DS434（Radiation Safety of Radioisotope Production Facilities）

COMMENTS BY REVIEWER Reviewer: Page.... of.... Country/Organization: Japan / Nuclear Regulation Authority, Japan Date:				RESOLUTION			
Comment No.	Para/ Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification /rejection
1	General	Good practices should be separated from body text of this guide. It would be better to move them to an annex, for example.	This draft describes not only guide but also good practices for radiation safety, for example; Local rules and supervision and Designation of controlled areas or supervised areas in Chapter 6, and TRAINING PROGRAMME in Chapter 7. Good practices should be separated from body text of this guide. It would be better to move them to an annex, for example. In this regard, review of entire document should be needed.				
2	1.8/1	~~The design and operation of reactors is outside the scope of this document. Also,~~ ~~t~~The use of …	According to para. 1.7 reactors are clearly out of scope.				
3	1.11/1 (p.3)	Consideration of non-radiological ~~non-radiation related~~ risks	Clarification. Paras. 11.8, 14.1, 14.3 and 16.5 use “non-radiological.”				

4	1.13/6 (p.3)	The safety assessment duties and radiation protection programme are described in Sections 5 and 6 respectively.	Clarification.				
5	1.17/2 (p.3)	Examples of a safety assessment structure and emergency response procedures can be found in the Annexes I and II respectively.	Clarification.				
6	2.4/4 (p.4)	IAEA Safety Guide ~~Publication~~ RS-G-1.9 [10] establishes	Editorial.				
7	4.1 (p.7)	The person or organization responsible for facilities and activities that give rise to radiation risks must ~~shall~~ have the prime responsibility for protection and safety. Other parties must ~~shall~~ have specified responsibilities for protection and safety.	Safety Guides do not use “shall statement” unless safety requirements are cited.				
8	4.8/3 (p.8)	The management system should be based on national or international standards [~~3, 12,~~ 14, 15, ~~16,~~ 17].	National or international standards specific to the management system are ref. 14,15 and 17.				
9	4.22(b)/2	If the ~~daily~~ dose exceeded the ~~limit~~ level set by the local rules they should report it to the manager or PRO.	Dose control by a daily dose limit may be a good practice but not safety regulations by the authority. “Limit” is confusing, because “dose limit” is not set by the local rules in general.				

10	6.8/1	The radiation protection programme ~~should include the company policies on radiation safety, and~~ should include a commitment by the management …	Company policies are not requested by safety regulatory authority.				
11	8.12	Eye dosimeters should be worn on close to the eyes or the collar for situations requiring the monitoring of the eye doses.	Eye dosimeters might not be able to be worn on forehead in some cases.				
12	Section 14 (p.58-62)	Regarding decommissioning, this Section only refers to GSR Part 6. If possible, more description should be added to this Section taken into account DS403 "*Decommissioning of Medical, Industrial and Research Facilities*" under step 9.	Clarification.				
13	14.5/7 (p.59)	Reference document No.10 is not relevant to decommissioning.	Editorial?				
14	References (p.72)	INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, ISO 9001:2015~~2000~~ Quality management systems – Requirements, ISO (2015~~2000~~).	ISO 9001:2015 is the latest version.				

DS434 Draft Safety Guide: Radiation Safety of Radioisotope Production facilities

COMMENTS BY REVIEWER Reviewer: Vera Starosttova Page.... of.... Country/Organization: Czech Republic/SÚJB Date: 11. 10. 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	general	In the text are used terms “emergency, accident, incident”. While emergency is defined (art. 16.1, pg 64), accident and incidents are not defined. And it is not clear what exactly these two words mean, if they mean the same as emergency or not. If they mean the same, one term should be used. If they do not mean the same, they should be defined and whole the text should be controlled if they are used).	The text is not clear and can cause confusion and misunderstandings.				
2	16.5/1	The explanation No. 8 (emergency arrangements) should be used earlier – para 4.21, point (f))	Emergency arrangements are used in the text before article 16.5 and the earlier explanation would be helpful.				

