U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

IRRS UNITED STATES 2010

Question and Response Report

for:

Module 09: Regulations and Guides

IRRS Question and Response Report

Question No: 098 **Module 09: Regulations and Guides**

Question

What regulations and guides are developed by the regulatory body?

Response

The U.S. Nuclear Regulatory Commission (NRC) develops all regulations and guides necessary to implement its mission: to license and regulate the Nation's use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment.

As discussed in the response to Question 102, these regulations are contained in Title 10 of the Code of Federal Regulations (10 CFR), "Energy," Parts 1–199. The NRC bases its regulations on national statutes dating back to the Atomic Energy Act of 1954, as amended (AEA). Other principal statutes by which qualified NRC staff drafts regulations include, but are not limited to, the Administrative Procedure Act; the Energy Reorganization Act of 1974, as amended; the National Environmental Policy Act of 1969; the Nuclear Non-Proliferation Act of 1978; the Nuclear Waste Policy Act of 1982; the Energy Policy Act of 1992; and the Energy Policy Act of 2005. Consistent with the legal framework in the United States, the NRC's regulations are thorough and comprehensive. The NRC's Office of the General Counsel provides professional legal assistance in all aspects of rulemaking.

The NRC ensures that the staff involved in rulemaking activities is qualified to perform its duties by requiring individuals to complete a training and qualification program. Information relevant to rulemaking is derived from industrial standards, operating experience, and both international and domestic technical research activities. This information is used to develop a regulatory basis for preparing new regulations that includes technical, policy, and legal considerations. The NRC staff prepares regulatory analyses to evaluate the costs and benefits of all new regulations being considered. The Advisory Committee on Reactor Safeguards provides an unbiased, third-party perspective to the Commission on technical and policy issues.

The procedures for developing regulations are captured in NRC Management Directive (MD) 6.3, "The Rulemaking Process," dated June 2, 2005, and the NRC's Regulations Handbook (NUREG/BR 0053). Individual offices within the NRC have more specific rulemaking procedures, such as the Office of Nuclear Reactor Regulation's Office Instruction LIC 300, "Rulemaking Procedures," the Office of Federal and State Materials and Environmental Management Programs' Policy and Procedure 6 10, "FSME Procedures for Preparation and Review of Rulemaking Packages," and the Office of New Reactors' NRO REG 114, "Rulemaking Procedures."

An extensive system of regulatory guides has been developed to provide guidance to licensees and applicants on implementing specific parts of the NRC's regulations, and on information needed by the staff in its review of applications for permits or licenses. An example is Regulatory Guide (RG) 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)." Other guidance is provided to licensees via a collection of NUREG reports used to provide regulatory information, policy guidance, or to address techniques for use by the NRC staff to evaluate specific problems or postulated accidents. For example, NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," provides specific guidance to the NRC staff on how to conduct technical evaluations of licensee applications.

The NRC also endorses standards developed by national consensus standard bodies in regulatory guides and regulations, when appropriate. Examples include 10 CFR 50.55a, "Codes and Standards," in which the NRC incorporates by reference into the regulations standards developed by the American Society of Mechanical Engineers on design, construction, installation, and testing of components and structures, and 10 CFR 50.48(c), which incorporates National Fire Protection Association Standard 805, "Performance-Based Standard For Fire Protection For Light Water Reactor Electric Generating Plants," as an acceptable fire protection approach for light-water reactors.

Question No: 098AS **Module 09: Regulations and Guides**

Question

How is the need for new regulatory documents identified and prioritized?

Response

The need for new regulatory documents may be identified from many sources. For regulations, the U.S. Congress can direct changes, industry or members of the public can petition for changes, or the agency itself may identify the need from its ongoing activities. Priority for completion of regulations depends upon applicable statutory requirements, contributions to safety (level of risk) or security, Commission direction, or role in improving effectiveness and efficiency of NRC or licensee activities.

IRRS Question and Response Report

Question No: 099 **Module 09: Regulations and Guides**

Question

What is the hierarchy of regulations and guides that are to be observed by the operator, list the current and future documents indicating their place in the hierarchy?

