

DS473
REGULATORY FUNCTIONS AND PROCESSES

RESOLUTION OF REVIEW COMMITTEE MEMBERS

COMMENTS

on

DPP-DS473 Version 4

CONTENTS

France (NUSSC)

Germany

Pakistan

USA

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REGULATORY FUNCTIONS AND PROCESSES

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer:		F. Féron		Page			
Country/Organization:		France / ASN		Date: 4 April 2013			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	6.	2) Principal Control Areas of a Regulatory Body	Can be included in the introduction	Y			
2.	6.	Modification or Revocation of Authorisations	Modification of authorization should be covered	Y			
3.	6.	Review and Assessment Objective of Review and Assessment <u>Documents to be reviewed</u> <u>Notification</u> <u>Authorization application</u> <u>Reported event</u> <u>Periodic report</u> Demonstration of Safety Review and Assessment Process Performance of Review and Assessment Record of Review and Assessment	The various occasions to perform review and assessment should be highlighted		The title, "Information to be reviewed and assessed" used as a more general topic. Not included the proposed list as subsection headings as it may not be exhaustive. The contents will be further developed during the consultancies, but will, as a minimum, address the list.		

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4.	6.	Review and Assessment Objective of Review and Assessment Demonstration of Safety Review and Assessment Process Performance of Review and Assessment Record of Review and Assessment	Demonstration of safety is a licensee duty, the regulator role is review and assessment of this demonstration.	Y			
5.	6.	Inspection Objective of Inspection Organisation of Regulatory Inspection Function Types of Regulatory Inspection Planning of Regulatory Inspection Performance of Regulatory Inspection Inspection Record of Regulatory Inspection <u>Follow-up on inspection findings</u>	Follow-up is needed	Y			
6.	6.	International cooperation	This function should be added			Y	Covered by DS472.
7.	6.	Emergency preparedness and response	This function should be added	Y			
/	/						

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

		COMMENTS BY REVIEWER			RESOLUTION			
		Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with comments of GRS) Country/Organization: Germany			Page 1 of 3 Date: 2013-04-19			
Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification / rejection
1	1	General	The proposed document is well structured and comprehensive. All relevant aspects seem to be covered. For some topics currently addressed in DS473, however, there are interfaces with DS472. Examples are Section 3 titled “Organization of the Regulatory Body”, and Section 4 titled “Communication and consultation with interested parties” in the table of content of DS472. These interfaces have to be considered when preparing the proposed Safety Guides.			Noted.		
3	2	Section 2	2 nd para, 2 nd sentence: “... the concept of Long Term Structure for the whole Safety Standards Series has been developed and the relevant <u>Safety</u> Requirements documents have been revised and replaced ...”	Wording.	Y			
3	3	Section 2	4 th para, last sentence: “... scope of “facilities and activities” (see definition of in the Safety Glossary) ...”	Editorial.	Y			
3	4	Section 4	1 st para, 2 nd sentence: “In addition, this s <u>S</u> afety g <u>G</u> uide will address the release of facilities and activities from regulatory control ...”	In conjunction with the IAEA Safety Standards Series, ‘Safety Guide’ should be used as	Y			

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Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification / rejection
				capitalized term consistently throughout the document.				
3	5	Section 6	2 nd sentence: “An outline <u>of</u> contents is set out below, however ...”	Missing word.		“of the” added		
3	6	Section 6, Table of content	List of topics under the bullet No. 4) with heading “Principal Regulatory Functions and Processes”: “Authorization and Notification Review and Assessment <u>of Facilities and Activities</u> Inspection <u>of Facilities and Activities</u> Enforcement <u>of Regulatory Requirements</u> Development of Regulations and Guides”	Complete the subheadings No. 2, 3 and 4 in order to be consistent with the list provided in Para 2.30 of GSR Part 3.	Y			
2	7	Section 6, Table of content	List of items under the topic “Review and Assessment” of bullet No. 4): “Objective of Review and Assessment <u>Demonstration of Safety</u> ”	The licensee is responsible for the demonstration of safety in support of an application for authorization of the facility	Y			

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Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification / rejection
			Review and Assessment Process ...”	or activity. The regulatory body has an obligation to review and assess this demonstration in accordance with clearly specified procedures prior to the granting of an authorization. Compare with Requirement 24 of GSR Part 1 “Governmental, Legal and Regulatory Framework for Safety”.				
3	8	Annex 2	Reference No. 1: “ SF-1 , Fundamental Safety Principles (2006)”	Harmonized citation of IAEA documents.	Y			
3	9	Annex 2	Reference No. 4: “GSR Part 3 (interim), Radiation Protection and Safety of Radiation Sources, International BSS (2011 Interim Edition).”	Redundant information.			Y	It is part of the number designation given to the safety standard, i.e. “No GSR Part 3 (Interim)”.
3	10	Annex 2	Delete the reference No. 8 “Regulations for the Safe Transport of Radioactive Material 2009 Edition”,	TS-R-1 has been superseded by SSR-6 “Regulations for the Safe	Y			

