para			
Sweden	8.20	See comment for para 8.6	There are also requirements in GSR Part 3, para 3.104 which would be worth mentioning	A			
USA	8.22, line 5	The last sentence should be more inclusive of the types of x-ray machines. Recommend revising as follows: "Dosimeters should not be put through scanners that utilize x rays (e.g., mail inspection systems, airport security scanners).	Completeness		A Normally dosimeters should not be put through scanners that utilize X rays (eg. Mail inspection systems, airport security scanners etc.). In exceptional circumstances, adequate control cards may be used to evaluate the actual exposure of the dosimeters		
Sweden	8.28	Perhaps some references should be added.	If private products should be avoided, ICRP and IAEA references could be given.		A Ref.[18] added.		

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	8.29, 8.30		Para 8.29 refers to DAC <1/10 for 131I. Para 8.30 talks about DAC > 1/10 for the "*applicable isotope*". The reason for not using the same phrase in 8.29 is not clear?		A Under normal conditions the contamination level in the air, in general should not exceed1/10 DAC (derived air concentrations) of the isotope ^{131}I. Guidance on DAC values and criteria for internal monitoring are available in the…		
Sweden	8.31 1st sentence	Suggest "*been exposed to high-level radiation fields or elevated levels of airborne contamination*" At least the first time, qualifiers should be used.	Exposed to a "*high-level radiation*" seems a bit informal. Contamination is only defined as presence of radioactive substances and gives no indication of the magnitude of the hazard involved (Def. in GSR Part 3)		A The operating organization should instruct workers to notify the RPO immediately if they know or suspect that they have been exposed to high level radiation fields (above the dose constraints or abnormal) or elevated airborne contamination		
UK	8.31	The operating organization should instruct workers to notify a RPO immediately if they know or suspect that they have been exposed to **high level** radiation or airborne contamination. If the individual(s) concerned was wearing a personal dosimeter, it should be sent immediately to the dosimetry laboratory and the laboratory should be informed of the urgency of the case. In the case of exposure to airborne contamination, the person should be monitored for the appropriate isotope.	'High level' needs definition [HSE]		A See comments resolution of Sweden		

