

Leadership, Management and Culture for Safety in Radioactive Waste Management (DS 477)

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Page 1 of 1 Country/Organization: Argentina/ARN Date: May 2020							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	5.118 c)	<p><i>(c) Assessment of the condition of the item, resolution of the non-conformance (e.g. rework, repair, <u>use as is</u>, or reject), and determination of the causes for the non-conformance so that corrective actions can be taken to prevent the non-conformance from recurring;</i></p> <p>Considering the scope of this safety standard and that a waste is defined as a "...Material in gaseous, liquid or solid form for which no further use is foreseen." The USE AS IS option seems not valid.</p>	Rephrasing or deleting "use as is" is recommended.	A	Text deleted in paras 5.118c) and 5.119 to satisfy both this comment and a related comment from Germany.		

Bulgaria's Comments on IAEA Draft Safety Guide
DS477 - The Management System for the Predisposal Management and Disposal of Radioactive Waste

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bulgarian Nuclear Regulatory Agency (BNRA): P.Stoyanova, N.Yankova Country/Organization: BULGARIA/BNRA Date: May 28, 2020					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1.	Page 3 Footnote 1	The second sentence to be replaced by: "The management system integrate several elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised"	The first and the second sentence use the word "elements" in different meaning. In the first sentence elements are all the component parts of the organization - organizational structure, resources, processes, organizational culture (IAEA Safety Glossary 2018 Edition). The meaning of the second sentence is that a single coherent management system addresses the totality of requirements on the organization (requirements of safety, health, environmental, security, quality...) in a way safety is not compromised. A clear distinction between the two has to be made. Furthermore it is misleading to refer to quality assurance and quality control systems as systems within the management system.	A	The definition is given in the first sentence. The second sentence is not needed. What to include in any second sentence is debatable and so the second sentence has been deleted.

2	Para 1.6.	<p>The replace existing text by “ This Safety Guide identifies the need to consider that the management system has to integrate its elements, including not only safety but also health, environmental, security, quality, human-and-organizational-factor, societal and economic elements. Specific requirements in terms of these elements are established in other IAEA safety standards and other international codes and standards”.</p>	<p>Not only security but also other elements should be mentioned in terms of integrated management system. The paragraph is rewritten on the basis of: GSR Part 2, para. 1.14 <i>(1.14. This Safety Requirements publication does not specify all those specific health, environment, security, quality and economic requirements to be addressed that have been established elsewhere (in other IAEA safety standards and in other international codes and standards).</i> and GSR Part 2, Requirement 6 <i>(“The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.”)</i></p>	R	<p>A paragraph such as para. 1.6 is standard practice in IAEA Safety Standards that interface to security. Para. 1.6 is necessary for acceptance by colleagues in Nuclear Security.</p>
3	Para 1.8(d)	<p>To include the obligation for keeping records not only for the conditioning steps.</p>	<p>The text is included in Para 1.8. which is of general nature. That is why point (d) should be generalized accordingly. Judging from figure 1 of the draft safety guide (page 8), for example, WAC are applied for conditioning, storage and disposal phase. Keeping records for these phases could facilitate the safe transfer of waste across different organisations and is important in terms of exercising regulatory control.</p>	A	

4	Para 2.9. (d)	(d) Ensuring continuity of understanding, knowledge, resources and culture for safety over long time periods.	For the purpose of aligning the terminology, incl. with the title of the document.	A	We acknowledge the comment. We recognize that there is a variation in usage across IAEA documents in the usage of the terms: safety culture, culture for safety and nuclear security culture - this cannot at present be resolved solely within DS477. Although some people do see a material difference between the terms “safety culture” and “culture for safety”, the relevant entry in the Safety Glossary is: “safety culture - Also: culture for safety”. GSR Part 2 contains 23 instances of “safety culture” and 6 instances of “culture for safety”. We have quoted GSR Part 2 and other Safety Standards faithfully.
5	Para. 3.14 First sentence	Our suggestion is that the provision be generalized in order to cover the overall responsibility for the licensing activities, not only the engagement to “liaise” (officially) with the regulatory body and RAW management facilities.	Basically, this provision (as we interpret it) is aimed for ensuring direct involvement of the senior management in the licensing process by official and direct contacts and collaboration with the respective regulatory body. The responsibilities of the senior management of the licensee are summarized in para.2.2.(a) of GSR Part 2 (“2.2. <i>The senior management of organizations, in accordance with their accountabilities:</i> <i>(a) Shall ensure the safe siting, design, construction, commissioning, operation and decommissioning (or closure) of facilities;</i>) In this respect, the senior management bears the responsibility for the implementation of the licensing process to be effective and legitimate. In our opinion, this is not clearly stated in para. 3.14 and in the draft document as a whole.	M	The paragraph referred to (now para. 3.15) is one of a series of paragraphs that discuss the need for continuing safety and clarity of responsibilities during the transfer of radioactive waste between organizations. The paragraph is addressed to the senior management of a licensee and so it is already the case that the organization in question holds a Licence and must, therefore, already have engaged with the licensing process. The text has been modified to further emphasize the guidance intended, which is that the waste generator should liaise (i.e. cooperate on a matter of mutual concern) with the regulatory body and relevant other organizations that might ultimately receive the waste concerning the arrangements for its generation, transfer and subsequent management.

6	Para 3.15.	There is no para. 2.13. in GSR Part 2.	Incorrect referring.	A	
7	Para 3.2.	The last sentence of para. 3.2. states that “The responsibilities of the regulatory body are defined in Requirement 3 of GSR Part 5 [3]”. This sentence should be revised (omitted, replaced or supplemented)	1. Paragraph 3.2. is related to the prime responsibility for safety which normally rests with the operator. 2. From a formal point of view, the content of this paragraph as a whole is connected with predisposal steps and disposal. But the last sentence of the paragraph refers to GSR Part 5 which is related only to the predisposal waste management (See para. 1.13. of GSR Part 5: “ <i>This publication establishes requirements that apply to all facilities and activities that are involved in the management of radioactive waste before disposal.</i> ”).	A	DS477 applies to the regulatory body as well as the operating organization (and others) as described in para 1.8. The last sentence of para 3.2 is the equivalent statement for the regulatory body as the first part of the paragraph is for the operating organization. The comment has been addressed by adding a reference to Requirement 2 of SSR-5. Note, however, that it is arguable that this is not necessary because GSR Part 5 is a General Requirement while SSR-5 is a Specific Requirement.
8	Para. 3.3	To replace the first part of the first sentence “The senior management of an operating organization is responsible for developing policies, objectives, strategies, goals and plans (see Requirement 4 of GSR Part 2 [5]),.....” by “The senior management of an operating organization is responsible for developing policies, goals, strategies, plans and objectives (see Requirement 4 of GSR Part 2 [5]),.....”	This would ensure the compliance of the text in para. 3.3 with Requirement 4 of GSR Part 2 and consistency between the meaning of goals and objective as specifying long and short term aspects in radioactive waste management, accordingly.	A	The text has been made consistent with GSR Part 2 Requirement 4.

9	Para. 3.15	The text to be replaced by “The operating organization is required to provide the regulatory body with all necessary safety related information (see para. 2.13 of GSR Part 1 [...]), and should initiate interactions with the regulatory body as soon as possible and before conditioning of the waste.”	The reference is not correct. There is no para. 2.13 in GSR Part 2. The reference should be to para 2.13 of GSR Part 1.	A	
10	Para. 5.2 c), 6.7, etc.	Consider replacing the wording “best practice” with “good practice”.	At several places the wording “best practice” is used. How it could be judged that a practice is the best.	M	<p>The text at the front of each Safety Standard includes: “The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety”.</p> <p>We are giving guidance, not establishing requirements; guidance is more aspirational. It would not be appropriate, for example, to guide people to adopt average standards of integrity or behaviour. The requirements in GSR Part 2 are for good practice, but the guidance is for consideration as appropriate of best practices.</p> <p>We have added a footnote.</p>
11	Para. 4.11	Para. 4.11 to be moved before para. 4.7	The para. 4.3 to 4.6 and 4.11 concern senior management and represent guidance to para. 3.1 of GSR Part 2, while para. 4.7 to 4.10 concern managers at all levels and represent guidance to para 3.2 of GSR Part 2.	A	
12	Para. 5.41	The whole text of para. 4.9 of GSR Part 2 to be included in para 5.41	It is important to have here the means by which the MS would ensure the safety goals to be achieved.	A	

Canada's Comments on IAEA Draft Safety Guide
DS477 - The Management System for the Predisposal Management and Disposal of Radioactive Waste

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Canadian Nuclear Safety Commission (CNSC)		Page 1 of 3					
Country/Organization: CANADA/CNSC							
Date: May 19, 2020							
Comment No.	Para/Lin e No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	Add to section 3 Responsibility for Safety, the following text: “Senior management should prepare plans to ensure essential functions can operate safely for a sustained period with a significant employee absenteeism (e.g. influenza outbreak). The regulatory bodies should regularly review those plans.”	Plans should be developed and kept current to ensure safety during a pandemic outbreak. This is a lesson learned during the recent Coronavirus outbreak. Recommend to keep this subject at a high level in DS477 until the IAEA develops a comprehensive document on this topic.	A	New para. 3.6. Implemented with very minor wording changes for consistency with IAEA style.		
2.	7.8	Add to section 7.8, an item regarding the assessment of commissioning activities, such as: “In practice, an assessment of commissioning activities is performed. During the commissioning stage, activities should be performed as per documentation, data to be collected and be prepared, records should be maintained, and interfaces between commissioning and operations activities should be defined.”	As commissioning is listed as a distinct stage in sections 3.2 and 5.130, assessments and self-assessments should also be performed for commissioning activities.	A	New para. 7.7(d). Implemented with minor wording changes for consistency with IAEA style.		

COMMENTS BY REVIEWER

Reviewer: Canadian Nuclear Safety Commission (CNSC)

Country/Organization: CANADA/CNSC

Date: May 19, 2020

RESOLUTION

Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3.	5.66	Add “commissioning” to the list of facility activities: <i>Records should also be created and retained to describe the history of radioactive waste management facilities, such as data obtained during facility design, construction, commissioning, operation and closure.</i>	Although commissioning is a distinct stage, as stated in sections 3.2 and 5.130, commissioning is not always included but it should be for consistency.	A			
4.	5.66	Suggest in item (b) to replace “certificate” with “records”: (b) Commissioning certificates records	Commissioning records is a better description of the results from the output of commissioning activities than certificates. The results of commissioning activities should be documented, reviewed and accepted.	A			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Canadian Nuclear Safety Commission (CNSC)		Page 3 of 3					
Country/Organization: CANADA/CNSC							
Date: May 19, 2020							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5.		Add to section 6.5, the following text: “The highest level of management system documentation for a management system should make safety the utmost priority, forming a basis for promoting safety culture. The management system documentation may describe the leadership role(s) encompassing the highest levels of responsibility for safety, as well as safety responsibilities for workers.”	To provide clarity to section 6.5 regarding the attributes for fostering a culture for safety in the management system documentation.	A	Edited for increased clarity and so that this text in para. 6.5 is consistent with, and does not repeat too much, existing text on responsibilities (Section 3), leadership (Section 4), and documentation (Section 5).		

Leadership, Management and Culture for Safety in Radioactive Waste Management (DS477)

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Peter Lietava Country/Organization: SÚJB Praha, Czech Republic 2020		Page 1 of 6 Date: 7 May			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted Modified Rejected	Rationale
1	General comment (whole text)	What is the reason using two terms, „culture for safety“ and „safety culture“, in the whole text of draft SG?	Use only terminology defined in IAEA Safety Glossary 2018 and used in GSR Part 2 and do not introduce new terms without clear clarification of their meaning and justification of their introduction.	A	We acknowledge the comment. We recognize that there is a variation in usage across IAEA documents in the usage of the terms: safety culture, culture for safety and nuclear security culture - this cannot at present be resolved solely within DS477. Although some people do see a material difference between the terms “safety culture” and “culture for safety”, the relevant entry in the Safety Glossary is: “safety culture - Also: culture for safety”. GSR Part 2 contains 23 instances of “safety culture” and 6 instances of “culture for safety”. We have quoted GSR Part 2 and other Safety Standards faithfully.
2	1.2/p.3	Requirements for the management and disposal of radioactive waste are established in IAEA Safety Standards Series No. GSR Part 5, ... and SSR-5.	The term “RAW management” includes disposal as the final step in RAW management process. To be consistent with the IAEA Safety Glossary 2018 we recommend this modification of the text.	A	

3	1.8/p.4	<p>The intention is that these recommendations will contribute to a high level of confidence that:</p> <p>a) Radioactive waste management activities will be conducted in compliance of general requirements defined in [5];</p> <p>b) Radioactive waste management activities will be conducted in a coherent, coordinated and controlled manner;</p> <p>...</p>	<p>The main intention of draft SG should be the compliance with general management system requirements as defined in GSR Part 2 (see paras 1.3, 1.15, ...). Then the originally first item in the list can be deleted as it is covered by the GSR Part 2 requirements.</p>	A	
4	2.6 b)/p.7	<p>...; this poses issues for the provision of resources, particularly the provision of human and financial resources, and for knowledge management.</p>	<p>Funding of RAW management and knowledge management, especially of disposal, also impacts many generations and should be highlighted in item b) of the list.</p>	A	
5	2.6 c)/p.7	<p>... Whilst the owner should retain overall responsibility for the waste, the licensee of the facility where the waste resides is responsible for its safety⁵-In some jurisdictions, ownership of and responsibility for radioactive waste is transferred when the waste moves from one organization to another; in others, ownership of and responsibility for radioactive waste always remains with the original generator of the waste.</p>	<p>The original text reflects the second option of the footnote text only. To avoid misunderstanding we propose replacing the last sentence in item c) by footnote text.</p>	A	<p>All times it should be clear who owns the waste and who is responsible for safety. There are different models for the ownership of waste in different Member States – this was noted in the footnote. As a result of this comment the footnote has been brought back into the main text. It is the licensee of the facility where the waste is located that is responsible for safety – this is an essential point that needs to be stated in the guide.</p>

6	2.7/p.8	Safety Standards Series Nos GSG-3, ... [15], and SSG-23, ...	As the term “Waste Package Specification” is not defined in the IAEA Safety Glossary 2018 provide its definition (e.g WPS are defined properties of the packaging and its content (RAW inventory) providing compliance with WAC of receiving RAW management organization) and link to WAC (see also para. 5.36).	A	
7	3.6, 3.7/ p.10, 11	3.6 Demonstrating safety involves the development of a safety case (see Requirement 13 of GSR Part 5 [3]) for each facility, including a consideration of the following:- ... 3.7 Recommendations on the development of the safety case are provided in IAEA [16].	Safety case has to consider much more items than listed in para 3.6 (e.g. safety assessments, OLCs, emergency arrangements, ...). To avoid development of long item list we recommend shortening para. 3.6 and merge it with para. 3.7, as they are closely interlinked.	A	
8	5.11/p.17	Management systems for radioactive waste management should be designed to ensure continuity in managing facilities and activities, and should contain provisions for managing changes, for example, in the following: (a) The ownership of radioactive waste and radioactive waste disposal management facilities;	It is not clear why only change of disposal facility ownership should be considered within the management system. We recommend widening this provision to all RAW management facilities.	A	

9	5.25/p.20	-	Develop recommendations how to proceed with disposal facility siting and development process, if there are no (and there will be no) volunteer communities in the whole country.	R	This aspect of the Safety Guide is about the Management System. Para 5.25 concludes with guidance on what the Management System should include. It is not the role of this Safety Guide to define or specify the process for identifying and interacting with interested parties, or to solve problems relating to a lack of volunteers. Those things are the subject of various research and would need to be incorporated in other publications.
10	5.45/p.25	The management system includes the safety assessments conducted to evaluate all aspects of facilities and activities that are relevant to safety, and the presentation of safety arguments and supporting evidence in the safety case for each radioactive waste management facility.	Safety assessment is a part of the safety case and safety case includes the management system. The whole para is misleading and we recommend deleting it or completely rephrasing it, depending on the initial intentions of authors.	A	We have deleted the paragraph. There are different views on whether the Management System or the Safety Case is the larger entity and on which one encompasses the other.
11	5.51 a)/p.26	... long term aspects of the radioactive waste management programme should be considered such as the following: (a) Providing adequate human, infrastructural and financial resources	We propose clarify which resources at least should be considered by the long term RAW management. New items on RAW management funding and infrastructure may be needed.	A	
12	5.57/p.28	For radioactive waste management facilities, consideration in the management system should be given to the following:	From the introduction text to the list it is not clear in which document these items should be considered (“appropriate” assessments, management system documents).	M	Implemented with minor wording improvements.