Response

The hierarchy of regulations and guides are delineated in Office of Nuclear Reactor Regulation Office Instruction, LIC 100, “Control of Licensing Bases for Operating Reactors.” LIC 100 describes the hierarchy and the roles of both the operator and the NRC:

Current licensing basis (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 54, 55, 70, 72, 73, 100, and appendices thereto; orders; license conditions; exemptions; and technical specifications. (LIC 100, page 1.1)

The CLB for a nuclear power reactor can be represented by a few categories of information that form a hierarchy structure in terms of associated change controls and reporting requirements. The approach to this hierarchy follows:

(1) Obligations are conditions or actions that are legally binding requirements imposed on licensees through applicable rules, regulations, orders, and licenses (including technical specifications and license conditions). The imposition of obligations should be reserved for matters that satisfy the criteria of 10 CFR 50.36, “Technical Specifications,” or are otherwise found to be of high safety or regulatory significance. The major distinction between obligations and other parts of the licensing bases is that changes generally cannot be made to obligations without prior NRC approval.
(2) Mandated licensing bases documents are documents, such as the updated final safety analysis report (FSAR), the quality assurance program, the security plan, and the emergency plan, for which the NRC has established requirements for content, change control, and reporting. The information that should be included in these documents is specified in applicable regulations and RGs. The change control mechanisms and reporting requirements are defined by regulations such as 10 CFR 50.59, “Changes, Tests and Experiments,” 10 CFR 50.54, “Conditions of Licenses,” and 10 CFR 50.71, “Maintenance of Records, Making of Reports.”
(3) Regulatory commitments are explicit statements to take a specific action agreed to, or volunteered by, a licensee and submitted in writing on the docket to the NRC. A regulatory commitment is appropriate for matters in which the staff has a significant interest but which do not warrant either a legally binding requirement or inclusion in the updated FSAR or a program subject to a formal regulatory change control mechanism. Control of these commitments is done within the applicable licensee programs and includes controls for evaluating changes and, when appropriate, reporting them to the NRC (LIC 100, pages 1.2–1.3).

Question No: 100 **Module 09: Regulations and Guides**

Question

What system of consultation with independent bodies and/or operators is in place to obtain opinions on regulations or guides produced by the Regulatory Body? Is this voluntary or required by legislation?

Response

As discussed in the response to Question 55, the NRC uses an independent body of experts, the Advisory Committee on Reactor Safeguards (ACRS), to advise the Commission on the adequacy of proposed reactor safety standards, review any generic issues or other matters referred to it by the Commission, and, on its own initiative, conduct reviews of specific generic matters or nuclear-facility safety-related items. There are also statutory review requirements in the enabling legislation that mandates ACRS review of certain matters (e.g., new licensing activities). The legislation (Section 29 of the AEA) established the ACRS. The Commission uses the advisory committee to obtain advice on regulations and associated regulatory guidance.

The NRC makes proposed requirements, including regulations and guidance, available for public comment (including the operators), and all comments are considered and resolved before issuance of a final rule. The notice and comment process is required by legislation (Administrative Procedures Act and National Environmental Policy Act).

IRRS Question and Response Report

Question No: 101 **Module 09: Regulations and Guides**

Question

What system of internal scrutiny and assessment has the Regulatory Body established to confirm the adequacy of any regulation or guide prior to its implementation?

Response

As discussed in the response to Question 100, the NRC follows a comprehensive internal review process to confirm the adequacy of any regulation or guide prior to its implementation. This process involves the Office of General Counsel (OGC), which provides either concurrence by stating “no legal objections,” or non-concurrence, with reasons stated. Approval at the highest levels of the agency, by a majority vote by the Commission, or in certain delegated circumstances, the Executive Director for Operations, is required before issuing a regulation. OGC assigns an attorney to each rulemaking working group responsible for drafting a regulation. This attorney interacts directly with technical, administrative, and managerial staff in developing the proposed and final rules. This attorney also provides legal counsel, which is crucial to the staff when preparing NRC mandated documents such as the regulatory and backfit analyses. Regulatory analyses are performed to ensure that the agency makes sound decisions regarding actions needed to protect the health and safety of the public or the common defense and security. The NRC’s backfit rules require that analyses be done to assess whether proposed regulatory actions imposing new or revised requirements are needed for operating nuclear power reactors. The NRC also makes proposed rules and many proposed guides available for public comment.

Question No: 102 **Module 09: Regulations and Guides**

Question

How do the regulations (which are mandatory) provide a framework for more detailed conditions in individual authorizations?

