FUEL CYCLE
LICENSING REVIEW HANDBOOK

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ANNUAL UPDATE

The Fuel Cycle Safety and Safeguards (FCSS) Licensing Review Handbook (LR Handbook) provides a description of the procedures for licensing-related actions and is intended to be a living document. The electronic version will be maintained in ADAMS by assigned staff in FCSS. A link to the LR Handbook will be maintained on the Nuclear Materials Safety and Safeguards (NMSS) internal website under the 'Important' drop down in the right hand column.

Proposed corrections, updates, and suggestions for the LR Handbook should be posted using the Ask option on the FCSS Project Manager Information community of practice (CoP) at the NRC Knowledge Center (NKC), or provided via email to the individuals listed on the title page of this document. (Note: Instructions for obtaining an account on the NKC are available at the NRC Knowledge Management website under Knowledge Center Resources/Request Access or in ADAMS at ML090930410).

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2009 Summary of Updates to the PM Handbook

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Minor	Date and location	i
Minor	Add Table of Changes	x
Minor	Modify list of what OGC must review	18
Minor	Notify interested parties 30 days before hearing	19
Minor	Closed meeting not published to PMNS	20
Major	**Added Template 4.4, 4.5, 4.6, 4.8 and 4.9**	**22**
Minor	No need for 665S/P when forward document to DPC	31
Minor	Example of withholding 2.390(a)(3) for historic and endangered species	40
Major	**Add list of Metric Deadlines**	**43**
Minor	Add information on Reviewing Officials review	47
Major	**Textual updates and add template 9.1**	**52**
Minor	Add note to publish FRN in accordance with Part 2.106	53
Minor	Add Note about 2.104-2.106	54
Major	**EA and FRN may be required for exemption**	**60-61**
Major	**Guidance on publishing hearing related information in FRNs**	**95**
Minor	Contested hearing for those who have standing	96
Minor	Added References to FRN checklist and templates	99
Major	**Rearrange Information Security Requirements section to separate SUNSI, Safeguards, and Confidential. Also, add links to additional guidance.**	**102-104**
Major	**Add examples and guidance on updating the internal and public Websites.**	**106-107**

ABSTRACT

The Project Manager (PM) is the lead U. S. Nuclear Regulatory Commission (NRC) staff representative in conducting agency business with applicants, licensees, contractors, other government agencies, industry, and the public. The Fuel Cycle Licensing Review Handbook (LR Handbook) is intended to assist PMs for Part 40 and Part 70 licensees and Part 76 Certificate of Compliance holders by providing a comprehensive reference for understanding and implementing functions and responsibilities. The LR Handbook is broken into two sections. Section I (Chapter 1-5) provides a general overview of the function and qualifications of the PM. This section covers key areas, such as roles and responsibilities, and the proper interaction between the NRC and stakeholders. Section II (Chapters 6-19) contains more detailed procedures for conducting common licensing tasks. In each chapter, appropriate examples and templates provide boilerplate language for many common licensing documents. The LR Handbook defines the responsibilities for managing fuel cycle licenses , provides the tools to assist in that management, as well as information useful to technical reviewers and other staff.

SECTION I
GENERAL PROJECT MANAGER GUIDANCE

CHAPTER 1
REGULATORY OVERVIEW

1.1 Introduction

This section provides a brief overview of the mission, goals, legal authorities, organization, and operational principles of the NRC. It provides the NRC staff with a frame of reference for understanding the overall expectations, functions, and roles of the PM, as well as expectations for all NRC staff and management.

1.2 Mission

The mission of the NRC is to license and regulate the Nation's civilian 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.

1.3 Goals

The NRC's strategic plan for Fiscal Year 2008-2013 (NUREG-1614) describes NRC's general goals. PMs need to be familiar with the goals described in the Strategic Plan as the foundation for their varied regulatory activities. The Plan establishes two strategic goals for the NRC to conduct an efficient regulatory program that strives to achieve the following:

I. Safety: Ensure adequate protection of public health and safety and the environment.

II. Security: Ensure adequate protection in the secure use and management of radioactive materials.

A broader discussion of the Strategic Plan can be viewed on the NRC internal web page under "NRC Organization/Strategic Plan (NUREG-1614)."

1.4 Legal Authorities

The NRC was created as an independent Federal Agency by the Energy Reorganization Act of 1974, which abolished the U. S. Atomic Energy Commission (AEC) The Act of 1974 assigned the Energy Research and Development Administration (ERDA, now the Department of Energy-DOE) the responsibility for the development and production of nuclear weapons, promotion of nuclear power, and other energy-related work, and assigned to the NRC the regulatory work, which does not include regulation of defense nuclear facilities. This act, along with the Atomic Energy Act of 1954, as amended, provides the foundation for regulation of the nation's nuclear fuel cycle facilities. The foundation established in these two Federal laws provides the fundamental policy of the United States for the peaceful uses of nuclear materials. Other important statutory authorities that govern the regulation and operation of the fuel cycle facilities include:

- National Environmental Policy Act of 1969, as amended;
- Nuclear Non-Proliferation Act of 1978;
- Low-Level Radioactive Policy Amendments Act of 1985;
- Energy Policy Act of 1992; and
- Energy Policy Act of 2005
- Solar, Wind, Waste and Geothermal Power Production Incentives Act of 1990

Based on these and other applicable statutes, NRC has issued regulations in Title 10, Chapter I of the United States Code of Federal Regulations (CFR). Copies of Title 10 CFR are distributed annually to PMs and are also available electronically on the NRC's home page (www.nrc.gov), via the Electronic Reading Room or in the Law Library in One White Flint North or the NRC Library in Two White Flint North.

1.5 NRC Organization

The internal NRC home page contains organizational charts under the heading "NRC Organization/Office Org Charts." This web page is revised frequently to reflect the many reorganizations that occur as the NRC seeks improved ways to fulfill its mission. The page describes the various components of the NRC, including the Commission, the major offices (e.g., EDO, NMSS, NRR, regional offices, etc.), staff office divisions, and branches. The web page also includes announcements on planned reorganizations.

1.6 NRC Safety Philosophy

The NRC safety philosophy comprises several closely interrelated elements: accountability to the public, defense in depth, licensee responsibility, regulatory effectiveness, and safety culture.

ACCOUNTABILITY TO THE PUBLIC dictates the NRC is accountable to the American people and their elected representatives, the Congress. In addition, the Atomic Energy Act ensures the public has an important role to play as the agency addresses issues of safety and health. For members of the pubic to perform that role, they need sound, complete, and up-to-date information from NRC.

DEFENSE IN DEPTH ensures that successive measures are incorporated into the design and operating procedures for nuclear installations to compensate for potential failures in protection or safety measures, wherever failures could lead to serious public or national security consequences.

LICENSEE RESPONSIBILITY means the licensee bears the primary responsibility for conducting nuclear activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them. This allows the agency to focus its inspection, licensing, and other activities on those areas where the need, and the likely safety and safeguards benefit, is greatest.

REGULATORY EFFECTIVENESS emphasizes that certain safety standards and practices will be required, whatever the cost. Over and above that baseline, additional safety upgrades will

be required only if their benefits justify the added cost. Moreover, the NRC strives to foster efficiency, so that a given level of safety and safeguards can be achieved through the most cost-effective means.

SAFETY CULTURE recognizes each licensee's responsibility to establish and maintain a set of attitudes that ensure safety issues get the attention they warrant. A safety culture encourages a questioning and learning attitude toward protection and safety and discourages complacency. It reflects an understanding that safety and protection are permanently the highest priority; that problems must be identified and addressed promptly and appropriately.

1.7 NRC Principles of Good Regulation

In 1991, the Commission issued the NRC Principles of Good Regulation as a guide to both agency decision-making and individual conduct of NRC employees. These principles of Independence, Openness, Efficiency, Clarity and Reliability are fundamental guideposts in ensuring the quality, correctness, and consistency of our regulatory activities. An explanation of each of these principles is discussed on the NRC internal web page under "NRC Organization/Principles of Good Regulation."

1.8 Safety and Compliance

As commonly understood, safety means freedom from exposure to danger or protection from harm. In the context of NRC regulation, safety is providing reasonable assurance of adequate protection for the public in connection with the use of source, byproduct and special nuclear materials. The definition of compliance is much simpler. Compliance simply means meeting applicable regulatory requirements.

The nexus between compliance and safety can be described as follows:

- Safety is the fundamental regulatory objective, and compliance with NRC requirements gives the NRC confidence that safety is being maintained.
- The NRC has statutory authority to require licensee actions above and beyond existing regulations necessary to maintain public health and safety, up to and including a cessation of licensed activities.
- The NRC may permit continued operations if noncompliance is not significant from a risk perspective and does not pose an undue risk to public health and safety.
- The NRC can and should take action to modify or remove requirements from the regulations or licenses that have no safety benefit.
- The NRC should use a risk-informed approach wherever possible when adding, removing, or modifying regulations.

This discussion on safety and compliance is taken from NRC Announcement No. 114 dated December 5, 1997. The Commission and the EDO expects that all regulatory staff understand the relationship between safety and compliance.

1.9 Reasonable Assurance

Safety is the licensee's/applicant's first and foremost responsibility, and remains with the licensee/applicant, even after a license is issued. Therefore, a licensee/applicant seeking authorization to perform activities that pose hazards or potential threats to the public health and safety must provide information that constitutes a sufficiently thorough safety evaluation and analysis in order for the regulator of those activities to make sure that the health and safety of the public is adequately protected. The information provided depends on the requirements levied on the licensee/applicant.

The NRC has the responsibility to review the applicant's safety analysis for thoroughness and completeness. The licensee's submittals should have sufficient documentation to demonstrate compliance with the regulatory requirements which are designed to protect health, safety, and the environment. The NRC's independent review is comprehensive. However, it but focuses on program commitments rather than a detailed review of the licensee's internal procedures. The scope of the review must be sufficient to persuade the PM and the reviewers that, given the licensee's infrastructure, license commitments, and the NRC inspection and oversight activities, the public health and safety will be adequately protected.

1.10 Risk-Informed, Performance-Based Regulation

NRC has adopted a risk-informed, performance-based regulatory approach, which applies to the full range of NRC rulemaking, licensing, inspection, assessment, enforcement, and other regulatory actions. A risk-informed, performance-based approach relies on risk insights, engineering analysis and judgment, and performance history. These data are used to (1) develop measurable and/or calculable parameters for monitoring systems and licensee performance, (2) establish objective criteria for evaluating performance, and (3) focus regulatory decision making on results.

The risk-informed, performance-based approach can be used to focus regulatory attention on health, safety, and security by considering risk in a more coherent and consistent manner. It can also be used, where appropriate, to reduce unnecessary conservatism in deterministic approaches. Or, it can identify areas with insufficient conservatism and provide the basis for additional requirements or regulatory actions. This approach emphasizes results rather than the process or method used by a licensee.

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CHAPTER 2
ROLES, RESPONSIBILITIES, AND TRAINING

2.1 Overview

FCSS PMs have the primary responsibility to oversee the review of licensing actions for their assigned facilities. In addition, they represent NRC during interactions with applicants, licensees, contractors, other government agencies, industry, and the public. FCSS staff may be assigned as primary and backup PMs. Backup PMs should be cognizant of the regulatory and operational status of assigned facilities so they can serve without interruption in the absence of the PM. Both should also be familiar with and use the NMSS guidelines for effective communication of work assignments, found in attachment 1 of NMSS Policy and Procedure Letter (P&PL) 1-87 (ML073241340), Office of Nuclear Material Safety and Safeguards Internal Communications.

For designated facilities, PMs serve as the NRC's:

- Liaison with the applicant or licensee/certificate holder on licensing issues,
- Focal point for licensing information and communications,
- Manager and administrator of licensing projects,
- Reviewer of licensing correspondence and evaluations,
- Maintainer of licensing documents and information,
- Lead for licensing related projects and assignments, and
- Lead for the coordination, preparation, and participation in licensing meetings, hearings, and briefings.

Principal Roles and Responsibilities of the Fuel Cycle Project Manager:

- Maintain focus on safety and security,
- Plan, manage, track, coordinate, and conduct reviews of licensing actions,
- Monitor safety and security issues and inform appropriate staff of significant events,
- Continue an open dialogue with inspection staff,
- Respond to inquiries and licensing actions in a timely manner,
- Communicate with applicant, licensees, technical reviewers and inspectors in an open, frequent, and forthright manner,
- Respond to public inquiries in a timely and responsible manner,
- Strive to attain certification as license reviewers in their areas of technical expertise,

- Review and sign the quarterly bills to licensees for their designated facilities in a conscientious and timely manner, and

- Handle sensitive (i.e., proprietary and classified) information appropriately.

2.2 Communications

The PM is the NRC's main point of contact (POC) with licensees. All communications (i.e., incoming and outgoing) should be through the PM. The PM should participate in frequent communications with regional counterparts regarding licensing activities at their facilities. The PM should attend significant meetings for their facilities and ensure that cognizant NRC staff and management are informed of the meetings and their output.

The PM should cultivate a close working relationship with licensee staff and management. To encourage this communication, PMs should visit their assigned licensees as directed in the September 5, 2007, Staff Memorandum, "Division of Fuel Cycle Safety and Safeguards Management Expectation for Project Manager Site Visits," (ML072190254)[1]. These visits should be scheduled in conjunction with other regulatory activities, such as licensing site visits or licensee performance review meetings. Direct and effective communication with licensee staff and management is vital to ensure the PM is informed about significant inspection and operational activities.

2.3 Information Management

The PM should maintain an updated License Application, Environmental Assessment, Emergency Plan, and other documents readily accessible to NRC staff and management.

The PM should maintain accurate files for licensing actions under review and, to some extent, of past actions. The PM should be aware of people who possess information about the facility, in order to obtain the information when necessary. The PM should stay apprised of information obtained from reports, inspections, enforcement, other NRC actions (i.e., fuel quality and transportation package reviews), and the media about the facility. When potential problem areas are identified, the PM should be ready to formulate or cause others to propose potential solutions for, and evaluations of, the problems.

The PM should be prepared to inform management about the status, problems, and progress of licensing activities at the facility. These transmissions need to be timely and effective. The PM also maintains liaison with Office of General Counsel (OGC) with respect to processing license amendments, orders, reviews, and exemptions. The PM is also responsible for handling technical problems that may affect preparation for a hearing or the hearing itself.

Refer to the Miscellaneous Chapter of this Handbook for additional information and guidance on how the PM is to manage licensing documents (i.e. decommissioning financial assurance

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[1] When clicking hyperlinks with accession numbers, a pop-up may appear requesting username and password. Generally clicking cancel on the pop-up will allow the document to open.

documents, event reports, Freedom of Information Act (FOIA) requests, Security Requirements for Classified and Sensitive Unclassified Non-safeguards Information).

2.4 Knowledge of NRC and Assigned Facility

The PM should have a working knowledge of NRC procedures, the regulatory basis for NRC decisions, and an understanding of the designated facility's systems and structures.

PMs should maintain unescorted access authorizations for designated facilities. Normally, such authorization would require current site access training. PMs should be prepared to escort senior Agency managers on facility tours.

The PM is expected to be familiar with NRC and licensee correspondence related to the designated facility (i.e., inspection reports, safety and safeguards evaluation reports, generic communications, enforcement correspondence, and licensee submittals). The PM should be able to identify necessary corrective action regarding any NRC action, inaction, or correspondence that is not consistent with licensing guidance and procedures.

2.5 Technical Review

When coordinating reviews, the PM should take into consideration the schedule and actions requested by the licensee and the schedule and availability of the technical reviewer. In this respect, the PM should be familiar with the resources available within the NRC and coordinate the input for licensing reviews. The PM should direct overall review efforts and insure the efforts are reasonable. The PM is the liaison between the licensee's managerial and technical personnel and NRC.

2.6 Problem Resolution

The PM should identify differences in viewpoints and either (1) resolve them constructively and outright, (2) resolve them in concert with others in the organization, or (3) request management intervention to seek resolution. The PM should resolve the great majority of controversial items through discussions with staff.

2.7 Objectivity

NRC staff must maintains objectivity when dealing with a licensee. To avoid actual or perceived loss of objectivity, the PM should:

- Adhere to NRC regulatory positions and policies when discussing issues with a licensee or NRC management,
- Maintain a professional relationship with the licensee without giving the appearance of an inappropriately close relationship,
- Focus reviews and Agency actions on safety and safeguards significant concerns, and
- Develop issues fairly and objectively, without biased interpretation or selected examination of the facts.

2.8 Duration of Assignments

The desired maximum tenure for a PM assignment to a particular facility is 5 years. Though facility and personnel issues may lead to deviations from this guidance, PMs are normally reassigned after this period to ensure objectivity and a balanced and fresh perspective. When a PM has been assigned to a facility for four years, discussions should be held with branch management about reassignment opportunities. Earlier transfers can be made consistent with Agency needs. However, to maximize productivity, efficiency, and consistency, a PM should expect to remain assigned to a particular facility for at least three years.

2.9 Training Requirements

FCSS PMs are required to successfully complete a qualification process, as described in Inspection Manual Chapter (IMC-1246). In terms of training requirements, the qualification process requires a combination of self-study, on-the-job training, and formal classroom study. Section VII of IMC-1246 establishes the specific courses required, including core courses, self-study, and on-the-job training. Training requirements should be completed within the time frame specified by the office metrics.

The office of Nuclear Material Safety and Safeguards (NMSS) has participated in developing an online community of practice (CoP) entitled Professional Development. This CoP contains the Inspection Manual Chapter Qualification program in webpage format, located at Professional Development >> NMSS Qualification Program >> FCSS (Qualification). A web-page has been created for each qualification card which lists the documents or training requirements with hyperlinks to key information. In addition the CoP capitalizes on the NKCs blogging capability to capture input and experience from multiple users to build a useful knowledge base. For additional information on NKC, refer to the Miscellaneous Chapter.

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CHAPTER 3
THE CONDUCT OF LICENSING REVIEWS

3.1 The NRC's Mandate

The NRC's approach to meeting its obligations mandated by the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and other legislation (see NUREG-0980), involves the licensing and inspection of specified nuclear facilities. The process starts with an applicant developing and submitting a license application for NRC review and approval. The content of that application for fuel cycle licenses is specified in 10 CFR 70.22 and 70.65(a). Furthermore, 10 CFR 70.23(a) provides the criteria the application must meet to protect health and minimize danger. The key legal concept is to ensure the submittal is "adequate to minimize danger," rather than to provide zero risk.

Guidance to determine the adequacy of the applicant's proposed equipment and procedures is provided in the Standard Review Plans (SRPs), which are available to the applicant and general public. The NRC technical reviewer is responsible for reviewing the application against the acceptance criteria and his/her professional experience. However, the applicant is not required to meet the SRP acceptance criteria. Other approaches can be proposed and be found acceptable as long as reasonable assurance of public health and safety can be demonstrated.

3.2 Responsibility to Ensure Safety

It is the licensee who is responsible for the safe design, construction, operation, modification, and maintenance of its facility, in accordance with the NRC's rules and regulations. The licensee must develop appropriate programs and management controls to assure the safety of the facility and compliance with the obligations specified in the NRC's rules and regulations and all of the conditions in its license. The NRC is an independent safety reviewer, not the design authority or facility operator.

The NRC assures adequate safety by conducting an independent review of the license application to determine whether there is reasonable assurance (discussed in chapter 1) of adequate safety. This review confirms that the applicant is proposing an adequate "safety envelop" around the process, involving all software and hardware aspects concerning the safe handling, storage, and processing of licensed material. As long as the licensee operates its facility within the "safety envelop," the NRC has reasonable assurance of adequate safety. The NRC supplements the licensing process by reviewing reportable events that challenge the "safety envelop" and conducting independent inspections. Enforcement action are taken in a graded approach (i.e., appropriate level of analysis, management controls, documentation, and/or necessary actions) to address any performance deficiencies, up to and including the issuance of an order to modify, suspend, or revoke the license.

3.3 The Scope of the Review

Both the licensing review and independent inspections conducted by the NRC involve a "sampling" approach. Neither the governing legislation nor the funding enacted by Congress provide for a 100% review of licensed activities. Therefore, judgment must be used in the selection of the "sample" size and depth of the technical reviews and inspections performed. The success of this approach has been demonstrated by over fifty years of civilian use of nuclear energy. While the rules and regulations have been revised and supplemented over the years with hard lessons learned, the basic nuclear legislation has remained relatively unchanged.

Reviews should be risk-informed, e.g. based on the material inventory, the level of radiological, toxicological, and chemical hazards involved in the process, as well as past events and operating history. A risk-informed review[2] should consist of two basic components, a horizontal and a vertical review. The horizontal review is a broad overview of the topic or program from beginning to end, for example: transportation from packaging through delivery. Based on the horizontal review, vertical reviews are conducted on specific processes or program areas. The vertical reviews drill down into the details of specific areas, for example: all aspects of a particular packaging machine within transportation. Selection of a vertical review's scope and depth depends upon risk.

3.4 Integrated Safety Analysis

Applicants for new licenses and persons holding certain 10 CFR Part 70 licenses must perform an Integrated Safety Analysis (ISA) and submit a summary (referred to as an "ISA Summary") to the NRC, for approval. The ISA identifies potential accident sequences in the facility's operations, designates items relied on for safety (IROFS) to either prevent such accidents or mitigate their consequences to an acceptable level, and describes management measures to provide reasonable assurance of the availability and reliability of IROFS. The ISA Summary is a synopsis of the results of the ISA.

NRC technical reviewers are expected to use "realistic conservatism" in performing their review, with the ultimate goal to achieve reasonable assurance of adequate safety. Realistic conservatism should be developed with due consideration of the integrated safety analysis framework, described in NUREG-1513, "Integrated Safety Analysis Guidance Document". For Part 70 license applications and amendments which require an ISA, technical reviewers must confirm that an ISA Summary or safety analysis meets the regulatory requirements, that suitable IROFS and management measures have been designated for higher-risk accident sequences, and that programmatic commitments to maintain the ISA and ISA Summary are acceptable. An applicant may submit, for NRC approval, one ISA Summary for the entire facility, or multiple ISA summaries for individual processes (or groups of processes) in the facility as they are completed. Reviews of ISA summaries may necessitate examination of the ISA and its supporting documentation to confirm the underpinnings of calculations, conclusions, and

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[2] Risk-informed means using risk insights to focus the review on those matters important to safety and regulatory compliance.

components of safety programs (see NUREG 1520 and NUREG 1718 for additional information on ISAs).

3.5 Realistic Conservatism

Realistic means establishing physically attainable goals based on the equipment, the process, and experience. The conservatism seeks to preserves adequate safety margins. This regulatory approach focuses on monitoring the effectiveness of an action, rather than prescribing how it's performed; reviewing outcomes, rather than inputs; and evaluating performance rather than programs. Additional information on this subject is available in the NRC Chairman's speech number S-03-009.

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CHAPTER 4
INTERACTING WITH STAKEHOLDERS

4.1 General Overview of Fuel Cycle Project Manager Functions

The PM performs two primary functions:

- Maintain the license through amendments, and
- Support the inspection staff in monitoring the licensee's onsite activities and performance.

The PM needs to review and perform licensing actions in accordance with Section II of this Handbook. The PM should prepare for management approval of facility-specific documents, (e.g., Safety and Safeguards Evaluation Reports (SERs), hearing notices, Federal Register notices, license amendments, hearing testimony, licensing correspondence and reviews, orders, exemptions, and environmental reviews) using input provided by technical reviewers, the OGC, the Regions, and other NRC staff.

