DS427 Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities

COMMENTS BY REVIEWER Reviewer: Page 1 of 1 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: 2015-10-12				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Contents	Limitation of dose AND CONSTRAINT OF DOse and risk → Limitation of dose and constraint of dose and risk	Editorial	X			
2	3.14/1 (p.15)	(paragraph 3.24 in the SF-1)	Editorial	X			
3	5.32/9 (p.30)	…at different locations~~)~~ and…	Editorial.	X			
4	Footnote 41/4	…kilogram or ~~G~~gray (Gy)…	Editorial	X			

DS427 Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities

COMMENTS BY REVIEWER	RESOLUTION
Reviewer: Page 1 of 2 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: 2015-10-09	

Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	activities and facilities → facilities and activities	Consistency with the title.	X			
2	General	Rearrange footnotes.	Footnotes No. 2, 15, 22 and 23 are missing.	X			
3	1.6/7 (p.5)	EIA covers not only biophysical ~~environmental~~ but ~~biophysical,~~ social, economic and other relevant effects…	Clarification	X			
4	1.14/4 (p.7)	These types of facilities and activities have **different and** ~~very~~ specific aspects…	Clarification	X			
5	Line 1 (p.11)	AUTHORIZATION PROCESS ~~(OR LICENSING PROCESS)~~	In this Safety Guide, the term "licensing process" is not used.	X			
6	5.4/5 (p.23)	The national regulatory body should ~~has to~~ agree that the methodology…	There is no description on this matter in Section 3 and other Safety Requirements such as GSR Part1 and Part3.	X			
7	5.5/4 (p.23)	exception criteria → exemption criteria	See para.5.41 of DS442.	X			
8	5.37/11 (p.31)	The following underlined word should be inserted. "… for example 50 years may be taken for intakes by adults and **up to age** 70 years for intakes by children."	The original description before modification is correct.	X	Some text was added. The period of integration depends on life expectancy. Just as an example: Children (10 years old) could live until 80 years old, implying a period of 70 years for integration. For adults (~20 -30 years old) an equivalent integration period could be 50 years. These are examples		.
9	6.3 (p.41)	The following last sentence in para.6.3 should be deleted.	The methods using "fuzzy numbers or belief functions" are	X	The new sentence remains as follows:		

		“Alternative methods such as fuzzy numbers or belief functions could be more relevant to represent expert judgment and to propagate such kind of uncertainties.”	not general in several States.		“Alternative methods ~~such as fuzzy numbers or belief functions~~ could be more relevant to represent expert judgment and to propagate such kind of uncertainties.”		

DS427 Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities

COMMENTS BY REVIEWER Reviewer: Page 2 of 2 Country/Organization: Japan/ Nuclear Regulation Authority (NRA) Date: 2015-10-09				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
10	After 6.3 (p.41)	The following two paragraphs should be revived after 6.3 [New para]. 6.5. The level of uncertainty in the assessments of facilities and activities for protection of the public and the environment should still ensure that the actual doses to members of the public do not exceed the dose limits set by the national regulatory body. Ref. [42] suggests that statistical methods and models could be used when assessing doses, noting that the parameter values and other data (habit data and dose coefficients) used in environmental models are usually represented by distributions, and provides examples on how these distributions can be chosen, as well as information on how to carry out calculations using these distributions and also on how to interpret the results. In general, for environmental parameters single recommended values in bibliography [13, 14, 57] or average measured values, when available, should be used. 6.6. For assessments using single values of habit data, high percentiles in some of the habit data distribution could be used (for instance, in particular food consumption rates); for assessments considering the distribution of the habit data, the resulting dose in the 95% percentile should be used to be compared with the established criteria.	Two paragraphs (deleted 6.5 and 6.6) give us significant optional method for radiological environmental impact assessment according to the ICRP Publication 101. There is no reason to remove this option. Confirmation Why these paragraphs have been deleted from the previous version?	X	The paragraphs in Draft 6 were edited as follows: The green part is based in [42] and is in para 6.2 in the current version. The blue part is also based in [42] and was re-worded in para. 6.3 (e.g in 6.3 in Draft 7, 'the statistical methods' the 'habit data" and ' the frequency distributions' are mentioned). The yellow part where recommendations provided by international experts during drafting interpreting ICRP 101. We will reincorporate with some edition. The purple part is in [42] and will be reincorporated too.		

