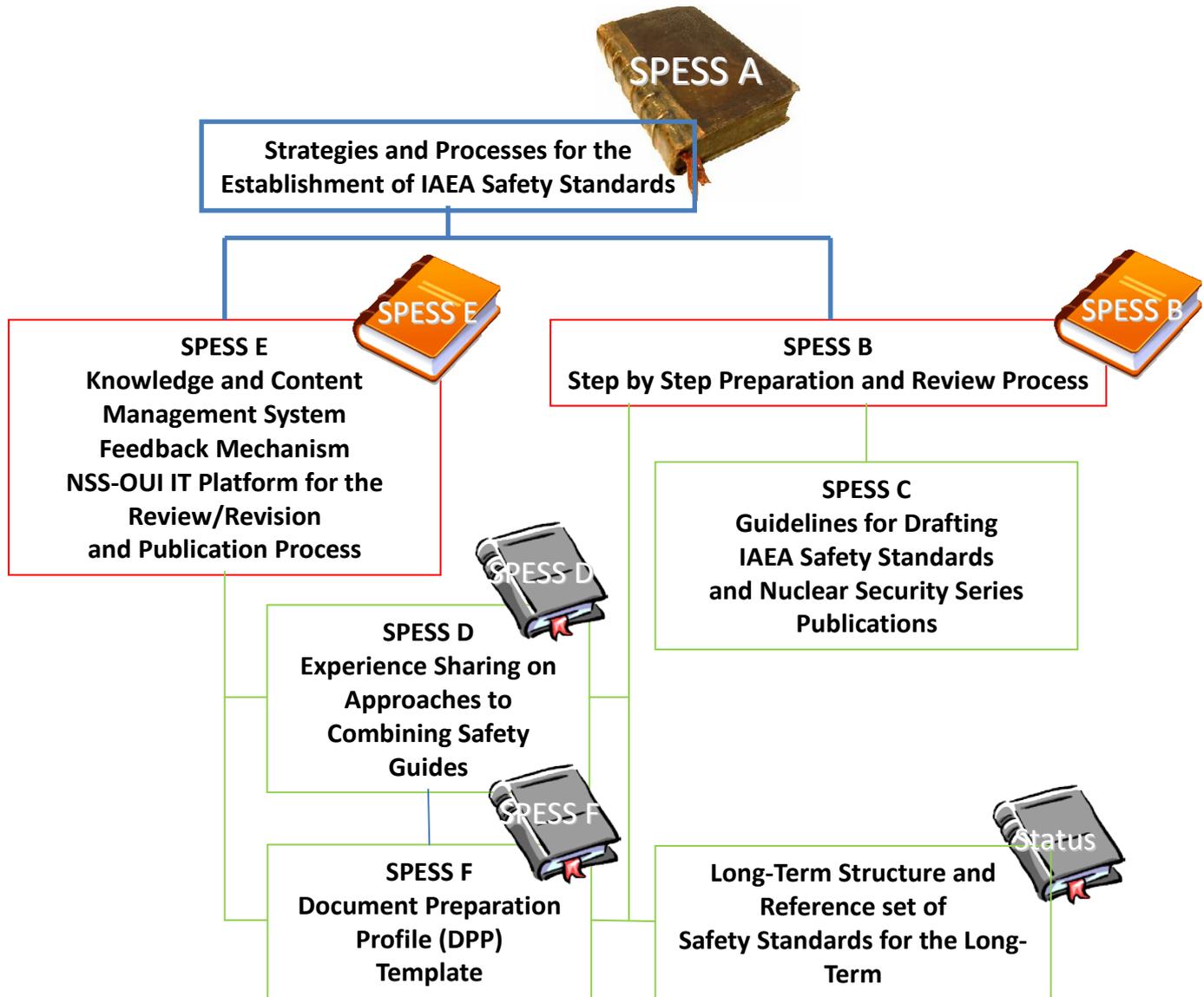


 IAEA International Atomic Energy Agency	Department NS	Code SPESS A	Rev. No 2.2	Date of entry into force 2015-11-16	Page 1 of 139
Quality Management System – Safety and Security Coordination Section					
STRATEGIES AND PROCESSES FOR THE ESTABLISHMENT OF IAEA SAFETY STANDARDS (SPESS) Version 2.2 – 16 November 2015					



The SPESS MANAGEMENT SYSTEM

COMMITMENT

The IAEA's Statute authorizes the Agency to establish standards of safety to protect health and minimize danger to life and property — standards that the IAEA must apply to its own operations, and that a State can apply by means of its regulatory provisions for safety. The IAEA has a fundamental part to play through the Safety Standards Series and their application in achieving in the Member States a high level of protection for people and the environment worldwide based on the IAEA safety standards as the global reference.

With the strong involvement of the members of the Safety Standards Committees and of the Commission on Safety Standards, the IAEA is committed to:

- Maintaining and improving an integrated, comprehensive and consistent set of up-to-date, user friendly and fit-for-purpose safety standards of high quality, which through their use and application in the Member States will provide for a worldwide harmonized high level of protection for people and the environment from harmful effects of ionizing radiation; and
- Promoting the global acceptance and the harmonized use and application of the IAEA safety standards.

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1. INTRODUCTION

A. Background

Mandate of the International Atomic Energy Agency

Under Article III.A.6 of its Statute, the IAEA is authorized “To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operation as well as to the operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision; and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangements, or, at the request of a State, to any of that State’s activities in the field of atomic energy”.

Legal nature of the safety standards

With regard to the legal nature of the IAEA Safety Standards vis-à-vis the Secretariat, they are legally binding on the Secretariat since, pursuant to Article III.A.6 of the Statute, it has adopted Radiation Safety Regulations which require the Secretariat to apply these standards to its own operations.

As to the legal nature of the IAEA Safety Standards vis-à-vis Member States, they are not, as such, legally binding on them. Member States may, however, adopt these standards at their own discretion, for use in national regulations in respect to their own activities.

For Agency projects, Article III.A.6 authorizes the Agency to apply “standards of safety” to operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision. In this connection, the provisions of Articles XI.E.3 and XII.A.2 are also relevant. Article XI.E.3 provides that before approving a project (which includes Technical Co-operation projects) under this article, the Board shall give due consideration to the adequacy of proposed health and safety standards for handling and storing materials and for operating facilities. Article

XII.A 2 provides that, with respect to any Agency project, the Agency shall have the following rights and responsibilities to the extent relevant to the project: “To require the observance of any health and safety measures prescribed by the Agency”.

In order to meet the above statutory requirements, the Board of Governors in 1960 approved Guiding Principles and General Operating Rules to Govern the Provision of Technical Assistance by the Agency, which included an obligation by the State to apply health and safety measures. An equivalent obligation is included in the Revised Guiding Principles and General Operating Rules to Govern the Provision of Technical Assistance by the Agency (INFCIRC/267), which provide in paragraph A.1(h) that “the Agency’s Safety Standards and Measures shall be applied, where relevant, to operations making use of technical assistance provided”.

In conformity with that requirement, Article II of the Revised Supplementary Agreement Concerning the Provision of Technical Assistance by the Agency (RSA) provides that the “Government shall apply to the operations making use of the technical assistance provided to it pursuant to this Agreement the Agency’s Safety Standards and Measures defined in document INFCIRC/18/Rev.1 and the applicable safety standards as they are established in accordance with that document and as they may be revised from time to time.”

Equally in conformity with the above requirements, Project and Supply Agreements (PSA) also include a provision to the effect that the “safety standards and measures specified in Annex A to this Agreement shall apply to the Project”.

The Agency being bound by the provisions of INFCIRC/267 and being party to the RSA and PSA, should, from a legal perspective, make acceptance and implementation of the aforementioned safety standards a condition for the provision of technical assistance (including TC projects). In view of the inherent discretionary nature of the Safety Guides, however, they are not mandatory for Agency projects and shall therefore only be used as providing guidance for the implementation of the Safety Fundamentals and Safety Requirements.

Finally, for Agency missions, it has to be noted that Article III.A.6 also authorizes the Agency to apply the IAEA Safety Standards: “at the request of the parties, to operations under any bilateral or multilateral arrangement; or, at the request of a State, to any of that State’s activities in the field of atomic energy”. In the past this has been used as the statutory basis

for the Agency's advisory safety missions, such as OSART and IRRS. Such missions are carried out at the request of States and, in effect, involve the application of the relevant safety standards to State activities in the field of atomic energy.

While the three categories of IAEA Safety Standards are issued under the authority of the Board of Governors, the authority to issue safety guides has been delegated to the Director General (see GOV/INF/772 and GOV/2004/6). Also, as can be taken from the various definitions of the different categories, Safety Fundamentals and Safety Requirements are expressed as "must" and "shall" statements and thus contain norms that must be met. Safety Guides are using "should" statements granting discretion to the addressee with respect to their implementation and providing guidance on how to comply with the Safety Fundamentals and Safety Requirements.

Historical perspective

Shortly after its inception in 1957, the Secretariat began developing and setting safety standards and the very first IAEA publication (STI/PUB/1) was Safety Series No. 1 on the safe handling of radioisotopes, published in December 1958.

Around 200 publications were subsequently issued in the Safety Series including the regulations for the safe transport of radioactive material in 1961, the basic safety standards for radiation protection in 1962 and safe radioactive waste disposal into the ground in 1965.

The further development can be categorized as the establishment of four programmes for nuclear installation safety, radiation safety, waste safety, and transport safety, each with a specific and different review process, as summarized here below.

For the radiation safety area and particularly the Basic Safety Standards, the first two editions in 1962 and 1967 were approved by the Board of Governors. The following revision, initiated at the beginning of the 1980s, was developed jointly with the International Labour Organization, the World Health Organization and the Nuclear Energy Agency of the Organization for Economic Co-operation and Development; This revision was issued in 1982. In 1990, following the revision of the International Commission on Radiological Protection (ICRP) recommendations, an Inter-Agency Committee on Radiation Safety (IACRS) was established. It comprised initially the Commission of the European Communities (CEC, now the European Commission), the Council for Mutual Economic Assistance (CMEA, now defunct), the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the

ILO, the OECD/NEA, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the World Health Organization (WHO). The Pan American Health Organization (PAHO) joined subsequently. Several other organizations — the, ICRP, the International Commission on Radiation Units (ICRU), the International Electrotechnical Commission (IEC), the International Radiation Protection Association (IRPA) and the International Organization for Standardization (ISO) — had an observer status in IACRS.

Taking account of the new developments and within the IACRS framework, the IAEA, FAO, ILO, OECD/NEA and WHO established a Joint Secretariat — co-ordinated by the IAEA — for the preparation of new International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources issued in 1996.

As nuclear power expanded globally, the need for a comprehensive set of safety standards for nuclear power plants emerged. As a result, in 1974, the IAEA launched a Nuclear Safety Standards programme (NUSS).

The review and approval process for the NUSS programme was established through a Senior Advisory Group (SAG) established in 1974, with five Technical Review Committees (TRC) to cover the five areas of governmental organization, siting, design, operation and quality assurance. The SAG and its five TRCs were replaced in 1988 by the Nuclear Safety Advisory Group (NUSSAG) composed of senior regulators.

With regard to safety standards on the transport of radioactive material, an IAEA Standing Advisory Group on the Safety Transport of Radioactive Material (SAGSTRAM) was established in 1977.

For the safety series on waste disposal, a Technical Review Committee on Underground Disposal of Radioactive Waste (TRCUD) was established in 1978 and continued its work until 1988. The radioactive waste safety (RADWASS) programme was initiated in 1988. At the time of its establishment, the drafts were reviewed by an ad hoc International Radioactive Waste Management Advisory Committee (INWAC) composed of experts nominated by Member States from research, operational and regulatory organizations. Because of the emphasis on safety related aspects, the composition of INWAC was extended in 1994 to formally include regulators from each country.

Over the years, the safety standards were also published in the IAEA Safety Series without distinction of status among the various safety related documents. In 1989, following a major

expansion of the IAEA safety related activities, the Secretariat introduced a hierarchical structure comprising Fundamentals, Standards, Guides and Practices.

This first part of the history of the safety standards, until 1996, was essentially a phase of response to several identified needs from the Member States and progressive establishment of a specific structure and review process for each programme in a bottom-up approach, collecting the experience in safety practices and guides, identifying requirements and later on fundamental principles. It resulted in the issue in the 1990s of three different Safety Fundamentals publications, in the areas of radioactive waste management, nuclear installation safety and radiation protection and the safety of sources.

By 1996, it became obvious that there were different processes for the preparation and review of Safety Series publications. This situation often resulted in a lack of compatibility among a number of Safety Series publications. On 1 January 1996, the IAEA modified its managerial structure creating the Department of Nuclear Safety with the specific responsibility of organizing the preparation and review of the IAEA safety standards. A renewed uniform preparation and review process was introduced covering all areas in which the IAEA establishes safety standards.

As part of this new preparation and review process, the Secretariat created a set of advisory bodies with harmonized terms of reference. These bodies included the Advisory Commission for Safety Standards (ACSS), the Nuclear Safety Standards Advisory Committee (NUSSAC), the Radiation Safety Standards Advisory Committee (NUSSAC), the Transport Safety Standards Advisory Committee (TRANSSAC) and the Waste Safety Standards Advisory Committee (WASSAC).

A decision was also made to replace the Safety Series by two new series of safety related publications, the Safety Standards Series and the Safety Reports Series. The purpose was to make a distinction between safety standards, which were intended to spell out objectives, concepts and principles, to serve as a basis for national regulations or to indicate how various safety requirements may be met, and publications issued for informational purposes. As part of this modification, the hierarchy of the Safety Standards Series publications was changed to include Safety Fundamentals, Safety Requirements and Safety Guides. The previous Safety Practices were replaced by the Safety Reports Series.

One additional change since the creation of the Commission and Committees in 1996, involves a change in name. Because the Commission and Committees are an integral part of the development process, the term “advisory” was eliminated from the titles and the Commission and Committees were renamed: the Commission on Safety Standards (CSS), Nuclear Safety Standards Committee (NUSSC), Radiation Safety Standards Committee (RASSC), Transport Safety Standards Committee (TRANSSC), and Waste Safety Standards Committee (WASSC).

With the changes in place in 1996 the establishment of an overall structure for the Safety Standards Series began and it was established with effect from 2003. However, it was more a juxtaposition of the four programmes than a real integration and there were still overlaps among the safety standards.

In 2006, a key milestone was reached with the issue of Fundamental Safety Principles, a single Safety Fundamentals publication¹, superseding the three previous independent Safety Fundamentals publications, covering the different areas of nuclear safety, radiation safety and waste safety and formulating for the first time a unified philosophy of nuclear safety and protection against ionizing radiation with a broad international consensus. Fundamental Safety Principles constitutes the conceptual basis for the IAEA's entire safety standards programme and provides the rationale for its wider safety and security related programme.

This resulted in 2006 in a major change in approach, initiated by a statement from the Commission on Safety Standards issued in June 2006 ([Annex I](#)), with the adoption of a top-down approach in order to ensure a logical application of the safety principles in the safety requirements and a logical implementation of the safety requirements in the safety guides. At the same time, the potential proliferation of safety guides led to the identification of a need to optimize the set of guides and improve their user friendliness.

¹ INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, Safety Standards Series No. SF -1, IAEA, Vienna (2006).

During the first decade after the establishment of the uniform review process, in 1996, the quality and relevance of the safety standards significantly increased, resulting in two main aspects. Firstly, the number of Member States using the safety standards increased, as did their commitment to actively participate in the establishment and review processes and secondly, the use of the safety standards in the Member States resulted in a request for regulatory stability as a new challenge for the safety standards.

The internationally agreed IAEA safety standards provide a basis for States to demonstrate their performance in fulfilling their obligations. They are a cornerstone of the Global Nuclear Safety and Security Regime, which supports the implementation of binding international instruments and national safety infrastructure.

With all these changes, the following vision was formulated at the occasion of the 50th anniversary of the IAEA safety standards in 2008.

Vision

Outcome: A harmonized high level of protection for people and the environment worldwide based on the IAEA safety standards as the global reference.

Output: IAEA safety standards will be seen as the global reference for protecting people and the environment from harmful effects of ionizing radiation. They will constitute an integrated, comprehensive and consistent set of up-to-date, user friendly and fit-for-purpose safety standards of high quality, which through their use and application in the Member States will provide for a worldwide harmonized high level of protection for people and the environment from harmful effects of ionizing radiation.

Need for this document

The change in the approach initiated in 2006 involved a number of aspects that necessitated the reinforcement of the management of the safety standards related processes:

- The adoption of a top-down management approach for the strategies, the process management and the structure of the safety standards programme, while keeping a bottom-up approach for the collection, analysis and incorporation into revisions of the safety standards of feedback from the Member States and from IAEA safety services, etc.;
- The integration of the thematic areas to avoid gaps and overlaps;

- The need for the establishment or adaptation of a number of policies on, inter alia the structure of the safety standards, their format, their user friendliness, the harmonization of terminology, the collection of feedback.

Preparation

At the 21st Commission on Safety Standards (CSS) meeting, in June 2007, the Secretariat informed the Commission of its initiative to revise the so-called “brown book” issued in 1998 on the preparation and review process for the safety standards, and to establish a system for the management of the entire planning, development, review/revision, approval and establishment of the IAEA safety standards. A draft table of contents was prepared in March 2007 and presented at the 21st CSS meeting. Progress reports were presented at the following meetings in 2007 and 2008.

On the basis of the table of contents prepared in March 2007, the Secretariat compiled a draft of the proposed system of strategies and processes by compiling material from various sources. A draft 0.1 was submitted to the Safety Standards Committees in February 2008 and the comments incorporated in a draft 0.2. Following the May 2008 and September 2008 CSS meetings where important policy papers were approved on the long-term structure of the safety standards ([Annexes II to V](#)), the Secretariat revised the draft to incorporate all policies recently adopted and articulate these into the relevant processes. This resulted in a draft 0.3 submitted for review to the Chairs of the Safety Standards Committee in January 2009. The incorporation of the comments from this meeting resulted in the draft 1 provided to the Safety Standards Committees in June 2009. The comments from the Committees members were discussed at a meeting with the four Committee Chairs on 3 July 2009. This resulted in the draft 2 submitted to the Commission on Safety Standards at its meeting in October 2009. The comments from the CSS were included in the version 2.5 submitted for comments to the Safety Standards Committees. The consideration of these comments during the four Committees Chairs meeting in January 2010 resulted in the draft 3 agreed by the CSS at its meeting in March 2010 and issued as version 1 in April 2010.

A first revision numbered 1.1 was issued in March 2011. It took into account the developments during the year 2010 and was reviewed by the four Chairs of the 2008-2010 term of the Safety Standards Committees. A revision 2 issued in October 2012 included developments in 2011 and early 2012, essentially the establishment of the new Nuclear Security Guidance Committee and the Interface Group. It also included additional functions

for the CSS discussed at the end of its fourth term and confirmed at the beginning of its fifth term. A revision 2.1 incorporated a few changes for further improvement of the document.

In 2015, a new Standards Committee was established, the Emergency Preparedness Standards Committee (EPreSC), with as ultimate goal a strengthened role and integration of EPR subject matter experts in the overall process of establishing Agency safety standards resulting in an increase in quality, transparency and consistency of EPR aspects within Agency safety standards, and an improved coordination of EPR among various publications.

This revision 2.2 integrates the establishment of EPreSC as well as the adoption by the CSS in April 2015 of a policy paper on qualitative/quantitative standards and the development of the Nuclear Safety and Security On line User Interface IT platform (NSS-OUI). It will be kept up-to-date and revised as necessary according to future development of strategies and processes.

B. Objective

The objective of this document is to describe the strategies, the processes and associated responsibilities for the planning, development, review and revision, approval and establishment of the IAEA safety standards.

The intent is to document and strengthen the process which started with the establishment of the Commission on Safety Standards and the Safety Standards Committees in 1996, in order to achieve by the end of 2015 and maintain beyond this time:

- A genuine integration of all areas in the Safety Standards Series, using a top-down approach based on the unified Safety Fundamentals;
- A rationalization of the Series with a reasonable and manageable number of Safety Guides;
- A significant improvement in ‘user-friendliness’; and
- A rigorous and efficient process for the establishment of additional standards and revision of existing ones.

It is expected that these factors cumulatively will result in a major change in the use and application of the safety standards in the Member States.

C. Scope

The main elements relating to the mandate of the IAEA, the vision for the role of the IAEA safety standards in the future and the policies and strategies necessary to achieve the vision are collected and articulated in a comprehensive manner. This also includes elements from the CSS statement issued in June 2006, the roadmap on the long term structure of the safety standards and its annexes approved at the May 2008 CSS meeting and policy papers adopted at the 2008 to 2010 CSS meetings. The document is complemented by a description of the main processes and associated responsibilities and functions.

This document covers responsibilities and requirements in the following areas:

- Project management: control and oversight;
- Planning, drafting, review/revision, approval and establishment of safety standards;
- Management of feedback mechanisms for the safety standards;
- Technical editorial control;
- Management of terminology: control and oversight;
- Knowledge management: records and continuity;
- Document management: version control and archiving;
- Cooperation: consultation and collaboration.

This document is accompanied by a separate SPESS B manual on Step by Step Preparation and Review Process providing the detailed step by step procedure for the development, review and approval of the draft safety standards. An additional manual on the feedback, review and revision decision making processes is also being developed. Detailed guidelines, instructions and/or examples are also issued for use by technical officers and reviewers (SPESS C and SPESS D).

D. Structure

The mandate of the IAEA with regard to the safety standards, a historical perspective, the vision on the future of the safety standards, the need for this document and the history of its development are presented in Section 1. Section 2 provides the basic strategy to achieve this vision and Section 3 describes the main processes involved and the related responsibilities

and functions. Section 4 describes the process for keeping this document up to date, including through the self-assessment of its application. Annexes containing the most important policy papers are included.

2. BASIC STRATEGIES IN ACHIEVING THE VISION

The 50th anniversary of the IAEA safety standards in 2008 was an opportunity to discuss the future of the safety standards and the strategy to achieve the vision as indicated in Section 1, repeated in the box here below.

Outcome: A harmonized high level of protection for people and the environment worldwide based on the IAEA safety standards as the global reference.

Output: IAEA safety standards will be seen as the global reference for protecting people and the environment from harmful effects of ionizing radiation. They will constitute an integrated, comprehensive and consistent set of up-to-date, user friendly and fit-for-purpose safety standards of high quality, which through their use and application in the Member States will provide for a worldwide harmonized high level of protection for people and the environment from harmful effects of ionizing radiation.

This was particularly addressed at the May and September 2008 CSS meetings and at the Senior Regulators' meeting organized during the 52nd General Conference of the IAEA in September 2008, which reached conclusions on the necessary following key conditions for the safety standards programme:

- **For the Safety Standards Series:**
 - Completeness,
 - Logical top-down relationship,
 - Consistency,
 - User friendliness,
 - Manageable number of publications

- **For the content of the safety standards:**
 - Consensus on high level of safety
- **For the review and approval process for the safety standards:**
 - Rigour,
 - Transparency,
 - High level approval,
 - Effectiveness of feedback mechanisms

Therefore, the following sub-sections develop the following strategies:

- A. Clear categories consistent with the Member States' needs and use.
- B. Clear, logical and integrated structure based on a unified safety philosophy.
- C. Clear scope in terms of areas covered and level of detail in each category.
- D. Consensus at the highest level on what constitutes a high level of safety.
- E. User friendliness.
- F. Manageable number of safety standards.
- G. Clarity, rigour and efficiency of the processes.
- H. Involvement of stakeholders.
- I. Effective feedback mechanism to improve the safety standards.
- J. Harmonized terminology.
- K. Promotion of the IAEA safety standards.
- L. Interface between safety and security.

