#### Canada Comments on DPP-472 Safety Guide: Organisation, Management and Staffing of a Regulatory Body

		COMMENTS BY REVIEWER			RESOLUTION		
Reviewer	:		Page 1 of 1				
Country	Organizatio	n; CNSC Staff/Division	Date -			_	
Comment	Para./Line	Proposed new text		Acce	Accepted but modified as follows	Reje	Reason for
No.	No.		Reason	pted		cted	modify/rejection
1		The table of content should include the use of technical support organizations			The use of TSOs will be addressed under "External expert support". As		
		(TSO) (INSAG-17: Independence in			indicated, it is planned that this		
		regulatory decision making; and GSG-4:			section will be based on GSG-4.		
		Use of external experts by the					
		regulatory body).					
2		One item not listed in the table of content is 'Reporting Requirements'				X	The meaning of "reporting requirement' for the RB would need to be clarified. Where exactly should it be added?

Title: Comments for DPP DS 472 on Organization, Management and Staffing of a Regulatory Body

		COMMENTS B	Y REVIEWER		RESOLUTION	1	
Reviewer:			Page 1 of				
Country/O	rganization:		Date: 13 April. 2013				
Commen	Para/Line	Proposed new text	Reason	Accepted	Accepted, but modified as	Reje	Reason for
t No.	No.				follows	cted	modification/rejection
1	TOC	Authorization	Delete 'including siting' as 'siting' is not a				
	item		function but an authorization stage or we may				
	3/line 5		write other stages also.				
2	Page	Regulations and Guides	Delete 'Development of' as no verb is used with				
	4/line 1		other core functions then why with this one.				
3	TOC		Management system is a broader topic which also				
	item 5		includes the entire topic of the proposed guide,				
			however, the vice versa is not true. It is proposed				
			that this may be addressed in a separate safety				
			guide and here only a reference to management				
			system guide may be included whereas the				
			contents listed here may be included in the				
			separate guide.				

#### TITLE: DS472 DPP Organisation, Management and Staffing of a Regulatory Body

Reviewer:		COMMENTS BY REVIEWER F. Féron	Page		RESO	LUTION	
	rganization:	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.	4	The objective of this Safety Guide is to provide practical guidance and recommendations to Regulatory Bodies on their organizational structure, management and staffing to support them in carrying out their responsibilities and functions in an independent manner, considering the number and types of facilities and activities being regulated.	To emphasize a grade appraoch				v
2.	6	Core Regulatory Functions Review and assessment Authorization (including siting) Inspection Enforcement Development of Regulations and Guides Emergency preparedness Other Functions Emergency preparedness Research and development International cooperation Public and media outreach	Emergency preparedness is a core function  Interactions with the public and the media is a function to be mentioned, as well as international cooperation				

		COMMENTS BY REVIEWER	RESOLUTION					
Reviewer:		F. Féron	Page					
Country/O	rganization:	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	
3.	6	5) Management System for the Regulatory Body General						
		Safety culture	Safety culture should be a separate item (the management					
		Management Systems	system supports safety culture					
		Safety culture	but is not enough by itself)					
		Documentation						
4.	6	Management Responsibilities  Management commitment and leadership  Interaction with Stakeholder						
		satisfaction Organizational Policies Planning Responsibility and authority for the management system Infrastructure and work environment Resource and staff planning	Satisfaction is too ambitious					

		COMMENTS BY REVIEWER	RESOLUTION					
Reviewer: Country/On	rganization:	F. Féron France /ASN	Page Date: 4 April 2013					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection	
5.	6	Process Implementation Development of processes Management of processes Generic management processes Non-conformance, corrective and preventative action  Measurement, assessment and Improvement Monitoring and measuring Self-assessment Independent assessment Management review Non-conformance, corrective and preventative action Improvement	It could be better located here.					
6.	/							
/	/							

# DPP for DS472 draft Safety Guide on "Organization, Management and Staffing of a Regulatory Body" (Version 4, March 2013)

		COMMENTS BY REVIEW	ER		RES	OLUT	ΓΙΟΝ
Reviewer Page 1 of							
_		n: Ukraine/ State Scientific and T	echnical Centre for Nuclear				
-	ation Safe	i. Oktaine, State Scientific and 1	Date: 12/04				
(uploaded			<b>2 000</b> 1 <b>2</b> , 0 .				
Comme	Para/Line	Proposed new text	Reason	Acce	Accepted, but modified	Rej	Reason for
nt No.	No.			pted	as follows	ect	modification/rejection
				_		ed	Į ,
		The document shall more	It is indicated at the				
1		clearly identify the role of					
		external experts and technical					
		support organizations in					
		activities of the regulatory	such as (approved for				
		body	publication) External Expert				
			Support for the Regulatory				
			Body, DS429.				
			However, involvement of				
			external experts and				
			technical support				
			organisations in activities of				
			the regulatory body is not				
			considered at all.				