Draft Safety Guide DS 427

***Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities* (August 2015)**

COMMENTS BY REVIEWER Reviewer: World Nuclear Association Page.... of.... Country/Organization: World Nuclear Association Date:8 October 2015				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	**General**	In general, this document provides a proportionate way to undertake a prospective radiological impact assessment to determine whether the planned facilities or activities will comply with current legislative and regulatory requirements on radiological protection of the public and the environment. The inclusion of the graded approach has been really helpful. Thank you for the work that has been undertaken to improve this document. We have one general comment. This Safety Guide should focus solely on radiological considerations, but it may be worth noting that Member states should be prepared to take decisions in all exposure situations based on a variety of other factors, like social and economic, which are out of the scope for this document (paras. 1.18 and 5.41 are examples of paras where this could be incorporated).		X X	A proposal of some additional text in para 1.25 in line with this comment in was added.		

Draft Safety Guide DS 427
***Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities* (August 2015)**

ENISS Comments

COMMENTS BY REVIEWER Reviewer: ENISS Country/Organization: ENISS			Pages 1 of 2 Date: 25.09.2015				
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
General		The current version is again a further improvement of the former drafts and now a well-balanced presentation of the protection of humans and animals and plants. Many of our comments have been taken into account. Thank you for that. The graded approach is now better explained, so the "small users" are more guided than before. The ICRP concept of reference animals and plants and the new system of ICRP 124 was put into context in a well-balanced way on the basic line of argumentation, that if man is protected also environment is protected adequately. We appreciate that. We have now only two hints for clarification regarding the application of ICRP 124. The proposed detailed changes are the following (marked in red).		X			
1	I-8	The derived consideration reference levels are a set of dose rate bands within which there is either no (for most of the reference animals and plants) or only some evidence of minor deleterious effects of ionizing radiation to individuals of flora and fauna, which may have implications in the structures or populations.	The correction corresponds with the Tables A.1 –A.4 of ICRP 124. The DCRLs have been chosen for those doses which gave no effect or only a minor effect.	X	The comment is noted. The text was amended to reflect more precisely ICRP 108/ 124.		

2	I-23	In a generic assessment as presented in this Annex, if the dose rates to the selected representative animals and plants are below the ~~lower~~ upper boundary of the relevant derived consideration reference level band, impact on population of flora and fauna could be considered 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, 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. The derived consideration reference levels are presented in Table I-1 above.	The text here is more stringent than the text in I-11: "*Because derived consideration reference levels are not defined as limits, the estimated doses could result within the band or even above the bands and the radiological situation can still be considered acceptable, taking into account different factors"*. It should be aligned with I-11 which is in our opinion more adequate. The corrections proposed are also necessary because the choice of the bands are very conservative and define a protection objective towards an individual. To differentiate between the lower and upper boundary indicates a level of precision which not exists. Because of the uncertainty ICRP had proposed a band instead of a single value. Thus the protection aim is achieved when the assessed dose meets the band or is below.			X	ICRP 124 indicates that in planned exposure situations the lower boundary of the relevant DCRL should be used as the appropriate reference point. It is truth (and it is acknowledged in DS427) that DCRLs are not limits and that the assessments could lead to results within the band and still considered acceptable. Being the IAEA proposal one of a generic character, the interpretation of results within the band are let to national regulators.

