
Handbook for Processing an Agreement

Date: July 19, 2007

**Office of Federal and State Materials and Environmental
Management Programs (FSME)
U.S. Nuclear Regulatory Commission**

Contact: William Rautzen

CONTENTS

Section 1.0 - INTRODUCTION

- 1.1 Purpose
- 1.2 Scope

Section 2.0 - BASIS OF THE GUIDANCE

- 2.1 Statutory Requirements
 - 2.1.1 Federal Statutes
 - 2.1.2 State Statutes
- 2.2 Commission Policy Statements
 - 2.2.1 *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement*
 - 2.2.2 *Statement of Principles and Policy for the Agreement State Programs*
 - 2.2.3 *Policy Statement on Adequacy and Compatibility of Agreement State Programs*
- 2.3 Directives and Procedures
 - 2.3.1 *NRC Management Directive 5.6, Integrated Materials Performance Evaluation Program (IMPEP)*
 - 2.3.2 *NRC Management Directive 5.8, Proposed 274b Agreements With States*
 - 2.3.3 *NRC Management Directive 8.8, Management of Allegations*
 - 2.3.4 *NRC Management Directive 5.9, Adequacy and Compatibility of Agreement State Programs; and FSME Procedure SA-200, Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*
 - 2.3.5 *FSME Internal Procedures - SA series*

Section 3.0 - REVIEW PROCEDURES

- 3.1 General Considerations
 - 3.1.1 Proprietary and Privacy Information
 - 3.1.2 Schedule for Processing an Agreement
 - 3.1.3 Form of the Request
 - 3.1.4 Questions
- 3.2 Expression of Interest

- 3.3 The Letter of Intent
 - 3.3.1 Content of Letter
 - 3.3.2 Response to Letter
- 3.4 The Draft Request
 - 3.4.1 Early Review of Legislation and Regulations
 - 3.4.2 Alert for Draft Request
 - 3.4.3 Review of the Draft Request
 - 3.4.4 Telephone Conference Calls
 - 3.4.5 Meetings and Visits
 - 3.4.6 Inspection and Licensing Staff Contacts
- 3.5 The Formal Request for an Agreement
 - 3.5.1 Project Schedule Adjustment
 - 3.5.2 Review of the Formal Request
 - 3.5.3 Transmission of Comments to the State
 - 3.5.4 Completion of the Review

Section 4.0 - INFORMATION NEEDED AND EVALUATION CRITERIA

- 4.1 Legal Elements
 - 4.1.1 Authority to Establish a Program and Enter an Agreement
 - 4.1.2 Organization of the Proposed Program
 - 4.1.3 Content of the Proposed Agreement
- 4.2 Regulatory Requirements Program Elements
 - 4.2.1 Standards for Protection Against Radiation
 - 4.2.2 Regulatory Requirements with Significant Transboundary Implications
 - 4.2.3 Regulatory Requirements Needed for an Orderly Pattern of Regulation or Which Have Particular Health and Safety Significance
- 4.3 Licensing Program Elements
 - 4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material
 - 4.3.2 Procedures for the Evaluation of Radiation Safety Information on Sealed Sources or Devices, and Registration for Distribution
 - 4.3.3 Procedure for Conducting the Technical Evaluation of a Proposed License for a Low Level Radioactive Waste Land Disposal Site
 - 4.3.4 Procedure for Conducting the Technical Evaluation of a Proposed Uranium or Thorium Recovery Facility

- 4.3 Licensing Program Elements, continued
 - 4.3.5 Procedures for Assuring the Technical Quality of Licenses
 - 4.3.6 Administrative Licensing Procedures
- 4.4 Inspection Program Elements
 - 4.4.1 Procedures for Inspecting Facilities Where Radioactive Material Is Stored or Used
 - 4.4.2 Procedures for Assuring the Technical Quality of Inspections and Inspection Reports
 - 4.4.3 Administrative Procedures for Inspections
- 4.5 Enforcement Program Elements
 - 4.5.1 Routine Enforcement Procedures
 - 4.5.2 Escalated Enforcement Procedures
- 4.6 Technical Staffing and Training Program Elements
 - 4.6.1 Technical Staff Organization
 - 4.6.2 Formal Qualification Plan
 - 4.6.3 Qualifications of Current Technical Staff
- 4.7 Event and Allegation Response Program Elements
 - 4.7.1 Procedures for Responding to Events and Allegations
 - 4.7.2 Procedures for Identifying Significant Events and Allegations, And for Entering Same into the Nuclear Materials Events Database

Glossary

Definitions

Appendix A

Cross Index Table - relating program elements, information required from the State, Policy Statement Criteria, and References from this Handbook Section 4.0

Appendix B

Staffing Analysis Forms

Appendix C

Sample Letters and Documents

1.0 INTRODUCTION

1.1 Purpose

This handbook provides guidance for the preparation and review of a State request for an Agreement. The Nuclear Regulatory Commission (NRC) staff should use the handbook for guidance in reviewing the request, or for an amendment to an existing Agreement. The State that is requesting an Agreement should use the handbook for guidance in preparing its request.