13	5.57/p.28	(l) The scope, age-frequency (or periodicity), and details of safety assessments and safety cases;	Proposed wording better reflects needs for periodic safety re-assessments.	M	Implemented with minor wording improvements.
14	5.62/p.30	Documents within the management system may include policies (statements of goals and objectives), strategies, plans, safety cases, safety assessments, management system processes and procedures, instructions, ...	Management system documents and safety assessments are parts of safety case and not vice versa. See also comment No. 10.	M	Text revised so as not to lose the key point that important documents should be controlled, while at the same time avoiding the differences of view noted above in response to comment 10.
15	5.64/p.30	(k) The safety functions fulfilled by the waste form or waste package during predisposal management and disposal.	Last item in the list of information in RAW records is redundant and should be deducted from the type of waste package. Safety functions of waste forms or waste packages are defined in safety assessments and in the case of licensed waste packages, in their safety documentation.	A	
16	5.109/p.43	(b) Inspection and testing, as appropriate, on receipt of items important to safety (e.g. waste packages), including verification of related certification and documentation; (e) Inspection, and testing on receipt, of items that are important to safety;	Delete item c) as it duplicates item b), but is not as comprehensive as item b) in the list.	A	

17	5.118/ p.45	The process and procedures should include the following actions: (a) Immediate reporting and documentation of non-conformities (b) Segregation ...	Reporting to the responsible person in compliance with management system and preparation of non-conformity documentation just after its occurrence is missing in the list.	M	Implemented but using the word “Timely” instead of “Immediate” for consistency with GSR Part 2.
18	5.189/ p.61 5.190/ p.62	(f) Measures for criticality control are in place, are effective and are maintained, if applicable (f) Measures for criticality control are in place, are effective and are maintained, if applicable	Items (f) in both list are applicable for RAW containing fissile material only.	A	
19	6.5/p.67	(b) The management system documentation; (c) Assessments and self-assessments of the culture for safety; (d) The management system documentation and associated processes and procedures for conducting radioactive waste management activities;	Merge items (b) and (d) as they are almost identical.	M	Implemented by shortening bullet point (d).
20	7.11/p.73	(e) Changes and regulatory requirements or regulatory guidance;	Delete item (c) as it is already covered by item (b). Changes in regulatory framework are equal to changes in regulatory requirements and guidance.	A	

21	7.14/p.73	(x) The quality of waste packages produced, if waste package performs some safety function	For some disposal facilities (especially DGR), the quality of waste package is at least as much important as for predisposal facilities. Keep this item in the list of specific aspects the review of RAW disposal facilities management system is focused on.	A	Implemented with minor wording improvements.
22	7.14/p.73	g) The safety case and long term performance of the radioactive waste disposal facility after the closure as may be determined by monitoring of the disposal system.	The wording of last item is unclear and combines aspects, such as safety case development (b) and performance of disposal facility (e) together. New wording should provide clarity and avoid repetition on the last item.	A	Implemented with minor wording improvements.

**ENISS comments on
IAEA draft DS477 Leadership, Management and Culture for Safety
in Radioactive Waste Management (April 2020)**

COMMENTS BY REVIEWER					RESOLUTION
Reviewer: ENISS 11 Country/Organization: ENISS 19/05/2020				Page 1 of	
				Date:	
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1	General comment	<p>The current version of the guide is improved and many of our previous comments have been taken into account. We appreciate the changes made in the submitted version of the Guide, and its adaptation of GSR Part 2 (Leadership and Management for Safety) to the area of Radioactive Waste Management. These adjustments led to its better clarification and clarity.</p> <p>However the combination of disposal and predisposal makes it difficult for an inexperienced operator/regulator to find out what is really necessary. Our suggestion for a better structure to ensure a graded approach between these two types of installations was not followed completely. However the new draft reflects the differences between predisposal and disposal in a better way.</p> <p>As disposal facilities are seldom and unique and a subject of governmental care, predisposal facilities are much more common and there may be hundreds or more such facilities worldwide so it would be wise to concentrate on predisposal facilities and leave out disposal.</p>		<p>A</p> <p>A</p> <p>R</p>	<p>We acknowledge these positive comments – no changes needed.</p> <p>We acknowledge these positive comments – no changes needed.</p> <p>To ensure proper treatment of the interdependencies between predisposal management and disposal of waste, the WASSC agreed at its 29th meeting in June 2010 to revise and combine:</p> <ul style="list-style-type: none"> • GS-G-3.3 “Management System for the Processing, Handling and Storage of Radioactive Waste” • GS-G-3.4 “Management System for the Disposal of Radioactive Waste”

	<p>A great number of provisions of this standard are not specific for predisposal or disposal. They should be deleted as they are already reflected in GSR Part 2. The question is if the quotations of GSR Part 2 and GSR Part 5 are really necessary. The citation makes the document not easy to read.</p> <p>There are a great number of redundancies or repetitions in the document. They should be deleted as far as possible.</p> <p>In the whole document there is a formulation often used ‘should ensure that’ or ‘is required’. This sounds like a requirement style, which is not appropriate in a Safety Guide.</p> <p>Scope of the document The title of the document refers to leadership, management system and safety culture in the radioactive waste management. However, the document gives relatively detailed guidance in some technical areas, such as e.g. waste record keeping or safety case, the guidance on which should be given in relation to predisposal or disposal of radioactive waste. It is recommended that the document excludes the</p>	<p>R</p> <p>A</p> <p>R</p> <p>R</p>	<p>The text of DS477 has been made specific to radioactive waste management wherever possible; GSR Part 2 applies much more broadly. General guidance to support the broader aspects of GSR Part 2 will be contained in General Safety Guide DS513, “Leadership, Management and Culture for Safety”, but that is not expected to be available for several years. It is standard practice for the IAEA Safety Guides to quote the Requirements that they are addressing. It is the IAEA approach to ensure that such quotes are accurate, and this was a major part of the process of checking and revision completed in the Step 10d Technical Editor’s review. Member States comments on DS477 include requests for guidance relevant to radioactive waste management on each aspect (all paragraphs) of GSR Part 2.</p> <p>We have removed unnecessary repetition. What remains may appear at first sight to be unnecessary repetition, but in fact this reflects the structure of the document which is inherited from GSR Part 2. Certain topics occur in slightly different ways under Responsibility for Safety, under Leadership for Safety, under Culture for Safety, etc.).</p> <p>This wording is normal practice in Safety Standards. For example, the phrase ‘is required’ is used where there is indeed a requirement in an overlying Safety Standard. It is used to ensure that a Safety Guide does not inadvertently “dilute” a requirement (a “shall statement”) by presenting it as a “should statement”. Again, checking the correct use of these phrases was a major part of the process of checking and revision completed in the Step 10d Technical Editor’s review.</p> <p>The document does give some relatively detailed guidance, but this is on the Management System for ‘controlling’ the technical (and other) work involved in radioactive waste management. Guidance on technical (and other) work involved in radioactive waste management itself is provided in separate Safety Standards publications.</p>
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		<p>activities on which guidance is given elsewhere and concentrate in issues listed in the title.</p> <p>Due to the large scope of the guide, it will be difficult for users to find recommendations specific to their role, scope and the activities they perform (i.e. large industrial radioactive waste management facilities, versus small facilities and activities such as the release of radionuclides into the environment).</p> <p>Political leadership Political decision makers set boundary conditions for license holders and regulators on radioactive waste management. Without political leadership the radioactive waste management program has limited possibilities to succeed. The report shall emphasize the importance of political leadership in creating circumstances where the license holders can succeed. Examples in some EU member states show that if the political decisions are made at right time the license holders can make significant progress in their radioactive waste management programs. Missing political leadership has, at the same time, put some radioactive waste or spent nuclear fuel management programs on hold in some countries</p> <p>Effective management system using graded approach The report is missing one important aspect of a management system: it should be such that the work can be done effectively and without unnecessary delays or costs. In its current form the document may lead to too complicated and inefficient management systems. Graded approach is mentioned in some parts of the document, but it should be highlighted more in the document.</p>	<p>R</p> <p>A</p> <p>M</p>	<p>This comment tends to contradict the preceding comment in as much that the former questions the provision of detailed guidance of the Management Systems for radioactive waste management, whereas this comment suggests that there is indeed a need for more detailed, specific guidance to try to address explicitly all of the different potential users of the guide.</p> <p>We have added some further text to para. 2.10 to reinforce the these points. It is hard to see that much more could be said in this guide that would be effective in acting on the behaviour of political leaders / decision makers.</p> <p>The graded approach is not missing from DS477. The draft report made 21 references to the ‘graded approach’. The requirements to apply a graded approach were quoted, and Section 5 contains a specific sub-section that addresses the application of the graded approach to the management system. A reference is given to a supporting TECDOC where further information on the use of a graded approach in the application of the management system requirements for facilities and activities can be found. The appendix provides a list of potential elements of the management system for organizations involved in the management of radioactive waste or its regulatory oversight. The first paragraph of the appendix emphasises that “Not all of the elements listed will be relevant</p>
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		<p>Management system of a larger nuclear site or company In many cases the radioactive waste management systems are a part of a larger nuclear facility, such as a nuclear power plant, or a larger company owning several nuclear facilities or power plants. In these cases the management systems of the company or a larger plant may cover the activities of a nuclear waste management facility. This means that separate management systems are not needed. In fact, having the radioactive waste management integrated in the management system should be the preferred alternative to achieve a safe and efficient waste management. This should be mentioned in the document.</p> <p>A number of amendments are listed below.</p>	<p>M</p>	<p>to all organizations involved in the management of radioactive waste or its regulatory oversight. In some case, further processes and procedures may be needed. The precise definitions of, and the boundaries between, the management system elements included in an organization’s management system, and the level of detail contained in the processes and procedures, should reflect the nature of the organization concerned, its role and situation, and be applied according to the graded approach.”</p> <p>Several further points on the graded approach have been added in response to comments received at Step 11b.</p> <p>We acknowledge these comments and consider that they will be particularly relevant for consideration in General Safety Guide DS513, “Leadership, Management and Culture for Safety”, and in any successor to GS-G-3.5 “The Management System for Nuclear Installations”.</p>
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2	2.6 (g)	The selection of definite options (i.e. discharge, clearance, predisposal or disposal) for the release of SF-1 radioactive waste from regulatory control.	Discharge and clearance are not part of waste management, according to the IAEA glossary. Disposal is always under regulatory control	M	The comment about the Safety Glossary is correct but misses the point that the text is making. It is not correct that ‘Disposal is always under regulatory control’; once disposal is complete there may be agreement that the facility can be released from regulatory control (e.g. see GSR Part 1 para 2.15). In such cases, authorization is no longer necessary and can be withdrawn (in some states this has been termed ‘delicensing’). As a further example, radionuclides migrating away from a waste disposal facility (e.g. in gas or groundwater) after the end of institutional control are not under regulatory control and nor should they be. Predisposal management (e.g. storage) is not a permanent solution for radioactive waste – by definition, storage is a temporary measure, whereas discharge, clearance and disposal are permanent. The text has been clarified.
3	2.6 (i)	International best practices and lessons from industry experience, <u>if applicable.</u>	For clarification	R	The preamble to all the Safety Standards states: “The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety.” Para 2.6 recommends only that international best practices and lessons from industry experience “warrant particular consideration.” It is important that lessons are learnt from experience where this exists.
4	2.9	The long-term nature of radioactive waste management, and particularly of radioactive waste disposal , means that particular attention should be paid to the following	Delete this part. Predisposal management is mostly no long-term in nature.	R	Predisposal management of radioactive waste is often a long-term activity. For example, it is not uncommon for storage periods for radioactive waste to be several decades. These durations are significant for management systems in many ways as noted in the guide. For example, the duration of waste storage may be longer than the entire working lifetime of many employees.
5	3.3	Safety should be considered first in <u>not be compromised by</u> all business decisions, activities and associated management system documentation.	This is the correct phrase from GSR Part 2	M	The exact quote from GSR Part 2 para. 4.9(d) is included at para. 5.41. The word “first” has been deleted and a quote has been added from SF-1 concerning the requirement for optimization.

