MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

February 22, 2001

FROM: Janice Dunn Lee, Director /RA/
Office of International Programs

SUBJECT: THE PREPARATION AND REVIEW PROCESS FOR IAEA SAFETY STANDARDS

The purpose of this memorandum is to inform the Commission about the IAEA's safety standards preparation and review process and note the participation by NRC staff.

Following establishment of the International Atomic Energy Agency (IAEA) in 1957, the Agency moved quickly to publish a set of basic radiation protection standards in 1962. Since then, the Agency has produced hundreds of standards and associated safety guides (similar to Regulatory Guides) in the area of nuclear, radiation, waste, and transport safety. These standards and guides have proved to be valuable to developing countries that are involved in nuclear activities but have limited capabilities to regulate nuclear safety. Certain of the standards and guides serve also as reference points for more advanced countries, to ensure national coverage of important issues.

NRC provides significant support to the IAEA's standards preparation and review process by helping to draft and review the various documents. The Executive Director for Operations, Dr. William Travers represents the U.S. on the highest standards review and approval board of the Agency, the Commission on Safety Standards. Other senior staff serve on the four Safety Standards Committees for nuclear, radiation, waste, and transport safety, and other staff participate on working groups which support these efforts.

A description of the preparation and review process for IAEA safety standards is at Attachment 1. A summary of current activities under discussion in the Commission on Safety Standards and the four safety standards committees is at Attachment 2.

Attachments: 1. Preparation and Review Process for IAEA Safety Standards
2. Current Activities in IAEA Safety Standards Committees

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CONTACT: C. Serpan, OIP
415-2341

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Following establishment of the International Atomic Energy Agency (IAEA) in 1957, the Agency moved quickly to publish a first set of basic radiation protection standards in 1962. Since then the Agency has produced hundreds of standards in the area of nuclear, radiation, waste and transport safety. These standards have proved to be of immense value to developing countries that are involved in nuclear activities but have small or inadequate capabilities to regulate or otherwise manage the intricacies of nuclear safety for so vast a range of topics. The standards have been beneficial as well to developed countries with significant nuclear programs as reference points to ensure national coverage of important issues.

The U. S. in general, and the NRC in particular, have provided significant support to the IAEA's standards preparation and review process through provision of staff to help in the writing and review process and for review at the Member State level. EDO William Travers represents the U.S. on the highest standards review and approval board of the Agency, the Commission on Safety Standards, while other staff are members or alternates on the four Safety Standards Committees for nuclear, radiation, waste and transport safety.

A description of the preparation and review process for IAEA safety standards is at Attachment 1. A short summary of current activities under discussion in the four safety standards committees is at Attachment 2.

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THE PREPARATION AND REVIEW PROCESS FOR IAEA SAFETY STANDARDS

Introduction

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of those standards to peaceful nuclear activities. To this end, the IAEA Board of Governors first approved basic radiation protection standards in 1962. Revised versions of those standards were issued in 1967 and 1982, culminating in 1994 with Board approval of the key radiation protection standard referred to around the world as "the BSS", the "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources."

In 1974, the IAEA launched the Nuclear Safety Standards (NUSS) program for establishing internationally agreed safety standards for land-based thermal-neutron power reactors; the resulting codes and guides were also published in the Safety Series, in addition to other documents in this series devoted to waste and transport safety. In 1989, following the Chernobyl accident, the IAEA expanded its safety-related activities to provide for a hierarchical structure for the Safety Series publications including:

- Fundamentals, which present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes;

- Standards, which establish the requirements that must be met to ensure safety, and are expressed as "shall" statements governed by the objectives and principles in the Safety Fundamentals; and

- Guides, which recommend actions, conditions or procedures for meeting safety requirements, and are expressed as "should" statements.

The 1974 NUSS program included the category of Practices, which gave examples and detailed descriptions of methods to be applied in implementing both the Standards and the Guides. In a revision of the program in 1995, however, the "Practice" category was dropped.

In 1996, the hierarchy of safety related publications was modified to provide a clearer distinction between safety standards established by the Agency pursuant to Article III of its Statute and publications issued by the Agency as part of its statutory function of fostering the exchange of safety related information. Thus, the former Safety Series was replaced by the "Safety Standards Series" for publications of a regulatory nature, and the "Safety Reports Series" for information exchange publications including publications that were formerly classed as Safety Practices and those for which a charge is made.