A. Clear categories consistent with the Member States' needs and use

Categorization of the safety standards

Since the establishment of the Safety Standards Series in 1996, the various reports on the safety standards development always recommended to keep a hierarchy of the safety standards with three categories, Safety Fundamentals, Safety Requirements and Safety Guides. Furthermore, in order to better respond to the needs of Member States, the definitions of three categories have been modified. The safety standards will continue to be issued in the IAEA Safety Standards Series:

SAFETY FUNDAMENTALS

The Safety Fundamentals SF-1 presents the fundamental safety objective and principles of protection and safety and provides the basis for the safety requirements.

SAFETY REQUIREMENTS

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. The General Safety Requirements and the Specific Safety Requirements² include overarching requirements and associated requirements, both expressed as “shall” statements. In addition, when necessary, the publication also includes explanatory text in support of the safety requirements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

² This does not currently apply to TS-R-1 (SSR 6)

SAFETY GUIDES

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

This strategy A is essentially implemented through the policy establishment process ([section 3 part B](#)).

**B. Clear, logical and integrated structure based on
a unified safety philosophy**

Relationship between the three categories of safety standards

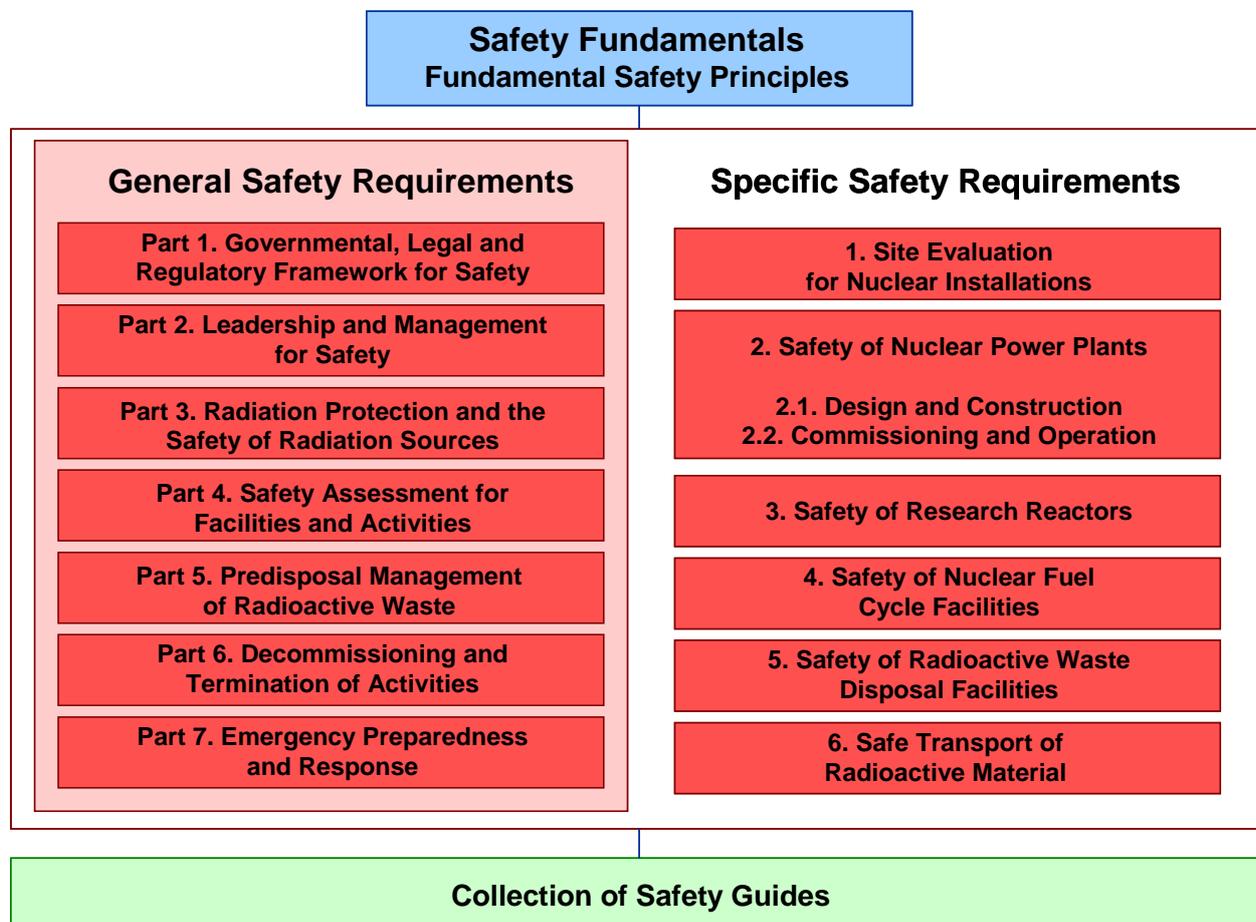
The structure of the safety standards has been recently reviewed in the light of the ten Fundamental Safety Principles and the “ROADMAP on the Long-Term Structure of the safety standards” approved in May 2008 ([Annexes II, III and IV](#)).

The main thrust of the new structure is the integration of the thematic Safety Requirements into a set of General Safety Requirements applicable to all facilities and activities. General Safety requirements are complemented by a series of facility and activity specific Safety Requirements. The complete set of Requirements should:

- Address all radiation exposure situations;
- Apply to any facility and activity³; and
- Take into account that safety and security measures must be designed and implemented in an integrated manner.

³ The term ‘facilities and activities’ — existing and new — encompasses any human activity that may cause people to be exposed to radiation risks arising from naturally occurring or artificial sources. ‘Facilities’ includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive materials are produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required. ‘Activities’ includes: the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.

The requirements will address what must be done while the guides will address how this may be achieved.

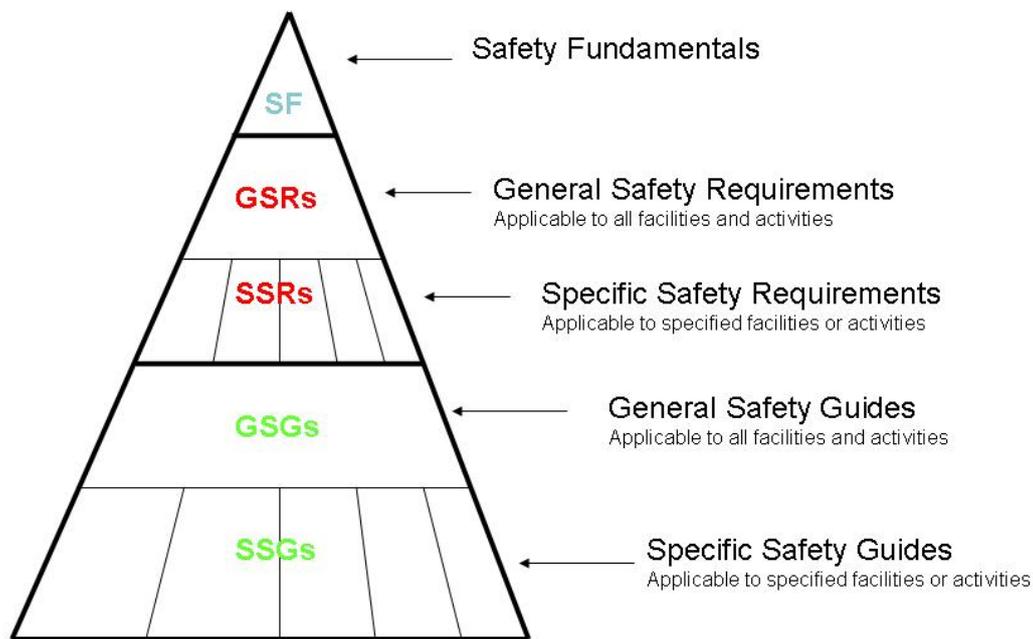


The long term structure of the IAEA Safety Standards Series

STRUCTURE OF THE SET OF SAFETY GUIDES

Safety Guides provide recommendations and guidance on how to comply with the Safety Requirements. The revision of the structure of the set of Safety Guides provides an opportunity to optimize their number as well as to review their comprehensiveness. In establishing and maintaining the list of safety guides, the following criteria were adopted:

- The overall picture is a matrix picture (not a tree structure with a list of safety guides below individual requirements, as is the case for the structure employed in the past) that allows for safety guides that implement several requirements and thus allows for the optimization of the whole set of guides.



Hierarchy of the safety standards

- To the extent practicable, safety guides in the general safety area should be generic for all facilities and activities. As an objective in principle, there should be one safety guide for each important theme unless a justification is provided that the importance of the differences between the recommendations for some facilities and activities leads to the need for a separate guide for a particular facility or activity, or a justification is provided that combining too many topics related to a single theme would not be practicable
- For safety guides in the specific area, the preferred approach is to have "vertical guides" integrating the necessary guidance material on all topics and for each type of facility or activity (user approach), except for nuclear power plants and research reactors where this would not be practicable, considering the number of topics to be covered. Nevertheless, when the recommendations on these topics can be applicable to nuclear power plants, research reactors and fuel cycle facilities, a common Safety Guide would be prepared, possibly with a graded approach for its implementation for

the different types of installations. When it is justified not to combine the guides for nuclear power plants, research reactors and fuel cycle facilities, the preference would still be given to try to integrate the guides for nuclear power plants and research reactors.

This is further described in [Annex IV](#).

FORMAT FOR SAFETY REQUIREMENTS AND SAFETY GUIDES

For General Safety Requirements and Specific Safety Requirements, a format has been adopted with a discrete set of overarching requirements followed by requirements of associated conditions to be met, both expressed as “shall” statements. In addition, when necessary, the publication also includes explanatory text in support of the safety requirements. When a decision is made to revise a Safety Requirements publication, the revision should include the adoption of this new format, consistent with the following aims:

- In term of user-friendliness, the format and style of the safety standards should facilitate their use for the establishment of the regulatory framework. The Safety Requirements should be short enough to encourage their reading and actual use in the Member States;
- In the Safety Requirements published before 2008, references were often made to specific concepts but the explanation was in many cases given in the associated Safety Guides. In the long term set, the explanation of the concepts should be provided in the Safety Requirements so as to facilitate their interpretation for use in establishing national regulatory requirements;
- In addition, each individual overarching requirement should be allocated a number in sequence. The requirements of associated conditions are referenced through the normal paragraph numbering system. By appropriate references in the Safety Guides, this will help building a logical relationship between Safety Requirements and Safety Guides. Thus, after completion of the set of Safety Requirements, the subsequent revision of Safety Guides should refer to these numbers;
- Safety Requirements address what must be achieved/done while the Safety Guides address how this may be achieved/done.

This strategy B is essentially implemented through the policy and programme establishment process ([Section 3 part B](#)) and the internal and external review process ([Section 3 part D](#)).

C. Clear scope in terms of areas covered and level of detail in each category

Scope of the safety standards and relationship/interface with other series

The structure and the format of the safety standards, approved in 2008, clarified the scope in terms of areas to be covered and the level of detail expected in the safety standards particularly for Safety Requirements. This includes the introduction of overarching requirements with requirements on associated conditions and the inclusion of explanations of the concepts in the Safety Requirements, while the Safety Guides focus on recommendations on how the requirements can be met.

The Safety Guides should clearly state:

- The types of facilities and activities being addressed.
- The topics being comprehensively covered.
- The related requirements and how each of these requirements can be met.
- The other safety standards that have to be consulted.

In 2015, the CSS also adopted a policy paper on quantitative/qualitative safety standards (provided in [Annex VI](#)).

Safety standards should also highlight any interface with security measures whenever they interplay and should include reference to the related security guidance in the Nuclear Security Series. (See [sub-section L](#) on Interface between safety and security)

For the application of the standards, reports on safety and protection in nuclear activities are issued as Safety Reports. Publications in the Safety Reports Series may complement, and be directly related to, Safety Requirements or Safety Guides. They may give practical examples and detailed methods that can be used to ensure the observance of Safety Requirements or Safety Guides. They may, for example, describe methods for performing certain calculations, illustrate types of form to be used in an auditing process, provide a compilation of data or describe methods for making a specific judgement concerning the fulfilment of safety or recommendations. Safety Reports may describe good practices but they do not establish requirements or present recommendations and therefore they do not contain prescriptive ‘shall’ statements and generally do not contain prescriptive ‘should’ statements.

In addition, publication as a TECDOC is relevant in the following situations:

- it may be that the lifetime of the publication is expected to be short;
- it may be of a tentative nature or in a preliminary form on which comments are requested before the manuscript is submitted for consideration as a priced publication (e.g. an interim report or a text issued to authorities in the Member States for comment);
- the subject matter may be of limited interest only so that sales of a priced publication would be correspondingly low;
- it may be a compilation of data that may be used or interpreted in future publications;
- it may be of relatively low significance to Member States.

The TECDOC Series also includes both proceedings of small meetings and monograph type reports.

Consensus guidance should however remain an integral part of Safety Guides, to facilitate application of the safety standards. Furthermore, part of the relevant information on the topic that is currently covered by Safety Reports and TECDOCs may be included as appendices when revising safety standards.

Other publications are issued by the IAEA. Among these, the Nuclear Energy Department has established a Nuclear Energy Series of publications which has an interface with the IAEA Safety Standards. In order to clarify this interface and the process for the review by the NS Department, an Interoffice Memorandum (IOM) has been established on 24 September 2009 and a detailed procedure was established in February 2010 ([Annex VII](#)). The IOM specifies in particular that:

- “IAEA Safety Standards should not be developed or revised in NE series documents. IAEA Safety Standards should be referred to in NE series documents as the current boundary conditions for the application of nuclear technology. When IAEA Safety Standards are reproduced in NE series documents, NE has the responsibility to update these documents, after Safety Standards are revised”, and that

“In order to check NE documents consistency with the current Safety Standards, NS is represented on the NE document coordination team and should review NE series documents

at various stages of development. This may involve timely consultation of the relevant Safety Standards Committees and the Commission on Safety Standards.”In implementing the above procedure, a few draft NE Series publications are therefore submitted to the Coordination Committee, which may suggest consultation of the Chairs of the Safety Standards Committees and of the Commission on Safety Standards. The Chairs may also recommend that the draft be reviewed by the relevant Safety Standards Committees and by the Commission on Safety Standards.

This strategy C is essentially implemented through the policy establishment process ([Section 3 part B](#)), through the drafting, internal and external review processes ([Section 3 part D](#)) and through the detailed procedure established between the Nuclear Energy Department and the Nuclear Safety and Security Department.

D. Consensus at the highest level on what constitutes a high level of safety

Approval process

The IAEA safety standards should reflect an international consensus on what constitutes a high level of protection of people and the environment ([Annex V](#)). The Commission and the Committees were established with the objective to achieve consensus, quality, coherence and consistency in the development of international standards for safety. Their terms of reference are provided in [Annex VIII](#) and [Annex IX](#). The Commission has a special overview role with regard to the IAEA safety standards. Safety standards are developed in close consultation with the Member States (through their representatives in the Commission and Committees and the 120 day commenting period) and with representatives of relevant international organizations.

Therefore, the consensus on what constitutes a high level of safety is reached at the highest level. Approval by the Board of Governors is required for the publication of Safety Fundamentals and Safety Requirements. The authority to issue Safety Guides has been delegated to the IAEA Director General.

For the category of Safety Guides it is stated, “The Safety Guides present international good practices and increasingly they reflect best practices to help users striving to achieve a high level of safety”. The level of safety reflected in a Safety Standards Series publication at the time of its issue is expected to remain adequate until its future revision.

This strategy D is essentially implemented through the establishment of the Committees and Commission ([Section 3 part A](#)) and through the review and approval process ([Section 3 part D](#)).

E. User friendliness

With a view to facilitating the use of the safety standards by Member States, the safety standards should be user friendly ([Annex II](#)).

This involves the following main aspects:

- The users of safety standards in the Member States differ depending on the category of safety standards. In any case, the principal users are regulatory bodies and other relevant national authorities. The safety standards are de facto also used by co-sponsoring organizations, many organizations that design, manufacture and operate nuclear facilities as well as organizations involved in the use of radiation related technologies;
- The structure of safety standards should be such that the users may easily identify among the whole collection of safety standards those that are particularly applicable to the specific facility or activity they are dealing with. The application of this concept is reflected by a safety standards structure with thematic safety requirements and guides applicable to all facilities and activities, which is complemented by a set of facility/activity specific safety requirements and guides ([see part B of this Section](#));
- The overall number of safety standards should be manageable. The application of this concept is reflected through the proposal for the long-term collection of safety standards ([see part F of this Section](#));
- The format and style of the safety standards and particularly the Safety Requirements should facilitate their use for the establishment of the regulatory framework in the Member States ([see part B of this Section](#)). To the extent practicable, the structure and layout of the Safety Standards Series publications should be uniform;
- The use of cross-references should be optimized to preserve the hierarchy of safety standards categories and should consider user friendliness. When small parts of other safety standards publications are to be used, it will be preferred to copy these, i.e. as quotes and not through re-wording or paraphrasing. When large parts of other safety standards are to be referenced, cross-referencing without duplicating the text will be the preferred option. The application of this concept will be facilitated with the long-term

structure through the integration of all the thematic Safety Requirements. It is also facilitated by the use of a numbering system for each individual discrete requirement and modern IT techniques such as the NSS-OUI IT Platform so as to help build a logical relationship between the set of safety requirements and the set of safety guides. Thus, after completion of the set of Safety Requirements, subsequent revisions of Safety Guides will refer to these numbers;

- The terminology used should be harmonized throughout the Safety Standards Series and such that the terms can be easily translated into different languages, also considering the legal aspects involved ([see part J of this Section](#)); and
- The Safety Guides are currently complemented by TECDOCs and Safety Reports. Part of this material could be incorporated as appendices to the future Safety Guides ([see part C of this Section](#)).

This strategy E is essentially implemented through the policy and programme establishment process ([Section 3 part B](#)), the drafting process and the internal and external review process ([Section 3 part D](#)) and the Safety Glossary related process ([Section 3 part E](#)).

F. Manageable number of safety standards

Optimization of the structure of safety standards

Safety Requirements

Through the development of the long-term structure of safety standards, the set of safety requirements should be stabilized with a General Safety Requirements in seven parts complemented by six specific Safety Requirements. The Safety Requirements will adopt a format with a set of overarching requirements ([see part B of this section](#)). The overarching requirements will help providing stability in regulatory approaches.

Strategy for work on Safety Guides

The main aim is to be responsive to the needs of the Member State users with a well-integrated set of Safety Guides, while optimizing the number of the Safety Guides. This should limit the burden on the Secretariat, the members of the Commission, Committees and the Member States as well as ensure stability in the set of Safety Guides.

In terms of structure ([see part B of this Section](#)), the policy adopted in the roadmap ([Annex II](#)) optimizes the number of safety guides by:

- Limiting the number of Safety Guides in the thematic areas to those of a generic nature;
- Developing Safety Guides in the facility specific areas that cover the whole lifetime of the facility (site evaluation, design, commissioning, operation and decommissioning);
- Identifying among the facility specific guides those that may be applicable to several types of facilities so as to avoid the establishment of guides addressing the same topical issue for different types of facilities/activities;

- Including, wherever possible, additional topics as part of the revision of existing Safety Guides, rather than by developing new Safety Guides.

An indication of a manageable number of safety standards used for establishing a reference set of safety standards in 2008 was around 80 to 100, including the Safety Fundamentals and the Safety Requirements⁴. As a result, a reference set of safety guides for the long term and criteria for its use have been established in 2009 (<http://www-ns.iaea.org/committees/files/CSS/252/ReferencesetofSafetyGuidesforthelongterm20090320.doc>) that is regularly updated based on the conclusion of the review of the proposed safety standards by the Committees and the CSS. A report is made at the beginning of each CSS meeting on the changes proposed to the initial reference set. The resulting updated set is reflected in the [status of safety standards](#) and is made available on the IAEA Safety Standards web site.

Criteria for the addition of new safety guides

The need for additional topics to be addressed in Safety Guides should be justified by a gap identification ([Annex IV](#)). The justification should consider which Safety Requirements the proposed additions relate to and should present the overall coverage (scope and issues addressed) of the current set of Safety Guides implementing these requirements.

The status of these existing safety guides should be reviewed with a view to indicating the time frame expected for their next revision. In most cases, it will be possible to address the additional need by expanding the scope of an existing guide at its next revision or through the production of addendum pages.

⁴ Over the past ten years 85 safety standards have been published. This provides a limit of 8-9 safety standards that can be completed within a given year with the current resources dedicated in the IAEA Secretariat and the Member States. Considering the ten year cycle of the revision of the standards it is important to keep this limit in mind when deciding on a manageable number of Safety Guides.

Therefore, once the result of a gap analysis identifies that there is a gap to be filled, a proposal for the establishment of a new Safety Guide in the whole collection, together with a Document Preparation Profile (DPP), ([See Section 3.D](#)) will be considered only if there is a justification for an urgent need and either:

1- This need cannot be achieved by expanding the scope of an existing Safety Guide; or

2- This need could be addressed by expanding the scope of an existing Safety Guide, but it is not expected to revise this Guide sufficiently soon to address the urgent need and the size of an addendum to cover the topic would not be practicable. The DPP will contain an additional line in the production section indicating the Safety Guide into which the material will be later integrated and the related target date for integration so as to maintain as far as possible the initial closed set of Safety Guides.

The prioritization of proposals for new safety guides or the revision of existing safety guides should be consistent with the main topics identified as priorities by the CSS, at the beginning of each term.

Moreover, throughout the review or any proposal, account should be taken of the fact that safety measures and security measures must be designed and implemented in an integrated manner.

A new DPP template was adopted in September 2008 and further improved afterwards. The DPP template was last updated in July 2015 (SPESS F 06 July 2015).

This strategy F is essentially implemented through the policy and programme establishment process ([Section 3 part B](#)) and the internal and external review process of the Document Preparation Profiles ([Section 3 part D](#)). A guideline document on approaches to combining safety guides has also been issued (SPESS D).

G. Clarity, rigour, transparency and efficiency of the processes

Clear, rigorous, transparent and efficient planning, preparation, consultation, approval, and publication processes should be maintained, involving the different users in the regulatory authorities and the industry in the Member States as well as cosponsoring international organizations before approval by the Safety Standards Committees, the Commission on Safety Standards and the Board of Governors.

The processes should be described and implemented in a transparent manner. The drafting process and the review and approval process should also be rigorous, with:

- knowledgeable expert contribution to the drafting from Member States,
- appropriate coordination and cooperation within the Secretariat,
- internal control of the application of the policies within the Secretariat before submission of DPPs or drafts to the Committees,
- optimized working methods for the Committees and the Commission ensuring timely submission of the DPPs and drafts,
- rigorous consideration of the comments received from the Safety Standards Committees, the Nuclear Security Guidance Committee, the Member States and the Commission on Safety Standards, rigorous reporting on the proposed resolution,
- interactions externally with competent organs of the United Nations, the specialized agencies concerned and as appropriate with other Intergovernmental Organizations and non-governmental Organizations,
- meeting or involvement of the Interface Group to identify the relevant Committees to be involved during the review process for DPPs being proposed by the Coordination Committee,
- meetings of the Chairs of the Safety Standards Committees and the Chair of the Nuclear Security Guidance Committee for the coordination for DPPs and drafts being submitted to several Committees

- careful consideration, in consultation with the relevant Chairs, and reporting on any change that may be requested by the Board of Governor or the Publication Committee after an approval by the Commission on Safety Standards.