Finland WASSC NUSSC comments on DS427

COMMENTS BY REVIEWER Reviewer: Page.... of.... Country/Organization: Finland/STUK Date: 5th Oct, 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	4.9	… different designs could also be still under scrutiny *and limited information available on the systems and analyses of the designs.*	Addition to an initial assessment.	X			

Draft Safety Guide DS427 "Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities"
(Draft Version 7 dated August 2015)
Status: STEP 11 – Second 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) Page 1 of 2 Country/Organization: **Germany** Date: 2015-10-09				RESOLUTION			
Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	1	General	We gratefully acknowledge that most of our comments on the previous draft version 6 have been accepted and the current version of DS427 has been further upgraded and aligned with the related Safety Guides DS432 and DS432. Germany also appreciates that new paragraphs inserted into the current version of DS427 are highlighted. This approach considerably facilitates the task of the reviewers. The remaining need for corrections in the text is addressed in our comments below.	Comment only.	X			
3	2	Footnotes	The footnotes No. 2, 15, 22 and 23 are missing in the document. A rearrangement of footnotes is required, in order to follow a consecutive numbering throughout the Safety Guide.	Editorial.	X			
3	3	3.13	"Requirement 13 of GSR Part 3, paragraph~~s~~ 3.31 [1] states …"	Grammar.	X			
3	4	4.14	Last sentence: "However, for most of the activities and facilities, typically ~~no releases~~ no releases or potential exposures are involved after decommissioning …"	Editorial.	X			
2	5	5.5	2nd sentence: "For example, for an installation with low levels of discharges, resulting in doses close to the ~~ex-~~	Clarification.	X			

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

			~~ception~~ exemption criteria, and low potential for accidents with consequences to the public and the environment, the use of detailed methods would not generally be necessary."					
2	6	5.9	Last sentence: "The different components of the assessment presented in Figure 2 are discussed in the following paragraphs ~~5.9 to 5.38~~ 5.10 to 5.40."	Wrong paragraphs are referred to.	X			
2	7	5.43	"The following paragraphs ~~5.42 to 5.71~~ 5.44 to 5.73 provide guidance which should be used to conduct the assessments of the potential exposures to members of the public, …"	Wrong paragraphs are referred to.	X			
2	8	5.53	2nd sentence: "The meteorological and hydrological data are discussed in more detail in paragraphs ~~5.12 to 5.24~~ 5.13 to 5.26 in the considerations of the dispersion and environmental transfer for normal operation."	Wrong paragraphs are referred to.	X			
2	9	5.70	1st sentence: "The regulatory body should establish a risk constraint [1, 6] for the consideration of potential exposures; this could be based on INSAG [51] or ICRP [50] guidance discussed in paragraph 5.69 ~~above (5.66)~~."	Wrong paragraph is referred to in brackets.	X			
3	10	6.4	2nd sentence: "The level of uncertainty should be considered when making a decision."	Grammar.	X			
3	11	Ref. [6]	"INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection of the Public and Protection of the Environment, IAEA, Vienna (Draft DS 432)."	Citation of the correct working title of DS432.	X			
3	12	Annex I, Footnote No. 43 to I-20	"Ref. [I-4] provides an equivalent different set of reference organisms."	Grammar.	X			
3	13	Annex II, II-1	"This ~~a~~Annex refers to the assessment of potential exposures for protection of the public …"	Editorial (harmonization of spelling).	X			

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

Member State Comments on draft Safety Standards on

[DS427–A General Framework for Prospective Radiological Environmental Impact Assessment and Protection of the Public – Master Copy]

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
1	1.2	I-2. As discussed in Section 5 of this Safety Guide, the assessment of the level of protection of members of the public is, in many instances, sufficient	See comment 5.73.– any claim made to suggest that the assessment for protection of members of the public is sufficient for this purpose should be justified by appropriate arguments and evidence.			X	See reply to comment 11 below.
2	1.8	Clarity is required on the use of either References 422 and/or 479 as these have different transfer factors although 479 is stated for environmental purposes only, its scientific data is much more robust that that in 422.			Note by the Secretariat: in Draft 8 paragraph is 1.7	X	Both Technical Reports (TRS 422 and TRS 479) are considered valid references. 422 refers to transfer to edible parts of biota (used to assess dose to humans). 479 refers to transfer to biota (used to assess dose to the biota)

