NUREG-1324

Proposed Method for Regulating Major Materials Licensees

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

The Materials Regulatory Review Task Force

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The Materials Regulatory Review Task Force

Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Those Who Receive NUREG-1324

Subject: Report of the Materials Regulatory Review Task Force (NUREG-1324): Request For Comments

I request your comments on this task force report that proposes a revised method for regulating major materials licensees. The method was developed from a completely fresh point of view. The task force was to propose an ideal method for regulating these licensees, unfettered by any existing regulations or regulatory guidance, concerns about backfitting, or limitations on resources of the Nuclear Regulatory Commission (NRC) or the licensees. Given this charter, the task force described a regulatory method that is admittedly highly idealistic.

The NRC has limited resources, however, and must establish priorities for any proposed actions to improve the existing regulatory method. Two NRC managers, who were not on the task force, independently analyzed this report and suggested a basis for assigning priorities to the recommendations in the report. Appendix A to this report includes their analysis and this basis.

My staff is particularly interested in obtaining the following types of comments on the report and on Appendix A:

1. Which of the recommendations should, or should not, be adopted and why?
2. Which of the recommendations should be modified, and, if any should, how and why?
3. What priority should be assigned each recommendation to be implemented and why?

The NRC has not yet decided to adopt any of the recommendations. Nonetheless, the staff finds some of them important and would like to implement these recommendations if sufficient resources are available.

We would value your comments on the report and on Appendix A and would appreciate receiving them within 60 days after you receive the report. If you wish to discuss any facet of this report, please call Mr. Charles Haughney (301-504-3328 or FTS 964-3328) or Mr. Willard Brown (301-504-2654 or FTS 964-2654).

Sincerely,

Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: NUREG-1324

ABSTRACT

The Director, Office of Nuclear Material Safety and Safeguards, U. S. Nuclear Regulatory Commission, appointed a Materials Regulatory Review Task Force to conduct a broad-based review of the Commission's current licensing and oversight programs for fuel cycle and large materials plants. The task force, as requested, defined the components and subcomponents of an ideal regulatory evaluation system for these types of licensed plants and compared them to the components and subcomponents of the existing regulatory evaluation system. This report discusses findings from this comparison and proposes recommendations on the basis of these findings.

CONTENTS

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ABBREVIATIONS

ACT	The Atomic Energy Act of 1954
AEOD	Analysis and Evaluation of Operational Data, Office for
ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
B&W	Babcock and Wilcox
CFR	Code of Federal Regulations, U. S.
DOE	Department of Energy, U. S.
EAL	emergency action level
FNMC	fundamental nuclear material control
GDC	general design criteria
GE	General Electric
IIT	Incident Investigation Team
IMNS	Industrial and Medical Nuclear Safety, Division of
MC	manual chapter
MC&A	material control and accounting
MORT	Management Oversight and Risk Tree
MOU	memorandum of understanding
NFS	Nuclear Fuel Services
NMSS	Nuclear Material Safety and Safeguards, Office of
NRC	Nuclear Regulatory Commission, U. S.
NRR	Nuclear Reactor Regulation, Office of
QA	quality assurance
QC	quality control
SALP	systematic assessment of licensee performance
SER	safety evaluation report
SNM	special nuclear material
UF_6	uranium hexafluoride

1 INTRODUCTION

After a U. S. Nuclear Regulatory Commission (NRC) team investigated the potential criticality incident that occurred at the General Electric (GE) Nuclear Fuel and Component Manufacturing facility on May 29, 1991 (see NUREG-1450, "Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991"), the NRC recognized possible generic weaknesses in its methods for regulating large materials licensees. During about the last two years, the NRC staff became aware of conditions at other NRC fuel cycle facilities that might have led to a degradation of criticality control. In view of these conditions, the NRC established the Materials Regulatory Review Task Force (1) to examine all facets of its existing regulatory method—unfettered by any existing regulations, guidance, and resource limitations—and (2) to propose an ideal method for regulating large materials licensees. Included were licensees for major fuel cycle facilities, major radiopharmaceutical firms, and any who had offsite emergency plans or who were subject to operational safety team assessments. The proposed ideal method would offer ways to revamp the existing one.

Two NRC managers independently analyzed this report and suggested a basis for assigning priorities to the recommendations in the report. Their analysis is presented as Appendix A to this report. Appendix B lists all the major fuel cycle and materials licensees the Task Force included in its review.

In the charter for the Task Force (see Appendix C), the Director, Office of Nuclear Material Safety and Safeguards (NMSS), requested that the Task Force first define the components and subcomponents of an ideal regulatory method. Second, it was to compare these components with those in the existing regulatory method to identify any weaknesses or missing components that are important to safe materials operations. The Task Force was to review the current regulatory method, including its licensing and inspection activities for this comparison. Finally, from this comparison and other information learned during the examination, it was to make specific recommendations to use in an action plan to correct or improve the existing method.

After a brief examination of the licensing and inspection programs for fuel cycle and large materials plants, including both safety and safeguards issues, the Task Force decided to restrict the scope of its examination to safety considerations so that it could meet the objectives of the charter within the established timeframe. The Task Force determined that although the staff need only improve the way it maintained the safeguards program, the safety aspects of the regulatory programs alone would require an extensive review and, perhaps, many revisions.

Section 2 of this report describes how the Task Force collected and evaluated the information needed to examine the status of NRC's current regulatory process for licensing and inspecting major fuel cycle and materials licensees.

Section 3 lists the essential topics that the Task Force learned should be covered in materials regulatory guidance or regulations. These topics should be included in (1) a new or revised standard format and content guide and a new or revised standard review plan to be developed as guidance for the licensing staff or in (2) a regulation designed to broaden the regulatory basis for licensing large materials processors.

Section 4 describes findings obtained during the examination of the information collected as described in Section 2.

Section 5 lists the recommendations that the Task Force believes are needed to correct deficiencies in the current method for licensing and inspecting fuel-cycle and materials operations.

Section 6 discusses the comparison of these recommendations with staff actions resulting from the investigation of the May 29, 1991, GE-Wilmington event.

Appendices D, E, F, and G present, respectively, existing guidance for the three areas of fuel cycle safety materials safety, and safeguards; a 1988 memorandum of understanding between the Department of Labor and the NRC related to worker protection at NRC-licensed facilities; a table showing how 1990 resources were allocated to inspect fuel cycle plants in the five regions; and, finally, a list of staff actions recommended after the GE fuel cycle event and the sections of this report that discuss corresponding staff actions the Task Force recommended.

2 THE APPROACH OF THE TASK FORCE

2.1 The NRC's Regulatory Role and the Purpose of Licensing and Inspection

The Atomic Energy Act of 1954 (Act), as amended, requires the regulation of nuclear materials to provide for the common defense and security and to protect the health and safety of the public. The Act authorizes the issuance of licenses to applicants "... who are equipped to observe and who agree to observe such safety standards to protect health and to minimize danger to life or property as the Commission may by rule establish; ...."

Clearly, on the basis of the Act, NRC's regulatory role is to ensure, with a high level of confidence, that individuals having a license to possess nuclear material do not use that material in any way that could impose undue risk to health, life, or property. This role means that the NRC shall identify any and all aspects of an applicant's operation that could result either in the unauthorized release of radioactive material beyond engineered confinement systems or in the unauthorized exposure of individuals to radiation above background levels. This role also means that the NRC shall define protective measures that would prevent these releases or exposures. To fulfill the NRC's regulatory role, the NMSS Division of Industrial and Medical Nuclear Safety (IMNS) has several responsibilities:

(1) establishing the policy and procedures that define the protective measures;

(2) issuing a materials license based on a licensee's ability to comply with these measures; and

(3) continually monitoring and assessing a licensee's activities to ensure that the licensee routinely uses the controls necessary to comply with these measures.

In essence then, after sufficient experience and expertise is accrued, the NRC's first step to meet its responsibilities is to define the requirements necessary for the protection of public health and safety. These requirements can be either prescriptive or performance-oriented. The Task Force noted strengths and weaknesses associated with each, but either can be used effectively. The second step is to develop detailed guidance to assist an applicant in preparing an application for a license. Central to this guidance are the standard format and content guide, which the applicant follows, and the associated standard review plan. The staff follows the latter when reviewing an application to see that it is complete and technically adequate. The staff attaches conditions to a license to clarify or augment any topics that are unclear, incomplete, or missing. After a license is issued, the third and last step in the regulatory process is to develop and implement a set of procedures that are used to monitor each licensee's performance to ensure safe operation. These procedures should be based on the standard review plan.

Close interaction between the licensing program staff and the inspection program staff fosters a cohesive and efficient regulatory program. The principal functions of the licensing program staff are to—

- interact with applicants and licensees who are preparing plans, or amendments to plans, to submit to the NRC;
- review license applications and license amendments to ensure that they meet NRC safety requirements;
- prepare and issue safety evaluation reports and environmental impact statements and licenses and license conditions;
- review amendments to ensure that any changes to licensed activities satisfy requirements and that any modified systems will continue to be operated safely (i.e., that the licensee adheres to regulations and guidance to ensure that radioactive material will be confined to engineered confinement systems and undisturbed by external influences and that radiation levels will be maintained at or below authorized levels); and
- ensure the adequacy of the technical basis of enforcement cases.

The principal functions of the inspection program staff are to—

- provide an independent assessment of safety in licensee plants;
- ascertain whether licensees are appropriately protecting their nuclear materials and facilities, the environment, and the health and safety of the workers and the public; and
- enforce Commission orders, regulations, and license provisions.

To fulfill these functions, the regional staff periodically inspects the licensees' plants, equipment, and operations and their training and managerial practices, in accordance with IMNS policies and procedures.

An adage about quality assurance (QA) says that the basis of QA is to "Say what you do and do what you say." Perhaps this simple concept can be used to define the basis of the relationship between licensing and inspection. In brief, two information loops exist between licensing and inspection. Those who license should describe in

detail what the licensee is expected to do and the inspectors should verify that the licensee is or is not doing what is expected. From information learned during inspection activities, inspectors should inform the licensing staff when a license does not meet the NRC's safety goals so that the contents and conditions of the license can be corrected. The continuing flow of information through these two loops provides the basis for the relationship between two basic NRC functions: licensing and inspection. Frequent interaction between the licensing and inspection staffs should not only be expected, but should be required so that the special knowledge and expertise of each group is applied to the safety evaluation of existing and pending licenses. This interaction would help to ensure that a common understanding of the licensee's application is developed that may serve as a basis for discussions with the licensee and that any license conditions required are both adequate to ensure safety and are inspectable and enforceable.

2.2 A Fresh Look at the Regulatory Process

Traditionally, NRC's reviews of applications for a license to possess nuclear material and NRC's reviews of requests for amendments to a license are rooted in the evaluation of plant processes and equipment to confine radioactive material and radiation and to ensure protection of the public and the environment. The Task Force asked itself, "On the basis of our knowledge and experience of well-managed and safely run plants versus poorly managed plants, what would we review if we were beginning a licensing and inspection process?"

To answer this question, it endeavored to develop a set of topics that an application for a license would include if it totally reflected how operations are conducted at a well-managed, safely run plant. These topics were subsequently used as criteria against which the current regulatory system was evaluated, including the existing regulations, guidance, standard review plans, and the inspection program. The topics were also used to help develop the recommendations presented in Section 5 of this report.

After drafting the aforementioned topics, the Task Force augmented its personal knowledge and experience by interviewing journeymen and experts in licensing, inspection, and legal aspects of the regulatory process for large materials licensees in the headquarters and regional offices. Information gained from these discussions was factored into the findings in this report, especially those about staff resources and training and qualification requirements.

The Task Force began the interviews and the conference calls with each of the regions with the following 15 questions:

1. From your perspective, what are the major deficiencies in the licensing process for large materials licensees, including fuel cycle plants?

2. Are you aware of deficiencies in the regulations?

3. Are license conditions clear and complete? Can you give examples of any that are not?

4. Should we look at the performance and the controls of licensee managers?

5. Is the licensing guidance sufficient, for example, the standard format and content guides, the standard review plans?

6. What problems exist with the inspection program?

   - Are the inspection manual chapters complete and satisfactory (2600 and 2800)?

   - Are the procedures clear, complete, and sufficiently detailed or too detailed?

7. Are NRC inspectors, the licensing staff, and supervisors for both programs adequately trained? If not, what type of training do they need?

8. Do you have sufficient resources and expertise available to detect unsafe conditions at a large plant? If not, what do you need to add?

9. What would be the first three items you would change if you ran the licensing and inspection programs?

10. Is communication between the staff in headquarters and the regions adequate? If not, how could it be improved?

11. What is your view of team inspections? How can they be improved?

12. Should we reconsider use of Systematic Assessment of Licensee Performance (SALP) for fuel facilities and large materials licensees?

13. Should we require process reviews or hazards analyses (see Sec. 3.3.1) at these plants, and should the NRC licensing and inspection staffs be trained to oversee the reviews?

14. Would requiring the licensee to complete a detailed hazard analysis, which is an integral part of an overall safety analysis, allow us to incorporate a 10 CFR

50.59-type provision into our regulatory process to eliminate the review and approval of many minor amendments?

15. Are environmental reviews consistently performed on major amendments and license renewals for large materials and fuel cycle plants?

2.3 A Review of Regulatory Documents, Programs, Resources, Reports, and Special Studies

Special Studies

Whenever a serious event involving nuclear materials has occurred, the NRC has evaluated the event to determine its root causes. These evaluations have traditionally covered not only conditions at the location of the event itself, but also the regulatory environment in which the event occurred that may have contributed to those conditions. One broad study, in fact, was limited solely to an evaluation of the regulatory environment; this study was completed by the Material Safety Regulation Study Group.

Two major events, the Sequoyah Fuels Corporation Facility accident (1986) and the General Electric Nuclear Fuel and Component Manufacturing Facility potential criticality incident (1991), resulted in an Augmented Inspection and an Incident Investigation, respectively. Although these two events were quite different in detail, a number of similar plant and regulatory practices existed in both environments in which the events occurred. Details of these events and specific recommendations from the associated evaluation reports (see NUREG–1450 and NUREG–1198, Supplement 1 "Release of UF_6 From a Ruptured Model 48Y Cylinder at Sequoyah Fuels Corporation Facility: Lessons-Learned Report") will not be discussed here. Rather, the important plant and regulatory conditions that pertained to the environment are discussed because they suggest a need for a change in NRC's regulatory approach.

One obvious conclusion about the two plants was that the managers were preoccupied with production, possibly to the exclusion of their other responsibilities. As a result, managerial policies and practices that should have led to a safe, well-managed, and tightly controlled operation had not been developed. These important deficits in practices included the lack of or deficient—

- ongoing use of clear, written procedures;
- approval process for issuing and revising procedures;
- prohibitions against violating procedures or making changes to them without safety reviews and approvals;
- posted admonitions against unsafe practices;
- training and retraining of staff on routine plant operations and safety practices. (At some plants, this weakness included a lack of training on criticality considerations);
- hazard analysis for process operations, components, and process changes;
- control of changes based on engineering safety reviews;
- use of internal and external audits and a rigorous audit recommendation tracking system; and
- control of measurements and sampling systems to ensure meaningful results for any analyses that could have safety implications.

These types of deficiencies in licensee managerial practices, coupled with a licensing and inspection program that focuses principally on radiological safety, can lead to a situation where any change in process conditions can result in an unanalyzed process condition with potential radiological consequences. Some of the licensing and inspection deficiencies identified by previous evaluations include—

- a focus on operational radiation safety rather than overall system safety, that is, a lack of balance in the regulatory program;
- insufficient resources in each region to cover the mix of skills necessary to inspect all areas of the process and the plant that are related to safety. As a result of insufficient resources, regional managers place radiation-protection inspectors in available positions because of the regulatory focus on radiation safety;
- inadequate expertise and technical training in areas other than radiation protection; for example, licensing and inspection staffs may have no training for process safety evaluations, criticality, or computer control of processes;
- license conditions, incorporated by reference, that are vague, uninspectable, or unenforceable;
- no requirement to determine which plant or process changes should be submitted for licensing review and approval; and
- lack of a complete comprehensive standard review plan for conducting licensing reviews.

Deficiencies in licensee practices can be addressed by promulgating new or revising existing regulations, issuing standard format and content guides, and developing standard review plans. For the short term, any revision to a regulation should be prescriptive to correct specific deficiencies. For the long term, performance-based regulations should be considered to ensure any deficiency is completely addressed and to permit licensees flexibility in

meeting their responsibilities. Understand though that after a performance-based regulation is developed, the NRC must develop specific detailed guidance for implementing it. Developing a performance-based regulation and its guidance places considerable demands on NRC's highly skilled staff, and implementing them, on the licensee's highly skilled staff.