Response

All NRC regulations are contained in 10 CFR Parts 1–199. Within the national legal framework, the CFR has the force of law and provides the means by which the NRC issues and enforces all of its regulations. NRC licensees must comply with these regulations.

However, a well-established regulatory framework provides a means for more detailed considerations in individual authorizations. Some NRC regulations specifically call for the inclusion of more detailed requirements in individual licenses. For example, 10 CFR 50.36(b), states, “Each license authorizing operation…will include technical specifications.” Technical specifications include safety limits, limiting conditions for operation, surveillance requirements, design features, administrative controls, and the like. The NRC uses performance-based regulations for issues that, by their nature, are most effectively regulated in this manner versus those that must be prescriptive in order to properly implement. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. The NRC previously approved performance-based approaches in 10 CFR Parts 20, 50 (Option B, Appendix J, and the Maintenance Rule, 10 CFR 50.65), 60, and 61.

The NRC uses a combination of processes to impose and verify compliance with its regulations; including licensing, safety oversight, performance assessment, inspections and enforcement, as well as both domestic and international operational experience evaluations.

The reactor licensing process provides for the review and approval of changes to a license after initial licensing. These provisions address amendments to the operating license to support plant changes, license renewal, changes of ownership and license transfer, exemptions or temporary relief from NRC regulations, and increasing reactor power level thermal limits (power uprates).

As mentioned in the response to Question 99, a hierarchy of regulations and guides are delineated in the Office of Nuclear Reactor Regulation Office Instruction, LIC 100. Documents issued by entities other than the NRC are also reviewed and may be endorsed by the NRC if found to adequately address public health and safety.

IRRS Question and Response Report

Question No: 103 **Module 09: Regulations and Guides**

Question

Do the regulations provide for the Regulatory Body be able to issue non-mandatory guidance? What is the legal status of such guidance?

Response

All NRC guidance documents, such as NRC RGs, are nonlegally binding unless the NRC and licensee have agreed that the guidance will be used to demonstrate compliance with the regulations.

The NRC issues RGs through a standardized process that allows for public comment. These RGs serve to advise licensees on ways of meeting regulatory requirements and may include examples of acceptable ways to comply with particular requirements. However, following these guides is not mandatory for a licensee or applicant, and other methods may be used to meet an NRC requirement if the licensee or applicant can justify an alternate method.

In addition to RGs, the NRC also makes publicly available many of its own internal staff guidance documents and procedures for use by licensees. Technical or regulatory basis documents from which regulations are drawn, and standard review plans used by NRC staff, are readily available to the public.

Question No: 104 **Module 09: Regulations and Guides**

Question

What mechanisms are in place to ensure that regulations and guidance which are not issued by the Regulatory Body are approved within appropriate time-scales?

Response

Generally, the NRC does not rely upon other entities to issue necessary regulations or guidance, and therefore such mechanisms to ensure appropriate time scales are not necessary. However, the NRC may incorporate references or endorse external documents issued by entities other than itself in order to enhance and improve the effectiveness of regulations and guides by incorporating an even broader scope of knowledge and expertise.

As discussed in the response to Question 98, regulatory guides are developed when necessary, or useful for implementation of regulatory requirements, and development of these guidance documents follows a process similar to the rulemaking process, but at a lower level of approval. For many applications, the NRC endorses standards developed by national consensus standard bodies. A prime example is 10 CFR 50.55a, in which the NRC incorporates by reference into the regulations standards developed by the American Society of Mechanical Engineers on design, construction, installation, and testing of components and structures. The incorporation of these references into regulations follows the same timescale metric to which all NRC regulations are subject.
On average, this is a 2 year process that includes 1 year for development and issuance of a proposed rule, a minimum 75 day public comment period, and 1 year for the development and issuance of a final rule.

As discussed in the response to Question 102, the NRC uses a balance of performance-based and prescriptive regulations to most effectively accomplish its mission

IRRS Question and Response Report

Question No: 105 **Module 09: Regulations and Guides**

Question

When developing regulations and guides, does the Regulatory Body take into account internationally recognized standards?

Response

NRC MD 6.5, “NRC Participation in the Development and Use of Consensus Standards,” dated November 2, 1999, provides guidance on and encourages the use of consensus standards, where practical. One of the objectives of this directive is to “Promote the efficient and effective use of NRC resources by focusing staff participation on the development of standards that address a defined current or anticipated regulatory need.”