6	3.5	Senior management should ensure provide that each step of radioactive waste management, from generation of waste to pre-disposal discharge, clearance or disposal, has consistent objectives and goals in order not to compromise the safety of the subsequent steps in the waste management process.	This is an example how to avoid phrases like ‘should ensure’. See also 3.9, 3.12, 3.15, 3.17, 4.2, 4.5, 4.7, 4.11, 5.4, 5.5, 5.9, 5.17, 5.23, 5.28, 5.40, 5.42, 5.44, 5.47, 5.79, 5.85, 5.86, 5.107, 5.131 (b), 5.146, 5.151, 5.167, 5.170, 5.173, 5.174, 5.179, 5.180, 6.9, Discharge and clearance are not part of waste management, according to the IAEA glossary.	R M	The text follows standard practice for the IAEA Safety Guides; ensuring this was a part of the process of checking and revision completed in the Step 10d Technical Editor’s review. See response to comment 2 above.
7	4.2	To improve the culture for safety and help individuals to develop professionally, managers at all levels are required to should demonstrate their commitment to ensure safety shall not be compromised as an overriding priority in resource allocation , in business planning, in documentation, and in all waste management activities: see paras 3.1 and 3.2 of GSR Part 2 [5]	Safety has to be guaranteed at all times and shall not be compromised but there are a number of other factors that have to be taken into account.	R	This wording is consistent with normal practice in Safety Standards. The phrase ‘are required to’ is used where there is a requirement in an overlying Safety Standard. It is used to ensure that a Safety Guide does not inadvertently “dilute” a requirement (a “shall statement”) by presenting it as a “should statement”. The wording “as an overriding priority” is from GSR Part 2 para. 3.1 (a).
8	4.3	Senior management should demonstrate a proactive and long term approach to safety issues in decision-making, especially in long term radioactive wastemanagement programmes.	For clarification.	A	The text has been revised and is now simpler.

9	4.6	<p>Senior management should demonstrate the highest standards of personal integrity and set an example for all personnel through their direct involvement in training on safety related activities and in the oversight of safety related activities.</p> <p>Owing to the <u>If there is a</u> long-term nature of radioactive waste management, senior management should take particular care to ensure effective knowledge transfer (e.g. recording and archiving of information) and succession planning for continuing good leadership.</p>	<p>To avoid exaggeration.</p> <p>For clarification.</p>	<p>M</p> <p>M</p>	<p>The text has been deleted in response to a comment received from a Member State.</p> <p>The text has been revised.</p>
10	4.7	<p>All managers should, through their own actions, promote safe ways of working, be visibly involved in safety related activities and reinforce good practices, for example, by contributing to the development and use of international safety standards. Managers are required <u>should</u> to promote the values of the organization and encourage open, transparent and questioning behaviours: see para. 3.2 of GSR Part</p>	<p>The example is misleading and not necessary.</p> <p>For clarification. Guidance style.</p>	<p>M</p> <p>R</p>	<p>The text has been improved to present the example more clearly.</p> <p>This wording is consistent with normal practice in Safety Standards – see responses above.</p>

11	4.8	Managers should promote ways for all personnel involved in the radioactive waste management programme to participate in the development, implementation and continuous improvement of the management system (see Section 7), with the ultimate aims of attaining a higher level of safety and achieving the organization's safety goals.	Continuous improvement has many aspects for instance efficiency of the system, economic factors, and safety.	M	The text has been revised to note the requirement for optimization and the achievement of the organization's safety goals.
12	5.2	The development of a management system for an organization should take into account, <u>if appropriate</u> , the following:	Not all of the listed items are always appropriate.	A	The words 'as appropriate' have been added.
13	5.18 (a)	A statement that safety will <u>not be compromised</u> be given overriding priority , in ensuring that other relevant requirements and provisions (e.g. for nuclear security) are also met.	See GSR Part 2	M	The words 'overriding priority' are from GSR Part 2. For example, "Section 2 of GSR Part 2 establishes requirements for the responsibility for safety and for protecting people and the environment against radiation risks as an overriding priority".
14	5.19 c), g)	The management system for each organization carrying out work to implement, support, regulate or evaluate a radioactive waste management programme should include a process for the periodic review of the organization's safety policy. Such reviews should take into account the following <u>as appropriate</u> :	According to the graded approach. Particularities of the different types of facilities should be taken into account.	A	The words 'as appropriate' have been added.

15	5.29	Processes and procedures for communication and interacting with interested parties, should be designed to be suitable for the long periods of time potentially involved in <u>in case of long term</u> radioactive waste management programmes.	For clarification.	M	The text has been revised in an alternative way but to the same effect (as a result of this comment and others).
16	5.42	The organizational structure should be clear and the reasons for the structure should be explained and justified.	Organizations are free to choose their structure by themselves.	R	Organizations are indeed free to determine their own structures. The idea has been retained not because it implies any external review or control of the organization's structure, but because understanding the reasons for the structure should help personnel working within the organization to understand and improve the management system.

17	5.44	<p>Importantly, at a national level, the governmental, legal and regulatory framework should ensure that the management systems of the various operating organizations are, where necessary and appropriate, compatible with one another. The compatibility of the various management systems should be assessed and documented, and the effectiveness of the governmental, legal and regulatory framework should be evaluated, for example, in terms of assessing the competence of operating organizations, the compatibility of the management systems and operations, and the achievement of the national radioactive waste management strategy. This integration is necessary so that the boundaries between governmental arrangements and operating organizations' management systems and operations, and between different management systems and operations, are seamless and properly managed.</p>	<p>Compatibility of management systems is not necessary at all. The key issue is to ensure that the interface is functioning well.</p>	A	<p>Yes, the key issue is that the management systems need to work well together at their interfaces. This is what was meant by compatibility 'where necessary and appropriate'. The text has been revised to clarify, while retaining the key point.</p>
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18	5.56	The method for applying the graded approach should be documented in the management system. Effective management involves the proportionate application of controls to facilities and activities on the basis of various criteria, including the following <u>for example</u>	Not all of these items are valid for everything.	A	The words ‘including the following:’ are normal practice in Safety Standards. The words ‘as appropriate’ have been added.
19	5.84	In particular, organizations that generate waste should ensure that sufficient funds are available before any radioactive waste is generated.	Funding may take different forms and is the responsibility of the respective country's government	A	The text has been deleted.
20	5.99 a)	Monitoring of discharges;	The term Special processes has a specific meaning in the nuclear field (i. e. link to the quality assurance and quality control). Monitoring of discharges is already at a technical level, being supported by management system manuals and procedures approved by state supervision, that it is not appropriate to state the provisions of point 5.98 a). In addition, monitoring of discharges is not considered as special process in the predisposal management of radioactive waste.	A	The text has been deleted.
21	5.99 b)	Monitoring for clearance purposes;	See reasons stated in para 5.99 a).	A	The text has been deleted.

22	5.189 (f)	<p><u>If necessary, M</u> measures for criticality control are in place, are effective and are maintained.</p>	For clarification.	A	The words ‘if applicable’ have been added. Other comments were also made on this point.
23	6.10 (a)	<p><u>The management system should provide the individual with sufficient knowledge</u> need not only consider immediate and short term safety, but should also consider the longer term <u>about the</u> safety implications of their activities, which in some instances might not be manifested until several generations later.</p>	<p>Long-term aspects are the responsibility of the whole management system.</p> <p>A single worker cannot consider his effect for several generations</p>	A	The text has been modified along these lines – the individual should have a good culture for safety and the management system should provide him/her with the information needed.

Draft Safety Guide DS477
“Leadership, Management and Culture for Safety in Radioactive Waste Management”
(Draft dated 07.04. 2020)
Status: STEP 11

		COMMENTS BY REVIEWER			RESOLUTION	
		Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with comments of GRS) Country/Organization: Germany			Pages: 3 Date: 03.06.2020	
Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted/Modified/Rejected	Rationale
2	1.	2.6	The following aspects warrant particular consideration in developing a management system for radioactive waste management: (a) The provision of adequate <u>financial</u> resources for the safe management of radioactive waste. In accordance with the ‘polluter pays’ principle, the organization that generates radioactive waste is responsible for ensuring that funds are available for the waste to be managed properly. (b) The timescales involved in radioactive waste management can span many human generations (see para 3.7 of SF-1 [2]); this poses issues for the provision of <u>not only technical and safety - related</u> resources, <u>but</u> particularly the provision of human resources, and <u>resources</u> for knowledge management.	Clarification for better understanding what types of resources are required	M	Minor wording differences to address this comment but also those received from others.
2	2.	3.3	The senior management of an operating organization is responsible for developing <u>its goals, strategies, plans and objectives</u> policies, objectives, strategies, goals and plans (see Requirement 4 of GSR Part 2 [5]), and for coordinating activities to achieve the fundamental safety objective without unduly limiting the operation of facilityies or the conduct of activities that give rise to radiation risks. Safety should be considered first in all business decisions, activities and	Please put in line with Requirement 4 of GSR Part 2	A R	 This minor edit would cause the tense of the sentence to be inconsistent.

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

			associated management system documentation. <u>Senior management shall ensure that goals, strategies and plans are periodically reviewed against the safety objectives, and that actions are taken where necessary to address any deviations.</u>		A	Implemented to make clear that this is a quote of GSR Part 2 para. 4.5.
2	3.	3.4 Line 4	... The senior management of an organization responsible for a radioactive waste management facility or activity should be accountable for managing the facility or activity and demonstrating <u>that</u> its safety, is consistent with the national policy and strategy for radioactive waste management and in compliance with regulatory requirements.	Clarification	M	The text has been revised for greater clarity. The proposed edit would have changed the meaning of the sentence and was not quite correct.
2	4.	3.9	The clear allocation of accountabilities and responsibilities is essential to ensure safety throughout the management of radioactive waste. Senior management should ensure that it is clear within the management system when, how and by whom decisions are to be made <u>and that all steps of decision making are documented.</u>	Documentation of all steps of decision making is important	M	Implemented with minor re-wording and a cross reference to the later section on records.
2	5.	4.3	Senior management should demonstrate a proactive and long term approach to safety issues in decision-making, especially in long term radioactive waste management programmes. Managers should also demonstrate their commitment to the implementation and continuous improvement of the management system by both their words and actions. <u>decisions, statements and actions.</u>	Suggestion of formulation in line with GSR Part 2, Para 3.2.	M	The text has been deleted in response to another comment.
2	6.	5.7	Senior management should appoint individuals <u>in the organisation</u> to have specific responsibilities and authorities for the management system in the following areas: ...	Clarification	A	

2	7.	5.118	The management system should include a process and procedures to control <u>deal with</u> non-conforming items. The process and procedures should include the following actions:	Clarification	A	
2	8.	5.119 Line 7	... Any non-conformance that is important to safety that is found after the emplacement of the waste (e.g. a design fault, defective package material or damage affecting the integrity of the package) should be rectified as far as possible. If rectification of the non-conformance is not possible, its impact on safety should be subjected to a detailed analysis and <i>used as appropriate to optimize the situation.</i>	How exactly the situation could be optimized? Please give an example	A	An example has been given.

Draft Safety Guide DS477 “Leadership, Management and Culture for Safety in Radioactive Waste Management”
(Version dated 07.04.2020)
Status: STEP 11

		COMMENTS BY REVIEWER			RESOLUTION	
		Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with comments of GRS) Country/Organization: Germany			Page 1 of 3 Date: 2020-04-17	
Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted/Modified/Rejected	Rationale
3	1	2.6 (d)	... (see para 3.29 of SF-1 [2] [2]) ... (see Requirement 12 of GSR Part 5 [3] [3])	Duplication	A	No change to Word document because duplication only appeared in the pdf version and not in the Word version.
2	2	3.2 footnote 6	... This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons <u>etc.</u>	Not limited to the mentioned persons/organizations.	R	<i>Inter alia</i> and etc are not both needed. Also, the text is a quote.
2	3	3.10	... In <u>such</u> situations, continuity...	Clarification	A	
3	4	3.15	... (see para. 2.13 of GSR Part 2 [5]), ...	Wrong reference, there is no para. 2.13 in GSR Part 2	A	

2	5	5.10 (g)	Ensuring that the process and any changes subsequently adopted are aligned with the <u>safety</u> goals, strategies, plans and objectives of the organization.	Clarification	A	Modified for consistency with GSR Part 2 Requirement 4.
2	6	5.14	... should seek to adhere to the waste hierarchy - see para. 3.29 of SF-1 [2] and Ref. [23].	The reference to 3.29 of SF-1 seems not reasonable.	R	The comment is unclear. Para 3.29 of SF-1 includes: "The generation of radioactive waste must be kept to the minimum practicable level by means of appropriate design measures and procedures, such as the recycling and reuse of material."
2	7	5.40	The management system is required to be aligned with the <u>safety</u> goals and strategies of the organization.	Clarification	A	
3	8	5.42	The development of processes is addressed in paras <u>5.87–5.117</u> .	Wrong reference	A	Correct cross references have been given to the subsection 'Management of processes and activities'.
3	9	5.53	Paragraph 4.15 of GSR Part 2 [5] states (citations removed):		A	
3	10	5.93 (a) Footnote 9	... radiation protection programme are established in GSR Part 3 [25].	Wrong reference; GSR Part 3 is not referenced in [25] and not listed in References.	A	A reference to GSR Part 3 has been added to the list and the references have been renumbered.
3	11	5.109 (b) and (c)	(b) Inspection and testing, as appropriate, on receipt of items important to safety (e.g. waste packages), including verification of related certification and documentation; (e) Inspection, and testing on receipt, of items that are important to safety;	Duplication	A	

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

1	12	5.118 (c) 5.119	Assessment of the condition of the item, resolution of the non-conformance (e.g. rework, repair, use as is , or reject),... The consequences of the non-conformance of an item should be evaluated to assess whether the item can be accepted and used as it is ,...	The resolution of a non-conformance should never be just “use as is”. This should be either deleted or specified under which conditions it can be used as it is.	A	Text deleted to satisfy both this comment and a related comment from Argentina.
3	13	5.176	... para. <u>4.33</u> of SSR-5 [4] states: ...	Wrong reference	A	
3	14	7.5	... in accordance with para. 6.2 of GSR Part 5 <u>2</u> [3] [5], ...	Wrong reference	A	

DS477 “Leadership, Management and Culture for Safety in Radioactive Waste Management”
(Draft dated 7 April 2020)
Status: STEP 11

Note: Blue parts are those to be added in the text. ~~Red parts~~ are those to be deleted in the text.

		COMMENTS BY REVIEWER			RESOLUTION	
		Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with comments of GRS and BASE) Country/Organization: Germany			Page 1 of 2 Date: 2020-04-23	
Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
3	1	3.12	If an authorization for a radioactive <u>waste</u> management facility or activity is terminated at any time, then the government should ensure that it is clear which parties are responsible for the safety of both the facility and the waste.	Missing word	A	
2	2	5.17	Hence, the management system <u>documentation</u> will consist of a dynamic collection of living documents.	Expected that the documentation is meant here.	A	
3	3	5.38	A key feature of the radioactive waste management process shown in Fig. 1 is that information flows in both directions.	There is no Fig. 1	R	Fig.1 appears in Section 2 and is correctly referred to here.
3	4	5.42	The development of processes is addressed in paras <u>5.87–5.117</u> .	Reference	A	Correct cross references have been given to the subsection ‘Management of processes and activities’.