1.2 Scope

A request for an Agreement consists of a formal statement by the Governor and a comprehensive description of the State's Agreement materials program with supporting information. This handbook addresses the supporting information that the State should include, and the criteria that NRC staff uses to evaluate it. The NRC staff must be able to reach a general conclusion that the information satisfies the Commission's review criteria.

Section 2.0 of the handbook addresses the statutes and policies that form the basis for the guidance in the handbook. Section 3.0 provides the detailed steps in the procedure followed by NRC staff to evaluate the request. Section 4.0 addresses the specific supporting information needed to evaluate each element of the State's program. It provides specific criteria for evaluating the information, and relates these criteria to the Commission's Criteria Policy Statement (See handbook Section 2.2 below). It also provides references to NRC and other documents related to the program element.

Appendix A is a cross reference table of the subsections in handbook Section 4.0 to the criteria in the criteria policy statement, and other guidance documents. Appendix B is a set of sample forms to guide the analysis of staffing needs in an Agreement materials program. Appendix C is a set of sample letters and documents developed in a previous review of a request for an Agreement.

2.0 BASIS OF THE GUIDANCE

2.1 Statutory Requirements

The guidance in this handbook is based on the requirements of Federal statutes, Commission Policies, NRC Management Directives, NRC Inspection Manual Chapters and Inspection Procedures, and Internal Procedures for the Office of Federal and State Materials and

Environmental Management Programs (FSME)¹ Agreement State Program. We will describe these in more detail below.

2.1.1 Federal Statutes

The Commission conducts the Agreement State program under Section 274 of the Atomic Energy Act of 1954, as amended (Act). Section 274b authorizes the Commission to enter an Agreement with the Governor of a State. Section 274c of the Act specifies those regulatory authorities that must be reserved to NRC. Sections 274d through 274g specify the Commission actions and obligations with respect to the Agreements. A State that proposes to regulate 11(e).2 byproduct material is subject to additional requirements in Section 274o. It must also comply with the applicable requirements of the Uranium Mill Tailings Radiation Control Act (UMTRCA).

2.1.2 State Statutes

Under Section 274, Agreement States do not regulate materials for the NRC. Rather, NRC discontinues, and the State assumes regulatory responsibility. Each Agreement State administers an independent regulatory program. The State agency designated to conduct the Agreement materials program must have authority under State law to discharge its functions. The legal authority required depends on the categories of materials that the Commission transfers to the State in the Agreement. Handbook Section 4.1 contains details on the provisions of State law that are required. A State seeking an Agreement must submit copies of its statutes for review.

2.2 Commission Policy Statements

The Commission has adopted three policy statements applicable to the Agreement State Program. They are discussed individually in the paragraphs below.

2.2.1 Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement (48 FR 33376, 7/21/83)

Known as the "criteria policy statement," it describes the specific requirements that a State must meet for the Commission to approve an Agreement. It also provides the basis for the NRC staff assessment of the State's proposed Agreement materials program. The criteria in the policy

¹As of October 1, 2006, NRC reorganized its nuclear materials and Agreement State programs into two new program offices. The newly created Office of Federal and State Materials and Environmental Management Programs (FSME) is comprised of the former Office of State and Tribal Programs and two technical divisions from the Office of Nuclear Material Safety and Safeguards.

statement are incorporated into handbook Section 4.0. A State program that meets the criteria policy statement requirements is determined to be adequate and compatible.

The first 28 criteria in the policy statement apply to all proposed Agreement State materials programs. The last seven criteria apply only to States that will regulate the 11e.(2) byproduct material from, and operation of, uranium and thorium mills.

2.2.2 *Statement of Principles and Policy for the Agreement State Programs* (62 FR 46517, 9/3/97)

This policy statement describes the overall principles, objectives, and goals of the Commission's Agreement State Program. NRC and State staff, when reviewing or preparing a request for an Agreement, should consider these principles, objectives, and goals.

2.2.3 *Policy Statement on Adequacy and Compatibility of Agreement State Programs* (62 FR 46517, 9/3/97)

This policy defines the terms "adequate" and "compatible." The policy identifies the basic program elements necessary for an adequate State program. It also establishes five categories of compatibility with criteria for each. NRC uses the basic program elements, and compatibility criteria, in the review of Agreement requests and in Integrated Materials Performance Evaluation Program (IMPEP) reviews.

2.3 Directives and Procedures²

Two levels of procedures guide NRC staff. First are the Management Directives (MD), which address activities whose responsibilities extend to more than one Office. For activities that are the responsibility of a single Office, the Office uses Internal Procedures, such as the FSME SA series. The following MDs and SAs guide the review of a request for an Agreement.

2.3.1 *NRC Management Directive 5.6, Integrated Materials Performance Evaluation Program*

MD 5.6 provides the process and criteria for evaluating the performance of both Agreement State and the NRC regional materials programs. The NRC staff assessment of a request for an Agreement must conclude that the State's proposed program, if implemented as described, would be found satisfactory in all applicable IMPEP performance indicators.