This directive advises that staff should seek out existing consensus standards to address a need for new or revised technical standards rather than writing a Government-unique standard. This could potentially include international standards. In order to improve agency understanding of consensus standards, this management directive encourages staff participation in the development of consensus standards. In addition, this directive implements Office of Management and Budget (OMB) Circular A 119 and states that “OMB Circular A 119 does not establish a preference between domestic and international consensus standards, but in the interests of promoting trade and implementing the provisions of international treaty agreements, international standards, such as those from the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC), are considered for agency regulatory and procurement applications.”

These international efforts include design, manufacturing, research and development, and marketing. With these international efforts comes the desire to harmonize the licensing requirements as much as possible. For NRC purposes, the international efforts are an opportunity to build upon work done by others and to benefit from their experience. International collaboration with other regulatory agencies and international standards organizations is useful for identifying the need for codes and standards and for facilitating their development.

The NRC technical staff members routinely provide input to the development of internationally recognized standards and act as agency representatives at international conferences affecting the development of internationally recognized standards. Knowledge gained from these interactions is used in the development of NRC regulations and regulatory guidance.

For further information, see the response to Question 16AS.

IRRS Question and Response Report

Question No: 106 **Module 09: Regulations and Guides**

Question

Do the regulations and guides cover the areas of pre-disposal, disposal and rehabilitation? Government shall ensure that adequate arrangements are

Response

The U.S. program for specific licensing of nuclear power plant operations, and for possession of fuel cycle materials (by waste processors and disposal facility operators), ensures that responsibilities are clearly delineated and enforceable. Reactor licensees are required, under regulation, to ensure the safe storage and disposal of their radioactive waste.

Applicable requirements and guidance for use by licensees and staff: the NRC has extensive regulations and guidance that cover these areas, including, but not limited to the following:

I. Predisposal – Waste classification and waste characteristics in 10 CFR 61.55, "Waste Classification," and 10 CFR 61.56, "Waste characteristics," respectively (imposes requirements on generator of solid radioactive waste prior to its disposal); General Design Criterion 60, "Control of Releases of Radioactive Materials to the Environment," of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," pertaining to the ability of a reactor operator to safely handle solid radioactive wastes; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," as it relates to radioactive material packaging for shipment offsite for processing or disposal.

II. Disposal – The NRC's regulation for low-level waste disposal facilities is contained in 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste." NUREG 1200, the Standard Review Plan for reviewing a 10 CFR Part 61 license application, contains dozens of references to staff guidance that has been developed over the last 25 years pertaining to low-level waste disposal.

III. Rehabilitation (decommissioning and release of sites) – The NRC's regulations for rehabilitation are contained in 10 CFR Part 20, Subpart E, "Radiological Criteria for License Termination," for all licensees, and for nuclear reactors in 10 CFR 50.82, "Termination of License," which references Subpart E of 10 CFR Part 20. Financial assurance provisions for ensuring that sufficient funds will be available to decommission a reactor are contained in 10 CFR 50.75, "Reporting and Recordkeeping for Decommissioning Planning." There are a number of guidance documents for these regulations, including NUREG 1700, Revision 1, "Standard Review Plan for Evaluating Nuclear Power Reactor License Termination Plans," issues April 2003; NUREG 1577, Revision 1, "Standard Review Plan on Power Reactor Licensee Financial Qualifications and Decommissioning Funding Assurance," issued February 1999; and NUREG 1757, Volume 1, Revision 2, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees," issued September 2006.

Nearly all low-level waste from operations and decommissioning has been permanently disposed of in low-level disposal facilities. The only category of waste that cannot be disposed of is greater-than-Class-C waste, and currently there is less than 1,000 cubic meters of this waste class from reactors in storage. Several reactors have been decommissioned and their sites released for unrestricted use (spent fuel remains in storage in a relatively small licensed facility at the site, pending disposal in a geologic repository). Others are in the process of being decommissioned.

The United States has no regulation that requires the reporting of inventories or reducing or preventing waste generation, but these objectives are met in practice. For inventories of power reactor waste, RG 1.21, "Measuring, Evaluating, and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Materials in Liquid and Gaseous Effluents from Light-Water-Cooled Nuclear Power Plants," Revision 1, is a template for an annual report of inventories of low-level waste from nuclear power plants. The NRC has a formal policy statement on waste minimization and volume reduction (see 46 Federal Register 51100; Oct. 16, 1981). In addition, the high cost of disposal in the United States has been an effective incentive for reactor licensees to prevent and minimize their radioactive waste generation.