Draft Safety Guide DS434 - Radiation Safety of Radioisotope Production Facilities
Status: STEP 7 – Submission to the review Committees

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of GRS) Page 1 of 6 Country/Organization: **Germany** Date: 2016-10-24							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	1.7.	(i) Low energy (<20 MeV/nucleon) cyclotrons for medical radioisotope production; (ii) 20 – 40 MeV/nucleon isotope production cyclotrons; (iii) > 40 MeV/nucleon cyclotrons for mixed research and radioisotope production;	The energy unit should be the same throughout the whole paragraph. Moreover, the total energy was probably not meant at all.				
2	2.1.	This may be taken as equivalent to the well-established principle of justification of practices, the operation of radioisotope production facilities being one example [9].	In order to cite/reference the principle of justification of practices, reference [9] should be used instead of [3].				
3	3.1.	see comment 1	see comment 1				
4	3.2.	~~The cyclotron~~ Accelerators for the production of radioisotopes ~~is~~ are generally located in the same building as where the ~~radiolabelled~~ radioisotope containing products are synthesized.	Using the term “accelerator” instead of “cyclotron” is more consistent with paragraphs 3.1. to 3.4. Moreover, 3.2. generally applies not only for cyclotrons. The term “radiolabelled” suggests that products are generally used as tracers				

			or labels, which is certainly not true.				
5	4.7.	For each incident, the question of acceptable behavior should be answered on a case by case basis and, ~~In investigating incidents, consideration may be given to what is acceptable behavior, however~~, in some cases, disciplinary measures may be taken.	It is difficult to understand the meaning/intention of the first half of the original statement. The proposed replacement might better reflect/express this intention.				
6	4.12.	(d) Facility in which particle accelerators and/or radioactive material will be processed and stored with particular attention paid to associated safety systems and equipment, e.g., radiation shielding, interlock systems, fume hoods, remote handling tools, effluent exhaust systems, monitoring systems, and warning systems;	Although a list of examples does not need to be comprehensive, the addition of monitoring systems, which are vital for any radioisotope production facility, might strengthen this bullet point.				
7	4.16.	(h) Ensuring that emergency plans and procedures are established and maintained and exercises are conducted as appropriate (see Section 16);	Explicitly mentioning emergency exercises is justified considering their importance for emergency preparedness and response in general.				
8	4.19.	(c) A knowledge of the emergency preparedness category of the facility in the context of the emergency preparedness and response (EPR) plans conforming to relevant requirements of the international standards [13];	The acronym EPR should be defined at first usage.				
9	4.22.	(b) Wear their individual dosimeters in the correct place at all times	Just referring to “the manager” might be too				

		during radiation work and record their daily doses. If the daily dose exceeded the limit they should report it to the responsible (senior) manager or RPO (see Section 6);	vague.				
10	5.4.	GSR Part 3 [3] states that the person or organization, or registrants and licensees, as appropriate, is required to conduct a safety assessment that, depending on the type of practice or source, is either generic or specific to the practice or source for which they are responsible.	The addition could emphasize that the choice between a generic or specific assessment should not be arbitrary.				
11	6.21.	In the ~~cyclotope~~ accelerator room there should be low probability of contamination and radiation and therefore can be operated as a supervised area.	Cyclotope is the name of a company.				
12	6.26.	The management system should include a mechanism for the collection and feedback of lessons learned from day to day operations, emergencies and incidents (including those reported both within the organization and in external reports), and how these lessons can be used to enhance safety.	Lessons learnt based on day to day operations are as valuable as those based on emergencies or incidents. Thus, a general feedback mechanism should be encouraged.				
13	7.7.	The operating organization should define necessary competences and knowledge for operating the facility. ~~be best placed to determine the competence and knowledge that is needed in its facility.~~	The original sentence is difficult to understand and slightly ambiguous.				
14	7.7.	In the case where an operating	Using the term “post-				