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

2	5	5.80	Human resource plans should be developed and should incorporate measures to ensure the continuous availability of a sufficient number of competent personnel throughout the lifetime of radioactive waste management facilities. For a radioactive waste disposal facility, this includes the period after waste emplacement but prior to closure , and the period of active institutional control during the post-closure period.	Not necessary to directly exclude closure here.	A	
2	6	Caption before 5.153	Application of the management system to <u>all</u> steps in the management of radioactive waste	The text and requirements refer to all steps of waste management.	A	
2	7	5.165	Site knowledge, facility design and safety arguments and assessments should be refined iteratively to develop a robust safety case and well-founded technical specifications to ensure that the facility will be safely constructed, operated and closed or decommissioned as appropriate. Typically, this proceeds as follows: (a) Development of a preliminary, conceptual design for the radioactive waste disposal <u>management</u> facility; (b)	This is not just applicable to waste disposal facilities.	A	

**TITLE
DSS477**

Leadership, Management and Culture for Safety in Radioactive Waste Management

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: M.Dionisi/N.Cipriani		Page.... of...			
Country/Organization: : ITALY /ISIN					
Date: 28 May 2020					
Comment No.	Para / Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1	1.9	<i>“This Safety Guide is intended to be used by the Regulatory Bodies and organizations with responsibilities for directing, planning, undertaking or regulating the management of radioactive waste</i>	the word “regulating” means that the Guide also addresses Regulatory Bodies, I think, but it is not so clear in this formulation.	A	
2	1.12	c) Decontamination of systems, structures, components and facilities	Often, before decommissioning of a facility, decontamination of systems, structures and components take place.	M	The term “structures, systems and components” is defined as: “A general term encompassing all of the elements (items) of a facility or activity that contribute to protection and safety, except human factors.”
3	1.12	e) Remediation e) Waste generated from remediation of incidents, including accidents, and from emergencies.	We suggest to collect e) and f)	R	The suggested change would exclude remediation of contaminated sites not contaminated by incidents, accidents and emergencies (e.g. former nuclear test sites).

4	5.62	<p><i>“Documents within the management system may include policies (statements of goals and objectives), strategies, plans, description of the operational structures of the organizations, safety cases, safety assessments, management system processes and procedures, instructions, specifications and drawings (or representations in other media), training materials, and any other documents that describe radioactive waste management processes and activities, specify requirements, or establish waste package specifications. All of these documents should be controlled. It should be ensured that document users are aware of, and use, appropriate and correct documents”</i></p>	<p>In the management system it is important a clear and formal clarification of roles and duties of each organization and the relationship between them (consistently with the point A.2.b. of the Appendix)</p>	M	<p>Paragraph 5.62 has been modified in response to other comments and so it is not sensible to address this comment now at para 5.62. But in any case, the point of the comment is already covered at paragraph 5.43.</p>
5	5.182 bis	<p>New par. after 5.182: 5.182bis The management system should ensure that the characteristics, properties and performances of waste package are qualified to demonstrate compliance with waste acceptance criteria. This qualification should be supported by appropriate studies, records of results of tests, analyses, and control of the manufacturing and conditioning process.</p>	<p>One important step in RWM is the qualification of waste packages, and it seems that this issue has not received sufficient attention in this DSS477. The waste packages should be prepared by the waste generator in a way to meet the waste acceptance criteria. On the other hand, it is essential for the storage/repository operator to ensure compliance of waste packages to be stored/disposed of, with the waste acceptance criteria. The objective of this management system is to ensure that waste packages comply with the waste acceptance criteria as approved by the appropriate national authority. Key elements addressed in the management system should be: systematic inspection of waste packages (checking documents, destructive and non-destructive examination of waste packages), characterization tests on non-radioactive mock-ups, sample collection methodologies, laboratory methods, data interpretation, assessment of activity of each waste package.</p>	R	<p>We agree with the point of the comment, but waste acceptance criteria are addressed in a later section of the document (paras 5.186 to 5.190).</p>

DS477 Leadership, Management and Culture for Safety in Radioactive Waste Management

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Page.... of.... Country/Organization: Japan Date:					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1.	General	<p>The term “long term” is used in this document. However, the implication such as mentioned in para. 2.5 which uses “very long time” should be clarified. Assumed period of time is quite different not only between storage facility and disposal facility which includes institutional control period, but also among readers. Hence relevant guidance could be emphasized.</p> <p>In addition, this draft kindly incorporates Figure 1, so the implication regarding “long term” emerges the importance of interdependency of radioactive waste management. Then, we would appreciate it if you could add guidance such as the feasibility of optimization throughout decommissioning to disposal.</p>	Clarification.	A	<p>A sentence has been added to para 2.5 to introduce some of the implications.</p> <p>The intention is to discuss the feasibility of optimization throughout decommissioning to disposal in DS526.</p>
2.	Section 1	Some description regarding DS513 or general guidance of management system would be helpful to clarify the scope.	Clarification. Although DS513 under development, such clarification would be needed.	R	We understand the comment and the reasons for it, but we cannot refer with certainty to the contents of DS513 at this time – this aspect will be considered in later Steps of the publication process.
3.	1.1/1 (p.3)	Radioactive waste is, for legal and regulatory purposes , material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels [1].	Correct citation of the definition in IAEA Safety Glossary 2018 edition.	A	

4.	1.2/1 (p.3)	Requirements for the predisposal management and disposal of radioactive waste...	Insert predisposal to be consistent with para. 1.7/line 4.	M	The text has been generalized to radioactive waste management.
5.	1.5 (p.3)	Move this paragraph to a footnote.	Both “waste” and “radioactive waste”, which have the same meaning as “radioactive waste”, are arbitrarily mixed and used. Isn't it better to move paragraph 1.5 to the footnote, not the text?	A	The use in this document of the terms ‘radioactive waste’ and ‘waste’ is not arbitrary.
6.	1.6/2 (p.3)	Could you add any references applicable to radioactive waste management?	Clarification.		
7.	1.8 (p.4)	Add items which appropriately cover high-level confidence of the long-term safety of disposal, which seems not to be included well in the current list. ex. design and characteristics of sites; quality of relevant assessments.	Clarification. Also, see comment No.8 to 10.	M	The text has been revised as a result of several comments and now refers to compliance with the requirements (which include those for the safety of disposal).
8.	1.8/2 (p.4)	safety during all steps of radioactive waste management, except transport,	As stated in para. 1.11, this guide does not address the management system for the transport of radioactive waste.	A	
9.	1.8/2 (p.4)	(d) Appropriate records of radioactive waste conditioning will be kept that enable radioactive waste identification, decisions and traceability on whether the radioactive waste meets and waste packages are compatible with the waste acceptance criteria for radioactive waste management facilities.	The waste traceability should be included in appropriate records? It would be better to align with 2.6(d) and add waste packages, rather than just radioactive waste, and assume that these meet the waste acceptance criteria.	A	The text has been revised as a result of several comments and now refers to compliance with the requirements (which include those for traceability of waste). The text of paras 1.8(d) and 2.6(d) has been made consistent with GSR Part 5 Requirement 12.

10.	1.8 (p.4)	As an important item, confidence of safety case should be added to this paragraph.	Clarification.	A	The text has been revised as a result of several comments and now refers to compliance with the requirements (which include those for the safety of disposal).
11.	Between 1.11 and 1.12 (p.5)	Revive the paragraph 1.20 in the Step 8 version. 1.20 This Safety Guide covers management systems for the activities involved in managing all types of radioactive waste. It covers waste from nuclear fuel cycle activities, including: a) Mining and processing of uranium ores and thorium ores; b) Uranium conversion; c) Uranium enrichment; d) Fuel fabrication; e) Reactor operation; f) Management (i.e. processing - including reprocessing, storage, and disposal) of waste fuel; g) Waste management (e.g. secondary waste); h) Decommissioning and environmental remediation.	These are necessary to be explicitly declared as target facilities and activities of this document.	R	The paragraph was not necessary and was deleted as part of the Technical Editor's review undertaken at Step 10. Nothing was lost by its deletion. More generally, for very practical reasons, we have to accept that changes to the document have been made for deliberate and positive reasons (principally in response to Member State's comments) so that we can move forwards. It is not really possible to go back to previous versions of the text because we know pretty much for sure that that will not be acceptable to others.
12.	1.12 (p.5)	It is better to clarify that "legacy waste" is also covered by this safety guide, although "legacy waste" is not defined in IAEA safety terminology yet.	Because legacy waste management is one of the most important issues in waste management activities.	A	
13.	1.12 (p.5)	Wastes associated with remediation are targeted, but management systems related to remediation activities are not targeted. In 1.13, radioactive waste generated from decommissioning is covered, but as other aspects of decommissioning are excluded, it is better to add a similar sentence to remediation.	Paragraph 1.12 mentions that a management system for remediation is included in this safety guide. However, there is no description of the management system regarding remediation in this guide.	A	

14.	1.14 (a) (p.5)	(a) Radioactive waste minimization <u>in the facilities and activities which generate radioactive waste;</u>	Clarification. Generation process of waste should be carefully managed to ensure the minimization of waste.	R	Radioactive waste is not only generated in facilities and activities.
15.	2.5/1,2 (p.7) Fig.1 (p.8)	Processing Conditioning , storage and disposal of radioactive waste may extend over a very long time (e.g. processing conditioning facilities and storage facilities for radioactive waste often operate for years or a few decades, disposal facility operation may potentially last more than a hundred years). In addition, “Waste conditioning” in Fig, 1 should be changed to “Waste processing.”	"Processing" should be used to consider not only "conditioning" but also "treatment". According to IAEA Safety Glossary 2018 edition, processing comprised with pretreatment, treatment and conditioning. Treatment includes volume reduction as illustrated in Fig.1 and conditioning includes packaging also illustrated in Fig.1.	A	We have also moved para 2.5 and merged it with para 2.8 – see comment number 20 below.
16.	2.6 (b) (p.7)	The timescales involved in radioactive waste management can span many human generations (see para 3.7 of SF-1 [2]); this poses issues for the provision of resources, particularly the provision of human resources, and for knowledge management and culture for safety .	The culture for safety should be inherited between generations too. Consistency with para.2.9 (d).	A	We accept the comment. We recognize that there is a variation in usage across IAEA documents in the usage of the terms: safety culture, culture for safety and nuclear security culture - this cannot at present be resolved solely within DS477. Although some people do see a material difference between the terms “safety culture” and “culture for safety”, the relevant entry in the Safety Glossary is: “safety culture - Also: culture for safety”. GSR Part 2 contains 23 instances of “safety culture” and 6 instances of “culture for safety”. We have quoted GSR Part 2 and other Safety Standards faithfully.
17.	2.7/7 (p.8)	F framework	Editorial.	A	

18.	2.7/6 (p.8)	Waste package specifications and waste acceptance criteria, <u>which are developed by the owners/operators of the facilities and interaction with regulatory body</u> , facilitate safe transfer of waste across the boundaries between management systems.	Clarification.	R	The comment is not fundamentally incorrect, but the insertion of this extra text at this point in the document would be a sidetrack and would obscure the point being made in the paragraph. Responsibilities for the development of WPS and WAC are discussed later in the document.
19.	2.7 Figure 1 (p.8)	Regarding Figure 1, more explanatory texts should be added to this Section and Figure 1 itself. For example, paragraph 5.38 refers to this figure. The information flown in both directions should be presented in Figure 1.	Clarification. Usefulness. Considering the importance of this Figure, how about moving this figure to the INTRODUCTION ?	A	Thank you for the comment about the usefulness of the figure. We have updated the figure accordingly. We are unable to move the figure to the Introduction because of the way Safety Standards are presented – one of the main impacts of the Step 10 editors review was to move material out of the Introduction.
20.	2.8 (p.8)	Paragraph 2.8 is similar with para. 2.5, so para. 2.5 should merge with para. 2.8.	To avoid duplication. The location of para. 2.5 seems not so appropriate regarding context.	A	We have moved para 2.5 and merged it with para 2.8.
21.	2.9 (p.8)	Graded approach can also be considered, according to a decrease of radio-toxicity of wastes with time after disposal. Without it, the licensee and owner would be required to sustain the items listed here with the same level of integrity for a significantly long time.	Clarification.	A	We have revised the text of the first bullet point.
22.	2.10/3 (p.9)	The text of “ <i>decision makers and leaders of the relevant organizations should place great emphasis on societal and ethical responsibilities, including the achievement of safety now and in the future</i> ” is true, however ethical responsibility would be controversial. Moderate statement would be acceptable.	Clarification. The description of the ethical point of view is limited to this paragraph, but there may be more. Consistency with other Safety Standards regarding ethical issues.	A	Text has been softened

23.	2.12 (p.9)	The contents of this paragraph are an introduction on leadership. Although Item (b) is true, it seems not a guidance, so deletion would be better. In addition, coordination with DS513 should be taken into account due to these items' cross-cutting nature.	Clarification. Cross-cutting aspects should be mentioned in DS513.	A	
24.	3.2 and others (p.10)	Some explanatory texts or footnote regarding "licensee" and "operating organization" should be added to appropriate location of a paragraph.	As a body having an immediate responsibility of the safety of a waste management facility, "operating organization" and "licensee" seems to be used interchangeably.	A	<p>The terms 'licensee' and 'operating organization' are not interchangeable and they are not used interchangeably.</p> <p>The licensee is "The holder of a current licence. The licensee is the person or organization having overall responsibility for a facility or activity."</p> <p>The operating organization may not be the holder of the Licence (e.g. it could be a contractor).</p> <p>In practice, for an authorized facility, the operating organization is normally also the registrant or licensee. However, the separate terms are retained to refer to the two different capacities.</p> <p>The footnote has been revised for greater clarity.</p>
25.	3.3/1 (p.10)	A word of "senior management" appears on p.9 (Para.2.12). So, footnote 7 should be attached to para. 2.12 instead para. 3.3.	Editorial.	A	
26.	3.3/2 (p.10)	Regarding citation of Requirement of GSR Part 2, the latter paragraph shows relevant texts, hence the paragraph number should be added such that (see Requirement 4 of GSR Part 2 [5] shown in paragraph 5.13.)	Usefulness.	A	