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
3	1.19	It would be useful if the section could include references to the need or otherwise for monitoring programmes when the assessed doses have been assessed as negligible.		X	The comment is noted. The need of monitoring for compliance (at least once before authorization for some installations with predicted negligible environmental impact but for reassurance) is discussed in DS442. Reference will be added in next draft. The Safety Guide on Environmental and Source Monitoring has started the process of review and the new version should address in more detail this issue.		
4	1.11	It is noted this guidance only applies to facilities nominated by the UK regulators. The affected facilities will be mainly nuclear licensed sites and other significant facilities. This approach is supported		X			

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
5	1.15	"it is reasonable to assume that the highest activity concentrations could be detected in any direction within a radius of up to 10 km"	See comment 5.73 – any claim made to suggest that the assessment for protection of members of the public is sufficient for this purpose should be justified by appropriate arguments and evidence.		Note by the Secretariat: in Draft 8 paragraph is I.15 in Annex 15.	X	This Annex I is out of the guidance. Here we discuss an example on assessment of exposure to flora and fauna. Here is valid to justify the methodology with the assumptions like 'in the first 10 km' you may find the highest concentrations' This could be used by national authorities, or other justification could be required.
6	4.1	Delete "medicine departments	While smaller medical departments may be excluded, some of the larger oncology departments can discharge significant levels of radioactive waste into the environment and so should be within the framework.	X	In draft 8 text is: 4.1. The government or the regulatory body should identify in advance the types of facilities and activities for which a radiological environmental impact assessment is required or the criteria to decide, on a case-by-case basis, the need (or no-need) of such an assessment. In general, X-Ray generators, small laboratories, applications in medicine for diagnostic or industrial applications using sealed sources, and any other facilities or activities where radiation sources or generators are used, processed or stored in a form and at a scale that impact to the public and the environment is not expected during normal and accidental situations, should be excluded from the need of such an assessment.		

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
7	4.13	It would aid clarify if a definition of 'significant effects' could be provided in this paragraph.		X	On Draft 8 paragraph is 4.16. Text modified ('significant effects' changed to 'radiation doses to the public')		
8	5.21	It would be useful if this paragraph also included references to the ingrowth of daughter radionuclides from the discharged parent e.g. Am from Pu		X	On Draft 8 paragraph is 5.24. It now mentions Am to Pu.		
9	5.23	We note that referenced documents have differing transfer factors which could lead to differences in the result of an assessment by two different parties		X	On Draft 8 paragraph is 5.25. The proper references will be corrected in next version (Ref 14 is not correct for this paragraph, because parameters in that reference are for full body of wildlife and not for edible parts of biota).		

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
10	5.33	This section should be supplemented with information regarding the assessment of external dose rates etc. doses to the skin.				X	This safety guide is intended to provide a general framework for radiological assessment. The exposure pathways are discussed at the general level too. For dosimetric calculations (external and internal) proper references are indicated.

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
11	5.73	5.73. **As set out in GSR Part 3 (see paras 4.1-4.5) there is a presumption that a radiological environmental impact assessment is required for most types of facility. However, s**ome States may consider that the assessment of the protection to members of the public during the operation of facilities or the conduct of activities would be sufficient to demonstrate protection of the environment. This position is based on the assumption that the assessment and control of exposure of humans to radiation provides appropriate protection of the other elements in the environment. In that case the **applicant must justify with appropriate evidence, to the regulatory body why it believes that a separate assessment is not necessary**	Para not in accordance with GSR part 3		**Note by Secretariat:** in current Daft 8, paragraph is 5.75, which says: 5.75. States may consider that the assessment of the protection to members of the public during the normal operation of facilities or conduct of activities is sufficient to demonstrate protection of the environment as well. This position is based on the assumption that the assessment and control of the exposure to radiation of humans, leading to very low and localized increments of radiation levels in air, water, sediments and soils, provides appropriated protection of the environment. In these cases the radiological environmental impact assessment does not need to include explicit consideration of additional specific components of the environment.	X	According to the discussions during WASSC/RASSC/NUSSC meetings, and many comments received from MS, the general consensus is that the Requirements in the BSS only refers to exposures to representative person (humans), as a mechanism to define the level of protection for public and the environment. It was acknowledged in the introduction of BSS (not in a requirement) that some states may consider the need to assess exposures to flora and fauna. The decision was that DS427 will i) guide only on assessment of exposures to human and ii) acknowledge that some states may consider flora and fauna, and this is let to national authorities decision (and the way to do it or if any justification is needed is also a national decision). For that authorities who so decide, DS427 provide an example in an Annex.