2	6, 2)	To add: Co-ordination (co- operation) of regulatory (supervisory) bodies of the State	should coordinate (interact with) several specialized regulatory (supervisory) bodies of the State (in the areas of environmental protection, health and epidemiological supervision, fire protection,		
			etc.)		

#### TITLE: DPP for DS472 "Organisation, Management and Staffing of a Regulatory Body"

		COMMENTS BY REVIEWER		RESOLUTION			
Reviewer:		es of America	Page1 of1				
Country/Org	ganization: U	J.S. Nuclear Regulatory Commission	Date: 4/17/2013				
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejec ted	Reason for modification/rejection
1	P. 3, Sec 5	Expand scope of proposed SG to include relevant SGs for radioactive waste disposal facilities.	Although the proposed SG encompasses "all facilities," relevant SG's for waste disposal facilities are not included in the consolidation. In particular, GS-G-3.1, GS-G-3.3, and GSG-4 appear amenable to review and consolidation in the proposed SG.			X	The Safety Guide provides guidance on the implementation of the requirements regarding the governmental, legal and regulatory framework, (GSR Part1). Other topics are address in relation to their dedicated requirements:  -Specific waste disposal aspects are addressed in the guidance supporting GSR Part 5.  -GS-G3.1 and GS-G-3.3 deal with management system which is addressed by GS-R-3 (under revision, see DS456).  GSG-4 (formerly DS429) is included.

## DPP DS472, Draft Safety Guide "Organisation, Management and Staffing of a Regulatory Body" (Version 4, March 2013)

Note: <u>Blue parts</u> are those to be added in the text. <u>Red parts</u> are those to be deleted in the text.

			COMMENTS BY REVIEWER nistry for the Environment, Nature Conser	•	RESOLUTION					
		rith comment organization:		Page 1 of 5 Date: 2013-04-19						
Rele- vance	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification / rejection		
2	1	Section 1	"Documents to be combined and revised: (approved for publication) Use of Ex- ternal Experts Support for by the Regulatory Body, 2013, GSG-4 DS429"	The new Safety Guide GSG-4 (ex DS429) has been published in February 2013.						
3	2	Section 2	1 <sup>st</sup> para, 2 <sup>nd</sup> sentence: " is a fundamental element outlined in Principle 2 of the IAEA's Safety Fundamental Safety Principles, SF-1."	Editorial.						
3	3	Section 2	2 <sup>nd</sup> para, 2 <sup>nd</sup> 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 re- vised and replaced"	Wording.						
3	4	Section 2	4 <sup>th</sup> para, last sentence: " scope of "facilities and activities" (see definition of in the Safety Glossary, 2007 Edition)"	Editorial.						
2	5	Section 2	4 <sup>th</sup> para, last sentence: Assign a footnote to the term "nuclear installations" with the following text: " <i>Nuclear installation</i> , any nuclear facility subject to authorization that is part of the							

Relevance: 1 – Essentials	2 – Clarification	3 – Wording/Editoria
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	1		T	T		1	
			nuclear fuel cycle, except facilities for the				
			mining or processing of uranium ores or				
			thorium ores and radioactive waste dis-				
			posal facilities.				
			The definition thus includes: nuclear				
			power plants; research reactors (including				
			subcritical and critical assemblies) and				
			any adjoining radioisotope production				
			facilities; spent fuel storage facilities;				
			facilities for the enrichment of uranium;				
			nuclear fuel fabrication facilities; conver-				
			sion facilities; facilities for the repro-				
			cessing of spent fuel; facilities for the				
			predisposal management of radioactive				
			waste arising from nuclear fuel cycle fa-				
			cilities; and nuclear fuel cycle related				
			research and development facilities."				
2	6	Section 5	2 <sup>nd</sup> para:	The new Safety Guide			
			"The Safety Guide will combine and re-	GSG-4 (ex DS429) has			
			vise the following documents:	been published in February			
			GSG-4 DS429 (approved for publication),	2013.			
			<u>Use of External Experts</u> Support for by				
			the Regulatory Body, 2013"				
3	7	Section 6	2 <sup>nd</sup> sentence:	Missing word.			
			"An outline of contents is set out below,				
			however"				
2	8	Section 6,	Bullet No. 3), 2 <sup>nd</sup> topic:	1.) The siting process for a			
		Table of	"Core Regulatory Functions	nuclear installation, i.e. site			
		content	Review and assessment of facilities	survey and site selection, is			
			and activities	generally a de-regulated			
			Authorization and notification (in-	activity. Therefore, no li-			
			<del>cluding siting)</del>	cense is required. Compare			
			Inspection of facilities and activities	with the Draft Safety Guide			
			Enforcement of regulatory require-	DS433 "Safety Aspects in			
			<u>ments</u>	Siting for Nuclear Installa-			
			Development of Regulations and	tions" (Version 00.16 dated			
			Guides"	18 March 2013), para 2.6.			