27.	3.4/1-3 (p.10)	The requirement for "safety policy" is also mentioned in Requirement 3 of IAEA safety standards series, No. SSR-4, Safety of nuclear fuel cycle facilities (2017). Why is this requirement not referred?	Clarification.	A	Requirement 3 for a "safety policy" is now explicitly mentioned at para 3.3. It is better to refer to a General Requirement than a Specific one.
28.	3.6(b) (p.10)	The characteristics of the site and the design of the facility.	Safety Case should consider the characteristics of the design of the facility.	M	We agree but due to other comments received, this particular comment has been dealt with by referring to the guidance on the safety case.
29.	3.10/4 (p.11)	In such situations, continuity of responsibility for safety is necessary throughout."	Quote correctly.	A	
30.	3.11/4-6 (p.11)	The responsible body at any given time is required to have an adequate management system that meets Requirements 6 of GSR Part 2 [5] to ensure that safety is not compromised.	Only the requirement 6 directly refers to the prevention of such compromises, and the requirements 7 to 8 are not directly related to the compromises of safety. It is enough to cite Requirement 6 only.	R	We prefer to highlight the applicable requirements – the sentence is not incorrect.
31.	3.13/4 (p.12)	Change 'other institutional control measures' to 'other passive institutional control measures'.	The word "passive" should be explicitly added just before the word "institutional" because "the end of active institutional control" is already mentioned in 3.13.	A	
32.	3.15/2 (p.12)	see para. 2.13 of GSR Part 2 [5])???	Since GSR Part 2 does not have para. 2.13, it is considered to be a mistake of "para. 2.13 of GSR Part 1 (Rev. 1) [29]".	A	

33.	3.19/1-3 (p.12)	<p>The following new expression is recommended as 3.19.</p> <p>The hazard assessment should take into account the characteristics of the waste, of the waste management facility, and of the site and its vicinity, at each stage in the lifetime of the facility (e.g. operation for all the facility, decommissioning for the waste management facility except the disposal facility, closure and post-closure for the disposal facility).</p>	<p>The waste management facility here should be clearly divided into the disposal facility and the other waste management facility, because the latter is related to decommissioning while the former instead related to closure and post-closure. Although the expression "as appropriate" might mean such difference, the relevant description here in the sentence is obliged to be considered confusing and is recommended to be differentiated explicitly in order not to erroneously understand the corresponding relationship.</p>	M	<p>The words ‘as appropriate’ were included to indicate that decommissioning should be considered for all facilities that would be decommissioned and that closure should be considered for the parts of disposal facilities that would not be decommissioned. But explaining this in detail is not central to the purpose of the paragraph and so we have proposed deletion of the in parenthesis.</p>
34.	4.3/1 (p.13)	<p>demonstrate a proactive and long-term sustaining approach</p>	<p>To avoid duplicate use of “long-term” which is used also in the next line.</p>	M	<p>Due to other comments received, this has been fixed in a slightly different way.</p>
35.	4.3/3 (p.13) 4.8/2 (p.14) 5.5/2 (p.15) 5.7/(a) (p.16) 5.18 (e) (p.18) 7.19/1, 3 (p.74)	<p>continuous improvement = > continual improvement (Excluding description in GSR)</p>	<p>The term "continuous" is not applicable in management system. The activity does not need to take place in all areas simultaneously.</p>	R	<p>GSR Part 2 uses ‘continuous’ and ‘continuously’. GSR Part 2 does not use ‘continual’. We remain consistent with GSR Part 2.</p>
36.	4.7/1 (p.13)	<p>Only this paragraph uses not “managers” but “all managers.” The implication of the word, “all managers”, is somewhat unclear. Is there any specific reason the difference? Some clarification would be needed.</p>	<p>Clarification.</p>	A	<p>We propose to delete the word ‘all’.</p>

37.	5.2 (c) (p.15)	Best practices in the nuclear and radioactive waste management industries;	The best practice is not unique for the whole nuclear and radioactive waste management industry in general, and is basically a case specific one. Hence plural notation such as best practices or good practices is appropriate.	A	
38.	5.5/6 (p.15)	and waste disposal facilities. --> , and waste disposal facilities and activities .	It is considered more appropriate to add activities for waste disposal facilities.	A	
39.	5.11/1 (p.16,17)	Previous version of this document (i.e. Step 8 version, para. 4.10) mentions “Roles and responsibilities for safety, and human and environmental protection in waste management and disposal...” Current draft changes the phrase to only “ safety .” What does this amendment mean?	Clarification. Confirmation.	A	It was decided to use the term safety in its generalized form (i.e. to mean protection and safety). Para 3.1 of SF-1 states: “For the purposes of this publication, ‘ <i>safety</i> ’ means the protection of people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks. ‘ <i>Safety</i> ’ as used here and in the IAEA safety standards includes the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material; it does not include non-radiation-related aspects of safety.”
40.	5.18 (j) (p.18)	A commitment to minimizing the generation of radioactive waste and disposing of radioactive the waste	Clarification. Minimization of the radioactive waste generation should be explicitly noted.	A	

41.	5.20 (p.19)	<p>Replace this paragraph by paragraphs 4.18 and 4.19 in the Step 8 version.</p> <p>4.18 The establishment of strategies, goals, plans and objectives is a primary role of senior management, and senior management should provide the direction for the organization and whilst also ensuring a high level of safety. This is particularly important in radioactive waste management because of the long time periods involved, the interdependencies and the potential changes in responsibility. All personnel within the organization should understand the direction set by senior management and should feel personally accountable for meeting its objectives. As a minimum, the priorities and objectives of the organization should be such as to ensure that regulatory requirements continue to be met.</p> <p>4.19 The policies of a waste management organization should cover safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic elements, but should also reflect the commitment of senior management to attaining their goals and objectives, their priorities, and the means by which continual improvement will be implemented and measured, including the items listed in para. 4.17.</p>	5.20 is too abstract. The original paragraphs are more concrete as a Guide.	R	<p>All of the points included in the Step 8 version of paras 4.18 and 4.19 are still included in the Step 11 version – nothing was lost on their deletion and there have been many comments urging the elimination of unnecessary duplication.</p> <p>As noted above, for very practical reasons, we have to accept that changes to the document have been made for deliberate and positive reasons (principally in response to Member State’s comments) so that we can move forwards. It is not really possible to go back to previous versions of the text because we know pretty much for sure that that will not be acceptable to others.</p>
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42.	5.30 (c) (p.22)	<p>Previous version of this document (i.e. Step 8 version, para. 4.26(b)) mentions “safety, human health and environmental protection, security and economic impacts of the waste management activities.” Current draft deleted the phrase. So, there is no aspect regarding environment protection.</p> <p>We propose following to include environmental protection.</p> <p>The safety, societal, environmental and economic impacts and the environmental protection of the radioactive waste management activities;</p>	Clarification.	R	As noted above, we are using the term safety in its generalized form (i.e. to mean protection and safety).
43.	5.32-5.38 (p.22-24) 4.11(p.14), 5.5(p.15), 5.43(p.24), 5.78(p.33)	Interdependency is also mentioned in para. 3.22 of SF-1, so it may also be referred in appropriate contexts.	Usefulness.	R	You are correct; however, we are in general writing Guidance on GSR Part 2 and the logic is that the Guidance refers to the Requirements and the Requirements in turn refer to the Fundamentals. We have referred to SF-1 directly in a few cases where this was particularly helpful, but in general this is not the practice.
44.	5.33/p.22 5.78/p.33 and so on	<p>Interdependencies and dependencies in radioactive waste management</p> <p>Only interdependencies are dealt with, however dependencies among the steps in radioactive waste management should also be addressed according to the real situation.</p>	Are the interdependencies and dependencies considered appropriate? The stream in radioactive waste management has to be directional from upper radioactive waste management down to lower one. Rather, problems of dependencies of latter waste management steps against the former steps should be highlighted and appropriately discussed and addressed.	R	<p>GSR Part 5 only uses the term interdependencies - it does not distinguish them from dependencies.</p> <p>Maybe we do not understand your comment correctly, but we do not think that the words ‘dependencies’ and ‘interdependencies’ imply some different directionality.</p> <p>We believe that the text does explicitly address the dependencies among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option.</p>
45.	5.42/4 (p.24)	[87-17] → [87- 117] in this section	Editorial.	A	

46.	5.49/2 (p.25)	...that there is an iterative interaction among site characterization, facility design and safety assessment.	The site characterization should be incorporated to iterative cycle.	R	We view site characterization as an important part of safety assessment. Its importance will vary from facility to facility and from site to site. We want to encourage the use of safety assessment for guiding research and characterization activities and not to suggest site characterization is necessary in all iterations of the design-assessment cycle.
47.	5.56 (j) (p.27)	...on nuclear power generation and radioactive...	Clarification.	A	
48.	5.57 (l) (p.28)	The scope, age maturity and...	What does the "age" of the safety case and assessment mean? How is this relevant for the consideration of a graded approach. "Maturity" seems better fit.	A	With minor modifications due to other, similar, comments received.
49.	5.64/new(e) (p.30)	The following is recommended to be newly added as (e). "Chemical properties including distribution coefficient of infillings such as mortar in the waste package"	Such information as distribution coefficient is necessary for post-closure long-term safety assessment for disposal. Such chemical information cannot be obtained after the waste package is already manufactured unless it is measured before packaging.	M	This is already covered by bullet point (b), but we have made that point a bit more explicit because of this comment.
50.	5.65/4 (p.31)	All important safety and security related information...	Clarification. Relevant description is found in the last text of para.3.12.	R	In concept you are correct, but this is a safety guide, and security is dealt with in the Nuclear Security Series publications.
51.	5.66 (p.31)	As additional information to record, interaction with regulatory body (e.g. indications from regulator and their responses) would be listed.	Practical sense, it is important.	A	

52.	Between 5.83 and 5.84 (p.34)	Revive paragraph 4.73 in the Step 8 version. 4.73 Knowledge management includes the assessment, structuring and integration of data and information into an interpreted, synthesized form that embodies the current knowledge and understanding on the matters concerned. The preservation and transfer of knowledge can also be considered from the point of view of risk management. The risk perspective raises the question of priorities: although ideally all information and knowledge should be preserved, practical efforts should be guided by considerations of the risks arising from the failures in this respect. Sometimes good syntheses of the information and knowledge may be more useful to future generations than the original vast amount of information (e.g. individual waste transfer notes).	The contents of knowledge management should be explained somewhere.	R	This is exactly the type of general information and guidance that would be appropriate for inclusion in DS513. As noted above, for very practical reasons, we have to accept that changes to the document have been made for deliberate and positive reasons (principally in response to Member State's comments) so that we can move forwards. It is not really possible to go back to previous versions of the text because we know pretty much for sure that that will not be acceptable to others.
53.	5.90 (p.37)	Arrange the numbering of items.	Editorial.	A	
54.	5.93 (p.39)	Arrange the numbering of items.	Editorial.	A	
55.	5.94 (p.39)	Arrange the numbering of items.	Editorial.	A	
56.	5.99, before (a) (p.40)	Revive (a) of paragraph 4.92 of Step 8 version. a) Analytical methods such as sampling protocols for waste characterization or process control;	Characterization and clearance are the important processes in the predisposal management.	A	This is a list of examples of Special Processes not important processes. The original bullet point has been re-written for greater clarity.
57.	5.117/2 (p.45)	and throughout each stage in facility development in an iterative, systematic and transparent manner,	Optimization of processes in the radioactive waste management should be understood as an iterative, systematic, and transparent evaluation of options.	A	

58.	5.117/(c)	For environmental impact assessment as well as for ongoing understanding of unaffected baseline conditions: minimizing disturbance of the environment;	Minimizing disturbance of the environment should be situated not only for environmental impact assessment, but for ongoing understanding of unaffected baseline conditions. Therefore, the latter should be also highlighted and shown similarly.	M	Implemented in bullet point (b)
59.	5.117/(g)	‘intended density’ should be replaced by ‘intended hydraulic conductivity’	The intended density shown here would not be very rigid from scientific viewpoint of minimizing the flow of water to the waste. Instead, "intended hydraulic conductivity" should be shown here although the parameter of ‘density’ would replace the hydraulic conductivity and be addressed when real construction work.	A	Minor re-wording
60.	5.119/3 (p.46)	If none of these options is practicable or the use of counterfeit and fraudulent Items [x] are figured out, the item should be rejected,... [x] IAEA Nuclear Energy Series No. NP-T-3.26, Managing Counterfeit and Fraudulent Items in the Nuclear Industry.	Although our comment regarding addition of some description of CFIs to Appendix II is shown as accepted in resolution table, Appendix II is deleted. So, we propose newly addition of a phrase to this paragraph. Usefulness.	A	Apologies, your comment reveals one difficulty in dealing with many sets of review comments in a sequence. The comment is accepted, and appropriate edits have been made at paras 5.117 and 5.118.
61.	5.124 (p.47)	A closed parenthesis is missing.	Editorial.	A	
62.	5.131 (a)/1 (p.49)	The management system should provide confidence ensure that	Clarification.	A	

63.	5.152/7 (p.53)	to guide stepwise and iterative decision-making on the selection	Optimization of processes in the radioactive waste management should be understood as an iterative, systematic, and transparent evaluation of options.	A	
64.	5.155/7-8	Insert 'isolate' after 'concentrate and contain'.	Fundamental concept of 'isolate' is missing here. That is, by adding 'isolate', the expression of 'delay and decay', 'concentrate and contain', 'isolate' and 'dilute and disperse' would be desired considering generic flow.	A	
65.	5.159/4, 5.164/1&4	Change 'intrusive' to 'disturbing'..	The expression, 'disturbing' would be better than 'intrusive' from the viewpoint of adequate implications.	M	'intrusive' deleted.
66.	5.176/1 (p.58)	With regard to the construction of radioactive waste disposal facilities, para. 4.33 of SSR-5 [4]	Editorial.	A	
67.	5.176/3 (p.59)	"Sufficiently flexibility in engineering	Editorial.	A	
68.	5.179 (p.59)	Records should be kept of the radioactive waste inventory of individual waste packages, particularly in cases where the waste stream might be heterogeneous. =<The meaning of inventory is ambiguous. It is impossible to obtain all nuclides inventories of individual waste packages. The inventory of appropriate nuclides that affect safety and facility design would be intended.	Clarification.	A	

69.	5.189 between (d) and (e) (p.61)	Revive item (e) of 4.162 in Step 8. e) Levels of surface contamination and surface dose rates meet requirements;	There is no reason to delete this item.	R	This is included in point (a).
70.	5.189 (h)(iii)/2 (p.61)	replacement, as needed, and for the detection of	Editorial.	M	The text has been clarified.
71.	5.190 between (d) and (e) (p.62)	Revive item (e) of 4.163 in Step 8. e) Levels of surface contamination and surface dose rates meet requirements;	There is no reason to delete this item.	R	This is included in point (a).
72.	5.190 (i) (p.62)	Suitable locations and space exist-exit within the facility for the waste. The management system for geological disposal facilities may also need to include a process and procedures to ensure ...	Editorial.	R	Comment is incorrect. The text is about whether there is enough space in the facility.
73.	5.191 (a)/2 (p.62)	(a) Video surveillance of the waste management processes (e.g. waste immobilization by cementation or vitrification , testing of package closure welds);	Clarification.	A	Just one more example.
74.	5.210 (new) (p.67)	<i>Monitoring of radioactive waste management facilities</i> 5.203-5.209 <i>Passive institutional control of radioactive waste disposal facilities</i> 5.210 (Concisely but adequately the introduction and explanation of the passive institutional control should be addressed.)	The monitoring ends in post-closure active institutional control of disposal facilities. This is OK, however, passive institutional control should also be explained as last one of Application of the management system to steps in the management of radioactive waste . Passive institutional control has to be newly addressed in Chapter 5. It is necessary because people are anxious about how long-term safety will be acquired after active institutional control.	R	The difficulty here is that once the facility has been released from regulatory control (de-licensed), there is no operating organization or regulatory body and we would be giving guidance to Government essentially about the application of the legal and regulatory framework.

