DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Unit of Facility Radiation Protection Page:1.. of...3 Country/Organization: Sweden/ Swedish Radiation Safety Authority Date: November 11, 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	1.2/5	*Incidents).*	The dot is missing	Yes			
2	3.1	*Safety requirements relevant to assessment of facilities and activities for protection of the public and protection of the environment from the IAEA Fundamental Safety Principles [2], the BSS [1] and other IAEA standards [28, 29]is applied illustrating the relevant safety requirements to conduct an assessment is applied for planned exposure situations. The requirements are addressed in more details in Section 4 and 5 of this Safety Guide.*	Consider to replace this paragraph with proposed text in order to remove direct extracts below and instead use their reference since repeating them does not bring anything new.	Yes	Despite it is truth that quoting requirements in the BSS and others seems to be an unnecessary repetition, rephrasing them is a risky task (which may result in changing unintentionally the original meaning). Using just the references (including paragraph numbers) could be an option. This could be sorted out once the 3 interrelated safety guides (DS442, DS432 and DS427) will be in their final		

					versions.		
3	3.2-3.19	*Remove paragraphs*	Consider to remove these extracts paragraphs(or at least remove the direct extracts and use reference instead) or put them in an annex since they only repeat what is written in the reference and it would be sufficient to write as suggested above.	Yes	See previous response.		
3	3.9/3	*……Guide uses as a reference on environmental protection from the IAEA Safety Guide on Radiation….*	If the above suggested removals is not accepted, there seems to be a "from" missing?	Yes	Not sure.		
4	4.8/9	*…. The IAEA includes generic guidance for different types of activities and facilities in….*	It seems like "of " is missing?	Yes			
5	4.19/4	*… an operator can evaluate the the systems to reduce radioactive….*	Remove "the"	Yes			
6	5.9/6	*…..compartments relevant for the identified exposure pathways and the site are considered…..*	Exposure pathways and relevant environmental compartments are dependent upon the site and it is important to early in the assessment process pinpoint that the specific characteristics of the site or sites has to be considered in the assessment.	Yes			
7	5,13/4	*….. and a conceptual model1 should be elaborated. The conceptual model should present the identified relevant dispersion and transfer pathways. Activity concentrations in environmental……*	Include sentence in order to stress the understanding of relevant processes in order to make an assessment.	Yes			
8	5.14/2	*… Two possible approaches of models and data for the assessment are: (i) a generic methodology which takes account of dilution, dispersion*	In order to make an assessment the transfer to the environmental medias also has to be taken into account.	Yes			

		and transfer of releases into the environment; or (ii) a detailed methodology —					
9	5.15/2	*….be able to simulate the dispersion, dilution, transfer, accumulation and decay (or other removal mechanism),…..*	Include the process accumulation also.	Yes			
10	5.15d/1	*…. (d) Transfer and accumulation of radionuclides to plants and animals in the food chain.*	See above.	Yes			
11	5.16/	*…. properties of the radionuclides being released necessary to assess, for example, the effective release height, water retention or flow rate, the effects on the dispersion of effluents by nearby buildings, or in water bodies effect of local bathymetry, and removal mechanisms like wet and dry deposition and sedimentation rate…..*	If dispersion in air is exemplified dispersion in water bodies should also be in order not to give the impression of bias in importance.	Yes			
12	5.25(f)	*(f) Ingestion of forest food (wild mushroom, wild berries, game).*	Consider including game as forest food.	Yes			
13	5.26/1	*Depending on the exposure scenarios and the site, not all the exposure pathways listed in the paragraphs above may need to be included in the assessment;…..*	Consider to include the site as a factor to consider when choosing the exposure pathways.	Yes			
14	5.38/6	*…. After the process of optimization of protection of the public is conducted, in accordance with the requirements in the BSS, a dose corresponding to and optimized level of discharge could be used for comparison to the results of the assessment. The process of optimization of the protection15 is*	Remove or rewrite this last section in the paragraph, without mixing in optimization (which is like comparing apples and pears here). The dose constraint should not be mixed with optimization, since the dose constraint is set to take into account all possible sources to the	Yes	Will be reformulated/rewrorded taking into account the valid comment.		

		discussed further in [41], [7], [44], [5 and 7].	dose to a representative person, and is therefore often lower between 0,1-1 mSv, in order to take into account other sources not because of optimization.				
15	5.41/4	*…. manage and control the exposure of radiation to humans, provides for appropriate protection…*	Replace to with of.	Yes	exposure to radiation of humans		
16	5.46/2	*]*	A bracket is missing after 32.	Yes			
17	5,53 and 5.54		Test is missing remove? Or add lost text.	Yes			
18	5.61/2		There is one to many comma after fauna.	Yes			

TITLE DPP on DS 427 "A General Framework for Prospective Radiological Environmental Impact Assessment and Protection of the Public".

COMMENTS BY REVIEWER Reviewer: Page.1 of 2 Country/Organization: Horacio Lee Gonzales/ Argentina/Nuclear Regulatory Authority Date: November 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	4.19. For example, as part of a process to evaluate the safety performance of and activity or facility, an operator can evaluate ~~the~~ the systems to reduce radioactive releases to the environment (i.e. normal operation filters or decay tanks) or systems to mitigate releases during accidental conditions (i.e. emergency filters).	4.19. For example, as part of a process to evaluate the safety performance of and activity or facility, an operator can evaluate the systems to reduce radioactive releases to the environment (i.e. normal operation filters or decay tanks) or systems to mitigate releases during accidental conditions (i.e. emergency filters).	Editorial	Yes			
2	5.53 and 5.54 Text is missing.		Editorial ?	Yes	The empty paragraph will be deleted.		
3	5.82. ……However, conservative assumptions are not straightforward, e.g. assumptions	……However, conservative assumptions are not straightforward, e.g. assumptions conservative for inhalation (i.e. that all the releases go to the	To consider the possibility of discharge to the aquatic media in general (freshwater, lake, estuarine, marine environment etc.).	Yes			

	conservative for inhalation (i.e. that all the releases go to the atmosphere instead of to a river) may be not conservative for ingestion of food produced with irrigation. When different pathways are involved, it might be not so easy to identify the most conservative assumption and a careful compromise should be evaluated.	atmosphere instead of to a water bodies ~~a river~~) may be not conservative for ingestion of food produced with irrigation. When different pathways are involved, it might be not so easy to identify the most conservative assumption and a careful compromise should be evaluated.					

Finland's comments on DS427

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: WASSC of....			Page....				
Country/Organization: Finland/STUK							
Date: 5.11.2014							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	Please condense the text.	It contains a lot of repetition.	Yes	Will be sorted out during future editorial revisions.		
2	p. 3, para 1.9	"These types of facilities and activities have very specific aspects related, for example, to *a risk of* ~~the~~ long term delayed releases to geosphere *e.g.* in the case of disposal and,…"	Disposal has failed if there is a release to geosphere, unless the release is insignificant. Release of radionuclides does not unavoidable happen.	Yes			
3	p. 6, para 2.3	"For some nuclear installations *and facilities* national or international regulations identify this decision process…."	E.g. uranium mining and milling facilities	Yes			
4	p. 15, para 4.9	"4.9. For facilities like nuclear power plants and reprocessing facilities, there are likely to be a number of stages in the authorization process. During those stages the assessment should normally be updated when more specific data is obtained."	The last sentence is ok, if it means safety assessment. However, when reading the text, the word "assessment" is used in connection of *radiological environmental impact assessment*. Which one is meant here? REIA might be done only a few times meanwhile the SA needs to be done periodically. See also figure 1.	Yes	In para. 4.9 The "assessment" refers to *radiological environmental impact assessment* (REIA). Para. 4.10 explains that "All the (radiological) assessments conducted in the stages previous to and during the operation of a nuclear facility are basically the same, incorporating more details and information to reduce the level of		

					uncertainty and reviewing the models and assumptions when this is deemed necessary". DS422 wants to give the idea that REIA have to be updated if changes arise, noting that this is not always necessary (unless big changes in the operational conditions or in the environmental situation happen). Most of the time, the update can be small and the REIA is basically the same. We will add some text to Para. 4.9.		
5	p. 17, para 4.14	"Once the authorization or license has been granted or for facilities already in operation, a periodic safety assessment review will be required [29]; this should include the review of the radiological impact assessment for protection of public and protection of the environment."	Here the text applies to safety assessments and the word "environmental" is missing although it exists in the title of the guide.	Yes	Will be clarified. See previous response.		
6	p. 22, para 5.5	"Different methodologies, including calculation tools and input data, can be used to carry out an assessment for demonstrating protection [8, 9]. The national regulatory body needs to be satisfied that the methodology adopted is adequate for the purposes of national practice and should decide — possibly in discussion with the	Is it a bit too prescriptive from the BR to decide the methodology? The operator should be allowed to choose a more strict and conservative methodology.	Yes	There are different views. Some Member States are very prescriptive and define the methodology (including the computational codes). Others leave everything to the decision of the		

		applicants of the facility or activity and other interested parties — which methodology is best suited to carry out a particular assessment."			operator. We have tried to find a balanced formulation in the text. We will discuss this in RASSC/WASSC.		
7	p. 25, para 5.19	"Radionuclides discharged to water bodies are dispersed by ~~general water movements and sedimentation~~ *environmental* processes."	Sedimentation can also cause accumulation of radionuclides. This can be seen e.g. in the Baltic Sea.	Yes			
8	p. 31, para 5.53-54	Paragraphs are missing			Numbers will be deleted.		
10	p. 32, para 5.55	Add reference information to the table, not only to the text.	Are there any other relevant references in addition to ICRP?	Yes	Reference to ICRP and other equivalent methodologies will be added (i.e. EC ERICA approach)		
11	p. 34, para 5.66	"…in the IAEA safety standards [1, 2, 48], those incidents and ~~incidents~~ *accidents*, with their probabilities, should be considered."	Typo.	Yes			

TITLE : DS427 A general framework for prospective radiological environmental impact assessment and protection of the public (version 5)

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	The new version of this draft has significantly improved compared to the previous version. There is however still issues to address (see following comments)		Yes			
2.	General	Too many repetition of requirements, with excessive focus on GSR Part 3 (and not enough on GSR Part 4)		Yes			
3.	General	Need to stress the role of the (future) licensee, not the regulator		No			GSR Part 3 has requirements to government and regulators, not only operators/applicants.
4.	General	Introducing “decision process” and “authorization/licensing process” brings additional complexity. Simplification would be beneficial by keeping one or the other…		No			From the DPP there was an intention to include radiological impact assessments related to an authorization process and also explain the differences/similitudes with an assessment of the radiological impact in the framework of an EIA (that we called ‘decision process’). This distinction is needed.

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5.	General	Trying to stress the differences between small and large facilities/activities as well as preliminary and final assessment across the document brings confusion. Why not changing the structure : 1) Generalities o Introduction o Concepts o Safety requirements 2) Radiological impact assessment related to the normal operation of small scale activities and facilities 3) Radiological impact assessment related to the normal operation of nuclear installations o Preliminary assessment o Final assessment 4) Radiological impact assessment related to potential accidents (potential exposure) 5) Appendixes and annexes		No			A general framework, as presented in DS427, is intended to cover all kind of activities and facilities, of course stressing the differences. The reason to stress the differences between small and large facilities is the mandatory graded approach (the efforts commensurate with the risk). The reason to stress the differences in preliminary and final assessment for large installations is that, the decision and authorization processes are large processes needing intermediate results and the information needed for an assessment is usually improved during this long process. The current structure has the disadvantage to impose the discussion on large/small and preliminary/final in the same sections, but has the advantage that the framework is general and avoid repetitions. The current framework was elaborated in a series of consultancy meetings and already discussed in several WASSC/RASSC/NUSSC meetings. Nevertheless, the new proposed structure will be explored once the concepts are agreed.

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
6.	General	On several occasions, the guide does not give recommendations but describes different possibilities (physical person vs theoretical person, conservative vs realistic, taking account of protective measure vs not taking account, worst case vs more realistic scenario…). This is acknowledged in 1.7 : "*It is recognized and discussed in this guidance that, for some aspects of the assessments, different States may have different approaches. This is due to the complexity and diversity of the options for management of environmental issues, which will depend on national circumstances*." A Safety Guide listing options is of less use than one giving a consensual recommendation. Options would be more relevant to a TecDoc. Consensus on a recommended approach should be reached in the Safety Guide or corresponding parts deleted.		No	The use of the term 'worst case scenario' introduce problems and will be revised.		Para. 1.7 explains the main reason for the existence of different approaches (see last sentence). If well done, all these options are valid. It would be difficult to define a single approach that will cover all the environmental situations related to releases from activities and facilities. Different possibilities like 'physical person vs theoretical person', 'conservative vs realistic', 'taking account of protective measure vs not taking account', 'worst case vs more realistic scenario' are usually consider in radiation protection of public. A more prescriptive Safety Guide could send the wrong message that there is only one way to do the things and this could cause misunderstandings and problems (for instance: a Member State could have no information or resources to obtain detailed site-specific data and could use a generic assessment with conservative criteria; other Member State could have site-specific data and could prefer to use more realistic assessment and less conservative criteria.

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
7.	General	Potential exposure chapter is to be significantly changed. A worst case scenario or simple assessment can be made for an NPP : just postulate that the full core and spent fuel inventory is released… This is however not the current practice as engineered features and emergency operating procedures are taken into account to define the release and that several accidents conditions are assessed as the type of release may differ….		Yes	The use of the full inventory in simple/small facilities/activities is justified by the need for graded approach (efforts proportional to the risk). For instance, if the dose resulting with the full inventory is below 1 mSv there is no need to spend more resources to estimate better the release fraction. Additionally, postulating that the full inventory in a hospital is released have some sense (a classical accident is that the there is a spillage of the full amount of I-131 by accident). For a NPP the allocation of more resources to make the assessment (e.g to estimate a more realistic source term) is justified, because the risk is higher, and to postulate that the full core and spent fuel inventory is released makes no sense. Source terms from NPPs must be estimated with safety analysis techniques, including the release fraction and the associated probabilities. This is the standard		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
8.	General	For potential exposure, the draft gives, as example, metrics of acceptable doses/risk (e.g. 5.102 and following), this is not the purpose of the guide and this should deleted.		No			The purpose of the guide is to provide and discuss the use of criteria for normal and potential exposures.
9.	General	In Annex III, it should be systematically made clear if descriptions covers all kind of facilities and activities (hospital, research lab, NPPs…) and information related to normal exposure should be removed.		Yes	This clarification will be added. Note: Annex III was produced with the contribution from Member States. Initially was considered only for potential exposures but some Member States suggested including also normal exposures. Other comments suggested deleting the full Annex III. The information in Annex III was used to define some of the methodologies described in DS427. It could be that Annex III will be deleted at the end, if so decided.		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
10.	1.2	(e.g. due to releases during normal operation) and potential exposures (e.g. exposures due to conceivable[2] incidents and accidents) [2] In the context of the Safety Guide, the term 'conceivable' means that the incidents and accidents to be considered are the result of a safety analysis, which includes the definition not only of the characteristic of the incident or accident but its probability.	Incidents and accidents are to be considered. True, but it has to be kept in mind that internal/external hazards do include malevolent act, which are postulated to occur (no probability). Is it consistent with footnote 6 of GSR Part 4 ?	No			Note: Despite an incorrect use of the term 'incidents' in DS427, which will be amended in future versions, DS427 only considers 'accidents'. There was a terminology issue and at some point someone suggested to replace the word 'accidents' by 'incidents', because incidents include accidents. But actually, DS427 does not consider internal/external hazard beyond design basis or malevolent acts: only consider accidents. This will be clarified in next WASSC/RASSC/NUSSC meetings.
11.	1.4	~~The approaches and methods given in this Safety Guide are to be considered adequate to carry out a prospective assessment of the level of public and environmental protection, as required in the BSS for planned exposure situation.~~	As this guide provides sometimes conflicting recommendations (physical vs theoretical person…), it is better to delete this sentence.	No			Different options, all valid, to assess radiological impact to public and the environment are not "conflicting". They are alternatives fully consistent. The reason to provides this alternatives in DS427 is explained in Resolution to Comment No 6.

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
12.	1.5	This Safety Guide is related to other guidance and reports published in the IAEA Safety Standards Series, ~~Safety Reports Series, and Technical Reports Series~~: these are the Safety Requirements on Safety Assessment [29], Safety Guides on criteria for protection of the public and protection of the environment against radiation exposure [5, 6] and on regulatory control of radioactive releases to the environment [7], ~~the Safety Report on methods and models to assess the impact of releases to the environment [8, 9] and Technical Reports relevant to environmental transfer parameter values [10, 11].~~ This Safety Guide provide a general framework that is consistent with and can be applied as a complement to other Safety Guides where radiological impact assessment is included, but discussed with less level of details~~, for example, in the frameworks of safety assessment for predisposal management of radioactive waste [Ref. to be added IAEA GSG-3] and safety assessment for the decommissioning of facilities using radioactive material [Ref. to be added IAEA WS-G-5.2].~~ This Safety Guide is also related to other documents published in the IAEA Safety Reports Series and Technical Reports Series such the Safety Report on methods and models to assess the impact of releases to the environment [8, 9] and Technical Reports relevant to environmental transfer parameter values [10, 11].	GSR Part 4 has a significant interface as it deals with identification of incidents/accidents to be dealt with. It is better to address first interface with Safety Standards, then mention supporting documents from other series.	Yes	IAEA GS-3 and WS-G-5.2 will be kept in the text because they are Safety Standards too.		