² Current copies of these Management Directives may be viewed at the NRC Internet website <http://www.nrc.gov/reading-rm/doc-collections/#man>

2.3.2 NRC Management Directive 5.8, *Proposed 274b Agreements With States*

MD 5.8 provides guidance on drafting a proposed Agreement. Handbook 5.8 includes a model Agreement. The State should draft its proposed Agreement based on the model. Changes from the model should include additional supporting information since staff must evaluate the changes to assure the adequacy and compatibility of the proposed Agreement program. Significant changes may require special approval by the Commission.

2.3.3 NRC Management Directive 8.8, *Management of Allegations*

MD 8.8 provides NRC policy and procedures for management of allegations. (State procedures for the management of allegations for the Agreement materials program should include the appropriate elements of MD 8.8)

2.3.4 NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*; and FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*

MD 5.9 provides the process and criteria used to identify the compatibility categories of the NRC program elements. It implements the *Policy Statement on Adequacy and Compatibility of Agreement State Programs*. FSME Procedure SA-200 documents the results of the process. The Appendix to SA-200 lists each NRC regulation and program element and its compatibility category that should be adopted by Agreement States.

2.3.5 Office of Federal and State Materials and Environmental Management Programs Internal Procedures - SA series³

The FSME procedures SA-100 through SA-105 and SA-107 through SA-110 provide guidance for the review of IMPEP performance indicators in Agreement material programs. They supplement the guidance in MD 5.6. SA-106 addresses the IMPEP Management Review Board and does not apply to the review of a request for an Agreement.

The STP internal procedures SA-201, *Review of State Regulations*, SA-300, *Reporting Material Events*, SA-400, *Management of Allegations*, SA-600, *Training Criteria for Agreement State Personnel*, and SA-900, *Termination of Uranium Mill Licenses in Agreement States*, also provide guidance that may be useful in reviewing a request.

³Please check the FSME Internet website <http://nrc-stp.ornl.gov/procedures.html> for the most current procedures.

3.0 REVIEW PROCEDURES

3.1 General Considerations

As the process has developed historically, entering an Agreement is a series of steps. First, the State staff expresses interest in an Agreement, and requests information. Next, the Governor sends the Chairman a letter expressing an intention to enter into an Agreement. The third step is the submission of a draft request by the State program Director or designee, which is reviewed by NRC. Comments are then provided to the State for resolution prior to the formal submittal by the Governor.

The fourth step is the submission of the formal Request for an Agreement by the Governor. If practical, all significant issues identified by NRC with the draft request will have been resolved by the State before the Governor submits the formal Request.

3.1.1 Proprietary and Privacy Information

Normally, States should not need to submit proprietary information or information subject to the Federal Privacy Act, or a State equivalent. All information needed to support a request for an Agreement should be in the public records of the State. NRC can protect proprietary or Privacy Act information if the State meets the requirements of 10 CFR Part 9. Before submitting information that the State believes should be withheld from public disclosure, the State program Director or designee should discuss the matter with the Division Director, DMSSA.

3.1.2 Schedule for Processing an Agreement

Appendix C contains a sample schedule for processing a request for an Agreement that is based on recent experience. The actual time required to review a request depends on the resolution of issues unique to each Agreement. The effective date of the Agreement is usually selected jointly by NRC and the State. A proposed date should consider the time required for the review, the signing of the Agreement, and the transfer of license files. This usually requires about nine months after the State submits the formal request.

In the sample schedule, we give processing milestones in terms of "elapsed weeks." Starting with the sample schedule, the project manager (PM) should organize a Project Schedule with suspense dates. The PM should update the Project Schedule frequently.

3.1.3 Form of the Request

The State may submit the request as electronic documents or on paper. The request should be complete, including the Governor's letter of certification and all supporting information. Electronic files may be in image format such as PDF files, or in text format such as WordPerfect

or Word. The State should contact the PM for further information on this capability.

If the State elects to submit a request on paper, it should submit one complete copy. NRC will scan the request into the Agency Document Access and Management System (ADAMS) for distribution to the review team. Photocopies of State laws, statewide procedures, etc., are acceptable if the quality of the copy is good enough to be scanned.

3.1.4 Questions

Routine questions about the program elements, review process, criteria, or progress of the review should be directed to the PM. Significant issues or written requests (requests other than minor clarification issues) should be directed to the Division Director, DMSSA. The State staff may also, in the same manner, contact individual members of the review team directly about comments on specific program elements. Alternately, the question will be forwarded to the team member for response.

3.2 **Expression of Interest**

In response to requests for information or an expression of interest in becoming an Agreement State, the NRC staff should provide, or confirm that the State has the following:

- a. Copies of Sections 11 and 274 of the Act;
- b. Copies of the *Suggested State Radiation Control Act*, published by the Council of State Governments (CSG);
- c. Copies of the Commission policy statements: *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement*; *Policy Statement on Adequacy and Compatibility of Agreement State Programs*; and *Statement of Principles and Policy for the Agreement State Program*;
- d. Copies of MD 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*; MD 5.8, *Proposed 274b Agreements with States*; and MD 5.9, *Adequacy and Compatibility of Agreement State Programs*; and the FSME Internal Procedures SA-series, if the State staff does not have Internet access.

