

TITLE : Radiation Safety of Accelerator Based Radioisotope Production Facilities (DS434)

COMMENTS BY REVIEWER				RESOLUTION			
May 2018							
Country	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
Germany	Table of Contents	The page number is incorrectly spaced: 1. INTRODUCTION - Scope		A			
Iran (R)	Contents	Scope	Editorial	A			
Iran (E)	1.3	"...for protection of people and the environment..."	In consistent with GSR Part 3 (for example 2.14, 3.43)	A			
Germany	1.7 and 3.1	Delete repetition or refer in para. 3.1 to para. 1.7	Identical wording	A			
France (R)	4.2		In France these duties are in charge of the licensee				
France (R)	4.9	If it necessary, the radiation protection officer should be independent of the production department.	To enforce radioprotection et safety decisions.	A			
France (R)	4.15	(d) : + a description of ventilation system of the building with the type of filters, air flow pattern, air pressure ... Add "p": an impact study of gaseous effluent exhausted into environment during current operations and accidental situations.	To prevent contaminations risk. In particularly if population live around the building.	A			
India (R)	Page 12/Item 4.15 (d), line no.3e.g. radiation shielding, interlock systems, fume hoods, remote handling tools, effluent exhaust systems, monitoring systems and warning systems, emergency stop switches/ trip wires , and their appropriate locations in the facility;	Emergency stop switches/trip wires is an essential safety system for accelerators and may be included	A			
Iran (R)	4.15	(P) List of documents such as standards and other technical documents related to requested application.	It's necessary to check standards compliance of radiation devices with their requirement.			R	List of standards should be available with regulators.

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Germany	4.22 (c)	Have knowledge of the emergency preparedness category of the facility in the context of the emergency preparedness and response plans in accordance with the relevant requirements.	“emergency plan” is an accepted expression of the IAEA SAFETY GLOSSARY	A			
France (R)	5.9	“this may include dispensing in positive pressure regimes”	Local French rules prohibit positive pressure regime between dispenser hot cell and laboratory. However positive pressure regime is allowed between dispenser hot cell and synthesis hot cell.	A Text is flexible – <i>may include</i>			
India (R)	Page 23/Item 5.14, line no. 4	Therefore a strippable layer of concrete of appropriate thickness may be incorporated which will be helpful during the decommissioning.	Text to be added; The concrete used in the vault walls for bunker type cyclotrons, should be built with about 20-30 cm strippable layer or as estimated by design, without affecting the concrete integrity, density etc. This layer of concrete may only be removed during decommissioning.	A			
France (R)	5.17	Leak tests on the shielded hot cell should be performed at a defined frequency and in any significant change of the design of the hot cell.	In particularly for synthesis hot cell. In case of extractor’s breakdowns, the leaktightness of the hot cell is the last barrier of defense. Moreover, leak tightness performance can decrease in time.	A			

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Iran (R)	5.18	No proposed text but comment	There is no description for fume hoods material like what mentioned in 5.23 for glove boxes.	A No suggested texts.			
Iran (R)	5.23	Glove boxes should be equipped with pressure control tools	To prevent pressure change that may cause release of gases or radioactive material.	A			
France (R)	5.25	An interlock should be also installed on the transfer system in order to prevent any transfer of radionuclides if the hot cell connected to the targets focused is open and if the pressure regime inside the hot cell is out of specifications. Another interlock should be also installed on hot cell doors in order to prevent any opening doors when the radiation level field is elevated.	To protect workers.	A			
France (R)	5.34	“Redundancy of essential ventilation systems” Redundancy of the process extractors (connected to the hot cells) is a good practice. However extractors should not be installed in series because of positive pressure risk in the exhaust air duct between these extractors.	Redundancy of the ventilation system is not necessary if all ventilation maintenances are performed during scheduled production shutdown.			R	Essential systems should be provided.
France (R)	5.37	The exhaust air duct of the synthesis process and the exhaust air duct of the cyclotron bunker should be separated from the others exhaust air duct of the building until to the reject emissary.	This kind of design should prevent the risk of high contamination of premises in case of extractor’s breakdowns.	A			

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India (R)	Page 27/Item 5.38; line no. 2	During the process of site selection, particular consideration should be given to potential hazards that cannot be addressed by means of engineering measures, such as hazards relating to geological phenomena in areas of potential or actual subsidence, uplift, collapse, faulting or volcanic activity.	Text to be removed; Such considerations may not be warranted, keeping in view the graded approach, as these natural phenomena which is beyond engineering measures, will not pose higher radiological safety significance		A		RASSC may advise.
Iran (E)	5.40/Line 8/	"...and external events of natural origin and human induced origin that could lead to accident emergency conditions."	Human induced may be intentional or unintentional. In case of intentional external events, using "accident" that means any unintended event is not correct.	A			
France (R)	5.42	add "change control" : Before operating any changes in design of the facility or process, an assessment of all modifications and their consequences should be performed.	"change control" allows to manage all modifications, for safety and radiation safety, so that they are not jeopardize.	A			
Iran (R)	5.42	Radiation resistance of other tools and equipment's (like camera, cables, sensors) used in the accelerator room should be considered in the safety assessment report.	Estimate life time of equipment for maintenance program and supply a plan to reduction the radiation damage	A			
France (R)	6.21	In the cyclotron bunker, the probability of irradiation and contamination is high, if the cyclotron is not self-shielded: This area is a controlled area. + In the storage room of gaseous exhausted effluents, the risk of contamination and irradiation is high: Controlled area.	For air compressing system and gaseous effluent tank storage or bottle storage for decay (for example).	A			