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13.	1.6	This Safety Guide provides recommendations and guidance on a general framework for performing prospective radiological impact assessments of facilities and activities, as identified under Scope, to estimate ~~and control, using criteria,~~ the radiological effects on public and effects on the environment.	Clarification. It is not the impact assessment that enables to define controls, it is the safety assessment…	No			Despite the framework for Radiological Environmental Impact Assessment (REIA) is presented as a stand-alone framework, REIA is part of Safety Assessment. REIA is used within Safety Assessment frameworks too, and REIA is used as the basis to stablish discharge limits. The use of criteria means that if you don't fulfil it you must not accept the activity or facility (until, for example, you have to reduce releases). This is control. This and the inclusion or not of criteria will be discussed during WASSC/RASSC/NUSSC meetings.
14.	1.7	"It is recognized and discussed in this guidance that, for some aspects of the assessments, different States may have different approaches. This is due to the complexity and diversity of the options for management of environmental issues, which will depend on national circumstances."	See general comment.	No			It was explained in the Resolution to Comment No 6.

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
15.	1.8	The exposures considered include those which are expected to occur as a result of normal operation (i.e. due to the authorized discharges) and also those which can be conceived, by mean of a safety analysis, as a result of an event or a sequence of events that might be an incident or accident (i.e. potential exposures).	Incidents and accidents are to be considered.	Yes	Note: Despite incident was used wrongly, DS427 covers only accidents (this will be amended and is further explained in Resolution to comment No 10.		
16.	1.9		Why such exception ? Further on in the guide, it is stated that prospective assessment could be performed with an unknown site (4.11, 4.18, 5.11)	No			The exposure scenarios for transport or waste disposal (after-closure) practices are very different to those of installations like those covered in this Safety Guide, and it is preferable to produce separated guidance. The exposure scenario of an unknown site for installations like a NPP could be evaluated with assumptions using, for example, regional information, and the methodology for the assessment is the same.

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
17.	1.11	The assessment for protection described in this Safety Guide is not intended to assess retrospectively the radiological impact from discharges during operations or the consequences resulting from an actual accident. ~~Nevertheless, the prospective assessment of potential exposures could provide preliminary information to be used in assessing the hazards and the related consequences for the purpose of establishing adequate level of emergency preparedness and response [14]~~.	The safety assessment, as defined in GSR Part 4, purpose includes to "*address all radiation risks that arise from normal operation (that is, when the facility is operating normally or the activity is being carried out normally) and from anticipated operational occurrences and accident conditions*" and to "*address all the radiation risks to individuals and population groups that arise from operation of the facility or conduct of the activity*."	No			The paragraph proposed here to be deleted was added after comments received on the need to make a clear distinction of 2 different topics: 1.Consideration of potential exposures for authorization. 2.Consideration of hazards for emergency preparedness and response. Both topics consider 'accidents' and could share the methodology of assessment, but the objectives and the way the accidents are considered for emergency planning is totally different. This paragraph was agreed with IEC. DS427 covers what GSR Part 4 requires for a safety assessment: normal operation and accident conditions. The REIA as described in this Safety Guide can be used within a framework of safety assessment.

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
18.	1.12	The prospective assessment of potential exposures for facilities and activities, as described in this Safety Guide, may require that accidents with very low probabilities of occurrence leading to consequences for the public and the environment are considered ~~and criteria for potential exposures are fulfilled. However, even if a facility or activity meets these criteria, it does not preclude the need for an assessment of hazards in relation to preparedness and response for a nuclear or radiological emergency, in line with requirements in Ref. [14].~~ Other aspects of the consequences of large accidental releases to the environment such as social and economic effects and other effects on the environment and on ecosystems are out of the scope of this Safety Guide.	Superfluous	No			Criteria for potential exposures must be fulfilled and emergency plans must be in place, no matter if the criteria for potential exposures are fulfilled. This paragraph was introduced after a request from IEC. The reason is that some organizations in Member States have been arguing that if the risk is very low (e.g potential exposures in terms of risk are low), there is no need to have an emergency plan. Emergency plans must not be based on risk assessment resulting from prospective safety analysis, but on hazards identified.
19.	1.13	This Safety Guide does not discuss in detail the specifications and characteristics of the events and incidents or accidents to be considered during the assessment of potential exposures, nor the methodology for their selection and analysis. The safety assessment of the facility or activity should provide for them [29]. ~~Such specifications and processes for analysis for nuclear installations are discussed in detail, for example, in the Safety Guide [45] and in other related publications in the IAEA Safety Standards Series.~~	A more general sentence and reference to IAEA safety requirements is better	Yes	Will be reworded in line with the comment.		

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
20.	1.14	This Safety Guide is focused on defining a general framework and discussing the general aspects of the methodologies for the assessments, and does not discuss in detail the models or the use of data. ~~In particular, the Safety Guide does not discuss the use of data from radiological environmental monitoring programmes, which are normally undertaken at pre-operational stages (for instance, to establish baselines of activity concentrations in environmental media and to provide information and data for dose assessment purposes [16]) or during the operation of the facility and activity (i.e. to verify compliance, check the conditions of operation, provide warning of unusual or unforeseen conditions and check the predictions of environmental models [16]).~~ For the purpose of this Safety Guide, it is assumed that monitoring programmes at the pre-operational and operational stages exist (or will exist) and provided (or will provide) the necessary information for adequate dose estimations and to verify that the models and assumptions used in prospective assessments are correct. ~~The prospective assessment as described in this Safety Guide should also be used to inform the definition of the site specific environmental monitoring programme. The IAEA provides guidance for source and environmental monitoring programmes in Ref. [16] and [17].~~	Superfluous Stay focus to what the guide addresses.	No			The discussions on environmental monitoring programs and the relation with DS427 were included as a result of many comments requesting clarification on this topic.

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
21.	1.17	The possible non-radiological impacts of facilities and activities, which are generally included in an EIA, such as the impacts on the environment from discharges of other hazardous substances (i.e. chemicals) and heated water, and of the construction of a facility, impacts on features of the environment such as historic monuments and cultural places or impacts on the landscape, as well as social and economic impacts, are not considered in the present Safety Guide. ~~States are subject to the nationally and internationally relevant treaties, conventions, codes of conduct and regulations. States also have an obligation of diligence and duty of care and are expected to fulfil their national and international undertakings and obligations. International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection [2].~~	Superfluous as obvious. A national legally binding requirement (even a regional induced requirement, like EU regulations) will override any IAEA guidance...	No			The Safety Guide is intended also to cover the needs in Member States with less experience (e.g. newcomers) and what could be considered 'superflous' for some experienced countries can be useful for others.

COMMENTS BY REVIEWER Reviewer: F. Féron Page Country/Organization: France /ASN Date: 12 nov 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
22.	2.1	Unless otherwise mentioned, terms are to be understood as defined in the IAEA Safety Glossary [4]. Section 2 provides an explanation of some of the concepts and terms used in this Safety Guide.	Add a reference to the Safety Glossary	Yes			
		~~While approaches may be in principle consistent with these concepts and terminology, the use of the terms defined in this section could differ from those used in States.~~	Superfluous	No			Same reason than in previous Resolution. Terminology can be an issue, especially at the international level and particularly for newcomers.

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
23.	2.3	In the context of this Safety Guide the term 'decision process' refers to the procedures carried out by the government, ~~or~~ governmental agencies or the regulatory body to decide whether an activity or a facility ~~will~~ may be undertaken, continued, ~~or~~ changed[4] or even stopped and where a radiological impact assessment is required to inform the decision. ~~It could also apply to areas of national policy such as whether to embark on a nuclear power programme [19]. A formal decision process is normally conducted at the early stages of a programme of development and, mainly, for activities or facilities that are foreseen to need a thorough assessment of their potential impact to the environment.~~ The decision process may occur at several stages in the lifecycle of a facility or activity, for example when a new facility or activity is considered, when an authorization to perform a new activity or to construct or operate a new facility is applied for, when a significant modification to an activity or facility is to be authorized, when the decommissioning of a nuclear installation is to be authorized… For some nuclear installations or other hazardous installations, national or international regulations identify this decision process with the term 'environmental impact assessment', which is explained later.	Regulator has to be included. Permanent shutdown is to be included Clarification Suggestion to use "decision process" throughout the document, making link to authorization process. In EU, EIA is not limited to nuclear installations…	Yes No Yes			The distinction between a decision-process and an authorization-process is considered necessary and useful to produce guidance, because the characteristics of the REIAs have similarities and differences which should be considered. For example, for an authorization process of a NPP you must have all the necessary site specific information to do an assessment. If you don't have this information, then the authorization cannot be granted. For a decision-process, for example, to decide whether your country enter or not to a nuclear program, you may have some basic regional information, perform an initial assessment and decide to move forward (or not) on this basis. Later, in the authorization process, you will require the more detailed information. Of course within an authorization process you make 'a decision'. If the name 'decision process' is confusing, we can explore others, but the 2 distinct process should remain.

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24.	2.4	Delete 2.4	Defined in the safety glossary	No			We think is useful because is one important term used extensively in DS427. See resolution below.
25.	2.5	Delete 2.5	Defined in the safety glossary	No			We think this and other explanation of terms is useful in view of the wide expected target audience (including interested parties outside the nuclear regulator and operators)
26.	2.6	~~In the context of this Safety Guide, an EIA refers to a national decision process for identifying, describing and assessing prospectively the effects and the risk of effects of a proposed activity or facility on the environment.~~	Using EIA in the guide should be avoided as it has more than often, a legal definition (for example in EU)	No			The need to consider EIA in DS427 started from the DPP. EIA is an internationally accepted acronym for a process established in many countires and some international legal instruments. However, EIA has different definitions and legal status in countries. We want to establish thea relation between a Radiological Environmental Impact Assessment (that described in DS427) and any EIA, no matter the legal definitions of EIA in each country. To avoid conflict or negative interferences, we were very generic in defining an EIA in DS427.
27.	2.8	Delete 2.8	Superfluous.	Yes			

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28.	2.10	Delete 2.10	Superfluous. Weakens the need for recommendation on protection of non-human species	No			Para 2.10 is important because indicates that the aim of radiological protection of the environment established in the IAEA Standards is at a high level (e.g protect ecosystems and populations of non-human species, as distinct to the protection of individuals). This is a crucial difference when you define a methodology to assess the impact to flora and fauna (indeed, you can accept that a few individuals can be relatively highly exposed if the population of that specie is not affected). This approach is completely different from the approach to protect (individual) humans. We also want to avoid misinterpretations like: 'before you only consider humans, so flora and fauna was at risk', This is not truth, the need to assess the level of protection to flora and fauna more explicitly than in the past is more to fill a conceptual gap and not due to concerns on the actual radiological impact to flora and fauna. The practical reason is: 'we progress in knowledge, we can do it, the system of radiation protection is evolving, is not resource consuming, let's do it'. Nevertheless, we can reword it and avoid quoting SF-1 if necessary.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
29.	2.14	The requirement to assess radiological environmental impacts is identified in the BSS, but the term 'radiological environmental impact assessment' is not formally defined. For the purpose of this Safety Guide, radiological environmental impact assessment is taken to be a form of prospective assessment that identifies the target(s), assesses the expected ~~(e.g exposures due to normal releases)~~ and conceivable ~~for purposes of authorization (e.g. potential exposures due to postulated incident scenarios)~~ radiological impacts~~, and compares the results with predefined criteria.~~ Within this Safety Guide radiological impact is taken to mean the estimated effects of radiation dose that may be caused by releases from a proposed facility or activity on human health and, if deemed necessary, other elements in the environment, for example flora and fauna. A radiological environmental impact assessment may be seen as one component of an EIA in the context of planning for nuclear facilities~~.~~ ~~The numerical criteria presented in this safety guide are in the form of dose criteria or risk criteria related to a level of dose.~~	Simplification Criteria may not be established at the beginning of the process…	Yes No No			Criteria should be defined at the begging of the process of assessment. Criteria presented in this Safety Guide is 1) established as a requirement in BSS or other requirements (dose limits, thresholds for countermeasures) 2) based in INSAG (risk criteria) and ICRP (risk criteria and reference criteria for flora and fauna) 3) based in experiences in Member States (dose constraint, acceptable ranges of doses for accidental scenarios). For 2) and 3) DS427 indicates that these criteria presented as examples should be used by national authorities to establish their own national criteria. The inclusion or not of criteria will be discussed at WASSC/RASSC/NUSSC Meetings.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
30.	2.15	Delete 2.15	Defined in IAEA safety glossary	No			We think this and other explanation of terms is useful in view of the wide expected target audience (including interested parties outside the regulator and operators)
31.	2.16	Delete 2.16	3.15 and 3.18 are enough	Yes	Will be considered.		
32.	3.1 to 3.12	Delete 3.1 to 3.12 and replace 3.1 by: Principles 2 and 7 of the IAEA Fundamental Safety Principles [2] establishes the general objective to protect people and the environment against radiation risks. IAEA Safety Requirements establish detailed requirements to support this general objective. In relation to the scope of this guide, they are in particular: - overarching requirements 7, 9, 12, 13, 29, 31, of the GSR Part 3 [1], - overaching requirement 6 of the GSR Part 4 [29] establish the requirements to conduct an assessment of the protection of the public and protection of the environment for planned and potential exposure situations.	No need to recopy all these requirements. Reference is enough	Yes	Simplification of Section 3 is being considered in line with the comments.		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
33.	3.15 to 3.16	Delete 3.15 to 3.16 an replace by: The purpose and general framework for a graded approach are established by Principle 5 of the Fundamental Safety Principles [5], Requirement 1 of GSR part 4 [29] and Requirement 6 of the GSR Part 3 [1].	No need to recopy all these requirements. Reference is enough	Yes	Simplification of Section 3 is being considered in line with the comments		
34.	3.19	Delete 3.19	Already addressed by modification suggested to 3.1	Yes	Simplification of Section 3 is being considered in line with the comments		
35.	4.1	Delete first part of 4.1 and locate the second part of 4.1 before 3.15 ~~As discussed in Section 3, a number of different formal processes, such as a decision process and authorization process, may require an assessment of the facility or activity for protection of the public and protection of the environment.~~ The need of a radiological environmental impact assessment and the level of complexity required for a decision or an authorization process may vary depending on the type of facility, the framework of the process, and its stage in the process.	Superfluous Deals with graded approach	No Yes	Will be moved or deleted.		It is an explanatory introduction.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
36.	4.2	The need of a radiological impact assessment should be defined by the ~~government or the regulatory body~~ State, considering the characteristics of the activity or facility, based on the consideration of the risk due to the expected and potential exposures. Activities and facilities which are ~~can be~~ exempted from regulatory control should not require a radiological environmental impact assessment[8] even if a generic radiological environmental impact assessment may have been performed to support the conclusion on exemption.	Clarifications A radiological impact assessment may have been developed as part of the justification of exemption	No Yes			'Government' and 'regulatory body' is the language used in GRS Part 3. State is too vague.
37.	4.4		Consider deletion	No			

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38.	4.5	The ~~national~~ regulatory body should establish the general requirements and criteria for the assessment taking into account the likelihood and expected magnitude of exposures, the characteristics of the facility and a number of additional factors. Examples of these factors and different elements are given in Table 1. Factors which are important to define the complexity of the assessment are: the source term[9], the level of doses, the safety characteristics of the activity or facility and the characteristics of the location. The scope and level of detail of the assessment may also vary depending on ~~the national regulations for each type of activity and facility and~~ the stage <u>of the facility/activity lifecycle where the decision process occur</u> ~~in the authorization process~~. ~~The applicant should define the level of detail of the assessment for a specific facility or activity considering the requirements and criteria established and present a proposal to the regulatory body for review and agreement. States may consider that, for certain facilities or activities, the level of detail of the assessment could be defined a priori by the regulatory body~~.	Superfluous Obvious and redundant with initial sentence Clarification Superfluous Already covered by the initial sentence	Yes	Will be considered		
39.	4.6	Transform 4.6 as a footnote to title of table 7		Yes			
40.	Table 1	~~Geometry (size, shape, height of release)~~	Too detailed for a grading process	No			This was suggested by other reviewer and is relevant to radiological impact assessment.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
41.	Table 1	~~Existence of other nuclear installations in the vicinity of the facilities or activities in question~~	Redundant with question on man-made hazards	Yes	Clarification on man-made hazards will be added to include sites with multiple nuclear installations		
42.	Table 1	Characteristics of ~~authorization~~ decision process for the particular activity or facility	Clarification	No			As explained before, we are keeping the distinction on 'decision' and 'authorization' processes.
43.	Table 1	Stage of the ~~authorization~~ decision process with regard to facility/activity lifecycle	Clarification	No			As explained before, we are keeping the distinction on 'decision' and 'authorization' processes.
44.	4.7	Factors and elements in Table 1 are not ranked in order of importance and should be used as general guidance as to whether a simple or complex assessment might be appropriate. 4.8 In principle an assessment for the authorization of a nuclear power plant requires a high degree of complexity, while for a ~~hospital~~ facility operating with a small ~~nuclear medicine department~~ of radionuclide, a ~~very detailed~~ simpler analysis may be ~~not~~ justified.	Clarification Avoid pointing on a specific practice.	Yes	Clarification will be considered but, in our view, mentioning NPPs and Hospitals facilitate the understanding.		
45.	4.8	Merge 4.8 with suggested new 4.8 (see previous comment).		Yes			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
46.	4.8	For some types of facilities, for example small laboratories using small sealed sources like radioimmunoassay kits, there may be no requirement for a radiological assessment because, due to the characteristic of the sources in use, a significant impact to the public and the environment is not expected, even following an accident. ~~In some cases a radiological assessment based on relatively simple models using some generic data and cautious assumptions may be sufficient for the authorization process.~~ The regulatory body should define the types of facilities not needing an environmental assessment. ~~For some installation, the regulatory body may define a simple generic methodology. The IAEA includes generic guidance for different types activities and facilities in [ad ref: IAEA-TECDOC Guidance on Generic Radiological Environmental Impact Assessment (in preparation)]~~.	Superfluous (already addressed in 4.7) Superfluous (see 4.5)	Yes	Repetitions will be avoided in future editorial revisions.		
47.	4.9	For ~~facilities~~ nuclear installations like nuclear power plants and reprocessing facilities, there are likely to be a number of stages with a decision ~~in the authorization~~ process. During those stages the assessment ~~should normally~~ may be updated as ~~when~~ more specific data is obtained.	Clarifications	Yes	Nuclear installations will be added, but distinction between 'decision' and 'authorization' processes will be kept.		
48.	4.10	Delete 4.10	No need to get into that level of explanations	No			4.10 describe Figure 1. Text will be revised for simplification.