Regulations

The Task Force primarily reviewed regulations dealing with safety and environmental protection, that is, Parts 20, 30, 40, 51, 70, and 71 of Title 10 of the U.S. Code of Federal Regulations (10 CFR). It reviewed the requirements in these parts against the topics listed in Section 3 of this report, identified omissions or significant deficiencies in the existing regulations, and recommended revisions to these regulations.

Licensing Guidance Documents

The quality of a licensing review depends on the level of detail contained in a licensee's submittal and on the skill, knowledge, and experience of NRC's reviewers. To ensure consistency and completeness of reviews, licensees should prepare their submittals in accordance with a standard format and content guide, and reviewers should evaluate the submittal against a detailed, high-quality standard review plan. Both are needed to define the scope and depth of the application and the review and to ensure that important topics are not omitted. Both are needed for the training of inexperienced reviewers, as well. In pursuing the review of these important guidance documents, the Task Force determined the availability of the guides and review plans needed and then reviewed existing guides against the topics listed in Section 3 of this report. Where appropriate, it recommended that certain documents be revised or developed.

Inspection Manual Chapters and Procedures

The Task Force reviewed all current and pertinent inspection manual chapters and associated procedures against the topics listed in Section 3 of this report and recommended, as appropriate, revising the existing procedures or developing new procedures.

Available Resources

On the basis of interviews with the staff, a review of the backlogs of licensing case work, and a review of current inspection requirements, the Task Force evaluated the adequacy of staff resources at both headquarters and the regions.

Staff Training and Qualification Programs

Recognizing the importance of staff training and qualification to successful licensing and inspection programs, the Task Force reviewed the current training and qualification programs for those individuals assigned to licensing and inspection activities. It identified significant deficiencies and offered recommendations to correct them.

Licensing and Inspection Programs

The licensing and inspection programs for fuel cycle plants and materials processors were examined through interviews of knowledgeable practitioners and review of documents (i.e., regulatory guides, standard review plans, branch technical positions, directives, and inspection manual chapters and associated guidance). It noted any deficiencies in these documents and recommended changes to them.

3 A SET OF IDEAL LICENSING REVIEW TOPICS

The Task Force determined that at least the following 18 topics would have to be addressed in any revision to a regulation or to regulatory guidance for large nuclear materials plant operations and would have to be covered in any standard format and content guide and standard review plan. While it realizes that these topics may not be totally inclusive, a licensing review program and inspection program based on this set of topics should significantly strengthen the regulatory process for fuel cycle and [illegible]aterials plants. The table at the end of this section [illegible]opics discussed and where they can be found in [illegible].

3.1 Organization Plan

The licensee should develop an organization plan to—

- describe each position of responsibility within the defined corporate entity holding the license;
- define the responsibilities and the authority assigned to each position; and
- indicate how quality, safety, and safeguards functions are independent of production operations and how those responsible for these functions are authorized to halt unsafe activities.

Indicate in the organization plan the checks and balances achieved through such an organizational separation of functions that the activities of one organizational entity provide a check on the activities of other entities. Assign the senior licensee nuclear officer the authority to settle disputes between these entities.

Design the structure of the organization delineated in the plan to ensure that persons in specific positions within a management chain are responsible and accountable for quality, safety, and safeguards in their operation.

Include in the plan the following three components:

- **Staffing Plan.** Define in a staffing plan the array of skills needed to perform the functions assigned to each department and indicate the minimum number of employees with each skill required to carry out the duties assigned.
- **Accountability of Managers.** Include a clear statement of accountability for the activities managed within the written delegation of and authority for each manager's position so that the incumbent has a clear understanding of what to do and how to do it and how to quickly explain any deviation from expected performance.
- **Personnel Qualifications.** Include a statement of the experience and training required for each position in the organization plan so that a judgment may be made about the competency of an individual to perform the functions of the position.

3.2 Managerial Controls and Oversight

3.2.1 Policies, Procedures, and Documentation

For the managers to adequately control and oversee an operation, the licensee should describe a program that ensures that procedures and documents are developed, revised, reviewed, approved, controlled, maintained, distributed, and used in accordance with written requirements and authorizations. The licensee should establish the following policies and procedures to encompass the activities and documents used by any staff person or any manager in a materials operation:

Corporate Policies and Procedures. Have the senior nuclear officer responsible for licensed actions approve a set of policies and procedures that discuss subjects related to safety, safeguards, and environmental protection practices. Issue all plant safety policies and procedures only after safety committee review (see Sec. 3.2.2) and designated managerial approval. Have these policies and procedures readily available to the plant staff who perform nuclear activities.

Division Policies and Procedures. Have each operating division prepare, if applicable, expanded safety policy and procedure statements.

Program Documents. Define in the program documents the general activities to be conducted for each program, for example, radiation protection program, environmental protection program.

Operating Procedures. Define in the operating procedures the actions to accomplish tasks. Define each step in a task in the task instructions, for example, "Open valve number 2." Include maintenance and testing procedures in the management control program.

Engineering Drawings, Calculations, and Specifications. Describe in procedures the steps needed to review, approve, control, retain, and change drawings, calculations, specifications, and calibration certificates.

Adherence to Procedures. Establish a program to ensure that clear, written procedures, authorized by persons in designated positions, are prepared and are followed. Prepare a procedure change and control program to ensure that the procedures are properly revised and distributed and that the most recently authorized version is available at all users' stations.

3.2.2 Safety Committees

Managers should establish safety committees to review and approve operating plans and procedures, design changes, nonconformances and corrective actions, audits, safety training programs, operating problems, and corrective actions for unsafe plant conditions. Include members of the staff who are not line managers on the committee. Have staff who are not directly associated with the operation of the plant independently evaluate safety matters for the committee. Have these committees conduct or assure the NRC of the conduct of in-depth safety reviews of process operations within the plant on an established schedule.

3.2.3 Audits and Independent Assessments

Qualified audit personnel should perform internal and external audits to evaluate whether the licensee is applying effective managerial controls and is implementing the programs related to activities significant to plant safety, safeguards, and environmental protection. These audits should be both compliance- and performance-based whenever possible. Correct any adverse conditions discovered during an audit to prevent their recurrence and to verify the adequacy of the corrective action. Through the audit program, track established key performance indicators so that these indicators can be used to analyze and develop trends that could indicate potential problem areas. In addition, have managers establish methods to independently assess the design of any safety systems and the effectiveness of any programs and their capabilities to achieve safety objectives.

3.2.4 Unusual Occurrence Policies

To evaluate and report an unusual occurrence, the licensee managers should establish policies requiring that its staff—

- identify and analyze the root causes of the occurrence;
- evaluate whether each member of its organization effectively responded during the occurrence;
- determine the effects of the occurrence on safeguards systems, radiological safety, criticality, and the environment; and
- report, as appropriate, the occurrence to plant and corporate managers, NRC, State, and local authorities.

3.2.5 Commitment Tracking System

Licensee managers should establish a system to monitor all internal and external commitments to improve plant safety, safeguards, and environmental protection programs.

3.2.6 Configuration Management

The licensee should develop an integrated process for managers to ensure—

- that the plant's physical and functional characteristics always conform with the plant's licensing and design basis;
- that operating, training, modification, and maintenance processes are consistent with current conditions of the design and licensing bases; and
- that the plant is operated and maintained within these conditions.

3.2.7 Records Management

The licensee should maintain an effective system for recording data, retaining these records, and promptly reporting information about the status of plant activities to managers to allow them to make prompt decisions.

3.2.8 Corrective Action System

The licensee should establish a corrective action system to ensure that its staff determines the cause of conditions adverse to safety, safeguards, or the environment and effectively acts to correct these conditions. The staff should document and report all corrective actions to their managers.

3.3 Operations

3.3.1 Hazards Analysis

A root-cause analysis of the Sequoyah Fuels and General Electric-Wilmington events suggests that failure to conduct a hazards analysis in both cases may have been a major contributor to these events. Once such a baseline analysis exists, licensee managers will have a basis to perform plant change analyses, configuration control, personnel training, and so forth.

Managers should establish a method to analyze systems and components and to predict the consequences of equipment failure under both normal and abnormal operating conditions. For a hazard analysis, analyze systems and components, both internal and external to the plant, that may affect operation of the plant. Have the licensee's engineering organization conduct these analyses for each step of the process to ensure that equipment has been designed and installed to achieve engineered safety requirements. Include a review and an evaluation of the integrity and operational status of safety and containment as an integral part of the process safety program.

Hazards analyses are an integral part of the safety analyses and must consider the impact of different types of off-normal conditions, including fire, explosion, criticality, radioactive material release, and applicable external events on the process and equipment in the

system being analyzed. The following basic steps describe the actions needed to conduct a hazards analysis:

- Describe the process and equipment involved in the defined system, including the intended operation and plausible unintended operations.
- Determine and describe the ways an accident could occur through a sequence of normal and abnormal events.
- Perform a multidisciplinary evaluation that postulates, describes, and analyzes a plausible set of process upsets and malfunctions affecting each operating station and system.
- Make the hazard evaluation formal and up to date to accommodate facility and operational changes.
- For each credible accident sequence identified in the hazard analysis, describe the barriers, either engineered features or administrative controls, which are intended to mitigate the identified risks.

3.3.2 Other Limits, Controls, and Tests

The licensee should incorporate operating bounds for each piece of equipment that is part of a material barrier system, reduces radiation levels, or is safety-related into the license or other appropriate document that can be traced to the license.

Establish procedures requiring scheduled walk-through reviews of process operations to ensure that the licensee's staff is following safety requirements.

Establish limits and controls on the quantity of in-process material in storage to ensure that criticality and fire safety are not compromised.

Establish a testing program to ensure that all installed equipment or systems have been tested for proper operation before their first use or after each major maintenance or modification.

Have plant engineering groups write adequate procedures to facilitate initial and periodic tests of safety-related equipment to ensure that it operates properly and to ensure that the equipment meets design objectives (e.g., flow, pressure, temperature).

3.4 Engineering Reviews

The licensee should establish procedures and controls to ensure that the staff reviews—

- each change to plant or equipment design to ensure the adequacy of radiation, criticality, industrial safety, and safeguards considerations, and maintenance of appropriate limits and
- each procurement document for safety-related equipment and systems to ensure that it contains appropriate information on established radiological and criticality safety requirements to ensure that vendors will supply equipment that will perform under expected service conditions.

3.5 Training and Qualification Program

The licensee managers for each materials operation should commit to ensuring that all key staff are adequately trained to perform their jobs and are continually aware of safety, safeguards, and environmental protection hazards.

To meet this commitment, managers should retrain all workers at established intervals and should establish policies and programs for retraining and requalification that they periodically review.

The training should include at least seven programs, offering radiation protection training to the entire staff, specialized training for staff filling certain positions, and even visitors.

Program	Who Attends
1. Initial training to cover plant radiological, chemical, criticality, and industrial safety	Entire staff
2. Radiation protection training to ensure professional performance of duties. Managers should review, approve, and document this training before it is offered.	Operators, technicians, maintenance staff, and staff who work where material is processed or stored
3. Criticality safety training to ensure each individual recognizes the importance of established controls to prevent a criticality incident.	Entire staff
4. Emergency brigade training to address each plant-accident scenario	Emergency response staff
5. Training to cover site-specific plant safety rules and plant evacuations in case of an emergency	All visitors allowed unescorted access
6. Training to cover maintenance of safety and safeguards equipment and systems	Maintenance personnel
7. Training programs to cover responsibilities in the areas of plant safety, safeguards, and environmental protection	All supervisors and managers

3.6 Quality Assurance Program

An applicant should define the elements of the quality assurance program that are appropriate for the materials operation, considering applicable criteria in 10 CFR Part 50, Appendix B.

3.7 Maintenance Programs

An adequate system for safely maintaining a materials operation should include at least three maintenance programs: corrective, preventive, and instrument calibration.

In a corrective maintenance program, ensure that prompt and effective maintenance is performed on malfunctioning safety and safeguards systems and equipment.

In a preventive maintenance program, ensure operability of those—

- systems and equipment that are identified as important to the safety and safeguards of the plant, such as radiation monitors and intrusion detection systems, and
- process systems and equipment that are essential to safe plant operations, such as emergency power, heat, ventilation, and air-conditioning systems.

A program with written procedures and calibration standards—traceable to the national standards system or to nationally accepted calibration techniques, as appropriate—should enable the staff to calibrate equipment and monitoring devices important to plant safety and safeguards.

3.8 Radiation Safety Programs, Systems, Design, and Permits

The licensee should establish a program that defines its actions to control radiation exposures to workers and the public. Include in a procedures manual for this program instructions to radiation protection technicians on all their required activities (e.g., conducting surveillance, counting samples, conducting radiation surveys). Establish an as low as is reasonably achievable (ALARA) program that clearly states a commitment to the ALARA requirement. Include in the program ALARA measures such as work planning, equipment design, personnel training, use of shielding as appropriate, and the work permit system.

Establish and maintain a respiratory protection program, an internal exposure control program, and an external exposure control program in accordance with 10 CFR Part 20 and other regulatory guidance.

Establish a bioassay program that complies with 10 CFR Part 20 and meets the guidance contained in Regulatory Guide 8.11, "Applications of Bioassay for Uranium," or other applicable regulatory guides or standards.

Establish a contamination control program that meets the guidance contained in applicable regulatory guides or other standards. Specify in this program that contamination beyond engineered barriers is not tolerated.

Ensure by the air-sampling methodology that information needed to estimate personnel internal accumulation of radioactive materials is routinely produced.

Establish internal and external audit programs used to determine the effectiveness of the radiation protection program, describe the use of independent groups, on site and off site, who conduct these audits.

Describe in the systems for radiation alarms the use and types of alarms installed in the plant for various purposes and describe the use of area alarms, process control alarms, liquid and gaseous discharge system alarms, and other routinely used local alarms.

Describe in the licensee's plant design how radiation and contamination are confined and include the policies and procedures to ensure that radioactive solids, liquids, and gases are confined in case of malfunctioning systems and equipment. Have managers periodically review these policies and procedures.

Design the applicant's system of radiation work permits to minimize the likelihood of occurrence of radiological accidents; describe the use of these work permits and the methods used to initiate, approve, control, complete, verify, and close out these permits.

3.9 Criticality Safety Program

3.9.1 Objectives

To properly develop and implement a successful criticality safety program, the licensee should accomplish four basic objectives. Accomplish the first two objectives before operating the work station or starting the system and accomplish the last two objectives continually during startup and operation—

- Determine the risks of a criticality accident in different portions of the plant and describe the operating station and system operations. Ensure that important facility descriptions are accurate. Perform multidisciplinary hazard analyses that postulate, describe, and analyze a plausible set of process upsets and malfunctions affecting each operating station and system. Make each hazard analysis formal and revise it to incorporate each facility and operational change.
- Control unacceptable risks that were identified during the hazard analysis. Have competent specialists identify, design, and develop the appropriate

controls so that unacceptable risks are greatly minimized and the double contingency principle is satisfied.

During plant startup testing and operation, the licensee should enforce the specified controls by accomplishing these two fundamental objectives—

- Maintain engineered controls intact and uncompromised to serve their basic safety function. Before modifying physical plant systems and components that perform safety functions, obtain the prior review and approval of the proposed modification by engineering and nuclear safety organizations and an appropriate review by the plant safety committee. Prescribe and perform at appropriate intervals preventive maintenance and surveillance testing. Promptly address and resolve and feed back abnormal results or conditions into the hazard analysis.
- Ensure the administrative controls that constitute or contribute to a safety control are formal, written, reviewed, and approved by appropriate elements of the plant organization. Train plant production personnel on the purpose, importance, and content of these administrative controls. Involve plant supervisory, managerial, audit, and nuclear safety personnel in systematic and periodic checks to ensure that the plant complies with these controls.

3.9.2 Achieving the Objectives

The remaining nine topics in Section 3.9 describe several examples of plant systems and practices that contribute to meeting the four objectives described in this section. The licensee should—

(1) establish an evaluation request system and define the methods used to initiate, approve, control, and complete requests for evaluating plant and equipment changes that may affect nuclear criticality safety;

(2) establish methods to verify that changes to limits, controls, and equipment have been made in accordance with approved designs and operational conditions and establish the methods and procedures used to evaluate plant and equipment changes affecting nuclear criticality safety. Describe in the procedures the controls needed to ensure that each evaluation has been independently reviewed and that the conclusions of the evaluations were independently verified;

(3) establish an audit program to determine the effectiveness of the nuclear criticality safety control program and, in procedures for this program, discuss use of independent, onsite or offsite groups or consultants to conduct audits;

(4) describe the criticality accident alarm system, referencing the applicable regulatory requirements and the logic used to ensure that the failure of any component would not preclude operation of the alarm system;

(5) establish a review system to assess compliance with procedural requirements and include in the system a mechanism to determine if the procedures are adequate;

(6) establish a special nuclear material (SNM) control system to ensure that accumulations of SNM do not exceed predetermined limits or values anywhere in the plant. Achieve this compliance by limiting masses and concentrations or through geometry or volume controls. Include in this system a program for the control and use of unfavorable geometry containers in the plant and controls on mass and concentration and a description of associated measurement methods used to verify the SNM contents of these containers. Have a safety committee periodically review the effectiveness of this system;

(7) describe how to use neutron absorbers for criticality control in accordance with appropriate regulatory guides and industry standards.