The United States has no regulation that defines the conditions under which materials may be cleared for unrestricted use or recycling. The NRC has considered such a rule recently but has deferred it for the time being. In the meantime, release of materials (including scrap metal) with radioactive surface contamination from commercial facilities, such as power plants, is controlled by NRC RG 1.86, "Termination of Operating Licenses for Nuclear Reactors," and case-by- case approvals are obtained using NRC's alternate disposal provision in 10 CFR 20.2002, "Method for Obtaining Approval of Proposed Disposal Procedures."

For spent fuel management, NRC regulations for transportation and storage cover the periods of predisposal, disposal, and rehabilitation, including the responsibilities of the various parties involved in the transportation, storage, and rehabilitation (or decommissioning). In some cases the regulations of other government agencies (e.g., U.S. Department of Transportation) have to be met in addition to the NRC regulations.

For radioactive waste management of high-level waste, U.S. laws provide roles and responsibilities for government agencies. High-level waste disposal in the United States involves three government agencies, the U.S. Environmental Protection Agency as the agency responsible for setting the standards, the NRC as the regulatory authority, and the U.S. Department of Energy as the developer of a high-level waste repository.

The regulatory body (NRC) has issued regulations that require information and documentation with respect to the inventory that is to be disposed at a high-level waste disposal facility. Further, the regulations provide for the long-term recordkeeping after closure of the disposal facility to ensure information regarding the disposed waste is preserved.

The regulations provide for the clear delineation of responsibilities and development of information with respect to the inventory of a high-level waste disposal facility, including the decommissioning and dismantlement of surface facilities. The regulations also provide specific requirements for (1) the

dismantling and decontamination of the surface facilities, (2) the establishment of markers and land-use controls to prevent inappropriate activities at the disposal facility after permanent, and (3) the transfer of regulatory oversight after closure of the facility (i.e., after permanent closure of the disposal facility, oversight of the facility is transferred from NRC to the U.S. Department of Energy—leaving a single U.S. Government agency responsible for safety of the high-level waste disposal facility).

IRRS Question and Response Report

Question No: 107 **Module 09: Regulations and Guides**

Question

How do the regulations address decommissioning activities?

Response

Summary

NRC decommissioning regulations and guidance documents are clear and comprehensive. In 10 CFR 20, Subpart E, the NRC defines the radiological criteria for unrestricted and restricted use for license termination. The power reactor decommissioning and license termination process is defined in 10 CFR 50.82. These regulations provide the mandatory and legal requirements. Guidance documents, such as RGs, standard review plans, and NUREGs, have been issued to provide licensees with programs and methodologies that are acceptable to the NRC staff.

Introduction

The NRC's nuclear regulatory activities include the decommissioning of nuclear facilities, which means “to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license; or release of the property under restricted conditions and termination of the license.” The NRC regulates the decontamination and decommissioning of nuclear facilities with the ultimate goal of license termination. In general, the NRC's regulatory process has five main components: (1) developing regulations and guidance for applicants and licensees, (2) licensing or certifying applicants to use nuclear materials or operate nuclear facilities or decommissioning that permits license termination, (3) overseeing licensee operations and facilities to ensure that licensees comply with safety requirements, (4) evaluating operational experience at licensed facilities or involving licensed activities, and (5) conducting research, holding hearings to address the concerns of parties affected by agency decisions, and obtaining independent reviews to support NRC regulatory decisions. This question focuses mostly on component 1. The process for all regulatory activities, including decommissioning, is described in detail at: http://www.nrc.gov/what-we-do/regulatory/rulemaking/rulemaking-process.html. Although the process for guidance is not as involved as for a rulemaking, there are still components that are shared (e.g., availability in draft for public comment and a need for a cost-benefit analysis). The decommissioning regulatory program addresses the following decommissioning activities:

-developing regulations and guidance to assist staff and the regulated community
-conducting research to develop data, techniques, and models used to assess public exposure from the release of radioactive material resulting from site decommissioning
-reviewing decommissioning plans and reviewing and approving license termination plans (LTPs)
-reviewing and approving license amendment requests for decommissioning facilities
-inspecting licensed and nonlicensed facilities undergoing decommissioning
-developing environmental assessments and environmental impact statements (EISs) to support the NRC’s reviews of decommissioning activities
-reviewing and approving final site status survey reports
-conducting confirmatory surveys

The NRC assures that safety requirements are being met throughout the decommissioning process by reviewing decommissioning or license termination plans, conducting inspections, and monitoring the status of activities to ensure that radioactive contamination is reduced or stabilized.