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Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	9.3	*"Production facilities have some specific requirements regarding work place monitoring on fixed and portable radiation dose rate meters, contamination control and air sampling"*	Are there extra requirements in GSR Part 3 as compared to the ones for example nuclear power plants or fuel factories? Which are these "extra" requirements (reference)? Or are we here using the word requirements in its general sense?		A Detailed guidance regarding workplace monitoring including the use of fixed and portable radiation dose rate meters, contamination control and air sampling are provided in Ref.[18].		
USA	9.5, line 2	Recommend revising as follows: "...type of radiation being emitted (e.g., photon, beta or neutron).	Completeness	A			
Brazil	p.40	Describe some useful portable neutron detectors	In the document there is no information concerning neutron detectors		A In the case of neutron surveys, portable BF_3 or ^3He detection counters may be used		
USA	9.6, item b	Using the term "plant" has the connotation that it is a nuclear power plant. Recommend removing "plant' from the sentence.	Reduce ambiguity	A			
Sweden	9.6 (a)	*...with a probe inside the enclosure interlocked to the door control*;	If the meaning of this is that *if the reading (dose rate level) is too high it is not possible to open the door* this should be more clearly written.		A editorial		
USA	9.8, third bullet	In the bullet on proportional detectors; add a sentence that portable He-3 or BF3 detectors may be used for neutron surveys.	Improve applicability	A			
Sweden	9.8, first bullet, inside the parenthesis	Suggest changing to: *"using chambers that have an inside desiccants inside, a hygroscopic substance that induces or sustains dryness, are is important considerations as humidity fluctuations may render the chamber inoperable"*	The rewording could improve the understanding for non-experts		A Para 9.8 edited. See UK comment		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	9.8		This paragraph is very long and appears to introduce a change in style /approach within the document. The language is rather vague in places, for example *"higher dose rates", "big dose-rates"* (both under bullet point 4 referring to GM probes)– what is meant by this? Such phrases dilute the usefulness of the guidance to the reader. Suggest that much of the technical information is moved to an annex. [PHE]		A Para 9.8 edited. These are some practical information that could be useful in facilities and hence prefer to be as part of the main text.		
Sweden	9.11 2nd sentence	Since this is identical to the first sentence of 9.9 it could be changed to: *Contamination surveys are often performed by swiping or other indirect means when the radiation background levels are varying or elevated.*	Change sentence or delete since the same sentence as the first sentence of 9.9.	A			
Sweden	9.11 3rd sentence	Change to *Routine contamination frequencies and criteria for acceptable surface activity levels (Bq/cm2) should be defined in the radiation protection programme.*	Original formulation is less clear and surface	A			
Sweden	9.11 5th sentence	Note sure of the meaning: *…to consider when stabling these values are swipe efficiency…?* Perhaps one could write: *Factors to consider when establishing such values are swipe efficiency….*	Not sure what the word *stabling* means in this context.		A Factors to consider during such instances are swipe efficiency, detection efficiency of the contamination meter for the radioisotope, geometry of the detector surface/swipe area, and counting time.		
USA	9.11, lines 7-10	The intent of the last sentence in this paragraph is ambiguous. Recommend revision to improve readability	Reduce ambiguity		A See resolution for Sweden comment		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	9.11 (lines 8 to 10)		Meaning of "stabling" and "s wipe to detector distance it will be used " both need clarification. [PHE]		A See resolution for Sweden comment		
Sweden	9.13 2nd sentence	This sentence is overlapping with the last sentence of 9.9. The prime responsibility should be with the operator/licensee while abiding to regulatory requirements. Perhaps the existing sentences could be reformulated in that way.	The formulation: *…but the practice should be commensurate with the risks at the production facility*…does not seem to be connected to whether the authority or the operator is defining the minimal frequencies for checks – or is there an implicit meaning here?		A Minimal frequencies for routine floor and surface checks may be determined in the radiation protection programme and may vary from weekly….		
Sweden	9.13 last sentence	Something is wrong with the ending of this sentence:…*direct checking the mop for contamination ea.*	What is the meaning of ea? Perhaps a typo?	A			
Sweden	9.14	Suggest changing to: *As needed, contamination surveys should be performed when:* *a) items enter or exit cells, glove-boxes and fume hoods;* *b) the potential to perform intervention work is evaluated in areas which may have non-fixed contamination (cyclotron bunkers and caves, cell, etc.); and* *c) packages are being prepared for shipment.*	The original sentence is not totally understandable and there seem to be unnecessary commas and words	A			
Sweden	9.15	The formulation: *…by performing a grab sample on a filter then removing the filter media for measurement at another location* needs reformulation.	Not understood.		A editorial		
Sweden	9.18 (9.18-9.20)	Suggest splitting the paragraph in two parts – two long.	Language -increased readability. Should 9.18-9.20 rather be bullets to 9.17 than have their own numbering?	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	9.19	Change to…*in locations of high risks for intakes of radioactive substances (…) and have the alarm registered? at a secondary location.*	For clarity. Unclear whteher it is the alarm that should be registered at a secondary location or if "the alarm register" should be positioned at a secondary location?		A Place alarming CAMs in locations of high risk for intakes of radioactive substances (radioiodine processing areas, waste, cyclotron/linear accelerator bunker and caves) and have the alarm register at appropriate access location		
Japan	9.22/ L3	Tests should be carried out by an organization that maintains reference radiation fields traceable to ~~a~~ national primary (metrology) standards ~~body~~.	"Traceable to the body" is not correct expression in the metrology field.		A …traceable to national/international primary standards.		
Indonesia	Page 45, section 10.2, line 2	Soil and groundwater samples maybe contain several amount of radioactivity from radioisotope produced by accelerator, e.g……	The selection of radioisotope 137Cs for environment monitoring object regarding the nuclear weapon test is not relevant since the focus of this document is radioisotope produced by the accelerator	A	Para 10.1, 10.2 and 10.3 modified.		