The transparency of the process will be ensured through the availability of the approved document preparation profiles, the latest drafts of safety standards and their status on the IAEA website sufficiently in advance of Commission and Committee meetings. Furthermore comments from the members of Committees, the Commission and the Member States should be provided within the applicable deadline to ensure that the Technical Officer can consider these and prepare proposals for their resolution. The proposed resolution of the comments during the review phase should also be made available on the Committees' website before their meetings. The identification of a lead Committee for each draft ensures that any change requested by one Committee is finally assessed by the lead Committee. The lead Committee undertakes the final review of the draft taking into account the comments from all Committees. For this reason, changes due to IAEA internal procedures should be implemented and reported before the final approval of the drafts. The meeting of the Chairs coordinates the DPPs and drafts being submitted to several Committees.

The timeline sequence should be optimized to avoid undue delay due to the sequence of review meetings. This should be also used to plan the drafting meetings (calculating backwards from the expected review meeting), so as to avoid effects such as a six month delay of the review phase due to a short delay in the drafting phases.

The development of a dedicated tool helped identify a better sequence of meetings, starting in 2009 as follows:

CSS meetings: beginning of March and beginning of October

SSCs meetings: end of June and beginning of November.

With careful consideration of the sensitivity of planning Committees and CSS meetings, proper planning of the drafting meetings, performance of technical editors review in parallel to the Committees review and efforts to avoid drafting duration exceeding 11 months, it is possible to save in average 10 months in the drafting and review/approval process, moving from an average duration of 36 months in the previous sequence to an average duration of 26 months with the new sequence.

This strategy G is essentially implemented through the establishment of the review process and its implementation ([Section 3 part E](#)) and through the involvement of stakeholders in the drafting and review process ([Section 3 part D](#)).

H. Involvement of stakeholders

1- Introduction

Under Article III.A.6 of its Statute, the IAEA is authorized “To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operation as well as to the operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision; and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangements, or, at the request of a State, to any of that State’s activities in the field of atomic energy”.

In application of this article, Member States, the United Nations, its specialized agencies⁵ concerned and other intergovernmental and non-governmental organizations are involved in various forms throughout the drafting, review and approval of the IAEA safety standards.

2- Purpose

The purpose of this section H is to establish a clear set of criteria to determine which organizations may be invited at the various stages of development of the IAEA safety standards.

The section also specifies the expected contribution from these invited stakeholders in the review and approval process, including contributions in terms of feedback from the

⁵ Specialized Agencies : FAO, ICAO, IFAD, ILO, IMO, IMF, ITU, UNESCO, UNIDO, UPU, World Bank Group, WHO, WIPO, WMO, UNWTO

application of the IAEA safety standards. Finally, the paper also deals with the issue of co-sponsorship of the IAEA safety standards.

3- Involvement in the drafting of safety standards

The involvement of the different users and stakeholders during the drafting phase is a long established practice of the IAEA. While the main channel for obtaining feedback and views of stakeholders is through representatives of the governments participating in the safety standards programme, stakeholders such as intergovernmental organizations, non-governmental organizations, industry, technical and scientific support organizations (TSOs) are often well-placed to provide feedback on topics and issues to be considered in the drafting phase.

The IAEA conducts technical meetings, consultants' meetings and other meetings in the early development of a new safety standard and during the review and revision of existing standards. The IAEA solicits Member State participation in these meetings and also invites independent experts from national regulatory bodies, industry and other interested parties to attend these meetings. Input from all these sources in the drafting of safety standards is important and should actively be sought by the IAEA.

4- Involvement in the review of draft safety standards

4.a Involvement in the review of safety standards as part of a national delegation

The Terms of Reference of the Safety Standards Committees states that each Member State will nominate a senior expert to represent the Member State at Safety Standards Committee meetings. The Member State representative is a senior expert in nuclear, radiation, transport or waste safety. Typically the Member State nominee is a senior regulator. .

Each Member State representative is expected to present a “national” position on IAEA safety standards, which should be based on appropriate consultation at the national level and coordination of the input of national interested parties. However, each member may be supported at the meetings by an advisor(s) including other national government representatives, national industry representatives or interested parties.

4.b Involvement in the review of safety standards by direct invitation to the Safety Standards Committees meetings

Other organizations and stakeholders have been invited by the IAEA to attend the Committee meetings. Organizations invited include United Nations specialized agencies, - programmes and – committees as well as other intergovernmental organizations, international commissions, international trade and industry organizations. This is specified in the terms of reference of the Safety Standards Committees, which states that “Invitations to attend EPRReSC/NUSSC/RASSC/TRANSSC/WASSC meetings as observers by candidate international organizations and non-governmental bodies may be considered on a case by case basis in accordance with established strategies and processes”.

In addition, the Secretariat receives direct expressions of interest in participating in the review process from many organizations. In all these cases, the Secretariat should request the candidate organization to submit an application based on the criteria below and should assess the expected technical contribution to the Safety Standards programme. Moreover, the Chairpersons of the Committees to which the organization is candidate and the Chair of the Commission on Safety Standards should be consulted and requested to provide a recommendation as to the technical suitability of the applicant organization. If the organization is deemed suitable, an invitation may be extended by the Deputy Director General to the organization to participate in the review process and attend as an observer the meetings of the relevant Committee.

In line with the Partnership and Resource Mobilization Policy of the IAEA, the following criteria should apply:

- An invitation to a Committee may be extended to an intergovernmental or non-governmental organization if it can reasonably be expected that the organization will make a significant technical contribution to the work of the relevant Committee. In determining whether an organization can make such a technical contribution, consideration should be given inter alia to whether the work of the organization is directly related to the work of the Committee, i.e. whether there are programmes or projects of the organization, past, current or projected that can reasonably be considered as demonstrating the relevance of the organization’s work and interest to those of the Committee.

- An invitation should not be extended to a non-governmental organization whose interest would be restricted to only a few of the fields of safety standards related activities, except on a case by case basis when in depth detailed expertise would be needed for a specific session.
- An invitation should not be extended to a non-governmental organization if that organization already has access to the work of the Committee through another organization. An organization is deemed to have access to a Committee or the Commission if its interests are adequately represented by another organization participating in the meeting. It is the responsibility of the applicant organization to demonstrate to the satisfaction of the Committee and the Secretariat that the specific interests it represents cannot adequately be represented by any organization already involved.
- An invitation should not be extended to a non-governmental organization where this could lead to an unfair advantage of that organization in commercial activities.
- An invitation should not be extended to a non-governmental organization whose composition or membership is considered to be inconsistent with the mandate and activities of the IAEA or which would diminish the Agency's integrity, independence or impartiality and in particular the independence of the safety standards establishment process.

5- Expected contribution from invited stakeholders in the drafting and review of safety standards

Contribution to the discussion of DPPs and drafts of safety standards is welcomed from all invited stakeholders. Organizations that have been invited are expected to provide expert information or advice in their special area of competence. It is also expected that the contributions are a priori validated within that organization as accurately representing the views of that organization.

It is the responsibility of the Chairperson of the respective Committee to allow the invited organization to present or summarize its contribution at the meeting. His/Her decision in this regard should be based on the guiding principle that it provides a significant technical contribution to the work of the Committee and would not unduly restrict the time dedicated to the Member States representatives' deliberations at the meetings.

It is solely the Member State representatives on the Committee who may decide on DPPs and drafts for proceeding to the next step in the review and approval process.

6- Involvement in the endorsement of safety standards by the Commission on Safety Standards

Since the Commission on Safety Standards is the Agency's body that actually endorses the safety standards, membership in the Commission should, in application of the Article III.A.6 of the Statute, be limited to Member States. Members in the Commission should be selected strictly on the basis of their technical competence in establishing standards and other regulatory documents relevant to nuclear, radiation, transport and waste safety.

The terms of reference of the Commission on Safety Standards states that "Observers from specialized international organizations and relevant non-governmental bodies may be invited by the Director General to attend Commission on Safety Standards meetings".

In application of the terms of reference and after consultation of the Chair of the Commission on Safety Standards, an invitation to attend meetings of the Commission on Safety Standards may be extended to an intergovernmental or non-governmental organization only if it can reasonably be expected that the organization will make a significant technical contribution to the work of the Commission. In determining whether an organization can make such a technical contribution, consideration should be given inter alia to the CSS special overview role with regard to the Agency's safety standards and its role in providing advice to the Director General on the overall programme on regulatory aspects of safety. Decisions by the Commission shall be taken by its members only.

7- Co-sponsorship of safety standards

A matter different from stakeholder involvement in the establishment of safety standards is the question of co-sponsorship of IAEA safety standards.

The United Nations, the specialized agencies concerned and other intergovernmental organizations provide advice to the national authorities of their respective Member States on health and safety, and serve as the secretariats and depositories for Conventions. Although these organizations have a number of their Member States in common, the organizations may liaise with different government agencies as their counterparts, e.g. Ministries of Health, Ministries of Labour, Ministries of Agriculture, Ministries of Transport, Ministries of Science and Technology. It is therefore essential that the United Nations, the specialized agencies

concerned and other intergovernmental organizations provide consistent advice and assistance to the various government agencies of their Member States.

Through the process of co-sponsorship of safety standards, harmonized policies and approaches are established and duplication of effort is avoided.

For this purpose, and in application of the Article III.A.6 of the Statute, potential co-sponsors of the safety standards are the competent organs of the United Nations and the specialized agencies concerned (such as FAO, ICAO, ILO, IMO, UPU, WHO), involved in the whole drafting and review process.

An invitation to co-sponsor established safety standards may be extended to other intergovernmental organizations that are competent in the field of standards setting but not to non-governmental organizations.

This strategy H is essentially implemented through the establishment of the review process and its implementation ([Section 3 part E](#)) and through the involvement of stakeholders in the drafting and review process ([Section 3 part D](#)). The SPESS B manual on the step-by-step process also includes an annex describing the process for co-sponsorship.

I. Effective feedback mechanisms to improve the safety standards and modern approach for their review/revision and content availability through electronic IT interface

After more than 50 years of history of the IAEA Safety Standards and after having a nearly complete set of standards covering all main safety areas, the Commission also discussed from 2010 to 2015 the proposal from the Secretariat that a more efficient approach be adopted for the future review, revision and publication of the safety standards, with the following key objectives:

- To ensure that the review and revision of published standards is based on a systematic feedback collection and analysis process
- To ensure that any revision of the safety standards or part of the safety standards is justified by the above mentioned feedback process, therefore also ensuring stability of the parts of the standards that remain valid
- To maintain the technical consistency among the standards through management of the standards as a complete collection rather than by individual management of individual standards
- To enhance semantic consistency through systematic use of harmonized terminology
- To ensure the completeness of the collection through a systematic top-down development approach complemented by topical gap analyses
- To support harmonized use and application of the safety standards by enhancing their user-friendliness and by providing tools for user to easily navigate within the whole collection.

In 2010, the Commission started discussions of the first objective in order to further improve the existing mechanisms to collect, analyse and use the feedback from the use of the IAEA Safety Standards for their future revision. A modular approach was presented whereby the set of overarching requirements could be used to categorize the information, store it and retrieve it for analysis on a topical basis. In 2011, a pilot study was presented showing the feasibility of that approach at the occasion of the revision of the Safety Requirements WS-R-5 (DS450)

on Decommissioning of Facilities Using Radioactive Material and the associated Safety Guides.

Moreover, based on that experience, the approach of topical oriented review/revision of the IAEA Safety Standards was selected by the Committees and the CSS for the review and revision of the IAEA Safety Requirements in light of the Fukushima Daiichi accident (DS462).

One particular advantage of this approach is that it addresses the second and third above mentioned objectives. The topical oriented review/revision process allows for focusing, during a revision, on those aspects for which there is a strong justification for amending the standards, thus ensuring at the same time both a rigorous justification process for their revision and the stability of those parts that remain valid. A second, also important advantage is to permit the synchronous revision of several standards for the parts that relate to the selected topics, thus ensuring the maintenance of the consistency between the standards, which is impossible with a document by document and sequential revision process.

This CSS discussion continued during its fifth term and expanded on the need for electronic publications of the IAEA Safety Standards. In particular, at the 32nd meeting held in October 2012, the Commission requested the Secretariat “to investigate issues relating to issuing safety standards essentially as electronic versions and the Safety Standards Committees to be consulted on future challenges on the publication process and use of electronic versions of safety standards, noting the support for the CSS on moving from a document by document revision process to a feedback based, topical oriented revision and addendum process.” It was noted in particular in this context that the easiest mechanism for the users to identify which are the valid safety standards was to refer to the electronic publications made available and to other tools such as web pages that include an overall status of the IAEA Safety Standards and the whole collection of established and valid safety standards.

Further significant developments were achieved during the years 2013 to 2015 and were regularly presented at each CSS meeting. The framework received full support from the CSS and went into operation in 2015. It is composed of the following key components:

- A content management system to manage the whole collection, the feedback mechanism, the content of the safety standards and the relationships between the standards
- An electronically supported review, revision and approval process management system
- An On-line User Interface (NSS-OUI) that facilitates access to the content of the Safety Standards and greatly enables in depth navigation through the collection

The content management system is based on a central storage principle and by operating an IT system that is primarily content oriented instead of format oriented. For the content management system a set of topical areas were determined (essentially using the overarching requirements as a tool to identify the main topical areas covered by the safety standards) to categorize any feedback and any topical relationship. A refined taxonomy/ontology was finalized in 2015 and is now used to tag each document as a whole and also each part of their detailed content. Relationships between the safety standards are also managed in this approach, in particular:

- a. Topical relationships, i.e. relationships between Safety Requirements addressing a similar topic
- b. Hierarchical relationships, i.e. relationships between the Safety Requirements and the Safety Guides, which also includes topical relationships, indicating which Safety Guides or part of Safety Guides cover a specific topical area addressed in a Safety Requirements publication
- c. Semantic relationships, i.e. relation with the IAEA Safety Glossary for harmonized use of the definitions and concepts

On the electronically supported review, revision and approval process management system, the concept is to support the feedback collection and allocation to topical areas, then to analyse the information accumulated for each topical areas so as to implement a decision making process on the justifications for the revision. This first part is now in operation. The concept is expected to be expanded to support the revision process by managing electronically the versions of the drafts, the comments submitted to the Secretariat and the resolution of these comments. The objective is also to keep complete electronic continuity of the successive versions throughout the whole review/revision/approval and publication process.

The electronic publication system aims at facilitating the update and fast availability of electronic versions of the revised safety standards after they have been revised using a topical oriented approach. It also significantly enhances user friendliness with the insertion of dynamic links for the above mentioned three types of relationship. In this regard, it was highlighted that the issue of user friendliness is not restricted to user friendliness of individual standards, but to user friendliness of the whole collection. Furthermore, other types of publications or tools are necessary for user-friendliness in addition to the individual safety standards, published as books, pdf versions and, in the future, other electronic formats. With a top-down development system, the published standards can only indicate the bottom-up relationship (each Safety Guide indicates which requirement it implements, but when reading the requirements one cannot find which are the relevant parts of the guides for their implementation). Therefore it is necessary to complement these publications by access, through the NSS-OUI interface to the top-down relationship. This complements other information, such as the overall status file and the whole collection of IAEA Safety Standards in all languages.

Finally, when these different outputs are available, any single part will de facto be linked to a specific topical area in the central database. This creates an easy mechanism to then channel any comment/feedback submitted on that part to the corresponding topical area and therefore also to the associated content of the IAEA Safety Standards, thus streamlining the feedback collection and storage process and expanding the possibilities by providing an opportunity to get feedback from any product linked to the IAEA Safety Standards.

The DPP or the set of DPPs for the revision of existing publications or the preparation of an addendum should include the summary of the feedback analysis that draws conclusions on the need for revising or providing an addendum to a publication. As necessary, a detailed feedback report should be attached to the proposed DPPs. The DPP and the feedback report will constitute a comprehensive basis for use by the drafting group.

This strategy I is essentially implemented through the collection and analysis of feedback ([Section 3 part C](#)), the related knowledge management process ([Section 3 part G](#)) and the drafting of revised safety standards ([Section 3 part D](#)).

J. Harmonized terminology

With the creation of the Department of Nuclear Safety in 1996, and the adoption of a harmonized procedure for the preparation and review of safety standards, the need for greater consistency in the use of terminology became evident. In the late 1990s with a view to harmonizing terminology and usage in the IAEA safety standards and in other IAEA publications, the development of a safety glossary was started.

The Safety Glossary serves a number of different purposes:

- To explain the meanings of technical terms that may be unfamiliar to the reader;
- To explain any special meanings ascribed to common words or terms (since words can have several different meanings, it may be necessary to clarify which meaning is intended, particularly for non-native English speakers);
- To define precisely how terms — whose general meaning may be clear to readers — are used, in order to avoid ambiguity concerning some important aspect(s) of their meaning;
- To explain the connections or differences between similar or related terms, or the specific meanings of the same technical term in different contexts;
- To clarify and, if possible, reconcile differences in the usage of specialist terms in different subject areas, since such differences in usage may be potentially misleading;
- To recommend terms that should be used in IAEA publications and documents (and those that should not), and the definitions that should be ascribed to them.

The 2007 Edition of the Safety Glossary is a compilation and, in most cases, attempts were made to achieve harmonization of defined terms in the published safety standards in a bottom-up approach. This results in some terms having still different definitions for different contexts and in some standards having their own glossary, leading to potential conflict and confusion among users.

In 2008, it was decided to adopt, as for the safety standards themselves, a top-down approach for the purpose of the further harmonization and clarification of usage of terminology in the

safety standards, with a view to endorsing the use, and the possible joint sponsorship, of a more prescriptive, globally agreed set of definitions of terms to be used throughout the whole Safety Standards Series, with a rigorous review and approval process. In reviewing and revising the Glossary, the translated version should be considered together with the English version.

USE OF THE IAEA SAFETY GLOSSARY BY DRAFTERS

Drafters of safety and security related IAEA publications — particularly safety standards — should, as far as possible, use the terms related to safety as recommended by the Safety Glossary. Unless otherwise justified and accepted through the review process, there should be no individual glossary in individual publications.

All IAEA publications should refer to the IAEA Safety Glossary for the definitions and explanations of safety related terms specifying in the list of references which edition of the Safety Glossary is used. This should be done in the ‘generic text’ (preliminary pages) and the reference list for the IAEA Safety Standards and in an editorial note and the reference list for other publications.

Each safety standards could include a section listing definitions, providing such definitions were copied directly from the IAEA Safety Glossary or were reviewed new or revised definitions, accepted for inclusion into the Safety Glossary. For example, when the Safety Glossary contains more than one definitions for one term (for historical reasons), this section could specify which specific definition applies for this specific safety standards. If a need to add or revise a definition of the IAEA Safety Glossary is identified through the development or revision of a safety standard, the proposal will be submitted to the review process and to the meeting of the Chairs and if agreed, the Safety Glossary will be updated accordingly and the agreed definition will then be included in the new/revised safety standard as well as in a revision of the Safety Glossary.

Moreover, it is recognized that for some publications there may be a need to define key specific new terms when no suitable safety related terms are included in the IAEA Safety Glossary. In this case, the proposed additional definition should be submitted to the technical officer responsible for the Safety Glossary. Once new terms are considered justified and the definitions and explanations have been approved (through the approval process of the related

draft), they may be included in the draft publication (in the main body of the text or in footnotes) with a statement that they apply for the purposes of the present publication only.

This strategy J is essentially implemented through the drafting process ([Section 3 part D](#)) and through the process for review and approval of the safety glossary ([Section 3 part E](#)).

K. Promotion of the IAEA safety standards

The Secretariat, the members of the Safety Standards Committees, the members of the Commission on Safety Standards and more generally any member involved in the safety standards planning, development, review/revision, approval and establishment process should actively promote the use and application worldwide of the safety standards and promote the dissemination of feedback from this use.

This strategy K is essentially implemented, within the Secretariat, through the feedback process ([Section 3 part C](#)) and the promotional process ([Section 3 part F](#)).

L. Interface between safety and security

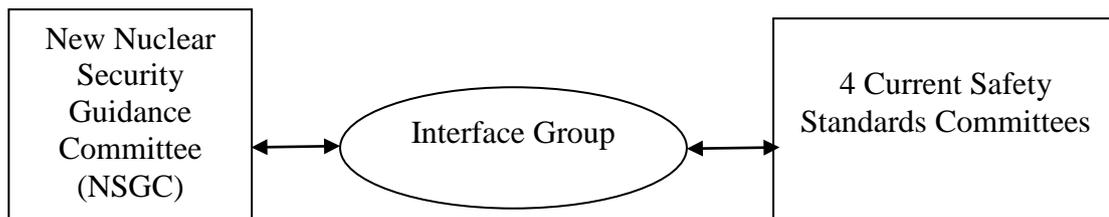
A joint session of the Advisory Group on Nuclear Security (AdSec) and the Commission on Safety Standards (CSS) was organized in April 2009, with the aim of exchanging views on issues relating to safety and security synergies and interfaces. A joint Adsec CSS Task force was established at the joint session. It met four times between October 2009 and May 2011.

At its last meeting, in May 2011, the task force agreed on the following four principles (The full report except its annexes can be found in [Annex X](#)):

1. Nuclear security and safety are equally important and the process for review/approval should reflect this;
2. Safety document preparation profiles (DPPs) and nuclear security DPPs should be reviewed to identify/define interfaces, if any;
3. Draft safety publications and draft nuclear security publications that have an identified interface should be developed in consultation;
4. After implementation of points 2 and 3, draft safety publications and draft nuclear security publications should be reviewed and approved to ensure the coordination has been effective and that they are in accordance with the Safety Fundamentals and the Nuclear Security Fundamentals.

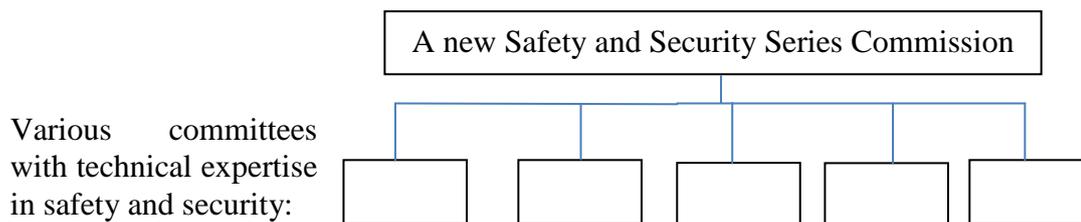
With regard to the review and approval process of draft safety and nuclear security publications, the task force reached a two-step conclusion for the committee structure, as follows:

- As an intermediate committee structure⁶:



whereby the ‘interface group’ reviews DPPs and refers them to the appropriate committee(s). The drafts safety standards approved by the Safety Standards Committees would continue to be submitted to the CSS, and the drafts nuclear security publications with interface with safety approved by the new NSGC would be submitted to the Deputy Director General (DDG) of the Department of Nuclear Safety and Security, who will decide on a case-by-case basis what further consultation is deemed necessary in order to ensure good cooperation and implementation of the four principles.