Applicable Regulations

-10 CFR Part 20, “Standards for Protection against Radiation”—Decommissioning radiological safety criteria are in NRC regulations at 10 CFR Part 20, Subpart E, which is also known as the License Termination Rule (LTR).
-10 CFR Part 50—Safety documentation information for each reactor decommissioning stage is described in 10 CFR 50.82. This regulation provides the major steps in the reactor decommissioning process: notification, submittal and review of the postshutdown decommissioning activities report (PSDAR), submittal and review of the LTP, implementation of the LTP, and completion of decommissioning. At each stage, documentation is provided to support the completion of the stage.

Staff Implementation

NUREG 1757 provides guidance for planning and implementing license termination under the LTR (10 CFR Part 20, Subpart E). NUREG 1700, Revision 1, provides guidance for NRC staff in conducting safety reviews of license termination plans, to ensure the quality and uniformity of reviews and to present a well-defined base from which to evaluate the requirements for terminating the license of a nuclear power plant.

Guidance to Licensees

Guidance is publicly available information. The primary decommissioning guidance documents are NUREG-1757, “Consolidated Decommissioning Guidance,” and the NUREG-1700, Revision 1, “Standard Review Plan for Evaluating Nuclear Power Reactor License Termination Plans,” issued April 2003. In addition, NUREG 1628, “Staff Responses to Frequently Asked Questions Concerning Decommissioning of Nuclear Power Reactors,” issued June 2000, reflects the feedback from public meetings and staff experience over the past regarding decommissioning. Additional guidance is provided at http://www.nrc.gov/what-we-do/regulatory/decommissioning/reg-guides-comm.html. Licensees are required to prepare the following information in accordance with 10 CFR 50.82:

-Notification: The licensee/operator is required to submit a written notification to the NRC within 30 days, certifying to the NRC that the nuclear fuel has been permanently removed from the reactor vessel.
-Submittal and Review of the Postshutdown Decommissioning Activities Report: Before or within 2 years following cessation of operations, the licensee must submit a PSDAR. The PSDAR must include a description and schedule for the planned decommissioning activities, an estimate of the expected costs, and a discussion that provides the means for concluding that the environmental impacts associated with the decommissioning activities will be bounded by appropriately issued EISs. The necessary components required in a PSDAR are documented in NRC RG 1.185, “Standard Format and Content for Post-Shutdown Decommissioning Activities Report.” Other guidance for decommissioning nuclear power plants is addressed in NRC RG 1.184, “Decommissioning of Nuclear Power Reactors.”
-License Termination Plan: Each power reactor must submit an application for termination of its license within 2 years before the planned license termination date. The LTP is a supplement or equivalent to the FSAR. The application must be accompanied or preceded by an LTP submitted for NRC approval. There are numerous opportunities built into the process to allow stakeholders and members of the general public to participate in such decisions. The technical review is guided by NUREG 1700. The LTP is approved by license amendment. NRC staff will inspect the licensee during decommissioning operations to ensure compliance with the approved LTP. These inspections will normally include in-process and confirmatory radiological surveys. Decommissioning must be completed within 60 years of permanent cessation of operations unless otherwise approved by the Commission.
-Completion of Decommissioning: At the conclusion of decommissioning activities, the licensee will submit a final radiation survey report. The NRC will terminate the license if it determines that the remaining dismantlement has been performed in accordance with the approved LTP, and that the final radiation survey and associated documentation demonstrates that the facility and site are suitable for release in accordance with the LTR. Decommissioning must be completed within 60 years of permanent cessation of operations unless otherwise approved by the Commission. Guidance documents on reactor decommissioning that may be useful to licensees and other stakeholders are NUREG 1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),” Revision 1, issued August 2000; NUREG-1628; NUREG-1577; RG 1.184; RG 1.191, “Fire Protection Program for Nuclear Power Plants during Decommissioning and Permanent Shutdown”; RG 1.185; and NUREG 0586, “Final Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities.”

IRRS Question and Response Report

Question No: 111 **Module 09: Regulations and Guides**

Question

Do they address practices and intervention situations?