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49.	Figure 1	Delete Figure 1	See comment on 4.10	No			Figure 1 is a schematic illustration considered useful.
50.	4.11	Delete 4.11	Superfluous (4.9 is enough)	No			4.11 provide guidance useful for newcomers.
51.	4.12	Delete 4.12	Superfluous (4.9 is enough) Furthermore, make it consistent with 1.8.	No			4.12 provide guidance useful for newcomers.
52.	4.13	Although a preliminary radiological impact assessment may have been performed earlier, for example at the siting stage of a new facility or activity, ~~before starting the operation of a facility or conducting an activity~~ an assessment ~~is normally performed~~ may have to be updated before starting the operation of a facility or conducting an activity to determine, for instance, the authorized discharge limits. Guidance on establishment of discharge limits is presented in [7].	Clarification	Yes	The assessment to determine authorized discharge limits is different to a radiological environmental impact assessment as described in DS427. This will be clarified.		.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
53.	4.14	~~Once the authorization or license has been granted or~~ for facilities and activities already in operation, a periodic safety assessment review ~~will be~~ is required [29] and may result in the update ~~; this should include the review~~ of the radiological impact assessment ~~for protection of public and protection of the environment~~. The radiological impact assessment ~~should~~ may also have to be re-evaluated if there are significant changes in the facility or activity or to its environment ~~source term, including in the total amount and the spectrum of radionuclides and in the location characteristics (see Table 1)~~.	Changes introduced to give flexibility while keeping link to periodic review or modifications.	Yes	The review of the radiological environmental impact assessment should be part of the safety assessment review. The update may or may be not necessary, but the review is not optional.		
54.	4.15	Delete 4.15		No			The consideration and discussion of decommissioning stage was requested by other reviewers.
55.	4.16	Delete 4.16	Redundant with 2.14	Yes	Maybe reworded. Redundancy will be prevented in future revisions.		
56.	4.17	Delete 4.17	Redundant with 4.7	Yes	Maybe reworded. Redundancy will be prevented in future revisions		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
57.	4.18	~~Subject to national requirements, an assessment during a decision process could have a single or multiple phase(s). The initial assessment may be relatively descriptive in nature and based on generic data and conservative assumptions, whilst further assessment may include more realistic and site specific information. However, an assessment for a decision process is normally conducted at early stages when considering a proposed activity or facility and the information at that stage would be of a more general character.~~ Generic assessments for similar facilities already in operation in equivalent sites can provide useful information. This is discussed further in Section 5.	Superfluous (4.9 and 4.13 are enough)	No			We consider this useful guidance to remark the particularities on a decision process. The explanation that a 'decision process' can have stages was requested by a reviewer (this the practice in some States).

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
58.	4.19	Operators outside a decision or an authorization processes can conduct a radiological environmental impact assessment for an activity or a facility. For example, as part of a process to evaluate the safety performance of and activity or facility, an operator can evaluate the the systems to reduce radioactive releases to the environment (i.e. normal operation filters or decay tanks) or systems to mitigate releases during accidental conditions (i.e. emergency filters). ~~This is normally done during the operation of facilities with the objective of introducing improvements in the safety systems. When performing such assessments, the same approaches as described in this safety guide should be applied to ensure that all the aspects of public and environmental protection are considered, including the expected exposures and the potential exposures.~~	Superfluous	No			We consider this useful. First, during drafting with the international expert it was noted that radiological environmental impact assessments (REIA) are done in the nuclear industry not only for a decision or authorization process but when evaluating options to increase safety or protection. The important recommendation is that all the aspects of a REIA should be considered when considering options to increase safety or protection, including potential exposures.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
59.	4.20	Requirement 36 of GSR Part 1 [28] requires that the regulatory body, either directly or through the applicant of a facility or activity, shall establish mechanism of communication to interested parties about the possible radiation risks and the processes and decisions of the regulatory body, in accordance with a graded approach. ~~The factors in Table 1 of this Safety Guide should be considered when establishing the contents and the level of detail in the reports for information provision to the relevant interested parties. Depending on the importance of the enterprise, the regulatory body should involve governmental authorities when such communication is considered necessary for effectively performing the public informational functions of the regulatory body.~~	Superfluous	No			We consider this useful information. In big enterprises governmental authorities (and not only the regulatory body) should be involved in the communication to interested parties (this is inspired in Requirement 36, para. 4.66 ,(b), in GSR Part 1)
60.	4.22	Delete 4.22	Out of the scope of the guide.	No			Communication of results is an important issue particularly in 'decision process' (EIA) or when dealing with interested parties which are not the regulator or the operator. In those cases, information on radiation effects and safety aspects have an important role, probably as important as the single result of an estimation of a dose and a comparison to a numerical criteria.

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61.	4.23	~~Despite the objective of the radiological impact assessment in order to grant an authorization is to demonstrate that the radiological effects on public and the environment are evaluated and controlled, e.g. that the radiation risk is acceptable,~~	Superfluous. 4.22 is on involvement of foreign States.	No			This introductory statement was added because there were concerns on the use of terms like "radiological impact on other country" or "impact that affects" other country". The idea behind this clarification is to denote that you are not communicating an 'impact to the affected foreign country', you are communicating an acceptable level of risk, in agreement with the international safety standards.
62.	4.24	~~Normally the government in consultation with the national regulatory body and other relevant national organizations should establish which information should be made available publicly. The responsibility to ensure the soundness of the restricted information should remain with the governmental agencies with functions related to safety and security.~~	Superfluous	No			This is important considering safety and security and similar recommendation are already in other IAEA Safety Standards. This need to define that some information could be restricted by governmental agencies (not by the applicant or operator) was proposed by international experts drafting DS427 and acknowledged as important by other reviewers from the Committees.

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63.	5.1	~~Practical advice, in the form of requirements to governments, regulatory bodies and operators, are described in the BSS, and frameworks of application and methods in IAEA technical safety guidance. Amongst the requirements in the BSS, in order to control the radiological impact due to radioactive releases during planned exposure situations, there is a need to conduct assessments that include the prospective estimation of the possible dose to members of the public and the likelihood and magnitude of potential exposures.~~	Superfluous (redundant with previous part of the guide)	Yes	Redundancy will be prevented in future editorial revisions.		
64.	5.2	This methodology is consistent with similar methods developed and used by <u>some</u> Sates for various purposes,…	Clarification	Yes			
65.	5.5	Delete 5.5	Does not bring much to 5.4….	No			There were many discussions during drafting and after comments received from the Committees on which are the adequate methodologies and who should define them.
66.	5.6	For these types of installations, regulatory bodies <u>or professional associations</u> may develop generic guidance on simple and cautious assessments that can be used.	The regulator is not the only that can help. Associations of users or vendors can also develop guidance that would help end-user assessment	Yes			
67.	5.6	~~In addition the uses of additional resources to gather more information for complex methodologies may not be justified by the improvement in the calculated results.~~	Superfluous	Yes			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
68.	5.7	For facilities needing complex assessments, the level of detail in the models and the data used for the assessment may ~~evolve during~~ depends on the stage in the facility or activity lifecycle where the decision process ~~and authorization process~~. ~~The evolution in the models and data requirements for an assessment during decision and authorization processes is further discussed in the following paragraphs. The following sections describe the characteristics of the assessments for protection of the public and protection of flora and fauna (as an option) in normal operations, and for protection of the public against potential exposure~~.	Clarification Superfluous	Yes			
69.	5.8	Delete 5.8	Superfluous.	No			There was a request from NSNI to include an introductory statement explaining that installations are built to have no or minimal impact and that the impact we are assessing is somehow a residual risk.

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70.	Figures 2, 3, 4	Add an "optimization" process in figures 2, 3, 4	Optimization is a fundamental part of the assessment, mentioned in the BSS	No			Optimization is more applied during design and safety assessment, and must consider -in an integrated manner - safety, protection of workers and protection of public. We are not including in DS427 all the elements that must be considered during an optimization process, we just cover assessment of the level of protection of public and the environment. REIA, as described in DS427, can be used in an optimization process, but should not be used alone to optimize protection and safety. Additional discussions on optimization of the protection of public and the environment are included in DS442 (setting discharge limits).

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
71.	5.11	~~Information on generic source terms for normal operation of nuclear reactors can be found in [34, 35].~~ Later, when more details are known about ~~the type of~~ facility design and operation ~~has been selected (e.g. the design and detailed characteristics of the nuclear power plant are known) and the possible sites have been identified or decided upon,~~ the source term should be more accurately characterized by means of an appropriate engineering analysis.	Superfluous Clarification Location of the facility does not influence the source term, only the dispersion of radioactivity and people/environment exposed.	No Yes			We consider useful information for less experienced Member States.
72.	5.12	The total estimated releases should be provided over the period required by the regulatory body — this is generally given in terms of activity released per year of operation. An assessment will typically assume that the discharges are continuous and constant over a year. Where this is not the case and there is a significant variation in the discharges over a short time period, e.g. ~~during special maintenance or refuelling of reactors~~ or for typical iodine-131 discharges to sewer from thyroid treatment departments at a hospital, then short term releases will need to be assessed.	Special maintenance is quite vague. Refueling may generate more effluent but discharge may be made over a longer period…	No			"Special maintenance" will be replaced with a less vague term. Refueling and other activities may generate a significant temporal increase on the rate of releases along the year; this should be considered in the assessments if relevant.
73.	5.13	~~Environmental models to assess dispersion and transfers of varying levels of complexity have been developed by several authors and were compiled and adapted by the IAEA [8, 36].~~	Superfluous	No			We consider useful information for less experienced Member States

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74.	5.13	The regulatory body should ~~decide~~ confirm if models and data presented by the applicant are appropriate…	It first up to the licensee to make such a decision	Yes			
75.	5.14	~~and should be defined by the regulatory body considering the factors discussed in Section 4~~.	Superfluous (redundant with 5.13)	No			This complement 5.13.
76.	5.16	Delete 5.16	Why limiting this paragraph to nuclear installations ? Physico-chemical form of radionuclide is relevant whatever the facility…	Yes	It will not be deleted but it will be expanded to cover all installations which may need detailed modelling of dispersion and environmental processes.		
77.	5.21	Delete 5.21		No			Accumulation in the environment is important. The convenience to include of this recommendation was remarked by various reviewers from the Committees.
78.	5.23	~~If there is a need to refine the assessment, for instance when the initial estimated doses using generic transfer factors are above or close to the dose criteria, transfer factors based on site specific measurements could be necessary. However, this could be difficult in the framework of prospective assessments.~~	Superfluous	No			The adequate selection of 'transfer factors' for dose estimations is crucial.
79.	5.24	Delete 5.24	Redundant with 5.11	No			5.11 refers to source terms and 5.24 refers to environmental dispersion and transfer.

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80.	5.30	The characteristics of the representative person should be defined ~~according to the national regulations and through a systematic process involving the regulator. For example, the regulatory body may require the use of more detailed and site specific habit data for assessments carried out for certain types of facilities or at later stages in the authorization process.~~	Superfluous Why requiring a systematic involvement of the regulatory body ? is the review by the regulator enough?	No			The selection of the characteristics of the representative person is complex and crucial for the adequate use of models to control public exposure. In some countries the representative person (location and habit data) is defined in the regulations. In others there is not a precise definition. In the last cases, there is a need of a systematic iterative discussion among the operator (the applicant) and the regulator (or the technical support organization supporting the regulator). The term 'review' is considered too vague for guidance.

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81.	5.32		So what is the IAEA recommendation ?	No			The paragraph will be reworded because there were some comments on the use of the term 'hypotetical"). However, the recommendation is, first, to take account of the factors reducing level of exposures (i.e. buildings shielding factors). Then, the guidance explain that the location of the representative person can be based on actual or hypothetical (for the purpose of the assessment) people. The two options are valid, if correctly applied. As explained in Resolution to comment No 6, alternative valid options are usual when dealing with public radiation protection and it is not advisable to be more prescriptive.

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82.	5.38 to 5.39	Delete 5.38 to 5.39 and replace by 5.38 Once the dose to the representative person or the representative has been determined, a decision on its acceptability should be made first by the operating organization, then by the regulatory body with account of the regulations in force and the ALARA principle..	The purpose of this guide is not to define dose constraints or acceptable limits.	No			The purpose of DS427 is to provide guidance on methods for the assessment and on the use of criteria. The need and general-way-of-use of criteria like dose and risk constraints are mentioned in GSR Part 3 but there are no numerical definitions. Therefore, DS427 must provide more details than GSR Part 3 and not just repeat the same or use very general recommendations. This Safety Guide is to assist member states to fulfil GSR Part 3 and provides possible criteria values, leaving the final decisions to national authorities.

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83.	5.41		So what is the IAEA recommendation ?	No			The recommendation (in basic words) is: 'States may use just humans or, if they want to follow the progress in the system of radiation protection and the international trends on protection of the environment, they may add flora and fauna to the assessment, in a simple a practical way'. Despite both approaches are valid (e.g., humans and non-humans would be well protected using any of the 2 approaches) the Secretariat, if endorsed by the Committees can be more prescriptive and say in the guidance: 'use always humans and flora and fauna'. However, some Member States indicated that, despite they don't dislike the proposal to include flora and fauna, they prefer to have it still as optional. One important thing is that the addition of flora and fauna to the assessment should not give the wrong message that, 'before, when using only humans, flora and fauna were not protected". Another important thing is that this addition does not produce additional burden to the operation or regulation. This will be discussed at WASSC/RASSC/NUSSC meetings.
84.	5.42		So what is the IAEA recommendation ?	No			See previous resolution.

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85.	5.43		So what is the IAEA recommendation ?	No			See previous resolution.
86.	5.44	The following paragraphs only apply to situations where the explicit assessment of the radiological impact to flora and fauna is required ~~deemed necessary by the regulatory body~~.	Clarification	No			'Deemed necessary' is considered the adequate language to avoid confusion with IAEA 'requirements'.
87.	5.48	Delete 5.48	This bring additional questions on why protection of flora and fauna is addressed and on why ICRP approach is sufficient…	No			Protection of the Environment must be addressed always. The inclusion or not in the assessment of flora and fauna is optional and the ICRP approach used in DS427 is generic. The existence of scenarios needing more detailed assessments (for instance, protected areas or endangered species) does not invalidate the option to assess flora and fauna protection in a generic manner for all the rest of the cases. These special scenarios in some cases are identified in Laws and for those cases, DS427 do not recommend a generic approach as described. ICRP approach is sufficient in all the rest of the cases and ICRP approach can be used as a 'screening method' for the special scenarios,

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88.	5.59	~~Although ecological characteristics may vary, in general, areas surrounding the effluent release points in the order of 100–400 km2 could be applied for most exposure scenarios relating to normal operation of activities or facilities. This is discussed further in Annex I.~~	Redundant with Annex I (where explanation is better introduced)	No			The way the radiological criteria of ICRP approach is used in DS427 (using the lower boundary of the criteria) is justified because there is a reference area around the source where activity concentrations are averaged. If you don't use this reference area for averaging, the use of the criteria should be different and the approach would be more complicated. We prefer this reference area in the main text of the guidance Other reviewers noted the convenience to have a clearly defined reference area.
89.	5.65	Delete 5.65	Too affirmative….	No			This is a technical paragraph guiding on the way the exposure to flora and fauna should be estimated.