Section II of this Handbook provides guidance on how licensing functions should be performed and provides examples in the form of templates. The PM is responsible for licensing actions from receipt and initial review to final approval or denial of the licensing request. Although the issuance of a licensing document may be considered a major milestone, the task is not complete until it has been implemented by the licensee and, in many cases, until NRC verifies its implementation. This verification is performed by NRC inspection staff.

When evaluating the safety basis of licensing actions, the PM should review the most recent renewal, amendments, environmental evaluations, submittals, and relevant license conditions. For licensing actions which involve multiple technical areas, the PM should coordinate with other technical reviewers (see guidance on issuing Technical Assistance Requests (TARs), Chapter 11 of this Handbook). Input of management, regional offices, and the OGC may also be required to complete a regulatory decision.

4.2 Interactions with Licensees

PROJECT MANAGER OBJECTIVITY
The PM should restrain from providing advice to the licensee or applicant to retain independence for evaluating the appropriateness and viability of the licensee's proposals. However, PMs should provide the licensee with guidance on the regulatory requirements, schedule constraints, precedents, and established NRC positions in order to promote a timely resolution of problems.

LICENSEE DOCUMENTS
Information submitted by the licensee, or applicant, in support of a licensing request should be docketed. Oral communications should not be used as a licensing basis unless confirmed in writing. Information received via telecommunications that impact a licensing action must be documented in the NRC Agencywide Document Access and Management System (ADAMS).

CONFERENCE CALLS
The PM should consider conference calls with the licensee or applicant as a method of obtaining or confirming information in a timely manner. Calls can also be used to promote a mutual understanding of the facts, positions, and concerns. Conference calls should be used cautiously during an event to prevent interference with the licensee's ability to safely and securely operate the plant. A written summary of the call should be prepared by the PM that includes a list of participants and a brief summary of the discussions. Any information discussed during the call that would lead to a licensing decision should be provided in writing by the licensee. This information and the conference call summary should be included in the docket file. For short, staff level calls, with a limited number of participants, the PM may summarize the call in an email to the participants, with a CC to the PM's branch chief. After obtaining comments from the participants, the PM should request the LA to docket the email. For more formal conference calls involving management or large numbers of participants, use the example under Templates to assist in drafting the conference call summary. PMs may choose to document a conference call using NRC Form 699, but the form is not required.

LETTERS
Letters provide the primary formal means of communication with the licensee or applicant. Communications between NRC and the licensee must be submitted in writing in accordance with 10 CFR Parts 2 and 9 and be available to the public, except for specified reasons (e.g., classified information, proprietary information, etc.). Letters should be written so that a knowledgeable third party will be able to understand the material.

SAFETY AND SAFEGUARDS EVALUATION REPORTS AND REQUEST FOR ADDITIONAL INFORMATION
Written regulatory decisions are usually documented in the form of Safety and Safeguards Evaluation Reports (SERs). An SER should provide the proper technical, safety, and legal basis that coherently supports the staff's decision (see the SAFETY AND SAFEGUARDS EVALUATION REPORTS chapter). Prior to the issuance of an SER, the PM must ensure that no outstanding safety or safeguards issues remain unresolved. NRC may Request Additional Information (RAI) from a licensee (see Request for Additional Information chapter) if unresolved questions arise during the review of the licensing submittal.

CONCURRENCE
The PM coordinates, concurs, and may sign licensing related correspondence with the licensee. Technical reviewer concerns must be resolved prior to concurrence. Signature levels and approval authorities are described in the Policy and Criteria for Processing of Licensing Actions chapter of this Handbook. (Note: documents can move forward with a "'non-concurrence." See Management Directive 10.158, NRC Non Concurrence Process).

INCOMPLETE OR NON-RESPONSIVE SUBMITTALS
The PM will intervene if the licensee displays a pattern of submitting incomplete or non-responsive submittals or is chronically late in responding to a RAI. The initial contact should be a telephone call to the licensee indicating that additional action may be forthcoming. If the telephone contact does not resolve the problem, the PM should initiate a more formal means of communication, such as letters or meetings. If the problem persists, NRC management should pursue resolution of the problem with the licensee.

4.3 Interactions with Inspection Staff

Inspections involving criticality safety and material control and accounting (MC&A) are conducted by HQ and NRC Region II staff. Other inspection areas are conducted by the Region II Division of Fuel Facility Inspection (DFFI). In addition, construction inspections are conducted by Region II Division of Center for Construction Inspection (DCCI). A full range of enforcement actions are available for violations of NRC regulations, including assessment of civil penalties and issuance of orders.

The PM works closely with inspection staff, including resident inspectors, for assessing safe and secure operations at the facility on a continuing basis. The regional office appoints a lead Project Inspector for licensees that do not have a resident inspector. Therefore, the PM and inspection staff should forge strong and effective working relationships that involve frequent contact and open communications.

The PM and inspection staff should assist and augment each other in their respective principal responsibilities. The PM does not direct the actions of the inspection staff, nor does the inspection staff direct the actions of the PM. Significant requests for action by either party beyond normal coordination should be directed to the branch chief at either HQ or the region. Examples of effective interactions and assistance include the following:

- The PM should keep inspection staff informed of significant licensing actions and regulatory commitments made by the licensee. The PM should use inspection reports to guide license reviews and seek input from the inspection staff on licensing requests.

- The PM and inspection staff should hold periodic phone calls as necessary to discuss topics such as facility modifications, significant events, noncompliance issues, open items, enforcement actions, allegations, media and Congressional interest, and relevant decisions by senior Agency management.

- The PM and inspection staff should consult during the preparation of plans for team inspections (see Management Directive 8.3 "NRC Incident Investigation Program"), such as Augmented Inspection Teams (AIT), Incident Investigation Teams (IIT), and readiness inspections.

- The PM and inspection staff should coordinate the development of any items of interest, daily items, or Preliminary Notifications that address both licensing and inspection activities.

- Visits to the licensee site or contacts with interested stakeholders in the vicinity of licensee facilities should be coordinated between the PM and inspection staff, particularly the resident inspector. Similarly, inspection staff should inform the PM of any significant planned meetings with the licensee or associated activities.

The objectives of these interactions are to enhance efficiency by eliminating unnecessary duplication and ensure a common understanding of the safety or safeguards significance of events and licensee actions. The PM and inspection staff should strive to demonstrate unity of purpose and effective teamwork to the licensee and other interested parties.

4.4 Interactions with the Office of the General Counsel

The OGC provides legal advice to the Commission and other agency officials and represents the agency in administrative and judicial proceedings. The office is under the supervision of the

General Counsel who reports to the Commission. OGC is responsible for ensuring that licensing actions are conducted in accordance with NRC administrative and substantive requirements in Title 10 of the Code of Federal Regulations, the Atomic Energy Act, and other statutes. The PM should interact with attorneys in OGC to ensure that the proper legal reviews have been completed.

Licensing actions which do not raise legal issues do not require OGC review prior to issuance. OGC review should be obtained on unique cases, novel legal issues, candidates for legal intervention, items likely to be contested by the licensee, etc. OGC attorneys need to review orders, exemptions, directors' decisions, and similar documents. In addition, the PM may identify generic issues that would benefit from a formal interpretation by OGC. In such cases, after consultation with management, the PM should document the issue and request an interpretation from OGC by a memorandum.

Documents sent to OGC for review, comment, or concurrence must be sent to the assigned attorney and the OGC mailroom. Sending the documents to the mailroom ensures the items get entered into the OGC tracking system, so managers can assign resources appropriately. The OGC mailroom email address is OGCMAILCENTER@NRC.GOV.

The OGC review focuses on ensuring the document's form and content will readily satisfy any anticipated follow-on legal challenges. OGC typically does not provide its “concurrence” on staff documents. Rather, OGC will mark on the official record copy that it has no legal objection (NLO) to the proposed action. OGC should review correspondence which involves legal issues or regulatory interpretations. Generally, OGC does not need to review documents that are only technical in nature.

No legal objection means that:

- The recommended action is legally sufficient.
- OGC is not taking a position with respect to the policy aspects of the recommendation.

OGC is required to review:

- Environmental Impact Statements
- Letters to Congress
- Replies to the public (if they involve an ongoing policy or legal issue, or as part of a formalized process).
- 2.206 Petitions
- Rulemakings
- Exemptions

OGC normally does not need to review the following items, unless they relate to a legal issue:

- Allegations,
- Correspondence that, in the view of the staff, is based solely on technical matters, unless it involves a legal determination
- Routine Licensing Documents
- 2.390 Approvals/Denials

OGC’s policy is to process licensing actions within ten working days of receipt if possible. If an action is identified as urgent, it will be processed on an expedited basis, depending on the degree of urgency. As with all scheduling, significant delays in obtaining OGC review should be promptly identified and escalated through management channels.

Effective coordination between OGC and the PM is vital to the Agency's success in hearings. OGC takes the lead role in hearings because of their familiarity with the process, the legal nature of filings, and possible contentions. OGC also represents the Agency before the Licensing Board or the Courts. In such proceedings, the PM serves the role of a consultant or advisor to OGC with the objective of ensuring the legal filings are factually correct, consistent with NRC regulations, and presented in the technical context. Typically, in a pre-briefing to the NRC staff, OGC will provide guidance for how to prepare and provide documents for a hearing file. As discussed in the Hearings chapter, 30 days prior to the hearing, the staff must work with their management and OGC to determine what information should be communicated to the Commission, Licensing Board, or Presiding Officers. For hearings where interveners may review sensitive information, the PM should review P&PL 1-86 (ML050810155), "NMSS STAFF SUPPORT OF HEARING PROCESS IN 10CFR PART 2".

4.5 Public Interactions

The PM has the obligation to be responsive to the public. When responding to the public, orally or in writing, the PM should strive to communicate clearly and at a level the public can understand. The message should present the safety considerations, the regulatory basis, and the expected effects of NRC decisions. At the same time, the PM should refrain from speculation and topics which are not directly within NRC's purview, such as economics, politics, etc.

4.6 Meeting Notices And Trip Reports

TYPES OF MEETINGS
The PM is expected to participate in the following meetings that involve their designated facilities:

- Licensee Performance Reviews at the Branch, Division, and Office levels,
- Public meetings conducted by NRC,
- Pre-decisional Enforcement Conferences,
- Enforcement Panel meetings,
- Allegation Review Boards (ARB) (i.e., if headquarters has the lead),
- Review meetings on 2.206 Petitions,
- Briefings for NRC senior managers on the facility,
- Event review meetings (i.e., following notification of NRC Operations Center), and
- Licensing meetings.

Attendance at other meetings that pertain to designated facilities may also be necessary and appropriate, depending upon the subjects to be discussed and the regulatory action that may be necessary to implement the outcome of the meetings.

MEETING NOTICE
The PM needs to determine if the meeting will be open, closed, or a combination of opened and closed for observation by the public, in accordance with MD-3.5, "Attendance at NRC Staff Sponsored Meetings." The subject matter is the primary criterion for determining whether the meeting will be open. If the meeting deals with substantive licensing or regulatory issues, the meeting should be open, unless the discussion will involve classified or sensitive/unclassified information. Portions of the meeting that do not involve such information should be open.

(Note: Additional information about the types of meeting can be found on the NRC Communications page at http://www.internal.nrc.gov/communications/).

As a matter of NRC policy, public meeting notices are to be posted on the NRC's public web site at least 10 calendar days prior to a meeting (see Management Directive 3.5, "Attendance at NRC Staff Sponsored Meetings"). Therefore, meeting notices need to be prepared sufficiently in advance to allow adequate time to be posted. The PM should ensure that the Licensing Assistant (LA) who processes the meeting notice transmits the notice to the Public Meeting Notification System (PMNS). PMNS typically requires one full day to post the notice. Meetings scheduled with less than 10 calendar days of public notice must be approved by the appropriate management before the notice is submitted to the PMNS. Note: Closed meeting notices do not need to be provided to the PMNS, since PMNS only distributes meeting information on public (open) meetings. However, the closed meeting notice must be docketed in public ADAMS, and a public version of the meeting summary should also be docketed.

The Project Manager should work closely with the LA and secretarial staff to ensure the PMNS receives the notice in a timely manner. Use the templates below to assist in drafting meeting notices.

Additional points:

1 Meeting notices, including agendas and supporting documentation, must be declared in ADAMS as official agency records and replicated before e-mailing them to PMNS for posting.

2 It is the responsibility of the PM (the originator of a meeting notice) to ensure that all accession numbers, links, and/or Web addresses being referenced in the meeting notice are tested to ensure that they can be accessed by the public before e-mailing to PMNS for posting.

See the Public Meeting Checklist on the internal NRC website for additional information.

The PM should also strive to ensure that inspection staff and other potentially interested groups within NRC (e.g., SFST, NRR, OE, OGC, etc.) are aware of the meeting and invited to participate. The PM should be especially sensitive to the need for a public meeting on topics that exhibit strong public interest and active involvement by elected officials, community groups, State representatives, other governmental agencies, or members of the press.

REQUIRED MEETING FORMS

At open meetings the PM must distribute copies of the public meeting feedback forms, available on Informs as NRC Form 659. The PM should enter the meeting date, title, and category as well as the return address information, located on the second page of the form (PM's name and mailing address). Meeting participants may complete the feedback form at the meeting or mail the form to the PM afterward.

CONDUCTING THE MEETING
At the beginning of open meetings, the PM should state the meeting is open for public observation and request either: (1) observers to withhold comments and questions until the end of the meeting or (2) observers to ask questions during the meeting. The PM should strive to follow the meeting agenda, conduct the meeting in an open and forthright manner, and foster a productive exchange of information. The PM should avoid providing staff positions or conclusions based on verbal discussions. Rather information should be requested in writing and placed in the docket.

At the conclusion of the meeting, the PM should recap the meeting and state any agreements or commitments that were reached during the meeting. The PM should ensure NRC representatives remain after the meeting to answer any questions from members of the public.

MEETING SUMMARY
The PM is responsible to write a meeting summary for both open and closed meetings, paying particular attention to any agreements, commitments, actions, or observations stated during the meeting. The summary should include the agenda, list of participants, description of information furnished or requested, positions taken, commitments made, and areas of agreement or disagreement, and any attachments. It should be clear and concise. The summary should be prepared and **issued within 30 working days** after the end of the meeting. The summary should be placed in ADAMS and on NRC's public website as necessary (see Templates). The licensee should receive a copy of the meeting report via a "cc" copy.

As required by MD 3.5, "Attendance at NRC Staff Sponsored Meetings," the summary must be entered into ADAMS under the appropriate docket number. When the meetings do not involve sensitive information (e.g., classified, proprietary, or safeguards), these reports should be filed in ADAMS as "publicly available" and for "immediate release." For closed meetings which involve sensitive information, the PM should prepare a short unclassified non-sensitive cover memo to be placed in the Docket File(s) and in ADAMS as "publicly available," in addition to the non-public meeting summary.

TRIP REPORTS
Trip reports are required whenever a trip is completed. Like meeting summaries, trip reports should be clear and concise and focus on agreements, commitments, actions, and observations. Trip reports should not include (1) conclusions that are more appropriate for inclusion in the Safety Evaluation Report (SERs), (2) information collected or exchanged subsequent to the trip, (3) policy decisions, or (4) closure of internally controlled items. Trip reports should normally be completed and issued within 30 days of the completion of the trip. Unless stated otherwise, trip reports are to be marked as nonpublic, for internal use only, and placed in ADAMS (see Templates).

4.7 Templates
Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 4.1 **Conference Call Summary (ML082470397)**

Template 4.2 **Content for Closed Standard Meeting Notice (ML082470399)**

Template 4.3 **Content for Open Standard Meeting Notice (ML082470416)**

Template 4.4 **Category 1 Public Meeting Notice (ML100780377)**

Template 4.5 **Category 2 Public Meeting Notice (ML100780382)**

Template 4.6 **Category 3 Public Meeting Notice (ML093130755)**

Template 4.7 **Content for Open and Closed Standard Meeting Notice* (ML082470406)**

Template 4.8 **PM/Licensee Meeting Summary (ML082470439)**

Template 4.9 **Public Meeting Summary (ML100920456)**

Template 4.10 **Trip Reports (ML082470493)**

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CHAPTER 5
HANDLING NON-LICENSING DOCUMENTS

5.1 Control of NRC Pre-decisional Information

MD-3.4, "Release of Information to the Public," specifies the requirements for the release of draft and predecisional documents and information. This policy emphasizes that NRC documents must be developed and issued without improper licensee or public influence, or the appearance of such, and must be available to the public in a timely manner. However, the management directive provides for the exchange and discussion of necessary communications during the normal course of agency business.

Upon approval and issuance of a final document, associated draft documents, background material, notes, and mark-ups should be destroyed by NRC staff, unless they should be saved in accordance with the guidance contained in MD-3.53, "NRC Records Management Program." Retention periods for NRC records are specified in NUREG-0910, "NRC Comprehensive Records Disposition Schedule."

5.2 Controlling Office of Investigation Reports

The Office of Investigation (OI) examines licensee violations of NRC regulations to determine if willfulness is involved. An OI special agent will prepare a Report of Investigation (ROI) containing especially sensitive information that may identify an alleger or contain confidential information. Information in the ROIs must be guarded to prevent unapproved public release of the ROI itself or information derived from the ROI (e.g., ROI Synopsis). ROIs are also exempt from public disclosure under FOIA Exemption 7.

5.3 Allegations

An allegation is a declaration, statement, or assertion of impropriety or inadequacy associated with NRC regulated activities, the validity of which has not been established. Allegations regarding specific facilities are usually referred to the appropriate regional office for action. However, NMSS staff may be assigned responsibility for the allegations. They may also be the recipient of allegations over the phone or in person while engaged in activities associated with a licensed facility. The PM should keep aware of open allegations that affect the assigned facility particularly those related to ongoing licensing actions. Agency wide procedures for handling and resolving allegations are provided in MD-8.8, "Management of Allegations," and P&PL 1-27, "Management of Allegations" (see ML031780097).

Any employee may receive an allegation verbally or in writing. In the case of verbal allegations, the NRC staff may use the allegations questionnaire located on the S drive at S:\Allegations\Allegation_Report.doc to guide the conversation. The information should be recorded and the alleger informed of NRC's identity, protection provisions, and limitations as described in MD-8.8. NRC staff will provide the originals of all allegation documentation to the NMSS Office Allegation Coordinator (OAC) within five calendar days of receipt. Additional allegation training is available through the NRC iLearn web site by searching "allegations."

ALLEGATION CHECKLIST

- ❑ If someone raises an allegation, listen attentively, ask questions, obtain as much information as possible about the concerns, describe NRC identity protection policy, and request the alleger's personal information (name, address, telephone number, employer and position). If the alleger refuses to identify themselves, accept the information as an anonymous allegation.
- ❑ Document the allegation on the Allegation Report form located in P&PL1-27 or on the S: drive.
- ❑ Describe Department of Labor (DOL) rights if a discrimination complaint is being made.
- ❑ Immediately inform your supervisor of the allegation.
- ❑ Gather all allegation documentation, make a copy of the material for yourself, place a blue cover sheet marked "Sensitive Allegation Material" (NRC Form 762) on top and forward the information to the appropriate OAC within 5 days of receiving the allegation. Destroy your copy of the information once you are sure the OAC has received the material.
- ❑ Attend the Allegation Review Board, if requested.

In general, all FCSS staff members are responsible to:

1. Ensure that the Office Allegation Coordinator (OAC) is immediately informed of allegations that are received by staff members.

2. Ensure that allegations assigned to them for action are acted upon and resolved in a timely manner.

3. Track the status or closeout information for assigned allegations, including all relevant review documentation.

4. Prevent the inadvertent disclosure of the alleger's identify by following procedures in MD 8.8 and NMSS P&PL 1-27.

5.4 Enforcement

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended. The Enforcement Policy describes the process the NRC applies in taking enforcement actions, while the Enforcement Manual describes the procedures that the NRC follows in reviewing potential enforcement actions in response to apparent violations of NRC requirements. The PM should become familiar with the Enforcement Manual and the Enforcement Policy. The enforcement manual contains procedures, requirements, and background information used by the staff to review inspection and investigation results and develop enforcement actions.

The NRC's enforcement program is based on the recognition that violations occur in a variety of activities and have varying levels of significance. Escalated enforcement actions under the traditional enforcement program consist of Orders, Civil Penalties, or Severity Level I, II, or III Notices of Violation (NOV) with or without a civil penalty. Non-escalated enforcement actions generally consist of Severity Level IV Notices of Violation, or non-cited violations (NCVs). The Enforcement Process Diagram is a graphical representation of the NRC's graded approach for processing violations.

Enforcement actions are generally initiated by the Regional offices, except in cases where headquarters has the lead inspection responsibility. When NRC management determines that escalated enforcement may be warranted, an enforcement panel meeting is convened to consider the matter. The NRC's Alternate Dispute Resolution program, commonly referred to as ADR, provides licensees or individuals an opportunity to use mediation to reach an agreement with the NRC regarding enforcement actions for discrimination and other wrongdoing violations. The PM should review any enforcement case that involves their designated facility, participate in any Predecisional Enforcement Conference (includes licensee) and/or Enforcement Panels (internal staff only), help ensure the technical accuracy, provide a licensing perspective, focus on the safety and security significance of the violations, and coordinate the licensing staff's views on proposed enforcement actions and strategies.

The PM can check with the office Enforcement Coordinator for scheduling inquiries.

ENFORCEMENT CHECKLIST

- ❏ Become familiar with Enforcement Manual and the Enforcement Policy.
- ❏ Review the enforcement case and participate in any enforcement panel and/or predecisional enforcement conference that consider violations for the PM's designated facility.
- ❏ Help insure the accuracy and provide a licensing perspective.
- ❏ Focus on the safety and security significance of the violations.
- ❏ Coordinate preparation of the FCSS's views on proposed enforcement actions and strategies.
- ❏ PMs should monitor inspection reports for apparent violations.
- ❏ NMSS Enforcement Coordinator should inform the PM when a panel is scheduled as a result of a violation at the PM's site
- ❏ PM should obtain a copy of the Enforcement Action Worksheet (EAW) and review it to determine if it is consistent with the Enforcement Policy

The PM should keep management informed of enforcement proceedings.

5.5 Environmental Assessments and Environmental Impact Statements

The PMs should obtain guidance on environmental issues from NUREG-1748 "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." Complex environmental reviews should be forwarded to the environmental task force in the Division of Waste Management and Environmental Protection. Additional information is available in NMSS P&PL 1-48,"Procedures for Preparing Environmental Assessments" (see ML031820777 or the Environmental Reviews and Finding of no Significant Impact (FONSI) chapter).

5.6 2.206 Petitions

A 2.206 petition is a request filed by any person, pursuant to 10 CFR 2.206, requesting a proceeding to modify, suspend, or revoke a license or for such other action as may be proper. The PM may be assigned to participate in, and in part direct, the Agency's response to a petition. A complete description of the procedures for 2.206 petitions may be found in MD-8.11, "Review Process for 10 CFR 2.206 Petitions."

5.7 Unsolicited Information

Unsolicited information must be adequately and promptly reviewed, screened to determine how it should be processed and recorded, and handled on the basis of its safety or security significance. If NRC staff discovers issues based on the unsolicited information, they must promptly inform the appropriate management, license reviewers, PM, and inspection staff. Effective regulatory actions must be initiated to respond to concerns and resolve any issues.

NRC staff may need to document receipt of the information in a personal log, in an internal memorandum, or place the information on the docket in ADAMS. Under certain conditions, the unsolicited information may constitute an allegation, which must be handled and processed accordingly.