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
12	Annex 1	From the layout and wording of the document it is uncertain whether Annex I should be present or not This is a reflection of the confused scope and function of the document noted at General comment				X	The comment is noted but it is to general.

COMMENTS BY REVIEWER					RESOLUTION		
Reviewer Country Organisation: Office for Nuclear Regulation, United Kingdom			Date: 7 July 2015		Note by IAEA Secretariat: for some unexpected reason this resolutions were not processed with the rest. We provide here the resolutions, considering Draft 8 text. My apologies, Diego Telleria		
Comment Nr	Para Nr. & Line	Proposed new text	Reason	Accepted	Accepted modified as follows	Rejected	Reason if modified/rejected
13	Annex 111	Should also include approaches for normal operation in the UK i.e. from discharges of effluents and disposals of solid wastes	The environment agencies in the UK regulate public and environmental exposures from planned radioactive waste disposals/discharges. See sections 2.4 and 2.5 in link below: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/296390/geho1202bklh-e-e.pdf Office for Nuclear Regulation regulates any other offsite public doses.	X	The inclusion of examples in and Annex II is being discussed (some proposals mention that the Annex is more for a TECDOC on applications, which is planned. This will be discussed during next meeting. If Annex II will remain, UK approaches will be included		

TITLE : DS 427 Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities (August 2015)

COMMENTS BY REVIEWER Reviewer: Country/Organization: France/ASN			Page Date: 20 Oct 2015	RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General		The draft has been greatly improved				
2.	4.6	For facilities or activities with relatively standardized practices, small radionuclide inventories and a low potential for accidental releases to the environment, but which still can produce some impact on public and the environment for example, hospital with nuclear medicine departments the regulatory body ~~could~~ may provide generic guidance identifying the necessary elements which should be included in the radiological environmental impact assessment.	Clarification	X			

COMMENTS BY REVIEWER Reviewer: Page Country/Organization: France/ASN Date: 20 Oct 2015				RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3.	4.6	~~This could also include the necessary assumptions (for example, for establishing the source terms for normal operation and the typical accidental scenarios) and, where possible, the methodology for the assessment.~~	Superfluous. This is covered by the "necessary elements" of the previous sentence.			X	Some comments from other MS requested the inclusion of a paragraph for small facilities (for example, Hospitals, etc). In those cases in general there is lack of experts in public radiological impact and in safety events analysis. DS427 recommends here that the regulatory body may provide generic guidance. We consider that it is useful to indicate some detail, so that the generic guidance cover normal and potential exposures. The MS requesting this addition welcomed the paragraph as it is.

COMMENTS BY REVIEWER Reviewer: Country/Organization: France/ASN			Page Date: 20 Oct 2015	RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
4.	4.6	~~The authorization process in these cases could be that the applicant presents the proposal of the assessment following the guidance established by the regulator, and an iterative process is conducted involving the regulatory body, where the refinement of the assessment is discussed as necessary until the approving of the assessment can be granted~~.	Authorization process is not the purpose of this guide.	X	The paragraph will be modified in next revision as follows: "The ~~authorization process~~ assessment process in these cases could be that the applicant presents the proposal of the assessment following the guidance established by the regulator, and an iterative process is conducted involving the regulatory body, where the refinement of the assessment is discussed as necessary until the approving of the assessment can be granted". This is somehow consistent with 4.7 and 4.8 for larger installations.		