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90.	5.66	During the safety assessments carried out for activities and facilities in the authorization process, various types of incidents and accidents are postulated to identify engineered safety features and operating actions to reduce their likelihood and, should they occur, their consequences. This safety assessment also enables to analyse whether adequate defence in depth has been achieved. The safety assessment can also give insights on the probability of various incidents and accidents, the potential source term and timescale for radioactive releases (if any) for such events, considering the safety measures in place and their effectiveness analysis may be carried out to determine theoretical source terms and the frequencies or probabilities of these events. The types of accidents to be considered depend on the characteristics of the activities and facilities under consideration. In order to assess prospectively the potential exposures to members of the public, as required in the IAEA safety standards [1, 2, 48], those incidents and incidents, with their probabilities, should be considered.	This paragraph should make a clear link between the safety assessment and the DID/safety features, so that these features are taken into account when calculating the source term as well as the probability of an event…	Yes			

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91.	5.67	~~The consideration of potential exposures in the assessment of facilities and activities for protection of the public may vary between States and should be subject to the regulations and guidelines of regulatory bodies. Annex III provides examples from different States of the consideration of potential exposures.~~ The following sections provide guidance to conduct the assessments of the potential exposures to members of the public, once the type and characteristics of the incidents or accidents are defined as a result of a safety assessment, considering the safety measures implemented at the facility or during the activity ~~analysis~~. ~~The regulatory body should define the characteristics of the events necessary for the assessments of potential exposures to members of the public to be used in an authorization of a decision processes. Guidance on definition and characteristics of the events which may be considered when assessing potential exposures to the public is found in [add IAEA references on Safety Assessment]~~	Superfluous.		To be considered when the new version is produced.		

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92.	5.68	For the purposes of this Safety Guide, the expression 'potential exposure scenarios' is used to include the characteristics of all the ~~incidents,~~ events or sequences of events that may lead to an incident or accident, including their source term characteristics -and when applicable their frequencies or probabilities as well as the engineered safety features and operating action foreseen for such events -, combined with the selected	Incidents and accidents are to be considered. Provision established as part of DiD should be credited.	Yes	With the clarification that DS427 covers only 'accidents'. See Resolution to comment No 10.		
93.	5.70	In general terms, the first step should be to ~~consider the defined~~ identify the potential exposure scenarios, based on the safety assessment.	Make a link with the safety assessment.	Yes	'based on the safety assessment and the environmental conditions'. Note: the 'potential exposure scenario' combines the accidental source terms and the environmental conditions.		
94.	5.71	Delete 5.71	There should always be a justified and representative set of scenarios (following paragraphs explains when this representative set could be a single scenario) .	Yes			

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95.	5.72	For facilities having a very small number of engineered safety features, The identification and selection of potential exposure scenarios ~~for facilities and activities needing simple assessments is a straightforward process. It~~ generally involves the consideration of typical industrial accidents or events leading to environmental releases -such as fires and spillage, and other inadvertent unexpected releases- combined with environmental conditions which tend to overestimate the exposures. ~~For example, for hospitals and small research laboratories, a single or a reduced number of industrial accidents involving the sources and conservative dispersion scenarios should be selected.~~	A simple assessment is not the criteria to put forward, it is the fact that the facility is simple so there are few barriers and system to consider in the assessment… Superfluous.	Yes	The identification of certain typical installations in the text (e.g Hospitals or NPPs) will be sorted after discussions with the Committees.		

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96.	5.73	For facilities <u>having many safety features, thus</u> necessitating complex assessments <u>to determine likelihood of events and potential consequences and to ensure that optimization process has been fulfilled</u>, a greater number ~~and more realistic set~~ of potential exposure scenarios may need to be considered. ~~Since the source terms could be higher and the facilities have more complex technological features, the identification and analysis of potential exposure scenarios may need to be carried out in greater detail~~. For these assessments, complex safety assessment techniques may be necessary, combining deterministic and probabilistic methods and, in some cases, expert judgement. <u>They will enable the definition of source terms for various accident conditions</u>	Clarification Superfluous Not a very good argument…	Yes			
97.	5.73	~~The IAEA has developed extensive guidance to assist in identifying initiating events of various types for potential exposure scenarios for nuclear power plants [55], research reactors [57] and other types of nuclear facilities [63].~~	Superfluous	Yes			
98.	5.74	Delete 5.74	Superfluous	Yes			

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99.	5.75 and Footnote 22	Transfer footnote 22 to 5.75 : The types and amounts and the physical and chemical characteristics of radionuclides released during an accident may differ considerably from those for discharges in normal operation. Source terms[22] should be estimated ~~by~~ after considering the events/sequences leading to an accidents and the safety measures aimed at limiting their consequences ~~range of possible releases and by using simple or complex techniques as dictated by the technological complexity of the facility or activity~~.	Clarification	Yes			
100.	5.76 to 5.77	Delete 5.76 to 5.77	To be consistent with comments made on 5.71 and 5.73	Yes			
101.	5.79	In estimating ~~more realistic~~ source terms, consideration should be given to the physical and chemical processes occurring during the accident sequence, the behaviour of any safety ~~systems~~ features or the effects of any mitigation measures, and the behaviour and movement of any radioactive material in the facility before it is released off site. A time profile for the release should be provided if needed.	Safety system has a very narrow definition in IAEA safety glossary. Clarification	Yes			
102.	5.81	Delete 5.81	Redundant with previous sections on installation lifecycle.	Yes			

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103.	5.83	Delete 5.83	It is a poor argument : results are bad so we change the calculations…	No			The iterative approach (e.g. starting with simple conservative, inexpensive, models which overestimate dose and improving the details and realism of the models if the initial overestimated doses are above the criteria) does not mean that results are "bad". Results are too conservative, and the calculations must be refined. This is done for the sake of graded approach (do not devote resources, unless the risk is high). Nevertheless, the wording will be revised to avoid misunderstandings.
104.	5.84 to 5.88	Delete 5.84 to 5.88	Too detailed for a guide covering all kind of facilities…	Yes	It could be deleted or simplified to the minimum necessary.		

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105.	5.91	Delete 5.91	So what is the IAEA recommendation ?	No			Due to the complexity of scenarios when considering potential exposures to public, including the ability to implement countermeasures, it is difficult to define a single prescriptively defined approach . The application of countermeasures to protect public depends on the type of facilities, the type of accident, and the existing level of preparation, which may be different installation by installation or country by country. The recommendation is that it should be clear if you are using or not countermeasures when you estimate potential exposures. Both options can be valid if you compare properly with the criteria and the countermeasures you propose make sense.
106.	5.92	Delete 5.92	Redundant with previous sections on installation lifecycle.	Yes			
107.	5.95	Delete 5.95	For the beginning, redundant with previous sections on installation lifecycle. End is redundant with 5.91	Yes	Redundancy will be prevented in future editorial revisions.		
108.	5.96	(for example, 10 mSv or 50 mSv if such value are threshold for protective measures)	Clarification	Yes			

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109.	5.96	"*In some States specific individual persons or groups of persons are selected while in others the distribution of doses or risks among larger affected population is taken into account. Though there could be flexibility on the ways to consider potential exposures, and different States can adopt different options, the endpoints and the criteria should be clearly defined and justified to avoid misunderstanding and misinterpretation of the results*."	So what is the IAEA recommendation ?	No			The recommendation is (in simple words): 'We know and accept that there are valid options to select representative persons for accidental conditions, but you should be clear indicating and justifying the options you have chosen. See previous Resolutions on flexibility with the options.

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110.	5.98	"*The use of an indication of risk should be applied on the basis of national practices and regulations*."	So what is the IAEA recommendation ?	No			Dose constraint and risk constraint, different to dose limits, have to be flexible considering, for example, (i) the uncertainties involved in the assessment, (ii) the different characteristics of installations, (iii) the complexity of environmental assessment, (iv) the management options and (v) the national context. For these and other reasons the definition and use of dose and risk constraint are flexible and should be considered on a case by case basis. DS427 provide as guidance risk criteria from INSAG and ICRP which is presented as a range or as "should not exceed" concept. The recommendation in this and other related paragraphs is (in simple words): 'Because you must consider potential exposures [BSS and others] and you must define a risk constraint [BSS], national authorities should define the risk constraint using, for example, the recommendations from INSAG and ICRPs. Alternatively, you can use a dose or a range of doses or some countermeasures that may be considered as non-acceptable. These doses or countermeasures should be defined considering the IAEA Requirements for emergency protective measures'.

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111.	5.101	The BSS require that the likelihood and magnitude of potential exposures be considered[23]. ~~and that~~ The BSS also states that restrictions may be established by the regulatory body[23] to ensure dose limits are not exceeded owing to possible combinations of exposures due to several authorized practices.	The initial text is not consistent with the BSS.	No			Para 5.101 refers to Requirement 29 of the BSS, which relates to responsibilities specific to public exposure. That Requirement (in para 3.120 in the BSS), states that "the government or regulatory body shall establish or approve constraints on dose and on risk to be used in the optimization of protection and safety for members of the public".

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112.	5.102 to 5.105	Delete 5.102 to 5.105	The purpose of the guide is to explain how to perform a prospective environmental assessment, not to define acceptable ranges of exposures.	No			As already mentioned in Resolution to Comment No 10, the purpose of the guide is to provide and discuss the use of criteria for normal and potential exposures which should be compared with the results of the assessment (an assessment without criteria does not allow to make decisions or define the level of protection). This discussions on the use of criteria is to guide on how to implement BSS requirements related to the establishment of criteria for potential exposures. Ranges of exposures can be used when, instead of using risk estimation, you use the estimation of dose resulting from a particular accident. Doses to be used as criteria could be either very low (a few mSv) or higher (in this case, the doses can be related to thresholds for protective measures, for instance 10-50 mSv).

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113.	5.106	~~If this approach is used, the regulatory body should define the decision criteria for countermeasures to be used for the assessment of the potential exposures in line with the requirements in [14]. Examples of use of those decision criteria for countermeasures are available in [6].~~	Superfluous	No			In order to be consistent with the IAEA requirements for countermeasures in case of emergencies, the considerations of potential exposures which use "acceptable countermeasures" as criteria should be in line with references [6] and [14]. This was indicated by IEC.
114.	5.107	Different criteria may be set for facilities and activities ~~the with varying levels of inventory and technological complexity. The criteria should also reflect the level of conservatism required for the analysis based on the severity of the potential exposures~~. For instance, the regulatory body may specify one set of criteria for the nuclear fuel cycle and another set of criteria for hospitals or small laboratories.	Superfluous.	Yes			
115.	5.108	Delete 5.108	Superfluous. Consistency between States is furthermore an assumption (for example if one State has NPP and neighboring State no NPP…°	No			Using an exaggerated example for clarification: If one State has no NPPs and a neighboring state plan to build one, and the representative person for accidental situations is located in the state with no NPP, the criteria for potential exposures should be in line with the criteria in DS427 and similar to the criteria adopted in the nuclear country.

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116.	5.111	In general, an assessment provides a single result for each endpoint — for example, the dose to the representative person - even if there are uncertainties on the hypothesis used for calculation and the modeling enabling the calculation. ~~This type of analysis is called deterministic analysis and is generally being based on reasonable conservative assumptions. For instance the assessment could use conservative assumption with regard to the exposure scenario and mean value for the model parameters. The distribution of the resulting doses can be estimated e.g. by means of statistical methods, as Monte Carlo calculations, using the frequency distributions of the model parameters as input for the dose assessment. Model uncertainties .~~ These should be addressed properly to facilitate the decisions by the governmental agencies and the regulators and the communication with other stakeholders, like the public.	Simplification This is not a good example for deterministic analysis….	No			Deterministic analysis is jargon used in radiation protection to define estimation of doses to representative persons using single values in the environmental transfer parameters (i.e. soil-to-crops or water-to-fish transfer factors). When using the range and the probabilistic distribution functions of the transfer parameters, the analysis is called probabilistic. This is not the same than 'deterministic safety analysis' or 'probabilistic safety analysis' used in nuclear safety.. Nevertheless, the wording will be clarified to avoid misunderstandings.

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117.	5.112	Delete 5.112	Initial sentence not true. Furthermore, it also introduces again, that rough assessment leading to bad results implies to revisit the assessment….	No			Environmental dispersion models used in the nuclear industry and 'representative person' approach is indeed very conservative. Experience shows that actual activity concentrations in the environment and actual doses to the population surrounding a NPP and other installations are usually below those estimated with models and assumptions like those mentioned in DS427 (order of magnitude below or even lower). Regarding "bad" results, please see Resolution to Comment No 103 (better wording will be considered).
118.	5.113	Delete 5.113	Not needed	No			Uncertainties is an issue needing consideration when doing radiological environmental impact assessment.
119.	5.115	Delete 5.115	This paragraph is not relevant for potential exposure (see 5.118)	Yes			VARIABILITY AND UNCERTAINTY IN THE ASSESSMENTS will be a Section 6 (does not refers only to potential exposures)

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120.	5.116	~~If insufficient information or data is available then a conservative estimate should be used but sensitivity studies should be carried out to determine how important an individual assumption is in determining the overall risk.~~ It should be avoided to combine many conservative assumptions and arrive at a result for the impact that is grossly pessimistic.	OK in principle but the draft should explain why a grossly pessimistic impact is not recommended….	Yes			

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121.	5.118 Bullet list	(a) Selection of potential exposures scenarios: The scenarios selected may not be representative of what might actually happen ~~and the list might not be complete, e.g. some types of scenario may have been overlooked~~.	This would warrant using worst case scenario, which is not was is recommended in the guide for complex facilities….	Yes	The existence of uncertainties does not mean that you can't use an assessment. The recognition of uncertainties, permit to make caution decisions when comparing to criteria. The use of the term 'worst case scenario' out of context could be an issue. Using an accident, resulting from a serious safety analysis with a very low probability (as recommended in IAEA Standards) could be consider a worst case by someone and not the worst case by others. Worst case scenarios tend to be unrealistic (which is Ok for a Hospital but can make problems for a NPP). Use of 'worst case' term will be revised.		

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122.	5.118 Bullet list	(b) The probability or frequency of the scenarios: Conservative analysis seeks to avoid the issue by assuming certain bounding representative initiating events and system failures ~~occur~~. If, for example, probabilistic safety analysis techniques are used to estimate accident frequencies, these frequencies are determined by combining many other frequencies and failure probabilities all with their own uncertainties ~~and so are usually subject to quite large uncertainties~~.	Superfluous	Yes			
123.	I.2	Risks of health effects to members of the public may arise from potential exposures related to accidental releases of radioactivity. ~~Annex III presents definitions of measures of risk which can be used in the potential exposures assessment. National authorities should be responsible for setting criteria for potential exposure since the appropriate value may vary according to the prevailing legal, economic and social conditions [61].~~ International schemes which could be used to define national approaches for criteria for potential exposures are summarized and discussed below and Annex III gives examples of existing practices.	Simplification	Yes			
124.	I.3	In 1995, The International Nuclear Safety Advisory Group (INSAG) considered safety goals for potential exposure (INSAG 9) [51] making the following statements for individual risk to a member of the public:	It is worth highlighting it was nearly 20 years ago… More generally, is it still useful to make such a reference ?	No			It is truth this was done 20 years ago; that doesn't mean it is not valid or useful.
125.	I.4	Delete I.4	Not the purpose of the guide.	Yes			

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126.	I.5	For nuclear power plants, in 1999, Risk targets from INSAG ~~3~~12 [62] are quoted: a severe core damage frequency…	Clarification	Yes			
127.	I.2	~~In most of the cases related to the operation of facilities and the conduct of activities, and particularly during normal operations, the increment in the radiation levels in the environment to which populations are exposed, is comparable with the variations on the natural radiation background~~.	Too affirmative without knowing the facility and its location…	Yes			
128.	I.7	~~Dosimetric models of the reference person are applied to the calculation of doses for a representative person and compared to a reference criterion. The habits used to characterize the representative person, including its location, are typical habits of a number of individuals representative of those most highly exposed, and not the extreme habits of a single member of the population [I-2].~~	Not relevant to protection of the environment	Yes			

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129.	I.9	Due to the annual distribution of wind directions and, in some cases, the directions of the water flows in rivers, lakes and oceans, the highest activity concentrations could be detected in any direction within a radius of up to ~~10 km~~ a few kilometers. ~~Therefore, reference area of approximately 100–400 km^2 located around the release point is indicated by the IAEA for generic assessments, as described in this safety guide.~~ The location of this area would ensure that highest environmental activity concentrations due to normal releases are found within that area used for the estimation of doses. Consequently, the plants and animals within that area would normally receive the highest radiation doses. The reference animals and plants located in that area around the release point, where the highest environmental activity concentrations are observed, can then be used for a generic assessment of the protection of the environment.	Better be less precise as facility and its location are unknown.	No			We think that the range provided (for instance, downwind distances up to 10 Km) is flexible enough and ensure that the maximal activity concentrations in the environment are included within that distance. Some wording could be added to explain that this distance is indicative and can be reassessed for certain facilities and locations.