(8) establish procedures that discuss the use of the double contingency principle in establishing the nuclear criticality safety controls and limits used throughout the plant. Include a description of actions to take if any of these controls or limits have been degraded and define redundancy for administrative/physical, physical/physical, or administrative/administrative controls or limits in the procedures; and

(9) establish safety margins and interaction criteria, basing the mass limits on experimental data or on calculations performed by a method that has been validated for the type of system being analyzed. Specify the maximum safe dimensions for small units, and identify the criteria to use in establishing allowable spacing between units of fissionable material.

3.10 Nonradiological Safety

General Safety and Housekeeping Policies. At a minimum, general safety conditions in a nuclear operation should meet Occupational Safety and Health Administration standards. Managers should issue a statement on its safety policy for the plant and a statement on its housekeeping policy. Generally, a nuclear operation must be maintained in a clean and orderly condition, free of dust, dirt, grease, and industrial refuse. Keep plant grounds free of debris and refuse. In the plan for landscaping, arrange the plant physical security features to avoid obstructing a person's field of vision, considering shadows

cast by lighting and trees, shrubs, or objects that would conceal an adversary.

Fire Protection Program. The applicant should have a fire protection plan, and a pre-fire plan. Design the protection plan to prevent, detect, contain, and suppress fires, and include in it fire systems testing and maintenance requirements. Give a copy of the pre-fire plan to local fire companies with site-specific information. Have the plant safety committee periodically review each plan.

Materials Storage. The applicant should control storage of materials, such as combustibles, explosives, chemicals, and other hazardous materials to prevent accidents that may affect nuclear materials. Have controls for storing these materials meet industrial standards or regulatory requirements, whichever are more restrictive. If the storage of waste is required for periodic processing, include provisions in the controls to ensure that waste is stored in a safe, neat manner.

Work Permits Systems. The applicant should establish a system of work permits (e.g., safety work permits and hot work permits) and lock-out procedures to minimize the likelihood of occurrence of nonradiological accidents that could involve radioactive materials. Describe the use of these work permits in the plant and include the methods used to initiate, approve, control, complete, verify, and close out these permits in the system.

3.11 Environmental Protection Programs

The licensee should establish two programs for effluent streams: one to control the streams and one to monitor radiation in the streams.

Include in the controls program written, management-approved procedures for sampling, measurement, data analysis, and control of effluent streams.

Include in the monitoring program capabilities for detection of radioactive releases, routine sampling and sample analysis, and alarms for releases that exceed established bounds. Describe in the program how to monitor onsite and offsite ionizing and nonionizing hazardous materials in soil, vegetation, surface and ground water, as applicable. Have managers independently review this program.

3.12 Safeguards: Material Control and Accounting, Physical Protection, and Fitness For Duty

The licensee should establish two plans and one program to safeguard its nuclear material.

Demonstrate in the fundamental nuclear material control (FNMC) plan how the basic capabilities specified in 10 CFR Parts 70 and 74, as applicable, will be achieved and maintained and how such capabilities will be used to achieve the performance objectives stated in the regulation.

Demonstrate in the physical protection plan how the basic capabilities specified in 10 CFR Part 73 will be achieved and maintained and how such capabilities will be used to achieve the performance objectives stated in the regulation.

Establish through the fitness-for-duty program a drug-free and alcohol-free workplace policy and program to meet industry standards or regulatory requirements.

3.13 Emergency Preparedne .s

To prepare for an emergency, the licensee should develop an emergency plan for the plant and an emergency plan for the site if the site is larger than the area covered by the plant.

Include in the plan for the plant the information required by applicable regulatory guides and industrial standards.

Include the plant area in the plan for the site, and address those actions to take to mitigate the consequences of incidents that occur at the plant on the site. Classify incidents that occur at the plant in accordance with the guidance in NUREG–0845, "Agency Procedures for the NRC Incident Response Plan."

To prepare these plans, the licensee must develop accident evaluations. In these evaluations, document the predetermined actions to take, which are based on evaluations and reliable safety indicators' emergency action levels (EALs) for each accident scenario identified for the plant. Incorporate the EAL concept of NUREG–0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Procedures." Make the indicators redundant and reliable and allow for classification of the emergency. Include, for example, indicators that classify such incidents as transfer of SNM to an unsafe geometry tank, failure to follow an administrative procedure, and a uranium hexafluoride release.

To ensure effective preparation for an emergency, the licensee should develop—

- implementing procedures to address the requirements specified in the emergency plan;
- a mechanism to ensure that the emergency plan is current and that individuals and organizations required to have the plan have current copies;
- lists of safety equipment that must be immediately available to personnel responding to an emergency. Ensure that this equipment is available and in good repair at all times; and

Finally, the licensee should conduct emergency exercises on an established schedule according to these plans. Include appropriate offsite agencies and organizations in the planning for and conduct of these exercises. Be certain that these exercises are more than plant evacuations; they should test such needs as emergency staffing, communications, and equipment.

3.14 Packaging and Transporting Nuclear Materials

To meet the primary objective of protecting the health and safety of the public when packaging and transporting nuclear materials, the licensee should establish a packaging and transportation program. Demonstrate in this program how the basic capabilities specified in 10 CFR Parts 71 and 73 and Title 49 of the CFR will be achieved and maintained and how such capabilities will be used to achieve the performance objectives in these regulations.

To support the packaging and transportation program, the licensee should conduct radiation surveys and establish a QA program and a program to audit the QA program. For radiation surveys, have managers review and approve radiation survey procedures before they are implemented for the fabrication and use of packages to transport radioactive material. Calibrate the radiation survey equipment at a predetermined frequency.

Establish for the packaging QA program philosophies and procedures to ensure that effective QA has been implemented and is being practiced.

Establish an audit program to ensure that high standards were implemented and practiced in the QA program, including contractor or vendor activities, and that timely corrective actions were performed.

3.15 Sampling and Analysis

The licensee should establish a sampling program that describes all sampling points related to samples taken for safety or safeguards purposes and that explains the purpose of the samples and the sampling techniques. The reliability of the sampling technique should be commensurate with the significance of the sample to safety or safeguards.

Provide in the sampling procedures for this program detailed, step-by-step instructions for the operator who takes the samples.

To detect sampling bias and random error, evaluate the sampling system to demonstrate that samples obtained by the prescribed sampling technique represent the bulk material sufficiently to meet the sampling objective. The licensee should establish a replicate program to demonstrate that the reproducibility of the sampling technique is adequate to meet the sampling objective. Finally, the licensee should establish a measurement quality control (QC) program to monitor measurements made for safety or safeguards purposes to ensure that measurement bias and reproducibility are sufficiently controlled to meet the objective of protecting the health and safety of the public. Describe the QC program applicable to sampling and analysis, including a description of the wet chemistry program, QC checks, cross-check sampling, and blind sample checks, that will be performed.

3.16 Waste Management Program

The licensee should establish a waste management program for handling liquid, gaseous, and solid waste and for incinerating waste. In this program, describe the methods for sampling and analyzing liquid and gaseous waste streams, and plan procedures for routinely monitoring the content of waste streams to determine their hazardous material content and their radionuclide content. For streams that have action points that define recycle, storage, or discharge conditions, indicate how decisions are made at those points (i.e., on what basis, and how they are documented). In addition, describe the processes used to solidify liquid waste, if applicable, and the containers for holding the waste.

For solid waste, describe the generation points for this waste and the processes used for collecting and consolidating these wastes. Discuss the methods used to determine the radionuclide and hazardous material content of the waste and how the waste is packaged and stored and where it is stored.

Finally, if incineration is used as a waste management technique, describe the methods for sampling and analyzing residual liquid and gaseous waste streams.

3.17 Accident Analyses

3.17.1 Hazard Analysis and Failure Mode and Effects

The licensee should conduct an engineering analysis of each major plant system and its components to determine maximum and minimum operating conditions, failure modes and scenarios, and consequences of failures. Document each analysis, including the means used to protect against identified failure modes and effects and include in it appropriate hazards that arise from outside the plant such as natural phenomena and fire. If applicable, specify the controls identified in this analysis in the plant license.

3.17.2 Containment System Failure Analysis

The licensee should evaluate and consider in the plant design the consequences and effects of a failure of each type of containment (confinement) system, such as hot cells, glove boxes, tank enclosures, rooms, and building walls. Include in the consequence analysis the service systems that will become contaminated with radioactive material, such as heating, ventilation, air-conditioning, and vacuum systems, and a justification for any use of a building as part of the engineered barrier system for containment of radioactive material.

3.18 Decommissioning Plan and Activities

The licensee should develop a general description of the plans and activities intended to ensure that the plant will be decommissioned and decontaminated in accordance with established regulatory guidance. Include in it a statement on financial surety. Be certain the plans and activities ensure that records of onsite burials, spills, and equipment malfunctions have been maintained throughout the life of the plant to assist in cleanup of the plant and the site during final decommissioning.

Large Materials Operations Programs, Plans, and Policies

Large Materials Operations Programs, Plans, and Policies (continued)

Large Materials Operations Programs, Plans, and Policies (continued)

4 FINDINGS

4.1 Regulations

For the most part, the regulations that are the bases for licensing the large materials processors, including the fuel cycle plants, provide safeguards against theft or sabotage of SNM and protection against exposure of workers and the public to radiation or radioactive materials. The principal regulations in Title 10 of the Code of Federal Regulations (CFR) that provide the requirements for the large materials processors are as follows:

- Part 20—"Standards for Protection Against Radiation";
- Part 30—"Rules of General Applicability to Domestic Licensing of Byproduct Material";
- Part 33—"Specific Domestic Licenses of Broad Scope for Byproduct Material" which, unlike Parts 30, 40, and 70, contains some explicit requirements for management, safety evaluations, and oversight by a radiation safety committee of proposed uses of byproduct material;
- Part 40—"Domestic Licensing of Source Material";
- Part 51—"Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions";
- Part 70—"Domestic Licensing of Special Nuclear Material";
- Part 71—"Packaging and Transportation of Radioactive Material";
- Part 72—"Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste" (this part, published in 1981, addresses many of the topics listed in Section 3 of this report and requires an applicant to describe how each requirement will be met);
- Part 73—"Physical Protection of Plants and Materials"; and
- Part 74—"Material Control and Accounting of Special Nuclear Material."

The Task Force reviewed these regulations against the topics in Section 3 of this report and concluded that the safeguards regulations, 10 CFR Parts 70, 73, and 74, are adequate. However, the safety regulations focus almost exclusively on radiological safety concerns, practically to the exclusion of process safety and managerial controls. To illustrate, 10 CFR Part 20 provides the "Standards for Protection Against Radiation" for all licensees. This part—

- prescribes radiation dose limits for workers and the public;
- requires radiation monitoring of the plant, the workers, and the environment;
- provides radioactive material limits on waste for disposal; and
- requires reports and notifications pertaining to the aforementioned activities.

The requirements contained in Part 20 are highly detailed and prescriptive and, in fact, provide an adequate level of radiological safety for workers and the public as long as plant conditions are maintained within normal bounds, that is, no process upsets, inadvertent material releases from confinement, or accidental criticalities occur.

In contrast, for example, Part 70 provides the basis for issuing licenses to possess and use SNM. Other than the requirements for radiological protection in Part 20 that, again, are highly prescriptive, Part 70 additionally requires that an applicant be qualified to have adequate equipment and facilities and adequate procedures to protect health and minimize danger to life or property. These performance-oriented statements may be satisfactory requirements for licensing purposes if accompanied by a detailed standard format and content guide and a standard review plan. The guide defines the topics and level of detail an applicant is to cover in an application, and the plan provides acceptance criteria the NRC staff is to use when reviewing an application. In the absence of such defining documents, however, these statements have little applicability to achieving a minimum level of safe plant operations.

One method of incorporating more prescriptive requirements in Parts 30, 40, and 70 would be to develop general design criteria (GDC) for major materials licensees. To begin developing these criteria, the NRC could use or adapt the GDC developed for licensing enrichment plants. The Task Force was not able to recommend whether GDC should be developed, whether they should be codified as a separate appendix in the rules, or whether explicit, technical criteria should be directly incorporated in the text of the rules.

In the absence of either prescriptive requirements or detailed guidance, the contents of applications can be expected to vary from applicant to applicant, and the review of licenses can be expected to vary from reviewer to reviewer because of differences in their training and experience, and to vary over time, depending on the managerial philosophy currently in vogue. The absence of detailed guidance also means that probably no criteria exist for training new, inexperienced reviewers. Further,

as experienced reviewers leave, license reviews could vary more in quality and content. The absence of guidance also means that the public has more difficulty participating in the licensing process. The Task Force believes that the NRC should develop such guidance, using the topics in Section 3 of this report as the basis for its development.

The Task Force realizes that ad hoc licensing approach can be used effectively when licensing reviews are conducted by experienced reviewers over a relatively short period for a few plants and that measures implemented to ensure radiological protection are, under routine conditions, adequate to protect public health and safety. However, as previously learned about operating reactors, plant operations, plant equipment and processes, and staff performance do not remain constant but are subject to change with time in a production environment. Sometimes those changes result in unconsidered potential safety hazards that should be evaluated but that, without proper managerial controls, are allowed to proceed in an uncontrolled manner. Therefore, each licensee needs a strong managerial program of controls and hazard assessments to ensure and maintain the level of safety that existed when it received the initial license.

As long as the focus of the regulations pertaining to large materials processors remains concentrated on radiological safety, NRC's attention to the adequacy of managerial controls (training of operators, process safety reviews, use of written procedures, proper sampling of materials to ensure meaningful measurements, change control over processes and procedures) will continue to languish. Lack of managerial controls contributed to both the Sequoyah Fuels event (1986) and the General Electric Plant incident (1991). The Materials Safety Regulation Study Group also noted this lack of controls.

Revised reporting requirements, intended to correct deficiencies in the existing reporting requirements, were published in final form on August 16, 1991. While the NRC did not revise the reporting requirements in 10 CFR 70.52 for accidental criticalities to clarify ambiguities in the need to report potential criticalities to NRC, the NRC did issue a bulletin on this subject (NRC Bulletin 91-01, Reporting Loss of Criticalay Safety Controls, October 18, 1991). The Task Force recommends that the NRC now track, record, and evaluate the reports accumulated from fuel and materials plants as a result of the revised rule and the bulletin to provide the NRC feedback for the continuing review of plant operations and to identify potential problem areas.

4.2 Guidance Documents

4.2.1 Standard Format and Content Guides and Standard Review Plans

A sound regulatory policy provides guidance to assist applicants and licensees in preparing their applications or requests for amendments and to assist the regulators in reviewing these applications and requests. Developed for this purpose, a standard format and content guide and standard review plan can ensure completeness of applicants' and licensees' submittals and consistency of licensing reviews and can inhibit repetitive and unnecessary regulation. Also, these guidance documents provide a basis for inspecting and ensure continuity and consistency for licensing materials operations.

For 10 categories of licenses, the Task Force identified the existing standard format and content guides, standard review plans, and drafts of these guidance documents or the lack of them (Appendix D). A brief review of the existing guidance documents indicates that most of them require extensive revision. In many cases, regulations have been changed without commensurate changes to the guidance. In other cases, the guidance documents are either partially drafted or only contain statements of objectives, without any details and practical examples. For those caterories that have no guidance, the Task Force recommends that the NRC develop and issue it.

Over a 10-year period, senior members of the Fuel Cycle Safety Branch, supported by specialists from two national laboratories, developed an Accident Analysis Handbook, which was published in 1988 as NUREG-1320. The handbook provides analytical methods for determining the release of radioactive material from potential incidents or accidents at nuclear fuel cycle facilities. The initiating events considered were fire, explosion, tornado, criticality, spill, and equipment failure. The types of plants considered were fuel fabrication, spent fuel storage, fuel reprocessing, and high-level waste storage and solidification. Uranium hexafluoride conversion was omitted.

Since publication of the handbook, the staff seldom used its analytical techniques in licensing actions and did not inform licensees of its intent to make substantial and routine use of the techniques. The handbook has not yet been subjected to formal, independent peer review, which seems appropriate for a document of its breadth and technical complexity. The Department of Energy (DOE) staff and its contractors have been using the handbook during some of its recent extensive safety reviews of DOE sites. The level of detail and the analytical rigor contained in the handbook comprise far greater guidance than that contained in any NRC standard review plan.