COMMENTS BY REVIEWER Reviewer: Page Country/Organization: France/ASN Date: 20 Oct 2015				RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5.	5.51	The accidental conditions in a facility or an activity could result in the loss of shielding or inadequate shielding and, in some cases~~, the accumulation of radioactive waste and contaminated debris on site that could~~ impact the public significantly with external radiation, in the case they are ~~living~~ in ~~or occupying the~~ close vicinity of the premises.	No need for such level of detail. Simplification	X	Direct irradiation" contributing to public exposures was found as missing by other reviewers (and this include during the assessment of exposures due to normal operation and during the assessment of the potential exposures). Because we have only 2 paragraph for something indicated as important by reviewers, we preferred to add some level of detail (so that readers have a clear understanding of what we are talking about). Nevertheless, we will revisit this paragraphs for "simplification" during next revision before submitting to CSS		

COMMENTS BY REVIEWER Reviewer: Page Country/Organization: France/ASN Date: 20 Oct 2015				RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
6.	5.51	~~In general, for large facilities there is some considerable distance from the plant to the public preventing or minimizing the possibility of direct irradiation, even during accidental scenarios. In installations like hospitals or industries, despite the radiation sources involved are relatively smaller, public can be found closer.~~ The contribution to potential exposures due to these scenarios should be considered and analysed using models to estimate external exposures that will contribute to the total doses of those exposed.	Superfluous (the previous sentence is enough). Furthermore, it may not be true as it is site dependent and site history dependent (the site may have been isolated when constructed but population and other industry may now be closer…)	X	See previous comment.		
7.	5.56	If there is potential for a large release, models to estimate the transfer and the dispersion of radionuclides in the environment at longer distances ~~(for instance, up to 100 km)~~ should be available.	The range is related to the source term.	X	Will be deleted in next version.		
8.	5.58	~~In some accidental scenarios, the direct irradiation to the public from the facility or the activity could be drastically enhanced when compared to that resulting from normal operation conditions. In those cases the following pathways could also be relevant:~~ ~~(i) Direct irradiation resulting from loss of shielding of the sources.~~ ~~(j) Direct irradiation due to wastes and contaminated debris resulting from the accident and deposited on site.~~	Duplication of 5.57 and 5.58 b)	X	Here we are talking about the exposure pathways due to direct irradiation and it make sense for completeness to have (i) and (j). Nevertheless, we will delete the text in the middle of (h) and (i)		

COMMENTS BY REVIEWER Reviewer: Country/Organization: France/ASN			Page Date: 20 Oct 2015	RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
9.	5.62	For instance, instead of the concept of the person representative of those more highly exposed (representative person), a specific location (for example the nearest town in the region), fixed distances (for example, 1 km, 5 km or 10 km) or a distance where certain relevant projected dose is exceeded (for example, 100 mSv in the first 7 days if such value is the threshold for protective measures~~, i.e. sheltering~~ [7]) can be used.	In table 3 of Ref [7] and in DS457, the 100 mSv in the first 7 days criteria is not associated only with sheltering. It encompasses also ”evacuation; decontamination; restriction of consumption of food, milk and water; contamination control; public reassurance”	X	We will delete sheltering in next draft before submission to CSS.		
10.	5.69	In respectively 1995 and 1992, The International Nuclear Safety Group (INSAG) [51] and the ICRP [50] discussed possible risk criteria for potential exposure of members of the public….	To highlight that these recommendation are quite “old” (more than 20 years !)	X	Will be considered to be included in next revision.		
11.	5.70	The Government or the regulatory body should establish or approve a risk constraint [1, 6], as appropriate, for the consideration of potential exposures; this could be based on INSAG [51] or ICRP [50] guidance discussed in paragraph above (5.66).	The initial wording is narrowing the possibilities offered by GSR Part 7. To be consistent with GSR Part 3	X	Will be added in next revision.		
12.	5.70	Some examples or risk criteria used by some States can be found in Annex III. The definition and use of risk constraints are discussed more extensively in [6].	Clarification	X	The maintenance or deletion of Annex III will be discussed in next WASSC,RASSC,NUSSC meetings		

