Document Preparation Profile (DPP)
DS473 Version 6

1. IDENTIFICATION

Document Category **Safety Guides**

Working ID: **DS473**

Proposed Title: **Regulatory Body Functions and Processes**

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

Documents to be combined and revised:

- **Review and assessment of nuclear facilities by the regulatory body, 2002, GS-G-1.2**
- **Regulatory inspection of nuclear facilities and enforcement by the regulatory body, 2002, GS-G-1.3**
- **Documentation for use in regulating nuclear facilities, 2002, GS-G-1.4**
- **Regulatory control of radiation sources, 2004, GS-G-1.5 (part of)**
- **Licensing Process for Nuclear Installations, 2010, SSG-12 (part of)**
- **Release of sites from regulatory control upon termination of practices, 2006 WS-G-5.1 (the regulatory component only)**

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

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2. BACKGROUND

Regulation is essential to ensure safety for all facilities and activities that give rise to radiation risks. The existence of a legally based, independent, fully resourced and technically competent regulatory body is a fundamental element outlined in Principle 2 of the IAEA's 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 in 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Series has been developed and the relevant Safety Requirements documents have been revised and replaced [GSR Part 1 superseded GS-R-1 in 2010, GSR Part 3 (Interim) superseded BSS 115 in 2011].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, GSG-4 and GSR Part 3 (Interim), or are currently being developed (e.g. DS 460).

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 in the Safety Glossary[1]) the proposed guidance will need to address the challenge of incorporating the content of the existing and draft guides, which have very different scopes ranging from "facilities and activities", "facilities", "activities" and "nuclear installations[2]" into one all-encompassing guide.

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 as well as the development of a graded approach are challenging.

More information is provided in the feedback analysis report in annex to the DPP (ANNEX 1).

3. JUSTIFICATION FOR THE PRODUCTION OF THE DOCUMENT

This Safety Guide will bring together several existing Safety Guides to make a coherent document in line with the intention behind the Long Term Structure of the Safety Standards. By covering facilities and activities, the Safety Guide will promote a more consistent approach to the safety regulation of such radiation risks.

As noted above, one of the important features of the Long Term Structure was to reduce the number of standards by combining existing standards as far as possible. Therefore the aim is to combine all of the Safety Guide documents related to Regulatory Bodies into two Safety Guides covering Regulatory Control of Facilities and Activities.

Promoting clear consistent guidance is particularly important for those Regulatory Bodies having responsibilities covering all facilities and activities that give rise to radiation risks or when interfaces are needed between various Regulatory Organisations, 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 for the Regulatory Body's functions and the methods and processes to implement those functions, as defined in GSR Part1 such as authorisation, notification, review and assessment of nuclear facilities and activities, inspections and

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[1] *Facilities and activities,* a general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources.

[2] *Nuclear installation,* any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and radioactive waste disposal 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; conversion facilities; facilities for the reprocessing of spent fuel; facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities; and nuclear fuel cycle related research and development facilities.

enforcement, licensing procedures. In addition this Safety Guide will address the release of facilities and activities from regulatory control (i.e. release of sites, material, equipment, buildings). The information is intended to be mainly used by Regulatory Bodies but can be also useful for governments. This Safety Guide is complementary and will be produced in parallel to the one covering the organization, management and staffing of the Regulatory Body, proposed in the DPP OMS.

The proposed Safety Guide will cover the functions and processes of a Regulatory Body for all facilities and activities that give rise to radiation risks.

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 regulatory aspects of the Safety Requirements on Governmental Legal and Regulatory Framework for Safety (GSR Part 1), in particular with requirements 2, 3, 4, 6, 8, 10, 22-36.

The following documents will be combined and revised:

- GS-G-1.2, Review and assessment of nuclear facilities by the regulatory body, 2002
- GS-G-1.3, Regulatory inspection of nuclear facilities and enforcement by the regulatory body, 2002
- GS-G-1.4, Documentation for use in regulating nuclear facilities, 2002
- GS-G-1.5, Regulatory control of radiation sources, 2004 (part of)
- SSG-12, Licensing Process for Nuclear Installations, 2010
- WS-G-5.1 Release of sites from regulatory control upon termination of practices, 2006 (the regulatory component only)

In addition, a list of documents that need to be taken into account and checked for consistency is annexed to this DPP (ANNEX 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 the 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) Core Regulatory Functions and Processes

Authorisation and Notification

General and Basic Principles
Information Needed in Making Notification and/or Applying for Authorisation
Form of Notification/Authorisation for a Facility or Activity
Form of Authorisation for Individuals
Authorization Conditions
Steps in the Authorisation Process
Modification or Revocation of Authorisations
Release from Regulatory Control

Review and Assessment of Facilities and Activities
- Objective of Review and Assessment
- Information to be reviewed and assessed
- Review and Assessment Process
- Performance of Review and Assessment
- Record of Review and Assessment

Inspection of Facilities and Activities
- Objective of Inspection
- Organisation of Regulatory Inspection Function
- Types of Regulatory Inspection
- Planning of Regulatory Inspection
- Performance of Regulatory Inspection
- Record of Regulatory Inspection
- Follow-up on Inspection Findings

Enforcement of Regulatory Requirements
- Objective of Enforcement
- Methods of Enforcement
- Factors in Determining Enforcement Actions
- Implementing Enforcement
- Records of Enforcement

Development of Regulations and Guides
- Process for Development of Regulations and Guides
- Processes for Ensuring Review and Revision of Regulations and Guides

Emergency Preparedness and Response

3) Graded Approach to Regulatory Body Functions

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	Q3 - 2015

Review in NS-SSCS	
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.