- As a long term vision:



A new Nuclear Security Guidance Committee (NSGC) was established early in 2012 as a standing body of senior representatives in the area of nuclear security to make recommendations to the DDG NS on the development and review of the IAEA Nuclear Security Series publications. The objective is to significantly contribute to greater transparency, consensus, quality, coherence and consistency by engaging more Member

⁶ The four Standards Committees referred to in the Joint AdSec CSS report were NUSSC, RASSC, TRANSSC and WASSC. The structure now includes EPRReSC

States in the development of international publications for nuclear security. The NSGC will also interface with the Safety Standards Committees and the Commission on Safety Standards to ensure that safety and security interface are properly addressed and reviewed in both safety and security publications.

The Interface Group is established as part of the intermediate Committee structure as recommended in the final AdSec CSS report to the DG dated 3 Nov. 2011. The initial composition consists of the Chairs of the Safety Standards Committees (NUSSC, RASSC, TRANSSC and WASSC) and four representatives of the NSGC. After the establishment of EPreSC, the Interface Group composition is amended to include the six Chairs of the Review Committees (EPreSC, NSGC, NUSSC, RASSC, TRANSSC and WASSC).

Its function is to review all DPPs for Departmental Safety Standards and Nuclear Security Guidance - excluding those for Technical Guidance - and, taking into account the views of the Coordination Committee, identify whether there is a safety/security interface, document the nature of the interface and refer them to the appropriate Committee(s) for review and approval.

In order to minimize as far as practicable the need for physical meeting and avoid undue delays, the IG is consulted, normally on a quarterly basis, on the DPPs by electronic means (dedicated web page, emails, telephone conferences,). A decision by consensus from the IG is expected within two weeks for most cases and in any case within a maximum of 30 days. An annual meeting would be dedicated to exchange feedback from experience and suggest process improvement where appropriate.

The facilitator is the Head of the NS/SSCS and the Scientific Secretariat is carried out by the Secretary of the Coordination Committee

The members report to their own Committee and the Interface Group informs the Coordination Committee of its decisions

This strategy J is essentially implemented through the drafting process ([Section 3 part D](#))

3. MAIN PROCESSES AND ASSOCIATED RESPONSIBILITIES AND FUNCTIONS

In order to implement the strategies described in Section 2, this Section presents the main processes involved together with the associated responsibilities and functions. Seven processes are described. For each process there is an assignment of the main responsibilities and description of the functions of, and expectations from all actors involved in the process. Detailed instructions, guidelines and examples are developed in the SPESS application manuals and complementary guidelines and instructions.

The actors involved are:

- The IAEA Board of Governors
- The IAEA Director General
- The IAEA Deputy Director General, Head of the Department of Nuclear Safety and Security
- The Head of the Safety and Security Coordination Section
- The Divisions Directors and Section Heads
- The Technical Officers
- The Coordination Committee
- The Member States
- The members and Chair of the Commission on Safety Standards
- The Coordinator, scientific secretary of the Commission on Safety Standards
- The members and Chairs of the Safety Standards Committees
- The members and Chair of the Nuclear Security Guidance Committee
- The Coordinators, scientific secretaries of the Safety Standards Committees and of the Nuclear Security Guidance Committee

- The members of the Interface Group
- The technical writers/editors.

A. Establishment of and nomination at the Safety Standards Committees and the Commission on Safety Standards

The CSS has a special overview role with regard to the IAEA safety standards and provides advice to the Director General on the overall programme on regulatory aspects of safety. The Terms of Reference are established by the IAEA Director General for a four year mandate. The current Terms of Reference are attached in [Annex VIII](#).

Accordingly, the CSS functions are:

- To provide guidance on the approach and strategy for establishing the Agency's safety standards, particularly in order to ensure coherence and consistency between standards;
- To resolve outstanding issues referred to it by the committees involved in the Agency's preparation and review process for safety standards;
- To endorse, in accordance with the Agency's preparation and review process for safety standards, the texts of the Safety Fundamentals and Safety Requirements to be submitted to the Board of Governors for approval and to determine the suitability of Safety Guides to be issued under the authority of the Director General;
- To provide general advice and guidance on safety standards issues, relevant regulatory issues and the Agency's safety standards activities and related programmes, including those for promoting the worldwide application of the standards.

In addition,

- The CSS should further promote universal application of the IAEA safety standards.
- The CSS should discuss reports from the Secretariat and the Safety Standards Committees on feedback from the application and use of IAEA safety standards.
- The CSS should discuss presentations from Member States on their application or use as well as insights from IAEA peer review mission reports and other relevant reports; and to provide guidance on the strategy and approach for enhancing the usefulness and effectiveness.
- The CSS should review proposals for new or revised safety standards to be developed and to approve the corresponding document preparation profiles (DPPs).
- The CSS should review at the request of the Secretariat draft publications in the Nuclear Security Series, the Nuclear Energy Series and other IAEA series for which there is an interface with safety.

At the end of each term of the Commission on Safety Standards, the Director General of the IAEA invites selected Member States, ensuring a balance of regional approaches and experience, to propose senior experts for their nomination for the following term of the Commission. Member States will be requested to nominate as candidates senior officials holding responsibilities in national regulatory organizations and having recognized expertise in nuclear, radiation, transport and waste safety.

The IAEA Director General nominates members of the Commission on Safety Standards for a four year term on the basis of proposals received from the Member States and proposals made by the Scientific Secretary of the Commission on Safety Standards, with clearance by the Directors of the Divisions, the Head of the Safety and Security Coordination Section and the Deputy Director General. CSS membership of a country is for the whole term such that any member may be replaced by a successor proposed by the Member States to the Director General.

Observers from specialized international organizations and relevant non-governmental bodies may be invited by the Director General to attend CSS meetings when their expertise contributes to enhance the quality and relevance of the safety standards. In addition the Chairpersons of the five Safety Standards Committees and of the Nuclear Security Guidance Committee will be invited to participate fully in the CSS meetings.

The Director General will appoint a Chairperson from among the CSS members for a four year term.

At the first meeting of each new term, the CSS will update its programme of work, indicating the main priorities for the new term, based on input from the Safety Standards Committees.

The Chairperson, in consultation with the Scientific Secretary, will submit (1) a report of each CSS meeting, (2) a mid-term report of the progress of the CSS on its programme of work and (3) an end of term report on its achievements over its four year term and its recommendations for the future.

The Chairperson may select one of the CSS member to act as Chair when necessary.

Five Safety Standards Committees for safety in the areas of emergency preparedness and response (EPreSC), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC) advise

the Deputy Director General on the overall programme for the development, review and revision of standards. Their objectives are to advise the Deputy Director General on respectively the nuclear installation/radiation/waste/transport safety programme for the development, review and revision of standards relating to nuclear/radiation/transport/waste safety and the programme for their application. A key objective is to provide feedback and recommendations to the Agency on respectively the nuclear installation/radiation/waste/transport safety programme and areas for improvement, and to achieve consensus, quality, coherence and consistency in the development of IAEA safety standards. Their terms of reference are established by the IAEA Director General for a three year mandate. The current terms of reference are attached in [Annex IX](#).

At the end of each term of the Safety Standards Committees, all the IAEA Member States are invited through *Notes Verbales* to nominate experts to participate at the meeting of the Safety Standards Committees or to act as corresponding members. Member States will be requested to nominate a senior expert in the area of review by the respective Committees to represent their views. The Deputy Director General will appoint the members for a term of three years. Based on the recommendations from the Safety Standards Committees, specialized international organizations and relevant non-governmental bodies may be invited by the Deputy Director General to attend the meetings as observers ([see section 2H](#)).

The Deputy Director General will appoint a chairperson for each Committee three-year term from among the Members States representatives. A note on the role of the Chairs of the Safety Standards Committees was also established in 2010, attached in [Annex XI](#).

A Nuclear Security Guidance Committee (NSGC) is also established to make recommendations to the DDG NS on the development and review of the IAEA nuclear Security Series publications. An Interface Group is also established for the transition phase as mentioned in the final AdSec CSS report to the DG ([Annex X](#)). It is composed of the Chairs of the Review Committees, EPRReSC, NSGC, NUSSC, RASSC, TRANSSC, WASSC. Its function is to review all DPPs for safety standards and Nuclear Security Series (except for Technical Guidance), as proposed by the Coordination Committee, and refer them to the appropriate Committee(s) and works essentially through consultation by electronic means (dedicated web page, emails), except at its first meeting when the DPPs for documents under development were reviewed

B. Establishment of policies and of the overall safety standards structure

The Deputy Director General is responsible for ensuring overall management of the safety standards programme in compliance with the IAEA statute and established obligations and rules. The Division Directors and Section Heads in the Department of Nuclear Safety and Security (or other Division Directors and Section Heads as appropriate) are responsible for ensuring that established policies and strategies are adhered to by the staff.

The Safety and Security Coordination Section and particularly the Coordinator of the Commission on Safety Standards is responsible for coordinating the formulation and monitoring the execution of the safety standards programme, including:

- General coordination of the development and review of safety standards;
- Advising senior management on all matters relating to the safety standards programme, policy and procedures;
- Coordinating and integrating the safety standards programme with other programmes of the IAEA;
- Making proposals on the future activities and trends in the safety standards programme.

Draft policy and strategy papers are prepared by the Coordinator of the Commission on Safety Standards. They may also be proposed by the Chairs of the Safety Standards Committees, the Chair of the Nuclear Security Guidance Committee and the Chair of the Commission on Safety Standards. These proposals are subject to clearance by the Head of the Safety and Security Coordination Section under the authority of the Deputy Director General for submission to the Coordination Committee and to clearance by the Coordination Committee. The terms of reference of the Coordination Committee, composed of the Section Heads of NSNI, NSRW, NSNS, NS-SSCS, NS-IEC and a representative from NE, are provided in [Annex XII](#). All proposals in terms of policy, strategy and processes are particularly discussed at the regular meeting of the Chairs of the Safety Standards Committees and the Nuclear Security Guidance Committee. The result is then reported to the meeting of the Chair of the CSS with the Chairs of the Committees.

The resulting drafts are then submitted for review by the Safety Standards Committees and the Nuclear Security Guidance Committee where appropriate, and finally for endorsement by the Commission on Safety Standards.

In addition, at the beginning of each new term, the Commission on Safety Standards, on the basis of recommendations from its members and/or from the Safety Standards Committees, establishes a list of priorities for the new term that addresses policy, strategy and process considerations for the safety standards structure.

C. Feedback on safety standards

Feedback on application of the safety standards is provided by users of the safety standards and members of the Safety Standards Committees and the Commission on Safety Standards. In addition, the Secretariat uses several additional mechanisms to obtain feedback on the safety standards. All of these mechanisms should continue to be further strengthened. Examples of mechanisms currently in use are:

– *Safety review missions and TC and EBP activities*

The IAEA safety review services use the safety standards as the basis for review. Feedback from such missions has been used in the ongoing revisions of various safety standards. This mechanism should be strengthened with the development and maintenance of databases findings and conclusion of reviews.

The IMSIMS management system links radiation, transport and waste safety related TC projects and application of the safety standards. It is envisaged to expand IMSIMS to cover TC projects dealing with nuclear safety.

– *Incident reporting systems*

The various incident reporting systems are a source of information, already stored in a structured way, relevant to the safety standards. This mechanism for obtaining feedback on the safety standards should be further strengthened to maximize its potential for yielding knowledge that could be fed back into the standards development process.

– *Meetings*

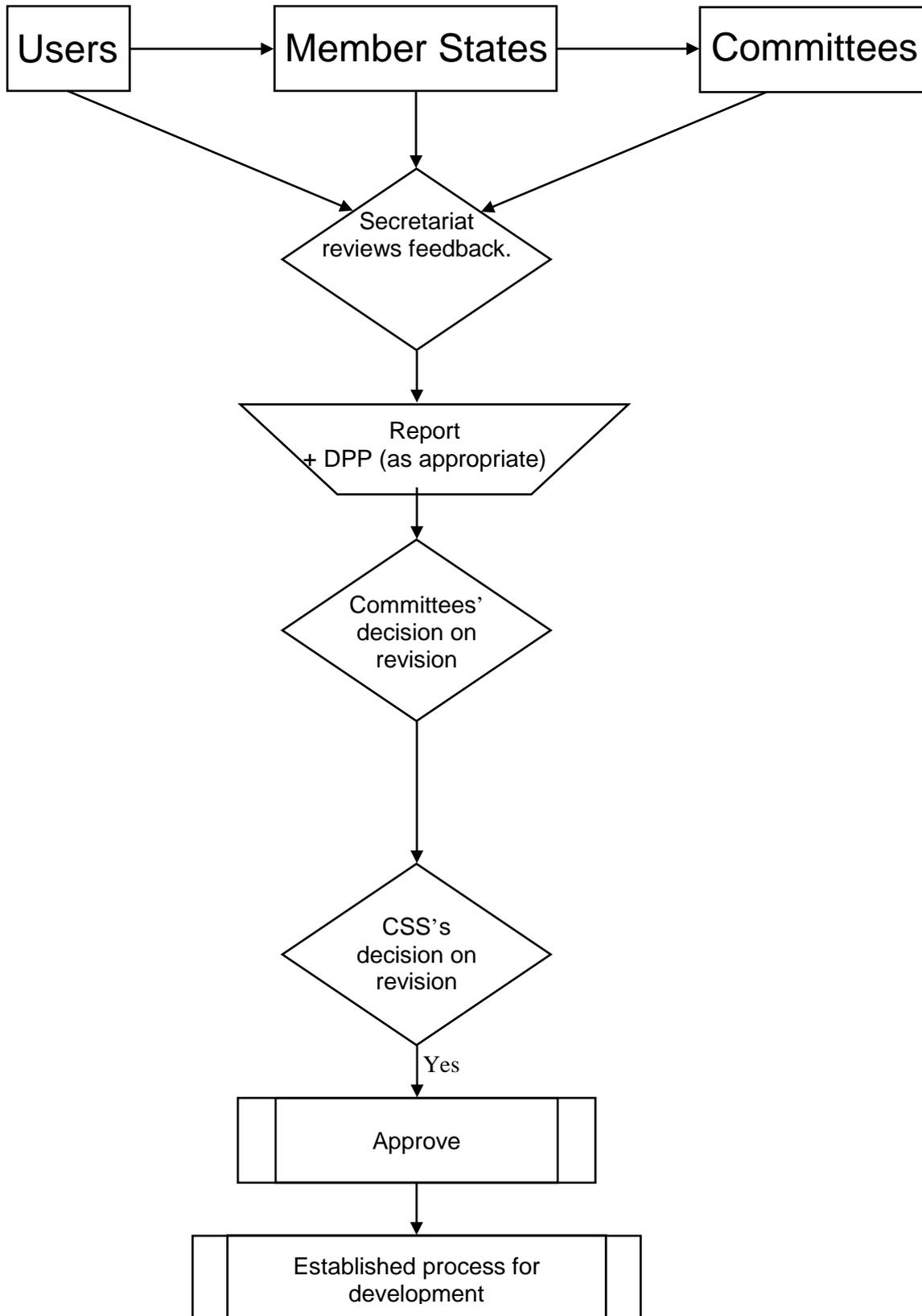
Review meetings of the Convention on Nuclear Safety and of the Joint Convention can yield knowledge derived from the application of the safety standards in various countries and on harmonization efforts. Such knowledge could be fed back into the standards' development process.

In addition, the IAEA frequently calls specialized meetings of Member States and international organizations to review specific safety standards.

– *Networking and interactions*

This is an important informal mechanism for obtaining feedback on the safety standards, and its flexibility ensures that the knowledge reaches the right person at the right time. All areas and individual staff members of the IAEA may gain knowledge from networks of personal contacts

The process for review and revision of a safety standard is outlined in the figure below.



Typically, safety standards should be reviewed every 5 years⁷, for the purpose of taking into account any relevant technical developments, together with information on their use and other feedback from users, so as to determine whether and when they would need to be revised. The safety standards may also need to be reviewed as a result of events or emerging issues. When a safety standard is subject to review, the feedback is compiled into a report, which is used as a basis for a decision on whether to revise the standard.

Users of the safety standards in the Member States

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Feedback may be provided via email to NS.Committees@iaea.org.

Members of the Safety Standards Committees and the Commission on Safety Standards

As part of the terms of reference of the Safety Standards Committees, the members have the function

- To compile feedback from the users of safety standards, including feedback on how they are being used and on any identified shortcomings or gaps, and to report on it to the relevant Committees.
 - To disseminate the draft safety standards in their respective States, to seek comments from their national stakeholders and to present a national position on each draft safety standard, which should be based on appropriate consultation at the national level and coordination of the input of national stakeholders.
 - To review reports on feedback from the Secretariat and Committees members on the application and use of the safety standards and to advise on enhancing their usefulness to
-

⁷ For the Transport Regulation, the review period established by the Board of Governors is 2 years

achieve high levels of safety, as well as on the timely review of and the need for revision of published nuclear/radiation/transport/waste safety standards.

Coordinators of the Safety Standards Committees

The five coordinators of the Safety Standards Committees are responsible for general coordination of the draft standards within each topical area, including collection of feedback from technical officers on the use of safety standards, review missions and the Committees. The coordinators are also responsible for ensuring that the feedback collected is channelled to the relevant standard.

Coordinator of the Commission on Safety Standards

The secretary (Coordinator) for the Commission is responsible, under the authority of the Head of the Safety and Security Coordination Section, for coordinating the formulation and monitoring the execution of the safety standards programme, including activities relating to obtaining and recording feedback on the safety standards.

Section Head

The general process for taking account of feedback in the review and revision of safety standards will be described in a separate application manual, which is under development. In particular:

- The Section Head should review information (feedback) collected on the validity and accuracy of the contents of the standards.
- The Section Head should then prepare a report (feedback report and, in the future, Document Review Profile) taking into account the feedback available on the standard to serve as the basis for the review by the relevant committees and subsequently by the Commission. This report serves as the input to the preparation and review process starting with the DPPs (see SPESS B manual).
- The outcome of the Secretariat's and Committees' review will be either a proposal that a revision is not necessary, in which case the Committees should decide on a date for a subsequent review; or a proposal to start with a revision, in which case a DPP or a set of DPPs should be prepared that clearly defines the areas to be revised and states what, if any, impact the revision is expected to have on the structure of the standards in the

particular area. The comprehensive feedback report should be attached to the DPP or set of DPPs.

Upon approval of the DPP(s) by the Commission (see SPESS B manual), the established procedure for the development of safety standards will be followed.

Technical officers

Technical officers are responsible for ensuring that all possible sources of feedback are taken into account in developing or revising a safety standard.

D. Drafting, review, approval and establishment of Document Preparation Profiles and draft safety standards

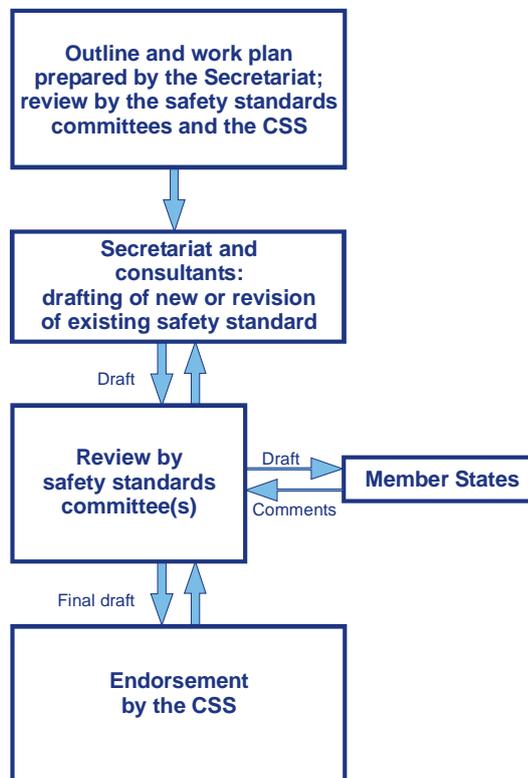
As a result of the feedback collection and analyses, the need for reviewing an existing safety standards or set of safety standards or the need for preparing an additional safety standard to fill an identified gap initiates the safety standards drafting process, which starts with the preparation of a DPP or a set of DPPs and, when approved, the drafting itself.

The objective of this Section is to describe the responsibilities involved in the drafting process and the main entities concerned by the review, approval, establishment and revision of the DPP and the safety standards.

The process described in this section corresponds to the establishment of a single safety standard. If it is agreed that a set of safety standards should be prepared or revised as a result of the feedback process, the set of safety standards follows the process described here in a concomitant manner, in order to maintain consistency between the various draft standards being established or drafted. In this case, the revision can be focused and optimized by implementing one single process for the whole set of proposed changes

The development and review of safety standards involves the IAEA Secretariat, five Safety Standards Committees for safety in the areas of emergency preparedness and response (EPreSC), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), the Nuclear Security Guidance Committee (NSGC) where appropriate and the Commission on Safety Standards (CSS), which oversees the entire safety standards programme and the consultation of the IAEA Member States.

OVERALL PROCESS FOR THE DEVELOPMENT OF THE IAEA SAFETY STANDARDS



In addition to the figure above, the SPESS B application manual provides a detailed description of the step by step procedure and a chart of the process flow. It also describes in detail the management of the interface between the safety and the security series, which is only summarized in this document.

Division Directors

Division Directors are responsible for designating a scientific secretary (coordinator) for the Safety Standards Committees, and a technical officer for development of each standard within their respective Divisions

Division Directors and Section Heads in the Department of Nuclear Safety and Security (or other Division Directors and Section Heads as appropriate) are responsible for:

- Putting into effect the recommendations of the Commission and the relevant Committees concerning the development of particular safety standards, governed by the programme provisions as approved by the Board of Governors and General Conference, the priorities foreseen and the funds available;
- Arranging and coordinating the preparation of a draft standard;
- Selecting IAEA staff members and consultants, considering the suggestions provided by Safety Standards Committees members, to prepare the draft standard and arrange the related meetings;
- Providing for appropriate consultation with all other relevant units in the IAEA, within and outside the originating Division;
- Ensuring that the technical quality of the draft standard is sufficiently high before its submission to the Coordination Committee, the Safety Standards Committee(s) and where appropriate the Nuclear Security Guidance Committee;
- Ensuring that the draft standards are in accordance with the approved DPP.
- Verifying that no comments, conclusions or recommendations are submitted for publication that run counter to the IAEA's policy or that would cause embarrassment to the IAEA or to a Member State or would cause offence to groups or individuals.