 $Relevance: \fbox{$1-Essentials$} \ \fbox{$2-Clarification$} \ \fbox{$3-Wording/Editorial$}$ 

				<ol> <li>According to GSR Part         <ol> <li>the term 'authorization' includes approval, written permission, licensing, certification and registration.</li> <li>Complete the subheading No. 2 with respect to notification in order to be consistent with the terminology used in</li> <li>the DPP for DS473 (see table of content),</li> <li>GSR Part 1 (Requirement 23),</li> <li>GSR Part 3 (Para 2.30 and Requirement 7).</li> </ol> </li> <li>Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from practices.</li> <li>Complete the subheadings No. 1, 3 and 4 in order</li> </ol>		
				3.) Complete the subhead-		
		~ .		of GSR Part 3.		
3	9	Section 6, Table of content	Bullet No. 3), last topic: "Supporting Functions Administrative support	External expert support does include consultants, technical support organisa-		
			Legal assistance External expert support and Consultants (from DS429)"	tions, advisory committees, academic bodies, research organizations, national laboratories,		
2	10	Section 6,	Please provide more information on the	Looking simply at the		

 $Relevance: \fbox{1-Essentials} \ \fbox{2-Clarification} \ \fbox{3-Wording/Editorial}$ 

		Toble of	planned content and storestions of built-	number of subbas dia as		J	
		Table of	planned content and structure of bullet	number of subheadings within the different sec-			
		content	No. 4) with heading "Communication and	tions in the table of con-			
			consultation with interested parties".				
				tent, bullet No. 4) needs to			
				become more elaborated.			
				The planned content should			
				be indicated by some sub-			
			and and	headings.			
2	11	Section 6,	Bullet No. 5), 3 <sup>rd</sup> topic:	Consistency with the ter-			
		Table of	"Management Responsibilities	minology used in the Draft			
		content	Management commitment and lead-	Safety Requirements			
			ership	DS456 "Leadership and			
			Stakeholder satisfaction Interactions	Management for Safety"			
			with interested parties	(Version dated 6 February			
			Organizational Ppolicies	2013), see Para 2.5 j and			
				Requirement 10.			
				Satisfaction of stakeholders			
				is very difficult to achieve.			
3	12	Section 6,	Bullet No. 5), 5 <sup>th</sup> topic:	Consistency with the ter-			
		Table of	"Measurement, <u>aAssessment, Evaluation</u>	minology used in the Draft			
		content	and Improvement	Safety Requirements			
			Monitoring and measuring	DS456 "Leadership and			
			Self-assessment	Management for Safety"			
			Independent assessment	(Version dated 6 February			
				2013), see Requirement 9			
				with subordinated paras.			
3	13	Section 6,	Renumber the last bullet as follows:	The numbering of bullets			
		Table of	"5) 6) Staffing and Competence of Staff"	in the table of content is			
		content		wrong. Bullet No. 5) is			
				inadvertently duplicated.			
2	14	Section 6,	Under the bullet No. 5) with heading	Recruitment of qualified			
		Table of	"Staffing and Competence of Staff", we	staff is primarily a need of			
		content	recommend to add a new item "Long-term	today and the near-term. A			
			planning of staff needs".	responsible planning, how-			
				ever, must also take into			
				account the future needs			
				over the next one or two			
		1		over the next one of two		1	

 $Relevance: \fbox{$1-Essentials$} \ \fbox{$2-Clarification$} \ \fbox{$3-Wording/Editorial$}$ 

				decades. This issue should also be addressed in the Safety Guide.		
3	15	Annex 2	Reference No. 1: "SF-1, Fundamental Safety Principles (2006)"	Harmonized citation of IAEA documents.		
3	16	Annex 2	Reference No. 3: "GSR Part 3 (interim), Radiation Protection and Safety of Radiation Sources, International BSS (2011 Interim Edition)."	Redundant information.		

### Japan Comments on DPP-472 (2013/4/19) Safety Guide: Organisation, Management and Staffing of a Regulatory Body

COMMENTS BY REVIEWER					DECOLUTION				
Reviewer: Page 1 of 1				RESOLUTION					
Country Organization; Japan/NRA			Date 2013/4/19						
Comment	omment Para./Line Proposed new text			Acce	Accepted but modified as follows	Reje	Reason for		
No.	No.		Reason	pted		cted	modify/rejection		
	a	7.1							
1	Section 5		Confirmation:						
	/5 <sup>th</sup> bullet		Has DS460 been drafted?						