Document Preparation Profile (DPP)
DS 472 - Version 5

1. IDENTIFICATION

Document Category **Safety Guides**

Working ID: **DS472**

Proposed Title: **Organisation, Management and Staffing of a Regulatory Body**

Proposed Action: **Revision and combination of existing guidance on organisation, management and staffing of a Regulatory Body, for all facilities and activities, into a single Safety Guide.**

Documents to be combined and revised:

- **Organization and Staffing of the Regulatory Body for Nuclear Facilities, 2002, GS-G-1.1**
- **Regulatory Control of Radiation Sources, 2004, GS-G-1.5 (part of)**
- **(draft) Management systems for regulatory bodies, DS113**
- **Use of External Experts by the Regulatory Body, 2013, GSG-4** [PJ1]
- **(DPP endorsed by CSS) Communication and Consultation with Interested Parties, DS460**

Review Committees: **NUSSC (lead), RASSC, WASSC, TRANSSC and NSGC**

Technical Officer(s): **Adriana Nicic (lead), Hazem Suman.**

2. BACKGROUND

Regulation is essential to ensure safety for all facilities and activities that give rise to radiation risks. The existence of a strong, legally based, independent, fully resourced and technically competent Regulatory Body is a fundamental element outlined in Principle 2 of the IAEA's [PJ2] ~~Safety~~ Fundamental Safety Principles, SF-1. This principle is reinforced and further defined as a requirement in the Safety Requirements on Governmental, Legal and Regulatory Framework for Safety, GSR Part 1 (2010) and on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 (2011, Interim edition).

Most of the supporting Safety Guides in this field are about ten years old and need to be reviewed. Since their publication, the concept of Long Term Structure for the whole Safety Standards Series has been developed and the relevant Safety [PJ3] Requirements documents have been revised and replaced [GSR Part 1 superseded GS-R-1 in 2010, GSR Part 3 (Interim) superseded BSS 115 in 2011].

When GS-R-1 was developed, initially four Safety Guides were produced to support it (GS-G-1.1 to GS-G-1.4). Later, more documents dealing with Regulatory Bodies and their functions have been finalised (e.g. SSG-12, GSR Part 3 (Interim), GSG-4) or are currently being developed (e.g. DS 460). The consistency between these numerous new requirements and guides produced since 2002 needs to be checked.

One of the objectives of the "Long Term Structure of the IAEA Safety Standards" is to reduce the overall number of Safety Standards. It was initially intended to produce one unique Safety Guide to the theme "Regulatory Control of Facilities and Activities". ". In order to match the overarching scope of "facilities and

activities" (see definition of in the Safety Glossary, [PJ4]2007 Edition) current guidance will need to be extended because existing and draft guides have a range of coverage from "facilities and activities", "facilities", "activities" to "nuclear installations".

After further analysis, however, having only one all-encompassing guide appeared not to be the most optimized solution. Indeed, while a relatively simple graded approach can be applied for all facilities and activities for the guidance on Organisation, Management and Staffing, with regard to Regulatory Functions and Processes, a clear separation is necessary to distinguish areas that apply to both facilities and activities and those that only apply to one or the other. It is therefore proposed to develop two documents: one on Organisation, Management and Staffing (DPP OMS), the other one on Regulatory Functions and Processes (DPP RFP).

The implementation of such an arrangement will have to be discussed at an early stage of development of both documents as the existence of clear differences in the regulatory approach for facilities and some activities and the development of a graded approach are expected to trigger difficulties.

More information is provided in the feedback analysis report in annexe to the DPP (ANNEXE 1).

3. JUSTIFICATION FOR THE PRODUCTION OF THE DOCUMENT

Organizational and managerial aspects have proven to be of fundamental importance for the regulatory body to be able to perform its functions in all circumstances. This is one of the lessons now being learned from the accident at TEPCO's Fukushima Daiichi Nuclear Power Plant. It is therefore essential that the guidance provided by the Agency in this field is up-to-date and consistent.

This Safety Guide will bring together several Safety Guides, some of them still being at a drafting stage, to make a single comprehensive and coherent document on organization, management and staffing aspects in line with the Long Term Structure of the Safety Standards. One of the important intentions of the Long Term Structure was to reduce the number of standards by combining existing standards as far as possible.

By covering the organizational structure, management and staffing of regulatory bodies ensuring the control of all facilities and activities, the Safety Guide will also promote a more consistent approach to organizational aspects and to resources needed. Promoting clear consistent guidance is particularly important for those Regulatory Bodies having responsibilities covering all types of facilities and activities or when interfaces are needed between various regulatory organizations, in order to facilitate co-ordination and co-operation.

4. OBJECTIVE AND SCOPE

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 taking into account the need for a graded approach in accordance with national circumstances and with radiation risks associated with facilities and activities.[PJ5] The document is relevant for the regulatory control of all facilities and activities that give rise to radiation risks.