Upon receipt of unsolicited information, NRC staff will promptly take the following three steps:

Step 1: Review
NRC staff review the unsolicited information to understand the purpose of the information, the technical details, and the regulatory actions being requested or required by the unsolicited information. If the information is not fully understood, NRC staff should conduct subsequent discussions with the source of the unsolicited information if accessible.

Step 2: Screen
Screening is most effectively performed by answering the following series of questions about the information:

- Does it concern the safety or security of a licensed facility,
- Does it contain alleged NRC employee or contractor impropriety,
- Does it contain alleged wrongdoing by the licensee,
- Should it be processed as controlled correspondence (i.e., an EDO or NMSS controlled ticket),
- Should it be forwarded to another regulatory authority?

Screening also determines whether the unsolicited information constitutes an official Agency record and requires docketing in accordance with NRC procedures (i.e., MD-3.50, "Document Management").

Step 3: Document
If the unsolicited information contains an allegation of improper operation, maintenance, design, or decommissioning of a licensed facility or of licensee wrongdoing, NRC staff treats and controls the unsolicited information as sensitive information and immediately informs the appropriate supervisor. The information should be handled in accordance with allegation guidance.

If the unsolicited information implies or directly states that an NRC employee or contractor has acted improperly or made improper statements while conducting official Agency business, NRC staff should control the unsolicited information as sensitive information and handle in accordance with MD-7.4, "Reporting Suspected Wrongdoing and Processing OIG Referrals."

If the unsolicited information is routine information that the staff will use in support of a licensing action, NRC staff should ensure that the information is placed in ADAMS and appropriately referenced in the subsequent licensing actions.

5.8 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 5.1 Allegations (ML082470341)

5.9 References

NMSS P&PL 1-27 "Management of Allegations" (ML031780097)

NRC Management Directive 8.8, "Management of Allegations"

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SECTION II
MATERIALS LICENSING PROCEDURES MANUAL

CHAPTER 6
MAIL AND THE DOCKETING SYSTEM

6.1 Docketing Of Incoming Correspondence

All license related unclassified correspondence (letters, reports, faxes, records of teleconferences, etc.) should be addressed as specified in 10 CFR 40.5, 70.5, and 76.5. Licensees, certificate holders and applicants should ensure that correspondence includes both the docket number and license/certificate of compliance number on the cover page. A copy of each submittal should be sent to the facility PM and the original sent to the Document Processing Center (DPC).

Classified information should be transmitted as specified in 10 CFR Part 95.39 to the following NRC classified mailing address:

U.S. Nuclear Regulatory Commission
Caller Box 2500
Rockville, MD 20852,

Non-classified information should be sent via express mail or hand-delivered to the following address:

Project Manager's Name: XXXXXXXX
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Fuel Cycle Safety and Safeguards
Fuel Facility Licensing Directorate
11555 Rockville Pike
Mail Stop: [PM's Mail Stop]
Rockville, MD. 20852

or via the new Electronic Information Exchange (EIE) process, which is available on the NRC's Electronic Submittals web page.

The licensee can transmit time sensitive information to the PM via express mail, facsimile, or e-mail (Note: See NRC Policy and Procedures for Handling, Marking, and Protecting Sensitive Unclassified Non-Safeguards Information (SUNSI) and the SUNSI website, for information on transporting SUNSI information). All documents, including handouts from meetings, drawings, pictures, and other information sent to the NRC staff must be docketed. Draft documents submitted by licensees or applicants can not be docketed, unless specifically authorized by the PM's supervisor. Proper handling of draft documents is discussed further in MD-3.4, "Release of Information to the Public."

When documents are received by the DPC, the Office of Information Services (OIS) staff does the following:

1. Scan the original document into the NRC's ADAMS.

2 E-mail the Adobe (PDF) file with accession number (ML) to the appropriate list of individuals, usually the PM, backup PM, and LA. The list is maintained in the electronic Regulatory Information Distribution System (eRIDS) by the OIS staff. Changes to the eRIDS distribution list must be submitted to OIS by the PM or LA.
NOTE: An eRIDS cover page is e-mailed with the document. The cover page provides a brief summary of the document, identifies NRC's receipt date, displays the document's distribution list, and provides a unique ML number which can be used to retrieve the document in ADAMS.

3. Arrange to have mailroom hand deliver the classified and safeguards documents to the appropriate individual in a red candy stripe envelope (NRC Form 188A). The recipient must have the appropriate clearance and sign NRC Form 253 before receiving the documents. These documents must be stored in a locked security container when unattended or not in actual use by an authorized staff member as specified in MD-12.7, "NRC Safeguards Information Security Program."

Documents placed in ADAMS are marked by the DPC as Non-Public, Non-Sensitive by default. The text, "Non-Public Pending Review" is added to the keyword field. The PM should review the profile in ADAMS and notify the secretary or LA of necessary changes.

Occasionally, the PM may receive an original document directly from the licensee before it has been processed by the DPC. When this occurs, the PM may forward the document to the DPC, but without the 665S/P form. Documents that are addressed to the DPC do not require the 665S/P. PMs may also work with the administrative support staff to docket the submittal directly, but should ensure a duplicate is not processed into ADAMS by the DPC, e.g. contact the document originator to ensure duplicates were not sent to the DPC and the PM. Financial assurance documents containing the original signature must be delivered to the Division of Waste Management and Environmental Protection (DWMEP) by the PM prior to forwarding to the DPC for processing. The PM should work with the licensee and the LA to ensure that DWMEP receives the original submittal and the DPC receives a copy.

Classified or safeguards documents (see Security Requirements for Classified or Sensitive Non-Classified Information in the Miscellaneous chapter for additional information), as well as Export Controlled Information (ECI) should be given to the LA for filing in the secure docket. The PM should make a copy to keep in the office locked security container. The submittal letter accompanying the document should be carefully reviewed to ensure it does not contain classified or safeguards information. The original or a redacted version should be placed in ADAMS to act as a place holder/reference to the secure document.

The two charts in Exhibit 6.1 and 6.2 provide an explanation of docket classifications and prefix codes for source material licenses and special nuclear material licenses.

6.2 Classified Information Exchange with Foreign Governments

Before exchanging information with a Foreign Country, NSIR's Division of Security Operations (DSO) should determine whether an applicable prerequisite government-to-government

agreement exists between the United States and the foreign country involved. If an agreement exists, DSO, with the assistance of OIP and OGC, will develop a separate classified information exchange agreement for each foreign government agency involved before initial transfer of classified information or before initial written or oral access. This information exchange agreement must specify the requirements necessary to ensure the security of the transferred classified information. The agreement will be compatible with the terms and conditions of existing government-to-government agreements applicable to the transfer of classified information. Classified documents to be transmitted to foreign governments must be forwarded to DSO for review and transmission. For additional information on handling classified information with foreign governments see Management Directive 12.2, "NRC Classified Information Security Program."

6.3 Electronic Submittals

The NRC's Electronic Submittals Web page allows certain information pertaining to licensing actions and other regulatory matters to be transmitted to the agency electronically. The application ensures that documents sent via the Internet are secure and unaltered during transmission. Licensees, interveners and NRC Staff counsel will also use this e-filing system for hearings on NRC licensing actions. A digital certificate is required in order to submit documents. For additional information on electronic submittals see the Electronic Submission Quick Start Instructional Guide**.**

6.4 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 6.1 Classified Mail Checklist (ML082470359)

Exhibit 6.1
Docket Classification

Each organization (i.e., licensee, certificate holder, or applicant) engaged in a nuclear activity licensed and regulated by NRC is assigned a docket (or project) number. Documents exchanged between NRC and the applicant, or licensee, are referenced by that number. The majority of documents in the docket files concern the licensing and inspection of nuclear facilities and the use, transportation, and disposal of nuclear materials. This information is organized into the following docket classifications:	
Docket 27	Low-level radioactive waste disposal sites (Pre-Part 61)
Docket 30	Possession or use of nuclear byproduct material in medicine, industry, agriculture or research
Docket 40	Domestic licensing of source material (uranium, mills, and uranium hexafluoride [UF_6] production plants)
Docket 50	Domestic licensing of production and utilization facilities (commercial power plants, experimental, test, and research reactors)
Docket 60	High-level waste repository
Docket 61	Low-level radioactive waste disposal sites
Docket 70	Domestic licensing of special nuclear materials (colleges and universities, fuel processing and fabrication plants, and irradiated fuel storage facilities)
Docket 71	Licensing of the designs and quality assurance programs for radioactive material packages (e.g., shipping casks)
Docket 72	Licensing of independent spent fuel storage installations
Docket 76	Gaseous Diffusion Plants
Project M	Materials Licensing Project

Exhibit 6.2
Source Materials License Prefix Codes

LETTER POSITION	DEFINITION
First	All source material license numbers are prefixed by the letter **S**. All special nuclear material licenses are prefixed by the letters SNM.
Second	The second letter indicates the type of source material: **U = uranium** **T = thorium** **M = both uranium and thorium** **I = import/export**
Third	The third letter indicates the general type of activity licensed: **A** - indicates processors of ore and includes, for example, uranium mills, thorium mills, upgraders and rare earth separation plants. **B** - indicates licensees using refined source materials for fabrication research and manufacturers of consumer products. Included in this category are ceramic, tile and glassware industries, manufacturers of refractories, uranium shields, fuel elements, analytical standards and most uses not elsewhere specifically classified. The bulk of the domestic licenses are in this group. **C** - indicates distribution, warehousing and storage, and others whose license authorizes possession but not processing or fabrication of any kind. **D** - limited to licenses authorizing sub-critical assembly. **E** - indicates an export license.

Examples of License Prefix Codes

SUA ..... uranium mill	SUB..... uranium shield fabricator
STA ..... thorium mill	SMB .... users of both uranium and thorium for manufacturing purposes
STE ..... thorium export license	SMC .... distributor of both uranium and thorium
SUI..... import/export Part 40	SUD .... uranium subcritical assembly

NOTE: The prefix SNM (not shown above) indicates a special nuclear material license.

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CHAPTER 7
PROCEDURES FOR LICENSING AND ROUTINE CORRESPONDENCE

7.1 Introduction

The following procedures will help ensure the efficiency of handling correspondence.

1. To initiate a concurrence package, the PM will e-mail a soft copy of the document(s) and NRC Form 665S (ML020170281) or 665P (ML020170279) to the secretary. The secretary will prepare a concurrence package; ensure the formatting (e.g. spelling, headers, footers, etc.), concurrence, and signature block are correct; and ensure that the document is profiled in ADAMS consistent with the submitted 665S or 665P.

2. The PM will review the document(s) in the package for any corrections, concur on the package, and deliver it to the LA. The LA will proofread the document(s) for administrative corrections such as spelling, format, distribution, and to make sure that NRC regulatory standards are being met. For amendments, the LA will edit the license and attach it to the concurrence package.

3. Individuals in the concurrence chain may recommend changes to the document(s). The PM remains responsible for reviewing and addressing these comments and ensuring the concurrence process is completed in a timely manner.

4. Once concurrence has been completed, the secretary will date the document(s), type **/RA/** (Request Approved) in the signature block of the ADAMS version, and place the document(s) in the ADAMS Document Processing Center folder. The ADAMS staff will make the document(s) an "Official Record" and release the submittal to the public, if appropriate. The secretary will mail the signed document(s) to the licensee, place a copy in the secretary's reading file, and provide a copy to the LA and the originator. A soft copy will be e-mailed to the staff on the concurrence chain and those on the distribution list.

Exhibit 7.1 shows the flow chart for processing licensing document(s).

The PM is responsible for assigning the individuals in the concurrence chain, based on the delegation of authority. See the Delegation of Authority section in the Policy and Criteria for Processing of Licensing Actions chapter for additional information.

7.2 Tracking Case Work – The Case Work Log

The LA will maintain a log of licensing actions and relevant information such as brief description, TAC, days till metric, etc. On a periodic basis the LA will request input from the PM to keep the log updated. The PM should provide input to the LA in the timeframe requested. The LA incorporates any updates into the log. The log is used to prepare the Month End Report which feeds directly into the Operating Plan each quarter.

PMs should keep a personal log to ensure all licensing actions are completed in a timely manner in accordance with the Operating Plan metrics (see example in Exhibit 7.2).

Exhibit 7.1
Flow Chart for Concurrence Process

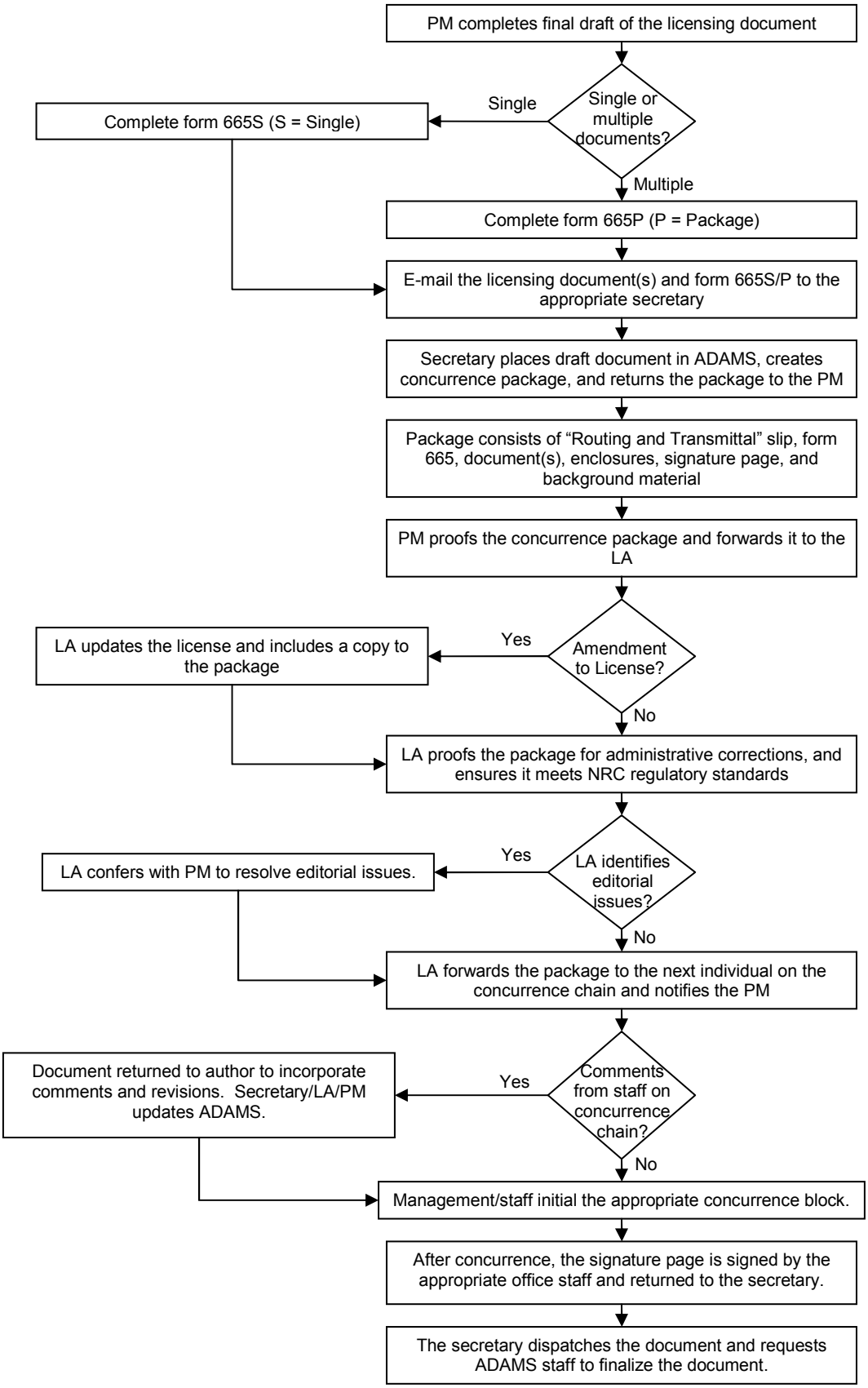

Exhibit 7.2
Example Personal Log for Project Manager

Green – Completed; Red – Next step

PM, Licensee Date	Subject	Document Status/Comments	Tac & ADAMS Docket #	Next Step
PM name GA 12/1/06	Request to release Building 21	11/27/06 - Received request and surveys from staff 11/30/06 - Received TAC from LA 12/6/06 - Acknowledgment letter on LA's desk 12/20/06 - Completed draft letter and SER, placed in folder	TAC L00000 ML063350173	12/1/06 - Create acknowledgment letter 12/06/06 - Acknowledgment letter in concurrrence 12/1/06 - Compare smart sample of final survey to decommissioning plan 12/21/06 - Wait for confirmatory inspection report from RIV
John Doe	Security plan changes	9/14/06 - Incoming received from licensee 9/16/06- Received TAC from LA. 9/18/06 Issued TAR to NSIR. 9/18/06- Invited staff to meeting with licensee on 10/5/06. 10/06/06 - Left message for Jane Doe 10/9/06 – Issued acceptance letter. 12/07/06 - RAIs to PM. 12/08/06- Left message for Jane Doe. 12/09/06- Discussed RAIs with NRC staff. 12/15/06- RAIs in typing. 12/20/06- RAIs issued to licensee.		12/06/06 - Perform acceptance review. 12/06/06 - Contact Jane Doe 10/5/09- Develop schedule. 12/09/08- Create RAI letter.
John Doe	Licensee Renewal	12/05/06 - Received renewal application 12/07/06- Received TAC from LA 12/10/06- Issue TARs to reviewers		1/05/09- Create acknowledgement letter.

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CHAPTER 8
WITHHOLDING DOCUMENTS FROM PUBLIC DISCLOSURE

8.1 Background

Section 189 of the Atomic Energy Act establishes the right to request a hearing by any person whose interest may be affected by a Commission proceeding, which includes all licensing actions. The public must have access to information about licensing actions to exercise this right. In addition, the Commission has a Strategic Goal of Openness. The NRC Strategic Plan (NUREG-1614) states that nuclear regulation is viewed as the public's business and, as such, it should be transacted openly and candidly in order to maintain the public's confidence. Therefore, information in NRC records and documents (both incoming and outgoing) is subject to public disclosure unless there is a compelling reason for withholding it. Information will generally be made available electronically for public inspection in the NRC Public Document Room or from ADAMS.

8.2 Processing Requests to Withhold Information

Licensees may request that information be withheld from public disclosure in accordance with the provisions of 10 CFR 2.390. The request for withholding must be made when the document is submitted and must comply with marking and affidavit requirements. NRC has no obligation to review documents which are not marked to identify information eligible for withholding.

The staff must review the request and determine whether there is a compelling reason to withhold the information (see NMSS P&PL 1-85,"Handling Requests to Withhold Proprietary Information from Public Disclosure," ML050340352). Care should be taken not to withhold more information than can reasonably be justified. The OGC should be consulted on unusual or complex requests. Routine requests may be processed without OGC review. The staff must inform the submitter whether it is granting or denying the request in accordance with 2.390(c). This section specifies when a submitter may withdraw information from consideration.

Withdrawn information cannot be referenced in any NRC document and must be treated as if never received. For this reason, it is very important that the disclosure determination be made quickly, even if the document will not be processed immediately. A partial denial document will contain some material that will be withheld in accordance with 10 CFR 2.390, but that certain other material should be released and placed in ADAMS. A sample acceptance denial, and partial denial letters are available as Templates.

As an example, 10 CFR 2.390(a)(3) specifies that information may be withheld from disclosure if those matters are specifically exempt from disclosure by statute. The National Historic Preservation Act, Section 304, and certain state statutes require withholding of locations of historic structures or archaeological sites from public disclosure. A similar principle applies to the location and types of endangered species. Withholding this information is intended to prevent trespassing, vandalism, theft of artifacts, and destruction of habitat. An approval letter citing the National Historic Preservation Act is available in ADAMS at ML071700634.

8.3 Security-Related Documents

Under 2.390(b), an affidavit is required to establish the basis for a finding that information should be withheld from the public. However, In 10 CFR 2.390(d), the Commission has established there is a compelling reason for withholding certain security-related information. Therefore, no affidavit is required for this type of information. For withholding information listed in 10 CFR 2.390(d), the PM does not need to respond to the licensee. For security related information not specifically listed in 10 CFR 2.390(d), the PM may include language similar to the following phrase in the response letter:

> We have determined that the enclosure to your *[date]* letter contains information meeting the requirements specified in 10 CFR 2.390(d). Accordingly, pursuant to Section 2.390(d)(1), such information is deemed to be commercial or financial information within the meaning of 10 CFR 9.17(a)(4) and shall be withheld from public disclosure unless subject to the provisions of 10 CFR 9.23.

The response letter should normally be issued within 30 days of receipt of the incoming request.

8.4 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 8.1 **Acceptance of Withholding Document (ML082470335)**

Template 8.2 **Denial of Withholding Document (ML082470431)**

Template 8.3 **Partial Acceptance of Withholding Document (ML082470460)**

8.5 References

See Appendix B, 9/12/94 Memorandum to Office Directors and Regional Administrators from James M. Taylor, EDO, with additional guidance on the review of proprietary documents (ML030090351).

NMSS Policy & Procedures 1-86, May 2008, "NMSS Staff Support of the Hearing Process in 10 CFR Part 2" (ML073511465).

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CHAPTER 9
POLICY AND CRITERIA FOR PROCESSING OF LICENSING ACTIONS

9.1 Purpose

Provide instruction to staff for processing an amendment, renewal, or a new license application, including receipt, acceptance/non-acceptance, denial, and issuance of an application. This chapter provides the format and examples for various licensing related correspondence in order to facilitate a timely review process. Failure to perform timely reviews can result in staff being unaware of actions that require expedited reviews because of safety-significance or business reasons.

Licensees are encouraged to have pre-submittal consultations on new licensing actions, particularly new licenses or new processes for existing licensees. This helps the licensee better understand NRC expectations for the application and should eliminate the need for an extensive request for additional information (RAIs).

For major license applications such as for new facilities, the staff will consider meeting with local elected officials and holding public meetings to discuss the NRC licensing process. This helps local officials and the public better understand NRC's licensing review process and opportunities for public involvement in the process.

9.2 Licensing Overview

Exhibit 9.1 illustrates the licensing process as a flow chart. This flow chart illustrates the standard licensing milestones. The metrics are listed in the NMSS Operations Plan Metrics (Ops Plan) The FCSS LAs can provide access to the most current Ops Plan, located at S:\FCSS Operating Plan. PMs should be aware of the following key metrics, based on the 2010 Ops Plan (Note: Unless specified otherwise, the times listed below are calendar days).

• Assign TAC	7 days from the docket date
• SUNSI Reviews	5 **business** days from the docket date
• Acceptance Review	45 day from the docket date
• Withholding (2.390)	60 days from acceptance
• Publication of FRN for Part 2 (Hearing)	Shortly after acceptance
• Completion of Non-Major Licensing Actions	150 days from acceptance
Completion of Major Licensing Actions	540 days from acceptance
• Public Meeting Notice on Web	10 days prior to the meeting
• Public Meeting Summary	30 **business** days after the meeting
• NRC Public Documents in ADAMS	5 **business** days from the document date

The following discussion focuses on the PM's role in the license review process.

Upon receipt of a licensing action, the PM requests the LA to open a TAC. PMs may provide an acknowledgement of receipt to the licensee via e-mail or phone, which may be docketed. An acceptance review must be conducted and completed within the time frame specified in the Ops Plan. Technical reviewers are selected to participate in the acceptance review. The goal of the

review is to determine if sufficient information has been provided to demonstrate regulatory compliance. The conclusion of the review is documented and sent to the licensee.

The acceptance review correspondence is considered an official record of a licensing decision and must be docketed. Templates available at the end of the chapter provide guidance on formatting the acceptance review response.