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Relevance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification / rejection
			IAEA Safety Standards Series No. TS-R-1, IAEA, Vienna (2009).	Transport of Radioactive Material, 2012 Edition” (published in October 2012). This publication is included in the list as reference No. 14.				
3	11	Annex 2	last reference: “NS-R-5 Safety of Nuclear Fuel Cycle Facilities (2008) (under revision through addendum , see DS439)”	Correct information. DS439 consists of two appendices with additional specific facility related safety requirements. These will supplement the general safety requirements for nuclear fuel cycle facilities specified in NS-R-5.		“(under revision through addition of addendum, see DS439)”.		
2	12	Annex 2	The list of documents to be taken into account for drafting should also include appropriate IAEA Safety Standards for radioactive waste disposal facilities. For example, the Specific Safety Requirements SSR-5 “Disposal of Radioactive Waste” (2011) are on the same hierarchical level as SSR-2/1, SSR-2/2 and SSR-6, all of which are listed in Annex 2.	According to Section 2 of the DPP, the proposed Safety Guide encompasses all types of facilities that give rise to radiation risks.	Y			

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

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Reviewer: Country/Organization: Pakistan		Page 1 of 2. Date: 18-04-2013					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	Page 3 and 4		The title of the guide is “Regulatory body functions and processes’ whereas only principle or core functions have been included. It is suggestion that the guide may also cover ‘other functions’ and support functions’ as mentioned in DPP for DS 472. Moreover, there is a need for consistency in the terminology used. In DPP for DS 472, term of ‘core functions’ is used whereas in DPP for DS 473 the term used is ‘principle function’.		“Core” used instead of Principal.		
1.	Page 4/Line 2	Authorization conditions	The term used in GSR Part 1 is ‘Authorization’.	Y			
2.	Page 4/Line 3	Steps in the Authorisation Process	The term used in GSR Part 1 is ‘Authorization’.	Y			
3.	Page 4/Line 16	Development of Inspection Program	Inspection program is a very important document which covers the entire inspection management process for any authorization stage and may need to be included under		Agree that the development of an inspection program is very important. It is proposed not to include it as a separate subsection		

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Reviewer:		Page 1 of 2.					
Country/Organization: Pakistan		Date: 18-04-2013					
			the section of safety guide on 'Inspections'.		as the current structure of the Inspection Section covers the content of this program, i.e. objective, organization, types, planning, performance and records.		

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COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: : United States of America		Page....1 of....1					
Country/Organization: U.S. Nuclear Regulatory Commission		Date: April 17, 2013					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Section 6, Overview	The following regulatory function should be considered for inclusion as a Principal Regulatory Function and Process: Incident Response			Added as a separate Section "Emergency Preparedness and Response." See also France comment no 7		
2	Section 6, Overview	The following regulatory function should be considered for inclusion as a Principal Regulatory Function and Process: Operating Experience Review and Evaluation				Y	Agreed that the requirement for the regulatory body to use operating experience to inform its conduct of regulatory functions and processes is important. Recommendations for complying with this requirement, for each regulatory function, are included in the existing safety guides that DS473 will replace. It is therefore proposed to use these existing recommendations in each of the chapters covering:

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Reviewer: : United States of America		Page....1 of....1					
Country/Organization: U.S. Nuclear Regulatory Commission		Date: April 17, 2013					
							authorization; review & assessment; inspection & enforcement; and development of regulations & guides, rather than having a separate section.
3	Section 6, Overview	The following regulatory function should be considered for inclusion as a Principal Regulatory Function and Process: Research				Y	Agreed that the requirement for the regulatory body to conduct research and use the research results to inform its conduct of its regulatory functions and processes is important. Recommendations for complying with this requirement, for each regulatory function, are included in the existing safety guides that DS473 will replace. It is therefore proposed to use these existing recommendations in each of the chapters covering:

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Country/Organization: U.S. Nuclear Regulatory Commission		Date: April 17, 2013					
							authorization; review & assessment; inspection & enforcement; and development of regulations & guides, rather than having a separate section.
4	Annex 2	- SSR-5 Disposal of Radioactive Waste Specific Safety Requirements - SSG-1 Borehole Disposal Facilities for Radioactive Waste Safety Guide - SSG-14 Geological Disposal Facilities for Radioactive Waste Specific Safety Guide - SSG-23 The Safety Case and Safety Assessment for the Disposal of Radioactive Waste	The evaluation should consider requirements and guides for disposal facilities that appear comparable to those listed for installations, to be consistent with stated purpose of SG.	Y			