		organization does not have the capability or resources to establish a training programme, the workers should attend a training programme on radiation protection and safety provided by competent training providers, including ~~colleges, universities,~~ post-secondary education institutions, radiation protection institutions and training consultants.	secondary education institutions" includes colleges and universities, but also includes other institutions, e.g. in countries without colleges.				
15	9.8.	These detectors are useful for obtaining a reliable dose rate at 1 meter distance for transport measurements, however, because of their size, they are difficult to use to evaluate contact readings or small diameter beams.	Addition of the word "distance" enhances readability.				
16	9.8.	Geiger Mueller (GM) type detectors are available in a variety of sizes and configurations.	The abbreviation GM should be defined at first usage.				
17	9.13.	It is normal practice to assume that 10% of loose contamination is removed on a swipe.	No change to the text is proposed. But if a reference for this statement exists, it should be added.				
18	10.2.	Soil samples will always contain trace ~~natural~~ amounts of ~~radioactivity~~ radioactive isotopes, e.g. ^{137}Cs~~,~~ due to atmospheric weapons testing or the naturally occurring ^{40}K, therefore soil samples should be compared to background soil away from the discharge stack.	Speaking of trace natural amounts and giving the example of Cs-137 due to weapons testing is rather inconsistent. The sentence has been modified accordingly and another (natural) example is given.				

19	10.12.	Experimental evidence should sometimes be used to validate sampling systems. One such example is to release an approved activity of ~~C-11~~ ^{11}C labelled carbon dioxide (11CO2) to calibrate systems at PET facilities.	Consistent notations should be used.				
20	13.1.	~~b) Portable radiation survey meters should be calibrated before their first use, after repair and at intervals as specified in local regulatory requirements. The pre-use test should include a test of the instrument's overload performance; that is, it should be tested to operate correctly up to the maximum foreseeable dose rate.~~	This is a literal duplication of paragraph 9.23. and, thus, should be deleted.				
21	13.10.	If it becomes necessary to bypass or disable a safety interlock, independent verification should be obtained either that the ~~cyclotron~~ accelerator is not on (e.g. ion source is not on).	This statement is valid for every type of accelerator.				
22	16.6.	The applicability of various sections of GSR Part 7 to Emergency Preparedness Category III is listed in the Table in Annex A-1 to GSR Part 7 and these should be used during the preparation of EPR plans for the facility.	In order to avoid confusion, it should be explicitly stated that reference is made to Annex A-1 to GRS Part 7.				
23	Annex I	At the outset, the ~~cyclotron~~ accelerator building design should comply with radiation safety requirements on protection of workers and public. Some of the key	This statement is valid for every type of accelerator. The Annex heading should be modified accordingly.				

		requirements are listed below:					
24	Annex II	~~Gamma/neutrons~~	The cross heading should be removed or explained.				

Comments on IAEA Draft Safety Guide
***Radiation Safety of Radioisotope Production Facilities* (DS434)**

COMMENTS BY REVIEWER Reviewer: US Nuclear Regulatory Commission (contact: Cindy Flannery, cindy.flannery@nrc.gov) Country/Organization: United States of America/US NRC Date: 28 Oct 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	The safety guide, as indicated from the title "Radiation Safety of Radioisotope Production Facilities," implies covering all radioisotope production facilities (i.e., radionuclide production in reactors and particle accelerators). However, the scope of the Safety Guide (as provided in Scope (paragraphs 1.6-1.12) and Section 3) is clearly limited to radioisotopes that have been produced in accelerators (principally cyclotrons), or purified from other sources. It also addresses elements of the design and operation of accelerators (principally cyclotrons) that pertain directly to the production of radioisotopes. Therefore, we recommend the title be modified to read "Radiation Safety of Accelerator Radioisotope Production Facilities."	The title should reflect the scope of the safety guide.				
2.	General	The document covered important aspects of radioactive waste safety and management, especially as described in Section 14. Nevertheless, we believe adequate characterization of radionuclides as required by regulatory authority and the disposal facility operators is necessary. In particular the safety guide should refer to waste manifest, coordination with facility operators, and establishing radionuclides detection limits as required by the operator, particularly for radionuclides with high mobility, before shipment in order to avoid controversy about waste acceptance criteria and	Accurate characterization of specific high mobility radionuclides in waste generated from radioisotope production facilities and handling (e.g. Tc-99/Mo-99, H-3, I-123/131, and Cl-36) could be crucial in waste disposal				