In the safeguards area, two standard format and content guides for material control and accounting were issued as NUREG-series reports. They should be redeveloped as regulatory guides so that the public will have the opportunity to participate in developing the guidance.

4.2.2 Associated Regulatory Guides

The NRC has more than 150 active regulatory guides pertinent to fuel cycle and materials licensing. The intent of the regulatory guides is to provide detailed technical guidance, often with practical examples that illustrate how certain specific requirements could be satisfied. The guides are intended to assist the applicants and licensees in preparing their applications or implementing the regulations. Regulatory guides are NRC-issued documents and, as such, provide NRC's technical position on a licensing issue. These guides should be regularly revised so that they are up to date and reflect regulatory changes, state-of-the-art technology, and revisions of national standards on which many guides are based. The consensus of the Task Force is that the entire body of regulatory guides should be reviewed and updated periodically, perhaps, every 5 years.

More than 70 percent of the fuel cycle and materials guides were issued at least 10 years ago and 50 percent were issued at least 15 years ago. More than 15 draft guides are in use that never have been issued in final form. This volume of standards work would represent a significant investment of both staff time and technical assistance but would provide assistance to applicants, licensees, and regulators and preserve the regulatory base.

In the safeguards area, approximately 30 regulatory guides are over 15 years old and approximately 10 more are over 10 years old. Many of these endorse American Society for Testing and Materials or American National Standards Institutue (ANSI) standards that have been updated at least twice or have been withdrawn from use since the issuance of the regulatory guide that endorses them. The NRC should also revise these guides about every 5 years.

4.3 Licensing Review Process

4.3.1 Responsibilities and Authorities

The NRC authority to license special, source, and byproduct nuclear materials stems from Sections 53, 62, 63, and 81 of the Atomic Energy Act of 1954, as amended. NRC issued rules to implement this authority, principally 10 CFR Parts 30, 40, 70, 71, 73, and 74. Rules to implement the National Environmental Policy Act are codified in 10 CFR Part 51. As described in other sections of this report, the staff also has issued a variety of regulatory guidance and staff positions to further describe its standards and intended actions for materials licensing.

The responsibilities for licensing the major materials plants has been divided among several NRC organizations for several years. The headquarters staff licenses the fuel cycle plants: the NMSS Fuel Cycle Safety Branch conducts the safety and environmental reviews, and the Division of Safeguards and Transportation conducts the safeguards reviews. Since about 1982, the appropriate regional staff licenses all other materials licensees, including the larger plants considered by this Task Force. The Medical, Academic, and Commercial Use Safety Branch in headquarters manages the licensing and inspection programs for these materials plants and provides or coordinates selected technical assistance on particular licensing issues, as requested by the regional staff.

4.3.2 Scope and Depth of Licensing Reviews

The following paragraphs describe the current process NRC uses to review the safety and environmental protection aspects of an application to renew a license for a major fuel cycle plant. The description is developed from the point of view of the project manager assigned as lead reviewer for the fuel plant in question.

Upon receiving the application, the staff ensures that copies of the application are properly distributed, docketed, and sent to the public document room; the supervisor determines the level of safety and environmental review required; and the staff sends a copy of the application to the NMSS Division of Safeguards and Transportation to ensure that it receives any needed safeguards review.

If the application is for a license renewal, the headquarters staff may be required to prepare an environmental assessment. For that reason, the staff will announce the receipt of the application for license renewal in the *Federal Register*, invite the opportunity for a hearing, and announce its intent to prepare an environmental assessment. The same process will be followed for major amendments if those amendments are of such a nature that the environmental impact exceeds the exemption categories listed for categorical exclusions in 10 CFR Part 51.

Since 1989, NRC rules of practice in 10 CFR Part 2, Subpart L, have permitted an informal hearing process for materials license proceedings. These informal hearings are intended to resolve cases more quickly and efficiently than the formal hearing process and reduce time and expense for the staff, the applicants, and any intervenors admitted to the proceeding.

While considering the nature and extent of the environmental review, the project manager will begin an initial review of the application, with several goals in mind. First,

the manager will determine the review's scope, the nature and extent of the technical review involved, and the amount of help needed from technical specialists, such as criticality engineers, health physicists, fire protection engineers, mechanical or structural engineers, instrumentation specialists, or other specialists. The manager's supervisor must carefully consider the case load that this project manager faces, and how many review specialists are needed to work on these cases.

Reviews of major amendments or license reviews seldom start until long after the NRC receives an application. This substantial delay is due to several reasons. The staff is typically endeavoring to issue renewals for licenses that have been awaiting renewal for several years. About 100 license amendment applications are received each year, and licensees are frequently anxious to receive expeditious approval of these amendments. Often these amendments involve process changes needed to improve the plant sufficiently to keep it operating satisfactorily. Although the staff is not directly concerned with a licensee's profit, a licensee must operate efficiently to generate the revenue needed to operate the plant safely. Accordingly, the staff listens carefully to licensee pleas for prompt action on amendments and considers the licensee's views when setting internal priorities.

In addition, the licensing staff routinely participates in regional inspections, mostly operational safety team assessments and special inspections following plant events. Although the inspections raise the licensing staff's understanding of a plant, they take significant time away from licensing casework. Event followup inspections are unscheduled and, thus, cause an unanticipated perturbation of licensing plans and schedules.

Finally, the staff must respond to many unanticipated administrative or technical requests. These items include plant events, executive correspondence, and requests for technical assistance or information from external organizations and from other parts of NRC. Frequently these unanticipated requests are given high priority and short deadlines and, thus, disrupt the flow of work on a major licensing action. This interruption causes a substantial loss of momentum during the conduct of major licensing reviews and results in replowing of old ground when the reviewer resumes work on the application. The supervisor attempts to be alert to these distractions and, where possible, attempts to minimize the disruption to reviewers working on a key safety review. However, in reality, the supervisor cannot eliminate all disruptions or, with a limited staff, isolate reviewers of major cases.

4.3.3 Interactions with Licensees and the Regions

Early in the review, most project managers quickly read the entire application to spot areas where the application is not clear. The project managers will then ask the licensee to clarify or agree to revise certain sections of the application to achieve clarity.

The project manager will typically meet with the section leader and the licensing assistant to develop a schedule for review of a major application. This schedule will establish major milestones for safety and environmental reviews. During this early stage, the project manager will typically schedule a site visit to tour the plant and see the proposed modified portions of the plant. The duration of this plant visit will depend on the project manager's prior experience at the facility and on the need for other reviewers to see the plant. During this site visit, the project manager will present the major issues he or she has uncovered during the initial review of the application. If these issues have not yet been sent in a letter to the licensee, they will be documented in the trip report describing the site visit. In any event, the discussion surrounding these issues typically will result in the licensee's agreement to revise the application.

At this stage, even though the licensee may be beginning to revise certain portions of the application, the staff initiates a detailed review. The project manager must coordinate the work of any assisting specialists to synchronize all the reviewers' efforts. Although reviewer techniques vary, most project managers read the entire application carefully and pencil questions in the margin of the application so that they can return to the notations and develop written questions that the licensee can easily understand. When the detailed review is completed, the project manager will draft the initial round of questions, attempt to incorporate the questions from other reviewing specialists and present the entire package to the supervisor to approve and transmit to the licensee. The NRC refers to this package as "a request for additional information."

In parallel with the safety review, an environmental review has similarly been proceeding with site visits, a round of questions, and preparation of a draft environmental assessment to support the license application. The supervisor attempts to schedule these reviews to complete the environmental assessment somewhat before the safety analysis so that the environmental assessment can be published with its accompanying *Federal Register* Notice. The public comment period and the safety evaluation can be completed shortly thereafter. The environmental assessment will typically include recommended license conditions that the safety reviewers will consider and normally adopt in the safety evaluation report and the license, after issuance of the final

environmental assessment. Major applications are frequently delayed because the environmental data from a plant, which is updated annually, may be 1 to 2 years out of date by the time the staff reviews the application, forcing the staff to ask licensees to update information in their environmental reports. These requests for updated information are always answered, but understandably with considerable frustration.

The number of questions the staff asks in a request-for-information package can vary, but may exceed 100, some of which require extensive effort to answer. For this reason, the staff will typically not receive an answer to a request for information for several months. Because of the understandable time lag and the extensive revision that typically follows, the staff's review of a revised application may be nearly as time consuming as the initial review. The results of the second review vary considerably. Sometimes, in spite of attempts by the staff to make the questions and issues clear, the response from a licensee may require further extensive dialogue between the staff and applicant. More often, many of the issues are clarified and the questions are answered quite well; a few may have some minor ambiguity; and a smaller fraction may have missed the mark. In some cases, only minor clarifications are required from the licensee before the staff is ready to publish the safety evaluation report and renew the license. The second reviews vary to such an extent that the staff may require a second, third, or even more rounds of questions to the licensee. These multiple rounds and application revisions increase the work load, prolong the license review process, and make precise scheduling virtually impossible.

4.3.4 License Conditions

Fuel facility license applications are submitted in two parts. Part 1 contains proposed license criteria, which represent the licensee's commitments; Part 2 contains the safety demonstration section, which explains how the licensee process and control systems will ensure public health and safety. The NRC does not consider the explanations in this section to be binding commitments by the licensee. This situation can be a source of conflict with the licensee, when a system described in Part 2, which has no established control criteria specified in Part 1, fails and is not promptly corrected by the licensee. The NRC staff can unilaterally issue license conditions in the license itself; however, many licensees prefer to add or revise the license criteria in Part 1 of their application rather than have NRC issue a large number of custom-made license conditions. This approach allows licensee personnel to more easily follow and understand the plant-specific requirements that apply to their facility. However, this process does not lead to the development or use of a standard set of license conditions. In contrast, safeguards reviewers have a set of standard license conditions that is inserted into all licenses. In addition, these reviewers add other conditions—generated from omissions, in a specific application—that are identified by comparing this specific application to a Standard Review Plan.

Regional staffs participate at several stages of the license review, suggesting questions and paying close attention to the wording of license conditions, which have a direct effect on the region's ability to enforce requirements. In addition, the regional staffs ensure that applicable findings from the most recent operational safety team assessments are incorporated into the license. NMSS practice has been to obtain agreement of the regional project inspector before finally issuing or renewing a license.

One additional scheduling anomaly affects those license applications that require changes to the emergency plan or, as it is often called, the radiological contingency plan. A recent regulation requires a 60-day period for offsite participating agencies to comment on proposed changes to the emergency plans. Licensees can accommodate that comment period in their initial submissions; however, revisions to the plan that may result during a licensing review are not predictable, and each revision of the emergency plan will trigger a new 60-day public comment period during which progress on the entire amendment package is deferred.

4.3.5 Technical Aids for License Reviewers

From interviewing project managers we learned that they use a variety of tools and aids to conduct a review:

- They keep personal copies of key agency memoranda on selected technical topics that they may encounter during licensing reviews. These project managers typically review those memoranda before beginning the initial round of reviews of a major amendment or license renewal application package.
- They use the existing regulatory guides and available standard review plans, principally to ensure that they have not forgotten some appropriate item. Some project managers were not happy with the quantity and the quality of published and unpublished guidance and believed it was particularly weak for new employees who lack NRC licensing experience.
- They look at other license amendment packages and license renewals to see how similar issues were addressed and in what depth they were reviewed.
- They use, as resources, applicable NUREG-series reports, information that the Office of Nuclear Reactor Regulation uses in the radiological health area, ANSI consensus standards, technical publications in the NRC library, scientific and engineering computer codes, and information from experienced staff members.

Another factor that seems to, at least indirectly, affect the process of license renewal is the indefinite time provisions in 10 CFR 2.109. These provisions offer virtually no incentive to a licensee to renew its license in a timely fashion. The regulation requires that a licensee submit an application to renew a license at least 30 days before it expires; but once the application is submitted, the licensee need not obtain the renewed license. One exception to this disincentive occurs, in some cases, when a licensee really endeavors to improve the controls and the clarity of the wording of an existing license and, therefore, becomes anxious to receive the renewed license to improve plant activities. In these exceptional cases, the licensee typically responds quickly and forthrightly to any request for information, and the renewal process proceeds more efficiently. Note that the former renewal time of 5 years was arbitrary, as is the present renewal time of 10 years; however, the provisions of the timely renewal regulation penalize neither the licensee nor the staff for not concluding the renewal process.

At least two reasons exist for periodically renewing licenses. The first is to "clean up" the license by incorporating into it all of the amendments accumulated since license issuance. The second is to force a periodic, systematic review of the licensee's regulatory performance over time. However, neither of these reasons may be sufficiently compelling to justify expending the resources needed for frequent license renewals.

4.3.6 Licensing Major Materials Plants

The only difference between the licensing process for the major fuel plants and that for the major non-fuel cycle materials is that the latter is less formal. For example, the staff currently does not routinely issue safety evaluation reports to document the basis for the staff's conclusion that reasonable assurance exists that the licensee can possess and use its nuclear materials safely. Instead, issuance of a renewed license or an amendment serves to document the fact that the staff has reached the reasonable-assurance conclusion. Although the conclusion may be valid, the license itself gives little indication of the basis for the staff's safety conclusion. As a result, other persons on the staff, in the industry, or in the general public cannot understand the content and conduct of the staff's review.

In its deliberations and interviews with experienced regional licensing staff, the Task Force explored whether the staff should (1) specifically assign project managers to the major materials licensees, (2) train and equip these project managers to write Safety Evaluation Reports (SERs) similar to those prepared for fuel cycle plants, and (3) require that the staff complete these actions as a matter of staff practice. Assigning a specific project manager to each plant would develop in that manager a sense of "ownership" at the assigned plant site. A project manager responsible for a plant would have hands-on involvement and intimate knowledge of the plant and would be knowledgeable about the plant processes and operations, personnel, and other activities. Most, but not all, staff agreed with this idea. The major materials licensees do not have criticality safety concerns or safeguards issues. Nonetheless, they do have questions about radiological safety and fire protection and, sometimes, chemical safety. Some of these licensees are located in urban areas with essentially no exclusion zones, so that adverse offsite impacts could occur. For these reasons, the Task Force recommends that the NRC consider assigning a project manager to each of these major facilities and developing regulatory guidance that will require the NRC to prepare and publish SERs for each major non-fuel-cycle plant.

Another difficulty in the licensing process for these plants is that, unlike applications for fuel cycle plants, applicants do not submit detailed plans that describe their managerial structure and controls, operating processes and conditions, and other information pertinent to a license review. Changes to such plans are routinely made by page-change submittals that are incorporated into the license by date.

Changes to small 10 CFR Part 70 licenses and materials licenses are made by letter submittals that describe the planned change and that are incorporated into the license by reference. This process is cumbersome at best and creates difficulty in keeping both headquarters and regional license files current. Revising the regulations or guidance to require submittal of applications in plan format and to make plan changes by page-change submittals would greatly simplify the process for the applicant, the licensing staff, and the inspection staff.

4.3.7 Licensing Conclusions

The Task Force concluded that the current licensing process for large fuel cycle and materials plants is weakened by the following four deficiencies:

(1) inadequate staff expertise and training;

(2) lack of standard review guidance;

(3) reviews conducted in a non-uniform and inconsistent manner; and

(4) inadequate staffing.

The Task Force specifically recommends in Section 5 of this report corrective actions to strengthen the licensing process for these types of plants.

4.4 Inspection Process

4.4.1 Responsibilities and Activities

NMSS is responsible for establishing inspection policies and developing programs for—

- inspecting licensees to determine whether they are complying with NRC regulations, orders, and license conditions and whether these licensees are acting appropriately to protect nuclear materials and plants, the environment, and the health and safety of the workers and the public;
- inspecting applicants for licenses;
- investigating incidents, accidents, allegations, and unusual circumstances, including loss, theft, or diversion of SNM;
- enforcing NRC orders, regulations, and license provisions; and
- recommending changes in licenses and standards that are based on the results of inspections, investigations, and enforcement actions.

The staff in NRC's five regional offices perform the following functions within each assigned geographical area—

- inspect applicants, licensees, and others subject to NRC jurisdiction;
- investigate incidents, accidents, allegations, and other unusual circumstances involving matters subject to NRC jurisdiction;
- evaluate licensee event reports and provide responses, as appropriate;
- implement the materials licensing program as delegated by NMSS;
- recommend changes in NRC programs that are based on the results of inspections and investigations; and
- take enforcement action, to the extent delegated, or recommend enforcement action to NRC's Office of Enforcement, as appropriate.

4.4.2 Prelicense Interaction between the Inspection and Licensing Staffs and the Applicant/Licensee

Effective interactions between the licensing and inspection staffs and the applicant or licensee before submission of an application should ensure mutual understanding among them about important issues in the application. Although the headquarters staff should initiate involving the regional staff in these activities, both staffs are responsible for maintaining effective communications about licensing and inspection activities. In addition, regional managers should ensure that resources required for these activities are included in the appropriate staffing plan as authorized by the headquarters program office as soon as they are identified.