Technical officers

Technical officers are responsible for the planning, drafting, review, revision and finalization of draft standards in accordance with the approved structure, procedures, policies and strategies adopted for the development of safety standards, including clearance by the Coordination Committee before submission of drafts to the Committees for review. Technical officers have the sole responsibility for the development of the draft standards that are assigned to them. This includes the following:

- To develop a draft DPP on the basis of the report on the review of existing publication or a gap identification;

- To ensure they have appropriate knowledge of other relevant safety related publications on the topic being addressed.
- To prepare the initial draft of a standard, if necessary with external consultants selected by the IAEA with consideration of the proposal on qualified experts made by members of the Safety Standards Committees, in accordance with the approved DPP.
- To ensure that consultants commissioned by the IAEA to help prepare draft standards are made aware of and observe the relevant policies and strategies for the preparation of draft standards and use the SPESS C guidelines for preparing safety standards.
- Ensuring that the text reflects the required degree of international consensus.
- To make effective use of the input of experts from Member States in the relevant technical areas involved and the expertise available in the Secretariat.
- To interact within the Secretariat with other Technical Officers in order to ensure that there is no conflict with other publications or draft publications.
- To consult with Chairs of the review Committees identified in the DPP when modifications are made to the scope or the objective of the document compared to the approved DPP and prepare in such cases a revision of the DPP for submission through the review and approval process.
- To ensure that due care is taken to determine and meet the needs of the intended users of the publication.
- To verify that usage of terms is consistent with the current edition of the IAEA Safety Glossary.
- To verify that the writing style and form are consistent with the intended category of the standard.
- To ensure quality in the drafting process rather than relying on subsequent review and revision.
- To effect the necessary interactions externally with competent organs of the United Nations, the specialized agencies concerned and as appropriate with other

Intergovernmental Organizations and non-governmental Organizations, and internally with NE, OLA, MTCD, etc.

- To collect any feedback on the use of the standards and submit these to the coordinator of the respective area.
- To adhere to the main principles of the IAEA publishing 'house style'.
- To ensure that no recommendations directed expressly to the IAEA itself are included in draft standards for publication by the IAEA.
- To ensure that the relevant obligations are complied with if any copyrighted material is taken from non-IAEA publications for reproduction, duplication, translation or use otherwise in or with draft standards for publication by the IAEA.

Technical officers have the following responsibilities in relation to scheduling the review and submission for publication of draft standards:

- To prepare a draft DPP for each draft standard to be developed and submit it to the Coordination Committee.
- To determine the resources (for meetings, translation, printing, etc.) that are required for the development of the draft standard, in order for the resources to be properly reflected in the IAEA's Programme and Budget.
- To schedule consultants meetings and other activities for the drafting of the standards so as to ensure that draft standards are prepared and reviewed in an efficient and timely manner.
- To comply with and maintain the production schedule.

- To keep the relevant coordinator informed of the status of the draft standard and to submit the draft standard for any internal review as required.
- To collate and take into account the comments received.
- To submit the draft standard⁸ to the relevant secretary or coordinator for inclusion on the agenda for the meetings of the Coordination Committee, the Safety Standards Committees, the Nuclear Security Guidance Committee and the Commission on Safety Standards (for Committee and Commission meetings, at least 2 months before the meeting).
- To present the draft standard during the meetings if requested and to take note of the proposed revisions.
- To ensure that the revisions arising from the Coordination Committee's review are appropriately reflected in the draft standard prior to proceeding to the next stage;
- To deal with comments from the Committees and potential co-sponsors, propose resolution of these comments or list of comments that need in depth discussion at the Committee meetings, and to prepare on the appropriate form a list of comments received stating how each comment was resolved;
- To check the changes proposed by Technical Editors and verify that these changes do not affect the substance of the recommendations. In doing so, the TO should report to the relevant Committees on any change which could be understood as affecting the substance and seek the view of the Committees on these. For any change made subsequently to the

⁸ In the case of an addendum to a safety standards or a set of safety standards, the process for review, approval and establishment is the same as for a new or a revised draft standards with only the following adjustments: (1) only the additions proposed are subject to review and approval by the Coordination Committee, the Committees, the CSS and, where appropriate the Board of Governors and (2) after final approval, a complete new publication that integrates the approved changes is issued and supersedes the previous publication.

review by the Committees, the TO should submit the proposal for approval to the Chair of the lead Committee;

- To deal with comments from the Member States and resolve any issues, and to prepare on the appropriate form a list of comments received stating how each comment was resolved.
- To prepare the revised draft of the draft standard after each meeting or, if a review was sought out of session, after receipt of comments.
- If necessary (for Safety Fundamentals and Safety Requirements), to submit the final text for the necessary internal clearances and for submission to the Board of Governors for approval.
- To complete a publication proposal form to initiate clearance for publication.
- To submit the publication proposal form together with the complete draft standard of the final draft version for checking and approval or for clearance, as relevant, by the Section Head, the Division Director, the Head of the Safety and Security Coordination Section and the Deputy Director General.
- To prepare a short summary of each publication (generally of 100–200 words) for promotional purposes and to revise as necessary the list provided by the Publishing Section of the most suitable journals to receive review copies of the publication.
- If necessary, to submit the final text to the Document Support Section of MTCDC for translation into other official languages.
- To keep records of all written comments and their resolution, including internal comments.

Coordinators

The five coordinators of the Safety Standards Committees are responsible for general coordination of the draft standards within each topical area, including the following aspects, and **the coordinator of the Nuclear Security Guidance Committees** organizes the review process by the NSGC for safety standards having interface with the nuclear security series:

- Close interaction with technical officers within their topical area and with the other coordinators.
- Advising technical officers on the procedures for the development of draft standards.
- Ensuring that technical officers are aware of the recommendations of the Committees and the Commission in relation to the development of draft standards.

The coordinators may make recommendations to the technical officer concerning:

- The appropriateness of the series, category and coverage of the proposed publication.
- Any incompatibility or overlap with existing publications or draft standards under development. Cross references to other safety standards should be carefully managed. When small parts of other safety standards publications are to be used, it will be preferred to copy these, i.e. as quotes and not through re-wording or paraphrasing. When large parts of other safety standards are to be referenced, cross-referencing without duplicating the text is the preferred option.
- Any change of emphasis or priorities needed to fill gaps in the Safety Standards Series.
- The need for cooperation with other Units and activities within the IAEA in relation to a publication that may be associated with more than one application area.
- Technical shortcomings identified in draft standards; however, review by the coordinators is intended not as a technical peer review but as a review for the purposes of the Safety Standards Series.

The five coordinators of the Safety Standards Committees are responsible for general coordination of the draft standards within each topical area, including:

- Organization of the meetings of their Safety Standards Committees.
- Maintaining the ManTIS (Manuscript Tracking Information System) current.
- Ensuring that it is brought to the attention of Section Heads the resources (for consultant services, meetings, translation, printing, etc.) required for the development of the draft standard, in order for the resources to be properly reflected in the IAEA's Programme and Budget and the Financial Plan of the respective Divisions.

- Verifying that the drafts have undergone any necessary coordination between sections and divisions to ensure that they are not in conflict with other publications within the Safety Standards Series.
- Verifying that the coordination and consultation necessary with other relevant Sections and Divisions within the IAEA have been identified and report to the management any duplication of activities.
- Effecting the necessary interactions externally with competent organs of the United Nations, the specialized agencies concerned and as appropriate with other Intergovernmental Organizations and non-governmental Organizations, and internally with NE, OLA, MTCD, etc.
- Ensuring that the text of the draft standards referring to legally binding instruments is verified by OLA.
- Planning and submission of draft standards to the Coordination Committee.
- Submission of draft standards to the Safety Standards Committee(s), to the Nuclear Security Guidance Committee and to the Commission for review
- Ensuring that any proposal from one Committee is ultimately assessed by the lead Committee.
- Submission of draft standards to the Coordination Committee secretary to be posted on the Committees' web sites to solicit formal comment from Member States and international organizations
- Preparation of the draft multiple letters (*Notes Verbales*) in accordance with the established procedures.
- Ensure that, for drafts submitted for review before for Member States consultation, the TO addresses the comments from the review Committees, provide to the Committees details of the proposed resolution of all comments and a list of issues to be discussed at the Committee meetings.
- Submission of draft standards to NS-SSCS for review by the technical editor before Member States consultation.

- Ensure that the TO interacts with the Chair of the lead Committee on changes that may be proposed after an approval stage and particularly before submission to the Commission on Safety Standards.
- Submission of the draft standard to the technical editor when possible before or at the latest in parallel to its submission to the review Committees for decision on final submission to the Commission for endorsement.
- Reviewing draft standards in their final draft form before their submission to the Publications Committee.
- Preparation of reports to the Committees and the Commission on the status of draft standards in their topical area.

The Coordinator of the Commission on Safety Standards

The Coordinator of the Commission on Safety Standards is responsible, under the authority of the Head of the Safety and Security Coordination Section, for coordinating the formulation and monitoring the execution of the safety standards programme, including close interaction with coordinators.

- General coordination of the development and review of safety standards.
- Organization of the meetings of the Commission.
- Planning and submission of DPPs and draft standards to the Commission.
- Acting as Secretary of the Departmental Coordination Committee of Section Heads.
- Providing the five coordinators with the relevant information for bringing to the attention of the technical officers.

Technical editor

The technical editor is responsible for:

- Maintaining editorial standards for the safety standards and controlling their text and their content in relation to the mandate of the IAEA, suitability in context, treatment of sensitive issues and the targeted audience.

- Achieving clear communication through standard use of language, clarity of exposition and expression, and appropriate and consistent presentation of information.
- Considering the use of language, particularly of special terms, in the texts of standards that will be translated into and issued in other official languages of the IAEA
- Establishing, maintaining and revising editorial policy and guidelines as in-house reference sources for application to safety standards.
- Briefing technical officers and/or consultants and meeting participants engaged in drafting and providing advice as requested, both in any of the drafting stages before the solicitation of comment from States and also before the submission of the draft to the Commission.
- Providing advice and expertise to management on editorial policy and practices and publication policy.
- Reviewing draft standards, as part of the quality control process to ensure that the draft standards comply with the requirements for the Safety Standards Series, before submission to Member States
- Reviewing comprehensively draft standards before review at the Safety Standards Committees meetings for decision on final submission to the Commission for endorsement (All draft Safety Requirements and, when feasible, Safety Guides, should be reviewed by the Technical Editor before being posted for approval by the Committees).
- Scheduling and supervising the performance of editorial tasks, including setting and meeting deadlines, to ensure the timely provision of high quality work.
- Ensuring that the necessary copyright rules have been observed and securing any necessary approvals, rights and permissions, either directly or through the originating unit or the authors concerned.
- Coordinating with the originating sections and with other services concerned (word processing, translation, production, design, publication, marketing, distribution, public information, etc.).
- Clearing draft safety standards prior to clearance by the head of the Coordination Section (NS-SSCS) before submission to the Publications Committee.

- Consideration of the appropriate modes of dissemination (whether in traditional book form or other hard copy, on CD-ROM or other electronic medium, via the Internet as downloadable portable document format (PDF) files or as hypertext (html), in database form with a network based interface, or in a portable electronic format such as for a personal data assistant (PDA)).

Coordination Committee

The objective of the Coordination Committee is to ensure coherency, consistency and quality of the Safety Standards Series and the Nuclear Security Series Publications. The scope includes all Safety Standards Series and Nuclear Security Series prepared by the NS Department, from their initial proposal to their publication (and translation) and their subsequent review and revision and all DPPs for other NS Department publications. Moreover, in application of the joint NS-NE IOM ([Annex VII](#)) and, in order to check NE documents consistency with the current Safety Standards, NS is represented on the NE document coordination team and the Coordination Committee members are consulted on draft NE series documents at various stages of development. This may also result in the timely involvement of the relevant Safety Standards Committees and the Commission on Safety Standards. In implementing the above procedure, a few draft NE Series publications are therefore submitted to the Coordination Committee, which may suggest consultation of the Chairs of the Safety Standards Committees and of the Commission on Safety Standards. The Chairs may also recommend that the draft be reviewed by the relevant Safety Standards Committees and by the Commission on Safety Standards.

The functions of the Coordination Committee (see terms of reference in [Annex XII](#)) are:

- To keep under review the structure of Safety Standards Series and Nuclear Security Series publications, to periodically evaluate/assess proposals for the review and revision of existing publications, and to identify publications which can be considered obsolete.
- To review and recommend for approval by DDG-NS all proposals for Safety Standards Series and Nuclear Security Series as well as proposals for other official publications (e.g. TECDOCs and Safety Reports), or revision of existing publications (document preparation profile, DPP): the objective, the scope, the content and the potential interface and overlap with other publications.

- To undertake a thorough review within the Secretariat of all draft Safety Standards Series and Nuclear Security Series publications that are subject to an external review procedure and recommend them for approval by DDG-NS prior to their submission to external advisory or review groups (e.g. submission to the Safety Standards Committees and submission to the NSGC).
- To review on a case by case basis other draft publications, including draft prepared by other IAEA Departments, when they relate to the Safety Standards or Nuclear Security Series.
- To keep under review the process of development of Safety Standards Series and Nuclear Security Series publications.

Interface Group

The Interface Group reviews all DPPs for safety standards and Nuclear Security Series (except for Technical Guidance), as proposed by the Coordination Committee, and refers them to the appropriate Committee(s).

Safety Standards Committees

The Safety Standards Committees advise the Deputy Director General on the overall programme for the development, review and revision of standards. Their objectives are “to provide feedback and recommendations to the Agency on the nuclear installation/radiation/transport/waste safety programme and areas for improvement, and to achieve consensus, quality, coherence and consistency in the development of IAEA safety standards”. Their terms of reference are attached in [Annex IX](#).

The Chairs of the Safety Standards Committees interact on those standards that are reviewed by several Committees and report to the CSS the result of their review. In reviewing individual DPPs and drafts, the Chairs facilitate the awareness of the members of the Committees on the whole Safety Standards Series. The meeting of the Chairs of the Committees is one of the opportunities to coordinate the result of the review by the Committees.

The Chair of the lead Committee

When the meeting of one or more other Committees happens to be after the meeting of the lead Committee, the Chair of the lead Committee reviews the changes proposed by these other Committees, in consultation with the Chairs of these other Committees, with the Technical Officers and the coordinators. The members of the lead Committees are kept informed of the changes proposed and the Chair of the lead Committee will determine if the review of these changes by the Committee is required.

The Commission on Safety Standards

The CSS has a special overview role with regard to the IAEA safety standards and provides advice to the Director General on the overall programme on regulatory aspects of safety. The Terms of Reference are attached in [Annex VIII](#). With regard to the review of DPPs and drafts, this includes:

- To resolve outstanding issues referred to it by the Committees involved in the preparation and review process for safety standards;
- To endorse, in accordance with the preparation and review process for safety standards, the texts of the Safety Fundamentals and Safety Requirements to be submitted to the Board of Governors for approval and to determine the suitability of Safety Guides to be issued under the authority of the Director General.

Member States

The process for the establishment of safety standards represents a consensus view of the IAEA's Member States. The Member States should actively participate in this commenting phase so as to ensure a broad consensus on the IAEA safety standards. After approval by the relevant Safety Standards Committees, the draft safety standard is submitted to the Member States for a 120 day commenting period. For this purpose, the drafts are made available for comment on a dedicated web page and a *Note Verbale* is issued identifying the responsible Technical Officer and the deadline for receiving the comments.

With a view to ensuring the consideration of all Member State comments and to facilitate the planning of the meeting to review and consider these comments, the Member States should comply with the established deadline, provide a unified set of comments after external consultation and send their comments through the official channel to the Secretariat and to the

attention of the technical officer. In circumstances when a co-sponsoring organization consults its Member States on the same draft, the Member States should strive to coordinate their answer.

**IAEA Board of Governors, IAEA Director General and IAEA Deputy Director General
— Head of the Department of Nuclear Safety and Security**

For Safety Fundamentals and Safety Requirements, the drafts endorsed by the Commission are submitted to the IAEA Board of Governors, and upon approval by the Board, the draft is established as an IAEA safety standard. For the Safety Guides, the draft endorsed by the Commission is submitted to the Director General, and upon approval by the Director General the draft is established as an IAEA safety standard; this responsibility is delegated to the Publications Committee. The IAEA Secretariat as publisher and the IAEA as corporate author have the ultimate legal responsibility for the IAEA safety standards and their content.

The Deputy Director General, Head of the Department of Nuclear Safety and Security, is responsible for clearing draft Safety Fundamentals and Safety Requirements for submission to the Board of Governors and to the Publications Committee, and for clearing draft Safety Guides for submission to the Publications Committee. This clearance confirms that the necessary cooperation and coordination has been achieved at interdepartmental and international levels.

E. Review and approval of the Safety Glossary

REVIEW OF THE SAFETY GLOSSARY

The September 2008 CSS meeting agreed an initiative to start a review/revision process of the 2007 Edition of the Safety Glossary. A specific procedure was prepared by the Secretariat and approved by the Safety Standards Committees. The objective of the review/revision is the further harmonization and clarification of usage of terminology in the safety standards, with a view to endorsing the use, and the possible joint sponsorship, of a more prescriptive, globally agreed set of definitions of terms in the safety standards.

UPDATING OF THE SAFETY GLOSSARY

During the review process of draft safety standards by the Committees and the Commission, any need to modify the defined terms or introduce new terms should be routinely reported at the meetings of the Chairs of the Committees and then at the CSS. This will allow for the Chairmen of other Committees and the Commission to assess jointly the need for changes to the glossary and their potential impact (including on other definitions cross-referenced in the glossary, on definitions used in the set of standards at that time, on translated versions and on possible use of the definitions outside the Safety Standards Series. Once approved, the changes introduced will be posted on the website. New or revised definitions will not apply retrospectively. The use of IT technology should allow for flexibility during the review and revision process of the safety Glossary and permits the establishment in the electronic version of the safety standards of hyperlinks to the defined terms in the safety glossary posted on the website. A database of the use of terms in the individual publications should allow a careful consideration of changes as well as a traceability of the definition considered at the time of approval of the individual publications.

The Technical Officers are responsible to inform the Coordinators of the Safety Standards Committees, the Coordinator of the Commission and the Technical Editor on needs to change the Safety Glossary (amendment of existing terms or definitions or adding new terms).

The technical writer/editor is responsible for:

- Acting as technical officer for the Safety Glossary

- Maintaining a thorough knowledge of technical English and in particular a command of terminology in nuclear safety and nuclear security.

The revision of the Safety Glossary includes a review and approval process by the Safety Standards Committees and the Commission on Safety Standards similar to the process for the review and approval of draft safety standards ([see part 3.D](#)).

F. Promotion of the IAEA safety standards

The best means of promoting the safety standards is through their quality. Since 1996, the quality of the safety standards has improved significantly. This is primarily due to the establishment, in the mid-1990s, of a new structure of oversight (by the Commission and the Committees) and a systematic approach for development and updating of the corpus of safety standards. Efforts are continuing to further strengthen the process of development of safety standards.

The further promotion of safety standards takes many forms and requires the cooperation of all those involved in the development and the use of the safety standards. The simplest form of promotion is making the safety standards easily available to the users. The translation of the English text into different languages (Arabic, Chinese, French, Russian and Spanish) helps in reaching a wider audience.

To promote safety standards, the Secretariat, in consultation with government representatives, has prepared a list of stakeholders (regulatory bodies, nuclear power plants operators, research reactor operators, research institutes, transport authorities, etc.) for free distribution of the safety standards, within the established limit in terms of available number of free drafts for distribution.

Further promotional activities include, inter alia, the use of the safety standards in education and training, the presentation of the IAEA Safety Standards Series at international events and the preparation of a booklet on the safety standards for distribution at the IAEA General Conference.

The Safety and Security Coordination Section and particularly the Coordinator of the Commission on Safety Standards is responsible for the implementation of the following main processes in place to this end:

- Updating the status of safety standards and including links to the published safety standards and their translation available on the website maintained by the Division of Conference and Document Services, and
- Organizing the free distribution of recently published safety standards to designated recipients.

In addition, the safety standards are promoted by **the Secretariat** through:

- Development of multimedia materials (video and PowerPoint presentations) to explain the content of the safety standards. Such materials have been prepared for several areas covered by the safety standards (i.e. legal and governmental infrastructure, site evaluation, nuclear power plant design and operation, and research reactors). These are made available free of charge to Member States.
- Development of training materials (textbooks, training packages and filmed lectures) based on the content of safety standards. These have been prepared for a number of areas (regulatory control, safety assessment, operational safety, research reactors) dealing with nuclear installations.
- Devoting specific sessions in international conferences, symposia and seminars to the application of relevant safety standards.
- Collecting materials (slides and presentations) used by members of the Committees and Commission in national seminars on the IAEA safety standards.
- Preparing videos, slides and brochures in official languages for distribution to the authorities in Member States for promoting the safety standards.

The safety standards are used a basis for the safety review missions and their use in Technical Cooperation missions is being strengthened.

According to their Terms of Reference in [Annex IX](#), **the Safety Standards Committees** also have specific functions in the promotion of safety standards:

- To disseminate the draft safety standards in their respective States, to seek comments from their potential users and to develop a national position on each draft safety standard.
- To promote awareness of the safety standards in their respective States.
- To share experience within the Committee on how safety standards are being used in their respective States.
- To suggest, on the basis of the expected broad audience, the languages into which the draft standards should be translated.

Finally the **Commission on Safety Standards**, according to its terms of reference, has also as one of its functions ‘to provide general advice and guidance on safety standards issues, ... including those for promoting the worldwide application of the standards’.

G. Knowledge management

KNOWLEDGE MANAGEMENT FOR SAFETY STANDARDS

This document and its application manuals detail the rigorous arrangements for the preparation and review of IAEA safety standards, which are charted in a detailed ‘process flow’ diagram, contained in the SPESS B application manual as well as in the forthcoming manual for the feedback process and the review/revision process. Knowledge, both explicit and tacit, in various domains and in various forms, is the primary resource employed in the development of safety standards and the arrangements made by the Secretariat for the management of information and knowledge as resources.

The arrangements are intended to provide an integrated and systematic approach to identifying, acquiring, developing, disseminating, using, sharing and preserving knowledge that is relevant to the formulation of the concepts, principles, requirements and recommendations established in IAEA safety standards. The three fundamental components of knowledge management for this process are individuals, processes and technology:

- *Individuals* and organizational culture for the sharing and use of knowledge;
- *Processes* or methods for identifying, creating, capturing and sharing knowledge;
- *Technology* for preserving knowledge and making it accessible and for allowing individual staff members and experts in Member States to communicate and collaborate.

The NSS-OUI IT Platform (see [section 2.I](#)) relates to the content management of the safety standards.

DOCUMENT DEVELOPMENT AND CONTROL PROCESS FOR SAFETY STANDARDS

The preparation process for safety standards includes a document development and control process for the preparation (in accordance with a reviewed and approved DPP), review, revision, approval and submission for publication of draft documents. An electronic document management system (with file sharing arrangements based on the Internet for external

purposes and on internal IAEA networks) is used for the control and management of draft DPPs and documents.

Livelihood and IAEA internal electronic networks are used to manage documentation for review by the Coordination Committee. The IAEA web site is used for communication with, and to manage administrative documentation and documentation for review by, the Safety Standards Committees and the Commission. Files are shared using the safety standards web site at <http://www-ns.iaea.org/standards>.

Information derived from the review of documents is retained and managed with the use of Internet based communication systems and computer applications for document control.

Decisions taken and observations made at meetings of the Coordination Committee, the Committees and the Commission are recorded in formal reports that are posted on the relevant Commission or Committee web sites and archived, and records are kept of comments and their resolution and retained for future reference.

The Coordinator for the Commission, who is responsible for coordinating the formulation and monitoring the execution of the safety standards programme, is responsible for the preparation of reports on the status of published and draft standards the management of databases and websites.

Versions of drafts are controlled and retained, and document histories are compiled for future reference in the review and revision process.

The status of the safety standards published (in all official languages) and being drafted is kept permanently available on the safety standards web site as a PDF file containing hyperlinks.