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130.	I.10	~~An area of 100-400 km^2 around the source[25], used to consider flora and fauna when performing radiological environmental impact assessments, is sufficiently large to ensure that mixing of the effluents with the environmental media occurs and that the number of individuals considered for the assessment is suitably large to ensure that the estimated doses and representative of those to the fraction of the population most highly exposed.~~	Superfluous	No			This explanation in the Annex justify the use of an area which is intended to avoid the use of the maximal exposure in a few individuals (for example, at the local hot spots where the radionuclides are still not diluted).
131.	II.1	~~The Fundamental Safety Principles [II-1] states that "Safety is concerned with both radiation risks under normal circumstances and radiation risks as a consequence of incidents"[26]. Since it also establishes that 'safety' means the protection of people and the environment against radiation risks, there is a clear requirement to assess and control the impact from potential exposures on people and the environment.~~	Superfluous (already in the main part of the guide)	Yes			
132.	II.3	The risk due to potential exposures is controlled starting from the design of facilities and activities, e.g. ~~by adding a multilevel system of sequential, independent~~ by provisions for protection and safety (defence in depth) that is commensurate with the likelihood and the magnitude of the potential exposures [II-3].	It is not true even for currently operating NPPs….	Yes			
133.	II.4	Delete II.4	Redundant with previous part or gives options and unsupported affirmations…	Yes			

COMMENTS BY REVIEWER Reviewer: F. Féron Country/Organization: France /ASN			Page Date: 12 nov 2014	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
134.	II.5	The estimation of potential exposures requires the assessment and quantification of the impact of accidents or events that might happen with very low probability. Generally — and certainly in the case for facilities like nuclear power plants and reprocessing plants — there will be a whole spectrum of possible potential exposure scenarios, ranging from those with little or no impact to those with a very high potential impact, the design and operation of the facility being such that accident with high impact have a lower probability than events with minor impact. ~~Accident scenarios with a high radiological impact could be postulated by, for example, assuming that every single safety feature in the facility fails simultaneously. Since the likelihood of such extreme scenarios is very low, it seems clear that the probability or frequency of occurrence must be taken into account for the postulated accidents with large radiological impacts. Accident scenarios could result also from the interaction of safety failures and the impact of severe external events like tornadoes and earthquakes.~~	Simplification This is probably not so evident to everybody…. No need for such focus.	Yes			
135.	II.9 and II.10	Delete II.9 and II.10	Not needed.	No			There is a need for a clear definition of risk.
136.	II.13 to II.17	Delete II.13 to II.17	See previous comments on potential exposures	Yes			
137.	II.21	Delete II.21	Superfluous (already in the main text of the guide)	Yes			

Draft Safety Guide DS427 "A general framework for prospective radiological environmental impact assessment and protection of the public"
(Draft Version 5 dated September 2014)
Status: STEP 7 – First review of the draft safety standard by the SSCs

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

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of GRS and BfS) Page 1 of 27 Country/Organization: **Germany** Date: 2014-11-12				RESOLUTION			
Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	1	Formal	The numbering of the draft versions of DS427 should be consecutive in ascending order. It is proposed to submit each new draft version of this Safety Guide in two different formats: one as 'clean' version, and another one as 'marked up' version.	Previous draft version 6.2 dated 15 April 2014, while current draft version 5 dated September 2014. This approach would considerably facilitate the work of the reviewer, e.g. whether the number of paragraphs changed and/or the text of a certain paragraph was modified. Otherwise it is difficult to correlate the IAEA comment resolution table to the new draft text, especially in Section 5 of DS427.	Yes			
1	2	General	Germany acknowledges that the current draft version of DS427 has been further improved. However, the scope of the document is still too imprecise. It should be clearly defined in Section 1 for which types of facilities and activities this Safety Guide is applicable.	In many countries, e.g. in all Member States of the European Union, it is clearly defined for which kind of nuclear facilities a radiological (sometimes called 'nuclear') environmental impact as-	Yes	Despite the safety guide is not intended to fulfil particular regulations of a country or region, the definition of the scope of DS427 will be improved taking into account this		

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				sessment – either as a separate document or as part of the general EIA report – is mandatory (Case 1) and for which facilities/activities Member States have to determine whether a project has to be made subject to a radiological EIA (Case 2) through either (a) a case-by-case examination, or (b) thresholds or criteria set by the Member State. Case 1 applies to nuclear installations (taking into account the revised definition of the term 'nuclear installations' which has been endorsed at the 32nd CSS meeting in October 2012), disposal facilities for spent fuel or radioactive waste, open-pit uranium mines, and facilities for the milling or processing of uranium ores. Case 2 applies to e.g. near surface landfill-type disposal facilities and underground uranium mines. For all other facilities and activities, e.g. laboratories, X-ray generators or medical application of radionuclides, no radiological EIA is required. These facilities and activities are licensed under		comment.		

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				national radiation protection law without a separate EIA report. Further details are provided in the Directive 2011/92/EU of 13 December 2011, which has been amended by the Directive 2014/52/EU of 16 April 2014. In other (non-EU) countries, a similar legal framework for EIA exists.				
2	3(part a)	General	Note: In our opinion, the concept of reference animals and plants (ICRP 108) and the new system for the protection of the environment (ICRP 124) are in too much detail described in this Safety Guide.	If this ICRP concept is considered as an option for national regulators, than alternatives should also be mentioned. Such an alternative is given by ICRP 103 which demonstrates the conviction that the protection of humans implies the protection of non-human species. It should also be noted that the IAEA BSS and the EU BSS (Council Directive 2013/59/EURATOM of 5 December 2013) are coincident regarding objective and scope, except for the protection of the environment (see Paras 1.32 to 1.34 of GSR Part 3) while this subject was removed from the EU BSS. It is only mentioned in the preamble of the EU BSS.	No			Para. 5.41 states that: "States may consider that the assessment of the protection to members of the public is sufficient to demonstrate protection of the environment as well. This position is based on the assumption that the system of protection and safety, which aims to assess, manage and control the exposure to radiation to humans, provides for appropriate protection of the environment from harmful effects of radiation. In that case the assessment may not need to include explicit consideration of the radiation exposures to flora and fauna as described below in this section". The explanations given by EU to remove environment from their BSS is that it's out of the scope Euratom. On the contrary, IAEA SF-1 and BSS identify protection of the environment as an issue to be considered during the assessment and management of radioactive releases.

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	3 (part b)		According to IAEA's response to the ENISS general comment on draft version 6.2, the DS427 will "*offer a very generic and simple assessment based on ICRP and as an option*".		Yes	We consider that the current option is generic and simple (using a generic reference area to estimate exposures and the reference animals and plants provided by ICRP). However, maybe the discussions in the text are still complex. We will try to simplify even more the text.		
3	4	1.5	2nd sentence: "This Safety Guide provides a general framework that is consistent with …"	Editorial.	Yes			
2	5	1.7	1st sentence: "This Safety Guide provides guidance and recommendations about the contents of such assessments, their use and the procedures for their implementation, as an aid to national regulatory bodies, persons or organizations and to other	Limitation to those types of facilities and activities for which either 1. a radiological EIA is mandatory, or 2. States have to determine whether a project has to	Yes			

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			interested parties applying for an authorization or being responsible for the operation of facilities and activities defined in the scope of this publication." be made subject to a radiological EIA. See also our corresponding comments No. 2, 6 and 7.					
1	6	1.8	1st sentence: "This Safety Guide is applicable to evaluate prospectively exposures and risk of exposures due to radioactive releases to the environment – and, when relevant, direct external radiation –, from facilities and activities which are located at or projected for a specific site. The Safety Guide covers those facilities and activities for which either (a) a radiological EIA is mandatory, or (b) States have to determine whether a project has to be made subject to a radiological EIA."	Amendment to specify the facilities and activities under the scope of this Safety Guide.	Yes			
1	7	after 1.8	Please add a new paragraph with the following text: "A radiological environment impact assessment is mandatory for nuclear installations (including nuclear power plants; research reactors; radioisotope production facilities; spent fuel storage facilities; facilities for the enrichment of uranium; nuclear fuel fabrication facilities; conversion facilities; facilities for the reprocessing of spent fuel; facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities; nuclear fuel cycle related research and development facilities), open-pit uranium mines, and facilities for the milling or processing of uranium ores. For certain facilities and activities, the States have to determine	This is an indispensable information which needs to be included in the subsection "Scope". A listing of the different types of facilities (if necessary) should take into account the revised definition of the term 'nuclear installations' which has been endorsed at the 32nd CSS meeting in October 2012. According to that definition, 'nuclear installation' means "*any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and*	Yes			

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			whether a project has to be made subject to a radiological environment impact assessment through either (a) a case-by-case examination, or (b) thresholds or criteria set by the State. This concerns e.g. near surface landfill-type disposal facilities and underground uranium mines. For all other facilities and activities, e.g. laboratories, X-ray generators or medical application of radionuclides, no radiological EIA is required."	*radioactive waste disposal facilities*". For radioactive waste disposal facilities, a radiological EIA is indeed mandatory. However, disposal facilities are outside the scope of this Safety Guide (see Para 1.9) since specific guidance on assessment for disposal is provided in the Safety Guide SSG-23.				
2	8	1.9	"It is beyond the scope of this Safety Guide to provide recommendations and guidance on equivalent prospective assessments of exposures resulting from the disposal of radioactive waste, the transport of radioactive material and the use of mobile radioactive sources. These types of facilities and activities have very specific aspects related, for example, to the long term delayed releases to geosphere in the case of geological disposal or to biosphere in the case of near-surface disposal not being a controlled discharge and, for mobile sources, to the uncertain characteristics of the locations, which are not considered in the present guidance. …"	Clarification and completeness with respect to the exclusion of disposal facilities from the scope of this Safety Guide.	Yes			
3	9	1.14	1st and 2nd sentence: "This Safety Guide is focused on defining a general framework and discussing the general aspects of the methodologies for the assessments, and does not discuss in detail the models or the use of data~~. In particular, the Safety Guide~~	Wording.	Yes			

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			~~does not discuss the use of data~~ from radiological environmental monitoring programmes, which are normally undertaken at pre-operational stages (…) or during the operation of the facility and the conduct of the activity (…).”					
3	10	1.17	1st sentence: “The possible non-radiological impacts of facilities and activities, which are generally included in an EIA, such as the impacts on the environment from discharges of other hazardous substances (i.e. chemicals) and heated water, and of the construction of a facility, impacts on features of the environment such as historic monuments and cultural places or impacts on endangered species or the landscape, as well as social and economic impacts, are not considered in the present Safety Guide.”	Inserted from Para 2.7 due to the proposed deletion of the second sentence in Para 2.7 (see our comment No. 14), which repeats the first sentence in Para 1.17 partially.	Yes			
3	11	2.2	“BSS defines a planned exposure situation as “a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure ~~from~~ due to a source. In planned exposure situations, exposure at some level can be expected to occur. If exposure is not expected to occur with certainty, but could result from an accident or from an event or a sequence of events that may occur but is not certain to occur, this is referred to as ‘potential exposure’ ” (BSS para 1.20 (~~i~~a)) [1]. …”	Correct citation of Para 1.20 (a) of GSR Part 3.				
2	12	2.3	Please add new sentence: “… For some nuclear installations national or international regulations iden-	Clarification. Compare with Para 1.14 and with the paragraph proposed				

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			tify this decision process with the term 'environmental impact assessment', which is explained later. Within the scope of this Safety Guide are those facilities and activities for which a radiological environmental impact assessment is mandatory or recommended."	to be included after Para 1.8 (see our comment No. 7).				
2	13	2.6	1st sentence: "Environmental impact assessment (EIA) is not formally defined in the IAEA safety standards ~~although~~ but it is described, e.g., in the IAEA publication [67] and is included in many international instruments and national legislations and regulations [20–27]." Add Ref. [67] to the list of references: "[67] INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Environmental Impact Assessment for Construction and Operation in New Nuclear Power Programmes, IAEA Nuclear Energy Series No. NG-T-3.11, IAEA, Vienna (2014)."	Although not yet defined in existing IAEA Safety Standards, environmental impact assessment is described in the Nuclear Energy Series publication NG-T-3.11 which has been published recently. For the sake of completion, please include a reference to this publication. In addition to that, the term 'environmental impact assessment' is well defined in Article 1 of the Convention on Environmental Impact Assessment in a Transboundary Context ('Espoo Convention', 1991). This definition is reproduced in Footnote 4 of the Safety Guide SSG-29 "Near Surface Disposal Facilities for Radioactive Waste".	Yes	Maybe be reworded. NG-T3.11 is not a Safety Standard but it could be mentioned as reference material with useful information.		
3	14	2.7	"The effects related to radioactive releases from activities and facilities to the environment likely to be considered in an EIA generally include radiological effects on human health and, in some cases, effects on flora and fauna. ~~Non-~~	The second sentence of Para 2.7 repeats the first sentence of Para 1.17 partially. With the proposed modification of Para 1.17 (see our comment No. 10), the sentence is dis-	Yes			

			~~radiological impacts such as the physical impact of the construction of the facility on the environment, social and economic impacts, the impact on historic monuments and cultural places, endangered species or the landscape, which are generally included in an EIA are not considered in the present guidance but are subject to the nationally and internationally applicable regulations.~~"	pensable and, thus, can be deleted.				
3	15	2.8	"In general, an EIA requires the involvement of the organizer of the proposed activity or facility, relevant governmental agencies, the regulatory body and a number of interested parties, including the public [20, 23 – 27, 67]."	For the sake of completeness, the relevant references should be included here. With regard to Ref. [67], see our comment on Para 2.6.	Yes			
2	16	2.11	"~~BSS specifies that the protection of the environment means protection and conservation of non-human species, both animal and plant, and their biodiversity; environmental goods and services such as the production of food and feed; resources used in agriculture, forestry, fisheries and tourism; amenities used in spiritual, cultural and recreational activities; media such as soil, sediments, water and air; and natural processes.~~"	Para 2.11 should be deleted because Para 2.12 describes what the protection of the environment from harmful effects of radiation means while Para 2.11 is related to the protection of the environment in general, although non-radiological impacts of facilities and activities are not considered in this Safety Guide (see Para 1.17).				
3	17	2.12	1st sentence: "The system of protection and safety described in the BSS [1] defines a framework to assess, manage and control exposure to radiation for humans which generally provides for appropriate protection of the environment from harmful effects of ionizing radiation."	Slight modification of wording to be in line with GSR Part 3 and SF-1.	Yes			

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2	18	2.13	"~~The BSS states that the protection of the environment is an issue necessitating assessment, allowing for flexibility in incorporating into decision making processes, the results of environmental assessments that are commensurate with the radiation risks. BSS establishes that the assessment of environmental impacts should be undertaken in accordance with national requirements [1].~~"	To be deleted for the same reason as mentioned for the deletion of Para 2.11. It can be taken for granted that the assessment of environmental impacts should be undertaken in accordance with national requirements.		Being considered		
3	19	Headline prior to 2.14	"~~RADIOLOGICAL ENVIRONMENTAL IMPACT ASSESSMENT~~"	It is proposed to delete this headline because the term 'radiological environmental impact assessment' is not formally defined (see Para 2.14) and to avoid conflicts with the term 'nuclear environmental impact assessment', which is used e.g. in the Nuclear Energy Series publication NG-T-3.11. In some States, there are two competent authorities with responsibilities for licensing (e.g. radiation protection agency and environmental agency). In the United Arab Emirates, for example, the licensee has to prepare two separate EIA reports for nuclear facilities: • a nuclear EIA report, and • a non-nuclear EIA report.		Being considered. However, we don't intend to use NG-T3.11 as a reference for definitions or procedures (just, if necessary, as an additional source of information)		
2	20	2.14	"The requirement to assess radiological environmental impacts is identified in the BSS, but the term 'radiological environmental impact assessment' is not	Because the term 'radiological environmental impact assessment' is not formally defined, we propose to move	Yes	We don't intend to use NG-T3.11 as a reference for definitions or procedures (just, if		

			formally defined. Sometimes the term 'nuclear environmental impact assessment' is used, e.g. in [67]. For the purpose of this Safety Guide, radiological environmental impact assessment is taken to be a form of prospective assessment that identifies the target(s), assesses the expected (e.g. exposures due to ~~normal~~ releases during normal operation) and conceivable ~~for purposes of authorization~~ (e.g. potential exposures due to postulated incident scenarios) radiological impacts for purposes of authorization, and compares the results with predefined criteria. Within this Safety Guide, radiological impact is taken to mean the estimated effects of radiation dose that may be caused by releases from a proposed facility or activity on human health (during normal operation and due to potential exposures) and, if deemed necessary, other elements in the environment, for example flora and fauna (during normal operation). A radiological environmental impact assessment may be seen as one component of an EIA in the context of planning for nuclear facilities. The numerical criteria presented in this ~~s~~Safety ~~g~~Guide are in the form of dose criteria or risk criteria related to a level of dose."	Para 2.14 into the subsection "ENVIRONMENTAL IMPACT ASSESSMENT" after Para 2.8. 2nd sentence: Insertion for clarification. With regard to Ref. [67], see our comment on Para 2.6. 3rd sentence: Modification of wording to be in line with the second sentence of Para 1.7. 4th sentence: Amendment to be in line with the scope of this Safety Guide (see Para 1.16) as well as with Para 5.69 which states that "*Potential exposures to flora and fauna are not taken into account, since those are not amenable to regulatory control under accidental situations.*" Last sentence: In conjunction with the publications issued in the IAEA Safety Standards Series, 'Safety Guide' and 'Safety Requirements' should be used as capitalized terms consistently throughout the document.		necessary, as an additional source of information). The rest of the comments are accepted		
2	21	3.17	"Requirement 6 of the BSS states that	Correct citation of Require-	Yes			