Indonesia	After point 10.2. page 45	Title "EFFLUENT DISCHARGE" should move to the next page		A editorial			
Sweden	10.16 1st and last sentence	Should the first sentence start with *Liquid effluents…* rather than *Liquid effluent…?* Last sentence: *If an aliquot is to be taken of the sample…then the sample also should be agitated to ensure adequate mixing before the aliquot is taken.* Perhaps this could be changed to: *If a sub-sample is to be taken from the representative sample (for example for liquid scintillation counting), the sample also should be agitated to ensure adequate mixing.*	Seems more appropriate with pluralis? - language Aliquot is a difficult word from the latin and is sometimes used in the sense (defined as): "*a sample or portion of a total amount of liquid*". It would then seems that we are taking a sample of the sample. Perhaps sub-sample could be used?	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	10.18 2nd and 3rd sentence	Should it be *Coolants* (plural) rather than coolant? The reference to the IAEA publication is already made in para 10.5. What is meant by: *...including its minimization options.* Rephrase!	The plural form seems more logical? Perhaps the words *in the IAEA publication* is not needed since already mentioned before but only the reference itself [33]. The last part is difficult since that would refer to: *The control of radioactive discharges* which should perhaps not be minimised...		A Deleted ..including its minimization options.		
Sweden	10.20 2nd part	Is it the cooling circuits which are referred to in the second sentence: *Therefore, they should be disposed of only after check of activity.*	Since this is under the header effluent discharges it is difficult to see why we are discussing solid wastes? Or are we referring to that radioactive substances (from activated surfaces or from leakages) can leak into the coolant (coolants)?			R	This is on the leaching of activated surfaces and leakages
Sweden	10.22	Consider generalising the statements for protection and put this somewhere in a more general context.	This is about workers maintaining draining installations and their protection. On the other hand, workers maintaining the delay tanks mentioned in para 10.16 could also need instructions and proper protection.	editorial			
Sweden	10.23	Move para 10.23 to after the header AIR EMISSIONS.	This paragraph should probably be after the header than before since it is about airstreams etc.	A			
Sweden	10.28	In order to be readable, divide it in 2-3 sentences.	The sentence is too long and the information content should be better structured - language	A editorial			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Brazil	p.49, item 10.28	Include the IAEA publication Safety Report Series 19 as a reference to this topic	Concerning this crucial topic of radioisotope production facilities, references should be provided for the readers, for the case where some additional details are needed.	A			
Sweden	10.32	Some of the bullets, e.g. iv,v are repeating the messages 10.31 and 10.32	In general the sections on effluent monitoring and minimising effluent discharges needs a second look on the logic and avoiding repetitions.	A			
Belgium	Page 50 §10.34 ii	, ii, [11C]CO2, [13N]NH3 and [18F]F2 can be removed from air streams with chemical trap. [13N]N2 is missing and cannot be removed from air streams			A Some PET cyclotron products (example $^{13}N_2$) cannot be removed from air stream. Some of the other products such as [^{11}C]-CH_4/CO_2, [^{18}F]-FCH_3 or F_2, [^{13}N]-NH_3 can be removed from air stream with suitable chemical trap		
USA	10.36	Paragraph 10.36 is difficult to follow. Recommend revising to: "The most efficient way ~~is~~ to control the release of contaminants ~~are~~ is to contain and trap the contaminants at the source itself using gas bags or traps (liquid nitrogen or cartridges)~~.~~ ~~Another possibility could be~~ or tank storage for decay (in case of the PET gases)."	Editorial and improve readability	A			
Sweden	11.2 (d)	Another reason for safety glasses is potential protection against beta radiation.		A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	11.2 d	Safety glasses or face shields for splash protection involving radiological liquids. Where an external radiation hazard is present the eyewear shall incorporate appropriate shielding material e.g. leaded glass.	Consider protection of the eye lens from external radiation hazard. [HSE]		A Safety glasses or face shields for splash protection involving radiological liquids/potential protection against beta radiation or leaded glasses for external radiation hazards		
UK	11.3 b		This paragraph refers to the use of lead aprons in emergency operations for handling situations with "high radiation". The wearing of a lead apron and its efficacy will depend on the radionuclide; for example, it may be prudent for I-125 but would not be not relevant for F-18. Does "high radiation" refer to high dose rates or to significant activity? This sentence requires clarification. [PHE]		A Changed to...high dose rates		
Sweden	11.5	Move this para before 11.2-11.4	It seems that this statement should be put already before 11.2			R	Current placement seems to be better.
Sweden	11.6	*To be covered for the medical examinations are for example allergies, impaired lung function, claustrophobia and hypertension that would limit or hinder the use of some of the PPE.*	Allergy and impaired /reduced lung function are other conditions that also could be important.	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
UK	11.6	The safety assessment should provide information for the job specification for each area and process. An employment medical examination which is carried out for health surveillance purposes, should be used to determine ~~and during the **medical examination** it must be determined~~ if a person is medically fit to use the prescribed PPE for the job. Some of the aspects to be covered for **medical examinations** are the possibility of claustrophobia and hypertension, for example, that would limit the use of some of the PPE.	Clarify the term 'medical examination' which means an employment medical examination for health surveillance purposes and not for a medical treatment. [HSE]	A			
UK	11.7	Contaminated re-usable PPE like expensive apparels and washed overalls, should be decayed, and if necessary, decontaminated in a decontamination room. Highly contaminated PPE should be left to decay before sending for washing. In cases where long-lived radionuclides are present, the RPO should decide if it can be considered as radioactive waste. Advice should be sought from qualified experts/radiation protection advisers (RPAs). on this matter.	Add RPA consultation. [HSE]			R	RPO is a competent person to decide if a PPE is contaminated or not usable/disposed off.