Safety Fundamentals and Safety Requirements require approval of the Board of Governors, while Safety Guides are issued under the authority of the Director General. It is important to note that the IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are, however, binding on countries wherein the IAEA implements its programs and to operations assisted by the IAEA. International modal transport organizations may, however, incorporate IAEA regulations, so acceptance by the U.S. of those modal

regulations or instruments can result in effective "involuntary" acceptance of agency transport regulations. Responsibility for preparation and review of agency safety standards is with the Department of Nuclear Safety.

The Safety Standards Program revision of 1995

The September 1995 Board of Governors approved a revised process for preparation of all safety related documents, described by the Secretariat in GOV/INF/722, August 17, 1995. At the heart of the process was establishment of an Advisory Commission for Safety Standards to provide final review and approval of all safety documents prior to submission to the Board of Governors, plus a lower tier of safety standards advisory committees for technical-level review of staff and consultant-developed documents in the areas of nuclear, radiation, waste and transportation safety.

A further refinement was made in April 2000 to better reflect the role of the Commission and Committees for development of standards development and to avoid confusion with other, long-standing "advisory" bodies of the IAEA, such as the International Safety Advisory Group, INSAG. The new titles are:

- Commission on Safety Standards (CSS);
- Nuclear Safety Standards Committee (NUSSC);
- Radiation Safety Standards Committee (RASSC);
- Waste Safety Standards Committee (WASSC); and
- Transport Safety Standards Committee (TRANSSC).

The Commission and Committees:

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, waste and transport safety. The Commission also has a special role with regard to the Agency's safety standards and provides advice to the Director General on the overall program on regulatory aspects of safety.

The functions of the CSS are:

- to provide guidance on the approach and strategy for establishing the Agency's safety standards, particularly to ensure coherency and consistency between standards;

- to resolve outstanding issues referred to it by any Committee 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 Safety Fundamentals and Safety Requirements to be submitted to the Board of Governors for approval, and of Safety Guides to be issued under the authority of the Director General; and

- to provide general advice and guidance on safety issues, relevant regulatory issues and the Agency's safety standards activities and related programs, including those for promoting the application of the standards.

Nuclear Safety Standards Committee (NUSSC)

Radiation Safety Standards Committee (RASSC)

Waste Safety Standards Committee (WASSC)

Transport Safety Standards Committee (TRANSSC)

Each of the four Safety Standards Committees is a standing body of senior regulatory officials with technical expertise in the specific areas. Each committee provides advice to the Secretariat on the overall program on regulatory aspects of those specific areas and has the primary role in the development of the Agency safety standards in those specific areas.

Functions of the safety standards committees are:

- to recommend the terms of reference of all standards in the Agency's respective nuclear, radiation, waste or transport safety standards programs and of the groups involved in the development of those standards, in order to promote coherence and consistency among the standards and between them and other safety-related publications of the Agency;

- to agree on texts of Safety Fundamentals and Safety Requirements to be submitted to the Board of Governors for approval and of Safety Guides to be issued under the authority of the Director General, and to make recommendations to the CSS in accordance with the Agency's preparation and review process for safety standards;

- to provide advice and guidance on a continuing program for reviewing and revising the Agency's respective nuclear, radiation, waste or transport safety standards;

- to provide advice and guidance on the respective nuclear, radiation, waste or transport safety standards, relevant regulatory issues, and activities for supporting the application of the Agency's safety standards; and

- to identify and advise on any necessary activities in support of the respective nuclear, radiation waste or transport safety programs.

Standards Preparation and Review Process

The following functions have been established to provide for a uniform safety standard preparation and review process:

- a set of Safety Standards Committees with harmonized terms of reference to assist the Secretariat in preparing and reviewing all standards;

- a Commission on Safety Standards to assist the Secretariat in co-ordinating the activities of the Committees;

- a Scientific Secretary assigned from the Agency's staff to each of these Committees and the Commission; and

- a Technical Officer appointed from the Agency's staff for the preparation of each standard.