A manuscript tracking information system, ManTIS, based on an Access database, is available within the Department for tracking the development of safety standards and other safety related publications.

There is an IAEA Intranet based NS Knowledge Portal which has the objective of providing NS staff with a tool for creating, sharing and archiving knowledge in a systematic and structured way, for day to day work, to contribute to efficient programme delivery. The portal provides an entry point to the relevant information and knowledge available in the department

while allowing the existing information repositories to remain unchanged. The Commission and Committee web sites also include centralized storage of archive information such as meeting reports, collections of presentations, etc.

This document itself and its maintenance serve a knowledge management function in collecting and articulating the established strategies and policies as well as the associated processes and procedures.

Likewise, the Safety Glossary represents an integration of knowledge on the definition and harmonized usage of terms in the safety standards.

4. MAINTENANCE OF THE SYSTEM OF STRATEGIES AND PROCESSES, ASSESSMENT AND PERFORMANCE INDICATORS

A. Review and revision of the SPESS Document

This SPESS document will be kept up to date in order to include new policies, strategies, processes and associated responsibilities and functions. The periodic assessment of its implementation may also result in a need to revise established policies and processes and thus also a need to revise the SPESS document.

The SPESS document should be reviewed every three to five years and revised as necessary. However, in case of important new policy decisions, the document should be updated by the Secretariat after the approval of the policy without awaiting the end of the review cycle.

The Head of the Safety and Security Publications Unit has the responsibility, under the authority of the Head of the Safety and Security Coordination Section, to initiate the review/revision process. The Coordination Committee reviews the report by the Head of the Safety and Security Publications Unit and decides on the need to revise SPESS.

Proposal for amendment of SPESS are firstly discussed at meeting of the Chairs of the Review Committees. The result is then reported to the meeting of the Chair of the CSS with the Chairs of the Review Committees. The Review Committees and the Commission on Safety Standards are kept informed of the revisions and are consulted on the successive revisions so as to ensure agreement that they reflect the approved strategies and processes.

In parallel with the revision of the document, the Head of the Safety and Security Publications Unit initiates the review and revision of the application manuals.

B. Assessment

The implementation of the system of strategies and processes should be periodically assessed by the Secretariat. An assessment should be conducted every three to five years as an input to

the review/revision cycle. The Deputy Director General initiates the process through the establishment of an assessment team.

C. Performance indicators

To be developed and reviewed through the implementation of SPESS

Some possible examples:

- Number of countries requesting involvement in the Safety Standards Committees
- Stability of the overall safety standards structure and of the overall number of Safety Guides
- Stability of the Safety Requirements (percentage of changes of bold requirements over a period of time)
- Percentage of approved safety standards among those submitted for approval
- Duration of the drafting, review and approval process
- Amount of input from Committee members on the feedback from stakeholders
- Feedback from safety review missions on the adequacy of the safety standards
- Completeness of the safety standards collection (reduction of the number of gaps identified over a period of time).

ANNEX I - STATEMENT BY THE CSS

June 2006

(Beyond the Action Plan on the Development and Application of Safety Standards)

The CSS recognizes that the quality of the safety standards in the new IAEA Safety Standards Series has been significantly enhanced, considering in particular that their content increasingly reflects good international practices and some of the best international practices.

With the aim of maintaining a continuous improvement, the CSS welcomes the report prepared by the Secretariat, which describes the achievements under the Action Plan, identifies new challenges and presents ways to respond to these in the future.

The CSS agrees that there are challenges giving rise to a need for further rationalization of the safety standards programme, including:

- the approval for publication of the unified Safety Fundamentals publication as the primary standard for the Safety Standards Series, which calls for a review of the relationship between the Safety Fundamentals and the various Safety;
- the increasing use of the IAEA safety standards by the Member States, which calls for greater stability;
- the strategic interest of achieving better international recognition and use of the safety standards as a reference and in particular of seeking joint sponsorship of the standards with other international organizations.

The CSS therefore supports the proposals from the IAEA Secretariat and requests it to elaborate on them further and to propose at its next meeting in November 2006 a policy paper together with a revised overall structure for the safety standards, which should:

- propose a vision on what the entire series would comprise in the future (the concept of a ‘closed set’ of safety standards);
- establish a logical relationship between the unified Safety Fundamentals and the various Safety Requirements, as well as logical relationships between the Safety Requirements and the subsequent Safety Guides;
- maintain a manageable number of publications and take into account the need for efficiency and timeliness for the future development of the Series.

For the transition period, an analysis of the differences between the proposed future set and the current set should be presented, together with a proposal for prioritization of the work to be done.

Moreover, the CSS requests the Secretariat to analyse the potential need for more detailed publications to assist the Member States in implementing the recommendations of the safety standards. The CSS, in view of the link with the safety standards publications and the actual use of these technical documents by a number of Member States, is of the opinion that it may be useful to consider identifying a dedicated category for these publications as well as a dedicated, clear and flexible process for their review.

The CSS considers that continuous improvement relies on a strong commitment by, and shared responsibilities between, the CSS, the Safety Standards Committees and the IAEA Secretariat, and is looking forward to considering the proposal from the Department of Nuclear Safety and Security management team after discussion at the Committees.

ANNEX II - ROADMAP on the Long-Term Structure of Safety Standards (2008-05-23)

(Modified at the October 2009 CSS meeting)

- 1) The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation.
- 2) Ten Safety Principles presented in SF-1 form the basis upon which Safety Requirements are developed and safety measures are implemented in order to achieve the fundamental safety objective.
- 3) Arriving at a unified set of Safety Fundamentals has been a difficult task. It constitutes an important evolution, and not a revolution, and must be considered as a key milestone in a continuous improvement process.
- 4) There is now a unique opportunity to draw the inferences from the publication of the single set of Safety Fundamentals and use a combination of a top-down approach and a Requirements gap analysis for the identification of the most efficient and effective structure for the set of Requirements needed to ensure their implementation. The long-term structure should keep the current hierarchy with three levels and take into account the need for stability in regulatory approaches.
- 5) The intention is to establish a General Safety Requirements integrating all thematic areas in a coherent and harmonized set of publications, complemented by a series of facilities and activities specific Safety Requirements. The complete set of Safety Requirements should address all radiation exposure situations (actual and potential). The General Safety Requirements should apply to any facility/activity (as defined in the footnote of the paragraph 1.9 of the Fundamental Safety Principles SF-1), whereas the others should apply to specific facilities/activities.
- 6) Safety measures and security measures must be designed and implemented in an integrated manner.
- 7) The treatment of NORM, radon and medical activities needs to be carefully considered and enhanced as appropriate.
- 8) Future documents should be user friendly; therefore, the concept of "user friendliness" must be clarified, keeping in mind that in most cases the national authorities and in particular the regulators are the principal users of the standards. The future collection of safety standards should also be manageable and therefore consist of a manageable number of publications each of them being as concise as possible and addressing the essence of the safety issues.
- 9) The final aim of the process is a clear and complete set of Safety Requirements. But the process itself should be stepwise and flexible. Sufficient time must be devoted to achieving a consensus on the long-term structure. A rigorous process must be in place to ensure a strong consensus and a clear benefit for all changes from the current structure. This should include

an evaluation of the overall impact for the Member States and the Secretariat and of the resources needed for the implementation of the process.

10) The work to be done cannot just be given to the Secretariat. There must be a personal involvement and leadership of the members of the Committees and the Commission, as it was the case for the Safety Fundamentals. The Task Force (involving the CSS and Committee chairmen as well as the NS managers) should further study how to achieve the ultimate objective of establishing the General Safety Requirements.

11) The BSS is being revised. The result will be a key element among the thematic requirements. It will integrate the new ICRP recommendations. The revision of the BSS should be pursued according to the approved DPP. The possibility of further extending its scope in a second step should be considered so that it can serve as the basis for the future General Safety Requirements. Like for the revision of the BSS, it will involve close consultation of, and collaboration with co-sponsoring organizations about the relationship between the revised BSS and the General Safety Requirements.

ANNEX A to the Roadmap

Safety standards User-Friendliness

With a view to facilitating the use of the safety standards by the Member States, the safety standards should be user-friendly. This involves the following main aspects:

- The users of safety standards in the Member States differ depending on the category of safety standards. In any case, the principal users are the regulatory bodies and other relevant national authorities. The safety standards are de facto also used by co-sponsoring organizations, many organizations that design, manufacture and operate nuclear facilities as well as organizations involved in the use of radiation related technologies;
- The structure of safety standards should be such that the users may easily identify among the whole collection of safety standards those that are particularly applicable to the specific facility or activity they are dealing with. The application of this concept is reflected by a safety standards Structure with general safety requirements and guides applicable to all facilities and activities complemented by a set of facility/activity specific safety requirements and guides;
- The overall number of safety standards should be manageable. The application of this concept is reflected through the proposal for the long-term collection of safety standards;
- The format and style of the safety standards and particularly the Safety Requirements should facilitate their use for the establishment of the regulatory framework in the Member States. The General Safety Requirements and the Specific Safety Requirements⁹ include overarching requirements and associated requirements, both expressed as “shall” statements. When necessary short explanations to support the safety requirements are provided¹⁰. To the extent practicable the structure and layout of the Safety Standards Series documents should be uniform;
- The use of cross-references should be optimized and should preserve the hierarchy of safety standards categories. When small parts of other safety standards publications are to be used, it will be preferred to copy these. When large parts of other safety standards are to be referenced, the cross-referencing without duplicating the text will

⁹ This does not currently apply to TS-R-1 (SSR 6)

¹⁰ Change as a result of the discussion at the 26th CSS meeting in October 2009

be the preferred option. The application of this concept will be facilitated in the long-term structure through the integration of all the general Safety Requirements into one publication which will then prevent the need for many cross-references. It will also be facilitated by the use of a numbering system for each individual overarching requirement and modern IT techniques such as hyperlinks so as to help building a logical relationship between the set of safety requirements and the set of safety guides. Thus, after completion of the set of Safety Requirements, the subsequent revision of Safety Guides will refer to these numbers. There are also other user-friendly techniques that can be used to facilitate the use of the safety standards, such as frequently asked questions, pictures and diagrams, and electronic media;

- The terminology used should be harmonized throughout the Safety Standards Series and such that the terms can be easily translated in different languages also considering the legal aspects involved; and
- The Safety Guides are currently complemented by TECDOCs and Safety Reports. Part of this material could be incorporated as annexes to the future Safety Guides.

ANNEX B to the roadmap

Format for the Safety Requirements

The General Safety Requirements and the Specific Safety Requirements¹¹ include overarching requirements and associated requirements, both expressed as “shall” statements. When necessary, short explanations to support the safety requirements are provided¹². When a compelling justification drives changes to a Safety Requirements, the revision should include the adoption of this new format. The status of the explanatory text and the expectations for its use will be made clear. It is also expected that the level of detail in each chapter will be similar (annex IV of the CSS subgroup report par A elaborates on a better definition of the level of the Safety Requirements with some examples). The main reasons are as follows:

- In term of user-friendliness, the format and style of the safety standards should facilitate their use for the establishment of the regulatory framework (see annex A to the roadmap on user-friendliness). The Safety Requirements should be short enough to encourage their reading and actual use in the Member States;
- In the current set of Safety Requirements, references are often made to specific concepts but their explanation is given in many cases in the subsequent Safety Guides. In the future, it is expected that the explanation of the concepts will be provided in the Safety Requirements so as to facilitate their interpretation for use in establishing national regulatory requirements. The purpose of the Safety Guides will not be to explain these concepts but to focus on the recommendations on how the requirements can be implemented;
- In addition, each individual overarching requirement will be allocated a number which, by appropriate references in the Safety Guides, will help building a logical relationship between the set of safety requirements and the set of safety guides. Thus, after completion of the set of Safety Requirements, the subsequent revision of Safety Guides will refer to these numbers; and
- Requirements must address what must be achieved/done while the guides will address how this could be achieved/done.

¹¹ This does not currently apply to TS-R-1 (SSR 6)

¹² Change as a result of the discussion at the 26th CSS meeting in October 2009

ANNEX C to the roadmap

Strategy for work on Safety Guides

The following strategy has been established to guide work on Safety Guides. It was described in the CSS Subgroup report part B:

Goals:

- To be responsive to the needs of Member States;
- To limit the burden to the Secretariat, the members of the Committees, the Commission and the Member States as well as ensuring stability in the set of Safety Guides, the complete set proposed is established on the basis of recently published safety standards and those in development;
- To have a manageable number of standards by:
 - Limiting the number of Safety Guides in the thematic areas to those of a generic nature;
 - Developing Safety Guides in the facility specific areas that cover the whole lifetime of the facility (site evaluation, design, commissioning, operation and decommissioning);
 - Identifying among the facility specific guides those that may be applicable to several types of facilities so as to avoid the establishment of guides addressing the same topical issue for different types of facilities/activities;
 - Including, wherever possible, additional topics as part of the revision of existing Safety Guides, rather than by developing new Safety Guides.

Strategy:

Therefore, in terms of process for the decision to work on safety guides, separate consideration will be given to the revision of existing guides and to the proposal for of new guides. In the latter case:

A report should be prepared to justify the need of additional topics to be addressed in Safety Guides. It should indicate to which Safety Requirements the proposed additions relates and presents the overall coverage (scope and issues addressed) of the current set of Safety Guides implementing these requirements.

The report should also review the status of these safety guides and indicate the time-frame expected for their next revision. In most cases, it will be possible to address the additional need by expanded the scope of an existing guide at its next revision or through the production of addendum pages.

Therefore, a proposal for the establishment of a new Safety Guides in the whole collection, together with a “SPECIAL DPP FOR ADDITIONAL PUBLICATION” will be considered by the Secretariat, the Committees and the Commission only if there is a justification for an urgent need and either:

- 1- This need cannot be achieved by expanding the scope of an existing Safety Guide;
- or

2- This need could be addressed by expanding the scope of an existing Safety Guide, but it is not expected to revise this Guide sufficiently soon to address the urgent need. In this case, the Special DPP will contain an additional line in the production section indicating to which Safety Guide the material will be later integrated and the related target date for integration so as to maintain as far as possible the initial closed set of Safety Guides.

A section should be added to each DPP on justification of the proposed publication in terms of member states need, result of gap analysis, expected safety improvements, overall cost/benefit. This should apply equally to documents being revised as well as new documents being proposed.

ANNEX III – Application of the ROADMAP - Long-term structure and format of Safety Requirements

Approved at the September 2008 CSS meeting and modified at the October 2009 meeting

The objective of this paper is to present in a single document important aspects already addressed in several previous documents and in particular the approved 23 May 2008 roadmap on the long-term structure of safety standards and the CSS Sub-group report part-A issued on 8 February 2007.

A- Structure of safety requirements

Background - Extracts from the roadmap and option discussed within the CSS task-force:

“4) There is now a unique opportunity to draw the inferences from the publication of the single set of Safety Fundamentals and use a combination of a top-down approach and a Requirements gap analysis for the identification of the most efficient and effective structure for the set of Requirements needed to ensure their implementation. The long-term structure should keep the current hierarchy with three level¹³s and take into account the need for stability in regulatory approaches.

5) The intention is to establish a General Safety Requirements integrating all thematic areas in a coherent and harmonized set of publications, complemented by a series of facilities and activities specific Safety Requirements. The complete set of Safety Requirements should address all radiation exposure situations (actual and potential). The General Safety Requirements should apply to any facility/activity (as defined in the footnote of the paragraph 1.9 of the Fundamental Safety Principles SF-1), whereas the others should apply to specific facilities/activities.

11) The BSS is being revised. The result will be a key element among the thematic requirements. It will integrate the new ICRP recommendations. The revision of the BSS should be pursued according to the approved DPP. The possibility of further extending its scope in a second step should be considered so that it can serve as the basis for the future General Safety Requirements. Like for the revision of the BSS, it will involve close consultation of, and collaboration with co-sponsoring organizations about the relationship between the revised BSS and the General Safety Requirements.”

6) Safety measures and security measures must be designed and implemented in an integrated manner.

At its September 2007 meeting, the CSS task force concluded that the possibility of further extending the scope of the revised BSS in a second step after its finalization, such that it would serve as the basis for the General Safety Requirements (GSR), was a practical option

¹³ Safety Fundamentals, Safety Requirements and Safety Guides

for the building of the General Safety Requirements. The concept was to construct the future GSR from the requirements on radiation protection and on the safety of radiation sources fully addressed by the revised BSS and, for the other thematic areas, from the additional requirements in GS-R-1, GS-R-2, GS-R-3, WS-R-5, DS348 and DS353, or their revision as appropriate.

Structure of the safety requirements:

As a result of the above general criteria, the long-term set of Safety Requirements would include a General Safety Requirements applicable to all facilities and activities with a graded approach and composed of a set of publications addressing the following eight themes: Governmental and Regulatory framework, Leadership and Management for Safety, Radiation Protection, Safety Assessment, Predisposal Management of Radioactive Waste, Decommissioning and Termination of Activities, Emergency Preparedness and Response, and Remediation. It will be complemented by a set of Facilities and Activities Specific Requirements.

In terms of set of publications, considering the interactions of the revised BSS with the other themes and the coverage within the revised BSS of the safety of facilities and activities other than nuclear facilities and activities¹⁴, the following set of publications is envisaged with a General Safety Requirements composed of seven volumes:

Vol.1- Governmental and Regulatory framework (on-going revision of GS-R-1, DS415)

Vol.2- Leadership and Management for Safety (future revision of GS-R-3)

Vol.3- Radiation Protection and Safety of Radiation Sources (on-going revision of the BSS, DS379)

Vol.4- Safety Assessment (DS348 or its future revision)

Vol.5- Radioactive Waste Management (revision of WS-R-2, DS353 approved by the CSS for submission to the BoG)

¹⁴ Nuclear facilities and activities are:

- nuclear installations : nuclear power plants, research reactor facilities (including subcritical and critical assemblies), spent fuel storage facilities, nuclear fuel fabrication facilities, conversion facilities, enrichment facilities or reprocessing facilities
- waste management facilities and activities, associated with nuclear installations, including decommissioning but excluding discharges to the environment
- facilities and activities for research and development associated with nuclear installations
- any other facilities and activities in which nuclear material and radioactive material are produced, processed, used, handled, stored or disposed of on such a scale that consideration of nuclear safety is required.

Vol.6- Decommissioning and Termination of Activities (future revision of WS-R-5)

Vol.7- Emergency Preparedness and Response (future revision of GS-R-2)

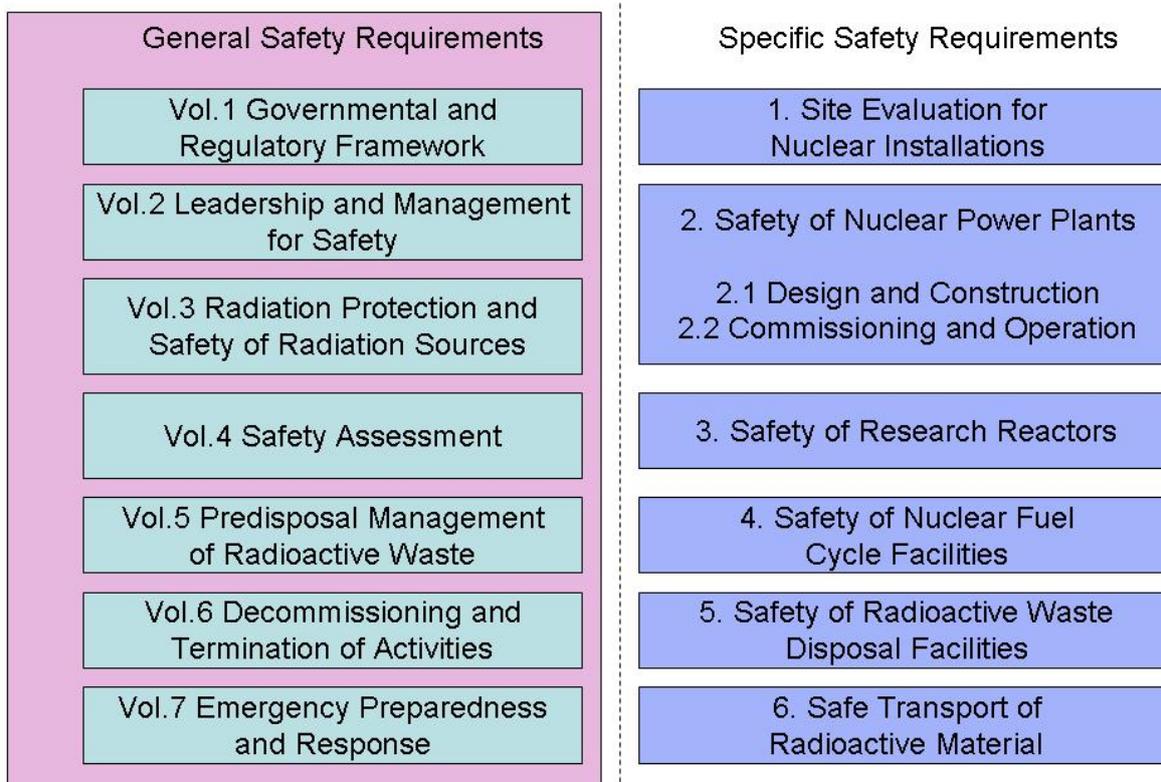
The existing WS-R-3 on remediation will be included in the section of the revised BSS on existing exposure situations. The future revision of GS-R-2 will focus on the management of emergency preparedness and response activities and refer to the revised BSS for the criteria and radiation protection issues. The revised BSS would keep its self-standing character with adequate references to other thematic areas.

This will be complemented by a set of six Facilities and Activities specific Safety Requirements:

- Site Evaluation for Nuclear Installations (future revision of NS-R-3)
- Safety of Nuclear Power Plants with one volume on design and construction (on-going revision of NS-R-1, DS414) and one volume on commissioning and operation of Nuclear Power Plants (on going revision of NS-R-2, DS413)
- Safety of Research Reactors (future revision of NS-R-4)
- Safety of Nuclear Fuel Cycle Facilities (DS316 and its future revision)
- Safety of Radioactive Waste Disposal Facilities (on going revision of WS-R-1 and WS-R-4, DS354)
- Safe Transport of Radioactive Material (on going revision of TS-R-1, DS345)

Through their development, practical means of ensuring the implementation of the item 6 of the roadmap on safety and security will be investigated and implemented.

STRUCTURE OF THE LONG-TERM SET OF SAFETY REQUIREMENTS



B- Definition and format for safety requirements

Background - Extracts from the roadmap Annex B and the CSS Sub-group report part-A:

“The General Safety Requirements and the Specific Safety Requirements¹⁵ include overarching requirements and associated requirements, both expressed as “shall” statements. When necessary short explanations to support the safety requirements are provided¹⁶. When a compelling justification drives changes to a Safety Requirement the revision should include the adoption of this new format. The status of the explanatory text and the expectations for its use will be made clear. It is also expected that the level of detail in each chapter will be similar (Annex IV of the CSS subgroup report part A elaborates on a better definition of the level of the Safety Requirements with some examples). The main reasons are as follows:

- *In term of user-friendliness, the format and style of the safety standards should facilitate their use for the establishment of the regulatory framework (see annex A to the roadmap on user-friendliness). The Safety Requirements should be short enough to encourage their reading and actual use in the Member States;*
- *In the current set of Safety Requirements, references are often made to specific concepts but their explanation is given in many cases in the subsequent Safety Guides. In the future, it is expected that the explanation of the concepts will be provided in the Safety Requirements so as to facilitate their interpretation for use in establishing national regulatory requirements. The purpose of the Safety Guides will not be to explain these concepts but to focus on the recommendations on how the requirements can be implemented;*
- *In addition, each individual overarching requirement will be allocated a number which, by appropriate references in the Safety Guides, will help building a logical relationship between the set of safety requirements and the set of safety guides. Thus, after completion of the set of Safety Requirements, the subsequent revision of Safety Guides will refer to these numbers; and*
- *Requirements must address what must be achieved/done while the guides will address how this could be achieved/done.*

With regard to the definition of the safety requirements the CSS Sub-group report part-A presented the overall definition of safety requirements and elaborated on this definition in its Annex IV.