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	12.5, lines 3-6	It is not recommended that measures in the GSR Part 3 be the only measures used to secure Category 1 sources. It is recommended to use the use the measures in NSS 11. Recommend the following changes: "For Category ~~1~~4-5 sources, for example, it is recommended that measures described in GSR Part 3 [3] are used. However, the element of intent involved in unauthorized access means that additional considerations apply for higher activity sources (Category 1 – 3), and additional and/or different security measures may be needed to protect against unauthorized access."	Technical accuracy	A			
USA	Section 13, Pages 53 and 55	In order to address recordkeeping for the control and inventory of radioisotopes produced and their distribution, recommend the subsection on "RECORDS" be expanded to include radioisotope inventory recordkeeping, storage, and records of radioisotope transfer. Further recommend that Section 13 title be modified to *"Testing and Maintenance of Equipment and Records."*	Completeness	A			
Brazil	Item 13, p.53	All the tests presented in this item should also be presented in item 5.	Matter of consistency			R	Not clear
UK	13.1	Particular attention should be paid to regular testing of components of the safety interlock system for correct operation, in accordance with the instructions of the equipment manufacturer. These tests should be carried out by appropriately qualified persons ~~in the presence of a RPO~~.	This seems particularly onerous to have every interlock safety check carried out in the presence of the RPO. If the person doing the check is appropriately qualified then it is not required. [HSE]		A Modified as:...with adequate information to the RPO		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	13.4	Define or explain the term "*radiation room*"	In this context "*radiation room*" is used (also further on, for example in 13.10) which might not be a standard term known to all readers – consider explaining!		A "Radiation room" changed to "facility"		
Sweden	13.4 (c)	*"It is good to practice a UPS on the cyclotron control system as power 'dips' can affect the operation of control units."*	The meaning is not clear? Should this read: *"It is good practice to use an UPS as backup power supply for the cyclotron control system as power 'dips' can affect the operation of control units"?*	A			
Indonesia		*Need to include "Registrants, licensees, report and record shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel dose records, records of calibration, radiation and contamination surveys, emergency preparedness and response, etc"*	Remarks on the Pg 55, record, 13.6 – 13.7 need to be elaborated. Other significant remarks and data should be written as well.		A Para 13.8 added. See USA comment		
Sweden	13.10	Should the word either be left out: *…independent verification should be obtained either that the accelerator is not on (e.g. ion source is not on).*	language	A			
Sweden	13.12	Change *…should be designed to obviate the necessity make it unnecessary to for bypassing safety interlocks.*	Obviate the abstruse! language	A			
Sweden	14.1	Change…*and to meet the acceptance criteria…*	language	A			
Sweden	14.2	Change to *…the highest concentration of radioactive substances is generated…* Change to *unsold product* to *unsold products* (pluralis).	language		A …highest activity concentration…		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Germany	14.2	"The waste with the highest activity concentration is generated from activated materials within the cyclotron, targets, synthesis processes and quality control testing. Archive samples and unsold product are other examples of waste."	Clarification	A			
Indonesia	Page 59	Paragraph that explain "OTHER HANDLING GUIDELINES" should be follow with numberings instead bullets			A Started with a para number		
Sweden	14.3 (14.4)	Suggest changing the first sentence to read: *Application of waste management protocols, clearance of materials after processing, storage for decay, reuse and recycling…*	Language (except for the qualifier "for decay" in connection with storage if this is what is meant)? (Furthermore, in para 14.4 clearance of material is not mentioned?)	A			
USA	14.5	Recommend addressing the availability of decommissioning funds by adding that the decommissioning plan include an estimation of cost, and provision of financial resources and assurances to cover the costs associated with decommissioning. The availability/adequacy of such funds should be reviewed periodically.	Completeness	A			
Korea	14.8	The production facility is responsible for developing following the waste acceptance criteria for approval by the regulatory body.	In Korea, the waste acceptance criteria is developed by the disposal facility operator, not the waste producer.		A The production facility (in consultation with waste disposal facilities) is responsible….		