			<p>The next expression is already discussed in 1.14, p.5-6.</p> <p>1.14 This Safety Guide also covers management systems for related process and activities, including:</p> <p>(a) ...</p> <p>(k) The institutional control of radioactive waste disposal facilities; covering both active control (e.g. nuclear security, surveillance and monitoring) and passive control (e.g. preservation of records, and restricted land use).</p>		
75.	6.10 (a)/2 (p.68)	Individuals need not only consider immediate and short term safety, but should also consider the longer term safety implications of their activities, which in some instances might not be manifested until several generations later.	Contradicting?	M	We do not believe that this is contradictory. The text has been revised slightly in response to this and other comments received.
76.	6.10/(e) (new) (p.68)	<p>The following (e) should be newly added.</p> <p>(e) Pre-closure safety such as operational safety and post-closure safety sometimes contradict each other. Those examples would be oxygen for work and reducing conditions for low solubility, use of incombustible materials and its adverse affect for barrier system, and mitigation (inflow and pumping-up) of high-pressure of groundwater and adverse affect for stagnant groundwater condition. Operational pre-closure safety and long-term post-closure safety must be consistently dealt with in a safety case and realized adequately.</p>	Contradiction between addressing for pre-closure operational safety and that for post-closure long-term safety has to be taken into consideration. How to address the contradiction in order not to affect adversely safety functions of barrier systems has to be very important issue.	A	Modified text.

77.	7.3 (p.70)	Delete this paragraph.	<p>Although it is true, the implication of this text could expand such that further guidance on management system are provided in ISO 9001. Is it an appropriate statement as IAEA Safety Standards?</p> <p>In addition, para. 5.2 mentions “<i>The development of a management system for an organization should take into account the following:</i> <i>(a) International standards such as ISO 9001:2015 for quality management systems [20], ISO...</i>”</p>	A	
78.	7.8/(d) (p.72)	<p>(d) During the operation stage</p> <p>(i) All prerequisites are being met before waste is emplaced (e.g. waste packages are being checked against the acceptance criteria, and these criteria are being satisfied);</p> <p>(ii) Waste is being emplaced in accordance with the safety case and the authorization issued by the regulatory body;</p> <p>(iii) Backfilling, sealing and other relevant activities of emplacement rooms or drifts are being carried out in accordance with the safety case and the authorization issued by the regulatory body;</p> <p>(iv) Monitoring is being conducted in accordance with the monitoring programme and the associated records are being maintained, and that monitoring instrumentation has not degraded in service</p>	<p>The stages of the operation, closure and post-closure are strongly recommended to be divided at least into the stage of the operation and the stages of the closure and post-closure, because the closure itself has to be conducted after the regulatory permission is gained that all of the regulatory requirements are met so that an implementer can start the closure without considering retrieval any more. The operation stage in which retrievability has to be dealt with as a fundamental policy and the stages of closure and post-closure in which the retrievability does not have to be considered any more are</p>	A	<p>Note that it is quite likely, particularly in geological disposal facilities, that some disposal areas will be operating and receiving waste at the same time that other areas are being backfilled etc.</p>

		<p>and has not been modified without proper change control;</p> <p>(v) The safety case and safety assessments are being periodically reviewed in a systematic, planned manner and are being upDate: 24-04-20d as necessary in the light of new data, and any necessary actions are being taken to ensure the remaining operational safety of the facility and the post-closure long-term safety;</p> <p>(e) During the closure and post-closure stages</p> <p>(i) Backfilling, sealing, plugging and other relevant activities of the facility are being carried out in accordance with the safety case and the authorization issued by the regulatory body;</p> <p>(ii) Active institutional control such as monitoring is being conducted in accordance with the monitoring programme as appropriate and to a certain period after closure whether or not it is based on regulatory demand or societal necessity, and the associated records are being maintained. Monitoring must be conducted in order not to adversely affect safety functions of barrier systems;</p> <p>(iii) Passive institutional control such as markers, preservation of records and restricted land use is being conducted not only after active institutional control but concurrently with active institutional control.</p> <p>(iv) The safety case and safety assessments are being periodically reviewed if needed according to regulation to ensure that no harmful effects arising from the facility can be recognized;</p>	<p>strictly differentiated due to essential difference of the management system.</p>		
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		(v) Appropriate information on the condition of the radioactive waste disposal facility has been transferred if responsibility for the facility has been transferred.			
79.	7.12/2 (p.73)	...any potential improvements that are identified and are implemented.	Editorial.	A	

**DS477, Leadership, Management and Culture for Safety in Radioactive Waste Management
(Revision and Combination of GS-G-3.3 & GS-G-3.4) (Step 11)**

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Page 1 of 2 Country/Organization: Republic of Korea / Korea Institute of Nuclear Safety (KINS) Date: 07/05/2020					
Comment No.	Para / Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1	3.15 / Line 2	... information (see para. 2.13 of GSR Part 2 [5]), ...	Para. 2.13 of GSR Part 2 does not exist. The number of para. has to be re-checked and corrected.	A	
2	5.18 (d) / Line 2	(d) A statement that it will be appropriate to the objectives and the activities of the organization, and contain statements on how societal and economic considerations are taken into consideration with regard to safety.	Clarification	A	
3	5.42 / Line 4	... The development of processes is addressed in paras 87–17.	The paras numbers have to be re-checked and corrected.	A	
4	5.43 / Line 6	Consequently, management systems need to be flexible and able to manage change as described further in Section 6.	Descriptions regarding 'being flexible' and 'managing change' do not seem to be in Section 6.	A	

TITLE: DS-477 Leadership, Management and Culture for Safety in Radioactive Waste Management (Step-11)

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: PNRA/WASSC Member		Page 1 of 4			
Country/Organization: Pakistan/PNRA		Date: May 21, 2020			
Comment No.	Para / Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1)	Section 1.1	Material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels as established by the regulatory body.	Radioactive waste terminology should be defined as mentioned in IAEA Safety Glossary, Edition 2018.	A	
2)	1.8	The objective of this Safety Guide is to provide recommendations on developing and implementing the management system for safety during all steps of radioactive waste management, including processing (pretreatment, treatment, and conditioning), storage and disposal, and during related processes and activities, including characterization of waste and clearance as mentioned at para 1.14.	May be added to make it consistent with the scope as given at para 1.14.	A	
3)	3.3	The senior management ⁷ of an operating organization is responsible for developing policies, objectives, strategies, goals and plans goals, strategies, plans and objectives (see Requirement 4 of GSR Part 2 [5]), and for coordinating activities to achieve the fundamental safety objective without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks.	Requirement 4 of GSR Part 2 is not on the development of policies. It is related to goals, strategies, plans and objectives which states that Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy. Further, the order of text " goals, strategies, plans and objectives " may be made same as per requirement 4.	A	The order of paras 3.3 and 3.4 has been swapped in order to keep the best possible consistency with GSR Part 2 in the order of discussing policies, goals, strategies, plans and objectives.

4)	3.8	<p>.....The senior management of processing facility, storage facility and disposal facility may also be addressed in the management system about the management of resources both human resources and financial resources.</p>	<p>This para address management of resources about the radioactive waste generator only. Therefore, management of resources in the management system at other facilities may also be added because radioactive waste is typically managed by a series of organizations, for example, radioactive waste generated by one organization may be transferred to another for processing (pretreatment, treatment and conditioning), to another for storage, and to yet another for disposal as mentioned at para 2.7 of DS.</p>	A	<p>Implemented so that the text addresses all organizations that manage radioactive waste.</p>
5)	3.15	<p>Please recheck the referred para i.e. 2.13 as given below because it does not exist in GSR Part 2. "The operating organization is required to provide the regulatory body with all necessary safety related information (see para. 2.13 of GSR Part 2 [5]), and should initiate interactions with the regulatory body as soon as possible and before conditioning of the waste."</p>	<p>Please rectify the reference as Para. 2.13 does not exist in GSR Part 2.</p>	A	<p>Implemented consistent with GSR Part 2 para. 2.13.</p>
6)	Section 4	<p>Please address information about para 3.3 of GSR Part 2 in the DS.</p>	<p>Information about para 3.3 of GSR Part 2 which states that "Managers at all levels in the organization: (a) Shall encourage and support all individuals in achieving safety goals and performing their tasks safely; (b) Shall engage all individuals in enhancing safety performance; (c) Shall communicate clearly the basis for decisions relevant to safety" is not addressed in the DS.</p>	A	<p>A new paragraph has been added at para. 4.12.</p>

7)	5.40	The management system is required to be aligned with the goals and strategies of the organization: see para. 4.8 of GSR Part 2 [5].	Para 4.8 of GSR Part 2 does not address strategies. Further, para 5.40 of DS refer to para 4.9 of GSR Part 2 which states that "The management system shall be applied to achieve goals safely, to enhance safety and to foster a strong safety culture by:" and does not require to achieve strategies so may be deleted to make consistency.	A	
8)	5.42	The management system is required to specify the structure of the organization and define the processes, responsibilities, accountabilities and , level of authorities of individuals and interfaces within the organization and with external organizations : see para. 4.11 of GSR Part 2 [5].	Para 4.11 of GSR Part 2 states that "The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system." so may be included.	A	Implemented consistent with GSR Part 2 para. 4.11.
9)	Section 7.21	The information about "independent assessment of leadership for safety and of safety culture" is not provided.	Para 6.10 of GSR part 2 states that "Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety", therefore, independent assessment may be included.	A	
10)	Footnote 9	Requirements for the protection of workers, including the establishment of a radiation protection programme are established in GSR Part 3 [25] .	IAEA GSG-6 is mentioned at reference [25]. Please add GSR Part 3 in references and assign a reference number to footnote 9 accordingly.	A	

Form for Comments

DS477 THE MANAGEMENT SYSTEM FOR THE PREDISPOSAL MANAGEMENT AND DISPOSAL OF RADIOACTIVE WASTE >

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bengt Hedberg Country/Organization: Sweden/Swedish Radiation Safety Authority Date: 2020-05-29					
Comment No.	Para / Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1	General	General comment	We would like to thank the secretariat for having taken due consideration and efforts to improve the draft document according to our comments on the previous version circulated for MS comments.	A	
2	General	General comment	<p>The structure and content of the document has changed considerably compared to the draft version distributed to MS for comments.</p> <p>Given this situation we would recommend the secretariat to consult WASSC chair and WASSC members on the possibility and potential benefit to allow MS to comment also on this updated draft version of the document.</p> <p>We are aware of that such a procedure might delay the development of the document somewhat at this stage. We are all the same convinced that such delay might very well be compensated by a smoother process for the further development and final approval process.</p>	R	<p>We understand this is clearly intended to be a helpful comment. It is not a specific comment on DS477 though and cannot, therefore, be addressed directly; it is more of a suggestion to change the process being followed. The secretariat has, therefore, to reject the comment at this time for the following reasons:</p> <p>Structure: The structure of guidance provided in DS477 has not changed significantly. The structure follows that of GSR Part 2 as was planned when the DPP was approved at Step 3, as was the case at Step 8, and as is still the case now at Step 11. Member States' comments at Steps 8 and 11 did not question the structure. A result of the Step 10d Technical Editor's review, which incidentally did not change the essential contents of the Safety Guide, was that some information was moved from the Background subsection in Section 1 into a new Section 2. This was part of bringing the Safety Guide up to date in terms of currently accepted practice in presenting Safety Standards. The Step 10d Technical Editor's review also included checking that the contents of the Safety Guide reflects properly the structure of the overlying requirements publications, checking that all quotes of safety requirements and definitions are correct, removing unnecessary duplication, improving consistency in the use of terminology, improving the clarity of the language, checking of references, and checking the quality of the document.</p> <p>Content: The content of the guide has developed in some ways since Step 8 - this has been in direct response to Member States comments. Notable changes included the insertion of a figure illustrating the overall waste management process (largely at the</p>

			<p>We would in this context like to express our position such that we value quality before speed, i.e. we prefer to allow some additional time for making sure that the document will meet the quality standard set for IAEA Safety Standards.</p>		<p>suggestion of Sweden), and developing a few new paragraphs to give additional guidance on the identification of interested parties (at the request of the UK and others).</p> <p>Process: It is not the Secretariat's role to take decisions on suggestions to deviate from the SPESS B process. It is the prerogative of the WASSC next at Step 11c to decide on the actions for proceeding to the next step. We consider, therefore, that the best course of action is for the WASSC to discuss the updated draft of the Safety Guide at its next meeting in the normal way. The next meeting of the WASSC, initially planned from 24 to 26 June 2020, is replaced by an online review and approval procedure.</p> <p>Delay: This set of comments was the only one to suggest a delay to the process. We note that the DPP for this Safety Guide was approved in 2013 and that the process for developing the Safety Guide has already been significantly delayed (e.g. in particular due to the time it took to develop and publish GSR Part 2). The current Safety Guides on the topic were published over ten years ago in 2008, and we receive an increasing number of requests from Member States for updated guidance in this area. We are not convinced that Member States' interests would be best served by further delay. In addition, it is unclear from these comments what would actually be done in the extra time requested or what benefit would accrue. The actions suggested in the comments below have either already been conducted part of the Step 10d Technical Editor's review or have been addressed in the draft which will go before the WASSC at its next meeting in July 2020. Comments have been received at Step 11 from 13 Member States and one other organization - these comments were not contentious, and they have all been attended to, as described in the associated Resolution Tables.</p>
3	General	General comment	<p>We propose to use subheadings to indicate what element(s) are addressed in different (sub)sections of the document, to facilitate for the reader.</p>	R	<p>The Step 10d Technical Editor's review included a careful review of the headings and sub-headings used in the safety guide. The headings and sub-headings are based on those contained in the overlying requirements publications. The current draft is consistent with currently accepted practice in presenting Safety Standards.</p>
4	General	General comment	<p>We find the structure and logic of the document to be somewhat inconsistent when it comes to reference to overarching requirements. We propose to review and ensure consistency with IAEA standards.</p>	R	<p>The comment is not specific. The proposed review has already been done as part of the Step 10d Technical Editor's review.</p>