The Safety Guide is complementary and will be produced in parallel to the one covering regulatory functions and processes, proposed in the DPP RFP.

5. PLACE IN THE OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFACES WITH EXISTING AND/OR PLANNED PUBLICATIONS

This Safety Guide will provide guidance on compliance with the Safety Requirements on Governmental Legal and Regulatory Framework for Safety (GSR Part 1), in particular with requirements 2, 3, 4, 7, 11, 13, 15-23 and 36.

The Safety Guide will combine and revise the following documents:

- GS-G-1.1, Organization and Staffing of the Regulatory Body for Nuclear Facilities, 2002
- GS-G-1.5 (part of), Regulatory Control of Radiation Sources, 2004
- DS113 (incomplete draft), Management systems for regulatory bodies
- GSG-4, Use of External Experts by the Regulatory Body, 2013 [PJ6]
  ~~DS429 (approved for publication), External Expert Support for the Regulatory Body~~
- DS460 (DPP endorsed by CSS) Communication and Consultation with Interested Parties

In addition, a list of documents that need to be taken into account and checked for consistency is annexed to this DPP (ANNEXE 2).

The subject and scope of the document would be compatible with potential interfaces with nuclear security series, therefore, as agreed by the Coordination Committee, this Safety Guide will be proposed as an Interface Document to the Interface Group.

6. OVERVIEW

The majority of the text that will be reviewed and incorporated, with revisions where necessary, in the new Safety Guide is available or is being developed concurrently. An outline of [PJ7] contents is set out below; however, the final contents may vary during the drafting process.

Table of content of the new publication

1) Introduction: Background – Objective – Scope – Structure

2) General Characteristics of a Regulatory Body:

General
Legal basis
Regulatory Independence
Funding of the Regulatory Body
Accountability of the Regulatory Body
International Co-operation
Graded Approach to Regulatory Body's Organisation, Management and Staffing.

3) Organization of the Regulatory Body

General

Core ~~Regulatory~~ Functions of the Regulatory Body
Review and assessment of facilities and activities [PJ8]
Authorization and notification [PJ9] ~~(including siting)~~
Inspection of facilities and activities [PJ10]
Enforcement of regulatory requirements [PJ11]
Development of Regulations and Guides

Emergency preparedness [PJ12] (*check for consistency with DS473*)
Communication and consultation with interested parties (*to be developed under DS460*)

~~Other Functions~~
~~Emergency preparedness~~
~~Research and development~~

~~Supporting~~ Functions supporting the discharge of the Regulatory Mandate
Administrative support
Legal assistance
External expert support ~~and Consultants~~ (*from ~~DS429)~~GSG-4*)) [PJ13]
Advisory committees
Research and development
Liaison with other organizations
International cooperation

~~4) Communication and consultation with interested parties (*to be developed under DS460*).~~

4~~5~~) Management System for the Regulatory Body (*based on early draft of DS113, but needs to be reconsidered against latest draft*)

General

Safety culture [PJ14]

Management Systems
~~Safety culture~~
Documentation

Management Responsibilities
Management commitment and leadership
Interaction with interested parties ~~Stakeholder satisfaction~~ [PJ15]
Organizational policies
Planning
Responsibility and authority for the management system
Infrastructure and work environment
Resource and staff planning

Process Implementation
Development of processes
Management of processes
Generic management processes

Measurement, A~~a~~ssessment and Improvement
Monitoring and measuring
Feedback from experience [PJ16]
Self-assessment
Independent assessment
Management review

Non-conformance, corrective and preventative action
Improvement

5) Staffing and Competence of Staff

General
Assessment of competence needs
Methods of acquiring competence (recruitment, external support for RB…)
Recruitment and long-term planning of staff needs
Qualifications of staff
Assessment of training needs
Initial training of staff
Continuing training of staff
Building competence of staff
Delivery and Administration of training

Appendices

References

7. PRODUCTION SCHEDULE: Provisional schedule for preparation of the document, outlining realistic expected dates for:

	Safety Guide
STEP 1: Preparing a DPP	DONE
STEP 2: Approval of DPP by the Coordination Committee	Q1 - 2013
STEP 3: Approval of DPP by the relevant review Committees	Q2 - 2013
STEP 4: Approval of DPP by the CSS	Q4 - 2013
STEP 5: Preparing the draft	Q4 - 2013 to Q2 - 2014
STEP 6: Approval of draft by the Coordination Committee	Q3 - 2014
STEP 7: Approval by the relevant review Committees for submission to Member States for comments	Q4 - 2014
STEP 8: Soliciting comments by Member States	Q1 - 2015
STEP 9: Addressing comments by Member States	Q2 - 2015
STEP 10: Approval of the revised draft by the Coordination Committee Review in NS-SSCS	Q3 - 2015
STEP 11: Approval by the relevant review Committees	Q4 - 2015
STEP 12: Endorsement by the CSS	Q1 - 2016
STEP 13: Establishment by the Publications Committee	Q2 - 2016
STEP 14: Target publication date	Q3 - 2016

8. RESOURCES

Estimated resources involved by the Secretariat (person-weeks) and the Member States (number and type of meetings)

2013:
3 CM to draft, 2 to 3 CM to review.
Lead TO - 6 weeks, other TOs - 3 weeks, one support staff - 10 weeks (to collect comments and prepare review).