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			"the application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures"."	ment 6 of GSR Part 3.				
3	22	3.19	"Requirement 29 of the BSS addresses the issue of exposure outside the territory under the jurisdiction or control of the State in which the source is located. Paragraph 3.124 of the BSS requires that …"	For completeness.	Yes			
2	23 (part a) 23 (part b	4.2	"The need of a radiological impact assessment is usually defined in the national legislation on EIA, and if not, it should be defined by the government or the regulatory body, considering the characteristics of the activity or facility, based on the consideration of the risk due to the expected and potential exposures. ~~Activities and facilities which can be exempted from regulatory control should not require a radiological environmental impact assessment.~~"	1st sentence: Amendment for clarification (see also our comment No. 2). 2nd sentence: Can be deleted, as this is a matter of course.	Yes NO	Will be reworded.		Some comments received indicated the need to stress that exempted practices would never require an environmental impact assessment.
2	24	4.4	"… For the sake of clarity, assessments discussed in this Safety Guide are categorized as either simple or complex. However, it is recognized that these terms are the two ends of the range of possible assessments and there are a large number of activities~~,~~ and facilities that require an assessment falling between these two categories. In many States, the national legislation on EIA	Amendment for clarification.	Yes	Will be reworded		

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			specifies the facilities and activities for which a radiological environmental impact assessment is required."					
1	25 a	4.7, 4.8	Combine and merge both paragraphs into one Para as follows: "Factors and elements in Table 1 are not ranked in order of importance and should be used as general guidance as to whether a simple or complex assessment might be appropriate. In principle, an assessment for the authorization of a nuclear power plant requires a high degree of complexity, while for a hospital operating a ~~small~~ nuclear medicine department a ~~very~~ detailed analysis may be not justified.	For the facilities mentioned in the first sentence of Para 4.8, no radiological environmental impact assessment is required, i.e. they are out of the scope of this Safety Guide. Compare with the paragraph proposed to be included after Para 1.8 (see our comment No. 7). Last sentence: Guidance on environmental impact assessment for nuclear power plants is provided in the Nuclear Energy Series publication NG-T-3.11. Please include a reference to this publication (see our related comment on Para 2.6).	Yes	This comment will be considered in the final edition.		
	25 b		~~For some types of facilities, for example small laboratories using small sealed sources like radioimmunoassay kits, there may be no requirement for a radiological assessment because, due to the characteristic of the sources in use, a significant impact to the public and the environment is not expected, even following an accident.~~		No			Some comments received indicated the need to stress that some practices would never require an environmental impact assessment
	25 c		In ~~some~~ such cases a radiological assessment based on relatively simple models using some generic data and cautious assumptions may be sufficient for the authorization process. ~~The regulatory body should define the types of facilities not needing an environmental assessment.~~ For some installations, the regulatory body may define a simple generic methodology.		No			We think we are talking of 3 topics: 1-some installations may need very simple generic-cautious assessments; 2-The regulators shoul identify those installations needing no-assessment; 3 for some installations the regulatory body could define a generic methodology.

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	25 d		The IAEA includes generic guidance for different types of activities and facilities in [ad ref: IAEA-TECDOC Guidance on Generic Radiological Environmental Impact Assessment (in preparation)] and in particular for nuclear power plants [67].”		Yes	As mentioned before, NG-T3.11 (not a safety standard) is not intended to be used as a reference for definitions and procedures but as a source of additional information which may be considered.		
3	26	4.9	“For nuclear installations ~~facilities~~ like nuclear power plants and reprocessing facilities, there are likely to be a number of stages in the authorization process [31]. During those stages the assessment should normally be updated when more specific data is obtained.”	Keeping in mind the definitions in the IAEA Safety Glossary (2007 Edition), a stepwise authorization process rather applies to nuclear installations than to facilities with small inventories of radioactive materials. This is also underlined by the examples mentioned in this sentence. A reference to the Safety Guide SSG-12 is recommended here.	Yes			
3	27	4.10	“For authorization, the organizations responsible for the nuclear installation ~~facility~~ should ensure that an assessment for the protection of public and environment is adequately provided at the different stages. Figure 1 (adapted from [31]) presents schematically the stages in the lifetime of a nuclear installation ~~facility~~; as an example, it shows where an assessment might be carried out at different stages in the authorization	Ensuring consistency with the scope of this Safety Guide as well as with the title of Figure 1. This figure is adapted from the Safety Guide SSG-12 which deals with the licensing process for nuclear installations. See also our related comment on Para 4.9.	Yes			

			process. All the assessments conducted in the stages previous to and during the operation of a nuclear installation ~~facility~~ are basically the same, incorporating more details and information to reduce the level of uncertainty and reviewing the models and assumptions when this is deemed necessary. …"					
3	28	4.12	1st sentence: "Once a site or a reduced number of sites are selected and the technology is ~~more~~ specified (e.g. the type of nuclear power plant is defined), a preliminary assessment for that particular locations is ~~(or those particular locations are)~~ normally ~~done~~ carried out using the available information."	Editorial.	Yes	The clarification "(or those particular locations are)" was proposed in comments from other reviewer and will be kept. We think is correct because we mention "a reduced number of sites" in the sentence.		
2	29	4.14	"Once the authorization or licen~~c~~se has been granted or for facilities already in operation, a periodic safety assessment review will be required [29]; this ~~should~~ includes a ~~the~~ review of the radiological impact assessment provided in the approved EIA report for the construction licence. If there are significant changes in the source term, including in the total amount and the spectrum of radionuclides and in the location characteristics (see Table 1), the radiological impact assessment for protection of the public and, if appropriate, for protection of the environment should be re-evaluated. ~~The assessment should also be re-evaluated if there are significant changes in the source term, including in the total amount and the spectrum of radionuclides and in the location characteristics~~	To be in line with the scope of this Safety Guide.	Yes			

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			~~(see Table 1).~~"					
3	30	4.15	Last sentence: "These situations should be analysed on a case by case basis and, for some of them, the methods for assessment and criteria described in this ~~s~~Safety ~~g~~Guide could be applied."	In conjunction with the publications issued in the IAEA Safety Standards Series, 'Safety Guide' and 'Safety Requirements' should be used as capitalized terms consistently throughout the document.	Yes			
3	31	4.16	1st sentence: "An assessment of the level of radiation protection to the public and to the environment may be required as part of a decision process, for example within an EIA, for certain types of nuclear ~~facilities~~ installations, for example nuclear reactors (see Ref. [67]), installations for reprocessing spent fuel or certain installations for waste processing ~~treatment~~ prior to disposal activities."	Consistency with the terminology in the IAEA Safety Glossary (2007 Edition). The term 'processing' is more comprehensive and includes 'pretreatment', 'treatment' and 'conditioning'. With regard to Ref. [67], see our comment on Para 2.6.	Yes			
2	32	4.19	"~~Operators outside a decision or an authorization processes can conduct a radiological environmental impact assessment for an activity or a facility. For example, as part of a process to evaluate the safety performance of and activity or facility, an operator can evaluate the the systems to reduce radioactive releases to the environment (i.e. normal operation filters or decay tanks) or systems to mitigate releases during accidental conditions (i.e. emergency filters). This is normally done during the operation of facilities with the objective of introducing improvements in the safety systems. When performing such assessments, the same approaches as~~	According to Para 4.14 (with our proposed modifications, see comment No. 29), a reassessment of the radiological impact on the public and, if appropriate, on the environment is recommended if there are significant changes in the source term. Consequently, Para 4.19 can be deleted.	No			It was noted in other comments that a radiological impact assessment can be done for other purposes than authorization or decision, for instance when an operator want to assess an improvement in the design during the operational face. We stress here that if that would be the case, a complete radiological impact assessment should be done, including the potential exposures.

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			~~described in this safety guide should be applied to ensure that all the aspects of public and environmental protection are considered, including the expected exposures and the potential exposures.~~"					
3	33	4.20	1st sentence: "Requirement 36 of GSR Part 1 [28] requires that the regulatory body, either directly or through the applicant of a facility or activity, shall establish effective mechanism of communication to interested parties about the possible radiation risks associated with the facility or activity, and about the processes and decisions of the regulatory body, in accordance with a graded approach."	Amendment to be in line with the wording used in GSR Part 1.	Yes			
3	34	4.21	Last sentence: "Information on the assessment should be made available in appropriate technical language. In addition to that, ~~for example, including~~ a non-technical summary that summarizes the relevant chapters of the more technical reports and outlines the key findings from the assessment could be useful for some of the interested parties, as described e.g. in [67]."	In order to improve the readability and comprehensibility of the entire statement, we propose splitting into two separate sentences. With regard to Ref. [67], see our comment on Para 2.6.	Yes			
2	35	4.23	"~~Despite the objective of the radiological impact assessment in order to grant an authorization is to demonstrate that the radiological effects on public and the environment are evaluated and controlled, e.g. that the radiation risk is acceptable, w~~Where the results of an assessment indicate that the information is relevant across national boundaries, this information should be shared with	The present construction of the first sentence is unnecessarily convoluted. Moreover, it is not clear what the introductory phrase "*Despite the objective of the radiological impact assessment …*" does mean in the context of this sentence. Streamlining of text is recommended. We	Yes			

			the States concerned. The State where the activity or facility is located should arrange with the affected States the means for exchange of information and consultations, as appropriate."	propose to delete the first part of the sentence since it does not offer additional information which is relevant here (compare with Para 4.21 of draft version 6.2).				
3	36	5.2	"… This methodology is consistent with similar methods developed and used by States for various purposes, including evaluation of impacts to the environment and decision making~~.~~ [64, 65, 66]. The concept of '~~R~~reference animals and plants' is discussed below in the section on assessment for protection of flora and fauna for normal operation."	Wording/Editorial.	Yes			
1	37	5.7	Last sentence: "The following sections describe the characteristics of the assessments for (a) ~~p~~Protection of the public ~~and protection of flora and fauna (as an option)~~ in normal operations~~,~~ and ~~for protection of the public~~ against potential exposure, following the principle of ICRP Publication 103 [3] that the protection of humans implies the protection of non-human species; and (b) Protection of flora and fauna (as an option) in normal operations based on ICRP Publications 108 and 124 [32, 33], in addition to the protection of the public."	For justification, see our related comment No. 3.	Yes	It will be reworded.		
3	38	5.25	4th sentence: "For releases to the sewerage system during normal operation (typically for ~~laboratories and~~ hospitals): (~~m~~l) Inhalation of resuspended sewage	The consecutive numbering of items in this paragraph is erroneous. For laboratories neither a	Yes	The numbering will be corrected. There are some laboratories with relative large releases (similar to hospitals or even greater). We will		

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

			sludge; (~~n~~m) External exposure from radionuclides in sewage sludge."	non-radiological environmental impact assessment nor a radiological environmental impact assessment is required by law. Compare with the paragraph proposed to be included after Para 1.8 (see our comment No. 7).		clarify this.		
1	39	5.25	5th and 6th sentence: "~~In some facilities or activities, radiation sources could contribute to doses to the member of the public living in the close vicinity of the installations or working on site. Additional pathways to be considered are:~~ ~~(o) Direct irradiation from sources stored in the facility (i. e. from spent fuel or radioactive waste storages);~~ ~~(p) Direct irradiation from sources used in the facility (i.e. from industrial irradiators); and~~ ~~(q) Direct irradiation from the facility (i.e. from components of the facility like nuclear reactors or coolant systems).~~"	It is proposed to delete this part of Para 5.25 without substitution. According to Para 5.12, the radiological environmental impact assessment covers only exposure pathways due to radioactive releases to the environment. Exposures due to direct irradiation from the facility, or from sources used or stored in the facility, are dealt with in the safety analysis report (SAR) as part of the overall safety assessment.	No			Direct irradiation to could be a relatively important source of radiation exposure of public in some cases. There were comments saying we should add direct radiation to the radiological impact assesment. Will be discussed at RASSC/WASSC/NUSSC meetings.
2	40	5.28	"~~It should also be noted that other exposure pathways may contribute to the dose received by individuals in particular circumstances, for example consumption of seasonal or atypical foods.~~"	It is proposed to delete this Para as it is irrelevant for a radiological environmental impact assessment.		Being considered		
3	41	5.35	Last sentence: "[5] provides guidance for the definition and use of dose constraint for protection of members of the public in planned exposure~~s~~ situations."	Editorial.	Yes			
3	42	5.38	1st sentence: "… a generic upper value of a dose	Wording.	Yes			

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

			constraint for different types of activities and facilities (i.e. for nuclear fuel cycle facilities), …"					
2	43	5.40	"~~The aim of protection of the environment is set at a high level, for instance: to provide for the maintenance of biological diversity, to ensure the conservation of species and the health of natural habitats, communities and ecosystems [32].~~ Within this Safety Guide, the general intent of the measures taken for the purposes of environmental protection is to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms) [2]."	It is proposed to delete the first sentence. The protection of the environment with the high level aim to maintain the biological diversity, the conservation of species and ecosystems, or the protection of rare and endangered species is reduced in disputable manner to the possible impact of the stressor 'radioactivity' in ICRP 108. Taking into account that the protection of flora and fauna is limited to normal operation, this abiotic environmental factor is of less or no relevance compared to other non-radiological parameters, e.g. enhanced water temperature, concentration of toxic substances in the environment, on-site ecological conditions etc. Moreover, in Para 1.8 it is explained that this Safety Guide is applicable to evaluate prospectively exposures due to radioactive releases to the environment. However, measures for the protection of e.g. the breeding ground of a rare or endangered bird species must be taken into account already	No			The high level aim of radiological protection of the environment, set by ICRP and also adopted by the IAEA, is appropriately achieved by managing the releases into the environment using the concept of 'representative plants and animals', estimating their radiation exposures and comparing with the relevant criteria (e.g. the ICRP Derived Consideration Reference Levels). This is agreed by the radiation protection community and international organizations in several forums, particularly for planned exposures situations (for instance, see http://gnssn.iaea.org/RTWS/cgrpe/Shared%20Documents/Meeting%20Final%20Reports/Final%20Report%205th%20Meeting%20(2013).pdf) It is truth that other non-radiological stressor can be of more relevance, but are out of the scope of DS427. DS427 notes that the use of ICRP approach, in a generic manner as described in this Safety Guide, could be not sufficient in the case of en-

				in the phase of site selection; i.e. if a breeding ground is identified at a possible site for a facility (irrespective of nuclear or non-nuclear), this site is to be excluded from further considerations.				dangered species or protected areas, and suggests a more detailed assessment in those cases).
2	44	5.41	"States may consider that the assessment of the protection to members of the public is sufficient to demonstrate protection of the environment as well. This position is based on the assumption that the system of protection and safety, which aims to assess, manage and control the exposure to radiation to humans, provides for appropriate protection of the environment from harmful effects of radiation, following the principle of ICRP Publication 103 [3]."	Ensuring consistency with our proposal for modification of Para 5.7 (see comment No. 37). Please refer to the relevant ICRP publication which underpins the position expressed here. For justification, see our related comment No. 3.	Yes	It's accepted but will be reworded		
3	45	5.43	"Normally, for activities or facilities requiring a simple assessment, like hospitals operating a nuclear medicine department ~~and small laboratories~~, the explicit consideration of protection to flora and fauna is not necessary, on the basis that a significant radiological impact to the environment is not foreseeable owing to, for example, the limited radionuclide~~s~~ inventory in the sources of the facilities or its intrinsically safe characteristics."	Ensuring consistency with our proposal for modification of Paras 4.7 and 4.8 (see comment No. 25).	Yes	See resolution of comment 25.		
3	46	5.45	1st sentence: "… the concepts of 'reference animals and plants', 'representative organism' …"	Editorial (missing quotation mark).	Yes			
3	47	5.46	"This Safety Guide presents an assessment for protection of flora and fauna of	Editorial.	Yes			