5	Para 1.8	General comment	<p>We have a concern as regards terminology related different meaning of “management system”. Our concern relates to the potential confusion for the reader between “waste management programme”, “waste management system”, “management system for radioactive waste management” and “management system for individual activities within a programme, but not the programme itself”. We propose to up front in the document define those concepts and make sure that they are used consistently throughout the document.</p>	A	<p>This comment discusses the use of the following terms:</p> <ul style="list-style-type: none"> • The definition of ‘management system’ is given in footnote 1 to paragraph 1.2. • The term ‘radioactive waste management’ is defined in the Safety Glossary as “All administrative and operational activities involved in the handling, pretreatment, treatment, conditioning, transport, storage and disposal of radioactive waste” – a footnote has been added to paragraph 1.2. • The term ‘radioactive waste management programme’ is not a new term and it is used in various Safety Standards including, SSR-4, SSG-40, SSG-41, SSG-45, GS-G-3.3, GS-G-3.4, NS-G-1.13, NS-G-2.7, NS-G-4.5, NS-G-4.6 and WS-G-5.1. However, the term is not included in the Safety Glossary (for unknown reasons) and so we have added a footnote of explanation to DS477. • The term ‘wastemanagement system’ is not defined in the Safety Glossary but is used to describe a waste management facility and its surrounding environment relevant to safety. The term is directly analogous to the term ‘disposal system’. For example, (and paraphrasing the Safety Glossary), a waste disposal facility is developed at a suitable location in a host environment and together the properties of engineered barriers of the facility and of the surrounding environment and other administrative controls comprise a disposal system that provides safety. <p>The correct and consistent use of these terms in the Safety Guide was checked during the Step 10d Technical Editor’s review and has been checked again as a result of this comment. Combinations of these terms in the text do not make new terms. The text “management system for individual activities within a programme, but not the programme itself” noted in the comment does not appear in the Safety Guide. We suggest that trying to get a agreement on precise definitions of the terms that are not in the Safety Glossary would likely be difficult and cause further unnecessary delay.</p>
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COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bengt Hedberg Country/Organization: Sweden/Swedish Radiation Safety Authority Date: 2020-05-29					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
6	Para 1.8	The objective of this Safety Guide is to provide recommendations on developing and implementing the management systems <u>to ensure</u> for safety during all steps of radioactive waste management, ...	An (integrated) management system integrating all relevant aspects of the operation (not only safety) should be in place for each organisation involved in waste management / the waste management process.	M	The use of 'for' is consistent with GSR Part 2, leadership <u>for</u> safety, management <u>for</u> safety, etc...
7	Para 2.6 (e)	The possibility that national authorities <u>or state organisations</u> might need to take responsibility for radioactive waste because this responsibility cannot be discharged by the generator of the waste.		A	
8	Para 2.6 (h)	Ensuring that, wherever possible, radioactive waste is contained, stored and <u>eventually</u> disposed of in a passively safe condition.	Not all radioactive waste need to be disposed of. Also, the situation in many countries are such that there is currently no disposal solution insight. And safe storage is considered an appropriate management option until a storage solution is in place.	M	The text has been revised in a way that avoids the implications either that all waste requires disposal, or that disposal for waste that does require disposal can be deferred indefinitely.

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bengt Hedberg Country/Organization: Sweden/Swedish Radiation Safety Authority Date: 2020-05-29					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
9	Para 2.7 and figure 1	We propose to expand the explanatory text and better explain the basis for the “cradle-to-grave” waste management process and in more detail address the aspect of leadership for safe management of waste for – and within – this process.	We consider understanding of the “cradle-to-grave” waste management process to be an important prerequisite in order to establish appropriate national arrangements for safe management of radioactive waste and spent fuel. And a key element is the proper leadership for safe management of radioactive waste and spent fuel. Especially as regards interfaces between the overall responsibility for managing the radioactive waste and spent fuel safely in the long term, resting with the waste generator, and the responsibility for safe management of the radioactive waste in the preceding management steps.	R	<p>This is a proposal for further development work, rather than a specific comment on the draft Safety Guide. As such it is not directly implementable.</p> <p>As noted above, the development of this Safety Guide has been in process since 2013. We have received various requests from Member States for updated guidance in this area and we are not convinced that Member States’ interests would be best served by further delay to undertake this type of document development work.</p>
10	Para 2.9 (c)	Comment: First time financial aspects (costs) are mentioned. We think that the importance of this element should be highlighted in some way earlier in the document.		R	Comment is incorrect. Financial aspects are first mentioned at para 2.5(a). There is no opportunity to introduce financial aspects even earlier in the document.

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bengt Hedberg Country/Organization: Sweden/Swedish Radiation Safety Authority Date: 2020-05-29					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted/ Modified/ Rejected	Rationale
11	Para 2.12 (a)	Leadership for safety depends on senior management possessing several qualities including the following: a) Leaders should have political awareness and judgement <u>to avoid being unduly influenced by non-safety related factors;</u>	Current wording could be understood such that the senior management should take political considerations in concern in e.g. decision-making.	M	The text has been revised in a slightly different way in response to this and other comment received.
12	Para 2.12 (b)	We propose to delete Leaders should be respected in the international radioactive waste management and scientific communities;	We do not consider this to be a quality to be possessed but rather something that a person can achieve by e.g. proper and responsible behaviour.	A	
13	Para 3.6, 3.7 and 3.18 and 3.19	We propose to review the draft document as regards logical sequence of element.	We think that addressing of the safety case comes rather sudden in paras 3.5 and 3.6, without an appropriate context. As does the addressing of the safety assessment in paras 3.18 and 3.19. We think those paragraphs could be put together as a separate section, preferably using some kind of subheadings.	R	See the reasoning presented above in the responses to comments 2 and 3. We are not convinced that Member States' interests would be best served by further delay to undertake work that could lead to what are only potentially minor improvements.

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bengt Hedberg Country/Organization: Sweden/Swedish Radiation Safety Authority Date: 2020-05-29					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
14	Para 5.11	<p>The roles and responsibilities for safety in radioactive waste management may continue for a long time, and may change during this time. Responsibilities for radioactive waste may <u>transfer between organisations and may</u> even transfer between States (e.g. in accordance with agreements on the repatriation of waste). Management systems for radioactive waste management should be designed to ensure continuity in managing facilities and activities, and should contain provisions for managing changes, for example, in the following:</p>	<p>Transfer of responsibilities may occur also within national borders.</p> <p>Highlighted text not clear and a bit confusing.</p>	<p>A</p> <p>A</p>	<p>The text has been simplified.</p>

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Bengt Hedberg Country/Organization: Sweden/Swedish Radiation Safety Authority Date: 2020-05-29					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
15	5.84	<p>We propose to delete:</p> <p>Responsibilities, mechanisms and schedules for providing the funds necessary for radioactive waste management should be established in advance, before the funds are needed. In particular, organizations that generate waste should ensure that sufficient funds are available before any radioactive waste is generated.</p>	<p>Although we sympathize with the idea, this is not how the real world functions, i.e. we cannot see this working in practice.</p> <p>We strongly support re-writing the text so that the importance of funding is still kept but by proposing a realistic approach and a associated wording.</p>	M	<p>The second sentence has been deleted in response to this and other comments. But the first sentence is correct; these things <i>should</i> be put in place before they are needed.</p>

DS477 – Leadership, Management and Culture for Safety in Radioactive Waste Management (Step 10)

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Denise Varley Page.1.of 8 Country/Organization: United Kingdom/Office for Nuclear Regulation Date: 4 June 2020					
Comment No.	Para / Line No.	Proposed new text	Reason	Accepted/ Modified/ Rejected	Rationale
1	General		The guide would benefit from more consideration on the application of a graded approach, particularly for section 5. The information is intended to cover facilities from a national geological disposal facility to a simple source store.	M	<p>The draft report made 21 references to the ‘graded approach’. The requirements to apply a graded approach were quoted, and Section 5 contained a specific sub-section that addressed the application of the graded approach to the management system. See also para. 5.62. A reference was given to a supporting TECDOC where further information on the use of a graded approach in the application of the management system requirements for facilities and activities can be found. The appendix provided a list of potential elements of the management system for organizations involved in the management of radioactive waste or its regulatory oversight. The first paragraph of the appendix emphasized that “Not all of the elements listed will be relevant to all organizations involved in the management of radioactive waste or its regulatory oversight. In some case, further processes and procedures may be needed. The precise definitions of, and the boundaries between, the management system elements included in an organization’s management system, and the level of detail contained in the processes and procedures, should reflect the nature of the organization concerned, its role and situation, and be applied according to the graded approach.”</p> <p>Several further points on the graded approach have been added in response to Member States’ comments at Step 11b, including those given below. However, this safety guide is a specific guide (specific to the management system for radioactive waste management), and it is also</p>

					<p>non-prescriptive. There is, therefore, quite a small area of ‘parameter space’ in which to work if trying to specify further specific but non-prescriptive guidance on the graded approach to the management system. In addition, the Safety Guides that are being replaced by DS477 were published over ten years ago in 2008, and we have received an increasing number of requests from Member States for updated guidance in this area. The process for developing the Safety Guide has already been significantly delayed (due to the time it took to develop and publish GSR Part 2). We are not convinced that Member States’ interests would be best served by further delaying this safety guide to work on the graded approach. The Secretariat is separately considering the development of a TECDOC on the graded approach in radioactive waste management.</p>
2	General		<p>The document makes a number of references to “the radioactive waste management programme” but does not define the term or state which body would be responsible for such a programme. Use of “programme” requires further consideration.</p>	A	<p>The term ‘radioactive waste management programme’ is not a new term and it is used in various Safety Standards including, SSR-4, SSG-40, SSG-41, SSG-45, GS-G-3.3, GS-G-3.4, NS-G-1.13, NS-G-2.7, NS-G-4.5, NS-G-4.6 and WS-G-5.1. However, the term is not included in the Safety Glossary (for unknown reasons) and so we have added a footnote of explanation to DS477.</p> <p>Depending on the circumstances and objectives, a radioactive waste management programme might be led by Government, an operating organization, a waste management organization, or a regulatory body, e.g. see GSR Part 1 Requirement 10. DS477 does not need to specify which organization would be responsible.</p>

3	General	Replace “best practice(s)” with “good practice(s)” where they appear	This is consistent with the terminology used in other IAEA standards.	M	<p>The preamble to all the Safety Standards states: “The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety.”</p> <p>In response to this and other comments received we have made sure to use the plural of best practices to acknowledge that there may not be a single best practice.</p> <p>Guidance is more aspirational. The requirements in GSR Part 2 are for good practice, but the guidance is to consider as appropriate best practices.</p>
4	General		The importance of minimisation of radioactive waste and application of the waste hierarchy does not feature strongly in the document, which is an important aspect of culture for radioactive waste management.	A	The minimization of radioactive waste generation is now called out explicitly in paras 1.10, 2.5(d), 5.33, 5.38, 5.88 and 5.154. The waste hierarchy is mentioned at para. 5.14 and reference to a supporting document on the topic is provided. A new bullet point has been added at para 6.10 to emphasize the link between waste minimization and the waste hierarchy, and culture for safety.
5	2.2, Line 3	Replace “manage effectively, motivate and inspire the individuals” with “establish and apply an effective management system”	This is more consistent with the expectations in GSR Part 2.	A	Proposed change made, but note that the result is that we offer essentially no guidance that is additional to the text in GSR Part 2.
6	2.6	Consider moving sections (c) and (e) to above (b)	Order would be more logical in relation to discussion of resources	A	
7	2.6 (f)	Replace “public and political sensitivities to decisions” with “the views of interested parties on decisions”	This is more consistent with IAEA terminology and would better reflect a graded approach for the range of activities and facilities covered by the guide.	A	

8	2.9 (a)	Replace “public confidence” with “ the confidence of interested parties, including the public”	This is more consistent with IAEA terminology.	A	
9	2.10	Consider deletion of last sentence.	This appears to go beyond the expectations of GSR Part 2 for the behaviours/attributes of leaders and can be considered to be adequately addressed by the first sentence. It is also an area in which a graded approach would be important.	A	Proposed change made, but note that the result is that we offer essentially no guidance that is additional to the text in GSR Part 2. The deleted text derived from the supporting reference.
10	2.11, 2 nd sentence	Add “and facilitate the achievement of policy aims”	This would clarify the benefits of effective radioactive waste management.	A	
11	2.12	Consider deletion or substantial reduction to only those aspects of specific relevance to radioactive waste management such as policies and strategies relating to the long timescales for radioactive waste management.	This paragraph seems to go beyond the expectations of GSR Part 2 in relation to leadership and the application of a graded approach would need to be considered.	A	As a result of this comment but also others, the text has been reduced and edited to be more clearly specific to radioactive waste management. A new bullet point on the graded approach has been added.

12	3.4 / 5.77	<p>Suggest add sentence to para 3.4: <i>Senior management should have the competence to perform this role.</i></p> <p>or</p> <p>Suggest change para 5.77 as follows: <i>The management system should include provisions to ensure that there are sufficient numbers of competent personnel at all levels, that these personnel are suitably qualified and experienced for the tasks allocated to them, and that they understand the safety implications of their work.</i></p>	The guide should contain greater emphasis on the competence requirements of senior management in order to discharge their responsibilities for radioactive waste management. GSR Part 2 (para 4.23) emphasises the requirement for competence at all levels.	A	Proposed change implemented at para 5.77
13	3.15		It is unclear why this paragraph refers only to conditioning of waste.	A	In response to this comment and others, the more general term 'processing' is now used.
14	3.16	Change last sentence to "Organizations assigned responsibility for radioactive waste management should provide strong and effective leadership."	Reference to individuals is not necessary	A	Comment relates to what was para. 3.14.
15	4.6	Delete first sentence of 4.6	This would appear to go beyond the relevant requirements in GSR Part 2 (paragraphs 4.23 and 4.26)	A	
16	4.7	Remove "for example by contributing to the development and use of international safety standards"	This may be difficult to achieve in practice for some organisations involved in radioactive waste management.	M	In response to other comments received, the sentence has been divided into two - a 'should' statement and an example. This is only guidance and neither sentence is mandatory or binding.
17	4.8	Change 1 st sentence to "Managers should promote ways for all personnel involved in radioactive waste management to participate in the	The term "higher level of safety" is subjective and levels of safety are subject to legal requirements.	M	In response to other comments received, the sentence has been revised in a slightly different way. We have deleted the reference to a "higher level of safety".

		development of, implementation and continuous improvement of the management system to achieve the organization's safety goals". Move last sentence to precede penultimate sentence. Consider whether the sentence discussing peer review etc. is necessary here, taking account of the need for a graded approach.	Some of the expectations in this section, e.g. peer reviews may only be possible for organizations with large resources so it is not clear what would be expected under a graded approach.		We have revised the start of the remainder of the paragraph, so it begins "Where relevant, and taking account of the need to apply a graded approach..."
18	4.4	Suggest change to first sentence to: <i>Senior management should acknowledge that safety encompasses interactions between people, technology and the organization and should ensure that processes and procedures are incorporated in the management system to identify and manage these factors.</i>	Better alignment to GSR Part 2, para 3.1(b).	M	The text has been revised slightly to achieve a balance between the language of GSR Part 2, that proposed by the commenter, and that which derived from the Step 10d Technical Editor's review.
19	4.10	Consider deletion	Paragraph does not add value and is not specific to radioactive waste management.	R	We have received a range of comments from the Member States at Step 11b - some suggesting deletion of general guidance, others requesting guidance on every part (sentence) of GSR Part 2, whether of an inevitably general character or not. Wherever we can, we have tried to make the text of DS477 specific to the management system for radioactive waste. The previous expectation that DS513 would be developed in parallel with and only shortly behind DS477 in time has altered, and it is not now thought that DS513 will be ready for publication for a good few years. In light of this, we have retained some general guidance statement such as this one in DS477.