The Ops Plan metric specifies the number of days allowed to complete a licensing action, starting from the date of the acceptance letter. Complex applications are allotted additional time for review, see Definition of a Complex Amendment. Once the deadline has been established, the PM should schedule major milestones of the review, such as developing RAIs, site visits, receiving RAI responses, developing SER inputs, etc.

To support the review of the licensing action, the PM may obtain relevant technical expertise through Technical Assistance Requests (TARs), arrange for the conduct of an environmental review, and contact external stakeholders (e.g. local, state, federal, etc.), as appropriate. The PM develops the SER with input from the technical reviewers. The PM also works with the LA to prepare the license or its amendment, if applicable. The PM completes the licensing action by sending a transmittal letter with any attachments, such as the SER and the licensing amendment, and obtains the appropriate staff and management concurrence. Note that the NMSS metric for completing a licensing action can be extended in rare circumstances.

9.3 Definition of a Complex Licensing Action

A complex licensing action involves one or more of the following criteria:

1. a license renewal;
2. coordination with any of the following: contractors, the Commission, or Federal, State, local, or foreign governments;
   - Licensing actions which require coordination with multiple outside agencies or Offices are more likely to be designated complex.
3. significant plant changes (e.g., doubling the facility size or material/chemical holdings);
4. a complex environmental assessment (EA);
   - the review requires coordination with DOE (regarding technology and/or safeguards)
   - a non-NMSS Office writes the EA
   - the EA addresses issues of high controversy (e.g., disputed transportation of nuclear material routes)
   - the EA addresses an issue not previously addressed in a National Environmental Policy Act document
5. an Environmental Impact Statement;
6. direct or indirect transfers of license;
7. hearings;
8. non-routine stakeholder interactions;
   - licensee disagreement or controversy over interpretation of regulations (example: LES level of detail issue)
   - State government non-concurrence on EA/finding of no significant impact (example: Historic preservation issue with AREVA-Richland)

- local residents' requests for special meetings to discuss topics of high interest or controversy (example: ground water contamination-Hematite)

9. inspection(s) or pending enforcement and/or allegation issues;
10. issuance of orders;
11. a complete revision of a security plan in response to new rulemaking or new security related orders being issued;
12. other licensing actions which the Director of FCSS determines to be complex.

9.4 Delegation of Authority

All licensing documents issued by the NRC must be concurred on and signed by the appropriate staff and management. The PM is responsible for identifying the individuals who must concur on each document. NMSS maintains a delegation of authority list to indicate what level of management should review and sign the document. The list is located in ADAMS Document Manager in the NMSS\NMSS DOA folder (see ML081330667 and ML082210421). Documents concurred on or signed by the Office Director must be concurred on by the NMSS technical editor and OGC.

9.5 Common Types of Licensing Documents

Acknowledgement of Licensing Action
PMs may acknowledge licensing actions upon receipt as a courtesy. Acknowledgements can be via a telephone call to the licensing contact or via e-mail.

Procedure for Issuing an Acknowledgement Letter

If the acknowledgement letter is sent via e-mail, use the following:

1. Send the acknowledgement letter via an e-mail addressed to the licensee's primary contact and copy (cc) the LA.

2. Provide the LA a Form 665S with the appropriate docketing information.

3. Notify the LA in person that the e-mail needs to be docketed in ADAMS.

See the Templates.

Overview of an Acceptance Review

Within the Ops Plan metric, the licensing staff should perform an acceptance review of the submittal. The acceptance review serves as the initial screening of an applicant's request and provides the initial estimate for allocating staff resources to support a complete licensing review. An applicant's request must provide sufficient information, both quality and quantity, by either inclusion or reference, to address the regulatory requirements of the proposed action.

The acceptance review includes, but is not limited to, the following:

- ❑ determining that all necessary sections of the application are complete and the application has been signed by the applicant's certifying official;

- ❏ verifying that the applicant included all documents identified as attachments in the submittal;
- ❏ determining that all drawings are legible;
- ❏ determining that sufficient information is provided in the submittal to support a detailed review;
- ❏ if the submittal is marked Official Use Only (OUO) or proprietary, ensuring that a redacted version and affidavit have been provided;
- ❏ determining that there are no obvious technical inadequacies;
- ❏ identifying any licensee requests for exemptions from the regulations;
- ❏ identifying any significant technical issues that could become problematic during the review or could impede the NRC's ability to license the facility. Other issues should be handled through the RAI process.

The staff should also identify any requests for expedited review for safety significant concerns (e.g., amendment requests resulting from the identification of safety-significant violations), regulatory compliance, or business reasons (e.g., change in ownership or other financial concerns).

Procedure for Issuing an Acceptance Letter

The acceptance letter should contain the following:

1. Acknowledge that the request for the licensing action has been received (unless an acknowledgement letter has already been sent) and has been accepted for review.

2. Note any deficiencies/omissions that were identified during the acceptance review that could delay further review.

3. Inform the licensee that the technical review may identify omissions in the submitted information, technical issues that require additional information or policy/technical issues that require coordination with other NRC offices.

4. Provide the licensee with an estimated time for completion of the licensing action. The estimated time for completion should account for any request for an expedited review and be in accordance with regulatory guidance or previously agreed on times for specific program areas.

5. For a license renewal, include a paragraph notifying the licensee of the status of timely renewal. The paragraph should state that the license "will not expire until the Commission makes a final determination on the renewal application, in accordance with the timely renewal provision of 10 CFR 40.42(a) or 10 CFR 70.38(a) or 10 CFR 76.55".

6. Note that the letter will be archived in ADAMS as publically available or as an Official Use Only (OUO) document.

See the Templates.

Procedure for Issuing an Acceptance Email

PMs may issue acceptance emails to the licensees for emergency plans, security plans, license amendment applications, and other licensing actions.

If the review leads the staff to determine that the submittal is acceptable, the PM sends an acceptance email to the licensee (see the renewals and amendments templates). The acceptance email should contain the following:

1. Within the Ops Plan metric, perform an acceptance review of the submittal.

2. Acknowledge that the request for the licensing action has been received and has been accepted for review.

For an example of an email acceptance, see the Templates.

Procedure for Reviewing Officials for Fingerprinting and Background Check

PMs receive requests from licensees for review of approving officials for implementing the fingerprinting order and criminal history background checks. The PM forwards the request along with the information on the proposed reviewer to the Facilities Securities Branch in the Office of Administration. Once they make a determination, they notify the PM via email of approval or the need for additional information. If the proposed reviewer is approved, the PM is responsible for providing an acceptance letter.

See Templates.

Overview of Nonacceptance Letter

If the submittal has obvious technical inadequacies, the staff should brief management prior to making a final decision regarding the submittals. If the review identifies technical inadequacies, the PM has two possible options. The PM can call the licensee and offer them the opportunity to withdraw the licensing action and re-submit or the PM may send a non-acceptance letter to the licensee (see templates for renewal non-acceptance letter or amendment non-acceptance letter).

Procedure for Non-Acceptance Letters

1. Acknowledge that the request for the licensing action has been received.

2. Clearly inform the licensee that the submittal has undergone an initial acceptance review.

3. Note that the submittal has not incorporated all essential elements to enable an adequate safety review.

4. Note that the NRC does not accept the submittal for formal review.

5. For a license renewal, include a paragraph indicating how the non-acceptance affects timely renewal status (STAFF NEEDS TO COORDINATE TIMELY RENEWAL IMPACTS WITH OGC).

6. Provide the specific deficiencies with the submittal.

7. Indicate the licensee may elect to resubmit the amendment at a future date after addressing the technical inadequacies.

8. Note the letter will be archived in ADAMS as publically available or as an Official Use Only (OUO) document.

Reference: NMSS Policy and Procedures Letter 1-51, "Initial Processing of Incoming Licensing Actions."

See the Templates.

Overview of Acceptance of Site Plans

NRC regulations in 10 CFR 40.35(f); 70.32; 76.91(o), and 95.19(b) allow licensees to make changes to the Emergency Plan, FNMC Plan, Physical Protection Plan, and Standard Practice Procedures Plan without prior approval by NRC provided that the changes do not decrease the effectiveness of licensee programs for public protection ("no decrease changes"). Specifically,

- 40.35(f) allows licensees to change emergency plans,
- 70.32(c)(1)(iii) allows licensees to make changes to the materials control and accounting (MC&A) programs,
- 70.32(d) allows licensees to change physical protection plans for special nuclear material in transit,
- 70.32(e) allows licensees to change security plans,
- 70.32(g) allows licensees to change safeguards contingency plans,
- 70.32(i) allows licensees to change emergency plans,
- 76.91 allows certificate holders to change emergency plans, and
- 95.19(b) allows licensees and certificate holders to change Standard Practice Procedures Plan for the safeguarding of classified information

In addition, certain licensees have performance-based conditions in their licenses that allow certain changes without prior approval from NRC.

In each case, the licensee is required to inform the NRC of these changes within a specified time period along with the determination that the changes do not decrease the effectiveness of the plan or program. The period allowed for reporting the change ranges from 2 to 6 months depending on the program and special nuclear material characteristics. If changes are requested that would decrease the effectiveness, then licensees are required to request the changes by filing an amendment application in accordance with 10 CFR 70.34.

The difference between 10 CFR 70.32 and 70.34 amendment requests is that 10 CFR 70.32 changes can be implemented before NRC issues the amendment, but 10 CFR 70.34 changes must receive pre-approval.

The Project Manager will **not review DRAFT submittals** of "no decrease changes." The onus is on the licensee to make the initial determination in accordance with 10 CFR 40.35 or 70.32. FCSS does not generally conduct a special inspection for these changes. The changes will, however, typically be reviewed as part of the next routine inspection that encompasses the change program (see Templates for example of a 10 CFR 70.32(c) letter).

If the staff's review indicates the changes decrease the effectiveness of the plan and the licensee has implemented the changes, enforcement is warranted. The PM will inform the licensee in writing of the conclusion and request that the original plan be restored (without the proposed changes).

Licensees may elect to resubmit the changes as a standard amendment request provided that the original plan is reinstated in the interim. In coordination with inspection staff, licensing staff will consult with the licensing reviewer and the Regional Office on whether a violation occurred in conformance with the NRC Enforcement Policy or the NRC Enforcement Manual. If an enforcement action is warranted, the Regional Office, in consultation with headquarters staff, will initiate the action. Headquarters staff will provide support to the region as needed to process the enforcement action.

Procedure for Acceptance Review for Site Plans

1. When changes are reported under 10 CFR 40.35, 70.32, 76.91, or 95.19, the PM, in conjunction with the lead licensing reviewer and technical staff, conducts an acceptance review.

2. The review should check the accuracy of the licensee's submittal under 10 CFR 40.35, 70.32, 76.91, or 95.19.

3. The PM should draft an acceptance letter or a non-acceptance letter (see Templates) based on the results of the review.

4. For all requests where the acceptance review must be coordinated with other Divisions, Offices, or the Regions, a Technical Assistance Request (TAR) should be prepared.

See the Templates.

Overview of Transmittal Letter for Issuing a Renewal or Amendment

When issuing a renewal license or amendment, a transmittal letter is sent to the licensee. The letter should clearly explain the changes made to the Materials License and display the wording of any new or revised license conditions. (*Exception: The Authorized Use condition that revises the submittal dates does not have to be displayed.)*

Procedure for Transmittal of Renewal, Amendment, or Site Plan Changes

1. The inside address consists of the addressee's name and title on the first lines, followed by company name and street address. An "ATTN" line should not be used.

2. Insert a subject line after the address and include the TAC Number in parenthesis at the end of the line.

3. The salutation shall read: Dear Mr./Ms. *[Surname]*.

4. The complimentary closing should be "Sincerely."

5. Place *[docket number]* and License SNM-*[license number]* information two lines below the signature block flush with the left margin.

6. Add Renewal/Amendment information at the bottom of the page (the line below "License *[number]*"), flush with the margin.

7. On the concurrence page, before "Distribution:" insert "**CLOSES TAC** *[insert TAC number]*." The number can be found as either the casework control number on the casework log or by contacting the LA.

8. In the text, reference the licensee's incoming correspondence and state specifically the nature of the request and what is approved and/or changed in the license conditions.

9. Enclosures to the transmittal letter should include: (1) a copy of the revised or renewed Materials License and (2) a copy of the Safety and/or Safeguards Evaluation Report(s).

10. The Materials License and the Evaluation Reports do not have a concurrence page. All reviewers for the licensing action concur in the transmittal letter.

See the Templates.

Overview of Denial Letter for Renewal, Amendment, or Site Plan Changes

For requests that lack significant required information, the staff should initiate actions to deny the request. Management should be briefed on the issue. Division management will decide whether to continue actions to deny the request or attempt resolution with the licensee; Division management will also coordinate with the Office Director at this time. The Office of General Counsel should be involved in the denial action. Depending on the denial action, it may be necessary to inform the Commission before taking final action. When a denial is issued, the licensee is entitled to an opportunity for hearing, see the Hearings chapter.

Procedure for Denial Letter for Renewal, Amendment, Site Plan Changes

1. The inside address consists of the addressee's name and title on the first lines, followed by company name and street address. An "ATTN" line should not be used.

2. Insert a subject line after the address and include the TAC Number in parenthesis at the end of the line.

3. The salutation shall read: Dear Mr./Ms. *[Surname]*.

4. The complimentary closing should be "Sincerely."

5. Place *[docket number]* and License SNM-*[license number]* information two lines below the signature block flush with the left margin.

6. On the concurrence page, before "Distribution:" insert "CLOSES TAC *[insert TAC number]*." The TAC number can be found as either the casework control number on the casework log or by contacting the LA.

See the Templates.

Procedure for Transmittal of a New License

1. The inside address consists of the addressee's name and title on the first lines, followed by company name and street address. An "ATTN" line should not be used.

2. Insert a subject line after the address and include the TAC Number in parenthesis at the end of the line.

3. The salutation shall read: Dear Mr./Ms. *[Surname]*.

4. The complimentary closing should be "Sincerely."

5. Place *[docket number]* and License SNM-*[license number]* information two lines below the signature block flush with the left margin.

6. On the concurrence page, before "Distribution:" insert "**CLOSES TAC** *[insert TAC number]*." The number can be found as either the casework control number on the casework log or by contacting the LA.

7. In the text, reference the licensee's incoming correspondence.

8. The enclosure to the transmittal letter is a copy of the Materials License.

9. The Materials License does not have a concurrence page. All reviewers for the licensing action concur in the transmittal letter.

See the Templates.

Procedure for a Letter of Intent

Applicants may submit pre-application letters of intent to file an application. NRC policy is that all important applications, such as letters of intent to file an application, be noticed on the NRC website. The NMSS P&PL 1-86 "NMSS Staff Support of the Hearing Process in 10 CFR Part 2" (dated May 2008) provides guidance for PMs on forwarding the information for posting to the NRC website:

1. Evaluate whether the licensing activity meets the criteria for posting on the NRC website.

2. Send a request for the posting to Office of Information Services. P&PL 1-86 describes the specific information to be contained in the request.

3. Verify that the posted information is correct.

4. Keep the entry up-to-date and request that it be deleted in the request to post the application.

The PM should prepare an acknowledgement letter that the letter of intent was received. See templates.

9.6 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 9.1 **Acceptance of 70.32 Change Template (ML100950581)**

Template 9.2 **Acceptance of Amendment Application (ML082470312)**

Template 9.3 **Acceptance of Amendment Application for Site Plans (ML082470319)**

Template 9.4 **Acceptance of Proposed Reviewing Officials (ML100910497)**

Template 9.5 **Acceptance of Renewal Application (ML082470323)**
Template 9.6 **Acceptance of 70.32 Change Template (ML100950581)**

Template 9.7 **Acknowledgement for Letter of Intent (ML082520258)**

Template 9.8 **Amendment Transmittal Letter for Site Plans (ML082470346)**

Template 9.9 **Amendment Transmittal Letter (ML082470351)**

Template 9.10 **Denial of Licensing Action Request (ML082470431)**

Template 9.11 **Email Acknowledgement Letter (ML082470337)**

Template 9.12 **Nonacceptance of Amendment Application (ML082470452)**

Template 9.13 **Nonacceptance of Amendment Application for Site Plans (ML082470455)**