Normally, prior to the receipt of a Letter of Intent, the Regional State Agreements Officer (RSAO) is the NRC staff lead for responding to informal questions and requests for additional information. The RSAO should coordinate with FSME staff and request assistance of other NRC staff as necessary. The State should submit questions regarding Commission policy or practice in writing to the Division Director, DMSSA.

3.3 The Letter of Intent

A Letter of Intent is a declaration by the Governor that the State is committing its resources to entering an Agreement. It should be addressed to the Chairman of the Commission.

3.3.1 Content of Letter

The letter should state a desire to enter an Agreement, and designate a contact person on the State staff. It should also suggest an effective date for the Agreement. A sample letter is in Appendix C.

The suggested effective date for the Agreement should take into consideration the time requirements for any needed legislation, regulations, or the program specific procedures. It should also consider the time needed for recruitment, training, and qualification of program staff.

3.3.2 Response to Letter

When NRC receives a letter of intent, the Division Director, DMSSA, assigns an FSME staff member to be the PM for processing the Agreement request.

3.3.2.1 Acknowledgment Letter

The PM prepares a response letter acknowledging receipt of the letter of intent. The response letter should be prepared for the signature of the Chairman. A sample letter is in Appendix C.

3.3.2.2 State Preparation of the Request for an Agreement

The PM coordinates with the RSAO and maintains liaison with the State contact on actions to prepare a draft request. The PM responds to State requests for assistance and coordinates any informal staff review or agency review of State information. The PM tracks the progress of the State in preparing the request for an Agreement. The PM provides current information about the State's progress to other NRC staff for budget development and work planning.

3.4 The Draft Request

Submitting a draft of the Governor's Request for an Agreement aids early identification of significant issues and areas where more information is needed.

3.4.1 Early Review of Legislation and Regulations

It usually requires a considerable amount of time to enact State legislation or to adopt regulations. The State should consider submitting these elements to NRC for review well before

the draft request. Early review by FSME and OGC can allow time for amendments to critical legislative or regulatory provisions, if required.

3.4.2 Alert for Draft Request

When the State alerts FSME that a draft request is forthcoming, NRC establishes a review team. Section V.C.2 in procedure SA-700 addresses timing of the alert, and the makeup of the review team. The PM selects a principal reviewer for each element of the proposed Agreement materials program.

3.4.3 Review of the Draft Request

The team conducts a completeness review of the draft request using the evaluation criteria in handbook Section 4.0. The completeness review has two objectives. First, it discovers whether the Agreement materials program description information addresses each of the applicable elements. Second, it judges whether the request contains sufficient information to permit staff to conduct a detailed review of the application.

3.4.3.1 Completeness Evaluation

Each principal reviewer evaluates the completeness of his or her assigned program element. Other team members may help in evaluating the completeness of elements. The evaluation should be completed by the end of elapsed week three.

3.4.3.2 Team Meeting

The team should meet during elapsed week four to discuss the findings of their completeness review. They should also draft a letter to the State program Director or designee presenting team findings. The PM should reserve use of a conference room for the full week. Team members should concur on the completeness of each program element. The team briefs the Division Director, DMSSA, on the completeness review findings at the end of elapsed week four.

3.4.3.3 Review Product

The principal review product is a letter to the State program Director or designee. If the draft request is complete, the letter should state that NRC staff believes the request is ready for submission. If the draft request is incomplete, the letter includes the team's findings and comments.

If the draft request is incomplete, the team should also hold a conference call with the State staff. The team may hold a meeting with the State staff at the State's option, following the State's receipt of the team's written review findings.

The letter should be ready for Office concurrence by the end of elapsed week four. Following Office concurrence, FSME should dispatch the letter by the end of elapsed week six.

3.4.4 Telephone Conference Calls

The PM, RSAO, Division Director, DMSSA, or designee, and the State program Director or designee should establish a schedule of periodic telephone conference calls. The calls should start during the review of the draft request. Subjects of the conference calls should include progress of the review, issues identified during the review, and additional information needed. Participants should include the PM, RSAO, and the State program Director or designee. Other NRC and State staff should participate as appropriate. Plan the calls for every other week to start, then adjust the schedule as needed.

3.4.5 Meetings and Visits

The PM and the RSAO should visit the State offices to gain first-hand knowledge of the State facilities and staff. If practical, coordinate the visit with the State's receipt of the completeness review letter. This will give the State an opportunity to discuss the NRC's comments in preparation for formulating the formal request. The State program Director or designee and senior State staff members should visit both the NRC regional and headquarters offices. Other meetings should supplement the telephone conference calls. The PM should also coordinate and schedule meetings and visits during the State's preparation of a request, as necessary.

3.4.6 Inspection and Licensing Staff Contacts

State inspectors should accompany NRC inspectors during inspections of the NRC licensee facilities in the State. The State inspectors may accompany NRC before a letter of intent is submitted. After the letter of intent is submitted, State inspectors should accompany NRC inspectors regularly.

State license reviewers should work with the NRC Regional license reviewers, starting at least one year before the anticipated effective date of the Agreement. The work should begin at least when the Governor submits the letter of intent. Give preference to actions for licenses that will transfer to the State when practical.