20	5.2	The development of a management system for an organization should <i>may</i> take into account the following:	The IAEA does not (to the best of our knowledge) mandate or recommend other standards. Further, small Operational Organizations may not find these standards appropriate to their purposes.	M	The words “as appropriate” have been added. The use of “may” in safety standards is discouraged because it gives a sense of permission.
21	5.6	Remove “programme” from 1 st sentence.	Word is unnecessary.	A	
22	5.7	Senior management should <i>may</i> appoint individuals to have specific responsibilities and authorities for the management system in the following areas:	Within smaller Operational Organizations, Senior Management may perform these roles themselves.	M	A footnote has been added to make it clearer that in small organizations for example, Senior Management may play these roles. The use of “may” in safety standards is discouraged because it gives a sense of permission.
23	5.9	Senior management shall retain accountability for the management system. Senior management should <i>may</i> appoint an individual manager to have overall responsibility for the organization’s management system that applies to the radioactive waste management programme.	IAEA GSR-Part 2 does not require a ‘Management Systems Manager’. Neither does ISO9001: 2015. The first sentence of the suggested change is taken from IAEA GSR-Part 2 paragraph 4.1.	M	The suggested first sentence has been implemented following the standard IAEA form. We agree that a ‘Management Systems Manager’ is not <i>required</i> , but the guidance is that it is good idea to appoint one (where this is appropriate to the circumstances and consistent with the graded approach). This is not new and was part of previous guidance. A footnote has been added to capture the thought that in small organizations for example Senior Management may play these roles. The use of “may” in safety standards is discouraged because it gives a sense of permission.
24	5.10	For each process within the management system (see paras 5.87–5.117), senior management should ensure that a designated individual is given the authority and responsibility is defined for:	IAEA GSR-Part 2 and ISO9001; 2015 do not require designated ‘Process Owners’. Additionally, for smaller Operational Organizations, senior management may perform these roles themselves.	M	See response above. A footnote has been added to capture the thought that in small organizations for example Senior Management may play these roles.

25	5.16	Consider deletion of the last sentence and/or the whole paragraph	It is not clear which organization this advice is aimed at, the State or a waste management organization? Would this be better addressed in the new Safety Guide DS526?	A	The responsibility for developing and implementing radioactive waste management strategies varies in different Member States and so the guidance here is aimed at those responsible without specifically identifying them. The topic will be expanded on in DS526.
26	5.18	Should there be additional items relating to the minimization of radioactive waste and the safe storage of radioactive waste pending future management steps?	It is not clear why only disposal would be mentioned in the safety policy.	A	The text has been revised in accordance with this comment and others.
27	5.24	Replace “for decades” with “over long time periods”		A	
28	5.26	Remove “ nuclear” from 2 nd sentence	Radioactive waste management facilities are operated by the nuclear industry and other sectors.	A	
29	5.31 2 nd sentence	Remove “closer”	Word is not necessary.	A	
30	5.34	Consider splitting into two paragraphs, starting at “Making these assessments....”	Aids reading	A	

31	5.44		Who would be responsible for evaluating the effectiveness of the whole framework and how would this be fed back into the management system? The meaning of the last sentence is not clear. This paragraph makes reference to GSR Part 1 and not Part 2. Is this the appropriate safety guide for the subject of this paragraph? This might also be addressed in DS526.	A	The responsibility for evaluating the effectiveness of the whole framework would have to lie with Government. The feedback mechanism would depend on how the evaluation was made but, for example, peer review findings could be considered as one input to maintaining and improving the management systems to which the findings are relevant. The last sentence has been clarified.
32	5.47	Replace “disposal” with requiring management and ultimately disposal	A particular management system may only relate to some steps in the management lifecycle short of disposal.	M	Implemented with slight wording change, “requiring predisposal management and disposal”.
33	5.47	remove “specific equipment’	This term is not defined anywhere else in the text.	A	
34	5.56 (b)	The potential dispersibility and /or mobility of the waste and the necessary degree of containment.	Separates the two issues.	M	Implemented with slight wording change. The use of ‘and / or’ in safety standards is discouraged.

35	5.57	Remove references to “level of” and “detail”	The words do not add clarity or value to the list, noting that quality is what is required.	M	I think there is a difference of view between the authors (not me incidentally) and the commenter. The authors feel that not only the items on the list matter, but that also the degrees (amounts, levels of) of certain attributes of the items (e.g. hazard, detail, complexity, duration, frequency, quantity) affect how the graded approach should be followed in applying the management system. So, for example, the authors would argue that it does matter how detailed the work instructions are, how well qualified the personnel are, what records need to be made and for how long, what the scope of safety audits is, etc. The list is only a list of items for consideration and the words ‘as appropriate’ have been added.
36	5.70	Add “Consideration should be given to backing up records for those deemed essential to maintain traceability of the waste	It does not matter if the records are electronic or paper, essential record should be backed up as a matter of course.	A	The text of para 5.71 has been revised to take account of this comment.
37	5.72	Add ‘ Records will need to be in a readable format for the new organization	Make it clear the new organization must be able to read the records	A	
38	5.97	Remove “as identified during monitoring for clearance purposes”	Does not add value or clarity.	A	
39	5.102		Is this relevant only to special processes?	-	Yes, it is. Non-destructive testing processes are special processes. We did consider removing the concept of ‘special processes’ altogether, but the concept is not only used in this particular area. We also considered removing this paragraph because it is probably one of the most detailed in the safety guide. No change.

40	5.103	Remove “in accordance with the directions of management”	Removes the scope for conflict between these and approved procedures.	A	
41	5.104		Should there be a new subtitle here as the following paragraphs are not about special processes?	M	5.104 to 5.107 have been moved to the end of the ‘Development of processes’ sub-section.
42	5.105 and 5.106		Should these be in the section on development?	A	See response 41 above.
43	5.109	Replace “regular” with “periodic” in (k)	This allows a graded approach.	A	
44	5.139		For the last sentence this would need to be qualified by the need to take account of security requirements (e.g. for storage facilities) and a graded approach would need to be taken.	A	
45	5.180/5.181	Delete 5.181, add “especially where the storage conditions are potentially corrosive (in which case the method(s) used for the physical identification of waste items should be suitably durable)”to 5.180.	Topic area is covered in 5.180	A	
46	6.5(c)	Suggest shorten to: <i>Assessments of the culture for safety.</i>	Ease of understanding.	A	

47	6.10 (b)	Suggest amend sentence to: <i>“Personnel, particularly at underground facilities, can sometimes be exposed to conventional safety risks that are greater than those posed by radiological hazard. The organization should ensure that risks are considered in an integrated manner and that effective overall controls are put in place”.</i>	The current sentence as written puts the responsibility on personnel exposed to the risk to take appropriate action.	A	
48	6.10 (b)	Change to “Where radioactive waste is transferred to other organizations....”	The meaning is clearer.	A	
49	6.10(c)	add “see also para. 5.119.	Link to the non-conformance process	A	

50	7.2 (a)	Add to the end. "It is also considered good practice to consider 'near miss' events".	There is no mention of tracking 'near miss' events and incidents which the organization can learn from.	M	<p>The term 'near miss' does not appear in GSR Part 2, or its predecessor GS-R-3, or in any of the other current GSR publications. The term does, however, appear in the Appendix to GS-G-3.5, 'The Management System for Nuclear Installations' – the guide to the superseded GS-R-3. It also appears in SSR-2/2 (Rev. 1), 'Safety of Nuclear Power Plants: Commissioning and Operation', and a few other guides. The only one of these publications that applies to radioactive waste management facilities and activities is SSG-50, 'Operating Experience Feedback for Nuclear Installations', which applies to predisposal management facilities and activities, but not to disposal facilities and activities.</p> <p>Para 5.31 of SSR-2/2 (Rev. 1) states: "The operating organization shall be responsible for instilling an attitude among plant personnel that encourages the reporting of all events, including low level events and near misses, potential problems relating to equipment failures, shortcomings in human performance, procedural deficiencies or inconsistencies in documentation that are relevant to safety".</p> <p>Because we can't introduce the concept of near misses into DS477 only in Section 7, we have introduced it at para. 4.10 and then we can consider the monitoring of near misses in Section 7. Because we can't make a change to para 7.2 as it is a quote, we have identified near misses in para 7.16.</p>
51	7.5		How will the effectiveness of processes be evaluated in relation to the transfer of wastes from one organization to another and who would undertake such an evaluation?	A	See response to comment no. 31. The text of para 7.5 has been modified so that it explicitly mentions waste transfers.

USA Comments on DS477 “Leadership, Management and Culture for Safety in Radioactive Waste Management”

COMMENTS BY REVIEWER				RESOLUTION	
Reviewer: Multiple - POC Bobby Eid (Bobby.abu-Eid@nrc.gov) - Page..1.. of...5. Country/Organization: USA/US NRC Date: 05/29/2020					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted / Modified / Rejected	Rationale
1	1.8(d)	“Appropriate records of radioactive waste generation and processing...”	Management of waste generation is a key component that is also later described, though inconsistently, in the Scope section. In addition, all methods of processing, not just conditioning, can affect the ability to meet WACs. In general, conditioning is often referred to throughout the document, when the more general processing appears more appropriate. For example, paragraph 3.15 discusses conditioning specifically, but processing may be more appropriate.	A	Text generalized to use processing rather than conditioning.
2	1.10	Consider adding “generation” to list of activities.	Management of waste generation is a key component that is described inconsistently in the Scope section	A	Added in terms of minimization of waste generation so as not to imply that this guide applies to processes such as the generation of nuclear power.

3	2.7	Figure 1 illustrates of the systemic control of radioactive waste management by operating organizations at different facilities working under a series of management systems, and under the governmental, legal and regulatory F framework		A	Typos fixed
4	2.8	Consider deleting or merging this paragraph with others (e.g., 2.5 or 2.7)	Repetitive to other paragraphs mentioned.	A	Merged with 2.5
5	2.11	Consider deleting or refocusing this paragraph	Paragraph lacks consistent focus and does not seem to be focused on the unique characteristics of radioactive waste management, which is the purpose of Section 2. The paragraph begins about communication, then balancing technical and socio-economic considerations, finally implementing policy aims	A	Text has been revised following this and other comments received.
6	2.11/last sentence	Modify the following sentence: “Decision makers and leaders at the highest levels of government should provide consistent drive to facilitate the achievement of policy aims.”	Not sure this is appropriate for this type of document – leaders exert political power? Very strange to be in a safety document.	A	Marked for deletion

7	2.11/last sentence	Modify statement (a): “Leaders should have awareness and judgement.	Similar to item 1 above – not sure the intent of stating this in a safety document – safety is the overriding concern and politics should be secondary – this gives an impression that safety could be subservient to politics – hard to justify the intent of these types of statements	A	‘political’ deleted.
8	3.6/3.7	Consider merging these paragraphs into the following: “Demonstrating safety involves the development of a safety case (see Requirement 13 of GSR Part 5 [3]) for each facility. Recommendations on the development of the safety case are provided in IAEA Safety Standards Series Nos GSG-3, The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste [15], and SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste [16].”	The sub-items of paragraph 3.6 are not clearly linked to GSG-3 or SSG23. Simply pointing to GSG-3 and SSG-23 simplifies this text, avoids missed issues like risks, defense-in-depth, etc., and ensures better consistency between this document and those two documents	A	Paras merged as suggested.
9	3.16	Relocate to follow 3.13	Paragraph 3.16 is related to ownership and topically follows Paragraphs 3.10-3.13. Paragraphs 3.14 and 3.15 seem more focused on responsibilities to provide regulatory body with information rather than ownership.	A	Para moved

10	3.17/1	First sentence reads “Senior management should direct and oversee the development, implementation, review, and revision of emergency plans”	Here and throughout the report– it is recommended that the document clarify the roles and responsibilities that is expected from the different management positions	A	We agree that the roles and responsibilities of the different staff and management positions should be clear. We identify and discuss the roles of Senior Managers (defined in footnote number 9 from the 2018 Safety Glossary), Managers (i.e. other than Senior Managers) and other personnel.
11	4.3/2-5 4.7/1-3 4.9/1	The cites listed include general thoughts such as: “Managers at all levels in the organization should possess leadership capabilities” – P. 4.9	The document is sprinkled with some general statements that provide little guidance or information – the document is quite long and its readability would be improved if it was shortened by removing some of the general statements that appear to be rather obvious and not very useful.	A	Para 4.3/2-5 vague text deleted Para 4.7/1-3 – text revised following other comments Para 4.9/1 - vague text deleted
12	5.93	Renumber list.	List contains two (a)’s.	A	Numbering checked and fixed
13	7.4	In cases where radioactive waste has long term safety, societal or economic implications, organizations that were not originally interested parties could inherit responsibility in the future for managing the waste and the associated facilities.	Unclear as written	A	Text re-written
14	7.8(d)	(iv) Appropriate information on the condition of the radioactive waste disposal facility has been transferred if responsibility for the facility has been transferred.	List item mis-numbered.	A	Numbering checked and revised

15	A.4	(a) Processes and procedures for establishing and maintaining the national inventory of radioactive waste and the inventories of waste at individual sites and facilities.		A	Text simplified to just 'the inventory of radioactive waste'.
16	A.4/A.5	Move A.4(b) to A.5.	Text is more relevant in A.5	M	Moved to A.2 because in different States different organizations have a larger or smaller role in developing the waste management strategy and program.