Template 9.14 **Nonacceptance of Renewal Application (ML082470457)**

Template 9.15 **Renewal Transmittal Letter (ML082470462)**

Template 9.16 **Transmittal Letter for New License (ML082670476)**

Exhibit 9.1
Licensing Flow Chart

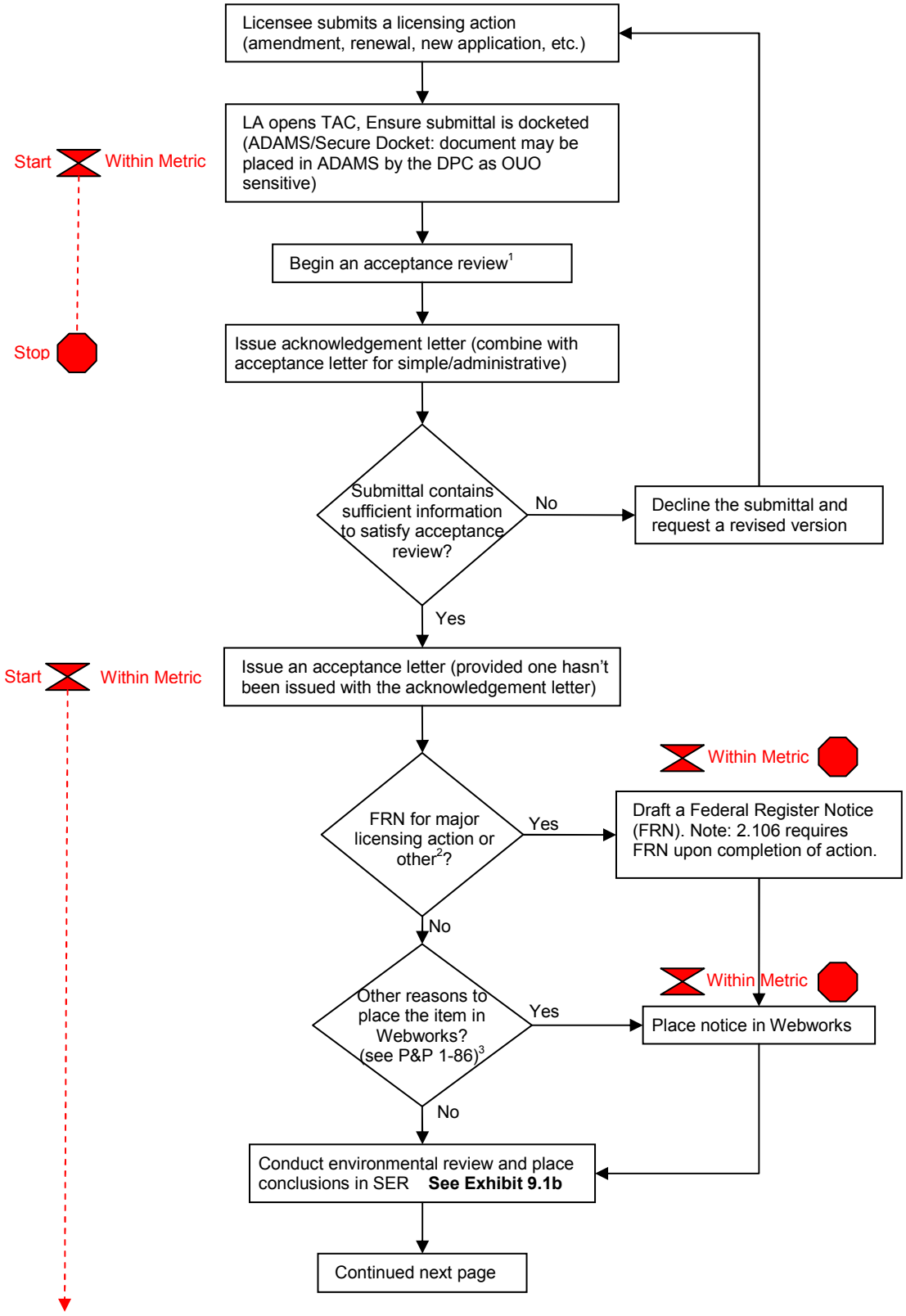

Exhibit 9.1
Licensing Flow Chart, continued

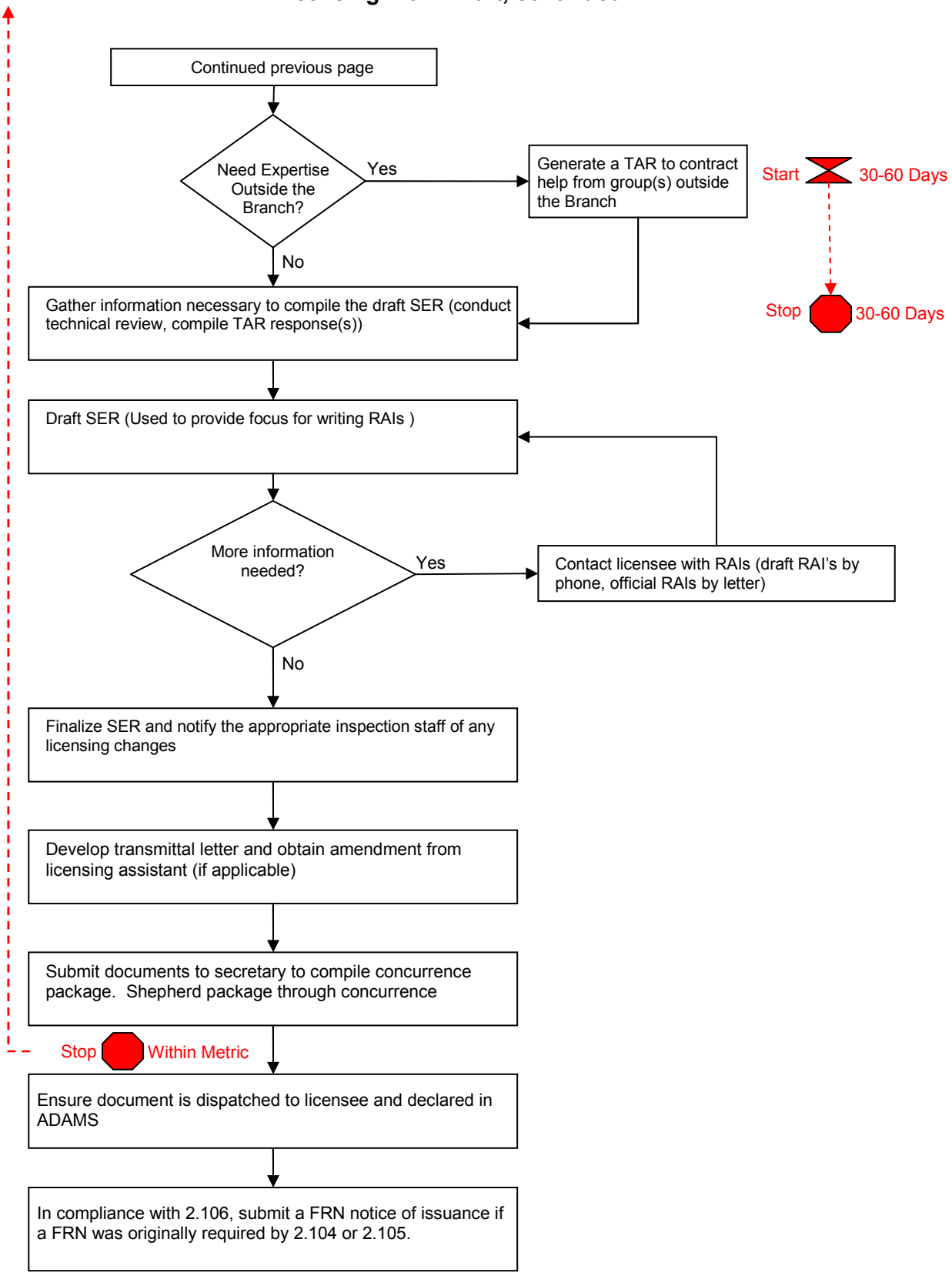

Exhibit 9.1b
Licensing Flow Chart, Environmental Review

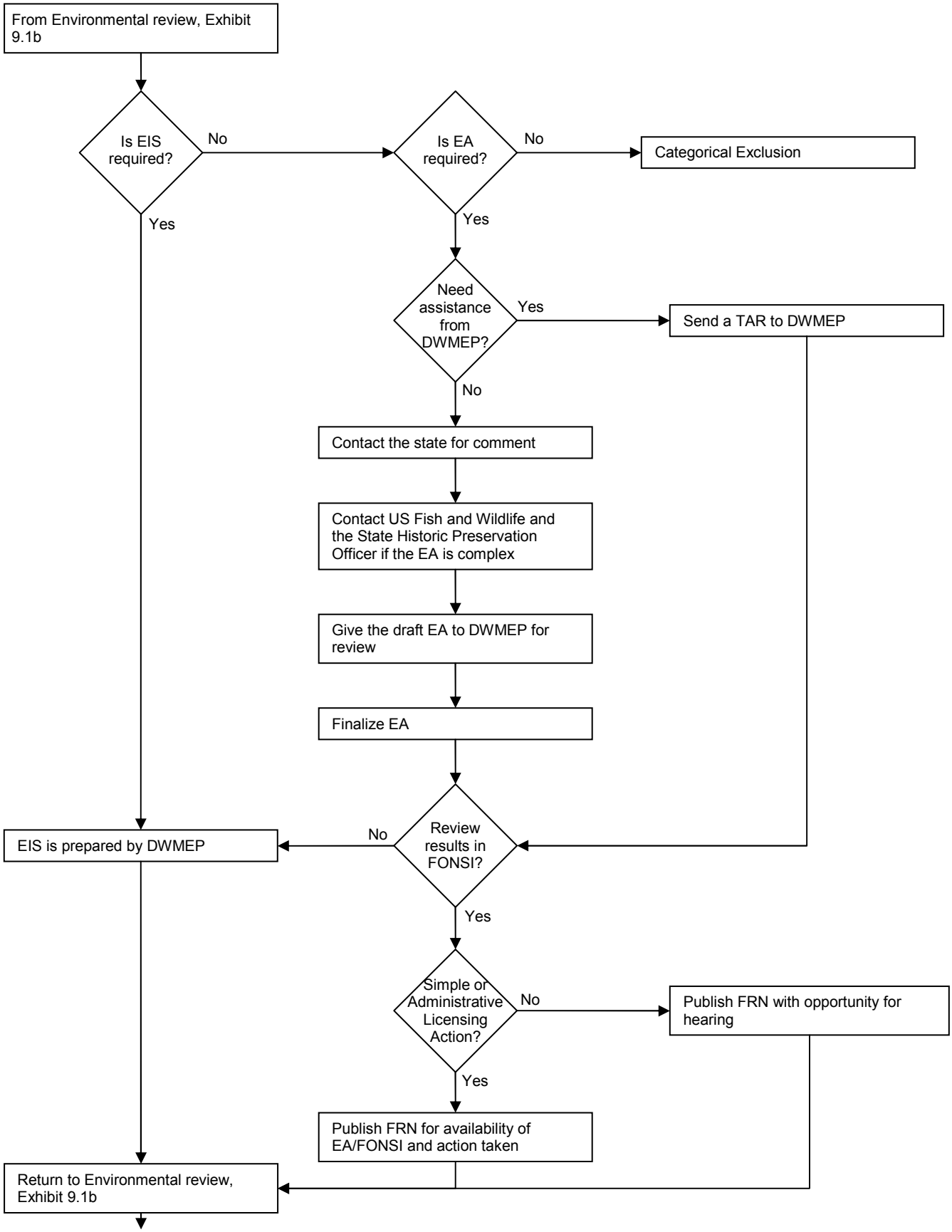

Exhibit 9.1
Explanations

1. Details of an acceptance review are located in this chapter under the title, "OVERVIEW OF AN ACCEPTANCE REVIEW"

2. Criteria for posting a licensing action in the Federal Register include: renewals, license transfers, new applications, and major federal actions, refer to 10 CFR Part 2.

3. Criteria for listing an item on Webworks include (Drawn from P&PL 1-86 "NMSS Staff Support of the Hearing Process in 10 CFR Part 2"):
   - Do not file to Webworks for license amendments involving matters such as adding administrative buildings, minor changes to processes, minor decommissioning amendments, and minor site modifications involving routine matters that normally would not meet the criteria for noticing on the NRC website.
   - Regulatory requirements for hearings or notice of an opportunity for hearings for a particular licensing action.
   - Preparation of an Environmental Impact Statement as stated in 10 CFR 51.20.
   - The activity involves a site-specific ISFSI license.
   - The facility to be licensed is required to prepare an emergency plan, for example under 10 CFR 70.32(i) or 10 CFR 40.31(j)(1)(ii). This applies to new licenses or modifications to a license that result in the need for an emergency plan.
   - The licensing action has a high degree of public interest that will likely result in requests for hearings being submitted. This type of interest may be expressed by major stakeholder groups, congressional interest, local or state government agencies, Indian tribes and officials, and others who may have standing under 10 CFR 2.309.

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CHAPTER 10
MATERIALS LICENSE AND CERTIFICATE OF COMPLIANCE

10.1 Format

10.1.1 Materials License

Licenses will be typed on pre-printed forms (NRC Form 374 and 374A). The license will not contain a concurrence page, but rather concurrence will be shown on the transmittal letter concurrence block. Examples of current materials licenses can be found by searching for a recent amendment to a specific license in ADAMS. (In ADAMS, enter the licensee's docket number (see ML033250147 and ML081720442 for lists of licensees and certificate of compliance holders), a recent date range, and search for amendment. Each amendment package contains a copy of the license.

For all licenses, Conditions 1 through 9 are considered generic license conditions:

1. Licensee name
2. Address
3. License Number
4. Expiration Date
5. Docket or Reference Number
6. Possession Limits (Isotopes)
7. Possession Limits (Chemical/Physical Form)
8. Possession Limits (Grams/Kilograms/Curies)
9. Authorized Place of Use

For those licenses containing multiple sections, for example Safety, Safeguards and Transportation Conditions, Condition 10 will be written to merge these conditions into one document and will read as follows:

Example:
[This license shall be deemed to contain three sections: Safety Conditions, Safeguards Conditions, and Transportation Conditions. These sections are part of the license, and the licensee is subject to compliance with all listed conditions in each section.]

The signature block will appear on the page containing Condition 10 for licenses that have both safety and safeguards conditions. For those licenses which contain only safety conditions, the signature block will appear on the last page of the license.

For licenses with safety and safeguards sections, license conditions will be numbered sequentially with a letter(s) prefix as follows:

- Safety Conditions: S-1, S-2, S-3, etc.
- Safeguards Conditions: SG-1, SG-2, SG-3, etc.
- Transportation Conditions: T-1, T-2, T-3, etc.

License Amendments are incorporated into the license by recording the date of the approval letter into the appropriate license condition.

10.1.2 Certificate of Compliance

Instead of a materials license, Gaseous Diffusion Plants (GDPs) are issued a Certificate of Compliance for them to operate. A certificate template is located in the FCSS G: drive. The certificate will not contain a concurrence page, but rather concurrence will be shown on the transmittal letter concurrence block. An example of a current certificate of compliance for Paducah can be found in the FCSS G: drive or by searching in ADAMS for “Certificate of Compliance for GDP.”

For all certificates, Conditions 1 through 6 are considered generic license conditions:

1. Certificate Number
2. Amendment Number
3. Expiration Date
4. Issued To (Name and Address)
5. Facility and Location
6. Docket Number

10.2 Temporary or One Time License/Certificate of Compliance Conditions

When a licensee requests to have a "temporary or one time license condition" added to its license, for a circumstance or a situation that may appear to be of short duration or of an insignificant nature (e.g. extension of a survey date deadline by a few days or weeks, authorization to accept a delivery of nuclear material which will remain onsite for a short period of time), a license condition must be added to the license documenting the change/deviation from the license. The following procedures should be followed:

1. The licensee must submit detailed information regarding the requested change to the license.

2. A license amendment should be issued incorporating the new or revised license condition into the license, including an expiration date or specific event at which the condition terminates.

3. State the expiration date or termination event in the transmittal letter.

4. After fulfillment or expiration of the condition, the license should be revised to delete the license condition text. The condition number should remain with a brief statement as to why the condition was deleted. The condition number will remain in the license until the next renewal, at which time it will be removed and the remaining conditions renumbered.

10.3 Deleting License/Certificate of Compliance Conditions

License and Certificate of Compliance conditions that have been satisfied should be deleted from the license or certificate through amendments. The text of the license/certificate condition will be deleted but the condition number will remain with an explanation as to why it was deleted, the date, and the applicable amendment number. The condition numbers will remain in the license or certificate until renewal.

10.4 Exemptions

Authority to grant *exemptions to the regulations* (10 CFR Parts 20, 30, 40, 70, 76), issued by license amendment, has been granted to NMSS Division Directors, but may be re-delegated in writing to Deputy Directors citing specific types of exemptions (see NMSS 2008 Delegation of Authority). When issuing a license or certificate amendment that grants an exemption to the regulations, the signing authority will be consistent with NMSS Delegation of Authority guidance. FCSS will process exemption requests in accordance with P&PL 1-58 (ML031840564) "Processing of Exemptions for Material Licensees and Certificate Holders".

The Commission approved the staff's procedures for reducing the need for exemptions and ensuring consistency of the exemption process. The Commission stated:

> "[t]he Commission believes that the staff should apply the regulatory criteria for exemptions objectively and without any preconceived notion that exemptions should either be limited or circumscribed or, conversely, readily available for anyone who seeks an exemption" [SRM on SECY-96-249].

Fuel cycle staff will apply this approach in discussions with licensees or certificate holders who may be seeking an exemption from a particular requirement. The staff is responsible for identifying regulations that engender an inordinate volume of exemption requests. Under these conditions, staff will promptly communicate the need for regulatory revisions to the rule making office (Office of Federal and State Materials and Environmental Management Programs - FSME) through a "User Need" memorandum. The rulemaking office collects a list of the number of exemption requests received and the number granted or denied in the semiannual updates of the Rulemaking Activity Plan.

Any exemption from the regulations shall be identified and entered into the License Tracking System (LTS) database by FSME, including the specific citation (example: 20.1301(a)(2)). When an exemption to the regulations occurs, the PM or the LA notify by e-mail the appropriate contact in FSME (Division of Materials Safety and State Agreements as of October 2006). This documentation should include the licensee's name, docket number and license number, the specific section of the regulation from which the exemption is requested, and the decision on the request. The PM should notify the LA if an amendment has any "hidden" exemptions. FSME will use the exemption reports and the information entered into the LTS to provide input to the semiannual update of the Rulemaking Activity Plan provided to the Commission.

When licenses are renewed, staff shall carefully review any previous exemptions that have been issued to the fuel cycle licensees and either reaffirm the appropriateness of the exemption or conclude that the exemption can no longer be justified. Exemptions should not simply continue based on past licensing experience without a proper and thorough review.
As with any action requiring prior NRC approval, an exemption requires an environmental review as part of the staff's evaluation. If the action falls into a category excluded from environmental review, the safety evaluation report (SER) must explain the staff's finding that the action meets a categorical exclusion, in accordance with 10 CFR 51.22(c) (see NUREG 1748 section 2.2.7). Otherwise, the SER must address the results of an environmental assessment performed in accordance with 10 CFR 51.30 (see NUREG-1748). Exemptions often involve special circumstances and there may be differing opinions on the need for an environmental assessment. PM's should consult with OGC early in the review to confirm a common understanding of the environmental review required for the action.

Traditionally, exemptions are implemented as a license condition for fuel cycle facilities. As a result, the exemption involves issuing a license amendment, which may require publication of a Federal Register Notice for an opportunity to request a hearing (see Section 18.1.2). OGC has notified NMSS that exemptions do not always require incorporation into the license as an amendment and may not require hearing rights (ML101330275). As of May, 2010 OGC was developing a Commission paper proposing a formalized procedure for issuing exemptions in NRC licensing proceedings. The Commission's response to this paper should provide additional guidance on an approved method for issuing exemptions. In the mean time, OGC has indicated they need to review each exemption to determine if hearing rights are required and if the exemption should be implemented as a license amendment.

10.5 License/Certificate of Compliance Terms of Less than Maximum

Generally, the terms for licenses issued by FCSS are typically between ten and twenty years, expiring at the end of the month of issuance. Certificates of Compliance are issued for 5 year terms.

In 2006, the NRC established a new maximum license term of forty years for 10 CFR Part 70 licensees who are required to submit Integrated Safety Analysis (ISA) Summaries (see 71 FR 70441, December 4, 2006). Licensees can request up to a forty-year term at the next license renewal. In this policy, the NRC also established a maximum license term of forty years for new 10 CFR Part 70 licenses where the applicant is required to submit an ISA. The 2006 policy did not affect the maximum license term of ten years for 10 CFR Part 70 Greater than Critical Mass licenses. When issuing new licenses or renewing existing licenses, reviewers should consider shorter license terms for the following types of cases:

1. New Technology. The industry, or the particular licensee, or the NRC, has not had extensive experience in using or regulating the proposed use of a new technology. (If a new technology is being added to an existing license, the staff should consider the need to inspect the facility on a more frequent basis. In addition, at the next license/certificate of compliance renewal, the staff should consider issuing the license/certificate of compliance for a term less than maximum.) Under these circumstances, NRC may want to revisit the specific conditions and requirements associated with new technologies more frequently. Possible candidates include new license categories for Department of Energy activities converted to commercial facilities.

2. Enforcement History. Licensees/certificate holders whose enforcement histories indicate that the licensing staff may need to review their programs in less than the maximum allowed timeframe. These would include licensees who have received a Severity Level I or II violation during the 3-year period immediately before the purposed renewal or licensees who have received non-escalated enforcement actions where additional or repetitive violations were identified during the 3-year period immediately before the proposed renewal.

3. Other. Any other situation that would warrant increased NRC attention, on a case-specific basis.

The staff analysis of the license/certificate of compliance term and justification for any terms less than the maximum allowed duration shall be documented in the SER that accompanies the license.

10.6 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled “NMSS-FCSS Templates” (ML082470284).

Template 10.1 GDP Certificate of Compliance (Not Currently Available)

Template 10.2 Materials License (see NRC Form 374)

Template 10.3 User Need Memorandum (Not Currently Available)

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CHAPTER 11
TECHNICAL ASSISTANCE REQUEST PROCESS

11.1 Introduction

This Division procedure is established to provide guidance in preparing and processing Technical Assistance Requests (TARs).

11.2 Function of TARs

The purpose of a TAR is to obtain a regulatory decision on a licensing action which provides reasonable assurance of adequate safety or security, and determines if the licensing request satisfies the regulatory requirements. The TAR process allows the PM to draw on the expertise of technical specialists outside the PM's branch. TARs are routinely used to request reviews on subjects for which other groups have lead responsibility (i.e. Nuclear Security and Incident Response, etc). Within the division of FCSS, TARs are not required between branches. However, the request for assistance should be made at the branch chief level.

11.3 Preparation of TARs

Since TARs are a formal request for assistance, they are prepared by the PM and forwarded to the PM's immediate supervisor. (Note: The PM may request the LA to proof the TAR and track the due dates in the case work log.) The PM's supervisor reviews the TAR and forwards the request via e-mail to the appropriate management in the group receiving the TAR. The receiving manager approves the request and appoints a staff member to provide the requested assistance.

- The TAR should be an e-mail in the form of a memo sent from the requesting organization to the responding group.
- The example provided in Template 11.1 should be filled out and e-mailed to the PM's supervisor as an attachment.
- The PM's supervisor will cut and paste the text (modified where necessary) into an e-mail to the manager of the group receiving the TAR, and CC the originator (PM) and the LA.
- The manager receiving the TAR will respond with an e-mail confirming the TAR agreement and providing the name of the assigned reviewer and the agreed upon response dates.
- The LA should put the e-mail as well as the reply in ADAMS. TARs and the responses should be designated as "Not Publicly Available" when entered into ADAMS.

11.4 TAR Content

TARs should be formatted in accordance with the Template 11.1, (see Template 11.1 examples). The TAR should contain the following:

- The background information needed to complete the request (e.g. Docket Number, technical assignment control (TAC) Number, and the ADAMS accession number of the licensing action);

- A paragraph stating the originators' requested action including: a concise description of the problem, a specific statement defining the actions requested, and recommended path forward, if appropriate;

- An estimate of total staff hours required to complete the tasks; and

- A proposed completion date for the items requested in the TAR.

11.5 Acceptance Review

TAR acceptance reviews should be completed by the assigned reviewer within 14 days of receipt. PMs have a limited time to issue an acknowledgment letter to accept for review or decline a licensing request. If a TAR acceptance review reveals significant problems with a submittal, the PM must be made aware before the acknowledgment letter is issued. To ensure the PM can meet the Ops Plan deadline, the TAR reviewer should return a recommendation of "accepted for review" or "declined for review" within 14 working days.

11.6 Approximate Time Frame: Start To Finish

When calculating the desired response date for the TAR, PM's should calculate backward from the Ops Plan deadline, taking into consideration time for the acceptance letter, Requests for Additional Information (RAI), licensee response to RAI's, and Safety Evaluation Report (SER). The TAR response should allow, as a minimum, 30 days for acceptance review, 30 days for RAI input, 30 days for RAI response from the licensee, and 30 days for SER input.

11.7 Storage and Access of TARs Documents

TARs and the response should be placed in ADAMS by the originating organization's LA. TAR responses are intended for use by NRC staff only and should be designated "Not Publicly Available" when entered into ADAMS. The TAR's title should contain the TAC number for easy search in ADAMS. TARs containing NRC safeguards (SGI) or classified information should be handled based on the guidance in Management Directive 12.2 and 12.6.

11.8 Concurrence

TARs do not pass through the normal concurrence process involving a package and signatures. The TAR is handled through a less formal e-mail chain from the PM to the immediate supervisor, then to the management in the group providing the review, and finally to the assigned reviewer.

11.9 Roles and Responsibilities

Licensing Assistant - The LA dockets the TAR and response in ADAMS. The LA may also note the TAR response dates for tracking in the case work log.

Management – Management prioritizes TARs with respect to other work assignments. The issuing PM's management reviews the TAR before e-mailing it to the desired reviewer's

immediate supervisor. The receiving manager fills in the completion dates, assigns a reviewer, and e-mails a response to the issuing PM. The managers should provide an e-mail copy of the TAR and the response to the LA for docketing.

Project Manager - The PM recognizes the need for a TAR, writes up the draft TAR, delivers the draft TAR to management, interacts with the reviewer to ensure the product meets expectations, incorporates the TAR response into the licensing action, and is ultimately responsible for the content and format of the licensing action. The PM is also responsible for ensuring that the reviewer's response to the TAR is docketed.

Reviewing Staff – The reviewer receives the TAR from management, provides the requested technical information, interacts with the originator to ensure the product meets expectations, and provides the TAR response within the agreed time frame.

11.10 Template

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 11.1 **Technical Assistance Request (ML082470489)**

Template 11.2 **NSIR Technical Assistance Request (ML082670354)**
Example (ML082240339)

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CHAPTER 12
SAFETY AND SAFEGUARDS EVALUATION REPORTS

12.1 Background

A "Safety Evaluation Report," or a "Safeguards Evaluation Report," will accompany an amendment, issuance, renewal, or termination of a license. This report will discuss the methodology and logic for determining that the renewal or amendment can be issued without posing significant hazards to public health and safety or the environment. If an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) is not warranted, then the report will contain a Categorical Exclusion (CE) determination.

Most SERs for relatively simple amendments will not exceed several pages in length. The SERs for complicated amendments or licenses should be as concise as possible, while ensuring sufficient documentation to allow an independent reviewer to confirm compliance with NRC requirements. SERs may be classified or otherwise withheld from public release because they contain safeguards or material control and accounting (MC&A) information. When the SER is withheld from the public, only the cover letter will be made public.

12.2 Format

SER's for new license applications are issued as formal NUREG documents. Example formats for these NUREGs are cited in Template 12.1. Guidance on preparing a NUREG can be found in Management Directive 3.7, "NUREG-Series Publication."

For all other licensing actions, the SER is issued as an official Agency record, but not as a NUREG. At a minimum the report should contain the following sections: Background, Technical Discussion, Environmental Review, and Conclusion. In general, the format of the report should mirror the topics listed in the SRP. It is not necessary to cover all the topics of the SRP, only those that are applicable. SERs that exceed six (6) pages in length should contain a table of contents.

A. The *BACKGROUND* section of the report discusses the requested action and cites all incoming applications and pertinent correspondence (written or verbal requests for additional information, supplements, revised applications, etc.) that the staff utilized in reviewing the requested action.

   For 10 CFR 70.32 changes, (Fundamental Nuclear Material Control (FNMC) Plans, Physical Protection Plans and Emergency Plans) a statement shall be included indicating that the changes do not decrease the effectiveness of the plan.

B. The *TECHNICAL DISCUSSION* section should cite the applicable regulations, provide a summary of the applicant's evaluation, indicate how the applicant meets or proposes to meet the regulations, and summarize the staff's evaluation. The staff's evaluation is the essential part of the SER. It should include the reviewer's basis for concluding the applicant's proposals and analysis are acceptable. The discussion should provide an overview of any confirmatory analyses or verifications. The section should also justify any new or revised license conditions. Each technical section should conclude with a statement of the reviewers finding of adequacy, consistent with the SRP, and include the reviewer's basis.

C. The ENVIRONMENTAL REVIEW section of the report should discuss the environmental findings that may be associated with the requested action. Describe the environmental documentation (i.e. CE, EA, finding of no significant impact (FONSI), EIS, and Record of Decision) that supports the action. For a FONSI and an EA, include the EA date, the FONSI publication date, and the FONSI conclusions.

D. In the CONCLUSION section, state the staff's recommendations for approving the requested action. The PM must put the following statement after the staff's recommendation:

   [Approval of the amendment application is recommended.]

   Since all licensing actions are to be coordinated with the inspection staff *[regional or Headquarters (i.e. TSB, MC&A Branch)]*, include the statement:

   [The Region (I, II, III, or IV) or HQ inspection staff has no objection to this proposed action.]

On the last page, at the end of the text, flush with the left margin, will be the heading, *[PRINCIPAL CONTRIBUTOR(S):]*. The names of all reviewers, who contributed to the SER, should be listed. SERs should not contain a concurrence block. Although reviewers do not officially concur on the SER, they may submit a non-concurrence (see Concurrence discussion under the Interactions with Licensees section). Concurrence will be reflected on the concurrence block of the transmittal letter.

12.3 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 12. 1 **Safety/Safeguards Evaluation Report Administrative (ML082470485)**

Template 12.2 **Safety/Safeguards Evaluation Report Major Licensing Action (ML082470487)**

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CHAPTER 13
REQUEST FOR ADDITIONAL INFORMATION

13.1 Objective

The objective of this guidance is to define the process and format for developing Request for Additional Information (RAI) in order to improve FCSS's efficiency and consistency when requesting licensees to provide additional information. An RAI is generated when clarification and additional information are needed to determine if the licensee's submittal complies with regulations.