		possible excessive disposal charges of waste.	acceptance criteria and disposal charges.				
3.	1.1, lines 3-4	Revise: “The facilities which produce them and in which they are processed are referred to collectively as ‘radioisotope production facilities.’” To: “The facilities which produce radionuclides and the facilities in which radionuclides are processed are referred to collectively as ‘radioisotope production facilities.’”	Editorial and improve readability				
4.	1.15, line 1	Remove extra period at the end of the first sentence.	Editorial				
5.	2.3, lines 1-3	“…formally expressed, many practices, such as the operation of radioisotope production facilities, were already in widespread use, and in general their justification was implicit.”	Add punctuation (commas) to improve readability				
6.	4.10, line 4	Revise: “…in a Safety Guide [18].” To: “…in GS-G-1.5 [18].”	Consistency with other similar references throughout the document				
7.	4.19 (a)	Revise: “Theoretical training that includes training in the properties of radiation as used in the radioisotope production facility:” To: “Theoretical training that includes training in radiation protection and the properties of radiation as used in the radioisotope production facility:”	Expand training to include the topic of radiation protection.				
8.	5.20	Suggest deleting 5.20 and adding pertinent information to the end of the first sentence in paragraph 5.22 as follows: “The exhaust air should be routed through an appropriate filtration system to limit releases of radioactive material to external environments.”	Eliminate redundancy				

9.	5.28, line 4	Revise: “controls should be so designed that any attempt...” To: “controls should be ~~so~~ designed so that any attempt…”	Editorial				
10.	5.33, line 2	Section 16 is referenced at the end of 5.33, but section 16 is related to emergency preparedness. Paragraph 5.33 should include reference to section 15, which is related to transportation. Revise to: “…described in section 15.”	Editorial				
11.	6.21, line 1	Change “cyclotope” to “cyclotron” or other intended term.	Editorial				
12.	7.10, page 33, items listed under “Shipping Clerks” heading	Several objectives listed under the “Shipping Clerks” heading should be moved to the beginning of paragraph 7.10 as fundamental concepts and applicable to other workers: —Effects of time, distance and shielding; —Individual monitoring, external and internal monitoring and how to interpret their doses; —Working practices to limit doses and maintain them as low as reasonably achievable; —Radiation protection programme;	Expand training to include topics applicable to all workers.				
13.	8.12	Eye dosimeters are not broadly available. The statement as written is not applicable in most cases. Suggest revising 8.12 to: “Eye dosimeters, if available, should be worn on forehead for situations requiring the monitoring of the eye doses. If lens-specific dosimeters are unavailable, the dose to the lens of the eye should be estimated using another dosimeter.”	Expand applicability				
14.	8.12	Consider adding the IAEA TECDOC No. 1731 “Implications for Occupational Radiation Protection of the New Dose Limit for the Lens of the Eye” as a reference to this paragraph and in the list of references at the end of the Safety Guide.	Completeness				