The uniform preparation and review process consists of:

- organizing expert group meetings whenever necessary to develop initial draft texts;
- arranging for internal review of draft texts at different stages of preparation;
- submitting documents to the relevant Safety Standards Committee(s) for review;
- submitting draft texts to the Agency's Member States for comment;
- obtaining the Publication Committee's approval of each document to ensure compliance with the Agency's publication policy;
- obtaining endorsement by the Commission on Safety Standards;
- submitting draft Safety Fundamentals and Safety Requirements publications to the Board of Governors for approval; and
- submitting Guides and Practices to the Director General for approval.

The Safety Standards Preparation and Review process could not proceed without the generous contribution of personnel resources by the Member States. In addition, review of the standards documents at an early stage by the Member States (for example, by experts in NRC, DOE, State, DOT and other relevant agencies), is necessary to ensure consistency with national standards and practices, and is considered a mandatory step in the process.

Other advisory input and coordination with NGOs

The primary advisory body to the Director General of the IAEA for nuclear safety matters is INSAG, the International Safety Advisory Group. The U.S. representative on INSAG is Ashok C. Thadani, NRC/RES. This group of senior experts is appointed by the DG to provide advice over a broad range of topics related to nuclear safety based on members own personal expertise and not necessarily reflecting the position of their country or employer. Advice from INSAG is an important input to the preparation and review process of the Agency, along with recommendations made by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP), and the International Commission on Radiation Units and Measurements (ICRU). IAEA Safety Guides are sometimes co-sponsored by other international organizations such as the International Labor Office, the Food and Agricultural Organization of the United Nations, the Nuclear Energy Agency of the Organization for Economic Cooperation and Development, the Pan American Health Organization, and the World Health Organization.

Current Activities of the Commission on Safety Standards

At the November 27-29, 2000, meeting of the Commission on Safety Standards (CSS), the following activities occurred:

Presentation and discussion of reports of activities by Chairmen and Technical Officers of the four Safety Standards Committees: RASSC, NUSSC, WASSC, and TRANSSC.

Endorsement by CSS of Safety Guides:

- Building competence in radiation protection and safe use of radiation sources (DS 73)
- Decommissioning of nuclear fuel cycle facilities (DS 171)
- Instrumentation and control for systems important to safety in NPPs (DS252)
- External person induced events in relation to NPP site evaluation (DS 258)
- Radiation protection in medical exposures (DS22)
- Safety assessment and verification for nuclear power plants (DS 253)
- Operating organization (DS250)

Review of Document Preparation Profiles:

- Design aspects of radiation protection in nuclear power plants (DS 313)
- Quality management systems in radiation safety for regulatory authority and users (DS 113) (Safety Guide)
- Quality management systems for technical services in radiation safety (DS314) (Safety Guide)
- Modifications to nuclear power plants (DS251)

Policy Issues

- Quality Assurance - The CSS reviewed the response to its request to the Director General to assure effective separation between safety standards setting and promotion of nuclear energy, specifically by placing full responsibility for safety standards for quality assurance within the Nuclear Safety Program.

- Nuclear fuel cycle facilities - The CSS directed that the NUSSC, RASSC and WASSC committees be involved in development of guides and standards for nuclear fuel cycle facilities, and proposed expansion of the scope of requirements in some additional areas.

- Overall structure of IAEA safety standards - The CSS asked that the general safety requirements for nuclear, radiation, waste and transport safety be included in the same kind of document; that is, either in a safety fundamentals or safety requirements document, and not split between the two as is now the case. Gaps and overlaps in the existing Safety Standards were identified, and an overall structure for the Safety Standards was set forth.

- Information paper to Member States describing the development of the IAEA's Safety Standards.