In the absence of specific guidance about including regional staff in prelicensing activities, they are inconsistently included in these activities. However, in those cases where they have interacted, the results have been gratifying, and the effort expended was justified.

4.4.3 Inspection Manual Chapters and Procedures

The Task Force reviewed Inspection Manual Chapters (MCs) and procedures related to fuel cycle plant safety (MC-2600), safeguards (MC-2681), and materials plants (MC-2800) for content and applicability to the inspection program. During this review, guidance applicable to both MC-2600 and MC-2800 was found in only one of the MCs. For instance, "Team Assessments of Fuel Cycle and Materials Licensees" is applicable to both MCs, but is only described or referenced in MC-2600. Conversely, MC-2820, "Followup Actions To Incidents That Involve Fuel Facility Or Materials Licensees, But That Do Not Require Emergency Response," is applicable to both MCs, but is only described or referenced in the MC-2800 series. This inconsistency in providing appropriate guidance for each inspection program document should be corrected.

The Task Force also determined that regional project inspectors were not routinely assigned to the large materials plants and, in some cases, not to the fuel cycle plants, as required. Assigning a specific inspector to each plant would develop in that inspector a sense of "ownership" for that plant site. An inspector responsible for a plant would have hands-on involvement and intimate knowledge of the plant and would be knowledgeable of the plant processes and operations, personnel, and other activities. Care should be taken to ensure that this staff inspector does not become a recordkeeper; these inspectors must retain first-hand knowledge of their assigned plants.

- **Fuel Cycle Facility Operational Safety Inspection Program (MC-2600)**

  During the review of MC-2600, the Task Force noted that its guidance was written in general terms to ensure the widest possible applicability. Very little specific guidance was provided about the conduct of the inspection program; no reference was made to available special procedures (e.g., Inspection MC-0312, about requests for technical assistance or Inspection Procedure 83890 about the conduct of confirmatory surveys); and the topics covered lacked balance—the majority of them emphasized

decommissioning facilities. As a minimum, each manual chapter should include specific guidance about such noninclusive topics as the adequacy of the licensee's approved criticality safety evaluations, process-oriented procedures, corrective actions for findings identified in internal and external audits, use and analysis of neutron poisons for criticality control, use of unsafe geometry containers, and applicability of posted signs to actual processing operations. In addition, the MC included no guidance about inspecting prelicensing or construction activities at fuel cycle plants and no reference to recently issued fire-protection inspection requirements. The MC should be revised to ensure completeness and to provide more detailed guidance to the inspectors.

- **Safeguards Inspection of Fuel Facilities, Transport of SNM (MC-2681)**

  MC-2681 provides general guidance about the overall approach to use in the conduct of safeguards inspection activities, defines each type of plant, and establishes inspection frequencies. In addition, it provides listings of inspection procedures to use during the conduct of physical protection and material control and accounting inspections. However, most of the inspection procedures referenced were out of date or were no longer being used. The MC should be revised to reference current inspection procedures.

  The headquarters branch responsible for conducting MC&A inspections has established an oversight review function to ensure that MC&A licensing and inspection activities are conducted in an appropriate manner. The Task Force found this activity commendable, but questioned the independence of this function (i.e., the branch inspecting should not audit its own work). As a result, the Task Force suggests that the oversight function be continued, but be assigned to an uninvolved group, if practical, within the Division of Safeguards and Transportation, which would ensure greater independence.

- **Materials Inspection Program (MC-2800)**

  Adequate guidance is provided in MC-2800 to ensure that the inspection program at most materials facilities is conducted in a defined, consistent manner. However, it provides no specific guidance that would ensure an adequate review of the complex operational activities found at large materials plants (e.g., Nuclear Metals Corporation, Concord, Massachusetts, or E. I. DuPont-NEN, Boston, Massachusetts). As a result, the NRC should consider either providing this type of guidance in MC-2800 or referring the inspector to MC-2600 for the required guidance.

Observations from the Task Force review of the inspection procedures associated with each of the inspection MCs follow.

4.4.3.1 Prelicense Inspections

None of the inspection MCs (fuel cycle, safeguards, or materials) addresses prelicensing or preoperational inspections. As a result, new inspection guidance is written and provided to the inspection staff for each case to facilitate inspections at new facilities. This inspection guidance is required in order to plan and execute effective and efficient inspections. While the NRC is reviewing a license application, the staff determines the adequacy of available inspection procedures and identifies any need to develop new inspection procedures.

Through a review of available documentation, the Task Force determined that specific guidance for prelicensing inspection activities has been or is being developed to cover safety and safeguards requirements at new facilities (e.g., independent spent fuel storage installations and enrichment facilities). However, no such guidance has been or is being developed for new materials plants. The Task Force recommends that the NRC develop guidance for the conduct of preoperational inspection activities for new plants and for renovations to existing plants.

4.4.3.2 Routine Inspections

Fuel Cycle Inspection Procedures. The fuel cycle inspection procedures have not been modified or revised since May 1984. As a result, these procedures are out of date and do not provide the guidance required to adequately review the licensee's programs. For example, the General Electric IIT Report (NUREG-1450) stated that the NRC inspection guidance focused on the administrative process for the licensee's facility change request procedure rather than on the quality of the criticality safety analyses used to support the change. In addition, this guidance did not focus on procedural compliance with criticality safety controls and did not ensure that licensee managers should maintain effective oversight of licensed activities. The fuel cycle inspection procedures should be modified to provide explicit guidance to ensure adequate review of the licensee's programs.

Safeguards Inspection Procedures. The procedures for safeguards inspections have been issued according to the strategic significance (low, moderate, or high) of the SNM being protected. These procedures are further segregated into safeguards activities (physical protection or MC&A).

The Task Force reviewed the safeguards inspection procedures and determined that the physical protection procedures (issued February 1991) and MC&A procedures (issued December 1990) for high strategic significance material were up to date and contained appropriate

guidance for the inspectors; the physical protection procedures (issued June 1985) and MC&A procedures (issued January 1986) for moderate strategic material were adequate and contained appropriate guidance for the inspectors, but have not been updated. The physical protection procedures (issued November 1985) and MC&A procedures (issued July 1986) for low strategic significance material were adequate and contained appropriate guidance for the inspectors, but have not been updated to incorporate the new performance-based regulation issued in 1986. In addition, the current guidance for physical protection systems at low strategic significance plants did not require the licensee to maintain records of alarms received or response actions taken. These inspection procedures should be updated to reflect current requirements.

Materials Inspection Procedure. A generic inspection procedure has been developed and issued to provide inspection guidance for all materials facilities, ranging from doctors' offices to complex industrial plants or foundry operations. As a result, the procedure does not provide adequate detailed guidance for inspecting all areas, especially complex industrial operations. The Task Force learned that the staff is revising this inspection procedure to provide separate guidance and inspection procedures for each type of materials licensee. Because of the complexity of operations at the large materials plants and the similarity of those operations to the fuel cycle plants, the NRC should consider including the large materials plants in the fuel cycle inspection program, which would result in the use of fuel cycle inspection procedures for these plants.

4.4.3.3 Team Assessments

A fatality occurred as a result of an event at the Sequoyah Fuels Corporation facility during 1986. From the investigation into that event, the staff concluded that NRC should not only review licensee activities directly associated with the use and handling of radioactive materials, but should also review the use and handling of nonradioactive materials that could affect safety. The NRC immediately reviewed these activities, assigning a team to assess each fuel cycle plant. Teams were subsequently assigned to assess large materials plants as well.

On the basis of the results of the initial team assessments, NRC managers decided to permanently incorporate team assessment into the Fuel Cycle Inspection program and MC-2600, but the activity was to be applied to both fuel cycle and large materials plants. These team assessments were to establish a system for in-depth evaluation of major fuel cycle and materials licensees' radiological and nonradiological programs. The radiological programs to be assessed were criticality and radiological safety, including emergency preparedness. The nonradiological programs included chemical safety, fire protection, industrial safety, and management controls and they were to be assessed for their effect on radiological and criticality safety at these plants. The MC provided guidelines and requirements for preparation and scheduling of the assessment, interaction with other agencies (Federal, State, and local), assessment topics, assigning priorities, tracking, reporting, follow-up actions, and use of resources. The first team assessment was conducted in July 1986, and team assessments have continued since that time.

On the basis of a review of several team assessment reports and discussions with NRC headquarters and regional staff, the Task Force concluded that the team assessment as currently structured is not achieving the desired objectives because the assessments evolved into expanded inspections rather than evaluations. They were time-consuming, were not uniformly conducted, and emphasized interacting with other agencies rather than evaluating licensee programs. In addition, these assessments primarily produced recommendations that the licensee was not required by either regulation or license condition to address. In at least one case, a licensee was initially reluctant to even respond to the recommendations. The Task Force believes, however, that some of these recommendations have merit and that response to these recommendations can be effected through license conditions or the issuance of an order.

Team assessments can be an effective means for identifying specific weaknesses in a licensee's operation or performance. However, the makeup of the team needs to be restructured. For example, the NRC could assign several permanent team leaders, based in headquarters or regional offices, and permanent staff proficient in assigned functional areas to ensure uniformity among assessments. Developing a roster of qualified individuals who may be called upon to act as team leaders could be an alternative to permanently assigned team leaders. The assessment team should include staff from the region knowledgeable about the plant being assessed. Extending the onsite assessment 1 to 2 weeks would improve the depth of the assessment. Deemphasizing the interaction with other agencies would narrow the focus of the assessment and provide the team more time to evaluate licensee performance. A regulation to require a licensee to respond to the teams' recommendations could make the assessment a more valuable regulatory tool. Also, more structured preplanning for the assessment by the team members would make the evaluations more efficient and effective.

The NRC staffs in headquarters and the regions have considerable skill and experience in nuclear manufacturing operations, process control, process safety, and health and safety. However, because some of these staff members are assigned to divisions other than the Division of Industrial and Medical Nuclear Safety in headquarters or the Division of Radiation Safety and Safeguards in the regions, they are not used in team assessments or other

types of evaluations. The NRC should consider using an informal matrix to assign staff to assessment teams to utilize available skill and to maximize the use of resources as priorities dictate. In addition, the NRC should consider the method that the Office for Analysis and Evaluation of Operational Data (AEOD) developed for the conduct of diagnostic team inspections at those plants that exhibit a degradation of managerial controls.

4.4.3.4 Resident Inspection Program

The NMSS resident inspection program for fuel cycle plants was initiated in 1978, as a result of identifying MC&A inadequacies at two fuel cycle plants. The two resident inspector positions were initially filled with NRC staff knowledgeable in safeguards matters. As a result, the initial residents, located at the Nuclear Fuel Services (NFS), Erwin, Tennessee, and the Babcock and Wilcox (B&W), Parks Township, Pennsylvania, plants were safeguards residents and were not safety inspectors. As the safeguards problems at these facilities were resolved, the residents assumed more and more activities in the area of safety. From 1981 to 1983, B&W terminated operation of the Parks Township plutonium fuel fabrication plant, and the assigned resident inspector returned to the regional office. The resident inspector assigned to the NFS plant was reassigned to the B&W Navy plant in 1987, but was eventually directed to work part-time at the NFS-Erwin plant as a result of newly identified safety-related problems there. Recently, the resident inspector assigned to the B&W plant retired, and the NRC decided to assign individual safety resident inspectors to these two fuel cycle plants (NFS and B&W).

While considering the fuel cycle resident inspector program, the Task Force determined that between 1978 and 1986, only draft guidance in the form of inspection MCs or inspection procedures were available for the two inspectors to use. In January 1986, MC-2610 was formally issued to provide guidance necessary to perform the resident inspection program at the NFS-Erwin plant. This MC and associated procedures covered both safety and safeguards inspection activities. In April 1991, Region II drafted revisions of the MC and associated inspection procedures to incorporate lessons learned from the the fuel cycle resident inspection program. Review of the documents indicated that the guidance was initially records-review oriented, rather than process-review oriented and did not stress adequacy of equipment or processes in the reviews. Headquarters staff are currently reviewing the April 1991 revision. The Task Force recommends that NRC revise and reissue the MC and modify the guidance to stress equipment and process reviews rather than records reviews.

4.4.4 Inspection Conclusions

The Task Force concluded that the current inspection process for large materials and fuel cycle plants is weakened by the following deficiencies—

- uneven staff expertise and training throughout the Regions;
- lack of specific guidance in applicable MCs and inspection procedures with regard to process, managerial controls, and criticality safety;
- non-universal use of project inspectors who are assigned to specific plants;
- lack of an established mechanism for evaluating licensee performance; and
- lack of an effective process for inspection teams to assess licensee operations.

The Task Force believes its specific recommendations in Section 5 of this report would strengthen the inspection process for these types of plants.

4.5 National Program Review

The headquarters staff conducts a National Program Review of regional licensing and inspection activities each year. This review is to ensure that these activities are conducted in accordance with the guidance provided in established fuel cycle directives and the inspection manual and that this guidance is applied in a consistent manner in all five regions.

The Task Force believes that this national review process itself is inconsistently applied and is ineffective in ensuring that the licensing and inspection programs are adequately implemented, partly because the time allotted for the reviews is too short. As a result, the Task Force suggests that the focus of the National Program Review be changed from review of implementation of the programs to a review of adequacy of the programs. This examination of adequacy could better be accomplished by focusing on a deep, vertical slice of a narrow portion of the NMSS inspection program, rather than on a broad, shallow review of the entire program. For example, one could choose to examine the inspection program for medical licenses. To accomplish this, the reviewing staff could examine inspection procedures, training of inspectors, qualifications of the inspectors and the supervisors, the frequency of inspections versus the MC requirements; the number of inspections conducted versus the total number of medical licensees in the Region; and a review of inspector field notes to determine the depth of the inspection.

4.6 Training

MC-1245 presents the training required for inspectors associated with materials and fuel cycle licensees. The

required technical training is devoted almost exclusively to radiological safety. This training is essentially the only training that is available for the headquarters staff, as well.

Many other areas of training are needed and have previously been identified for headquarters staff, but the NRC has not pursued developing a customized course because there are too few potential headquarters students for the broad array of topics that should be covered in a complete training syllabus and because much of the proposed headquarters training is not required in MC-1245 for inspectors. If the training needs for courses outside of radiological safety were combined for both headquarters and regional staff, including supervisors, there would be a sufficient number of students to warrant the development of a curriculum that covers the topics listed in Section 3 of this report. Should this training be developed, it should emphasize courses on the assessment of managers, managerial controls and organization, hazards analysis techniques, use and storage of nonradiological hazardous materials, and, for fuel cycle personnel, and criticality safety. Emphasis on training in the area of hazards analysis and criticality safety should be directed at developing sufficient expertise in the NRC staff so that they can identify licensee problems. Once identified, the problems should be referred to qualified NRC staff or contractors to resolve.

4.7 Licensees' Performance

Two significant events, the Sequoyah Fuels Corporation UF_6 release in 1986 and General Electric's potential criticality incident in 1991, had some similar root causes, which indicates that generic problems exist in licensee operations that should be corrected. The most important of these common root causes are—

- licensee managers are not sufficiently safety conscious, that is, are preoccupied with production;
- managerial controls are weak—procedures may not exist or, if they do, are unclear and are not followed; audits are not performed or, if they are, are ignored; personnel training is inadequate; change control for both procedures and processes is not followed; feedback of reports to managers on plant status is weak; managers are infrequently present in the plant area; and
- hazards analyses or engineering safety analyses of plant systems and components are not routinely performed.

If these weaknesses in licensees' programs had been corrected before these two events they probably would not have occurred. The Task Force specifically recommends in Section 5 of this report ways to improve the licensing and inspection process. It also expects that an improved licensing and inspection process will positively affect the licensees' performance.

4.8 Legal Issues

The extent to which the NRC staff should look at nonradiological health and safety issues is a continuing concern in materials licensing and inspection. The General Counsel has concluded that the Commission may confine its jurisdiction to nuclear materials, but also may take a view of its public health and safety responsibilities for those materials to include the nonradiological health hazards immediately associated with them. (Memorandum of the General Counsel to the Commissioners, "Analysis of Jurisdictional Issues (Regulatory Gap) Associated with Non-radiological Hazards," September 23, 1986.) For example, the Commission has used the chemical toxicity of uranium as the action criterion for emergency planning (see 10 CFR 40.31(j)). Assertion of jurisdiction over the health hazards of nonlicensable material may be legally questionable, but review of plant safety matters, such as fire protection, as they affect radiation safety, is a legitimate regulatory practice. In order to address the perceived regulatory gap associated with nonradiological hazards, a Memorandum of Understanding (MOU) between the NRC and OSHA was issued on October 31, 1988 (53 FR 43950). This MOU presents guidance about overseeing nonradiological hazards observed at NRC-licensed plants. A copy of the MOU is provided in Appendix E.