Response

The NRC regulations and guides address practices and intervention situations in the areas of occupational exposure and public exposure. The NRC's regulations are found in 10 CFR 20. This regulation imposes requirements for annual personnel radiation exposure limits, establishes radiation protection methods, establishes a philosophy of operations that radiation exposures must be “as low as is reasonably achievable” (ALARA), authorizes discharge or release of radioactive materials in effluents within limitations, and establishes recordkeeping requirements. Licensees are required to have procedures that are used to implement their ALARA program. The ALARA procedures typically consist of job planning, prejob briefings, and job coverage to maintain radiation dose to ALARA.

RGs are issued in 10 divisions and are intended to aid licensees and others in implementing regulations (see references below). The RGs that are most applicable to radiation protection are provided as Division 1, “Power Reactors,” and Division 8, “Occupational Health.” There are reports on radiation exposure data, and guidance concerning the recording and reporting of occupational exposure is made publically available through the NUREG 0713 (“Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities”) reports.

In cases where actual personnel radiation exposures arise from an accident or from an inadequately controlled work practice, licensees are required to notify the NRC in a time frame that is proportional to the severity of the event. For example, unplanned radiation exposure events exceeding 100 millirem (1 millisievert) are reported using a quarterly performance indicator program. For more serious events such as overexposures, licensees are required to report to the NRC in accordance with 10 CFR 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors.” For accident conditions, licensees are required to promptly report using an emergency telephone system to the NRC Operational Center (24 hours per day, 7 days per week).

The NRC inspects the routine operational radiation protection program and ensures that the licensee procedures and ALARA programs are effective in reducing and averting personnel radiation exposures. The regulatory inspection program is conducted under the NRC Reactor Oversight Process (ROP). The ROP is discussed in detail in the responses to Questions 139 and 140. The NRC has full-time, onsite NRC resident inspectors that perform prompt inspection and regulatory response to accidents or radiation overexposure events. The NRC also has specialized health physics inspectors in the NRC regional offices that provide periodic specialized radiation protection inspections and are available to respond to radiological events and provide specialized inspection and evaluation support to the nuclear facility. If the licensee is in noncompliance with regulatory requirements, the NRC has the authority to issue the licensee a violation of regulatory requirements or a finding of a performance deficiency. The violations or findings are evaluated by the NRC to determine their significance. The significance levels range from green findings of very low safety significance, to white findings of low safety significance, to yellow findings of moderate safety significance, to red findings of high safety significance.

The licensees are required to utilize a corrective action program to investigate and correct performance deficiencies (including radiological performance deficiencies). Normally, the licensee corrective action program is sufficient to correct deficiencies. However, if further NRC intervention is required, the NRC can issue a Confirmatory Action Letter that suspends the licensee activities until the issues are resolved. If further action is needed, The NRC can suspend licensee activities by order (see 10 CFR Part 2, Subpart B, “Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties.”)

For nuclear accidents, the NRC will activate the NRC Headquarters Emergency Response Center. Specialized radiological incident support is also provided by other Federal agencies (e.g., Department of Energy, Department of Homeland Security Federal Emergency Management Agency). Normal responsibility for local intervention rests with State authorities. The NRC performs independent assessments and provides results, when requested, for consideration by designated Federal or State emergency response officials during emergencies at reactor sites.

IRRS Question and Response Report

Question No: 112 **Module 09: Regulations and Guides**

Question

How do the regulations (which are mandatory) provide a framework for more detailed conditions in individual authorizations for different types of radiation source?

Response

Activities associated with possession, use, processing, exporting, importing, and certain aspects of transporting nuclear materials and waste are licensed by the NRC. To be licensed to use nuclear materials or operate a facility that uses nuclear materials, an entity or individual submits an application to the NRC based on applicable requirements coded in different parts of 10 CFR, Chapter I, “Nuclear Regulatory Commission.” For example, the cite at 10 CFR 50.54 contains paragraphs that are conditions in every nuclear power reactor operating license issued under 10 CFR Part 50 except where specifically noted. NRC staff reviews this information, using standard review plans that are based on the applicable regulations, to ensure that the applicant's assumptions are technically correct and that the environment will not be adversely affected by a nuclear operation or facility. The regulations and standard review plans also promote the common defense and security that must be addressed by the applicant as well.