Tentative list of standards to be reviewed at the next CSS meeting:

- DS 43, Preparedness and response for nuclear and radiological emergencies (Safety requirements)

- DS 187 Radiation protection and radioactive waste management in NPP operation (Safety guide)

- DS 247 Organization and staffing of the nuclear regulatory body for nuclear facilities (Safety guide)

- DS 248 Review and assessment of nuclear facilities by the regulatory body (Safety guide)

- DS 289 Regulatory inspection of nuclear facilities and enforcement by the regulatory body (Safety guide)

- DS 290 Documentation produced and required in regulating nuclear facilities (Safety guide)

U. S. Representative on CSS: W. D. Travers, EDO, NRC

Participation by NRC personnel in CY2000: W. D. Travers in June and November

Current Activities in the Radiation Safety Standards Committee

At the October 9-11, 2000, meeting of the Radiation Safety Standards Committee (RASSC) in Vienna, the following were approved:

- Safety Guide on Radiation Protection in Medical Exposures (for CSS approval);
- Safety Standard on Building Competence in Radiation Protection and the Safe Use of Radiation Sources (for CSS approval);
- Document Preparation Profile (DPP) for Design Aspects of Radiation Protection for Nuclear Power Plants; and
- Safety Guide on Mining and Processing of Raw Materials (for Member States).

RASSC reviewed progress on the following documents:

- Safety Guide on Security of Sources (agreed to combine with Safety of sources);
- Safety Guides on Emergency Response;
- Current activities on Regulatory Infrastructure (providing guidance on exemption, exclusion, and consumer products);
- DPP and background paper on Quality Assurance (needs another document for service providers);
- Environmental Monitoring (agreed to preparation of a DPP);
- Revision of the Basic Safety Standards (needs a proposal for the revision process);
- Status of activities between IAEA and WHO on Iodine Prophylaxis (joint statement in process);
- Requirements and Guidance documents on Cleanup of Areas Contaminated from Past Practices and Accidents (in agreement with WASSC); and
- Review of status of the model project to build competent infrastructures in IAEA Member States, efforts in education and training, occupational radiation protection, and the action plan for safety of sources.

RASSC disagreed with WASSC concerning acceptability for review by the CSS of the combined Common Safety Fundamentals document as developed by INSAG, and recommended instead that the work needed to progress more slowly.

New areas of work undertaken by RASSC included:

- Development of guidance on intervention levels for commodities (in response to General Conference Resolution GC(44)/RES/15);
- Completion of the RADEV (Radiation Events) computer database (to properly incorporate NRC's NMED database); and
- Combine the draft Safety Guides on the Safety of Radiation Sources and the Security of Radiation Sources (using a risk-informed approach).

Because of the complementary nature of issues facing both the RASSC and the Waste Safety Standards Committee (WASSC) the two committees have decided to hold joint as well as separate meetings in the future.

U. S. Representative on RASSC: Donald Cool, NRC/NMSS

Participation by NRC personnel in CY2000:
D. A. Cool in March and October
L. D. Camper in March (joint with WASSC)
J. M. Piccone in May
D. A. Broaddus in July

Current Activities of the Nuclear Safety Standards Committee

At the October 16-18, 2000, meeting of the Nuclear Safety Standards Committee (NUSSC) in Vienna, the following were approved:

- Document Preparation Profile (DPP) on Safety Guide on Design Aspects of Radiation Protection for NPPs;
- Draft Safety guide on Extreme Meteorological Events in Nuclear Power Plant Site Evaluation (for Member State review);
- Draft Operations Safety Guide on The Operating Organization (for CSS approval);
- Draft Design Safety Guide on Safety Assessment and Verification (for CSS approval);
- Draft Operations Safety Guide on Plant Modifications (for CSS approval); and
- Draft Design Safety Guide on Safety Assessment and Verification (for CSS approval).

NUSSC reviewed progress on the following documents:

- Draft Design Safety Guide on Emergency Power Systems at Nuclear Power Plants (needs more time for comments);
- Draft Safety Guide on Periodic Safety Review of Nuclear Power Plants (needs more time for comments);
- Related to the Draft Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities, a new document combining Regulatory Independence, IAEA Safety Series Requirements and a review of findings from recent IRRT Missions.

NUSSC agreed with RASSC (and thus disagreed with WASSC) that the combined Safety Fundamentals document needed more time for review.

U. S. Representative on NUSSC: Joseph Murphy, NRC/RES.

Participation by NRC personnel in CY 2000:
D. A. Lange in April
J. A. Murphy in October
F. Kantor in October

Current Activities in Waste Safety Standards Committee

At the October 2-5, 2000, WASSC meeting, the following four draft Safety Guides were reviewed and accepted for further review by the CSS:

- Organization and Staffing of the Regulatory Body for Nuclear Facilities;
- Review and Assessment by the Regulatory Body for Nuclear Facilities;
- Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body; and
- Documentation Produced and Required in Regulating Nuclear Facilities.