13.2 RAI Time Table, Planning, and Preparation

Step 1
The NRC receives a licensing action such as an amendment, renewal, ISA update, etc. The PM oversees a preliminary review for acceptance and sends the licensee an acceptance letter letter.

Step 2
From the date of acceptance, the PM has a limited number of days, determined by the Ops Plan, to conclude the licensing action. The PM, with assistance from the technical reviewers, develops a draft SER based on the submittal. If portions of the submittal lack sufficient information to ensure regulatory compliance, the PM places a note in the draft SER and develops an RAI.

Step 3
The PM compiles RAIs from all the technical reviewers. Once the full RAI list is compiled, the PM, technical reviewers, and the licensee may participate in a teleconference to exchange information and make sure the RAIs are clear for both the technical reviewers and the applicant or licensee. A written summary should be prepared to document the conference call.

Step 4
The PM prepares a formal letter to the licensee with the unresolved RAIs enclosed. The PM should consider e-mailing or faxing the RAIs informally in addition to mailing the letter. This allows the licensee to begin developing answers to the RAI immediately. The PM should set a reply date to the RAI letter of 30 to 60 days to ensure the licensing action can be completed within the metric timeframe.

Step 5
The licensee responds to the NRC letter with sufficient additional information to address each RAI. If the RAI response does not provide sufficient information, the PM should seek further input from the licensee by written correspondence. A conference call with the applicant/licensee may also be scheduled to discuss the RAI responses before submittal to ensure that the responses meet the technical reviewers' needs. The PM should prepare a written summary to document the call. The NRC technical reviewers will use the RAI responses to complete the draft SER. Once the submittal meets regulatory compliance, the NRC issues the licensing action.

13.3 General

Ideally, submittals should not require an RAI. Nevertheless, one RAI round is considered acceptable. The PM should work with the licensee to establish an agreed upon timeframe to receive the additional information, but typically, 30 to 60 days response will be expected. Staff should develop RAIs which are comprehensive and specify all information deficiencies in the application. RAIs should be written to communicate to the licensee exactly the information being requested. The licensee's response to the RAI should provide sufficient information to demonstrate compliance with the regulations.

A draft SER should be written before the RAI input is provided to the licensee. This ensures the RAI encompasses the entire submittal. RAIs must be limited to obtaining information necessary to ensure regulatory compliance. Each RAI must have a stated connection to existing regulatory requirements or established review guidance, which does not include the SRP.

RAIs should state the issues and relevant problems in a manner that is clear and concise. They should not, however, tell the licensee what to do nor state specific changes to the language of the submittal. RAIs may include requests for administrative changes such as editorial changes, typographical errors, and drawing revisions.

13.4 Composing RAIs

The RAI package should begin with a cover page and preamble containing a description of the application. The PM prepares the cover page and preamble.

Each discreet RAI should have two parts:

- Action Needed
  A concise statement of the information needed. RAIs should be statements rather than questions and should use action verbs, such as those listed in Table 1.

- The regulatory basis for the RAI
  Cite the regulation that the requested information should address. The citation should be as specific as possible. General requirements in the regulations can be used as the regulatory basis for asking specific RAI questions (see examples below).

The purpose of the RAI can often be improved by adding a brief explanation of why the NRC made the request, such as identifying the information provided by the licensee and the deficiency. Language from the SRP can be used to describe the basis for the RAI, but it should not be directly cited (e.g., "the SRP says...") since the SRP is only guidance and not regulation.

TABLE 1: SAMPLE LIST OF ACTION VERBS			
analyze	assess	attach	choose
clarify	classify	combine	compare
conclude	contrast	construct	defend
define	demonstrate	determine	describe
differentiate	discuss	distinguish	establish
evaluate	explain	find	identify
illustrate	indicate	justify	label
list	measure	name	perform
show	position	provide	rate
reproduce	resolve	revise	select
specify	summarize	support	
state	use	translate	

13.5 Organization of RAIs

The numbering scheme for RAIs must be logical and allow each request to be uniquely identified. For example, the PM may choose to delineate the numbering scheme by SRP chapter and section or in the order that information is presented in the submittal.

If the same regulatory issue occurs in more than one technical section, the issue should be addressed once in a general section rather than multiple times in each section. RAIs that reference the same specific regulation may be grouped together rather than repeated throughout the RAI. In this case, the regulatory reference should be placed in an introduction to the group.

13.6 Communication on RAIs

Once RAIs have been provided to the licensee, the PM should establish conference calls or, if appropriate, a site visit between the reviewers and the licensee. The purpose of these interactions is to facilitate a clear understanding of the RAIs with the intent to ensure a complete licensee response, thereby minimizing the likelihood of follow-on questions. These discussions promote the licensee's understanding of the RAIs and allow the NRC to address questions. Telephone conversations and site visits concerning RAIs should be summarized and docketed in ADAMS. Information that the staff uses to reach a safety decision must be docketed.

13.7 Proprietary Information

If proprietary information is requested by an RAI, the RAI should be worded in a non-sensitive manner, so it can be released to the public domain. If information in an RAI is determined to be proprietary, the proprietary items should be grouped together and placed in a separate enclosure to the transmittal letter and the non-proprietary RAI.

13.8 Example RAIs

Each of the following RAIs were written by a different individual using a slightly different format. Yet, each question contains the “Needed Action” and the “Regulatory Basis” required for an RAI. Note that in the examples entitled Nuclear Criticality Analysis and General Information the reviewer provides an expanded explanation to clarify the purpose of the RAI.

RADIATION PROTECTION
With regard to the radiation surveys and monitoring programs required under 10 CFR 20.1502, please provide the following information:

- Specify a minimal time frame for assessing personal dosimeters.
- Provide a description of the air monitoring alarms, their type, sensitivity, and maintenance frequency.
- Identify the facility’s administrative exposure levels at which actions are taken to investigate the cause of exposures exceeding these levels. Differentiate between alpha contamination and beta/gamma contamination.
- Define additional contamination control procedures in place to control the concentration of airborne radioactive material, such as control of access, limitation of exposure times to licensed materials, and use of respiratory protection equipment.

CHEMICAL SAFETY PROGRAM
List the chemical process hazards present at the site and the chemical exposure levels used to assess the chemical accident consequences. Confirm if chemical exposure levels will be updated if the values of these standards change. This information is necessary to determine compliance with the requirements of 10 CFR 70.65(b)(7).

NUCLEAR CRITICALITY ANALYSIS
Provide a demonstration for the following assumptions: (1) the assumption that the presence of Pu241 can be neglected, and (2) the assumption that 1-inch of water can be used to conservatively represent reflection.

Demonstration of these assumptions, used in designing the facility, is necessary to ensure that the process remains subcritical under both normal and credible abnormal conditions in accordance with 10 CFR 70.61(d).

GENERAL INFORMATION
Provide the page changes needed to update Table I-1.1 (Specific Locations of Authorized Activities) of the license application to reflect all the changes needed regarding this amendment request.

Basis: Chapter 1, Table I-1.1 of the license application contains the current location, types of Special Nuclear Material (SNM) used at that location, and authorized activity at that location. *[The licensee]* did not include any changes to Table I-1.1 in the amendment request. Therefore, the requested information is required to keep Table I-1.1 complete and accurate as to the location, types of SNM, and authorized activities at the plant as required by 10 CFR 70.22 - Contents of Applications; and 10 CFR 70.34 -Amendment of Licenses.

13.9 Concurrence

Technical reviewers provide their input, in the proper format, to the PM. The technical reviewer's supervisor has the discretion to formally or informally concur on the reviewer's input, prior to it being submitted to the PM. The PM compiles the RAI package and reviews it for consistency and protection of proprietary information.

In the case where the PM proposes changes to the reviewers' input that may alter the technical meaning and basis of the review or eliminate an RAI, the PM should seek the technical reviewers' concurrence. The assigned PM issues the RAI with the concurrence of the licensing supervisor.

13.10 Roles And Responsibilities

PROJECT MANAGER
The PM coordinates the preparation, review, and issuance of RAI. The PM receives input from technical reviewers but is ultimately responsible for the content and format of the RAI package.

SUPERVISOR
The PM's supervisor reviews and concurs on RAI packages. The supervisor will verify that the RAIs are complete, accurate, and formatted correctly.

TECHNICAL REVIEWER
Technical reviewers are responsible for providing a quality review of the licensing document, and quality, properly formatted RAIs. Technical reviewers must submit their input on a date that supports the established schedule.

13.11 Procedure for Request for Additional Information Letter

1. The inside address consists of the addressee's name and title on the first lines, followed by company name and street address. An "ATTN" line should not be used.

2. Insert a subject line after the address and include the TAC Number in parenthesis at the end of the line.

3. The salutation shall read: Dear Mr./Ms. *[Surname]*.

4. The opening paragraph should reference the licensee's submittal and conclude with: "Our review of your application has identified additional information that is needed before final action can be taken on your *[type of document (ex. license renewal)]* application."

5. The body of the letter should consist of a preamble containing a description of the application and an overview of the RAIs, contained in an enclosure attached to the letter. Depending on the length of the request, the RAIs may be included directly in the letter.

6. Near the conclusion of the letter, provide the timeframe for the licensee to respond to the RAI's, typically between 30 to 60 days, depending on the number and complexity of the questions.

7. The complimentary closing should be "Sincerely."

8. Place Docket *[docket number]* and License SNM-*[license number]* information two lines below the signature block flush with the left margin.

13.12 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 13.1 Request for Additional Information (ML082470484)

13.13 References

NUREG-1513 "Integrated Safety Analysis Guidance Document"

NUREG-1520 "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility"

NUREG-1569 "Standard Review Plan for In Situ Leach Uranium Extraction License Applications"

NUREG-1620 "Standard Review Plan for the Review of a Reclamation Plan for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act of 1978," Rev. 1.

NUREG-1621 "Final Standard Review Plan for the Review of Remedial Action of Inactive Mill Tailings Sites under Title I of the UMTRCA" (ML040650045)

NUREG-1671 "Standard Review Plan for the Recertification of Gaseous Diffusion Plants," Draft Report for Comment"

NUREG-1718 "Standard Review Plan for the Review of a License Application for a Mixed Oxide (MOX) Fuel Fabrication Facility"

"Technical Position on Financial Assurances for Reclamation, Decommissioning, and Long-Term Surveillance and Control of Uranium Recovery Facilities," October 1988

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CHAPTER 14
REVIEW OF INTEGRATED SAFETY ANALYSIS UPDATES

14.1 Objective

The objective for the review of ISA summary updates is to determine whether the changes made by the fuel cycle facility licensees, as reported in their annual reporting of changes and ISA updates, are in compliance with 10 CFR Part 70 requirements.

14.2 Acceptance Review

Upon receipt of the annual summary update of fuel cycle facility changes and ISA updates, the PM should ensure that the documents are placed in the ADAMS non-public library, if appropriate. The PM should perform an acceptance review to ensure that the documents contain sufficient information to perform the initial screening. The annual summary update should contain:

- A summary of changes to process safety information, the ISA, and the management measures (including both facility changes associated with and not associated with ISA annual summary update changes).
- For those facility changes that resulted in modifications to the ISA annual summary update, a cross-reference to the affected ISA portions.
- For those facility changes that did not result in ISA summary update changes, an explanation of why a change to the ISA was not needed.
- For all changes (facility changes and ISA changes), a description of the change in sufficient detail for staff to understand the impact of the change.

The Exhibit "Integrated Safety Analysis Annual Summary Updates Checklist" provides a checklist to facilitate the PMs review. In addition, a flow diagram entitled "Process Flow Diagram for ISA Summary Annual Updates" has also been added to the exhibits.

14.3 Initial Screening

The PM should conduct the initial screening to determine which changes can be clearly screened out as insignificant based on the five regulatory criteria from 10 CFR 70.72(c). These are:

1. Does not create a new type of accident sequence that, unless mitigated or prevented, would exceed the performance requirements of 70.61;
2. Does not use new processes, technologies, or control systems for which the licensee has no prior experience;
3. Does not remove an item relied on for safety (IROFS) without equivalent replacement of the safety function;
4. Does not alter any sole IROFS;

5. Is not prohibited by other regulations.

The PM should consult with the technical staff for assistance during the initial screening, if necessary. Changes remaining after the initial screening will be subject to the smart review process.

14.4 Smart Review Process

To focus licensing and inspection resources on risk significant issues, the PM will review the changes remaining after the initial screening and prioritize them based on risk. For example, risk-significance can be informed by identifying IROFS for which the greater risk reduction credit is taken. Additionally, risk significance can be based on a qualitative judgment of the hazard protected against, such as release of bulk hazardous chemicals with off-site consequences, or criticality from plutonium and high enriched uranium liquid systems with high on-site consequences, but limited off site consequences.

Due to the uniqueness of the Part 70 licensees, a common or exhaustive set of risk significant changes can not be developed; however, examples of categories of items on the annual list of changes that affect the ISA summary that should be given high priority are:

- ❑ Engineered IROFS that have been replaced by administrative IROFS
- ❑ Multiple IROFS that have been replaced by sole IROFS
- ❑ Systems that have been redesigned so that the accident sequences are no longer deemed credible
- ❑ Changes in data used in calculations that after re-analysis, move the consequence from high or intermediate to low, or high to intermediate
- ❑ Areas of weakness in IROFS that have been identified at the licensee's facility or in like operations at other facilities
- ❑ Areas that have been questioned by the license reviewer with regard to licensee reliability or maintenance data
- ❑ Changes to lower the assigned IROFS indices
- ❑ Other changes identified by the licensee, inspectors, or project managers or in event reports that reduce the safety margin in meeting the performance requirements

The PM will prepare a TAR to acquire the appropriate technical review for the changes identified in the smart review process.

14.5 Technical Review Guidance

The assigned technical reviewer will evaluate the changes using the guidance in NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility." If additional information or clarification is needed in order to make a determination of compliance, the technical reviewer will prepare a list of questions that identify the specific information needed and the regulatory basis.

The PM will arrange a phone call with the licensee and the appropriate technical reviewer(s), to address the issues or concerns that have arisen from the review. If, following the initial phone call, more information or additional ISA summary update changes are needed from the licensee, a written request for additional information/documentation should be prepared and issued. If the review of the changes reveals a possible risk-significant safety problem, the problem should be

promptly brought to the attention of the appropriate licensing supervisor. The supervisor should determine the necessary follow-up actions.

14.6 Documenting the review

Technical review findings should be documented and provided to the PM. At a minimum, the documentation should include: (1) the changes reviewed, (2) the review findings, and (3) the regulatory basis for the findings. The licensing supervisor or designee will issue a letter to the licensee to inform them that the list of facility changes has been submitted in accordance with regulations (see Template).

The licensing supervisor or designee will issue a memo to Region II to inform the Region that the review of annual changes to the facility has been completed and suggest that an inspection be performed in areas where on-site inspection may be warranted (see "Review of Annual Changes Memo to RII Example").

14.7 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 14.1 **Facility Change ISA Summary (ML082470445)**

Example Review of Annual Changes Memo to RII (ML081140389)

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Exhibit 14.1
Integrated Safety Analysis
Annual Updates Checklist

Licensee: _____ Docket No. _____ License No. _____

PM should ensure that:

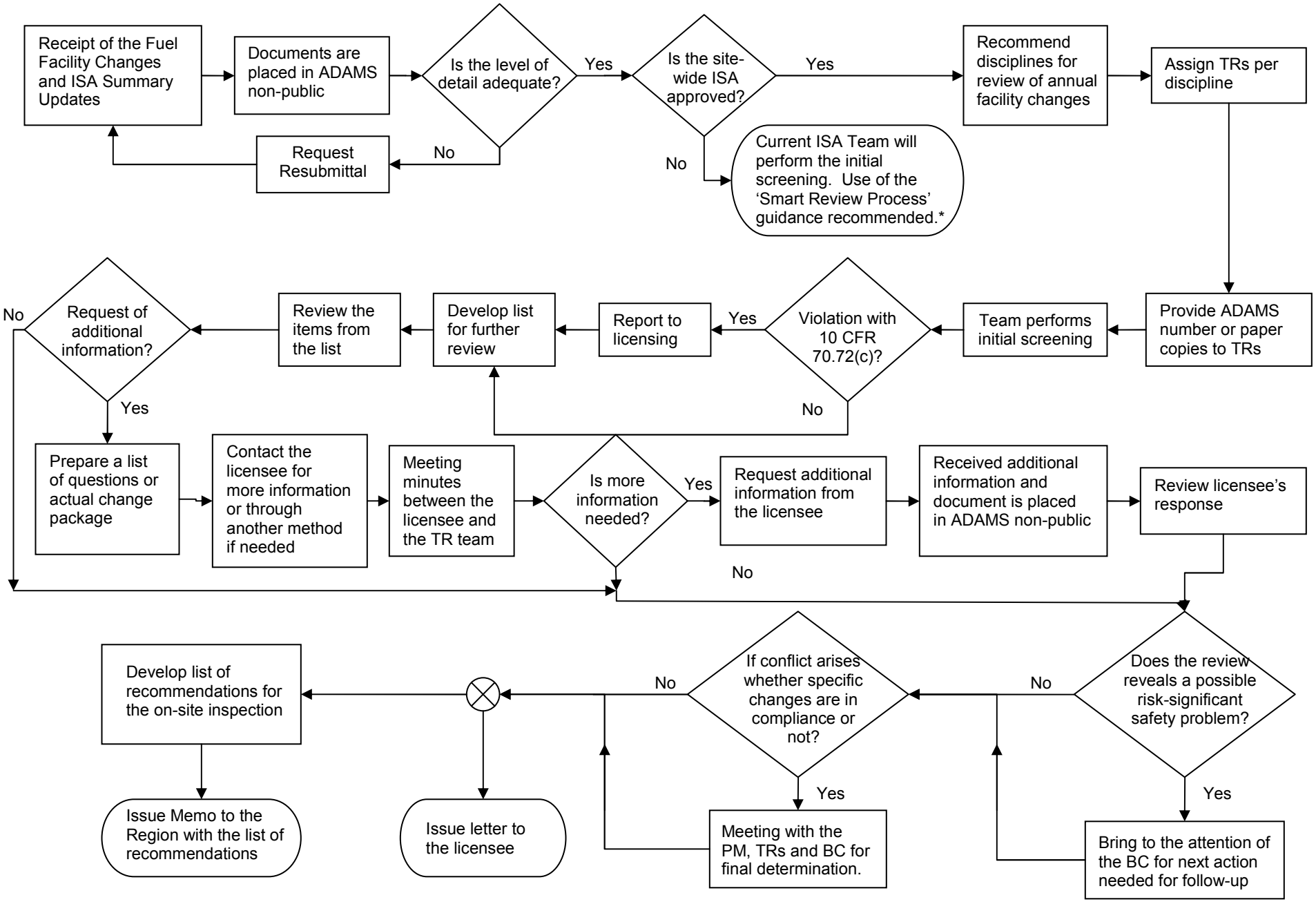
- ❑ The Document is placed in ADAMS non-public, ML _____
- ❑ Is sufficient level of detail available? ❑ Yes ❑ No
- ❑ If no, request resubmittal? ❑ Yes ❑ No
  - ❑ If no, explain briefly why: _____
- ❑ Is the ISA approved? ❑ Yes ❑ No
  - ❑ If no, the current ISA review team should perform the initial screening (use of the "Smart Review Process" guide recommended)
- ❑ The PM performed the initial screening performed based on the five regulatory criteria from 10 CFR 70.72(c)
- ❑ The PM performed the smart review and identified risk-significant changes for TR team review. Disciplines recommended for the review:
  - ❑ General Information (i.e. Organization and Administration, PSI/ISA Summary/Management Measures)
  - ❑ Radiological Protection
  - ❑ Criticality Safety
  - ❑ Chemical Safety
  - ❑ Fire Safety
  - ❑ Emergency Management
  - ❑ Environmental Protection
  - ❑ Decommission and Financial Assurance
  - ❑ Material Control and Accounting
  - ❑ Security

The branch chief assigned the TRs per discipline needed for review

- ❑ General Information _____
- ❑ Radiological Protection _____
- ❑ Criticality Safety _____
- ❑ Chemical Safety _____
- ❑ Fire Safety _____
- ❑ Emergency Management _____
- ❑ Environmental Protection _____
- ❑ Decommission and Financial Assurance _____
- ❑ Material Control and Accounting _____
- ❑ Security _____

- ❑ Provided ADMAS ML number or paper copies to the TR team
- ❑ If necessary, the TR team provided a list of changes that requires additional information from the licensee to the PM
  - ❑ Develop list of changes to request additional information provided by the team
  - ❑ Contacted the licensee on: _____
  - ❑ The TR team reviewed the additional information requested, if applicable
  - ❑ Request more information after first request? ❑ Yes ❑ No
    - ❑ If yes, ML _____ (If applicable)
    - ❑ Response reviewed by the TR team
- ❑ Possible risk-significant safety problem revealed? ❑ Yes ❑ No
  - ❑ If yes, bring to the attention of the BC
- ❑ Are conflicts on specific changes in compliance or not? ❑ Yes ❑ No
  - ❑ If yes, meeting held with the PM, TRs and BC on _____
- ❑ Developed letter for the licensee
- ❑ Developed list of recommendations for on-site inspection
- ❑ Developed Memo of recommendations for the Region.
- ❑ The BC approved letter for the licensee
- ❑ The BC reviewed list of recommendations for the on-site inspection
- ❑ The BC approved Memo with recommendations for inspections for the Region

Exhibit 14.2
Process Flow Diagram for ISA Summary Annual Updates



* See the current Operating Plan for the schedule.

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CHAPTER 15
ENVIRONMENTAL REVIEWS

15.1 Background

The National Environmental Policy Act (NEPA) of 1969, requires that an environmental review be conducted for all major federal actions significantly affecting the quality of the human environment. NEPA requires that the environmental effects and values of the proposed action and alternatives be identified so they can be evaluated with respect to the economic and technical considerations. The environmental information must be available to both those making the decisions and the public prior to approval of any proposed action. Within the NRC, certain specified licensing and rulemaking actions are considered major federal actions (10 CFR Part 51). Most of the information relied upon in conducting the review is provided by the licensee or applicant in the form of an Environmental Report, as required in 10 CFR Part 51. NMSS staff should use NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," when reviewing licensing actions.

15.2 Categorical Exclusions (CE)

Usually, fuel cycle licensing actions either are categorically excluded from an environmental review (see NUREG-1748 "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs" Chapter 2) or require an environmental assessment (EA) (see NUREG-1748 Chapter 3). The criteria for categorical exclusions (CATX) are listed in 10 CFR 51.22. Generally, license renewals for educational institutions meet the criteria for a CATX (10 CFR 51.22(c)(14)(v)). The majority of license amendment applications will also meet one of the criteria for a CATX.

<u>Categorical Exclusion (CE) Options</u>

The CATX options are described in detail in chapter 2 of NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." NUREG-1748 also provides examples of standardized CATX paragraphs which should be used in the SER.

15.3 Environmental Impact Statements (EIS)

The actions which require the NRC to prepare an EIS are specified in 10 CFR 51.20 with additional guidance available in NUREG-1748. The licensing actions associated with the fuel cycle which would require an EIS are:

1. issuance of a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride pursuant to 10 CFR Part 70,

2. issuance of a license to possess and use source material for uranium milling or production of uranium hexafluoride pursuant to 10 CFR Part 40,

3. issuance of a license for a uranium enrichment facility, or

4. any other action that NRC determines could significantly affect the environment (e.g., based on an Environmental Assessment (EA)).