From the legal perspective, the prime purposes of licensing are to ensure compliance with the Atomic Energy Act and the Commission's regulations governing materials and activity and to ensure that specific requirements for health, safety, and environmental protection are stated in the licensing record in a manner that allows unclouded enforcement. Such a licensing record is also a prerequisite to focused inspection. Because the Commission's regulations are largely procedural or broadly stated performance objectives, to the extent that the licensing record does not state the needed requirements with specificity, the bases for enforcement are weakened.

4.9 Adequacy of Resources

During this study, the Task Force attempted to identify specific areas associated with licensing and inspecting fuel cycle and large material[illegible]ants that the NRC should consider improving. It recognizes that some of these enhancements could require additional resources. However, as a result of time constraints, the Task Force made no attempt to quantify these additional resources. The NRC should consider adding staff or outside contractor assistance to accomplish the following program improvements—

- staff to oversee the development of regulatory guidance and the development of the training program;
- permanently assigned assessment team leaders from headquarters or the regions;
- technical assistance/staffing for developing and revising licensing guidance documents;
- technical assistance/staffing for revising inspection program documents;
- technical assistance/staffing for developing fuel cycle/materials training programs (e.g., criticality and process safety evaluations);
- region-based project managers and project inspectors for large materials plant and fuel facility licensing, where required;
- budgeted funds for occasional use of staff who have specialized engineering skills available within the NRC; and
- possibly, fuel cycle residents at additional sites.

The Task Force analyzed available information on inspection activities in each region but had difficulty obtaining information on inspector utilization at mixed-plant types (fuel cycle and materials) from the computerized regional manpower utilization system. It obtained information only on fuel cycle plant inspections. The data provided in Appendix F were normalized to the number of plants for which information was available. Because all the desired information was not available, no attempt was made to compare the results to budgeted resources.

On the basis of the data provided and analyzed in Appendix F, the Task Force concluded that, on average, sufficient regional resources are available to perform assigned programmatic inspection activities in an appropriate manner, (i.e., 22 hours per module per plant per year). Further, these data indicate that, while the average time spent per module is sufficient to carry out the defined program, the time spent per region varies considerably. The Task Force believes the NRC should investigate the reasons for this variation during the National Program Review.

4.10 Use of Systematic Assessment of Licensee Performance

The Task Force considered the use of a SALP to obtain better licensee performance in operations management. However, for fuel facilities and materials processors, the formal SALP process does not appear to be the proper vehicle to achieve this objective. One alternative would be to conduct periodic regional meetings with each licensee, using the SALP criteria as a basis for developing the agenda for each meeting. Managerial performance could be discussed in depth, and the region could issue a management meeting report (inspection report) to document meeting results. This meeting should be open to the public. Region II conducted similar meetings with licensee managers during Fiscal Year 1991, and the meetings appeared to work reasonably well.

5 RECOMMENDATIONS

The Task Force placed its recommendations in six categories. Those that apply to (1) licensing activities, (2) inspection activities, (3) regulations, (4) organization of the NMSS and NRC staff, (5) training for the NRC staff, and (6) the National Program Review. It did not attempt to assign them priorities. Of all the recommendations, however, it believes the NRC needs to expedite the recommendation requiring that each large material and fuel cycle plant licensee conduct process hazards analyses (see Sec. 5.3.1).

To ensure that the Task Force had not overlooked any significant regulatory problems identified by the General Electric-Wilmington Incident Investigation Team, the Task Force compared the staff actions assigned by J. M. Taylor's August 13, 1991, memorandum with the recommended actions in this report. It did not include site-specific staff actions in the comparison. The Task Force recommendations address all regulatory-related staff actions in this report (see Appendix G).

5.1 Licensing

5.1.1 Licensing Guidance

Good regulatory policy dictates that licensing actions be based on a standard review plan and supported with a standard format and content guide. In Appendix C to this report, the Task Force identified for each major materials operation the standard format and content guides and standard review plans that are missing or inadequate. It recommends that the NRC—

- develop those that are missing or revise those that are inadequate to incorporate the topics listed in Section 3 of this report;
- reissue the two safeguards standard format and content reports (NUREG–1280 and NUREG–1065) as regulatory guides;
- incorporate appropriate sections of branch technical positions on quality management controls/quality assurance, requirements for operations, chemical safety, and fire protection (53 FR 11590) into appropriate standard format and content guides and standard review plans;
- develop detailed information for a single document containing the standard format and content guide and standard review plan to serve as a basis for evaluating managers and managerial controls. Include in this material details about plant management, including its organization and structure, safety functions, and internal controls, plus the essential functions of management obtained from a systems-analysis approach to management, such as the Management Oversight and Risk Tree (MORT). Anticipate that, in many cases, technical assistance will be required to develop the detailed criteria associated with each topic; and
- subject the Accident Analysis Handbook (NUREG–1320) to a formal, independent peer review. After completing that review, incorporate the analytical techniques described in the handbook directly or by reference in the applicable sections of the standard review plans.

5.1.2 Maintenance of Regulatory Guides

The NMSS regulatory guide program requires resources to continually review, correct, and maintain the fuel cycle, materials, and safeguards regulatory guides. We recommend a 5-year cycle of review and revision. In particular, the approximately 150 guides pertinent to fuel cycle and materials licensing, some of which are more than 10 to 15 years old, need redevelopment and reissuance. Develop a plan for continually updating and reissuing the guides. Similarly, review and update the safeguards regulatory guides.

5.1.3 Project Managers' Handbook

Develop, publish, and distribute a project managers' handbook, similar to that used by NRR's project managers, for NMSS' project managers. The Task Force conducted an initial review of NRR's document and identified areas to be revised to make it useful for NMSS reviewers.

5.1.4 Designated Project Managers

Formally designate project managers for major materials licensees to provide for continuity of licensing actions.

5.1.5 Safety Evaluation Reports

Analyze the costs and benefits of performing safety analyses and preparing safety evaluation reports for initial materials licensing, renewal, and major amendment actions for the large materials plants. Base management decisions about these issues on the results of that analysis.

5.1.6 Evaluation of Operating Experience

Develop a program for evaluation of operating experience at fuel cycle and large materials plants that includes a review and analysis of the reports provided by the licensee as required by 10 CFR Parts 30.50, 40.50, 70.50, and 70.52.

5.2 Inspection

5.2.1 Update Inspection Manual Chapters

Revise Manual Chapters 2600 and 2800 and associated inspection procedures to incorporate explicit guidance concerning each of the topics listed in Section 3 of this report. Incorporate appropriate sections of branch technical positions on managerial controls/quality assurance, requirements for operations, chemical safety, and fire protection (53 FR 11590) into appropriate MCs and associated inspection procedures. Develop materials for inspection guidance to serve as a basis for evaluating managers and managerial controls. Include in these materials plant management, organization and structure; safety functions; and internal controls, plus the essential functions of managers obtained from a systems analysis approach to management such as the MORT. The Task Force anticipates that, in many cases, technical assistance will be required to develop the detailed criteria associated with these topics.

5.2.2 Inspect Large Materials Processors With Fuel Cycle Procedures

Because large materials processors are similar to fuel cycle plants in operation, include large materials processors in the fuel cycle inspection program rather than the materials inspection program. This would allow inspectors to use MC-2600 procedures for inspecting these plants, rather than the less appropriate MC-2800 procedures. The latter are more health physics than process-oriented.

5.2.3 Project Inspectors for Major Materials Licensees

Create a system of project inspectors for major materials licensees and fuel cycle facilities to provide continuity to the inspection activity.

5.2.4 Process Safety Evaluations

Revise MC-2800 to include process safety evaluations in this inspection program.

5.2.5 Prelicensing Inspections

Develop generic guidance for prelicensing inspections of large materials and fuel cycle plants.

5.2.6 Update Safeguards Inspection MC

Revise MC-2681 to reference the use of current inspection procedures and update procedures for inspections of moderate and low SNM licensees to reflect current requirements.

5.2.7 Resident Inspector Procedures

Revise the resident inspection procedures to include actual inspector activities, for example, performance of equipment and process reviews rather than just the performance of records reviews. Prioritize equipment and process (systems) reviews commensurate to the potential safety risk involved with their operation.

5.2.8 Licensee Evaluations

In lieu of the conduct of systematic assessments of licensee performance (SALP) evaluations, conduct periodic regional meetings with each licensee. Use the SALP criteria as the basis for the developing the agenda for these meetings.

5.2.9 Informal Matrix Management for Team Assessment Assignments

Consider use of an informal matrix for team assessment assignments to take advantage of skills and experience in manufacturing processes, process controls, and process safety, that exist across NRC organizations and regional staff.

5.3 Regulations

5.3.1 Hazard Analyses

Revise the regulations in 10 CFR Parts 30, 40, and 70 to require that a hazards analysis be performed for each system and component within each process that contains radioactive material or that serves as a barrier to the release of radioactive material to an unauthorized location. Require that the plant engineering staff and the plant safety committee review and approve these analyses. Likewise, analyze and review all changes to such systems and components before operation is authorized.

5.3.2 Need for Detailed Requirements

Provide specific technical and managerial requirements needed to strengthen licensee practices by revising 10 CFR Parts 30, 40, and 70 to ensure that prescriptive requirements are specified or by developing detailed standard review plan and standard format and content guides to define the technical criteria and managerial controls desired. For example, the prescriptive requirements for criticality alarm systems specified in 10 CFR Part 70.24 could be augmented with other sections containing similar detail on the topics listed in Section 3 of this report, or these details could be put in guidance documents that are based on the performance-oriented objectives contained in 10 CFR Part 70.22.

Evaluate the need for general design criteria (GDC) for major materials licensees. The GDC could provide a focus for the standard format and content guide and the

standard review plan and help bound the scope of the licensing review. To begin, consider using some or all of the GDC being used for the Louisiana Energy Services centrifuge enrichment plant for the major materials licensees (53 FR 13276). For the GDC, consider the issues of backfitting and grandfathering for existing plants.

5.3.3 Revision of 10 CFR Part 70.22(f)

Revise 10 CFR Part 70.22(f) to make it apply to all fuel cycle plants, rather than just plutonium processors. However, the extent to which plants should be required to provide protection against natural phenomena should be determined as part of the rule revision process. Insert a similar paragraph in the contents of applications sections of 10 CFR Parts 30 and 40 for large materials processors. Consider applying this provision to large irradiator facilities. Provide in the licensees' quality assurance and control programs, developed pursuant to the revised 10 CFR Part 70.22(f), assurance that the uncertainty in sampling and measurements on processes that are important to safety is controlled commensurate with the ultimate use of the data.

5.3.4 Restricted External Contamination

Revise 10 CFR Parts 30, 40, and 70 to prohibit contamination of areas external to structures and engineered confinements and to require immediate decontamination of areas inadvertently contaminated with radioactive material.

5.3.5 10 CFR Part 50.59-Type Changes

Revise 10 CFR Parts 30, 40, and 70 to allow licensees to make 10 CFR Part 50.59-type changes to procedures and the plant only after a hazards analysis of the affected area has been performed, documented, reviewed, and approved by the plant safety committee. Otherwise, continue to require NRC approval for all changes to the plant as described in the license.

5.3.6 Criticality Reporting

Revise 10 CFR Part 70.52 to clarify the requirements for reporting criticalities, potential criticalities, or loss of control of a potentially critical mass of material.

5.3.7 License Condition Process

Revise 10 CFR Parts 30, 40, and 70, as appropriate, to require applicants to submit applications according to a standard format and to revise plans by submitting each changed page.

5.4 Staffing

5.4.1 Establish an Organization for Inspection and Guidance

Establish and staff an organization in NMSS and assign it direct responsibility and accountability for ensuring that actions pertaining to revision of MCs, procedures, and regulatory guides, and for developing criteria for courses to train and qualify fuel cycle headquarters and regional staff are completed.

5.4.2 Resources

Reevaluate staffing and technical assistance funding levels required to implement the Task Force approach to program direction, licensing, and inspection. Include in this evaluation a comprehensive review of the resources needed to revise regulations and to review, develop, reissue, or update the needed regulations and regulatory guidance for the major materials licensees. Reevaluate the allocation and use of available resources in the regions to ensure that all inspection activities at fuel cycle plants can be accommodated by the available resources.

5.4.3 Team Assessments

Establish and staff a special organization in NMSS, charged with the conduct of team assessments at fuel cycle and large materials plants. Restructure the makeup of assessment teams to assign permanent team leaders in headquarters or the regions and other individuals in assigned areas, so that assessments are uniformly conducted. Extend the duration of the assessments from 1 to 2 weeks, deemphasize interacting with other agencies, and include on the teams region-based individuals who know the plant being assessed. Revise MC-2601 to ensure that the assessments properly examine plant and managerial performance.

5.5 Training

5.5.1 Training Program Development

Develop and offer formal training to the headquarters and regional staff, both initial and refresher training, to provide the basis for inspecting and licensing process operations and performing the associated safety analyses. Include in this training fundamentals of criticality safety, understanding of plant processes and equipment, process design and operation, process safety considerations, and handling and storage of radioactive and nonradioactive hazardous materials.

5.5.2 Training Program Content

Establish a special working group to consider the content of the training courses discussed in this report. Staff from the Technical Training Center, NMSS, and the regions should be represented on this special working group.

5.6 Other Recommendations

5.6.1 National Program Review

Revise the National Program Review of materials and fuel cycle licensing and inspection activities and programs to ensure that the NRC reviews program adequacy rather than implementation. This revision can be accomplished through an in-depth analysis of a selected portion of the program, rather than by conducting a broad, shallow review of the entire program. Perform an in-depth review of the basis used for allocating and using inspection resources in all the regions during National Program Reviews.

5.6.2 Upgraded Resource Utilization Tracking System

Reevaluate the computer programs and codes used to track inspection activities in the regions to ensure that useful data can be obtained when required.

APPENDIX A

INDEPENDENT ANALYSIS OF MATERIALS REGULATORY REVIEW TASK FORCE REPORT

by

Richard E. Cunningham
Director, Division of Industrial and Medical Nuclear Safety, NMSS

and

Malcolm R. Knapp
Director, Division of Radiation Safety and Safeguards, Region I

APPENDIX A

Independent Analysis of Materials Regulatory Review Task Force Report

Background

This supplement provides an analysis which leads to prioritization of the Materials Regulatory Review Task Force Report (Report) recommendations concerning fuel cycle and major materials manufacturing.

The Report demonstrates considerable insight into the regulation of fuel cycle and large material manufacturing facilities. It recommends a substantially increased effort in almost all aspects of the regulatory regime governing safety. This effort includes regulations, licensing and inspection as well as supplements to these fundamental components of regulation such as licensing guides, inspection manuals, and training. Its specific recommendations lead to alternatives in direction and emphasis in the regulatory regime, e.g., more prescriptive regulations and increased emphasis on licensing.

It will require a very substantial increase in resources and take years to complete action on all of the Report's recommendations. Given the characteristics of the facilities at which the Report's regulatory improvements are directed, the reality of agency resource constraints, and the availability of required skills, it is essential to prioritize the Report's recommendations.

This supplement assigns broad priorities to the Report's recommendations concerning fuel cycle and large materials manufacturing facilities. It appears most appropriate to prioritize the Report's recommendations among the three main areas of the regulatory regime; regulations, licensing, and inspection. To review fundamentals, regulations document agency-wide requirements and have the force of law. They are the basis for licensing and inspection. Licenses set licensee-specific requirements to meet regulations and are also a basis for inspection. Inspections evaluate safety, determine compliance, and ideally, identify needed changes in the license and regulations.

Prioritization among these areas must reflect which will be most cost effective in increasing the safety of the present industry. At this time, the fuel cycle and large materials manufacturing industry is mature. No new fuel cycle facilities are anticipated over the next decade with the possible exception of enrichment facilities. The long term viability of fuel cycle plants is an open question because of foreign competition, production costs, and, for at least two facilities, because of cuts in military spending. Of course, a new generation of fuel cycle plants would be required to accommodate a change in the fuel used in present reactors, e.g., mixed oxide fuel or a new reactor design. However, this is not expected to occur in the immediate future.

Similarly, the large materials manufacturing industry presently is not undergoing significant growth, and current research, development and marketing activities do not appear to be likely to cause this situation to change in the next few years. Therefore, almost no new license applications are expected for either type of facility, and few amendments for significant changes in operation are expected. Thus, in the short term, there appears to be little benefit from changes in regulations or guidance that address new technologies or support the submission or review of new license applications. Instead, the improvement program should first be aimed at increasing the safety of ongoing operations. This can best be accomplished through a rigorous inspection program which emphasizes and identifies plant-specific safety issues. A variety of regulatory mechanisms are presently available to address such safety issues.