The Safety Fundamentals document "Objectives and Principles of Nuclear, Radiation, Radioactive Waste and Transport Safety" was reviewed, and comments combined with those from other SSC's for further consideration by CSS at the November 2000 meeting.

The CSS asked WASSC for views on the development of a suite of standards on Nuclear Fuel Cycle Facilities, but WASSC will reply that it prefers to write just one requirements document with chapters for specific topics such as mining and minerals processing, uranium conversion and enrichment, fuel fabrication and reprocessing, and criticality.

A Document Preparation Profile will be prepared for a guide document on Environmental Monitoring.

Proposed Safety Guides deemed needing more work included:

- Monitoring and Surveillance of Near Surface Facilities;
- Geological Disposal of Radioactive Waste; and
- Cleanup of Areas Contaminated by Past Activities and Accidents.

Two additional proposed Safety Guides were approved for Member State review:

- Storage of Radioactive Waste; and
- Management of Radioactive Waste from Mining and Milling of U/Th Ores.

Because of the complementary nature of issues facing both the WASSC and the Radiation Safety Standards Committee (RASSC) the two committees have decided to hold joint as well as separate meetings in the future.

U. S. Representative to WASSC: Andrew Wallo III, DOE.
NRC Alternate to WASSC: Larry Camper, NMSS.

Participation by NRC personnel in CY 2000:
J. R. Hall in January
L. D. Camper in March (joint with RASSC)
T. H. Essig in September and October

Current Activities of the Transportation Safety Standards Committee

The May 15-19, 2000 meeting of the Transport Safety Standards Committee (TRANSSC) in Vienna, focused on the 2001 implementation date for world-wide adoption of IAEA's 1996 transport regulations (ST-1). Of particular interest was the identification of potential safety issues that could arise during the transition period. In addition, TRANSSC considered preparations for the change to the new, two-year regulatory revision cycle; the first such cycle begins in 2000 and will result in the 2003 edition of the regulations. TRANSSC approved the following:

- Issuance of an ST-1 Errata (English version) that corrects several editorial problems, and the reprinting of ST-1 (1996) to include the errata;
- A letter to international modal organizations requesting that they take steps to support a harmonized adoption date and transition period for ST-1, and an agreement to approach the European Commission to identify the need for domestic legislation on the transition;
- Terms of reference for the September 4-8, 2000 Revision Panel Meeting, the first significant meeting under the two-year regulatory revision cycle;
- Minor amendments to the schedule for the current (2000-2003) revision cycle;
- Endorsement of agency efforts to initiate a Coordinated Research Program (CRP) on radiological aspects of package and conveyance contamination; and
- endorsement of agency efforts to publish (annually and on the IAEA website) a list of competent authorities, and to publish and maintain the PACKTRAM database.

TRANSSC reviewed progress on the following:

- Efforts to publish the advisory and explanatory material (ST-2) and emergency response guidance (ST-3) that are complementary documents to ST-1;
- TECDOC report - results of Sea Transport CRP;
- TECDOC report - results of Uranium Hexaflouride Package Fire Performance CRP;
- Ongoing CRPs on risk assessment, air transport, and low-specific activity and surface contaminated objects; and
- Status of IAEA's transport safety appraisal services (TransSAS) offered to member states.

New areas of work undertaken by TRANSSC included:

- A recommendation to convene consultant services meetings (CSMs) to develop guidance or rule change proposals addressing: (1) compliance during transition from 1985 to 1996 editions of the regulations; (2) transitional/grandfather issues under the new two-year revision cycle; and (3) radiation protection programs.

TRANSSC next meets in Vienna February 5-9, 2001; R. J. Lewis will substitute for Mr. Brach.

U. S. Representative to TRANSSC: Richard Boyle, DOT
NRC Alternate to TRANSSC: F. William Brach, NMSS

Participation by NRC personnel in CY 2000:
R. J. Lewis in March and October
S. F. Shankman in May
N. L. Osgood in October