Since these activities are centered in the Region, the RSAO usually leads coordination of these activities with the Regional liaisons and inspection staff.

3.5 The Formal Request for an Agreement

The formal request should be the draft request modified to address NRC comments on the draft. The Act requires that the formal request be signed by the Governor. It should be addressed to

the Chairman.

The information supplied in a request for an Agreement must support two findings by the Commission. First, the Commission must find that the State has an Agreement materials program that is adequate to protect public health and safety. Second, it must also find that the program is compatible with the NRC materials program. The Commission bases its findings on the NRC staff assessment.

The staff assessment documents the evaluation of the information by the review team. The assessment should describe how the program satisfies the Commission's criteria. The table in handbook Appendix A shows the relationship between the program elements in handbook Section 4.0 and the criteria in the criteria statement.

3.5.1 Project Schedule Adjustment

The sample processing schedule in handbook Appendix C allots eight weeks for the State to prepare and submit the formal request. This is an estimate of the time required based on experience. It is not a requirement. The State should submit the formal request as soon as practical following incorporation into the application of any changes resulting from the completeness review. The PM should adjust the Project Schedule to reflect the actual date FSME receives the formal request.

3.5.2 Review of the Formal Request

The team conducts a detailed review of the program description information in the formal request. The same team that reviewed the draft request for completeness should also review the formal request.

3.5.2.1 Principal Review

Each principal reviewer conducts a detailed evaluation of an element of the proposed program. Other team members may help in evaluating the element. Team members may discuss their questions about the formal request directly with the State staff. Using the evaluation criteria in handbook Section 4.0, the principal review should take 8 weeks and be completed by the end of elapsed week 21.

3.5.2.2 Major Issues

A major issue is one that raises questions about the adequacy or compatibility of the proposed State Agreement materials program. On identification of a major issue, the reviewer should notify the PM immediately. The PM alerts the Division Director, DMSSA, and schedules a meeting of the team to discuss the issue. After the meeting, the team briefs the Division

Director, DMSSA, and other management as appropriate. The State program Director or designee and Director, FSME are kept informed of the staff activity to resolve the issue.

3.5.2.3 Team Findings and the Draft Assessment

During elapsed week 22 the team meets to discuss their findings and prepare the draft NRC staff assessment. The PM should reserve a conference room for two weeks.

If the request satisfies the evaluation criteria for a program element, the principal reviewer drafts assessment text for the relevant criteria in the criteria policy statement. Team members should concur on the findings for each program element, and the assessment text. The full draft assessment should be completed by the end of elapsed week 24.

3.5.3 Transmission of Comments to the State

If the request does not satisfy a criteria policy statement criterion, the principal reviewer prepares a draft comment. Each comment should describe the issue and, where practical, provide guidance to resolve the issue. Team members should concur on the comments.

The team prepares a letter transmitting its comments, if any, on the formal request. The letter is from the Director, FSME, to the State program Director or designee, and should be completed by the end of elapsed week 24. Following Office concurrence, FSME should dispatch the letter as quickly as possible.

The State should address the comments by submitting revised pages or sections to the formal request to the Secretary of the Commission with a copy to the Director, FSME. When the team receives the revisions, it reviews only the revisions. The PM will need to revise the schedule.

3.5.4 Completion of the Review

When the team concludes that the criteria policy statement is satisfied, it completes the draft staff assessment and the Commission paper. Procedures for the publication of the proposed Agreement, and for the approval, signing, and implementation of the final Agreement are provided in Sections V.F through V.K of FSME Procedure SA-700.

4.0 INFORMATION NEEDED AND EVALUATION CRITERIA

4.1 Legal Elements

The Act does not permit the Commission to delegate its authority to the States. Under the Act, Agreement States administer independent regulatory programs under State Statutes. Each State program must derive its authority from its own State law.

4.1.1 Authority to Establish a Program and Enter an Agreement

State laws should provide specific elements of authority to the Agreement materials program. In 1983, the CSG published a generic model Radiation Control Act in *Suggested State Legislation*, Volume 42. States may, but are not required to, use the suggested State legislation as models for their own laws.

4.1.1.1 Information Needed

For all categories of materials the State should submit State law that:

- a. establishes the materials program, defines its structure, and authorizes the Governor to enter an Agreement with the Commission;
- b. authorizes the program to issue licenses;
 1. authorizes the program to impose additional license requirements.
 2. authorizes the program to give exemptions from the licensure requirements.
 3. authorizes the program to recognize the licenses of other jurisdictions.
 4. makes it unlawful to acquire, possess, store, use, transfer, or dispose of materials without a valid license, or to violate the conditions of a license.
 5. authorizes the program to recognize licenses transferred from NRC under the Agreement as State licenses, if necessary.
- c. authorizes the program to adopt regulations.
 1. specifies the procedures and requirements for adoption of regulations, including public participation.
 2. allows the program to impose requirements in the form of other generic legally binding requirements, such as orders.
- d. authorizes representatives of the program to enter premises and conduct inspections.
- e. authorizes the program to require compliance with regulatory requirements by both licensees and unlicensed individuals.
- f. authorizes the program to impose sanctions for violations of the regulations, orders, or

license conditions.

g. establishes conflict of interest and ethics regulations or procedures applicable to those portions of the State radiation control program covered by the Agreement.