Definition and format for safety requirements:

The overall definition for the future requirements would generally be maintained. It should be slightly modified as not all sentences would be established as shall statements. The revised definition would thus be as follows:

¹⁵ This does not currently apply to TS-R-1 (SSR 6)

¹⁶ Change as a result of the discussion at the 26th CSS meeting in October 2009

“Safety Requirements publications establish the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objectives and principles of the Safety Fundamentals. If they are not met, measures must be taken to reach or restore the required level of safety. Their format and style facilitate their use by Member States for the establishment, in a harmonized manner, of their national regulatory framework.”

The annex IV of the CSS Sub-group report part A is also slightly updated, particularly for the examples, which were extracted from existing requirements.

The type one requirements described in the annex will be established as overarching requirements expressed in bold and be allocated a discrete number. They should be written in plain language, with clear and short sentences. The requirements on associated conditions to be met described as type two requirements in the annex will be established below the overarching requirements and will be considered as an integral part of the safety requirements. When necessary, explanatory text in support of the safety requirements can be included¹⁷.

¹⁷ Change as a result of the discussion at the 26th CSS meeting in October 2009

Detailed definition of the Safety Requirements

Types of requirements	Examples
<p>1.Overarching requirements</p> <p>A requirement to do or not to do something</p> <p>A requirement to establish a body, a process, a program or to allocate a responsibility.</p> <p>It indicates <i>who</i> shall do or establish <i>what</i> and, as appropriate, <i>when</i></p>	<p>A regulatory body shall be established.</p> <p>A program for monitoring individual occupational exposure of workers shall be established.</p> <p>The operating organization shall prepare and implement a programme of maintenance, testing, surveillance and inspection of ...</p> <p>The operating organization shall establish and implement a programme to ensure that, in all operational states, doses due to exposure to ionizing radiation in the plant or due to any planned releases of radioactive material from the plant are kept below prescribed limits and as low as reasonably achievable.</p>
<p>2.Conditions associated with the overarching requirements</p> <p>Set of requirements on the main features of the process or program to be established according to the above category 1 requirement: This</p>	<p>This program shall be¹⁸ in place prior to the fuel loading and takes into account operational limits and conditions</p> <p>The program for monitoring of the workplace shall specify the quantities</p>

¹⁸ Changed as a result of the discussion at the 26th CSS meeting in October 2009

<p>includes the scope of the process or program in terms of what it shall consider, include or cover, Requirements related to the main safety strategy that shall be adopted, Requirements related to the organizational aspects to be considered and, where appropriate the interaction among different organizations or bodies, and where appropriate steps of the process or program.</p> <p>This also include Requirements related to the evaluation/assessment of the effectiveness and efficiency of the program/processes</p>	<p>to be measured, when and where the measurements are to be made, measurements methods and procedures, reference levels and action to be taken if they are exceeded.</p> <p>Boundaries of controlled areas shall be based on the magnitude of expected normal exposure and the likelihood and magnitude of potential exposure.</p> <p>The (radiation protection) program shall covers:</p> <ul style="list-style-type: none"> - classification of areas and access control, including local information on actual dose rates and contamination levels; - instruments and equipment for monitoring; - equipment for personnel protection ... <p>The program of maintenance, testing ... shall include periodic inspections or tests of systems, structures and components important to safety.</p> <p>In determining the site characteristics that are important to the assessment of the design and safety of near surface disposal facilities, the following shall be considered as a minimum: geology, hydrogeology, geochemistry, tectonic and seismicity, surface processes, meteorology, climate and impact of human activities.</p> <p>The controlled areas shall be delineated by physical means.</p> <p>The monitoring of workers occupational exposure shall be based on individual monitoring.</p> <p>A radiation protection officer shall be designated</p> <p>The tasks and responsibilities of different organizational units and persons in outages shall be clearly defined in writing.</p> <p>The monitoring program shall be regularly assessed.</p> <p>The program for maintenance, testing, ... shall be re-evaluated in the light of experience.</p>
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ANNEX IV – Application of the ROADMAP – Criteria for the long-term set of safety guides

Approved at the September 2008 CSS meeting

As indicated in the 23 May 2008 roadmap on the long-term structure of safety standards, “*The future collection of safety standards should [also] be manageable and therefore consist of a manageable number of publications each of them being as concise as possible and addressing the essence of the safety issues.*”

The annex C of the roadmap on the strategy for the work on the safety guides indicates that “*separate consideration will be given to the revision of existing guides and to the proposal of new guides*”. The annex C presents the criteria for the addition of new guides. These are developed in the part B here below. Therefore, the purpose of the part A of this paper is to complement the criteria with those applicable to the optimization of the current set of existing or planned safety guides.

A- Criteria for the optimization of the current set of safety guides

- An indication of the reasonable total number of safety standards: around 80 to 100.
- The overall picture is a matrix picture (not a tree structure with a set of safety guide below individual requirements as this is the case in the current structure). A matrix structure allows for safety guides implementing several requirements and thus allows for the optimization of the whole set of guides.
- Safety Guides in the general safety area should be generic for all facilities and activities. As an objective in principle, there should be one safety guide for each important theme (the eight themes are Governmental and Regulatory framework, Leadership and Management for Safety, Radiation Protection, Safety Assessment, Predisposal Management of Radioactive Waste, Decommissioning and Termination of Activities, Emergency Preparedness and Response, and Remediation) unless a justification is provided that the importance of the differences between the recommendations for some facilities and activities lead to the preparation of a separate guide for these facilities or activities, or a justification is provided that combining too many topics related to a single theme would not be practicable
- For the facility and activities specific guides, the overall approach is as follows:
 - for fuel cycle facilities, waste disposal facilities and radiation related facilities and activities, the preferred approach is to have "vertical guides" integrating the necessary guidance material on all topics and for each type of facility or activity (user approach). Topics that are common to many users should be developed as modules to be incorporated in the specific guides. When however a module is too large to be incorporated in the specific guides, it may be envisaged to prepare one guide on this topic.

- for transport activities there is a general safety guide (TS-G-1.1) complemented by a few other guides with a reasonable overall number.
- for the nuclear installations, the approach is an horizontal approach with topic specific safety guides. Nevertheless, when the recommendations on these topics can be applicable to nuclear power plants, research reactors and fuel cycle facilities, a common Safety Guide would be prepared, possibly with a graded approach for its implementation for the different types of installations. When it is justified not to combine the guides for nuclear power plants, research reactors and fuel cycle facilities, the preference would still be given to try integrating the guides for nuclear power plants and research reactors. If justified we could end up with three guides for one topic, one for the nuclear power plants, one for the research reactors and one for fuel cycle facilities.
- moreover, for the nuclear reactors, there may be different ways of combining the safety guides: A vertical way, like integrating as far as possible what relates to the site, integrating as far as possible what relates to the design and integrating as far as possible what relates to the operation. This will be the preferred approach because it corresponds to giving recommendations for actual activities at a specific time and because the expertise needed for siting, design and operation is different. However necessary cross-references should be made to prevent an artificial separation of design and operation.

An example of a matrix is attached with a view to illustrating the overall approach for the optimization of the set of safety guides. At the top of the matrix, the different users in terms of facilities and activities are indicated. The standards applicable to them are the ones vertically below their identification. Of course the general safety requirements apply, their specific safety requirements, the generic guides and finally the set of specific guides.

B- Criteria for the addition of new safety guides

The need for additional topics to be addressed in Safety Guides should be justified by a gap identification. The justification should consider which Safety Requirements the proposed additions relates to and present the overall coverage (scope and issues addressed) of the current set of Safety Guides implementing these requirements.

The status of these existing safety guides should be reviewed with a view to indicating the time-frame expected for their next revision. In most cases, it will be possible to address the additional need by expanded the scope of an existing guide at its next revision or through the production of addendum pages.

Therefore, once the result of a gap analysis identify that there is a gap to be filled, a proposal for the establishment of a new Safety Guide in the whole collection, together the DPP will be considered only if there is a justification for an urgent need and either:

- 1- This need cannot be achieved by expanding the scope of an existing Safety Guide¹⁹; or
- 2- This need could be addressed by expanding the scope of an existing Safety Guide, but it is not expected to revise this Guide sufficiently soon to address the urgent need²⁰. In this case, the Special DPP will contain an additional line in the production section indicating to which Safety Guide the material will be later integrated and the related target date for integration so as to maintain as far as possible the initial closed set of Safety Guides.

The prioritization of proposals for new safety guides or the revision of existing safety guides should be consistent with the main topics identified as priorities by the CSS, at the beginning of each term.

Moreover, throughout the review or any proposal, account should be taken that safety measures and security measures must be designed and implemented in an integrated manner.

¹⁹ An example is DS424 on establishing nuclear installations safety infrastructure. There is an urgent need; it does not fit in any existing guide.

²⁰ An example is DS416 on licensing process. There is an urgent need. It could be integrated into the proposed guide on functions of the regulatory body but it is not expected to revise this one very soon. It is therefore acceptable to develop a separate guide as a temporary solution. The new guide will later be integrated into the future guide on functions of the regulatory bodies.

ANNEX V – Generic text on the IAEA safety standards

Initial approved text 9 October 2008 – revised 19 October 2009

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care and are expected to fulfill their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and several security measures²¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1):

Safety Fundamentals

The Safety Fundamentals SF-1 presents the fundamental safety objective and principles of protection and safety and provides the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. The safety requirements include overarching requirements and requirements on concomitant associated conditions to be met (using for both “shall” statements. In addition, when necessary, the publication also includes explanatory text in support of the safety requirements, expressed in a different style so as to separate what is a requirement and what is a descriptive or explanatory text²². Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as ‘should’ statements.

²¹ See also publications issued in the IAEA Nuclear Security Series

²² Change as a result of the discussion at the 26th CSS meeting in October 2009

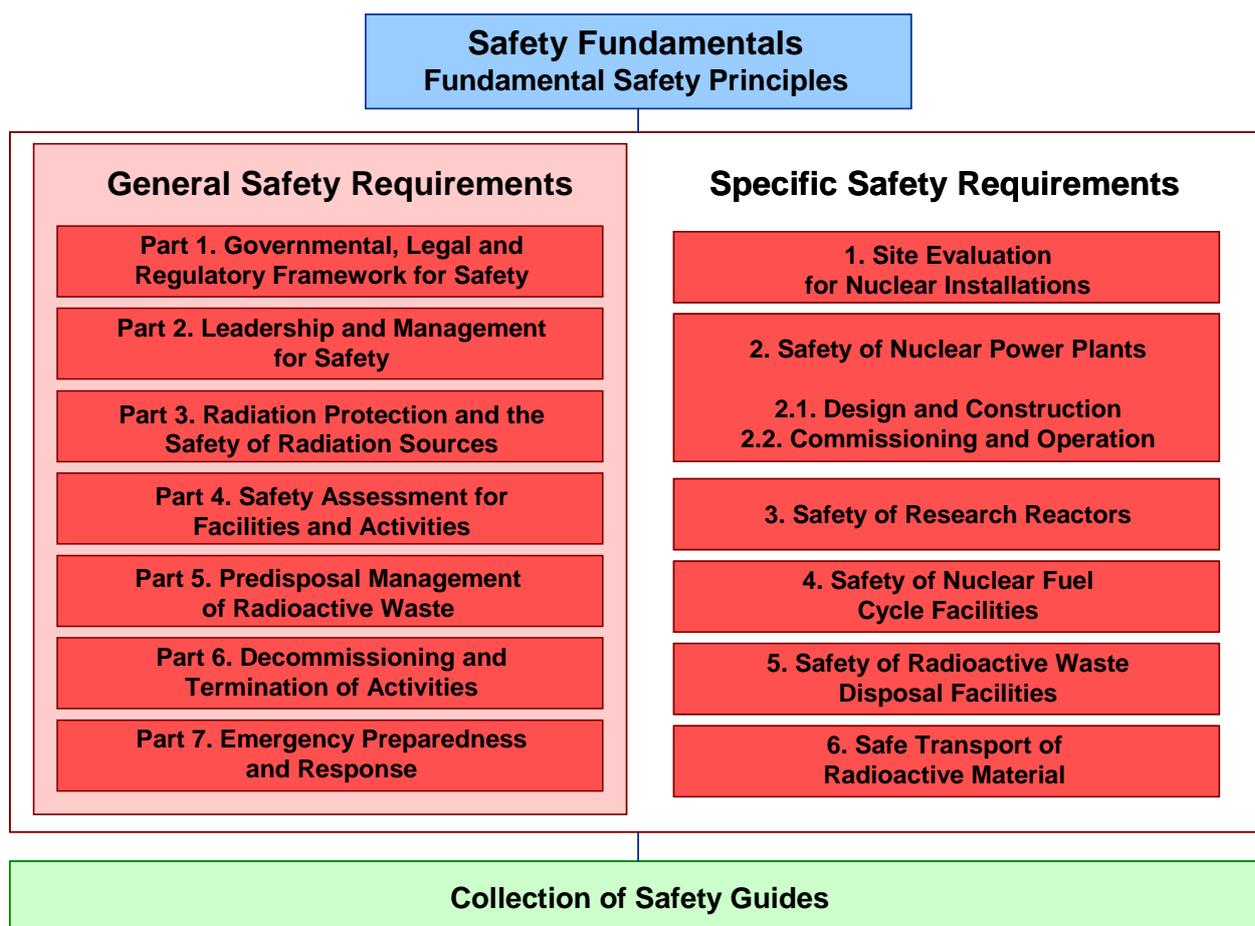


FIG. 1. The long term structure for the IAEA Safety Standards Series.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including developing educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to

be assessed at the national level. For example, many of the IAEA safety standards, particularly those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four²³ safety standards committees for safety in the areas of nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS), which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the CSS is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision on the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

²³ Now five with EPRESC

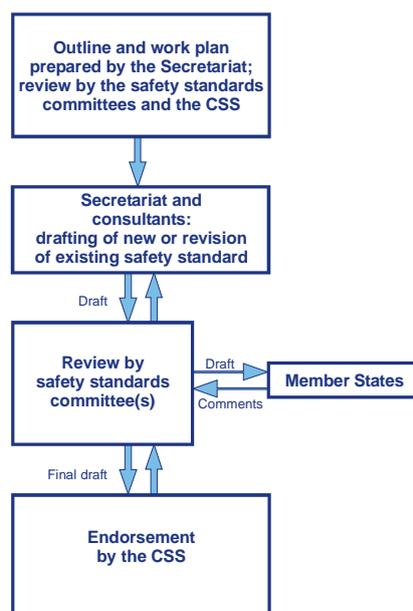


FIG. 2. The process for developing a new safety standard or revising an existing standard.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms not specifically defined in a publication are to be understood as defined in the IAEA Safety Glossary (<http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the main text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the main text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

ANNEX VI – policy paper on quantitative/qualitative safety standards

3 March 2015

Background

At the Commission on Safety Standards the issue of establishing quantitative versus qualitative safety standards was addressed very regularly. But no clear conclusion or policy was actually established on this issue.

The collection of safety standards includes standards of both categories and it would be appropriate to clarify the policy aspects that were de facto considered without being clearly established.

At a recent review by the Office of Internal Oversight Services of the standards for the operation of nuclear power plants and research reactors, this issue was further discussed with involvement of several member states representatives, including representatives who are also members of the CSS. The result of these exchanges was summarized in the report, thus providing an opportunity to use this summary as a key input for a policy paper on quantitative/qualitative safety standards.

Policy aspects

Many safety standards establish criteria in terms of radiation protection for which harmonized worldwide use is endeavoured, particularly *where these criteria apply directly to people, i.e. workers, patient and members of the public.*

This is typically the case for radiation protection criteria established by GSR Part 3 for dose limits for occupational exposures and public exposures in planned exposure situations. In some instances, the standards provide an upper limit for establishing national criteria, like for the annual average activity concentration due to Radon indoors.

In areas like emergency response, generic criteria are established in the safety standards on the basis of generic optimization and considering a range of conditions. National criteria are then expected to be developed on that basis. For some other criteria like the reference level for developing a protection strategy in an emergency situation, the safety standards provide a range, for example on the residual dose.

Another general aspect is for *criteria applying to sources that are widely used by many users* in medicine, industry, agriculture, research and education and *that are also transported* from countries to countries. This is another reason for which it is desirable to establish precise criteria to be used in a harmonized manner. This includes standards like for the categorization of sources (RS-G-1.9) with the concept of D value and standards on the safe transport of radioactive material.

In these first two main categories of standards, a quantitative approach is preferred though not in a prescriptive manner (range or upper limit for the national criteria or generic criteria). Moreover, the application of these quantitative criteria is not sufficient since optimization of protection and safety

needs to be applied for ensuring that the magnitude and likelihood of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. Similarly, the standards are applied with a graded approach, both requiring expert judgment.

In other areas, and particularly for what relates to the safety of facilities, the standards are designed to be qualitative and performance based rather than quantitative. This involves several considerations like the objective of establishing technology neutral standards that can be widely used by member states for a wide variety of designs. It was also noted that the reliance on quantitative standards could undermine the important use of engineering judgement and would not be in line with the safety philosophy of continuous improvement. Another aspect is that it might be more difficult to obtain consensus from member states on quantitative standards reflecting a high level of safety. A further consideration is that establishing quantitative criteria also implies establishing a consensus on how to assess/measure compliance with these criteria which, for facilities and activities would be very difficult in a technology neutral approach. Moreover, the standards establish responsibilities and processes and stipulate decisions to be made, i.e. obligation of means rather than obligation of minimum results. Nevertheless, for certain criteria and where there is a consensus to establish criteria to achieve a high level of safety, it could be envisaged to include a range for these criteria that would represent the variety of designs and provide an incentive to select the most ambitious part of the range in national regulations. Otherwise safety reports and TECDOCs may be developed to provide more details or example of such criteria used in national frameworks.

ANNEX VII – Interface between NS Safety Standards series documents and NE series documents

Interoffice Memorandum

To: All NS and NE Directors and Section Heads

From: Y.A. Sokolov,
DDG-NE
T. Taniguchi, DDG-NS,
DDG-NE

Reference:

Date: 2009-09-24

Subject: Interface between NS Safety Standards series documents and NE series documents

NS and NE are responsible for different document series: IAEA Safety Standards for NS and IAEA Nuclear Energy series for NE. The two document series fulfill different objectives. The new series of NE documents have emphasised the need to establish a clear relationship between the NE series documents and the existing series of Safety Standards and safety documents published by NS.

In establishing such a clear relationship the following principles should apply:

1. NS produces “standards of safety for protection of health and minimization of danger to life and property” in response to the functions of the IAEA as defined in the Statute Article III, A.6. These Safety Standards are not legally binding on Member States. However, it must be noted that the Statute requires that they are binding on the IAEA for its own operations and on States, in relation to operations assisted by the IAEA as well as in developing documents related to safety. In addition, NS produces supporting safety documents, such as Safety reports and TECDOCs.

The Safety Standards are developed and approved through a comprehensive and open review process involving the consultation of all Member States and the review and approval by the relevant Safety Standards Committees, the Commission on Safety Standards (CSS) and, for the two highest categories of safety standards (Fundamentals and Requirements), by the Board of Governors.

The IAEA Safety Standards are primarily written in a regulatory style; the principal users being the regulatory bodies and other relevant national authorities. The Safety Standards are also used by many organizations that site, design, manufacture and operate nuclear facilities as well as by co-sponsoring organizations. Also, the safety standards form the basis for the NS safety review services to regulatory bodies, industry and other licensees in Member States.

2. NE, according to the IAEA statute Article III, A, "... encourage and assist research on, and development and practical application of, atomic energy for peaceful uses ...". As a part of fulfilling this role, NE produces documents in the NE series regarding "the application of nuclear technology that provides analysis for and advice, assistance and guidance to the Member States (MS). These documents represent developments and achievements in their subject areas within the nuclear industry and research community, based upon input from international experts". (Source: Nuclear Energy Series, Document System Structure, December 2007, Version 6.0). A review process involving Member States representatives is being established for NE Series documents.
3. IAEA Safety Standards should not be developed or revised in NE series documents. IAEA Safety Standards should be referred to in NE series documents as the current boundary conditions for the application of nuclear technology. When IAEA Safety Standards are reproduced in NE series documents, NE has the responsibility to update these documents, after Safety Standards are revised.

NE documents presenting the best practices, state-of-the-art and recommendations in the use/development of technology and in management provide one of the bases for the development of the Safety Standards.

4. The principle under item 3 should be applied in the cases when NE series touches on safety issues, since:
 - Safety is integral part of technology,
 - Some activities in the Agency have a cross-cutting nature or cover a wide spectrum of issues, especially in project cases such as INPRO, where collaborative projects and documents contains safety issues, and
 - Support to operating organization for their cultivation of ownership and responsibility for safety very often includes "safety management" issues.
5. In order to check NE documents consistency with the current Safety Standards, NS is represented on the NE document coordination team and should review NE series documents at various stages of development. This may involve timely consultation of the relevant Safety Standards Committees and the Commission on Safety Standards.
6. In order to review draft Safety Standards, NE is represented on the NS coordination committee, which reviews the draft Safety Standards at all stages of development before they are submitted to committees, CSS and Member States.

Rev 3 - 12 Feb. 2010

NE-NS DETAILED PROCESS FOR DOCUMENT PRODUCTION

DPP

All proposals for new or revised NE series publications must have a Document Preparation Profile (DPP) submitted to the NE Document Coordination Team (DCT) meeting, held once a month. The NS representative at the DCT meeting reviews the proposal and suggests, as appropriate, NS involvement in the drafting of the document. He/she also suggests a preliminary list of safety standards or draft safety standards to be considered during the drafting or referred to in the draft, which may involve consultation with the members of the NS Coordination Committee (CC).

NE updates the DPP, taking into account the comments addressed and maintains a table of on-going publications, which indicates when NS cooperation was requested, as well as details of who was requested to participate in the document production. This table is regularly provided for, and reviewed at the CC meeting. All DPPs and the table are made available to the CC members on a Livelink folder.

The table is also made available to the Publications Committee.

DRAFTING

During the drafting stage, NE implements the recommendations documented in the DPP and cooperates with NS TOs as agreed above. NE also implements the principles stated in the NE-NS IOM, dated 24 September 2009 (See Annex).

Possible initial contribution of NS to the drafting of NE documents

It is the responsibility of the relevant NE manager to contact the designated Section(s) within NS and to agree on the expected contribution from NS and the time frame²⁴.