The radiation sources inside a nuclear power plant are controlled by the licensee’s radiation protection staff. The licensee must meet the 10 CFR 20 standards for protection against radiation. These regulations require that sources be identified, quantified, and posted with signs to advise workers of the radiation. Radiation areas, High Radiation Areas, and Very High Radiation Areas are controlled, as well as airborne radioactivity and surface contamination. Work activities are planned and controlled by planners and radiation protection staff with respect to radiation exposure, and radiation exposures are maintained ALARA.

Applicable Requirements

The NRC regulates the following activities associated with nuclear power plant uses of nuclear materials in addition to the nuclear fuel that is used in the plant:

Nuclear power plants are licensed to use 10 CFR Part 30 (“Rules of General Applicability to Domestic Licensing of Byproduct Material”) sources that are manufactured as either specifically licensed or generally licensed sources. The specifically licensed sources are those sources typically used in calibration of equipment and startup of the reactor. The generally licensed sources are those sources typically used in explosive detectors by the security force.

The NRC's regulations are found in 10 CFR Chapter I. Chapter I is divided into Parts 1 through 199. The following are the principal parts governing the licensing of nuclear materials: Part 19, “Notices, Instructions and Reports to Workers; Inspection and Investigations”; Part 20;Part 21, “Reporting of Defects and Noncompliance”; Part 30; Part 32, “Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material”; Part 33, “Specific Domestic Licenses of Broad Scope for Byproduct Material”; Part 40, “Domestic Licensing of Source Material”; Part 70, “Domestic Licensing of Special Nuclear Material”; Part 71, “Packaging and Transportation of Radioactive Material”; Part 110, “Export and Import of Nuclear Equipment and Material”; and Part 150.20, “Recognition of Agreement State Licenses.”

Guidance

The following RGs are the ones most relevant to industrial uses of nuclear material: RG 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data”; RG 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program”; RG 8.13, “Instruction Concerning Prenatal Radiation Exposure”; RG 8.15, “Acceptable Programs for Respiratory Protection”; RG 8.20, “Applications for Bioassay for I 125 and I-131”; RG 8.25, “Air Sampling in the Workplace”; RG 8.29, “Instruction Concerning Risks from Occupational Radiation Exposure”; RG 8.32, “Criteria for Establishing a Tritium Bioassay Program”; RG 8.34, “Monitoring Criteria and Methods To Calculate Occupational Radiation Doses”; RG 8.35, “Planned Special Exposures”; and RG 8.36, “Radiation Dose to the Embryo/Fetus.”

IRRS Question and Response Report

Question No: 113 **Module 09: Regulations and Guides**

Question

I. How are the recognized international standards taken into account during the development and modification of regulatory requirements and guides?
II. How is the consistency of different regulatory requirements and guidance assured?
III. Is there an approved process for elaborating and modifying the regulatory requirements and guides?

Response

I. As further discussed in the response to Question 105, NRC MD 6.5 “provides guidance on and encourages the use of consensus standards, where practical. A consensus standard is defined as a technical standard developed or adopted by a domestic or international voluntary consensus body.

MD 6.5 advises that staff should seek out existing consensus standards to address a need for new or revised technical standards rather than writing an NRC-unique standard; thus, an international standard could be used. In addition, NRC technical staff routinely participates in international meetings for the development of standards. Knowledge gained from these interactions may be used in the development of new or revised NRC regulations and regulatory guidance.

II. The NRC Rulemaking Coordinating Committee (RCC) was established in 1998, to ensure that the NRC rulemaking process remains consistent among the program offices. The RCC is chaired by the Office of Administration and consists of representatives from the primary offices involved in rulemaking. The focus of the RCC is to ensure consistency in methods used to develop and promulgate rules and to facilitate initiatives for improving all aspects of the rulemaking process. The RCC meets every month.

III. MD 6.3 describes rulemaking activities and provides guidelines for the NRC program offices for coordinating, concurring, and reporting on rulemakings. MD 6.3 was revised in 2005 to incorporate recommendations from the Rulemaking Improvement Task Force Working Group Report. Each program office has internal procedures and instructions that provide additional rulemaking and regulatory modification guidance. The Office of Nuclear Regulatory Research is responsible for modifying existing guides and developing new guides in cooperation with the other program offices. Specific office instructions exist to control the RG and rulemaking development, revision, and withdrawal process.

IV. The NRC staff follows the procedures for rulemaking and regulatory guidance development and modification.