2014:
1 CM to address comments, 1 CM if necessary.
Lead TO - 6 weeks, other TOs - 3 weeks, one support staff - 10 weeks.

2015:
1 CM to review final draft.
Lead TO - 6 weeks, other TOs – 2 weeks.

ANNEXE 1

FEEDBACK ANALYSIS REPORT - Organization, Management and Staffing of a Regulatory Body Safety Guide

Introduction
As described in SPESS A, the objective of the feedback report is to provide a justification for a revision to the safety standards based on a systematic collection and analysis of feedback from the use of the safety standards.
Justification for the revision of the safety standards listed in this DPP is provided by the safety standards long term structure. Consequently, the analysis of feedback justifying the revision has not been performed at that stage but it will be performed and used for the development of the safety guide. It will notably take into account feedback from safety review missions, i.e. IRRS, lessons learned from event reporting and feedback on the use of the safety standards collected by the Secretariat.

Within the IAEA Safety Standards, guidance in the field of organisation, management and staffing of a Regulatory Body has been developed in several Safety Guides (SG), for Member States to better implement the Safety Requirements (SR) on *Governmental, Legal and Regulatory Framework for Safety* (GSR Part 1). While some of these SGs have been published over ten years ago, others are currently under development as follow:

- 2002, GS-G-1.1, *Organization and Staffing of the Regulatory Body for Nuclear Facilities*
- 2004, GS-G-1.5, (part of), *Regulatory Control of Radiation Sources*
- (draft), DS113, *Management systems for regulatory bodies*
- (approved for publication), DS429 *External Expert Support for the Regulatory Body*
- (DPP endorsed by CSS), DS460 *Communication and Consultation with Interested Parties*

A revision of these SGs is proposed as it would respond to the following needs and objectives:

1) *Implement the transition to the "long-term structure" of the SGs supporting GSR part 1*

a. Reduction of the number of SGs supporting GSR Part 1

The revision and compilation of these guides is proposed following the adoption, in 2008, of a new, **long-term structure** for the safety standards, to help users easily identify those safety standards that are applicable to the specific facility or activity they are dealing with. The recommendation for the transition to this new structure, currently underway, was to merge the various Safety Guides for the application of GSR Part 1 into a single document.

Following a more in depth analysis, the project to gather all SGs supporting GSR Part 1 in one unique guide appeared difficult in practice. The over whole content seemed too heterogeneous to be synthetized and logically presented in one document but could be easily split into two topical groups: organization, management and staffing of a Regulatory Body on the one hand and regulatory functions and processes on the other hand.

b. Reorganization of SGs supporting GSR Part 1 into two SGs

The existence of strong relations and interlinks between organizational and management aspects as well as human resource makes it logical to address them together. Although the size and role of a Regulatory Body varies considerably from country to country – for example depending if a nuclear

power programme is in place –, aspects related to **organization, management and staffing** can be addressed in the same way through a **graded approach**.

On the other hand, the **functions and processes** of a Regulatory Body in country with operating nuclear power plants and in a country dealing only with industrial or medical nuclear application are very different and appropriate guidance needs to address the variety of these situations and roles. A **clear separation is necessary** to distinguish functions and processes that apply to both nuclear facilities and activities and those that only apply to one or the other.

It is therefore proposed to revise and merge the Safety Guides for the implementation of the Requirements from GSR Part 1 into:

- a Safety Guide on "Organization, Management and Staffing of a Regulatory Body" and
- a Safety Guide on "Regulatory Functions and Processes".

2) Update of content of long produced guidance

The guidance provided in the Safety Standards on *Organization and Staffing of the Regulatory Body for Nuclear Facilities* and the related chapters within the *Regulatory Control of Radiation Sources Safety Guide* have been produced over ten years ago and need to be revised to take into account possible updated good practices from practical experience and review mechanisms.

New safety guidance is also being developed on communication and consultation with interested parties that is not addressed in the current SGs. The Revision of SGs supporting GSR Part 1 therefore represents an opportunity to include this new field as a part of the revised SG on Organization, Management and Staffing of a Regulatory Body.