COMMENTS BY REVIEWER Reviewer: Country/Organization: France/ASN			Page Date: 20 Oct 2015	RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13.	After 5.72	5.73 Different criteria may be set for facilities and activities with varying levels of inventory and technological complexity. 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.	This paragraph was in the previous version of DS427 and is now deleted. It is worth keeping it.			X	Note the comment from other MS: "It is proposed to delete this paragraph. For the protection of the public it is irrelevant what type of facility causes an exposure leading to a certain dose. The protection of the public should be based on the potential doses but should not rely on the type of facility. In case of a lower inventory, also the resulting dose in case of a release would likely be lower. In addition, for all potential releases not only dose limits or intervention levels have to be considered, but also the principle of minimizing radio-logical impacts has to be applied".
14.	5.73	~~When considering transboundary impacts the criteria used for the consideration of potential exposures in other States should be in line with the criteria discussed in this safety guide and, in principle, may be the same used in the State where the facility or activity is located.~~	It is optimistic, especially the end of the sentence !			X	

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
15.	6.2	The level of uncertainty in the prospective radiological environmental impact assessments ~~shall~~ should still ~~ensure~~ enable a conclusion on whether~~that~~ the ~~actual~~ calculated doses to members of the public do or not exceed the dose limits set by the national regulatory body. When insufficient information or data are available, ~~then~~ conservative assumptions should be used [42]. However, use of a large number of conservative assumptions can result in unrealistic overestimation of doses and this should be avoided [42].	Clarification. This is a prospective assessment	X	Will be changed in line with the comment in next version, before submission to CSS.		
16.	6.5	~~The assessment methodology as described in this Safety Guide, including the definition of models and radiological criteria, needs to be conservative in order to avoid underestimating the impact. If the doses calculated are below the dose constraints, simple conservative methodologies could be considered sufficient. When the doses estimated conservatively are equal to or above the criteria or the decisions to be made with respect to the technology to reduce releases could have a high impact on the level of investment, the regulatory body should decide whether more detailed methodologies, including, for instance, the use of site specific data, are necessary to increase the realism in the assessment.~~	Delete 6.5. This para could be understood as, if not having a "good" result, then change calculations paramaters to get a "good" result. This para is not about uncertainty but on the amount of efforts. This idea is already captured and better written in 5.5, 5.6, 5.45 and 5.46…	X	Will be deleted in next version.		

COMMENTS BY REVIEWER Reviewer: Page Country/Organization: France/ASN Date: 20 Oct 2015				RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
17.	6.6	The establishment of source and environmental monitoring programmes, once the installation is operating is useful to check whether the discharges comply with the authorized limits and whether the dispersion models used are reasonably conservative ~~and do not underestimate real doses~~.	Clarification Dose calculation requires other input (food habits…) which are not within the scope of environmental monitoring nor discharge monitoring	X	Will be changed in line with the comment in next version.		
18.	6.8 (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. If, for example, probabilistic safety analysis techniques are used to estimate accident frequencies, these frequencies are determined by combining many ~~other frequencies and~~ events and/or failure probabilities all with their own uncertainties.	Clarification	X	Will be changed in line with the comment in next version		
19.	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:….	To highlight that these recommendation are quite “old” (20 years !)	X	Will be changed in line with the comment in next version		

COMMENTS BY REVIEWER Reviewer: Page Country/Organization: France/ASN Date: 20 Oct 2015				RESOLUTION NOTE by Secretariat: These comments arrived on the 22nd of October			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
20.	I.4	For nuclear power plants, risk targets from INSAG 12 [58], published in 1999, are quoted: a severe core damage frequency of less than 10^{-4} events per year for existing nuclear power plants which with the application of all safety principles should be not more than 10^{-5} events per year for new nuclear power plants.	Mentioning the date is important as the text refers to *existing* nuclear power plants, i.e. exiting at that time, not when DS427 is published.	X	Will be changed in line with the comment in next version		
21.	I.5	In 1992, The International Commission on Radiological Protection (ICRP) has recommended that for the treatment of potential exposure, the risk limits should be of the same order of magnitude as the health risk implied by the dose limits for exposures [50].	To highlight that these recommendation are quite "old" (more than 20 years !)	X	Will be changed in line with the comment in next version		