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	Page 57, Para 14.8	Waste generation at radioisotope production facilities should be addressed as related to waste management, transport, and disposition. After paragraph 14.7, recommend adding the following (or similar) text: "Operators should provide a list of anticipated waste streams and sources to be generated at the facility including waste forms (e.g.; solid, liquid, and/or gaseous); estimate of waste volumes, waste categories and plans for waste storage, disposition and/or disposal."	Completeness	A			
Sweden	14.9	Change…*the material in their possession contains radioactivity below the clearance level…* to read: …*the amount or concentration of radioactive substances in the material in their possession are below the clearance level…*	Radioactivity is the phenomenon: *the emission of ionizing radiation or particles caused by the spontaneous disintegration of atomic nuclei…*and as far as I know it cannot be above or below levels.		A …demonstrate that the quantity or concentration of radioactive substances in the material…		
Korea	14.11	Waste should be first segregated into two categories: waste that is known or is suspected of being radioactive, and waste that is believed to be non-radioactive under the clearance levels. The latter category should be verified to meet the clearance criteria.	Before a regulatory approval on a clearance, a waste producer should manage all wastes as a radioactive waste. In this regard, the use of the term "non-radioactive" is not desirable because it could mislead a waste producer.		A Non-radioactive under the clearance level..		
Sweden	14.12	…*or pH adjusted of liquids to render them safe.*	Should this read: …*pH adjustment of liquids to render them safe*?		A See Germany comment		
USA	14.13	Recommend adding at the end of paragraph 14.13 the following sentence to address handling of liquid waste in an appropriate manner: "Liquid waste should be safely stored in proper storage tanks, contained, and subsequently consolidated for ultimate disposal."	Completeness	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Germany	14.12	"Liquids can require chemical adjustment (e.g. pH important for radioiodines must remain alkaline) and immobilization prior to transport."	Wording/ Clarification		A …liquids that may require chemical treatment (e.g.; pH important for radioiodine and must remain alkaline) for safe storage, transport or disposal.		
Belgium	Page 59, 4th bullet of "OTHER HANDLING GUIDELINES	Remove (preferably metal)	There seems to be no specific reason why it should be metal	A			
Sweden	The last bullet under the Header OTHER HANDLING GUIDELINES (14.15?)	It is written: *The area where target reconditioning is performed needs to shield the operators body and extremities.* The meaning of this is not clear.	The area could not shield anything. Some explanation is needed.		A The area where target reconditioning is performed needs to be shielded to protect the operator's whole body and extremities.		
USA	Section 14	Add a new paragraph (14.22) addressing that a regulatory permit or authorization to receive the radioactive waste is required for facilities where the radioactive waste will be disposed.	Completeness		A Authorization or a regulatory permit to receive the radioactive waste should be required for facilities where the radioactive waste will be stored/disposed.		
Sweden	14.16	Perhaps "airborne radioactive substances" or acceptable but not good "airborne activity" could be used.	Radioactivity cannot be volatile (see comment 80 above)	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
Sweden	14.17	*An alarming continuous air monitor and respiratory protection may also be used to optimize safety in this room.*	This sentence needs more work. GSR Part 3 use optimization of protection and safety. The use of respiratory protection might be a more accurate expression. However, how is the use of the monitor and the respiratory protection optimising radiation protection?		A …control internal exposures in this room. Deleted optimize safety		
Sweden	14.18	Is it the *waste storage* or the *waste storage location* that should be planned and designed – seems a bit of both? Is it *the risk of incurring potential radiation doses* or *the potential radiation doses* that should be minimised?		A editorial			
Sweden	14.20	It is perhaps not the water quality that should be monitored but rather, in this context, the content of radioactive substances?			A Water quality including activity concentration….		
Sweden	15.7, 4th line	*Signed by* should be changed to *signed by* (no capital S)	typo	A			
Germany	16.1	"…necessitates prompt action, primarily to avoid or to mitigate a hazard…"	It is possible during an emergency situation that consequences can be completely avoided by proper actions.	A			
UK	16.15	Additional bullet point: • Personnel monitoring equipment	Consider addition of personnel monitoring equipment to list of equipment to be considered for use in an emergency. [LB]	A			
Indonesia	Page 70, no.33	This document has been revised to DS 442, so in References the new one should be stated.	WS-G-2.3 has been revised as a new document. Therefore the attached document should be based on the revision of WE-G-2.3	A Editor to fix finally			
USA	Page 71, Annex I	Recommend adding a new item (as #4) as follows: "Ensure doors to high radiation areas have interlocks"	Completeness	A			