If the program will include jurisdiction for licensing the receipt of low-level radioactive waste (LLW) from others for purposes of disposal the State should submit the law that authorizes the regulation of a LLW disposal site.

If the program will include the regulation of byproduct material as defined in Section 11e.(2) of the Act, the State should submit the law that authorizes the regulation of uranium and thorium recovery facilities including disposal of mill tailings.

4.1.1.2 Evaluation Criteria

(Note: The team may use the CSG suggested legislation as guidance. However, the State is not required to follow either the content or the format of the model legislation. If the Agreement will cover Section 11e.(2) byproduct material, Section 8 of the model legislation provides valuable suggested guidance on the Statutory provisions necessary to assume 11e.(2) byproduct material authority. If the Agreement will cover LLW disposal, see Section 9 of the model legislation.)

- a. State law must authorize the Governor to enter the Agreement. It must also designate a radiation control agency and provide it the necessary legal authority to be effective. [1, 24]⁴
- b. State law must not create duplications, gaps or conflicts in regulation. This includes duplications, gaps or conflicts between the State and NRC, State agencies, or State and local agencies. The law must not seek to regulate materials or activities reserved to NRC. [21, 24]
- c. State law must authorize issuing licenses as the means of giving the authority to possess and use materials. It should also authorize the reciprocal recognition of specific licenses issued by NRC or other Agreement States. [13, 27]
- d. State law should authorize the use of license conditions to address matters unique to the licensee. The law should allow license conditions to impose additional requirements when required to protect public health and safety. If the law restricts the use of license conditions, the State should show that they can provide adequate protection under the restrictions. The protection should be at least equivalent to using license conditions and orders. [12]

⁴ The numbers in brackets correlate to the numbered criteria in the Commission criteria policy statement (see handbook Section 2.2.1).

e. The law should permit exemptions from licensing requirements if the exemptions do not adversely affect public health and safety. This should include exemption from the requirement to obtain a license. The law should authorize exemptions from licensing substantially equivalent to the following (or such exemptions must be included in the State's regulations): [28]

i. Prime contractors working for the U.S. Department of Energy (DOE) at U.S. Government-owned or controlled sites;

ii. Prime contractors researching, developing, manufacturing, storing, testing, or transporting atomic weapons or components;

iii. Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

iv. Any other prime contractor (or subcontractors) of DOE or NRC when the State and NRC jointly determine (i) that the terms of the contract provide adequate assurance that the contractor can accomplish the work without undue risk to public health and safety and (ii) that the law authorizes the exemption.

f. The law must authorize the materials program to enforce regulations or generic legally binding requirements other than regulations. The law may authorize another agency (such as a board of health) to adopt the regulations. When appropriate, the law should provide for public participation. [19, 23]

g. The law must authorize inspections of licensee operations to ensure compliance with regulatory requirements. It should authorize inspections of unlicensed facilities to assess the risk resulting from accidents or environmental releases of materials. The law should permit access at all reasonable times. [17]

h. The law must provide authority to take prompt enforcement action, and should provide a variety of legal sanctions. The law should provide authority to suspend licenses and to impound materials. In cases of an imminent threat to public health and safety, the law should authorize immediate suspension without prior hearing. [19, 23]

i. The law should authorize suspension or revocation of a license for repeated or continued noncompliance. The authority to suspend or revoke a license may be conditioned on a prior administrative or judicial hearing. The program should also have authority to seek injunctive relief, and refer licensees for criminal prosecution. The program should also consider authority to impose civil or administrative monetary penalties. [19, 23]

The State must resolve any questions of interpretation of State law. NRC will accept interpretations provided by the State Attorney General, or other attorney designated as legal

advisor to the materials program.

4.1.1.3 Additional Evaluation Criteria for Low-level Waste Agreements

The law must authorize appropriate restrictions on land ownership and use of sites used for disposal of LLW for an indefinite period after closure of the site.

4.1.1.4 Additional Evaluation Criteria for 11e.(2) Byproduct Material Agreements

The law should clearly empower the program to carry out the requirements of the UMTRCA. Specifically, the law should:

- a. Authorize the program to regulate 11e.(2) byproduct material; [29]
- b. Authorize the program to require licensees to provide a financial surety arrangement. The arrangement should assure that sufficient funds will be available to cover the costs of both decommissioning and long-term surveillance and maintenance; [29]
- c. Require the program, before issuing an 11e.(2) byproduct material license, to do the following:
 - (1) give notice of the proposed licensing action and accept written comments during a public comment period; [29]
 - (2) prepare a written environmental analysis; [31]
 - (3) hold a public hearing with a transcript and cross examination; [29]
 - (4) prepare a written decision based on evidence presented during the public comment period. The decision must be subject to judicial review; [29]
 - (5) ban major construction before the completion of the written environmental analysis.
- d. Require the program to provide an opportunity for public participation through written comments or public hearings during rulemaking. The law must also make rules subject to judicial review; [29]
- e. Require the program, before terminating an 11e.(2) byproduct material license, to do the following:

- (1) transfer funds collected for decommissioning and long-term surveillance and maintenance to the United States. The law must require this transfer when custody of the disposal site transfers to the United States. Funds transferred must include all funds collected from a licensee or its surety. The only exceptions are funds collected for decommissioning if it is completed; [29]
- (2) choose whether or not to take title to the disposal site and byproduct material; [30]
- (3) obtain a determination from the Commission that all applicable standards are satisfied. [30]

The State law must consider the authorities reserved to the NRC under UMTRCA (see 10 CFR 150.15a), including the authority to: [30]

- a. Establish minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of the byproduct material;
- b. Determine, before the termination of a license, that the licensee has complied with decontamination, decommissioning and reclamation standards, and ownership requirements for sites at which 11e.(2) byproduct material is present;
- c. Require, before termination of a license for 11e.(2) byproduct material or for any activity that results in the production of such material, that the title to the byproduct material and the disposal site are transferred to the Federal Government (or the State at the option of the State, provided the State exercises the option before termination of the license);
- d. Require monitoring, maintenance, and emergency measures after the license is terminated as may be necessary to protect the public health and safety for those materials and property for which the State has assumed custody;
- e. Permit use of the surface or subsurface estate, or both, of the disposal site land transferred to the United States or the State;
- f. Exempt land ownership transfer requirements of Section 83(b)(1)(A) of the Act.

4.1.1.5 References

- a. Criteria Policy Statement, criteria 1, 9b, 12, 13, 17, 19, 21, 23, 24, 27, 28, 29, 30, and 31
- b. Council of State Governments *Suggested State Legislation*, 1983
- c. *Statement of Principles and Policy for the Agreement State Program* (62 FR 46517, 9/3/97)

4.1.2 Organization of the Proposed Program

The organization of a materials program provides the basic structure and resources to conduct the program activities. The program organization thus influences the ability of the program to protect public health and safety against radiation hazards.

4.1.2.1 Information Needed

The State should submit a concise narrative description of the materials program. The narrative should include:

- a. A brief history of radiation control in the State;
- b. A description of the current structure of the program, including regional offices;
- c. Individual discussions of each of the program elements in this handbook Section 4.0;
- d. For each program element, cross-references to the pertinent portions of the supporting information.

The State should submit organization charts. The charts should show:

- a. All organizational levels between the Governor and the State program Director or designee;
- b. The structure and staff of the materials program;
- c. Regional offices and staff.

The State should submit a copy of each Memorandum of Understanding (MOU) that will affect the materials program.

4.1.2.2 Evaluation Criteria

The organization of the Agreement materials program must cover all of the program elements in this handbook Section 4.0. For this criterion, it is only necessary to show that responsibility for each program element is assigned to a unit of the organization. [1]

The State may divide the program elements among separate agencies. If law does not specify the division, the State should describe how it divides the regulatory responsibility. The State should submit copies of MOU's describing the responsibilities of each agency. MOU's should also describe the efforts to assure cooperation and to ensure an orderly and consistent regulatory approach. The organization charts should clearly show the position of the program within the State government structure. [1, 24, 33]

The program organization charts should show both the technical staff and support staff positions. They should show positions assigned to the program both full-time and part-time. If the program uses the resources of another agency, the program narrative description should detail the relationship. The narrative description should also discuss any use of contract services and advisory bodies. (NOTE: the criteria for evaluation of the technical staff are in this handbook Section 4.6.1) [1]

4.1.2.3 References

- a. Criteria Policy Statement, criteria 1, 24, and 33
- b. Program descriptions of existing Agreement States (from IMPEP reports or previous Agreement requests)
- c. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- d. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix B

4.1.3 Content of the Proposed Agreement

An Agreement may transfer to a State the authority to regulate any one or more of the following materials within the State:

- a. Byproduct materials as defined in section 11e.(1) of the Atomic Energy Act;
- b. Byproduct materials as defined in section 11e.(2) of the Atomic Energy Act;
- c. Byproduct materials as defined in section 11e.(3) of the Atomic Energy Act;

- d. Byproduct materials as defined in section 11e.(4) of the Atomic Energy Act:
- e. Source materials;
- f. Special nuclear materials, in quantities not sufficient to form a critical mass.

In addition, an Agreement may transfer to a State the specific authority to conduct one or more of the following activities, which otherwise remain under NRC jurisdiction:

- a. The regulation of the land disposal of byproduct, source, or special nuclear waste materials received from other persons;
- b. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in the regulations or orders of the Commission.

MD 5.8 contains a standard Agreement format and text. The standard Agreement is based on the transfer of all categories of materials (known as a "full Agreement"). Agreements that do not transfer all of the categories (known as a "limited Agreement") should delete the appropriate provisions as shown in MD 5.8, Handbook. Staff is to consult with the Commission prior to proposing a final limited Agreement in instances where there is no clear precedent.

4.1.3.1 Information Needed

The State should submit a proposed Agreement. The Agreement should contain the categories of materials and specific authorities that the State wants to regulate.