Draft Safety Guide DS 427 –USA Comments

Prospective Radiological Environmental Impact Assessment and Protection of the Public for Facilities and Activities

COMMENTS BY REVIEWER Reviewer: US NRC (Contact: Boby Eid, Boby.abu-eid@nrc.gov) Page..1.of 3... Country/Organization: USA/US NRC Date: October 9, 2015				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text/Comment	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
General Comments							
1.	**General**	The current DS427 version has been improved substantially from previous draft revisions. The US provided 22 comments on the previous document version; all were accepted except for two. We believe safety requirements for protection of human should be adequate for protection of non-human species through development of exposure scenarios based on the assumption that human is living and interacting with such environments surrounding facilities or activities. This recommended approach was inserted in the document as it is quite adequate for planned exposure situations. Nevertheless, we do recognize that under certain circumstances, (e.g.; particularly under existing exposure or emergency exposure situations) restrictions on human access from living in, or interacting with, such environment can be imposed. Therefore, there could be a need for ecological risk assessment using ICRP dose assessment methodology to non-human species in order to support decision-making for legacy sites remediation or after severe accident. We also recognize that uncertainties in dose assessment of non-human species are so large that need to be taken into consideration for any decision-making. Social, financial, and economic aspects need also to be considered when considering extensive remedial actions, or restrictive decisions, based on ecological risk assessment.	Clarity	X			

Specific Comments & Editorials							
1.	4.12	For facilities already in operation and activities being conducted, ~~a subsequent update of the safety assessment – e.g. a periodic safety assessment review – is required~~ the safety assessment –should be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements [5];…	The recommended change brings the sentence more in line with the recommendations of GSR 4 (Ref 5) paragraph 5.10.	X			
2.	5.18	**Current text:** The models used to estimate activity concentrations in environmental media (e.g., in the air, in the aquatic media, on the ground and through the soil) should take account of the physicochemical properties of the radionuclides being released ~~necessary to assess~~, for example, ….	Improves readability	X			
3.	5.51	5.51. [New para.] ~~The accidental conditions in a facility or an activity could result in the loss of shielding and, in some cases, the accumulation of radioactive waste and contaminated debris on site that could impact the public significantly with external radiation, in the case they are living in or occupying the close vicinity of the premises.~~ In general, for large facilities there is some considerable distance from the plant to the public preventing or minimizing the possibility of direct irradiation, even during accidental scenarios. In installations like hospitals or industries, despite the radiation sources involved are relatively smaller, public can be found closer. ….	The sentence describes accident scenarios that are beyond the scope of this document			X	"Direct irradiation" contributing to public exposures was found as missing by other reviewers (and this include during the assessment of exposures due to normal operation and during the assessment of the potential exposures)
4.	4.12	For facilities already in operation and activities being conducted, a subsequent update of the safety assessment - e.g. a periodic safety assessment review (or alternative arrangements as established in SSG-25, Paragraph 2.8) - is required [5]; this review should include the consideration of the possible changes in the assumptions used to perform the prospective radiological environmental impact assessment and the results of source and environmental monitoring programmes conducted during the operation. …..	Words added to maintain consistency with SSG-25			X	The wording in 4.12 was changed following suggestion in Specific Comment No. 1 (above). The main ideas that 'a) a periodically review is necessary following regulatory requirements' and 'b) the inclusion in that

							review of the radiological impact assessment, when necessary, is recommended' are already in para. 4.12.. We think that the additional text proposed here is not necessary because is a detail which may lead to confusions (e.g. " or alternative arrangements") and, nevertheless,. Reference SSG-25 is mentioned (i.e.. ref [5])
5.	Page 68, paragraph III-11	Replace 10 CFR Part 51" with "Title 10 of the Code of Federal Regulations (10 CFR) Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"	editorial	X			
6.	Page 68, paragraph III-12	Add a closed parenthesis at the end of the first sentence;	editorial	X			
7.	Page 68, paragraph III-13	Add a period at the end of the paragraph.	editorial	X			