DCT REVIEW OF THE DRAFT

Before its publication, the complete draft is submitted for review by the DCT. This is implemented in two stages:

STAGE 1: When a final draft is first submitted to the DCT for review, the Team identifies a main reviewer, within NE and/or NS. If appropriate, at this meeting the NS representative on the DCT will

²⁴ It is the responsibility of the designated Section with NS to discuss with the relevant NE manager any specific arrangements for the drafting and review of the document.

suggest one NS CC member as main reviewer. At this stage also, the NS representative submits the draft to all members of the CC for comments.

As part of this screening, the NS CC members may suggest to the Chair of the CC that the draft be reviewed at a CC meeting. The CC meeting may recommend timely consultation of the relevant safety standards Committees and the CSS (although this is generally not envisaged for level 3 documents). In that case, the relevant Coordinators provide the draft to the Chair for a decision on whether this can be done by (a) comments from the Chairs (b) consultation with the Committees members by correspondence or (c) submission for review at the next meeting of the Committees.

All comments are forwarded to the DCT by the NS representative. Resolution of these comments is prepared by the NE Scientific Secretary in cooperation with NS and documented in a "DCT review form".

STAGE 2: After the actions described above are completed, the resolution of the comments addressed during the Stage 1 is reported to the DCT. If the DCT, including the NS representative, is satisfied that the final draft appropriately addresses all comments, the DCT endorses the document for publication.

Publication Committee

When reviewing the final draft, the Publications Committee verifies that the cooperation required at the DPP stage, that has been recorded in both the DPP and the table maintained by NE, is mentioned and signed off on the interdivisional cooperation field of the form.

ANNEX VIII

Terms of Reference of the Commission on Safety Standards (October 2007)

COMMISSION ON SAFETY STANDARDS

The Commission on Safety Standards (CSS) is a standing body of senior government officials holding national responsibilities for establishing standards and other regulatory documents relevant to nuclear, radiation, transport and waste safety.

The CSS has a special overview role with regard to the Agency's safety standards and provides advice to the Director General on the overall programme on regulatory aspects of safety.

Functions

The functions of the CSS are:

- To provide guidance on the approach and strategy for establishing the Agency's safety standards, particularly in order to ensure coherence and consistency between standards;
- To resolve outstanding issues referred to it by the committees involved in the Agency's preparation and review process for safety standards;
- To endorse, in accordance with the Agency's preparation and review process for safety standards, the texts of the Safety Fundamentals and Safety Requirements to be submitted to the Board of Governors for approval and to determine the suitability of Safety Guides to be issued under the authority of the Director General;
- To provide general advice and guidance on safety standards issues, relevant regulatory issues and the Agency's safety standards activities and related programmes, including those for promoting the worldwide application of the standards.

Membership

- Member States will be requested to nominate senior officials holding responsibilities in national regulatory organizations and having recognized expertise in nuclear, radiation, transport and waste safety as candidates. In appointing the CSS members, the Director General will seek to ensure a balance of regional approaches and experience in the areas

covered by the Agency's safety standards. The Director General will appoint the members for a term of four years. The members may each be accompanied by one technical adviser when attending the CSS meetings. In addition the Chairpersons of the four²⁵ committees on safety standards will be invited to participate fully in the CSS meetings.

- Observers from specialized international organizations and relevant non-governmental bodies may be invited by the Director General to attend CSS meetings.
- The Deputy Director General, Department of Nuclear Safety and Security, or a designated substitute will participate in all CSS meetings.

Working Methods

- The Director General will appoint a Chairperson from among the CSS members for a four year term.
- A Scientific Secretary to serve the CSS will be designated by the Deputy Director General, Department of Nuclear Safety and Security.
- Ordinarily, the CSS will meet twice a year for up to five working days. Extraordinary meetings may be called as required.
- The CSS will submit an annual report on its work to the Director General.
- Meetings will be conducted in English.

Resources

- The Secretariat will provide all the resources necessary to permit the efficient working of the CSS.
- All costs involved in the participation of each CSS member, including travel and per diem expenses, will be borne by the nominating Member State.

²⁵ Now five with EPRESC

ANNEX IX

Terms of Reference of the Safety Standards Committees (July 2015)

EMERGENCY PREPAREDNESS/NUCLEAR SAFETY /RADIATION SAFETY /TRANSPORT SAFETY /WASTE SAFETY STANDARDS COMMITTEE

The five Safety Standards Committees — the Emergency Preparedness and Response Standards Committee (EPReSC), the Nuclear Safety Standards Committee (NUSSC), the Radiation Safety Standards Committee (RASSC), the Transport Safety Standards Committee (TRANSSC), the Waste Safety Standards Committee (WASSC), — are standing bodies of senior representatives in the areas of emergency preparedness and response (EPR)/nuclear/radiation/transport/waste safety, open to all International Atomic Energy Agency (IAEA) Member States and established by the Deputy Director General, Head of the Department of Nuclear Safety and Security [the Deputy Director General], to make recommendations on the IAEA's programme for the development, review and revision of EPR/nuclear/radiation/transport/waste safety standards and on activities to support the use and application of these standards. The five Committees provide feedback and recommendations to the IAEA on its EPR/nuclear installation/radiation/transport/waste safety programmes and on areas for improvement, with a view to achieving greater transparency, consensus, quality, coherence and consistency in the development of IAEA safety standards.

Functions

The functions of EPReSC/NUSSC/RASSC/TRANSSC/WASSC are:

- To periodically review and provide advice and guidance on the strategy, priorities and programme for the development of the EPR/nuclear/radiation/transport/waste safety standards issued in the IAEA Safety Standards Series.
- To review reports on feedback received from the Secretariat and from members of the Safety Standards Committees as well as of the Nuclear Security Guidance Committee (NSGC), if any, regarding the application and use of EPR/nuclear/radiation/transport/waste safety standards and to provide advice on enhancing their usefulness to achieve high levels of safety, as well as on the timely review and the need for revision of published EPR/nuclear/radiation/transport/waste safety standards.
- To review and approve proposals for the development of documents to be published in the IAEA Safety Standards Series, i.e. draft document preparation profiles (DPPs).
- To review and clear DPPs for the development of documents to be published as part of the IAEA Nuclear Security Series.
- To review and approve the text of draft EPR/nuclear/radiation/transport/waste safety standards before their submission to Member States for comment.
- To review and approve the text of draft EPR/nuclear/radiation/transport/waste safety standards before their final endorsement for publication.
- To review and clear draft nuclear security guidance documents for which there are safety–security interfaces before their submission to Member States for comment.
- To review and clear draft nuclear security guidance documents for which there are safety–security interfaces before their final endorsement for publication.

- To provide recommendations, upon request from the Deputy Director General, regarding the IAEA Safety Standards Series development and approval process.
- To ensure, in full cooperation with the Commission on Safety Standards (CSS) and the other Safety Standards Committees as well as the NSGC, that safety–security interface issues are properly addressed and reviewed in both safety and security publications.
- To review, upon request by the Deputy Director General, draft documents intended for publication in the IAEA Nuclear Energy Series and in other IAEA publication series where there is an interface with EPR/nuclear/radiation/transport/waste safety standards.

Membership

At the beginning of each new term, Member States will be invited to nominate five senior representatives and, if desired, alternates, each as a candidate for membership of one of the Safety Standards Committees. Member States may also determine instead to nominate only a ‘corresponding member’ who may not generally attend meetings of the relevant Committee but would have the same function and therefore would in all cases receive correspondence and documents like all other members and, as requested, would submit written comments on such documents. The Deputy Director General will then appoint the nominated members for the new term. Member States may opt to have the member or alternate accompanied at meetings of the Committees by other experts.

The Committee members are expected to prepare for and attend the meetings of their Committee and are encouraged to contribute actively to its work, to report on feedback from users of publications in the IAEA Safety Standards Series in the respective Member States and, based on appropriate consultation at the national level and coordination of the input of national stakeholders, to present a national view on the issues under discussion.

The invitation of candidate international organizations and non-governmental bodies to attend the Committees’ meetings as observers, either permanently or for specific meetings, may be considered on a case-by-case basis in accordance with established strategies and processes.

The Head of the Incident and Emergency Centre or his/her appointee will participate in all EPRESC meetings, the Director of the Division of Nuclear Installation Safety or his/her appointee will participate in all NUSSC meetings, the Director of the Division of Radiation, Transport and Waste Safety or his/her appointee will participate in all RASSC, TRANSSC and WASSC meetings.

The Head of the Incident and Emergency Centre will designate a Scientific Secretary for EPRESC, the Director of the Division of Nuclear Installation Safety will designate a Scientific Secretary for NUSSC, the Director of the Division of Radiation, Transport and Waste Safety will designate a Scientific Secretary for RASSC, for TRANSSC, and for WASSC.

Working methods

The Deputy Director General will appoint a Chairperson for the term of each Committee from among the Committee members. If the Chairperson is unavailable for a meeting, the Deputy Director General, in consultation with the Chairperson, will appoint an acting Chairperson for that meeting from among the Committee members.

Each Committee will report to the Deputy Director General.

Each Committee will normally meet twice a year (with each meeting lasting up to five working days) to perform the above functions. Extraordinary meetings or meetings of an ad-hoc working group of Committee members may be called when required. Electronic or other means of communication may be used for follow-up on the Committees' activities.

The Chairperson, in conjunction with the Scientific Secretary, will prepare a report on each meeting and a report at the end of each term on the progress made so far.

The Chairperson, or his/her appointee, should attend meetings of the Committee chairs and meetings of the CSS, or such meetings as the Deputy Director General may convene in order to ensure that safety and security issues are coordinated in an appropriate manner.

Each Committee will liaise with the other Safety Standards Committees as well as the NSGC and the CSS in order to ensure that safety and security publications issued by the IAEA are consistent and mutually supporting. The mechanism for determining the draft documents for which there are such safety–security interfaces is the Interface Group, a body with separate Terms of Reference whose members are appointed by the Deputy Director General from among the members of the Safety Standards Committees and the NSGC in order to ensure a balanced representation of safety and security expertise.

The Committee meetings will be conducted in English.

Resources

The Secretariat will provide the resources necessary for ensuring the efficient working of the Committees. The Secretariat will provide copies (normally in electronic format only) of relevant documents and background materials sufficiently in advance of meetings to support the efficient functioning of the Committees and the Committee members.

All costs relating to the participation at the Committees' meetings are normally to be borne by the nominating Member State or observer organization, but there is the provision for exceptions to be made at the discretion of the Deputy Director General.

ANNEX X

Report of the Joint AdSec CSS Task Force endorsed by the Advisory Group on Nuclear Security and the Commission on Safety Standards on 1st November 2011

(3 November 2011)

Establishment of the joint task force

A joint session of the Advisory Group on Nuclear Security (AdSec) and the Commission on Safety Standards (CSS) was organized in April 2009, with the aim of exchanging views on issues relating to safety and security synergies and interfaces. At this joint session three options were presented for the future of the Safety Standards Series and the Nuclear Security Series:

- Option 1 was the full integration of both series (the Safety Standards Series and the Nuclear Security Series) into a new series with full coverage of safety and security issues;
- Option 2 was the status quo, keeping both series separated;
- Option 3 was integration of the security related aspects in the Safety Standards Series and discontinuation of the Nuclear Security Series.

The joint session recommended and the Secretariat decided to establish a joint AdSec-CSS task force, to be co-chaired by the Chairman of AdSec and the Chairman of the CSS, with equal participation of members from both groups and with active participation from the Secretariat. The initial aim in establishing the task force was to explore two topics, namely: practical improvement of the process for review and approval of draft Nuclear Security Series publications; and the long term feasibility of developing an integrated series of safety and security standards.

Activities of the joint task force

The task force met four times between October 2009 and May 2011. In advance of each meeting, members of the task force contributed informal papers, made detailed proposals and liaised with each other and with the Secretariat to reach agreement on various issues.

At its first meeting in October 2009, the task force finalized its terms of reference (see Annex I), including a short term objective aimed at improving the process for review and approval of Nuclear Security Series publications, and a long term objective to study the feasibility of the establishment of a Safety and Security Standards Series that would cover both safety and nuclear security.

At its second meeting in March 2010, based on discussions with the Agency's Legal Advisor, the task force concluded that there are no impediments to establishing nuclear security standards or to establishing combined safety and security standards. Throughout the discussion in 2010 it also became clear that option 3 mentioned above would not be appropriate.

In March 2010, the task force also launched two preliminary tasks:

- An analysis of the various thematic and operational areas of the nuclear security and safety domains, in order to determine where the domains may overlap, and where associating the domains might be feasible;
- A mapping exercise to determine how to put together the current structures of safety standards and the nuclear security guidance.

The Secretariat then carried out a systematic review of all the published and draft Safety Requirements in order to better identify the areas of interface with the Nuclear Security Series. The objective was to determine, paragraph by paragraph, whether the text of the requirements was directly applicable to security, whether it was applicable to security but with a need for substantial adjustment, whether it referred to a similar concept, albeit the application of the concept to security was different, or whether it was not applicable to security. This exercise indicated that a few General Safety Requirements (GSR Part 1, Governmental, Legal and Regulatory Framework for Safety; GSR Part 2, Leadership and Management for Safety; and GSR Part 7, Emergency Preparedness and Response) included a significant number of requirements that either could be applicable to security or would be applicable after adjustments. These Safety Requirements could therefore be complemented/accompanied by appropriate recommendation to also cover security issues. Moreover, all Specific Safety Requirements, while addressing only the safety related issues in their current edition, could also be complemented/accompanied by facilities and activities specific security recommendations. An exercise of comparing the safety fundamentals and the security fundamentals was also carried out by individual members of the task force, who indicated that it seemed feasible to combine these, if appropriate, in the long term.

A systematic gap analysis and mapping exercise for the Nuclear Security Series was also carried out in order to design a comprehensive suite of publications that would better address the needs of Member States. The preparation of the proposed plan involved both a top down approach based on the draft Nuclear Security Fundamentals and the draft Nuclear Security Recommendations, to determine the set of guidance necessary to implement the elements and recommendations established in these draft publications, and a bottom up approach using the set of safety standards to identify potential areas to be covered by the Nuclear Security Series. The outcomes of these exercises led to the proposed suite of Nuclear Security Series publications, available under:

<http://www-ns.iaea.org/committees/files/adsec/819/NuclearSecuritySeriesPlanShortJune21.xls>

In 2010 the Secretariat also proposed the establishment of a Nuclear Security Guidance Committee (NSGC), to address in part the short term issue of improving the process for review and approval of draft Nuclear Security Series publications.

At its third meeting, in September 2010, the task force further discussed the different possible options and established list of 12 criteria (see Annex II) to be used to assess the feasibility of the different possible options for the future of the Nuclear Security Series and the Safety Standards Series.

Between September and March 2011, a new 'hybrid option' emerged as an additional potential option. It consisted of the establishment of a new series covering both safety and security for regulated facilities and activities to be reviewed by the Safety Standards Committees and the new NSGC before approval by a new Safety and Security Standards Commission. The new series would also include as a separate area the domain outside the regulated facilities and activities, for which only the new NSGC would be involved for the review and approval of the draft publications.

Conclusions of the joint task force

The fourth meeting of the task force was held in May 2011, in which the task force took account of the work that had been conducted by the task force and the Secretariat over the previous two years and reached final conclusions on the way forward.

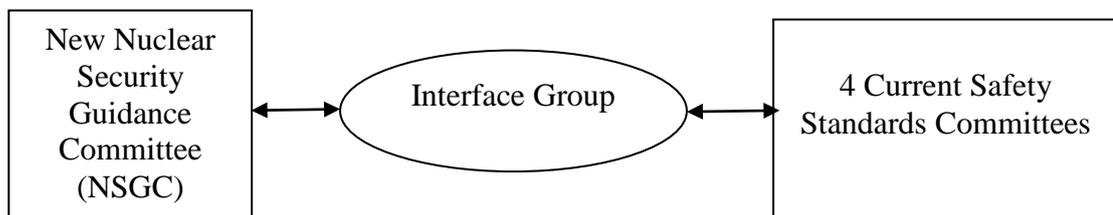
The task force agreed on the following four principles:

1. Nuclear security and safety are equally important and the process for review/approval should reflect this;
2. Safety document preparation profiles (DPPs) and nuclear security DPPs should be reviewed to identify/define interfaces, if any;
3. Draft safety publications and draft nuclear security publications that have an identified interface should be developed in consultation;
4. After implementation of points 2 and 3, draft safety publications and draft nuclear security publications should be reviewed and approved to ensure the coordination has been effective and that they are in accordance with the Safety Fundamentals and the Nuclear Security Fundamentals.

Instead of establishing a priori a detailed structure for the future Safety and Security Series, as suggested by the hybrid option, the task force discussed the process for further studying this long term structure.

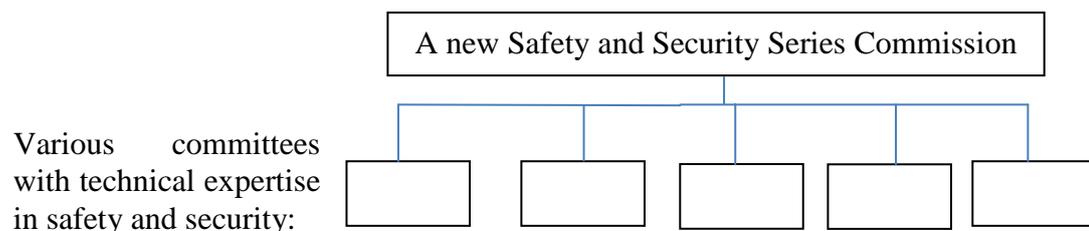
In this regard, the task force reached a two-step conclusion for the committee structure for the review and approval of draft safety and nuclear security publications, as follows:

- As an intermediate committee structure:



whereby the 'interface group' reviews DPPs and refers them to the appropriate committee(s). The four Safety Standards Committees would continue to report to the CSS, as they currently do, and the new NSGC would report to the Deputy Director General (DDG) of the Department of Nuclear Safety and Security, who will decide on a case-by-case basis what further consultation is deemed necessary in order to ensure good cooperation and implementation of the four principles.

- As a long term vision:



The task force proposed that the Director General should establish the NSGC, with terms of reference consistent with the four principles above (see Annex III, modified to incorporate the comments discussed by the CSS and AdSec), and implement the intermediate structure as soon as possible. The task force also suggested that the functioning of the intermediate structure should be reviewed – in particular as to whether it meets the four principles – after a suitable interval of operation, and the long term vision revised if necessary.

ANNEX XI

Role of the Chairs of the Safety Standards Committees

(10 September 2012)

In addition to the role of the Chairs with regard to the normal conduct of the Safety Standards Committees meeting and compliance to the terms of reference of the Safety Standards Committees, the SPESS document highlight specific functional role of the chairs, including the issues addressed at the regular meeting of the chairs, in a number of areas:

- Participation and membership at the Commission on Safety Standards meeting
- Proposal on policy and strategies
- Coordination for DPPs and drafts being submitted to several Committees
- Verification of changes to initially agreed DPPs
- Validation of changes made on draft already approved
- Represent the Safety Standards Committees at the Interface Group
- Assessment of candidate IGOs and NGOs
- Conduct of the meetings with regards to intervention of IGOs and NGOs
- Assessment of proposed changes to the Safety Glossary
- Review of updates of the SPESS document

Moreover, for the implementation of the Interoffice Memorandum on Interface between NS Safety Standards series documents and NE series documents, the Chairs of the Committees are kept informed of the list of draft NE Series publications and may be consulted on specific drafts when recommended by the Coordination Committee, so as to check its consistency with the current Safety Standards.

ANNEX XII
Terms of Reference of the Coordination Committee on Safety
Standards and Nuclear Security Series Publications
(24/02/2012)

1. Objective

To ensure coherency, consistency and quality of the Safety Standards Series and the Nuclear Security Series Publications and to facilitate the coordination for other official publications.

2. Structure

Membership: The Coordination Committee (CC) comprises the Section Heads from NSNI, NSW, NSNS, NS-SSCS, NS-IEC and NE-NPES as well as the Unit Head in NS-SSCS in charge of the coordination process for the NS Department publications. The Section Head NS-SSCS chairs the meetings and the Unit Head of NS-SSCS provides the secretariat for the CC.

Attendance: Members of the CC who are present in the VIC are required to attend meetings. Otherwise, persons officially designated as 'acting Section Head' will represent the Section Head. The Section Head NS-SSCS may exceptionally delegate chairmanship of a meeting to a member of the CC. The Coordinators of the Standards Committees and of the Nuclear Security Guidance Committee (NSGC) and technical editors from the NS Department are invited to attend. The Chair, on request, may invite as appropriate other staff members (e.g. Directors and Technical Officers).

3. Scope

All Safety Standards Series and Nuclear Security Series²⁶ prepared by the NS Department, from their initial proposal to their publication (and translation) and their subsequent review and revision and all DPPs for other NS Department publications. The Committee may also review on a case by case basis other draft publications, including draft prepared by other IAEA Departments, when they relate to the Safety Standards or Nuclear Security Series.

4. Functions

The functions of the CC are:

1. To keep under review the structure of Safety Standards Series and Nuclear Security Series publications, to periodically evaluate/assess proposals for the review and revision of existing publications, and to identify publications which can be considered obsolete.
2. To review and recommend for approval by DDG-NS all proposals for Safety Standards Series and Nuclear Security Series as well as proposals for other official publications (e.g. TECDOCs and Safety Reports), or revision of existing publications (document preparation profile, DPP): the objective, the scope, the content and the potential interface and overlap with other publications.
3. To undertake a thorough review within the Secretariat of all draft Safety Standards Series and Nuclear Security Series publications that are subject to an external review procedure and recommend them for approval by DDG-NS prior to their submission to external advisory or review groups (e.g. submission to the Safety Standards Committees and submission to the NSGC).
4. To review on a case by case basis other draft publications, including draft prepared by other IAEA Departments, when they relate to the Safety Standards or Nuclear Security Series.
5. To keep under review the process of development of Safety Standards Series and Nuclear Security Series publications.

5. Operations

The CC will meet in principle every two weeks. Material for review by the CC is submitted to the Secretary of the CC two weeks in advance to the meetings. Individual or group assignments may be given to CC members, as needed, to prepare input for CC review. Material is made available for comments in a dedicated folder of the NS Knowledge Portal where the CC members can upload comments prior to the meetings.

Minutes of all meetings are prepared and posted within a week after each meeting and are approved at the following meeting. The CC Chair reports to the DDG-NS on the results of the meetings.

The CC will only review documents that have been developed in consultations with the appropriate Sections.

²⁶ In the context of the Coordination Committee, this relates to the categories Fundamentals, Recommendations and Implementing Guides

In those cases when the CC cannot recommend approval of a draft Safety Standards Series or a draft Nuclear Security Series document or agree on a proposed DPP, the relevant issues should firstly be addressed in cooperation between the relevant Sections, and the result reported back to the CC through the Section Heads. The minutes of the CC meeting will include summary records of the issues and results. Remaining unresolved issues will be reported by the Chair of the CC to the DDG for subsequent decision.

While implementing its functions, the CC should ensure that

- (a) feedback from, inter alia, review services and training events conducted in Member States are appropriately taken into account in the development of Safety Standards Series and Nuclear Security Series publications;
- (b) recommendations related to safety standards and security guidance made by IAEA Policy Making Organs, CSS, AdSec and DDG-NS are appropriately implemented; and that
- (c) all relevant parts of the organization are involved and appropriately consulted in the development of the documents.