If the proposed action is one requiring an EIS, then an EA need not be prepared. If an EIS is to be prepared, then the regulations specified in 10 CFR Part 51 describing the procedure for preparing an EIS must be followed, including issuing a notice of intent, conducting the scoping process, preparing the draft EIS, circulating and noticing the draft EIS, revising the draft EIS, and publishing the final EIS and Record of Decision. The Environmental Review Branch in FSME/DWMEP has the lead for preparing the EIS, coordinating with other agencies, and for scheduling the required public meetings.

15.4 Environmental Assessments (EA)

An EA (see NUREG-1748 Chapter 3) is defined as a concise public document that serves to briefly provide sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact (FONSI). The EA should focus on the impacts of the proposed action and should be no more than 15 pages, unless necessary to explain any complicated environmental issues associated with the proposed action. The EA should demonstrate compliance with NEPA when no EIS is necessary or may facilitate the preparation of an EIS when one is necessary.

Unless categorically excluded, renewals of the following types of licenses require an EA:

1. Uranium Fuel Fabrication Facilities
2. Uranium Conversion Facilities
3. Fresh Fuel Storage at Reactor Sites
4. Critical Mass Facilities
5. Fuel Cycle Research and Development Facilities
6. Source Material - Ore processing

Amendment requests that generally require an EA are those proposing a significant change in the amount of effluents, a change in processes, addition of new processes, or an increase in possession limits. An EA may be prepared, at the discretion of NRC management, for a license amendment request meeting the criteria for a Categorical Exclusion (CE).

Licensing actions where an exemption from the regulations is requested also require an EA. As specified in 10 CFR 51.30, an EA shall contain, as a minimum, the following information:

1. Description of the proposed action,
2. The need for the proposed action,
3. Reasonable alternatives to the proposed action,
4. Environmental impacts of the proposed action and alternatives, as appropriate,
5. A list of agencies and persons consulted and identification of sources used.

EAs are prepared by the licensing PM with the assistance of FSME/DWMEP. The EA supports a decision on whether to prepare a FONSI or an EIS. A FONSI is appropriate if there is no significant impact to the environment. An EIS should be prepared if there are major unresolved issues that could adversely impact the human health or the environment.

After the FONSI is prepared, it will be published in the Federal Register in accordance with the requirements of 10 CFR 51.35.

15.5 Finding Of No Significant Impact (FONSI)

Upon completion of an environmental assessment (EA), it will be determined whether to prepare an environmental impact statement (EIS) or a Finding of No Significant Impact (FONSI) (see NUREG-1748 Section 3.6) for the proposed action. The FONSI will be prepared if, based on the EA, it can be determined that the proposed action will not significantly impact the environment. In accordance with 10 CFR 51.35, the FONSI will be published in the Federal Register. The proposed action will not proceed (issue a new license, an amendment, or renewal) until after the finding has been published in the Federal Register.

If an opportunity for a hearing on a license amendment, issuance, or renewal has not previously been offered by a notice in the Federal Register, the FONSI notice will include an Opportunity for a Hearing. However, Notice of Opportunity for a Hearing should be published as soon as possible after the acceptance review to avoid undue delays (e.g., 30 days) in the licensing process.

As described below, 10 CFR 51.32 explains what needs to be included in a FONSI. According to 10 CFR 51.32 Finding of No Significant Impact will:

1. Identify the proposed action;

2. State that the Commission has determined not to prepare an environmental impact statement for the proposed action;

3. Briefly present the reasons why the proposed action will not have a significant effect on the quality of the human environment;

4. Include the environmental assessment or a summary of the environmental assessment. If the assessment is included, the finding need not repeat any of the discussion in the assessment but may incorporate it by reference;

5. Note any other related environmental documents; and

6. State that the finding and any related environmental documents are available for public inspection and where the documents may be inspected.

After completing the FONSI and EA, either: (1) send a letter to the licensee transmitting copies of the documents or (2) include the documents as part of the final licensing package (new license, amendment, or renewal), see Template 15.1.

15.6 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 15.1 Letter Transmitting FONSI and EA to Licensee
(Templates maintained by Office of Administration)

15.7 References

NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,"

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CHAPTER 16
EMERGENCY PLANS

16.1 Background

In accordance with 10 CFR 40.31(j)(1)(ii), 70.22(i)(1)(ii), and 76.35(f), certain applicants/licensees must provide an Emergency Plan (Plan). These emergency plans are kept as Official Use Only documents in ADAMS. On their own volition the licensee may also supply implementing procedures for the Plan. This information should be kept as an attachment supporting the Plan. The NRC's Office of Nuclear Security and Incident Response (NSIR) is responsible for reviewing the Plan.

NRC regulations in 10 CFR Parts 40.35 and 70.32 allow licensees to make changes to emergency plans without prior approval by NRC, provided the changes do not decrease the effectiveness of licensee programs for public protection ("no decrease changes"). Review procedures for these types of changes are described in the "Policy and Criteria for Processing of Licensing Actions" chapter.

PMs should routinely review the license every 6 months to assure that all Plan changes have been incorporated and that the license condition references the latest revision. In addition, PMs should make sure that the Plan is in the NRC's e-library since the Operations Center does not maintain hard copies.

16.2 Files

Submittals of Plan changes are placed in ADAMS upon receipt. Once the changes have been reviewed, a response letter is sent confirming or declining that the changes conform to 10 CFR 70.32. Approved changes are added to the license by amendment. Rather than issue an amendment for the Plan alone, the PM may choose to incorporate the revision in an unrelated licensing action. Depending on the date of the most recent submittal, the Plan on file in ADAMS may not incorporate the licensee's latest revisions.

In addition to the electronic documents, PMs should maintain an up-to-date, hard copy of the emergency plan. If an event occurs at a fuel facility and NRC activates the Operations Center, the PM for that facility (or backup PM if the primary PM is not available) will retrieve the up-to-date plan and report to the Operations Center, in accordance with NRC emergency response procedures.

The PM should consult with the regional staff prior to approving revisions to the Plan. If a regional inspection or a biennial exercise could influence the review of the Plan, the review should be postponed to incorporate the findings.

16.3 References

"Policy and Guidance Directive 01-11, Standard Review Plan (SRP) for Emergency Plans for Fuel Cycle and Material Licensees," (formerly PGD FC 84-14) (ML031750245)

Regulatory Guide 3.67 "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities" (ML003739885)

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CHAPTER 17
IMPLEMENTATION OF U.S.-IAEA SAFEGUARDS AGREEMENT

17.1 Background

Countries that have brought into force safeguards agreements associated with the Nuclear Non-Proliferation Treaty (NPT) are subject to International Atomic Energy Agency (IAEA) safeguards inspections (Appendix C). The NPT establishes the authority for the IAEA to conduct inspections to verify the accuracy and completeness of declarations regarding nuclear materials at nuclear facilities. The U.S.-IAEA Safeguards Agreement requires the U.S. to maintain a list of facilities in the U.S. that are not of direct national security significance that could be inspected by the IAEA. The IAEA may select facilities for inspection or material accounting reporting from this U.S. Eligible Facilities List. If the IAEA selects a facility from the U.S. Eligible Facilities List, the U.S. must provide IAEA with a Design Information Questionnaire (DIQ) on the facility. A DIQ is a document that provides the IAEA inspectors with information to develop a safeguards approach and prepare a Facility Attachment (or Transitional Facility Attachment for "reporting only" facilities) that establishes the safeguards inspection and/or reporting requirements for the facility. The type of information included in the DIQ is as follows:

1. description of the facility;
2. the form, quantity, location, and flow of nuclear material being used;
3. facility layout; and
4. containment features and procedures for nuclear material accountancy and control.

17.2 Procedures

Procedures for submitting DIQs to the IAEA are as follows:

1. Upon receipt of a license application to construct a new fuel fabrication facility (other than a facility of direct national security significance), the facility will be added to the U.S. Eligible Facilities List. The revised Eligible Facilities List will undergo a 60-day Congressional Review before becoming final. The U.S. Department of State (DOS) will provide the IAEA with a revised Eligible Facilities List and inform the IAEA that the facility has been added to the List.

2. If the IAEA selects the facility from the List, the International Safeguards Coordinator (NMSS/FCSS/MCAB) will request that the NMSS or NRR PM responsible for the facility notify the facility, in writing, that they have been selected for IAEA inspection or reporting and are subject to 10 CFR Part 75 (e.g., pursuant to 10 CFR 70.21(g) for fuel cycle licensees).

3. The PM will request that the licensee prepare a DIQ and submit an initial physical inventory to the U.S. Nuclear Material Management and Safeguards System (NMMSS) in accordance with 10 CFR Part 75. The licensee will provide information for the DIQ on forms supplied by the Commission (IAEA Form N-71 and associated forms) or on internally generated forms that follow the IAEA's DIQ format.

4. Upon receipt of the design information from the licensee, the PM will forward the DIQ to the IAEA Safeguards Coordinator for review and approval. The PM will be responsible for ensuring that the licensee makes necessary changes to the DIQ. The DIQ will then

be submitted by the IAEA Safeguards Coordinator to the U.S. Subgroup on IAEA Safeguards in the United States (SISUS) for approval. The IAEA Safeguards Coordinator then will provide the DIQ to Department of State (DOS) and DOS will transmit it to the IAEA.

5. Whenever the facility design and procedures change from that stated in the DIQ, the licensee should provide updated DIQ information. The revised DIQ will be submitted to the IAEA through the same process as the initial DIQ. Updates may be made through page changes instead of regenerating the whole DIQ.

6. At least 180 days prior to the first receipt of nuclear material at the facility, a completed DIQ will be prepared and transmitted to the IAEA.

7. After receipt of the DIQ, the IAEA will generate safeguards approach and will conduct design information verification visits to confirm that the facility design matches that described in the DIQ. After the safeguards approach has been approved, the IAEA and U.S. will negotiate a Facility Attachment that establishes the inspection and reporting requirements. A Facility Attachment contains, inter alia:

    a. A short description of the facility;
    b. A provision to submit to the IAEA changes in the information on the facility;
    c. Accountancy measures for the facility;
    d. Provisions for containment and surveillance measures;
    e. Specific provisions and criteria for termination of and exemption from safeguards of nuclear materials;
    f. A detailed description of the records and reports system;
    g. A description of the mode and the scope of IAEA routine inspections; and
    h. Provisions for administrative procedures concerning the facility.

8. When the U.S. and IAEA approve the safeguards approach for the Facility, the PM should prepare and issue a license amendment incorporating the IAEA safeguards inspection and reporting requirements into the facility's license.

9. When a facility is deselected for inspections (no inventory-taking procedures are established or scheduled, but the licensee is still required to report accounting data), the IAEA may reselect the facility for reporting only and a Transitional Facility Attachment will be prepared by the IAEA.

10. When the facility has been closed and the license has been terminated or decommissioning has advanced to the stage where all equipment essential for operations has been removed, or when the facility's mission has changed such that it becomes of direct national security significance, the facility is removed from the Eligible Facilities List.

When the U.S. determines that the facility has been adequately decommissioned or that the mission has changed; DOS will notify all affected entities of the facility's removal from the List.

17.3 References

10 CFR 70.21(g) states:
In response to a written request by the Commission, an applicant for a license to possess and use more than one effective kilogram of special nuclear material shall file with the Commission the installation information described in § 75.11 of this chapter on (IAEA) Form N-71. The applicant shall also permit verification of such installation information by the International Atomic Energy Agency and take such other action as may be necessary to implement the US/IAEA Safeguards Agreement, in the manner set forth in § 75.6 and §§ 75.11 through 75.14 of this chapter.

10 CFR Part 75, Safeguards on Nuclear Material - Implementation of the U.S.-IAEA Safeguards Agreement.

NRC Portion of the U.S. Eligible Facilities List

INFCIRC/288, Agreement between the United States of America and the International Atomic Energy Agency for the Application of Safeguards in the United States of America

U.S. Subsidiary Arrangements to the U.S.-IAEA Safeguards Agreement

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CHAPTER 18
HEARINGS

18.1 Background

The NRC regulations that govern the hearing process are in Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders (10 CFR Part 2). Major licensing actions for fuel cycle facilities may be involved in two types of hearings – mandatory and contested

NMSS P&PL 1-86 "NMSS Staff Support of the Hearing Process in 10 CFR Part 2" (ML073511465) provides guidance on supporting the hearing process as contained in 10 CFR Part 2. When required by the regulations or Commission policy, a Federal Register Notice (FRN) must be prepared that includes the notice of opportunity to file a request for hearing. If the licensing action references sensitive unclassified non-safeguards information (SUNSI) or safeguards information (SGI), the FRN must include an Order Imposing Procedures for Access to SUNSI or SGI for Contention Preparation. Section XV and Attachment 2 of P&PL 1-86 contain additional guidance.

Note: Beginning 30 days prior to the start of a hearing, the NRC staff is obligated to keep the Atomic Safety and Licensing Boards, Presiding Officers, and the Commission apprised of significant new information in pending adjudicatory proceedings. The staff should work with their management and OGC to determine what information should be provided.

18.1.1 Mandatory Hearings

Mandatory hearings, required by the Atomic Energy Act, §189, are held by a panel of judges from the Atomic Safety and Licensing Board (ASLB) to determine whether the safety and environmental record is sufficient to support license issuance and to determine if the NRC staff's review of the application was adequate. The panel of judges makes decisions about what portions of the licensing action to review.

18.1.2 Notice of Opportunity to Request a Hearing and FRNs

The types of publications required by Part 2 include a Notice of Hearing (2.104) for mandatory hearings, or a Notice or Proposed Action (2.105), which includes an opportunity to request a hearing. In addition to the FRN, a notice should also be published on the NRC public website at Hearing Opportunities and License Applications. A FRN may also be required as part of the environmental review (NUREG 1748) and if the application is approved, as a Notice of Issuance (2.106).

Many of the notices required by 10 CFR 2.105 don't apply to fuel cycle facilities due to the definition of "facility" in 10 CFR 2.4. However, it is NMSS policy that 2.105(a)(9) applies to complex licensing actions including renewals, new applications, etc. (see section 9.3). Therefore, PMs are required to publish a notice of proposed action and opportunity to request a hearing in the Federal Register for complex licensing actions. In addition, 2.1301 requires a FRN for transfer of control applications.

The Office of Administration provides a Federal Register Checklist and a list of Federal Register Templates on the internal website. The PM's should use the guidance and templates for

drafting FRNs. (Note: FRN concurrence packages must include documented evidence (e.g. email) of OGC concurrence before being dispatched from the Division. FRN packages which do not contain this evidence will be held by SECY until a written verification has been provided.)

18.1.3 Contested Hearings

Contested hearings, under the Atomic Energy Act, §189, may be granted to stakeholders who have demonstrated the appropriate standing. For major licensing actions for fuel cycle facilities, the public is notified of the opportunity to request a hearing through the *Federal Register* and/or on the NRC website at Hearing Opportunities and License Applications. Hearing requests and intervention petitions ordinarily must be filed within 60 days of the date of *Federal Register* publication of the "Notice of Opportunity for Hearing." If a *Federal Register* notice of opportunity for hearing is not published, hearing requests and intervention petitions ordinarily must be filed within 60 days of either the date that notice is provided at Hearing Opportunities and License Applications, or within 60 days after the requestor receives actual notice of a pending application, but not more than 60 days after the NRC takes final action on the application.

To request an NRC hearing or petition to intervene, members of the public must explain the nature of their interest in the proposed NRC licensing and describe the reasons and bases for their concerns. To be admitted to the hearing (i.e., qualify as an intervener), a party must have standing and file at least one litigable contention. To demonstrate standing, a potential party must show that they have an interest that will be affected by the proposed licensing action and that could be harmed by the outcome of the proceeding. A litigable contention is a specific concern or issue that the potential party seeks to bring before the panel of judges for litigation in the proceeding. A contention usually alleges that the applicant has failed to satisfy either a legal or technical regulatory requirement. Generally, hearings are requested by those who reside or work near an affected facility and who believe that a proposed action raises environmental or safety questions. Participants in NRC hearings may include individuals, citizen groups, private businesses, and governmental bodies.

Upon determination that a request for hearing/petition to intervene should be granted and a hearing held, the Commission, the presiding officer, or the ASLB will determine the specific hearing procedure or track. 10 CFR Part 2 specifies the different types of tracks for different types of NRC proceedings. NMSS P&PL 1-86 provides additional guidance concerning the hearing tracks. Subpart C of 10 CFR Part 2 is the general procedure for all hearings and is used in conjunction with all the other Subparts.

18.2 10 CFR Part 2, Subpart G - Rules Applicable to Most Formal Hearings

Subpart G governs the conduct of "more formal" adjudications, including enforcement proceedings initiated under Subpart B of Part 2, unless otherwise agreed to by the parties. Proceedings that involve licensing the construction and operation of a uranium enrichment facility are required by law to be conducted as a single hearing in a formal adjudication under Subpart G. Also, the Commission may elect to consider other significant materials licensing actions in formal proceedings under Subpart G, where it determines that this would be in the public interest.

The staff will generally be expected to respond to discovery, prepare documents which reflect the staff's review of pertinent issues, and develop affidavits and testimony for presentation in the proceeding. Staff members may be called upon to present sworn written or oral testimony

before the ASLB or presiding officer, at which time other parties will have an opportunity to conduct cross-examination as to the bases and validity of their views.

Following the conclusion of evidentiary hearings, the parties will file proposed findings of fact and conclusions of law, which reflect their view of the evidence and legal arguments presented for decision by the ASLB or presiding officer. The ASLB or presiding officer will then issue an initial decision, and any party aggrieved by the outcome may request reconsideration or file a petition seeking Commission review.

18.3 10 CFR Part 2, Subpart L - Informal Hearing Procedures For Adjudications

Subpart L is a less formal hearing process than Subpart G intended to balance the need for formal procedures and the timely resolution of contested matters. Subpart L is the default track for adjudicatory proceedings and can also be used upon mutual agreement of the parties in enforcement proceedings. Subpart L hearings can take the form of either an oral hearing or a hearing consisting of written comments. Subpart L proceedings require mandatory disclosure at the discovery phase and generally limits cross- examination by the parties.

The staff will be expected to prepare a hearing file which contains all relevant material. The staff is not required to participate as a party in a proceeding convened in response to a third party's request for hearing, but, with consultation from OGC, may choose become a party. P&PL 1-86 provides additional guidance on the decision whether to participate. Under Subpart L, no discovery is conducted and the presiding officer's decision is normally based on the hearing file and written presentations submitted by the parties. Oral presentations are permitted only if the presiding officer finds that the written presentations are insufficient to resolve the issues – and even then, the presiding officer is to question the witnesses rather than allow cross examination by the parties.

18.4 10 CFR Subpart N – Expedited Proceedings with Oral Hearings

Hearings under Subpart N are informal. The purpose of this type of hearing is to provide simplified procedures for the expeditious resolution of disputes in an informal hearing process. Proceedings under Subpart N are expected to take less than 2 days of oral hearings and can be used when mutually agreed upon by both parties, except as determined through the application of 10 CFR 2.310 (b)-(g). The “fast track” procedures of Subpart N may be particularly useful for cases involving small licenses, where the issues can be handled in a simple, inexpensive, and informal proceeding before an independent decision maker.

18.5 NMSS Policy and Procedure Letter 1-86 for Support of the Hearing Procedure

P&PL 1-86, “NMSS Staff Support of the Hearing Process in 10 CFR Part 2” (dated May 2008) provides guidance on supporting hearings. The document discusses staff actions prior to a hearing request for major licensing actions, staff participation in the hearing, hearing files and discovery, oral hearings, Presiding Officer Notifications review of proposed findings of fact and conclusions of law, and model milestones and pre-hearing conferences. The document also describes the NMSS policy on posting Opportunities to Request a Hearing on the NRC website under Adjudication (Hearings).

The Office of General Counsel (OGC) has developed reference materials and a toolkit for staff at http://www.internal.nrc.gov/OGC/.

The letter contains the following parts:

- Notices on NRC Website (P&PL 1-86, Section II, pp. 1-6),
- Hearing track (P&PL 1-86, Section III, pg 6),
- Decision to participate as party in hearing (P&PL 1-86, Section IV, pp 8-9)
- Model milestones and prehearing conference (P&PL 1-86, Section V, 9-11)
- Hearing file and discovery (P&PL 1-86, Section VI, pp. 11-14)
- Formal discovery (Subpart G) (P&PL 1-86, Section VII, p 15)
- Summary disposition (P&PL 1-86, Section VIII, p 15)
- Testimony in the hearing (P&PL 1-86, Section IX, pp 15-18)
- Settlement negotiations (P&PL 1-86, Section X, p 18)
- Presiding officer notifications (P&PL 1-7, Revision 1 (November 27, 2001) ADAMS ML013370143)
- Notice to presiding officer of action underlying regulatory matter (subpart L and Subpart N) (P&PL 1-86, Section XII, pp 18-19)
- Findings of fact and conclusions of law (P&P 1-86, Section XIII, p 19)
- Initial decision (P&PL 1-86, Section XIV, p 19)
- NMSS Implementation of SRM-SECY-07-0215 (P&PL 1-86. Section XV, p 19)

The Office of Federal and State Materials and Environmental Management Programs has developed P&PL 6-9 entitled "Support of The Hearing Process for Materials Licensees (ML073320188). This procedure provides additional information similar to NMSS' P&P 1-86.

18.6 Procedures to Allow Potential Intervenors Access to Relevant records that Contain Sensitive Unclassified Non-Safeguards Information (SUNSI) and Safeguards Information (SGI)

Section XV of P&PL 1-86 describes NMSS implementation of the final procedures addressing how potential parties to certain NRC proceedings may request access to documents containing SUNSI and SGI. The final procedures are discussed in the SRM (ML080320502) and available in an OGC document (ML080380626). In addition, Attachment 2 to P&PL 1-86 is an internal memorandum "OGC Guidance and Recommendations for Program Offices Regarding Implementation of SRM-SECY-07-0215."

18.7 E-Filing Revision: License Amendment Notice of Opportunity for Hearing

A request for hearing or a petition for leave to intervene must be filed in accordance with 10 CFR 2.302 through the E-Filing process. The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver. Additional information is available on the NRC public website under Electronic Submittals.

Parties are ordinarily required to serve motions, pleadings, and other documents on parties and file them with the Secretary of the NRC electronically by e-mail or facsimile. See §§2.305(c), and 2.302(a)(3)-(4). However, at this time, the new rule does not permit filing a pure electronic document without filing a signed paper copy. Accordingly, the new rule provides that if a motion or document is served or filed electronically, one signed and two paper copies must also be filed with the Secretary (see §2.304(f)).

18.8 Electronic Hearing Docket

The NRC's Electronic Hearing Docket is available on the NRC public website.

18.9 References

Federal Register Checklist,
http://www.internal.nrc.gov/ADM/DAS/cag/RM01/rmpdfs/Notices%20Checklist.pdf

Federal Register Templates, http://www.internal.nrc.gov/ADM/DAS/cag/notices/ntemps.html

Comments Not Addressed in the Statements of Considerations for Changes to the Adjudicatory Process: Final Rule, 12/17/2003, ML033510327.

Final Rule (signed by the Secretary), 12/24/2003, ML033510003.

FSME Policy and Procedure No. 6-9, "Support of The Hearing Process for Materials Licensees," ML073320188.

Office of General Council Reference Materials and Toolkit, Available on the OGC website.

Policy and Procedures No. 1-86, "NMSS Staff Support of the Hearing Process in 10 CFR Part 2," ML073511465.