ANNEX 1

FEEDBACK ANALYSIS REPORT - Regulatory Body Functions and Processes 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 already provided by the safety standards long term structure, as discussed in the DPP. Consequently, the analysis of feedback justifying the revision has not currently been performed. However, a feedback analysis, taking 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, will be performed and used to inform the development of the safety guide.

Within the IAEA Safety Standards, guidance in the field of functions and processes 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 several of these SGs have been published over ten years ago, others are recent as follow:

- 2002, GS-G-1.2, *Review and Assessment of Nuclear Facilities by the Regulatory Body*
- 2002, GS-G-1.3, *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*
- 2002, GS-G-1.4, *Documentation for Use in Regulating Nuclear Facilities*
- 2004, GS-G-1.5, (part of) *Regulatory Control of Radiation Sources*
- 2010, SSG-12, (part of) *Licensing Process for Nuclear Installations*
- 2006, WS-G-5.1, (part of) *Release of sites from regulatory control upon termination of practices*

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 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 "review and assessment of nuclear facilities", on "inspection of nuclear facilities and enforcement by the regulatory body" and on "documentation" used for regulating nuclear facilities 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.

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 regulatory functions and processes and the different times of their development cause problems for the consistency of the guidance produced in this field e.g. evolution of several definitions (the Safety Glossary was issued in 2007). Eight years passed between the publication of the first SGs (GS-G-1.2, GS-G-1.3 and GS-G-1.4) and the Specific Safety Guide on Licensing Process for Nuclear Installations, published in 2010.

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

Currently, the existing SGs addressing the Regulatory Body's functions and processes, do not all address the same type of regulated item: some cover the "nuclear facilities" (GS-G-1.2, GS-G-1.3 and GS-G-1.4), while other cover "nuclear installations" (SSG-12) or only nuclear activities ("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.

ANNEX 2

List of documents to be taken into account when drafting the Safety Guide on Regulatory Functions and Processes

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 OMS.

- SF-1, Fundamental Safety Principles (2006)
- GSR Part 1, Governmental, Legal and Regulatory Framework for Safety (2010) – (revision through addenda, see also DS462)
- DPP DS 460 Communication and Consultation with Interested Parties
- GSR Part 3 (interim), Radiation Protection and Safety of Radiation Sources, International BSS (2011 Interim Edition).
- GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency (2002) – (under revision, see DS457)
- GSR Part 4, Safety Assessment for Facilities and Activities (2009) – (revision through addenda, see also DS462)
- GSR Part 5: Predisposal Management of Radioactive Waste (2009)
- WS-R-5 Decommissioning of Facilities Using Radioactive Material (2006) – (under revision, see DS450)
- WS-G-2.3 Regulatory control of radioactive discharges to the environment (2000) – (under revision, see DS442)
- Draft Safety Report "Managing the competence of the regulatory body"
- SSR-2/1, Safety of Nuclear Power Plants: Design (2012) – (revision through addenda, see also DS462)
- SSR-2/2, Safety of Nuclear Power Plants: Commissioning and Operation (2011) – (revision through addenda, see also DS462)
- SSR-6, Regulations for the Safe Transport of Radioactive Material (2012)
- NS-R-3, Site Evaluation for Nuclear Installations (2003) – (revision through addenda, see also DS462)
- GS-G-4.1, Format and Content of the Safety Analysis Report for Nuclear power Plants (2004) – (revision through addenda, see also DS449)
- SSG-2, Deterministic Safety Analysis for Nuclear Power Plants (2010)
- NS-G-2.3, Modifications to Nuclear Power Plants Safety Guide (2001) – (revision planned, no DS number yet)
- NS-G-2.8, Recruitment, Qualification and Training of Personnel for Nuclear Power Plants (2002) – (under revision, see DS349)
- NS-G-2.9, Commissioning for Nuclear Power Plants (2003) - (under revision, see DS446)
- NS-G-2.10, Periodic Safety Review of Nuclear Power Plants (2003) - (under revision, see DS426)
- NS-G-2.12, Ageing Management for Nuclear Power Plants (2009) – (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)
- NS-R-4, Safety of Research Reactors (2005)
- NS-R-5 Safety of Nuclear Fuel Cycle Facilities (2008) (under revision through addition of addendum, see DS439)
- 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