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Germany	6.21	Normally in the accelerator room the probability of contamination and radiation will be low [not actually a should statement, I think]; however, considering the risks associated with the failure of a target, the accelerator room should be designated as a controlled area.	“Normally [...] low” is not a scientific assessment and dose rates in the accelerator room may be rather high	A Will be modified incorporating France comment			
Pakistan (R)	6.21	Normally in the accelerator room the probability of contamination and radiation will be low [not actually a should statement, I think]; however, considering the risks associated with the failure of a target, the accelerator room should be designated as a controlled area.	Text editing	A			
Iran (R)	6.28	(g) making arrangement to comply with regulatory body requirements and review reports that should be submit to regulatory body	Radiation Safety Committee should have very constructive engagement with regulatory body. This is a one of most important responsibilities of them	A			
Iran (R)	8.4	No proposed text but comment	8.4 should be transferred to radiation protection program in the content of “ designation of controlled area or supervised area” headline	A			
Pakistan (R)	8.10	...on record keeping and on quality management are provided in GSG-7 [19] [20].	Text editing	A			
France (R)	8.14	This may be relevant for workers involved in cyclotron or targets maintenance, production, quality control, waste handling and expedition.		A			

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France (R)	8.15	This may be relevant for workers performing maintenance of cyclotron and targets.		A			
USA (R)	Para 8.15	At present, eye dosimeters are not broadly available. Therefore, the statement as written is not applicable in most cases. Implementation of other methods for measuring lens of the eye dose using dosimeters for other quantities will be necessary. Recommend revising as follows: “Appropriate eye dosimeters should be worn or an established method for measuring the equivalent dose to the lens of the eye for situations requiring...”	Expand applicability	A			
France (R)	9.6 (b)	Remove “waste room” and add “quality control room”, and “expedition room”.	The irradiation level in the waste room is stable. However, in the quality control and expedition rooms, the irradiation level is variable according to the activities of the manipulated samples or final products.	A			
France (R)	10.22	“For particles filter”	Only for particles filter (not really appropriate for charcoal filter)			R	Proposed text is not clear
France (R)	13.10	+ bypass or disabling access should be restricted by a code or key and only for a limited persons.	To enhance workers security.	A			

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Pakistan (R)	Section 14	Classification of radioactive waste may be included in this section.	As per GSR Part 5 Requirement 9: "Characterization and classification of radioactive waste ". Waste classification is necessary before processing, storage, transportation or disposal of radioactive waste. In this regard, the information related to waste classification should be included in relevant section of this draft document.			R	GSG-1 provides detailed guidance on classification of radioactive waste.
Pakistan (R)	14.1/4	Radioactive waste should be addressed in the safety assessment prior to its generation Non-radiological hazards (e.g. biohazards and chemical hazards)	Text editing	A			
France (R)	14.14	"it may be acceptable to dilute and dispense"	Voluntary dilution of radioactive material to comply with a requirement, or a limit is prohibited in France.			R	Text is flexible enough.
Turkey	16.1	The first and the third paragraphs of the "emergency" definition have more or less similar meanings and either they can be combined into one paragraph or one of these paragraphs can be deleted from the text.				R	First is more general and the second is specific to radiological emergency.
Turkey	16.3	Loss of off-site power can be added to the typical incidents list.		A			
Germany	16.5 / 4-5	Emergency arrangements that correspond to this category should be established for any the radioisotope production facility.	Wording	A			

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Pakistan (R)	16.5/4	Emergency arrangements that correspond to this category should be established for the radioisotope production facility.	Text editing	A			
Turkey	16.8	The on-site emergency plan is addressed in the text but there is not any information about the off-site emergency plan and compatibility of the on-site and off-site plans with each-other. These provisions can be added to the text.				R	No significant off-site consequences envisaged.
Turkey	16.9	The following procedures can be added emergency procedures list: - The responsibilities and the actions to be performed by the “emergency response manager” (“facility response director” according to EPR-Method 2003) - Arrangements for allocation of the roles and responsibilities - Arrangements for radiological monitoring				R	Not limited to.. Already added in the beginning.
Turkey	16.9	Emergency procedures related to the notification of an emergency and activation of an emergency response should include the emergency classification and use of operational criteria during emergency classification. The extent of emergency response should be in line with the declared emergency class. The emergency procedure statement can be revised by taking into account the explanation above.				R	Relevant items should be identified in the emergency plan.

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Pakistan (R)	General	Examples of incidents at the radioisotope production facilities may be included in the guide.	It will be helpful to know the causes of incidents and the lessons learned.			R	Relevant EPR series documents may be referred.
Turkey	16.9	Emergency procedures related to the communication and coordination arrangements may include the assignment of facility response director and the order of undertakers (departments and titles of the persons) in case of the non-presence of facility response director on-site in the event of an emergency situation. The emergency procedure statement can be revised by taking into account the explanation above.				R	All relevant EPR safety guides are referenced in the section.
Turkey	16.20	The following statements can be added to the training subjects list: - Use of personnel protective equipment - Use of radiological monitoring equipment		A			
Turkey	16.21	The paragraphs 16.13 and 16.21 states more or less similar provisions. They can be either combined or one of these paragraphs can be deleted form the text.		A			
Turkey	16.24	The statement "(c) The root causes of the emergency" can be written as "(c) The specific causes of the emergency"				R	Better description