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

			generic character, consistent with the ICRP approach for protection of the environment [32]~~,~~. A generic assessment, as described below, implies the use of the ICRP reference animals and plants (RAPs) relevant for the specific ecological scenarios (e.g. ~~T~~terrestrial, marine, freshwater) and the use of cautious assumptions …"	The abbreviation RAP should be explained here because it is not introduced elsewhere in the document but is further used in Paras 5.49, 5.61 and 5.64.				
1	48 a 48 b	5.47	"~~For most facilities and activities and environmental situations, a generic assessment would be sufficient to demonstrate protection of flora and fauna.~~ ~~However, a generic approach may not be appropriate for the assessment of the impact to flora and fauna in particular circumstances, for example when dealing with protected or endangered species or when very sensitive ecological niches are identified.~~"	It has already been discussed in Paras 5.43 to 5.46 that, for most facilities or activities, a generic assessment would be sufficient to demonstrate protection of flora and fauna. Therefore, the first sentence can be deleted. The second sentence is suspect since the protection of rare or endangered species or the conservation of sensitive ecological niches can only be ensured if the primary living conditions are maintained. If a facility will be constructed at a site where a sensitive ecological niche exists, this niche would be irrecoverably destroyed.	Yes No			See resolution to comment 43. The construction of a facility can or cannot impact significantly to a sensitive ecological niche. That is why it has to be considered on a case by case basis and with detailed assessment approaches. We think this para is valid.
1	49	5.53, 5.54	Please include missing information.	No text is provided in both paragraphs.	Yes	Numbers will be deleted		
3	50	5.56, 5.57	Combine and merge both paragraphs into one Para as follows: "The types of animals and plants pre-	Paras 5.57 and 5.58 provide an explanation of Table 2 and are closely related to	Yes			

			sented in Table 2 are related to reference animals and plants defined by ICRP [32]. They are representative of marine, terrestrial and freshwater ecosystems and have a wide geographical variation. The reference animals and plants are a set of hypothetical entities defined for the procedure of dose estimation and for considering the relation between doses and their effects for managing environmental situations from the radiation protection point of view. ~~The reference animals and plants indicated in Table 2 are representative of marine, terrestrial and freshwater ecosystems and have a wide geographical variation.~~"	each other.				
3	51	5.62	1st sentence: "The derived consideration reference levels [32] ~~is~~ are a set of dose rate bands …"	Editorial.	Yes			
1	52	5.64	"In a generic assessment as presented in this Safety Guide, if the dose rates to the RAPs are below the ~~lower~~ upper boundary of the relevant derived consideration reference level band, impact on population of flora and fauna could be considered as very low or negligible and the level of protection of environment can be considered adequate. ~~In the case where the estimated dose rates are within the bands the situation can still be acceptable, but the regulatory body could decide whether additional considerations (i.e. improvement in the level of details of the assessment) or practical mitigation measures would be needed,~~	Sure, the proposal to take reference to the upper boundary of the relevant derived consideration reference level band, instead to the lower boundary, was indeed rejected by the IAEA (compare with the resolution table to draft version 6.2, ENISS comment No. 20). Nevertheless, according to Para 5.62 "*The derived consideration reference levels [32] is a set of dose rate bands within which there is some very low*	No			We understand the reasoning by SSK but we have some additional reasons to choose first the lower boundary and then, giving the chance to the regulator to decide on more detailed assessment or simple mitigation measures if the dose is between the band. The IAEA proposal (based on ICRP) is applied in a very generic manner, and for that reason, we adopt a cautious use of the DCRLs. For instance, ICRP proposes that the RAPs should be somehow related to the actual flora and fauna and the IAEA proposal

			~~bearing in mind that derived consideration reference levels are reference points, not limits.~~ If the resulting dose rates are above the upper boundary of the relevant derived consideration reference level band, the regulatory body should decide if this implies a ~~stronger~~ need to consider more control on the source or further protection efforts."	*probability of deleterious effects of ionizing radiation to individuals of flora and fauna, which may have implications in the structures or populations.*" and "… *for dose rates below the lower level of the bands, no effects have been observed* …" Keeping also in mind that the upper boundary of the DCRLs for the reference animals (Table 2) is about 3 to 4 orders of magnitude lower than the values of the 50% lethal dose of these reference animals, any deleterious effects of ionizing radiation at the corresponding upper boundaries of DCRLs can widely be excluded in the case of a linear dose-response relationship, i.e. the DCRLs for the reference animals are indeed very conservative. Furthermore, a similar approach in radiation protection was established in the past by implementation of a 'band', i.e. exceeding the lower boundary means 'you can implement mitigation measures' while exceeding the upper boundary means 'you must implement mitigation measures'. This ap-				indicates to use just the ICRP RAPs as a reference (avoiding the need to study in more detail the actual flora and fauna). Additionally, the IAEA defined a reference area around the source (100-400 km^2) where exposures to the RAPs should be averaged. Averaging implies that certain number of individuals can receive higher doses than the estimated average. This, in our understanding, adds a need of additional caution in the use of DCRLs. Nevertheless, the use of the lower boundary of the criteria in combination with a generic assessment would not imply a burden to the industry, because for most if not any of the facilities in normal operation, the level of impact to humans dominates the amount which can be releases and the assessment of the impact to flora and fauna is a kind of confirmation that the environment is well protected. In simple, words, the use of a very generic approach should be accompanied by a cautious application of the criteria. We will discuss this during WASSC/RASSC/NUSSC.

				proach resulted in the conversion of the meaning of the lower boundary to that of a maximum permissible value. Such tendency should be avoided. For this reason, the German Radiation Protection Commission (SSK) recommends to apply the upper boundary of the DCRLs (Ref.: SSK draft recommendation "Protection of the Environment" dated October 2014).				
2	53	Headline prior to 5.65	"ASSESSMENT FOR ~~OF~~ PROTECTION OF THE PUBLIC AGAINST POTENTIAL EXPOSURE" We propose to place this subsection (Paras 5.65 to 5.108) directly after the subsection "ASSESSMENT FOR PROTECTION OF THE PUBLIC FOR NORMAL OPERATION" (Paras 5.8 to 5.39) and before the subsection "ASSESSMENT FOR PROTECTION OF FLORA AND FAUNA FOR NORMAL OPERATION" (Paras 5.40 to 5.64).	Editorial correction to be consistent with the headlines of the other subsections on assessment in Section 5. Normal operation and potential exposures are subject to a typical radiological environmental impact assessment with the structure and content described e.g. in the IAEA Nuclear Energy Series publication NG-T-3.11. Such an EIA report does not evaluate the radiological impact to flora and fauna. See also our related proposal for modification of Para 5.7.	Yes			
2	54	5.65	"Facilities and activities that use or process radioactive sources or materials, are to be designed, constructed, commissioned, operated or conducted, maintained and decommissioned in such	Clarification and consistency with the first sentence of Para 5.8. The fundamental safety objective applies for all facilities and activities,	Yes			

			a way as ~~order~~ to prevent and mitigate incidents and accidents that, in the vast majority of cases, result in no radiological consequences for the public …"	and for all stages in the lifetime of a facility, including commissioning.				
2	55	5.66	"… The types of accidents to be considered depend on the characteristics of the activities and facilities under consideration. In order to assess prospectively the potential exposures to members of the public, as required in the IAEA safety standards [1, 2, 48], those ~~incidents and~~ incidents, events or sequences of events that may lead to an accident, with their frequencies or probabilities, should be considered."	Ensuring consistency with the first and second sentence of this Para as well as with Para 5.68 which states "*For the purposes of this Safety Guide, the expression 'potential exposure scenarios' is used to include the characteristics of all the incidents, events or sequences of events that may lead to an accident, including their source term characteristics – and when applicable their frequencies or probabilities –, combined with the selected environmental conditions which are taken into account to assess the potential exposures.*"	Yes			
3	56	5.78	1st sentence: "For ~~facilities~~ complex nuclear installations, such as nuclear power plants, large research reactors ~~or laboratories~~, radioactive waste management facilities and ~~nuclear~~ spent fuel reprocessing plants, which have large inventories and where the physical, chemical or nuclear characteristics may facilitate large releases in accident scenarios, …"	Wording.	Yes			
3	57	5.103	Last sentence: "More detailed information on criteria for consideration of potential exposures	Wrong Annex is cited in this paragraph.	Yes			

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

			is provided in Appendix I and discussed in Annex II ~~III~~."					
3	58	5.105	"… Although the endpoint and the criteria of this type of assessment are in term of doses, owing to the fact that some frequencies are involved, there is an implicit notion of risk and the results can be related to the criteria discussed in Appendix I. This is more discussed in Annex II ~~III~~."	Wrong Annex is cited in this paragraph.	Yes			
2	59	5.110	Please add new sentence: "Sensitivity analyses techniques can be useful for identifying important parameters for determining the overall impacts and should be applied when possible. Such techniques include a systematic variation of the individual parameters or scenarios that are used in modelling, in order to determine their influence on the results of the assessments."	In order to assist the reader of this document, it seems to be useful to include a quick explanation what sensitivity analyses stand for.	Yes			
3	60	5.111	Last sentence: "Model uncertainties should be addressed properly to facilitate the decisions by the governmental agencies and the regulators, on the one hand, as well as ~~and~~ the communication with ~~other stakeholders, like~~ interested parties such as the public, on the other hand."	Wording. Elsewhere in this document, the term 'interested parties' is used (see e.g. Paras 1.7, 2.8 and 4.20).	Yes			
3	61	5.115	"… would provide confidence that the predicted doses are reasonable and do not underestimate~~d~~ real doses."	Editorial.	Yes			
3	62	List of references	Note: We recommend to delete the references [50], [53] and [56] since they are not cited in the text of the document.	In the previous draft version 6.2, these references were assigned to paragraphs in the subsection "ASSESSMENT OF PROTECTION OF THE PUBLIC AGAINST PO-	Yes			

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

				TENTIAL EXPOSURE". As the current draft version 5 does not discuss anymore the possible accidents to be considered, the abovementioned subsection has been revised and several paragraphs and footnotes have been deleted, including those referring to [50], [53] and [56].				
3	63	Ref. [7]	"INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive ~~Releases~~ Discharges to the Environment ~~from Facilities and Activities~~ (Revision of WS-G-2.3), IAEA, Vienna (Draft DS 442)."	Citation of the correct title of DS442 (see draft version 3 dated October 2014).	Yes			
3	64	Ref. [12]	"INTERNATIONAL ATOMIC ENERGY AGENCY, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste ~~Details~~, IAEA Safety Standards Series No. SSG-23, IAEA, Vienna (2012)."	Editorial.	Yes			
3	65	Appendix I, I.2	"Risks of health effects to members of the public may arise from potential exposures related to accidental releases of radioactivity. Annex II ~~III~~ presents definitions of measures of risk which can be used in the potential exposures assessment. …"	Wrong Annex is cited in this paragraph. Definitions of measures of risk which can be used in the assessment of potential exposures are presented in Annex II, Paras II-6 to II-11.	Yes			
3	66	Appendix I, I.4	"… the currently accepted value of approximately 0.05 for the probability of death per Sv for members of the general ~~population~~ public; …"	Wording.	Yes			

DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Page 1 of 3 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: Nov. 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Title	A general framework for prospective radiological environmental impact assessment ~~and protection of the public~~	WASSC decided to change the title at the last meeting, however it is deemed to need further discussion. The context of radiological environmental impact assessment implies both regarding "*protection of public*" and "*protection of the environment*". Hence to simplify the title of this document, the latter part "*protection of public*" should be deleted See para.2.14. ICRP Publ.124 defines "Environmental radiation protection."	Yes	The final tittle is still under consideration but the comment is valid and will be considered.		
2	General	Clear allocation of information and guidance should be considered between DS432 and DS427. For example DS432 provides the concept of protection of the environment, however Section 2 of DS427 mentions "*Section 2 provides an explanation of some of the **concepts** and **terms** used in this Safety Guide*". Basic information including terms should be moved to DS432.	Clarification	Yes	The comment is valid This will be sorted out during the final edition of the 2 documents.		
3	General	Change "BSS" to "GSR Part3"	Editorial	Yes	GSR Part 3 will be used in following versions.		

4	General	Change “activities and facilities” to “facilities and activities”	Both “facilities and activities” and “activities and facilities” are used together in this document. As the former term is defined in IAEA Safety Glossary, the term should be aligned.	Yes			

DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Page 2 of 3 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: Nov. 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5	General	Format of citation of other Safety Standards should be consisted among Safety Guides (DS442, 432, 427).	Clarification. Examples would be found in other Safety Guides such as SSG-23 (Section3) and SSG-29 (Section 3 to 7.)	Yes			
6	General	Paragraph consisted of short statement should be consolidated with an appropriate paragraph. For example paras.4.6, 5.50 and 5.56.	To avoid unnecessary partitioning.	Yes	Will be sorted out during future editions		
7	2.6/3	Add GSG-3 to these references.	GSG-3 is also relevant.	Yes			
8	3.17	Requirement 6 of ~~the BSS~~ GSR Part3 states that "the application of the requirements … and likelihood of the exposures".	Editorial However this comment is based on the current format of citation. See Comment No.5.	Yes			
9	4.8/the last text	What is the TECDOC mentioned in this paragraph? There is no presentation on this TECDOC in both WASSC36 and WASSC37. We would appreciate if the Technical officer could provide information on this TECDOC to WASSC members.	Confirmation	Yes	During discussions at WASSC the need of applications of the general framework proposed in DS427 to specific practices was indicated. The IAEA will develop a TECDOC/TECDOCs with cases.		
10	4.20	Add *DS460* "*Communication and Consultation with Interested Parties by the Regulatory Body*" as a reference to this paragraph or elsewhere.	Clarification	Yes			

11	5.1/6	What is IAEA technical safety guidance?	Confirmation Safety Guides? TECDOC? NE-Series publication?	Yes	Will be amended to "IAEA Safety Guides"		
12	Figure 1, 2, 3	Captions of these Figures should be moved to the bottom.	Editorial	Yes			

DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Page 3 of 3 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: Nov. 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13	5.38/2,9	.. (i.e. for nuclear fuel cycle facilities), ... is discussed further in [5, 7, 41, 44]~~, [7], [44], [5 and 7]~~	Editorial				
14	5.53, 5.54	Delete both paragraphs.	Although these paragraphs are blank, the basis of the selection of RAPs has been described in the latter paragraphs.				
15	5.66/6	.. in the IAEA safety standards [1, 2, 48], those incidents and accidents ~~incidents~~, with their probabilities, ..	Editorial Consistency with para.5.65.				
16	5.89	Add following text to after 2nd text. In addition, highly concentrated radioactivity in waste could be arisen due to collection, storage and incineration and of radioactively contaminated waste following an accident, such a specific case would also be an important exposure pathway.	Lessons learned from off-site experience of Fukushima Dai-ichi NPP accident.				
17	5.111/7 (p.43)	Model uncertainties should be addressed properly to facilitate the decisions by the governmental agencies and the regulators and the communication with other interested parties ~~stakeholders~~, like the public.	Editorial				

DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Page 1 of 3 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: Nov. 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Title	A general framework for prospective radiological environmental impact assessment ~~and protection of the public~~	WASSC decided to change the title at the last meeting, however it is deemed to need further discussion. The context of radiological environmental impact assessment implies both regarding "*protection of public*" and "*protection of the environment*". Hence to simplify the title of this document, the latter part "*protection of public*" should be deleted See para.2.14. ICRP Publ.124 defines "Environmental radiation protection."	Yes	The final tittle is still under consideration but the comment is valid and will be considered.		
2	General	Clear allocation of information and guidance should be considered between DS432 and DS427. For example DS432 provides the concept of protection of the environment, however Section 2 of DS427 mentions "*Section 2 provides an explanation of some of the **concepts** and **terms** used in this Safety Guide*". Basic information including terms should be moved to DS432.	Clarification	Yes	The comment is valid This will be sorted out during the final edition of the 2 documents.		
3	General	Change "BSS" to "GSR Part3"	Editorial	Yes	GSR Part 3 will be used in following versions.		