3) Revision for better consistency of guidance provided to Regulatory Bodies

a. Consistency with the Requirement Document (GSR Part 1)

Some of the SGs addressing the "Regulatory Control of Facilities and Activities" are over ten years old and may not be consistent anymore with the latest version of the Safety Requirement for the implementation of which they are intended to give guidance. Indeed, in 2010, GSR Part 1 superseded the previous version of the Requirements, GS-R-1, titled *Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*, which was published in 2000.

b. Consistency among SGs supporting GSR Part 1

Both the number of SGs addressing organization, management and staffing of a Regulatory Body and the different times of their development cause problems for the consistency of the guidance in this field. More than ten years passed between the SG on *Organization and Staffing of the Regulatory Body for Nuclear Facilities* (GS-G-1.1) and the upcoming SG on External Expert Support for the Regulatory Body.

c. Consistency of guidance on regulatory control of facilities and activities

Currently, the existing SGs addressing the Regulatory Body's organization, management and staffing, do not all address the same type of regulated item: some cover the "nuclear facilities" (GS-G-1.1), while other cover nuclear activities only ("practices" in GS-G-1.5).

In many of the Member States with nuclear facilities, the Regulatory Body is in charge of both aspects. Therefore providing a comprehensive guidance, for cases where the Regulatory Body deals with activities, facilities or both, would be clearer and more convenient for such countries. Current Safety Guide would need extension to cover each of these situations.

Such approach would also be in line with the "long-term structure" which groups SGs supporting GSR part 1 under the title "Regulatory Control of Facilities and Activities".

4) Taking into account the lessons from the accident at Fukushima Daiichi NPPs

a. Action Plan on Nuclear Safety

After the accident at the TEPCO's Fukushima Daiichi NPPs, the IAEA Action Plan on Nuclear Safety (GOV/2011/59-GC(55)/14) includes an action to "**Review and strengthen IAEA Safety Standards and improve their implementation**". The Secretariat carried out a first review on the basis of the lessons from the information that was available up to September 2011.

This work on the lessons learned led to the decision to revise, through several addenda, GSR Part 1, NS-R-3, SSR-2/1, SSR-2/2 and GSR Part 4 (DS462). Since the revision of these Safety Requirements is expected to be finalised in 2014, relevant aspects should be incorporated in this Safety Guide for it to be fully up-to-date.

b. Other feedbacks on the accident in Fukushima Daiichi NPPs

Additional inputs on lessons learned from Fukushima Daiichi's accident have also been provided by several meetings, including the **extraordinary meeting of the Convention on Nuclear Safety** in August 2012. The revision of the guidance on the implementation of GSR Part1 will allow taking into account these new important inputs and updates which go more in detail and contain more information than what will be reflected at the level of Safety Requirement.

ANNEXE 2

List of documents to be taken into account when drafting the Safety Guide on Organization, Management and Staffing

N.B.: The below list is not intended to be final or exhaustive and drafters may consider other documents, in particular such as those listed in DPP RFP.

- SF-1 [PJ17] Fundamental Safety Principles (2006)
- GSR Part 1, Governmental, Legal and Regulatory Framework for Safety (2010) – (revision through addenda, see also DS462)
- GSR Part 3 (interim), Radiation Protection and Safety of Radiation Sources, International BSS (2011 Interim Edition).
- GS-R-3, Management Systems for Facilities and Activities (2006) - (under revision, see DS456)
- GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency (2002) – (under revision, see DS457)
- SSR-6, Regulations for the Safe Transport of Radioactive Material (2012)
- NG-G-2.1, Managing Human Resources in the Field of Nuclear Energy (2009)
- SSG-16, Establishing the Safety Infrastructure for a Nuclear Power Programme (2011)
- Safety Reports Series No. 79, Managing the Competence of the Regulatory Body (2013)
- SSR-2/2, Safety of Nuclear Power Plants: Commissioning and Operation (2011) – (revision through addenda, see also DS462)
- GSR Part 4, Safety Assessment for Facilities and Activities (2009) – (revision through addenda, see also DS462)
- NS-G-2.8, Recruitment, Qualification and Training of Personnel for Nuclear Power Plants (2002) – (under revision, see DS349)
- RS-G-1.4, Building Competence in Radiation Protection and the Safe Use of Radiation Sources (2001) – (under revision, see DS455)
- RS-G-1.3, Assessment of Occupational Exposure Due to External Sources of Radiation (1999) – (under revision, see DS453)
- NS-G-2.11, A System for the Feedback of Experience from Events in Nuclear Installations (2006) – (revision planned, no DS number yet)
- TECDOC 1502, Authorization of NPP Control Room Personnel (2006)
- TECDOC 1525, Notification and Authorization for the Use of Radiation Sources (2010)
- TECDOC 1526 Inspection of Radiation Sources and Regulatory Enforcement (2007)