COMMENTS BY REVIEWER November 2017				RESOLUTION			
Country	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
USA	Page 71, Annex I	Recommend revising item 11 as follows: "Decommissioning plan and financial assurance"	Completeness	A			
USA	Page 71, Annex I	Recommend adding a new item (after item 16) as follows: "Verification of authorized recipients of transferred radioactive material"	Completeness	A			
UK	Annex II.II, heading	~~Gamma and neutrons~~	Why only address gamma and neutron hazards? The actions listed in paragraphs II.II and II.III appear to be relevant to emergencies involving all type of radiation hazard. Remove heading. [LB]	A			
UK	II.III (c)	Confirms ~~that~~ whether off-site protective actions are ~~not~~ needed;	The RPO should determine if off-site support is needed, as well as if it isn't. [LB]	A			
UK	Throughout document		Minor point: it is unusual to see the term "RPA" in publications – this term is only used in the UK. Suggest it is removed. [PHE]	editorial			
Brazil	Additional comment	In the topic "shielding" (p.18) there aren't any discussions about neutron generation and the consequent necessary shielding. This is a very important concern in a radioisotope production facility.			A New para added.		
Brazil		There is plenty of very important security systems that were not mentioned in the document.				R	Section 12 provides security considerations. No specific suggestions.

Para 5.25 (Sweden)

Apart from the text already given one could also refer to relevant reports/references (should be checked by some expert for usefulness, select some of them):

1) Silari M. *Special Radiation Protection Aspects of Medical Accelerators* Radiation Protection Dosimetry Vol. 96, No. 4, pp. 381–392 (2001) Nuclear Technology Publishing.

2) H.R. Vega-Carrillo, *Neutron energy spectra inside a PET cyclotron vault room*, Nucl. Instrum. Meth. A463(2001)375.

3) L.R. Carroll, *2001 Predicting long-lived, neutron-induced activation of concrete in a cyclotron vault,* AIP Conf. Proc. 576 301.

4) NCRP: *"Radiation Protection for Particle Accelerator Facilities,"* National Council on Radiation Protection and Measurements, Bethesda, MD 144, 2003/12/31/ 2003.
5) Mukherjee B, Sartori E. A *Radiological Safety and Health Physics Database for Cyclotrons Accelerating Protons and Deuterons.* Paris: Nuclear Energy Agency (NEA)/Organisation for Economic Co-operation and Development (OECD); NEA-1694 SATIF/CYCLO-RADSAFE; NEA-1694 SATIF/CYCLO-RADSAFE; 2004.
6) Facure, A. and França, W. F. *Optimal shielding design for bunkers of compact cyclotrons used in the production of medical radionuclides.* Med. Phys., (2010) 37: 6332–6337.
7) Fujibuchi, T. et al. *Comparison of neutron fluxes in ab 18-MeV unshielded cyclotron room and a 16.5-MeV self-shielded cyclotron room.* Radiol Phys Technol, (2012) 5:156-165.
8) Mukherjee B. *Radiation safety issues relevant to proton therapy and radioisotope production medical cyclotrons*. Radiat Prot Environ 2012;35:126-34.
9) Dodd, Adam C. et al. *Activation of air and concrete in medical isotope production facilities.* AIP Conference Proceedings 1845, 020006 (2017); doi: http://dx.doi.org/10.1063/1.4983537
10) D.G. Jang, J.M. Kim and J.H. Kim *Design of the shielding wall of a cyclotron room and the activation interpretation using the Monte Carlo simulation* Journal of Instrumentation, Vol. 12, January 2017
Perhaps there are more relevant IAEA-reports on the issue?