Near-Term Improvement Program

Near-term improvements pertain to those changes that can be implemented within about one year. The previous discussion provided the basis for focussing such improvements on inspection of operating plants. Improvement of inspections requires consideration of all of the components of the regulatory program that contribute to them. These components can be divided into four areas: inspection guidance, inspection resources, the license, and the inspections themselves.

Inspection guidance includes regulations, regulatory guides, the Inspection Manual, and headquarters and regional instructions. Since regulations normally take at least two years to promulgate, they will not be a source of near-term improvements. Similarly, revisions to regulatory guides are unlikely to be issued in less than one year. Therefore, near-term improvements in inspection guidance must be limited to the Inspection Manual, instructions, and less formal mechanisms. The staff would update the Inspection Manual as recommended in Section 5.2.1 of the Report, with emphasis on addressing all safety-significant concepts.

Inspection resources denote both the number and the capabilities of inspectors. Inspector capabilities result from ability, formal education, experience, and agency-specific training. Short-term actions will include identifying the needed number of individuals with the

skills necessary to improve the inspection program. Specific skills that should be considered include organization, management oversight, operations, engineering, maintenance and surveillance, criticality safety, radiological safety, environmental protection, non-radiological safety, safeguards, emergency preparedness, and accident analysis. It is expected that these skills will be obtained from NRC Headquarters, from the Regions, and from consultants.

In addition to the above skills, staff will need initial or refresher training in the inspection process. Further, some training in licensing will be needed so inspectors can better understand how licensees confront significant safety issues. This training will be consistent with the recommendations in Section 5.5 of the Report.

The license should be reviewed carefully prior to conducting an inspection so the inspectors can learn how and whether the licensee has dealt with current safety issues. This review, as well as the inspection itself, may result in changes to the license to improve safety.

The above changes would be made on a priority basis for the purpose of supporting enhanced inspections during FY92. Several recommendations in the Report address how this inspection program might proceed. The Report recommends creation of project inspectors (Section 5.2.3) and revision of resident inspector procedures (Section 5.2.7). These changes would not be made in the near term in order to be able to concentrate on the improvements discussed above. The changes would be considered as possible long-term actions.

Near-term inspection enhancements are expected to be based on team efforts of five to ten inspectors who would take six to eight weeks for preparation, inspection, and documentation. About two weeks of that time will be spent on site. Teams would initially consist of almost all NRC staff, with consultants taking an increasing role as the inspection process becomes routine after the first few inspections. Over the longer term, as new staff are hired and become trained, consultant support might return to a lower level.

Finally, after several inspections, the lessons learned from the above activities would be used to feed back into licensing improvement which is an ongoing activity regardless of other enhancements, and to help drive the long-term improvement program.

Long-Term Improvement Program

The long-term improvement program is intended to address changes in fuel cycle and large materials manufacturing regulation over the next five to ten years. The changes would be based on the NRC's improved understanding of safety issues and anticipated changes in the industry.

Projecting changes the industry is likely to experience over the next five to ten years is beyond the scope of this supplement. However, one limiting assumption appears to be reasonable. Neither technology nor economics presently appears to offer incentives for significant new fuel cycle facility or major materials manufacturing construction or major process changes over the next five years, and probably the next ten unless concepts like "weapons into plowshares" take hold. Any significant regulatory changes are more likely to result from identification of new safety issues or from changes in the NRC's regulatory policies. As discussed above, near-term improvements in the inspection process will be directed, in part, to identify safety issues that new regulations and regulatory guides should address.

A regulatory policy issue that may lead to revised regulations is the relative merit of prescriptive versus performance-based regulations. This issue is raised in Section 5.3.1 of the Report. The fundamental difference between the two types of regulations is that prescriptive regulations specify in detail what must be done to ensure protection of health and safety, while performance-based regulations can give the licensee considerable flexibility in how to implement its program, as long as health and safety are properly protected. Prescriptive regulations are more difficult to write, place a greater responsibility for safety on the NRC, and are likely to need more frequent revision as technology changes. On the other hand, prescriptive regulations more clearly document exactly what is expected of a licensee and are simpler to inspect against. By contrast, performance-based regulations require more experienced and sophisticated inspectors and license reviewers to evaluate just how well a licensee's program is protecting health and safety. The Report concludes that present regulations and licenses could profit by becoming more prescriptive than they now are. Perhaps, but this recommendation deserves further reflection as experience is gained during the near-term phase and the direction of the industry becomes more clear.

A second long-term regulatory issue would be optimization of inspection responsibilities. Topics to be considered should include the balance between individual and team inspections, the merit of creating project inspectors (Section 5.2.3), the role of resident inspectors (Section 5.2.7), and the advantages of headquarters versus region-based inspections. The extent to which individual assignments should include both inspection and licensing responsibilities to familiarize staff with both elements of the regulatory process also should be addressed.

Finally, as the issues identified above are resolved, it will be necessary to specify the types of resources needed to

implement the improved program. The technical skills needed probably would be the same as those identified in the near-term section above, but would be applied to revision of regulations and regulatory guides as well as inspection guidance. Further, in addition to staff and consultants, it probably would be appropriate to initiate several technical assistance contracts to address sophisticated technical issues.

Summary

This supplement provides a basis for prioritizing responses to the Report. The supplement recognizes that the fuel cycle and large materials manufacturing industries are not likely to change substantially in the next few years. Therefore, near-term responses should emphasize inspection issues rather than regulatory or licensing changes. An improvement program focussing on inspection is discussed including inspection guidance and resources, review of the license, the inspections themselves, and feedback. Longer term actions include projecting changes to the industry and emphasizing regulatory and program changes that respond to them.

APPENDIX B

MAJOR FUEL CYCLE AND MATERIALS LICENSEES INCLUDED IN TASK FORCE REVIEW

APPENDIX B

Major Fuel Cycle and Materials Licensees Included in Task Force Review

Docket	Licensee	Facility
30-16055	Advanced Medical Systems, Inc.	Manufacturing Operations
70-1257	Siemens Nuclear Power Corporation	
40-3392	Allied-Signal, Inc.	Metropolis Works
70-1201	B&W Fuel Company	Commercial Nuclear Fuel Plant
70-824	Babcock & Wilcox Company	Lynchburg Research Center
70-27	Babcock & Wilcox Company	Naval Nuclear Fuel Division
70-687	Cintichem, Inc.	Hot Laboratories
70-1100	Combustion Engineering, Inc.	Windsor Nuclear Fuel Manufacturing
70-36	Combustion Engineering, Inc.	Hematite Nuclear Fuel Manufacturing
30-32013	DuPont Merck Pharmaceutical Company	NEN Products—Billerica
30-28902	E.I. DuPont de Nemours & Co., Inc.	NEN Products—Boston
30-05222	E.R. Squibb and Sons, Inc.	Squibb Inst. for Medical Research
70-734	General Atomics	TRIGA Fuel Fabrication
70-1113	General Electric Company	Wilmington Nuc. Fuel & Comp. Manuf.
72-0001	General Electric Company	Morris Operation
30-00001	Mallinckrodt, Inc.	Radiopharmaceutical Operations
30-04951	Minnesota Mining & Manufacturing Co.	Twin Cities Army Ammunition Plant
70-143	Nuclear Fuel Services, Inc.	
30-05982	Safety Light Corporation	
40-8027	Sequoyah Fuels Corporation	
70-398	U.S. Department of Commerce	Nat. Inst. of Standards & Tech.
70-371	UNC, Inc.	UNC Naval Products Division
70-1151	Westinghouse Electric Corporation	Columbia Fuel Fabrication Facility
40-0672	Nuclear Metals Incorporated	
70-698	Westinghouse Electric Corporation	Waltz Mill Nuc. Service Opns.

APPENDIX C

THE MATERIALS REGULATORY REVIEW TASK FORCE CHARTER

APPENDIX C

The Materials Regulatory Review Task Force Charter

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

August 12, 1991

MEMORANDUM FOR: James M. Taylor
Executive Director
for Operations

FROM: Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: MATERIALS REGULATORY REVIEW TASK FORCE CHARTER

I have constitued a task force to systematically identify and classify those issues in our regulatory system, including both licensing and inspection processes, which need correction. I have enclosed the charter for this task force, whose members are Charles Haughney (Chairman), Willard Brown, Philip Ting, and Jerry Roth, from Region I.

The goal of this task force is to examine the regulatory process for large material facilities from beginning to end. This effort is to start with an examination of the full range of safety, safeguards, and environmental issues that should be considered in the regulation of large material licensees. I expect that this task force will not operate entirely on its own, but rather will make use of the expertise of other senior license reviewers and regional inspectors to accomplish their goal. The recommendations contained in the IIT Report of the GE incident (NUREG-1450) will be included as a part of the task force's efforts; however, the task force charter is to look far more broadly at problems in the regulation of major materials licensees.

I have directed the task force to complete its efforts and report its results by September 20, 1991.

Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

MATERIALS REGULATORY REVIEW TASK FORCE CHARTER

I. BACKGROUND

In response to identified deficiencies in the staff's materials licensing and inspection processes, we have formed a task force to completely reexamine these processes not only considering the implications of the recent General Electric-Wilmington event, but also considering other significant events and known shortcomings that the staff has recognized from other events and has not yet had the opportunity to correct. The licensing and inspection activities for the major materials licensees have been highly licensee-specific. The principal reason for this variation is the wide variety of nuclear materials and plant process systems used by these licensees. In addition, individual inspectors and license reviewers have been provided with largely general guidance and left to their own discretion to formulate the detailed nature of their inspection and licensing reviews. The variability of individual staff efforts has been partly tempered by oversight from supervisors and by assistance from senior staff members. The findings from the Incident Investigation Team (IIT), published in NUREG-1450, point clearly to a need to reexamine the entire regulatory foundation the staff uses in materials licensing. Mere correction of the individual staff action items resulting from the IIT, while important, will not serve to correct the root and contributing causes to the regulatory shortcomings. Findings related to staff actions

concerning the regulatory process that are listed in NUREG-1450 have a troubling echo from the findings of 5 years ago following a uranium hexafluoride cylinder rupture. Through the efforts of this task force and implementation of needed follow-on actions, we hope to correct the fundamental weaknesses in the materials regulatory process.

The Charter of this task force is to examine the regulatory process for large material facilities from beginning to end. This effort is to start with an examination of the full range of safety, safeguards, and environmental issues that should be considered in the regulation of large material licensees. The task force should systematically identify and classify those issues in a regulatory system that can be addressed by licensees in their license applications and engineering documents and then reviewed and acted upon by the staff. The task force effort should include the outlines of documents such as a Standard Format and Content for License Applications, a Standard Review Plan, a Standard License Format and Content, and an Inspection Manual Chapter and accompanying procedures.

Members of this task force should consider that they have a clean slate. No existing regulatory document should be considered sacred. The task force should examine licenses, standard review plans, regulatory guides (especially the standard format and content guides), the NRC Inspection Manual and procedures, and the rules. The eventual outcome of the task force efforts should be a clearer description of the materials licensing and inspection basis, which both the staff and licensees can understand.

II. LICENSEES

Which materials licensees should be considered within the scope of this review? Clearly the major fuel cycle licensees, which are under the 10-year license renewal process should be included. In addition, major radiopharmaceutical firms, such as Mallinckrodt, contain large amounts of nuclear material with a variety of complex systems and processes and could benefit from a more consistent and coherent review and inspection process. Perhaps the best mechanism for selecting licensees that should be within the scope of this review is to include those licensees which have offsite emergency plans. Another consideration would be those licensees that are subject to Operational Safety Team Assessments.

III. TASK FORCE MAKEUP

The following personnel are assigned full time to the task force from August 12, 1991, until September 20, 1991: Charles Haughney (Task Force Chairman), Willard Brown, Philip Ting, and Jerry Roth from Region I. These four task force members will have access to other staff members for their views on both the weak and effective parts of the regulatory process. Consideration should be given to allow task force members to interview selected licensee representatives to obtain their perspective on needed improvements in the regulatory process. These interviews should be conducted with caution, for many licensees are interested primarily in streamlining the regulatory process rather than improving it.

V. CONDUCT OF REVIEW

The task force should consider that it has the freedom to revise and restructure as much as is necessary of the materials licensing and inspection program for major plants in order to obtain a fresh and effective regulatory strategy. The scope of the effort should include the inspection and licensing process for safety, safeguards, and environmental considerations. The following types of questions should be explored by the task force, but the task force should not consider this list of topics to be all inclusive:

1. What safety, safeguards, and environmental topics should be reviewed during the initial licensing, license amendment reviews, or renewal process? The list of topics would form the basis for an outline of the standard review plan. The list would be comprehensive and would not necessarily apply in its entirety to any particular materials licensee. The licensing reviewers and the licensee would have to recognize which topics should be eliminated during a particular license review.

2. In developing this list of topics, the task force might consider developing lists by technical discipline, by type of process system, and by type of room or confinement such as hot cell or glove box.

3. A crucial question involves the scope and depth of the review for a particular topic. For instance, can the reviewers rely merely on the written description of systems operation and configuration as contained in the license application, or must the reviewer examine the engineering drawings, specifications, and design calculations in order to reach a reasonable assurance of conclusion of system acceptability? A difficulty in materials licensing is that the rules for all but plutonium fabrication plants, which are all shut down, do not require a formal quality assurance program with its intended design control and document control features, which would make these engineering documents readily accessible in a coherent form to either a license reviewer or inspector. If the staff decides that such additional features are needed, rulemaking will be required.

4. For a given topic, how much control and restriction upon the licensee's activities should be stated in the text of a license condition? In several significant events involving materials licensees, examination of the license has disclosed either a lack of coherent limits or such general limits that the licensee had considerable freedom to operate the plant in highly off-normal conditions without reporting problems to the NRC. The task force should consider means of ensuring that licensees know when to report evolving problems.

5. The licensing staff is burdened with processing a fair number of mundane amendments, which have little safety, safeguards, or environmental significance. The task force should consider whether the licensing documents are sufficiently robust or need strengthening to allow something analogous to 10 CFR 50.59, which allows the reactor licensees to make changes to their procedures or modify their plants without prior NRC approval providing their change does not create an unreviewed safety question. With major fuel cycle licenses being renewed for 10 years, the staff should consider the need for a safety analysis report that would provide sufficient basis for determining whether or not they were creating unreviewed safety questions as they change their plants. This process could substantially reduce the number of relatively insignificant license amendments the staff is processing.

6. The task force should interview other knowledgable staff members, both license reviewers and inspectors. This interaction should endeavor to uncover the following types of information as it relates to regulatory processes:

   a. Lessons from significant past events
   b. What's missing in the licenses with which you are familiar?
   c. What's unduly restrictive in the licenses, regulatory guides, and standard review plans sections?

d. What needs revision in the standard format and content and regulatory guides?

e. How and what should we incorporate from the March 1989 Branch Technical Positions on Management Controls/Quality Assurance, Requirements for Operations, and Chemical Safety?

f. What standard review plan sections need revision? What new sections need creation?

g. What items should be added to the inspection manual, what inspection procedures should be revised and how?

V. TASK FORCE SCHEDULE

The task force will begin its activities on August 12, 1991, and endeavor to conclude its activity by September 20, 1991.

VI. EXPECTED PRODUCT

By the conclusion of its efforts, the task force should produce a report that contains three sections:

1. A description of the task force findings.
2. A description of the methods for implementation of task force recommendations. In developing these recommendations, the task force should attempt to systematically identify and classify those issues in the materials regulatory system in a manner which shows how

they should be: 1) addressed by licensees in their application and commitments; 2) reviewed by the staff during the license review process; and 3) inspected by the regional office during the plant lifetime.

3. An action plan for the correction of each item. This plan should include, as appropriate, both the items developed by this task force and those action items directed by the EDO memorandum resulting from the GE-Wilmington IIT report.