15.	8.13, line 1	Change “overall” to “overalls” or other intended meaning.	Editorial				
16.	8.14, line 1	The term “periodical check” is ambiguous. Recommend revising to: “~~The periodical check of dD~~osimeters should be processed [or evaluated or read] ~~done~~ at ~~a minimum on~~ least quarterly, ~~basis~~ or more frequently, depending…”	Reduce ambiguity				
17.	8.14, line 2	Change “character” to “nature.”	Editorial				
18.	8.14, lines 3-4; 8.19, lines 4-6	The concept in paragraph 8.14 is addressed in paragraph 8.19. Recommend deleting the second half of the sentence in paragraph 8.14 regarding the dosimeters being processed by an approved lab because this issue is addressed in paragraph 8.19. Recommend revising paragraph 8.14 to: “Dosimeters should be processed [or evaluated or read] at least quarterly, or more frequently, depending on the nature of the work and technical specification of the dosimeter.”	Eliminate redundancy				
19.	8.16 and 8.17	Paragraphs 8.16, 8.17, and 8.18 should be moved up to the beginning of the section. Paragraphs 8.16 and 8.17 should precede paragraph 8.9. Paragraph 8.18 should follow paragraph 8.9.	Improve organization of external monitoring section				
20.	8.18	Paragraph 8.9 already describes that each worker should wear a whole-body dosimeter. To eliminate redundancy, paragraph 8.18 should be revised to read: “Hot cell operators, RPOs, pharmacists, decontamination workers, laboratory technicians and maintenance staff who routinely enter controlled areas should ~~be subject to individual dose monitoring. These individuals should wear whole body monitors (e.g. a film badge, thermoluminescent dosimeter or optically stimulated luminescent dosimeter) and~~ also wear an electronic personal dosimeter to ensure effective dose management.	Eliminate redundancy				

21.	9.6 and 9.9	Information in paragraph 9.6 is the same as paragraph 9.9. Suggest deleting 9.9.	Eliminate redundancy				
22.	9.10, lines 3-7; 9.14, lines 2-6	The second and third sentences in paragraph 9.10 are the same as the second and third sentences in paragraph 9.14. Suggest merging the information from both paragraphs into one paragraph.	Eliminate redundancy				
23.	9.12, lines 6-7	The word "in" is used twice. Revise to: "…converted to units in which the detector reports ~~in~~ (cps or cpm) for ease of use…"	Editorial				
24.	9.12, line 8	The word "stabling" is ambiguous. Recommend revising the word to an intended meaning.	Reduce ambiguity				
25.	9.14, lines 7-9	The last sentence is difficult to follow. Recommend revising to improve readability.	Improve readability				
26.	9.15	Paragraph 9.15 is difficult to follow. Recommend revising to improve readability.	Improve readability				
27.	9.23 and 13.1 (b)	Information in paragraph 9.23 is the same as paragraph 13.1(b). Suggest deleting either 9.23 or 13.1(b).	Eliminate redundancy				
28.	10.2, lines 2-4	Suggest revising the second sentence to: "Soil samples ~~will always contain trace natural amounts of radioactivity, e.g. 137Cs, due to atmospheric weapons testing~~ near the facility may contain contamination from effluents released from the facility, therefore soil samples should be compared to background soil away from the ~~discharge stack~~ facility."	Improve applicability				
29.	10.37	Paragraph 10.37 is difficult to follow. Recommend revising to: "The most efficient ways ~~is~~ to control the release of contaminants are to contain and trap the contaminants at the source itself ~~with~~ using gas bags or traps (liquid nitrogen or cartridges)~~.~~ ~~Another possibility could be~~ or tank storage for decay (in case of the PET gases)."	Improve readability				
30.	Section 14	Section 14 briefly addresses the decommissioning aspects of radioisotope production facilities to include preparation of a decommissioning plan.	Completeness				

		In this regard, suggest adding text to address: a) Update of the decommissioning plan based on radiological monitoring data and unplanned releases or discharges; b) Allocation of decommissioning funds in accordance with regulatory requirements and cost of remediation.					
31.	Reference 20	The current transportation regulations were last updated in 2012. Remove (2014) at the end of the reference and replace it with (2012).	Accuracy				
32.	Reference 43	SSG-26 was last updated in 2012. Remove (2014) at the end of the reference and replace it with (2012).	Accuracy				