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CHAPTER 19
MISCELLANEOUS

19.1 Knowledge Management

The agency has implemented the NRC Knowledge Management Website (NKC) to facilitate the efficient transfer of knowledge between employees. The website uses a software package developed by Tomoye Corporation to facilitate the collection, sharing, and discussion of knowledge within a Community of Practice (CoP). CoPs are groups of people who have a common topic or area of interest, e.g. Project Management, Criticality, New Employees, etc. The NKC serves as a platform for these individuals to manage, exchange, and capture information online.

The NKC is created by the individual users, who can add web content, on-line discussions, links to ADAMS and the Web, uploaded documents, or a personal blog. The NKC requires a user name and password, but all NRC employees may point their web browser to http://nrcknowledgecenter.nrc.gov and request an account. Once an account has been granted, individuals may explore the majority of CoPs, including web links, documents, discussions, etc. Individuals may join existing CoPs or create new ones.

The NKC has existed as a pilot program since 2006. As the project moves from pilot phase to full implementation, additional guidance has been developed. The following documents provide additional information:

- NKC Desk Guide
- NKC Guidance Documentation
- NKC First Time Users Guide

The division of FCSS has developed the following CoPs at the time of this revision.

- FMB & ECB Qualification Program (License Reviewer) CoP
- Material Control &Accountability (MC&A) Qualification Programs CoP
- Nuclear Criticality Safety CoP
- NSPDP (NMSS) CoP
- Part 70 Overview CoP
- Project Manager Information CoP

For additional information or help with questions about the NKC, a contact list is maintained at http://papaya.nrc.gov/NRCKC/POCs.pdf.

19.2 Records Management

A PM will have to manage licensing documents. Records management involves planning, controlling, directing, organizing, training, promoting, and other activities required to manage the agency's records for their entire life cycle. These activities include the creation, maintenance (use, storage, retrieval), and proper disposal of information (records), regardless of their form or media. PMs should familiarize themselves with the information and guidance shown below, which has been provided to help the staff meet their records management responsibilities. Links to these guidance documents can be found on the Office of Information Services homepage under Records Management >> Guidance.

Finally, a PM should be familiar with P&PL 1-30 (ML032230097),"Availability, Security, and Integrity of Material License File." PMs may record information as a "Note to the File," (see Tmplt 19.3 "Format Note to the File").

19.3 Information Security Requirements

Three primary types of information protected by the agency are: Sensitive Unclassified Non-Safeguards Information (SUNSI), Safeguards Information (SGI), and Classified Information. Each of these types of protected information is described in brief below.

SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI)

The NRC strives to be as open as possible and continues to encourage public participation in its licensing and oversight of the civilian uses of radioactive materials. However, following the events of September 11, 2001, the agency changed its procedures and practices to ensure it does not unnecessarily release information that terrorists could use to plan or execute an attack.

Certain types of information previously considered in the public domain are no longer routinely released and will be treated as sensitive unclassified information. With respect to managing licensing documentation, the PM will find it useful to become familiar with the SUNSI guidance listed below. Note that the guidance below is interim. The Commission has directed the staff to use the existing SUNSI policy, but to defer implementation of the policy with respect to the use of encrypted e-mail until the Executive Branch standardizes a Federal government wide policy.

For handling and storing sensitive, unclassified information, staff will follow the procedures discussed in MD-12.6, "NRC Sensitive Unclassified Information Security Program". In addition, the licensing branch in FCSS has developed SUNSI guidance for the division, draft as of October 2007, located in ADAMS at (ML072840423) "FCSS Staff Enclosure - Quick Screening Process for Determining the Presence of Security-Related Controlled Unclassified Information in Fuel Cycle-Related Documents".

For additional information on SUNSI see:

- **NRC REGULATORY ISSUE SUMMARY 2005-31 CONTROL OF SUNSI (12/22/05)**
- SUNSI Handling Requirements Summary Tables by Information Group
- NRC Policy for Handling, Marking, and Protecting SUNSI Information
- Marking SUNSI in Electronic Formats
- Sensitive Unclassified Non-Safeguards Info (**SUNSI**)

SAFEGUARDS INFORMATION (SGI)

"Safeguards Information" and "Safeguards Information -Modified Handling," in general, refer to *detailed* information about security measures that would be useful to an adversary planning an attack, as defined in Part 73. Licensees and all persons who produce, receive, or acquire SGI must ensure proper handling and protection of this information. Access to SGI is limited to persons who have established the need-to-know the information, and are considered to be trustworthy and reliable. Each person who produces, receives, or acquires SGI shall ensure that this information is protected against unauthorized disclosure. Additional information is

available in NMSS "Modified Handling Requirements for the Protection of Certain Safeguards Information (SGI-M)" (see ML042980006).

Guidance on handling safeguards information is provided in MD-12.7, "NRC Safeguards Information Security Program," issued June 2008.

A concurrence package which contains safeguards information should have a non-sensitive transmittal letter. This letter should include the following statement at the bottom of the page (preferably in a text box): "The document(s) transmitted herewith contain SAFEGUARDS INFORMATION. When separated from the sensitive information, this document is DECONTROLLED."

With regard to routing for concurrence, only those staff members with a need to know may have access to the Safeguards Information. The transmittal letter can be routed through concurrence with a note that the sensitive enclosure can be provided upon request. Authors should take care not to leave SGI with reviewers overnight unless the reviewer has a proper storage container (lock-bar cabinet or safe). When mailing Safeguards information outside the NRC, use the guidance in MD 12.7 and the Safeguards section of the "Minimum Requirements for Handling Classified and Safeguards Information" card, listed below.

For additional information on safeguards see:

- Minimum Requirements for Handling Classified and Safeguards Information
- Designation Guide for Safeguards Information (DG-SGI-1)
- Guide to Marking Safeguards Information (ML082530264)
- Designation Guide for Safeguards Information
- List of Safeguards Information (**SGI**) Designators

CLASSIFIED INFORMATION

MD-12.2, "NRC Classified Information Security Program," provides the policy and procedures for handling and marking classified information. Most classified information can be grouped into two categories: (1) Restricted Data and (2) National Security Information. In each category there are three levels of classification (1) top secret, (2) secret, and (3) confidential. Staff access to information is limited based on the requirements in MD 12.3, "NRC Personnel Security Program."

CONFIDENTIAL markings on classified information should not be confused with 'Business Confidential" markings on proprietary information. If in doubt, staff should protect information marked CONFIDENTIAL as classified information. Licensees should be encouraged to mark SUNSI information with a different term (i.e., proprietary, etc.).

For additional information on classified information see:

- Minimum Requirements for Handling Classified and Safeguards Information
- Classified Info Storage
- Marking Booklet for Classified Information

COMPUTER USE FOR CLASSIFIED AND SAFEGUARDS DOCUMENTS

Classified and Safeguards documents shall be prepared and revised on a stand alone computer without a hard drive and disconnected from the LAN. PMs may work in the FCSS secure area when working on classified information. Use of a stand alone computer hard drive and the secure area should be coordinated with the Material Control and Accounting Branch Chief and must be in accordance with the FCSS Security Plan.

INFORMATION SECURITY

For more information and guidance on information security, refer to the Security website on the NRC webpage under the topic of Information Security. The following information security topics and guidance links provide additional information.

- Personally Identifiable Information (**PII**)
- Screening Documents for Security-Related Info that Could be Useful to a Terrorist
- NRC Overseas Travel Brief
- Privacy Act

19.4 Security Assessment

As a result of the terrorist attacks on September 11, 2001, the NRC conducted a thorough review of NRC's safeguards and security programs. Part of this review assessed the potential consequences and risks of terrorist attacks on a broad range of licensed facilities and activities. The Commission instructed the staff to develop a simple, clear decision making framework to conduct safety assessments (SA) for these type of risks.

As a result of this effort, a decision-making framework has been developed as a tool for NRC use to determine the appropriate level of mitigative strategies required for a given threat scenario. These tools can be used to conduct a security assessment and are available at , "Security Assessment Framework to Facilitate Knowledge Management for Fuel Cycle and Non-Fuel Cycle Materials Facilities" (ML072970865)

19.5 Decommissioning Financial Assurance Documents

The original copies of all decommissioning financial assurance documents are maintained by the Materials Decommissioning Branch, Division of Waste Management and Environmental Protection (DWMEP), in a fire resistant safe. When these documents are received by the staff, the originals should be hand delivered to DWMEP and copies to the PM/LA so that copies may be made for docketing (black out the account number and amount upon request). FCSS will review and manage financial assurance documents in accordance with MD 8.12 "Decommissioning Financial Assurance Instrument Security Program" and NUREG-1757 "Consolidated Decommissioning Guidance".

19.6 Identification of Potential Abnormal Occurrences and Event Reporting

After the office reorganization in 2007, NMSS created the function of Events Coordinator in FCSS to review events and evaluate their potential as Abnormal Occurrences (AOs). The Event Coordinator's responsibilities are described in the memorandum to FCSS dated April 11, 2007, "Division of Fuel Cycle Safety and Safeguards Events Coordination," located in ADAMS at ML070710244. Questions regarding events that may be AOs should be directed to the events coordinator. Additional guidance on AOs is available in:

- MD Management Directive 8.1, "Abnormal Occurrence Reporting Procedure,"
- P&PL 1-6, (ML031700328) "Abnormal Occurrence Reporting Procedures," and
- Revised Abnormal Occurrence Criteria (PDF) on the Nuclear Material Events Database (NMED) website (https://nmed.inl.gov/), under "Help."

Event Reports for Cat I Fuel Cycle Facilities must be reviewed for sensitive information before they can be made public. Cat I PMs should refer to the October 5, 2007 Memorandum for the office policy on handling this topic (ML072770042). This policy is in accordance with SECY-07-0129, *Revisions to Policy Governing Public Availability of Information Associated with Category I Fuel Facilities.* PMs will be notified of events by the appropriate supervisor, event coordinator or point of contact. Within three business days, the PM shall redact the event description in accordance with the office internal guidance (SUNSI guidance). The redacted version shall be provided via e-mail to the Headquarters OPs Center (HOO1@nrc.gov).

NRC has developed a web site called The Materials OpE Gateway, located on FSME's homepage. This site facilitates the dissemination, evaluation and application of operational experience and information. The Gateway allows NRC staff to have easy access to events notifications, reports, material related news, agreement states information, licensing toolboxes, and many other tools useful for the regulatory process. Staff can upload documents to share their operational experience with other personnel. The Materials OpE program effectively communicates the operational experience, lessons learned, and regulatory decisions to the non-power reactors groups.

Additional guidance on event reporting is found in P&PL-1-60 (ML031840640), "Inclusion of Nuclear Materials Events Database (NMED) Item Number on Event-Related Documents,"

19.7 Inspection Feeder Reports

At times, members of the FCSS staff may participate in an inspection of the licensee's facility. Upon completion of the inspection, staff must provide the inspection staff with input (Feeder Report). Prior to distribution of the Feeder Report, the report should be reviewed by the PM's supervisor.

Reports should be written in accordance with criteria in Inspection Manual Chapter 0610 "Nuclear Material Safety and Safeguards Inspection Reports". Staff hours for inspection related functions should be recorded to the appropriate TAC in ADAMS in accordance with NMSS Policy & Procedures Letter 2-3 (ML031880883), "Regulatory Information Tracking System" (see Chapter 9).

19.8 Freedom of Information Act, Privacy Act and Privileged Information under 10 CFR 2.390

The Freedom of Information Act (FOIA) of 1966 protects the rights of the public to access information and makes provisions for individuals to obtain information on the operation of federal agencies. OIS manages NRCs FOIA Program and coordinates responses to requests under the Act. NRC has a program that administers policies and procedures to ensure NRC compliance with FOIA and the Privacy Act (PA), 5 U.S.C. 552 and 5 U.S.C. 552a. NRC's regulations on public records are found in 10 CFR Part 9 of the Code of Federal Regulations. NRC's Deputy Executive Director for Information Services and Chief Information Officer is designated as the NRC Chief FOIA Officer.

FOIA generally provides any person the right, enforceable in court, to obtain access to Federal agency records. The objectives of the Privacy Act are to restrict disclosure of personally identifiable records maintained by Federal agencies, grant individuals rights to their personal information maintained in agency records, grant individuals the right to seek amendment of agency records maintained on themselves, and to require agencies to comply with statutory norms for collection, maintenance, and dissemination of records. More information related to the FOIA and Privacy Act is available on the NRC internal web site under the OIS homepage.

When a PM receives a FOIA request for a document which has been determined to contain information protected under 10 CFR 2.390, the PM should close the loop by sending the NMSS FOIA Coordinator a copy of the FOIA request, the incoming letter, an affidavit, and NRC's response letter. In addition, the PM should ensure the information is recorded on the docket, so the agency has a record of the prepared response to the request. If a response letter was inadvertently never sent to the submitter, provide the FOIA office with that information.

PMs should be familiar with the December 12, 1994 EDO letter (ML030090351), "Review of Proprietary Documents" as well as P&PL 1-71, "Release of Information to the Public," and P&PL 1-85 (ML050340371), "Handling Requests to Withhold Proprietary Information from Public Disclosure."

19.9 Web Site

PMs are required by 10 CFR Part 2 and 51 to provide the public notice of certain types of licensing actions via the NRC website. The P&PL 1-86, May 2005 (ML050810187), "NMSS Staff Support of the Hearing Process in 10 CFR Part 2," has criteria on and examples of when to place letters of intent and license amendments on the website. Some examples include: stated regulatory requirements, an action requiring the preparation of an Environmental Impact Statement, a site-specific Independent Spent Fuel Storage Installation license, a new license requiring an emergency plan, and licensing actions involving a high degree of public interest. .

The following information regarding major licensing actions should be posted on the public website::

1. Notices for major licensing actions example
   (posted with support from the Licensing Assistant)
2. Public Meeting Notices example
3. New Fuel Cycle Facility Licensing information example
   - Plant Licensing Overview example
     includes links to Licensing Documents, Correspondence and Other Licensing Review Information, Meeting and Call Summaries
   - Frequently Asked Questions example
   - Contact Us example

- Communications Plan example

The Division has an assigned individual (Content Provider) who serves as a liaison for implementing edits to the NRC's internal and external web pages. To request an edit, individuals must fill out a Web Input Form (see Templates). This document must be concurred on by the individual's branch chief and the Content Provider. Once the form is properly signed, the Content Provider works with the Web Contractor Resource to implement the requested change.

19.10 Reviewing Officials

The Energy Policy Act of 2005 (EPAct) amended the AEA to require fingerprinting and a Federal Bureau of Investigation (FBI) identification and criminal history records check of any person who is to be permitted to have access to Safeguards Information. The NRC issued Orders to the fuel cycle licensees imposing additional requirements. Copies of these Security Orders are available for review on the NRC website under Enforcement Documents>Security Orders.

One of the requirements of these Orders is that the licensees nominate a Reviewing Official, an individual who will have responsibility to review the trustworthiness and reliability of other licensee employees. Licensees should submit requests to change their Reviewing Official(s) to NMSS, through a project manager. The letter transmitting the request should be docketed in the non-public ADAMS and a copy forwarded to the Office of Administration (ADM) (Mail Stop T6E46). The licensees also submit fingerprint cards under separate cover or electronically, directly to ADM. ADM will make a determination on the Reviewing Official nominee and send an email to the project manager. The project manager should prepare a letter to the licensee accepting the Reviewing Official (see Template "Acceptance of Proposed Reviewing Officials").

19.11 Orders Tracking Database

Developed by FSME, NMSS has an account on the Interim Compensatory Security Measures for Material Licensees (ICSM) Tracking System, maintained by FSME. The database is used to track the issuance of Orders, licensee responses, correspondence related to Orders, questions and answers, and the names of the Reviewing Officials for each licensee. See the FCSS point of contact to enter information into ICSM.

19.12 Communications Plans

For high visibility projects, project managers may develop written communications plans to assist in internal and external understanding of the project. A communication plan identifies primary and secondary audiences and key messages and themes that will likely resonate with these groups. The PM should solicit information from other offices (e.g., Office of Public Affairs, Office of Congressional Affairs and any other NRC Offices, as applicable) when creating a communications plan (see the NRC intranet for examples of communication plans and guidance). The NRC's communications page on the internal NRC website contains useful Guidance on Communication Tools & Plans.

19.13 Templates

Back to Templates Index ↑

The Templates listed below are located in an ADAMS package entitled "NMSS-FCSS Templates" (ML082470284).

Template 19.1 **Decommissioning Financial Assurance Memo (ML082470420)**

Template 19.2 **Format Note to the File (ML082470435)**
Example (ML052720356)

Template 19.3 **Transmittal Letter of Credit (ML082470490)**

Template 19.4 **Web Input Form (ML101110723)**

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APPENDIX A
Acronyms

ACRS	Advisory Committee on Reactor Safeguards
ACNW	Advisory Committee on Nuclear Waste
ADAMS	Agencywide Document Access and Management System
ADM	Office of Administration
AEC	Atomic Energy Commission
AEOD	Office for Analysis and Evaluation of Operational Data
AI	Additional Information
AIT	Augmented Inspection Team
ANS	American Nuclear Society
ANSI	America National Standards Institute
ASLB	Atomic Safety and Licensing Board
ASME	America Society of Mechanical Engineers
BC	Branch Chief
BTP	Branch Technical Position
CE	Categorical Exclusion
CEO	Council on Environmental Quality
CFR	Code of Federal Regulations
CH	Chemical Safety
CRESS	Central Regulatory Electronic Stenographic System
CRGR	Committee to Review Generic Requirements
CS	Criticality Safety
DCB	Document Control Branch
DCS	Document Control System
DPC	Document Processing Center
D&D	Decontamination and Decommissioning
DES	Draft Environmental Statement
DFA	Decommissioning Financial Assurance
DFP	Decommissioning Financial Plan
DIQ	Design Information Questionnaire
DOE	Department of Energy
DWM	Division of Waste Management
EA	Environmental Assessment
ECS	Electronic Composition Services
EDO	Office of the Executive Director for Operations
EIS	Environmental Impact Statement
Env PM	Environmental Project Manager
EP	Emergency Plan
EPA	Environmental Protection Agency
ER	Environmental Report
ERIDS	Electronic Regulatory Information Distribution System
ES	Environmental Statement
ESR	Early Site Review
ESRP	Environmental Standard Review Plan
FC	Fuel Cycle
FCOB	Operations Branch, FCSS
FCSS	Division of Fuel Cycle Safety and Safeguards
FSPB	Special Projects Branch, FCSS
FEMA	Federal Emergency Management Agency
FES	Final Environmental Statement
FNMCP	Fundamental Nuclear Material Control Plan
FONSI	Finding of No Significant Impact
FP	Fire protection
FR	Federal Register
FRIB	Regulatory and International Safeguards Branch, FCSS
FRN	Federal Register Notice
FSAR	Final Safety Analysis Report
FSME	Office of Federal and State Materials and Environmental Management Programs
HEU	Highly Enriched Uranium
HLW	High-Level Waste
HP	Health Physicist
IMNS	Division of Industrial and Medical Nuclear Safety, NMSS
ISA	Integrated Safety Analysis
LA	Licensing Assistant
LER	Licensee Event Report
LEU	Low-Enriched Uranium
LFARB	License Fee and Accounts Retrievable Branch, OC
LIB	Licensing and International Safeguards Branch
LLW	Low-Level Waste
LPDR	Local Public Document Room
LPM	Licensing Project Manager
LTS	License Tracking System
LWA	Limited Work Authorization
MC	Manual Chapter
MC&A	Material Control and Accountability
MD	Management Directive
ML	Accession Number
NCS	Nuclear Criticality Safety
ND	Negative Declaration
NEPA	National Environmental Policy Act of 1969
NMSS	Office of Nuclear Material Safety and Safeguards
NPDES	National Pollution Discharge Elimination System
NPR	National Program Review
NRC	Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NWPA	Nuclear Waste Policy Act
OCA	Office of Congressional Affairs
OE	Office of Enforcement
OC	Office of the Controller
OGC	Office of the General Counsel
OI	Office of Investigations
OIG	Office of the Inspector General
OIP	Office of International Programs
OIS	Office of Information Services
OL	Operating License
OMB	Office of Management and Budget
OPA	Office of Public Affairs
OSP	Office of State Programs
OUO	Official Use Only
PAVS	Printing and Audiovisual Services Branch
PDF	Adobe – Portable Document Format
PDR	Public Document Room
PM	Project Manager
PMDA	Program Management, Policy Development and Analysis Staff
POL	Possession Only License
PRA	Probabilistic Risk Assessment
PSAR	Preliminary Safety Analysis Report
R I	Region I
R II	Region II

R III	Region III
R IV	Region IV
RAI	Request for Additional Information
RCP	Radiological Contingency Plan
RES	Office of Nuclear Regulatory Research
RG	Regulatory Guide
RI	Resident Inspector
RIDS	Regulatory Information Distribution System
RITS	Regulatory Information Tracking System
RO	Regional Office
RPB	Regulatory Publications Branch
SALP	Systematic Assessment of Licensee Performance
SAR	Safety Analysis Report
SC	Section Chief
SE	Safety Evaluation
SECY	Office of the Secretary
SER	Safety Evaluation Report Safeguards Evaluation Report
SHO	State Health Official
SIR	Staff Input Report
SNM	Special Nuclear Material
SRP	Standard Review Plan
SSNM	Strategic Special Nuclear Material
SUNSI	Sensitive Unclassified Non-Safeguards Information
TAR	Technical Assistance Request
TER	Technical Evaluation Report
TL	Team Leader
TP	Technical Position
TSB	Technical Support Branch
USI	Unresolved Safety Issue
WCFO	Walnut Creek Field Office, Region I

APPENDIX B
Non-Proliferation Treaty (NPT) Summary

The Treaty on the Non-Proliferation of Nuclear Weapons, commonly known as the Non-Proliferation Treaty (NPT), is the most important international political instrument aimed at preventing further spread of nuclear weapons.

Article I of the NPT states that (1) nuclear weapon States party to the Treaty undertake not to transfer to any recipient whatsoever nuclear weapons or any other nuclear explosive devices or control over them, and (2) not to support manufacture or acquisition of such weapons or devices by any non-nuclear weapon States. Article II states that non-nuclear-weapon States party to the NPT, according to Article II, undertake not to receive any nuclear weapons or other nuclear explosive devices from any transferor and not to manufacture such weapons or devices, nor to accept assistance in this respect.

Article III states that non-nuclear-weapon States, party to the NPT, undertake to accept IAEA safeguards as set forth in an agreement to be concluded with the IAEA. They undertake further, not to provide source and special fissionable material and relevant equipment to any other non-nuclear-weapon State unless the material is covered by IAEA safeguards.

Article IV stipulates that the NPT should not affect the right of its parties to develop and use nuclear energy for peaceful purposes. All the parties to the NPT undertake further to facilitate and have the right to participate in the fullest possible exchange of equipment, materials and information on peaceful uses of nuclear energy.

Article VI states that each of the parties to the NPT undertakes according to Article VI to pursue negotiations on effective measures relating to an early cessation of the nuclear arms race, to nuclear disarmament and to general and complete disarmament under international control.

The NPT was opened for signature on 1 July 1968, and entered into force on 5 March 1970. In 1995, the Treaty was extended indefinitely. The number of States party to the Treaty had reached 187 States as of December 31, 2001. The full text of the NPT is published in IAEA document INFCIRC/140. The guidelines for the Director General to use in negotiating safeguards agreements were prepared by a special committee of the Board of Governors of the IAEA, were approved by the board in 1971, and published as IAEA document INFCIRC/153. A special committee established by the Board of Governors prepared an additional Protocol that expands the IAEA's authority to collect information and provide access to a State's nuclear fuel cycle and other nuclear related activities. The Protocol was approved by the Board of Governors in the June 2007.