4	General	Change “activities and facilities” to “facilities and activities”	Both “facilities and activities” and “activities and facilities” are used together in this document. As the former term is defined in IAEA Safety Glossary, the term should be aligned.	Yes			

DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Page 2 of 3 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: Nov. 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5	General	Format of citation of other Safety Standards should be consisted among Safety Guides (DS442, 432, 427).	Clarification. Examples would be found in other Safety Guides such as SSG-23 (Section3) and SSG-29 (Section 3 to 7.)	Yes			
6	General	Paragraph consisted of short statement should be consolidated with an appropriate paragraph. For example paras.4.6, 5.50 and 5.56.	To avoid unnecessary partitioning.	Yes	Will be sorted out during future editions		
7	2.6/3	Add GSG-3 to these references.	GSG-3 is also relevant.	Yes			
8	3.17	Requirement 6 of ~~the BSS~~ GSR Part3 states that "the application of the requirements … and likelihood of the exposures".	Editorial However this comment is based on the current format of citation. See Comment No.5.	Yes			
9	4.8/the last text	What is the TECDOC mentioned in this paragraph? There is no presentation on this TECDOC in both WASSC36 and WASSC37. We would appreciate if the Technical officer could provide information on this TECDOC to WASSC members.	Confirmation	Yes	During discussions at WASSC the need of applications of the general framework proposed in DS427 to specific practices was indicated. The IAEA will develop a TECDOC/TECDOCs with cases.		
10	4.20	Add *DS460* "*Communication and Consultation with Interested Parties by the Regulatory Body*" as a reference to this paragraph or elsewhere.	Clarification	Yes			

11	5.1/6	What is IAEA technical safety guidance?	Confirmation Safety Guides? TECDOC? NE-Series publication?	Yes	Will be amended to "IAEA Safety Guides"		
12	Figure 1, 2, 3	Captions of these Figures should be moved to the bottom.	Editorial	Yes			

DS427 A general framework for prospective radiological environmental impact assessment and protection of the public

COMMENTS BY REVIEWER Reviewer: Page 3 of 3 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: Nov. 2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13	5.38/2,9	.. (i.e. for nuclear fuel cycle facilities), ... is discussed further in [5, 7, 41, 44]~~, [7], [44], [5 and 7]~~	Editorial	Yes			
14	5.53, 5.54	Delete both paragraphs.	Although these paragraphs are blank, the basis of the selection of RAPs has been described in the latter paragraphs.	Yes			
15	5.66/6	.. in the IAEA safety standards [1, 2, 48], those incidents and accidents ~~incidents~~, with their probabilities, ..	Editorial Consistency with para.5.65.	Yes			
16	5.89	Add following text to after 2nd text. In addition, highly concentrated radioactivity in waste could be arisen due to collection, storage and incineration and of radioactively contaminated waste following an accident, such a specific case would also be an important exposure pathway.	Lessons learned from off-site experience of Fukushima Dai-ichi NPP accident.	No			Despite this is very important, we are trying to be as general as possible. If we introduce this particular case, other cases should be included. DS427 applies to incineration of wastes.
17	5.111/7 (p.43)	Model uncertainties should be addressed properly to facilitate the decisions by the governmental agencies and the regulators and the communication with other interested parties ~~stakeholders~~, like the public.	Editorial	Yes			

USA Comments on IAEA Draft Safety Guide DS427:
"A General Framework for Prospective Radiological Environmental Impact Assessment and Protection of the Public"

COMMENTS BY REVIEWER Reviewer: Multiple (Coordinator: Boby Eid; Boby.abu-Eid@nrc.gov) Page 1 of 7 Country/Organization: USA/NRC Date: 11/12/2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
Major Comments							
1	General	DS427 allotted an extensive Section (pages 29-34) on "Assessment for Protection of Flora and Fauna for Normal Operation." This Section does not correspond to a specific safety requirement in the BSS (GSR Part 3). In other words, this Section does not correspond to any required need for demonstration of compliance with certain protection or dose criteria in the BSS (e.g.; dose/risk criteria for fauna and flora).. In fact, the BSS (Para 1.34) stated: *"Radiological impacts in a particular environment constitute only one type of impact and, in most cases, may not be the dominant impact of a particular facility or activity. Furthermore, the assessment of impacts on the environment needs to be viewed in an integrated manner with other features of the system of protection and safety to establish the requirements applicable to a particular source."*	For consistency with IAEA safety requirements, the Section on dose impacts to fauna and flora (Pages 29-34) should be moved to Annex I. This information though useful, it does not correspond to IAEA specific requirement of establishing reference or risk/dose level to non-human species. Protection of the environment should be dealt with in an integrated and sustainable fashion considering numerous environmental,	To be discussed	The need to consider protection of the environment is identified in SF-1 and BSS. The explicit inclusion of flora and fauna in the radiological impact assessment is subject to national practices. Some MS already have regulations and others may soon require so. Some international frameworks already requires the explicit inclusion of flora and fauna.		

COMMENTS BY REVIEWER Reviewer: Multiple (Coordinator: Boby Eid; Boby.abu-Eid@nrc.gov) Page 1 of 7 Country/Organization: USA/NRC Date: 11/12/2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		Therefore, the Sections on the procedure and exposure pathways, and selection of a representative animal and plant s, though useful, need to be moved to Annex I "Considerations on Assessment for Protection of the Environment." This action will alleviate concerns regarding comparison of dose rates with reference levels not adopted by IAEA or stated in any safety requirements. In addition, uncertainties for assessment of risk and dose rate impacts to fauna and flora are so large due to severe influence of numerous environmental and ecological parameters, such that the dose rates or reference levels invoked would be a challenge for regulatory implementation. (See also USA Comments #2, 3,7,11, and #17 on the previous DS427 draft revision pertaining to the scope and dose criteria to fauna and flora).	climate, and ecological factors.		During discussions in RASSC/WASSC it was noted that, despite this is a new topic, it is convenient that IAEA provides ASAP guidance based on the current level of scientific knowledge. DS427 intend to provide guidance based on ICRP approach. ICRP approach is recognized as scientifically sound and practical by the international radiation protection community. ICRP approach includes criteria.		

COMMENTS BY REVIEWER Reviewer: Multiple (Coordinator: Boby Eid; Boby.abu-Eid@nrc.gov) Page 1 of 7 Country/Organization: USA/NRC Date: 11/12/2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
					Equivalent approaches are already in use in some Member States (in Europe, USA and Canada) for different purposes. Criteria in all those approaches is consistent with ICRP criteria. Nevertheless, the convenience to move part of the section to the Appendix will be discussed at next WASSC/RASSSC meeting.		
2	Paras 5.40, 5.41,and 5.42	Move Para 5.40 to Annex I. Keep Para 5.41 (Becomes Para 5.40) and 5.42 (Becomes 5.41) 5.40 States may consider that the assessment of the protection to members of the public is sufficient to demonstrate protection of the environment as well.	The suggested changes will accommodate the information needed regarding non-human dose assessment for those	To be discussed.	Will be considered together with previous.		

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		This position is based on the assumption that the system of protection and safety, which aims to assess, manage and control the exposure to radiation to humans (through assumption that human continuously and directly interacts with non-human species), provides for appropriate protection of the environment from harmful effects of radiation. In that case the assessment may not need to include explicit consideration of the radiation exposures to flora and fauna as described below in this section. 5.41. Other States may require the more explicit and inclusion in the assessments of additional specific components of the environment, for instance, dose impacts to flora and fauna. See Annex I, for detailed information on procedures, pathways, representative animals and dose rates with reference levels.	seeking to adopt reference levels for flora and fauna.				
3	4.14	Modify Para 4.14 to read: Once the authorization or license has been granted or for facilities already in operation; subsequent update of safety assessment may be necessary to reflect changes in safety features and	Clarity: Periodic assessment is typically conducted based on changes in safety functions or features	YES			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		performance measures, if any. Therefore; a periodic safety assessment review will be required [29] to ensure ~~; this should include the review of the radiological impact assessment for~~ protection of the public and protection of the environment under new safety conditions. The assessment should also be re-evaluated if there are significant changes in the source term, including in the total activities ~~amount~~ and concentrations of ~~and the spectrum~~ radionuclides and in the location and characteristics of contaminated environmental media (see Table 1).	and/or changes in performance measures based on monitoring data and inspections. Therefore, a qualifying statement should be added to elucidate and link periodic assessment with safety functions and performance measures.				
4	5.84	"For facilities like nuclear power plants, meteorological and hydrological data collected over at least a year should be used to specify characteristic accident dispersion conditions [39, 40]."	Accuracy and Consistency: Reliance on data from a single year may not be consistent with longer climatic trends. Suggest lengthening to rely on data collected over at least 3-5 years.	YES	Recommendation of lengthy measurements (3-5 years) will be added.		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5	5.19	"… ~~There may also be discharges of radionuclides to the sewerage system.~~ …"	These discharges are discussed fully in immediately following paragraph 5.20.				
6	Para 5.53 and Para 5.54, Page 31	Under sub-section "Selection of Representative Animals and Plants" two paras were left blank with no text.	Need to add a text to Paras 5.53 and 5.54 or delete.	YES	Will be deleted.		
7	5.101	The concept of using "endpoints" that use a "risk" or "dose" should be elaborated further. We suggest using the term "end-state" rather than "end point." The BSS require that the likelihood and magnitude of potential exposures be considered and that restrictions be established by the regulatory body. Restrictions can be related to institutional controls, land uses, or other economic or social factors. In addition, stakeholders and the public may influence the outcome of the end-state. Therefore, consideration of potential exposures, or a 'measure of the risk' as "endpoints" may indeed be significant factors in the final status decision-making; nevertheless, it might not be the	Consistency and Clarity: "Endpoint" for termination of a licensed activity, or a licensed facility, is typically related to several other factors besides "dose" or "risk" criteria. The guidance should use the term "end-state" as more appropriate term. This section should be elaborated further to discuss	YES	Will be clarified		

COMMENTS BY REVIEWER Reviewer: Multiple (Coordinator: Boby Eid; Boby.abu-Eid@nrc.gov) Page 1 of 7 Country/Organization: USA/NRC Date: 11/12/2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		"endpoint." In addition, the text used "risk" and "dose" as synonym terms. The text should explain the relationship between "dose" and "risk" particularly when addressing environmental risk.	other factors influencing decision-making for the end-state.				
8	III-10	"…source material, ~~by product~~ byproduct material, and special nuclear material…"	As defined in Atomic Energy Act and NRC regulations.	Yes			
9	III-12	The NRC ~~analyses~~ analyzes radiological consequences under normal conditions against the requirements of 10 CFR Part 20, "Standards for Protection Against Radiation." ~~and affluent~~ Effluent release limits are specified in 10 CFR ~~(~~Part 20, Appendix B~~)~~. ~~as well as "Standards for Protection Against Radiation,"~~ The NRC also has specific criteria under 10 CFR Part 50, Appendix I, to keep the public dose from radioactive effluents as low as reasonably achievable (ALARA).	Clarify NRC regulatory requirements.	Yes			
Editorial Comments							
1	5.46	"This Safety Guide presents an assessment for protection of flora and fauna of generic character, consistent	Editorial - need either additional references or to	Yes			

COMMENTS BY REVIEWER Reviewer: Multiple (Coordinator: Boby Eid; Boby.abu-Eid@nrc.gov) Page 1 of 7 Country/Organization: USA/NRC Date: 11/12/2014				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		with the ICRP approach for protection of the environment [32, ."	close the parens.				
2	5.61	"Ref. [11] and [46] provide environmental media to biota concentration ratios for different flora and fauna."	Editorial – deleted comma before final period	Yes			
3	5.69	"As it is explained in the section Scope, this Safety Guide covers only health effects due to radiation doses resulting from hypothetical accidents to members of the public at the individual level."	Suggest revising to "credible" accidents, as hypothetical may be mis-understood as not fully based in reality	Yes	Hypothetical must be changed. We will find an alternative wording.		
4	1.6	"to estimate and control, using criteria, the radiological effects on the public and effects on the environment."	Editorial - added "the" before "public"	Yes			
5	1.10	"The prospective assessment as described in this Safety Guide can serve multiple purposes including, …"	Editorial – delete "to" between "serve" and "multiple"	Yes			
6	1.10	"The process to establish discharge limits and optimize the protection of the public is covered in a separate Safety Guide [7]."	Editorial – replaced "separated" with "separate"	Yes			
7	III_13	The NRC ~~analyses~~ analyzes design basis accident…	Editorial.	Yes			

DS427 - Draft Safety Guide: A General Framework for Prospective Radiological Environmental Impact Assessment

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: 3			Page 1 of				
Country/Organization: EC			Date: 9 Nov 2014				
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection

1. General	2.13 and Section 5, 3.7	Following the decision of WASSC 37 for change of the title, the Guide now covers both assessment of public and environment without discussing how the results of these assessments can be interpreted and used by operators or regulators in the definition of operational limits and conditions and (see para 3.7) and/or decision making process (see para 2.13)	The integration of the results of the radiological assessments (discussed in Section 5) will need to be explained and their input to the safety cases (e.g. predisposal waste management, see SSG-3)	No			DS427 defines a framework for Radiological Environmental Impact Assessment (REIA) to be used within an authorization process in order to define a priory the general acceptability of a facility or activity, with respect to public and the environment protection. A REIA is just a part in the authorization process. Other parts (not included in DS427) are, for example, safety assessment, optimization, definition of operational limits and conditions. Safety Assessment, including optimization, is covered in other Safety Guides (i.e. SSG-3). Operational limits for releases to the environment, including optimization. Are discussed in DS442.
2. General	Section 5, 1.4; 1.14, 3.3.	The document refers to "a methodology", "methodologies" "methods" and "procedures"	Clarification of terminology used in the Guide	Yes	Will be sorted out during future editions.		

3. General	Section 3	In case that this Safety Guide is overarching for the existing Safety Guides on safety assessment (GSG-3, WS-G-5.2, etc.) it will need to address the iteration, model selection an validation, and design optimization,	Address the main elements of safety assessment that are included in the existing Safety Guides (for the purpose of consistency)	No			Despite DS427 provides a stand-alone framework for REIA (and there are valid reasons for doing so) DS427 is not overarching Safety Guides on Safety Assessment. On the contrary, the methodologies presented in DS427 may be considered as the description, with more level of details. Of the section about REIA in the Safety Guides on Safety Assessment. Safety Assessment Guides may be the overarching guidance. DS427 serves to the chapter on REIA in those Safety Assessment Guidance. Model selection and validation is discussed in DS427. Optimization is out of the scope of DS427. Optimization should be first discussed in a broader framework (that of Safety Assessment). Finally optimization of the protection of public with respect to discharges is discussed in DS442.

4. General	Annex 3	Examples of Member States experiences/approaches is usually in the scope of supporting IAEA TECDOCs or Safety Reports	Consistency of the format of the Safety Guides	Yes	During the elaboration of DS427 the use of different approaches by Member States was noted. The examples were incorporated to support the definitions of the general methodology presented. At some point, the Annex can be deleted. This will be discussed at RASSC/WASSC/ NUSSC/		
5.	Fig. 2, 3, 4	As mentioned before these figures are not fully consistent with the steps identified in the SSG-3 and WS-G-5-3; e.g. selection and verification of models is not included; and also Fig 4 sequence of steps 1 and 2 needs to be changed (first start with the inventory and facility description) and then discuss potential scenarios. An important aspect that is to be included is the iteration process in the safety assessment.	Suggested to make the Figures in line with existing Safety Guides	No			As noted in footnote 11 in DS427, figures are conceived to illustrate at a general level the elements of radiological impact assessments facilitate their discussions and are not proposed to be used as detailed procedure. The figures does not represent, neither replaces other procedures in other documents.

6.	2.14	Revision suggested "…in the context of planning for nuclear and other facilities"	EIA can be required for other facilities as well (e.g. waste management facilities)	Yes			
7.	Section 3	It is unclear why optimization is out of the scope of this Safety Guide, when it aims to support the BSS	Clarification needed	No			As explained before in response to comment 3, optimization of the protection in general (workers, public and the environment) should be first conducted in a broader framework than DS427 (e.g. in the major framework of Safety Assessment). Optimization of the protection of the public against discharges is normally done when stablishing discharge limits (and this is included in DS442).
8.	4.15	"For the decommissioning stage…."	EIA is required for the whole decommissioning projects, not only at the end of such projects. As radiological EIA is an element of EIA, the text would need to be broader and cover all stages of decommissioning	Yes	Will be clarified		

9.	4.16	"may be" to be replaced with "shall"	Assessment of radiation protection of public and environment is a requirement in the BSS and other IAEA Safety requirements for predisposal and decommissioning	Yes	Despite EIA (that we identified as a "decision-process) is not required in IAEA Safety Standards, if other regulatory framework request a EIA, the IAEA Safety Standards must be used. This will be clarified.		
10.	4.17	Suggested to remove or revise the sentence	The level of complexity of the radiological assessments is not to be defined by the regulatory body. The regulators shall establish safety requirements and criteria, and the operator needs to demonstrate safety and decide on the level of complexity of the assessment (e.g. based on the existing and potential hazards)	Yes	Will be revised and made consistent with other parts of the document.		
11.	5.118	Suggested to add source term as a potential source of uncertainty	For some new facilities of facilities under decommissioning the inventory may not be certain and this can affect the assessment results	Yes	Source term is implicit, but will be added explicitly.		

12. Editorial	1.14, 1.15	Numbering of references needs to be revised	Sequence is not correct	Yes	Will be sorted out during future editions		
Editorial	5.53 and 5.54	Remove empty paras		Yes	Will be sorted out during future editions		