APPENDIX D

AVAILABLE GUIDANCE FOR FUEL CYCLE SAFETY, SAFEGUARDS, AND ENVIRONMENTAL PROTECTION

APPENDIX D

Available Guidance for Fuel Cycle Safety, Safeguards, and Environmental Protection

Type of License (SRP)		Standard Format and Content Guide (SF&CG)	Standard Review Plan
FUEL CYCLE SAFETY	U-Processing and Fuel Fabrication	R.G. 3.52 • Only covers 6 topics • Only contains statements • No examples provided	Draft SRP Incomplete (only 4 chapters written)
	UF_6 Production	R.G. 3.55 • Only contains statements • Only covers 6 topics • No examples provided	See Item 1
	Environmental Protection for UF_6 Conversion and Fuel Fabrication Plants	Draft R.G. • Wrong format • Needs major rewrite	Draft SRP Needs major rewrite and final issuance as a NUREG
	Termination of FC SNM License	R.G. 3.65 Should be updated	SRP • Included in the Policy and Guidance Directive • Should be updated and issued as a NUREG
	U-Enrichment Facilities	R.G. 3.25 • Issued in 1974; based on the old 10 CFR Part 52 • Focused on construction phase; no details on operations	No corresponding SRP
	Independent Spent Fuel Storage Installation	R.G. 3.44 (water storage) Should be updated	No corresponding SRP
		R.G. 3.48 (dry storage) Should be updated	Corresponding draft SRP Should be finalized and issued as a NUREG
		R.G. 3.61 (dry storage cask) Should be updated	No corresponding SRP
		R.G. 3.62 (on-site storage cask) Should be updated	

Available Guidance for Fuel Cycle Safety, Safeguards, and Environmental Protection Protection (continued)

Type of License (SRP)		Standard Format and Content Guide (SF&CG)	Standard Review Plan
MATERIALS SAFETY	Type A Licenses of Broad Scope	No corresponding SF&CG	SRP • Included in the Policy and Guidance Directive • Should be updated and issued as a NUREG
	Source Material Licenses	No corresponding SF&CG	SRP • Included in the Policy and Guidance Directive • Should be updated and issued as a NUREG
SAFEGUARDS	Material Control and Accounting	NUREG-1280 (Cat I) NUREG-1065 (Cat III) Draft R.G. (U-Enrichment) The two NUREGs should be updated and issued as regulatory guides	NUREG-1280 (Cat I) NUREG-1065 (Cat III) Draft NUREG (U-Enrichment) The two published NUREGs should be updated
	Physical Security	R.G. 5.52 (Cat I) Needs to be redeveloped and reissued	NUREG-0721 (Cat I) Should be updated
		R.G. 5.59 (Cat II & III) Should be updated	R.G. 5.59 (Cat II & III) Should be updated

APPENDIX E

MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. NUCLEAR REGULATORY COMMISSION AND THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION: WORKER PROTECTION AT NRC-LICENSED FACILITIES

APPENDIX E

Memorandum of Understanding Between NRC and OSHA; Worker Protection at NRC-Licensed Facilities

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

NUCLEAR REGULATORY COMMISSION

Memorandum of Understanding Between The Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-licensed Facilities

The Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) have entered into a Memorandum of Understanding (MOU) to provide general guidelines for interface activities between the two agencies. The MOU is designed to ensure that there will be no gaps in the protection of workers at NRC-licensed facilities where the OSHA also has health and safety jurisdiction. At the same time, the MOU is designed to avoid duplication of effort on the part of the two agencies in those cases where it is not always practical to sharply identify boundaries between the NRC's responsibilities for nuclear safety and the OSHA's responsibilities for industrial safety.

The MOU, which replaces an existing procedure for interagency activities, defines the general areas of responsibilities of both agencies, describes generally the efforts of each to achieve worker protection at NRC-licensed facilities, and provides several procedures for the coordination of interface activities and exchange of information between the NRC and OSHA. The text of the MOU is set out below.

Purpose and Background

1. The purpose of this Memorandum of Understanding between the U.S. Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) is to delineate the general areas of responsibility of each agency; to describe generally the efforts of the agencies to achieve worker protection at facilities licensed by the NRC; and to provide guidelines for coordination of interface activities between the two agencies. If NRC licenses observe OSHA's standards and regulations, this will help minimize workplace hazards.

2. Both NRC and OSHA have jurisdiction over occupational safety and health at NRC-licensed facilities. Because it is not always practical to sharply identify boundaries between the nuclear and radiological safety NRC regulates and the industrial safety OSHA regulates, a coordinated interagency effort can ensure against gaps in the protection of workers and at the same time, avoid duplication of effort. This memorandum replaces an existing procedure for interagency activities, "General Guidelines for Interface Activities between the NRC Regional Offices and the OSHA."

Hazards Associated With Nuclear Facilities

3. There are four kinds of hazards that may be associated with NRC-licensed nuclear facilities.

a. Radiation risk produced by radioactive materials;

b. Chemical risk produced by radioactive materials;

c. Plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk to workers. For example, these might produce a fire or an explosion, and thereby cause a release of radioactive materials;

d. Other industrial hazards in the workplace. For example, there might be exposure to toxic nonradioactive materials and other industrial hazards in the workplace.

Generally, NRC covers the first three hazards listed in paragraph 3 (a, b, and c), and OSHA covers the fourth hazard described in paragraph 3 (d). NRC and OSHA responsibilities and actions are described more fully in paragraphs 4 and 5 below.

NRC Responsibilities

4. NRC is responsible for licensing and regulating nuclear facilities and materials and for conducting research in support of the licensing and regulatory process, as mandated by the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and the Nuclear Nonproliferation Act of 1978; and in accordance with the National Environmental Policy Act of 1969, as amended, and other applicable statutes. These NRC responsibilities cover the first three nuclear facility hazards identified in paragraph 3 (a, b, c). NRC does not have statutory authority for the fourth hazard described in paragraph 3 (d).

NRC responsibilities include protecting public health and safety; protecting the environment; protecting and safeguarding materials and plants in the interest of national security; and assuring conformity with antitrust laws for certain types of facilities, e.g., nuclear power reactors. Agency functions are performed through: Standards-setting and rulemaking;

materials or an unsafe reactor condition; and,

d. Plant conditions which result in an occupational risk, but do not affect the safety of licensed radioactive materials, technical reviews and studies; conduct of public hearings; issuance of authorizations, permits and licenses; inspection, investigation and enforcement; evaluation of operating experience, and confirmatory research.

OSHA Responsibilities

5. OSHA is responsible for administering the requirements established under the Occupational Safety and Health Act (OSHA Act) (29 U.S.C. 651 *et seq.*), which was enacted in 1970. OSHA's authority to engage in the kinds of activities described below does not apply to those workplace safety and health conditions for which other Federal agencies exercise statutory authority to prescribe and enforce standards, rules or regulations.

Under the OSH Act, every employer has a general duty to furnish each employee with a place of employment that is free from recognized hazards that can cause death or serious physical harm and to comply with all OSHA standards, rules, and regulations.

OSHA standards contain requirements designed to protect employees against workplace hazards. In general, safety standards are intended to protect against traumatic injury, while health standards are designed to address potential overexposure to toxic substances and harmful physical agents, and protect against illnesses which do not manifest themselves for many years after initial exposure.

OSHA standards cover employee exposures from all radiation sources not regulated by NRC. Examples include x-ray equipment, accelerators, accelerator-produced materials, electron microscopes and betatrons, and naturally occurring radioactive materials such as radium.

It is estimated that the Act covers nearly 6 million workplaces employing more than 80 million workers. Federal OSHA covers approximately three-fifths, or four million, of these workplaces. States which operate OSHA-approved job safety and health programs, or "Plans," cover the remainder.

OSHA State Plan States are encouraged, but not required, to delineate their authority for occupational safety and health at NRC-licensed facilities in the same manner as Federal OSHA.

The OSHA areas of responsibility described in this memorandum are subject to all applicable requirements and authorities of the OSH Act. However, the industrial safety record at NRC-licensed nuclear power plants is such that OSHA inspections at these facilities are conducted normally as a result of accidents, fatalities, referrals, or worker complaints.

Interface Procedures

6. In recognition of the agencies' authorities and responsibilities enumerated above, the following procedures will be followed:

Although NRC does not conduct inspections of industrial safety, in the course of inspections of radiological and nuclear safety, NRC personnel may identify safety concerns within the area of OSHA responsibility or may receive complaints from an employee about OSHA-covered working conditions. In such instances, NRC will bring the matter to the attention of licensee management. NRC inspectors are not to perform the role of OSHA inspectors; however, they are to elevate OSHA safety issues to the attention of NRC Regional management when appropriate. If significant safety concerns are identified or if the licensee demonstrates a pattern of unresponsiveness to identified concerns, the NRC Regional Office will inform the appropriate OSHA Regional Office. In the case of complaints, NRC will withhold, from the licensee, the identity of the employee. In addition, when known to NRC, NRC will encourage licensees to report to OSHA accidents resulting in a fatality or multiple hospitalizations.

When such instances occur within OSHA State Plan States' jurisdiction, the OSHA Regional Office will refer the matter to the State for appropriate action.

7. OSHA Regional Offices will inform the appropriate NRC Regional Office of matters which are in the purview of NRC, when these come to their attention during Federal or State safety and health inspections or through complaints. The following are examples of matters that would be reported to the NRC:

a. Lax security control or work practices that would affect nuclear or radiological health and safety.

b. Improper posting of radiation areas.

c. Licensee employee allegations of NRC license or regulation violations.

8. The NRC and OSHA need not normally conduct joint inspections at NRC-licensed facilities. However, under certain conditions, such as investigations or inspections following accidents or resulting from reported activities as discussed in items 6 and 7 above, it may be mutually agreed on a case-by-case basis that joint investigations are in the public interest.

9. The chemical processing of nuclear materials at some NRC-licensed fuel and materials facilities presents chemical and nuclear operational safety hazards which can best be evaluated by joint NRC-OSHA team assessments. Each agency will make its best efforts to support such assessments at about 20 facilities once every five years. Of these facilities, about one-third are in the OSHA Plan States. OSHA will also assist in promoting such participation by State personnel in OSHA Plan States.

10. Based upon reports of injury or complaints at nuclear power plant sites, OSHA will provide NRC with information on those sites where increased management attention to worker safety is needed. The NRC will bring such information indicating significant breakdown in worker safety to the attention of licensee management and monitor corrective actions. This will not interfere with OSHA authority and responsibility to investigate industrial accidents and worker complaints.

11. Power reactor sites are inspected by NRC Region-based and Resident Inspectors. Personnel from NRC Regional Offices routinely conduct inspections at most fuel and materials licensed facilities. In order to enhance the ability of NRC personnel to identify safety matters under OSHA purview during nuclear and radiological safety inspections, OSHA will provide NRC Regional personnel with basic chemical and industrial safety training and indoctrination in OSHA safety standards, consistent with ongoing OSHA training programs. To enhance the ability of OSHA and State Plan personnel to effectively participate in the Operational Safety Team Assessments, NRC will provide training in basic radiation safety requirements, consistent with ongoing NRC training programs. Details of such training will be as mutually agreed by the NRC Technical Training Center and the

OSHA National Training Institute.

12. Resolution of policy issues concerning agency jurisdiction and operational relations will be coordinated by the NRC Deputy Executive Director for Operations, and by the OSHA Director of Policy. Appropriate Headquarters points of contact will be established.

13. Resolution of issues concerning inspection and enforcement activities involving both NRC and OSHA jurisdiction at NRC-licensed facilities will be handled between NRC's Office of Enforcement and OSHA's Directorate of Compliance Programs. Each NRC and OSHA Regional Office will designate points of contact for carrying out interface activities.

For the Nuclear Regulatory Commission.

Victor Stello, Jr.,

Executive Director for Operations.

October 21, 1988.

For the Occupational Safety and Health Administration.

John A. Pendergrass,

Assistant Secretary.

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APPENDIX F

EXPENDITURE OF FUEL CYCLE INSPECTION RESOURCES FOR FISCAL YEAR 1990

APPENDIX F

Expenditure of Fuel Cycle Inspection Resources for Fiscal Year 1990

Region	No. of plants*	Manpower hours used		Inspection hours per plant		Inspection hours per module** PER plant	
		Total	Onsite	Total	Onsite	Total	Onsite
I	5	2,265	911	450	180	30	12
II	6	8,798	4,431	1,470	740	90	46
III	4	1,609	613	400	155	25	12
IV	1	1,138	525	1,138	525	70	33
V	4	1,560	750	390	187	24	12
Nationwide	20	15,370	7,230	769	361	48	22

*Plants by region:

Region I UNC–Naval Products, National Institute of Standards and Technology, Cintichem, UNC–Recovery Operations, Combustion Engineering-Windsor;

Region II Babcock and Wilcox-Naval Products, Babcock and Wilcox-Research, Babcock and Wilcox-Commercial, Nuclear Fuel Services, General Electric, Westinghouse;

Region III Allied, Battelle-Columbus, Combustion Engineering–Hematite, General Electric–Morris;

Region IV Sequoyah Fuels; and

Region V Rockwell, General Atomics, General Electric-Vallecitos, Advanced Nuclear Fuels.

**Number of major inspection modules assumed to be used – 16.

APPENDIX G

SECTIONS FOR ACTIONS THE TASK FORCE RECOMMENDED THAT CORRESPOND TO STAFF ACTIONS INVESTIGATORS RECOMMENDED AFTER THE MAY 29, 1991, GENERAL ELECTRIC–WILMINGTON EVENT

APPENDIX G

Sections for Actions the Task Force Recommended That Correspond to Staff Actions Investigators Recommended After the May 29, 1991, General Electric–Wilmington Event

Staff actions recommended after the investigation of the May 29, 1991, event at the GE–Wilmington plant	Task Force recommended actions that correspond to those from the GE event
1. Issue: Adequacy of Criticality Safety Reviews	
• Evaluate existing regulatory requirements, guidance, and review standards for criticality safety analyses for fuels facility licensees to make process, procedural, and facility changes and to develop new regulatory guidance, requirements, and review standards.	5.1.1 5.1.2 5.1.5 5.3.1 5.3.4
• Evaluate the use of safety operating specifications for radiation and nuclear safety instruments and controls.	5.1.1
• Evaluate the need to change the licensing practice of incorporating a license condition by reference in fuel facility licenses. Assure the resolution of this evaluation is mutually understood by all involved in the process.	5.3.6
• Evaluate the existing NRC programs for the inspection of changes to criticality safety controls at fuel fabrication facilities and develop new guidance.	5.2.1 5.2.3 5.2.4 5.2.7
• Evaluate the adequacy of the NRC training and qualification programs to effectively support criticality safety inspections at fuel facilities and develop enhancements to the training program.	5.4.1 5.5
2. Issue: Adequacy of Facility Operational Safety	
• Upgrade existing inspection guidance related to managerial controls and oversight, including audits, personnel training, procedural adequacy, and compliance for broad-scope licensees.	5.2.1 5.2.2 5.4.3 5.5
• Determine the need for regulatory requirements, guidance, and standard review plans regarding managerial controls and oversight, including audits, personnel training, procedural adequacy, and compliance for broad-scope licensees. Conduct inspections at selected fuel fabrication facilities to collect additional information on managerial controls and practices. On the basis of these assessments, develop new guidance, requirements, and standards, as appropriate.	5.1.1

APPENDIX G

Sections for Actions the Task Force Recommended That Correspond to Staff Actions Investigators Recommended After the May 29, 1991, General Electric–Wilmington Event (continued)

Staff actions recommended after the investigation of the May 29, 1991, event at the GE–Wilmington plant	Task Force recommended actions that correspond to those from the GE event
• Examine the overall inspection process for monitoring and collecting fuel facility safety performance information. Include in the evaluation the merits of (a) a resident inspector program, (b) more frequent inspections, including use of team inspections, and (c) establishing a systematic performance appraisal and feedback program analogous to the SALP program for Part 50 licensees.	5.2.1 5.2.3 5.2.4 5.2.5 5.2.6 5.2.7 5.2.8 5.4.3 5.5 5.6.1
• Evaluate the adequacy of the NRC training and qualification program to effectively support fuel cycle facility inspections and develop enhancements to the training program.	5.4.1 5.5
3. Issue: Adequacy of Emergency Preparedness	
Ensure that the final version of proposed regulatory guide DG–3005, "Standard Format and Content for Emergency Plans for Fuel Cycle and Material Facilities," addresses potential criticality events.	5.1.1 5.3.1
4. Issue: Adequacy of Operating Experience Reviews	
• Reevaluate regulatory requirements and guidance for event reporting for fuels facilities as it relates to potential criticalities and failed contingencies (barriers). Develop additional guidance and requirements, as appropriate.	5.1.2 5.3.1 5.3.5
• Reevaluate NRC operating experience review and feedback program for fuel facilities. Revise the program, as appropriate.	5.1.6
• Develop NRC inspection guidance for licensee event reporting and reviews for fuel facilities. Issue new guidance, as appropriate.	5.2.1
• Develop and implement an independent NRC operating experience program for nuclear materials licensees, including nuclear fuel fabrication facilities.	5.4.3 5.6.1

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U.S. NUCLEAR REGULATORY COMMISSION

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

The Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, appointed a Materials Regulatory Review Task Force to conduct a broad-based review of the Commission's current licensing and oversight programs for fuel cycle and large materials plants. The task force, as requested, defined the components and subcomponents of an ideal regulatory evaluation system for these types of licensed plants and compared them to the components and subcomponents of the existing regulatory evaluation system. This report discusses findings from this comparison and proposed recommendations on the basis of these findings.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

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