The Agreement should follow the format and content of the standard Agreement in Exhibit 1 of MD 5.8, Handbook. If the State does not follow the standard Agreement, it must explain why. The explanation should describe the intent and the expected effect of the deviation.

4.1.3.2 Evaluation Criteria

The proposed Agreement must be consistent with the purpose of Section 274 of the Act. It must promote an orderly pattern of regulation. Nothing in it may create a duplication, conflict, or gap in the nationwide program for the regulation of materials. [27]

The Agreement should be consistent with the format and content of the standard Agreement in MD 5.8. The State should delete or modify articles in the standard Agreement only as shown in MD 5.8. Any other change requires additional information describing the need for the change and the expected result. Such changes may require separate approval by the Commission. The

information submitted must provide a basis for the Commission to approve the change. [26, 27]

The Agreement must transfer regulatory authority over all licensees in each category of materials listed in the Agreement. If the Agreement does not include all categories of materials and specific authorities, it should include Article III of the standard Agreement (see the exhibit to the handbook in MD 5.8). [27]

4.1.3.3 References

- a. Criteria Policy Statement, criteria 26, and 27
- b. NRC Management Directive 5.8, *Proposed 274b Agreements With States*

4.2 Regulatory Requirements Program Elements

A State may adopt regulatory requirements in a State specific format, or adopt the NRC regulations by reference. Alternately, the State may use the *Suggested State Regulations (SSR)*, published by the Conference of Radiation Control Program Directors (CRCPD), as a model for its regulations.⁵

4.2.1 Standards for Protection Against Radiation

The standards for protection against radiation include:

- a. the dose limits for occupationally exposed persons and members of the public;
- b. limits on the concentration and quantity of materials released to the environment;
- c. technical definitions and terminology, units of radioactivity and radiation dose, and radiation symbols, labels and warning signs.

4.2.1.1 Information Needed

The State should submit its regulations, or generic legally binding requirements, that prescribe the standards for protection against radiation.

⁵If using the SSR, the State should consult with the RSAO or PM to identify any compatibility issues, and the current status of NRC's compatibility determination on specific SSR parts. Note, SSR development and promulgation may lag behind the issuance of final NRC regulations.

If the State wants to regulate the disposal of low level radioactive waste at a land disposal site, it should submit its regulation equivalent to 10 CFR 61.41.

4.2.1.2 Evaluation Criteria

The State standards for protection against radiation must satisfy the criteria for compatibility category A. The criteria are given in the Handbook to MD 5.9. FSME Procedure SA-200, Appendix A, lists the equivalent NRC regulations. FSME Procedure SA-201, Appendices A and B, provide additional guidance. [2, 3, 5, 6, 9a, 11, 22]

The standards must apply to all categories of materials covered by the Agreement. They should also apply to all other sources of radiation regulated by the State. [2]

The standards must require consideration of the total occupational dose to individuals. [4]

If the State adopts generic legally binding requirements other than regulations, it should assure consistency in their application. The requirements should not confuse either the licensees or the regulatory program staff. The State must show that the alternative requirements are legally binding under State law.

4.2.1.3 References

- a. Criteria Policy Statement, criteria 2, 3, 4, 5, 6, 9a, 11, and 22
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Title 10 CFR Parts 20, 30, 35, 40, 61, 71, and 150
- e. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.2.2 Regulatory Requirements with Significant Transboundary Implications

The regulatory requirements with significant transboundary implications are:

- a. regulations that affect the movement of materials across State borders;
- b. certain other regulations, such as the limits for quantities and concentrations of materials exempt from licensing, requirements for sealed sources and devices (SS&D), and the waste classification system in 10 CFR Part 61.

4.2.2.1 Information Needed

The State should submit its regulations, or generic legally binding requirements, that prescribe the regulatory requirements with significant transboundary implications.

4.2.2.2 Evaluation Criteria

If the State adopts the NRC regulations by reference, the State rule should disclaim any intent to regulate materials or activities over which NRC retains jurisdiction.

The State regulations that may have significant effect across jurisdictional boundaries must satisfy the criteria for compatibility category B. The criteria are given in the Handbook to MD 5.9. FSME Procedure SA-200, Appendix A, lists the equivalent NRC regulations. [6, 9a, 10]

4.2.2.3 References

- a. Criteria Policy Statement, criteria 6, 9a, and 10
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Title 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150
- e. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.2.3 Regulatory Requirements Needed for an Orderly Pattern of Regulation or Which Have Particular Health and Safety Significance

The regulatory requirements needed for an orderly pattern of regulation or which have particular health and safety significance are:

- a. regulations whose essential objectives are needed to prevent undesirable consequences. Examples of such consequences are given in MD 5.9, Handbook, Part II, Section C.
- b. regulations needed for health and safety. Examples are given in MD 5.9, Handbook, Part II, Section E.

4.2.3.1 Information Needed

The State should submit its regulations, or generic legally binding requirements, that apply the essential objectives of the NRC regulations designated compatibility category C or H&S.

If the State wants to regulate uranium and thorium mill tailings, it should submit a copy of its requirements equivalent to 10 CFR Part 40, Appendix A.

If the State wants to regulate the disposal of LLRW at a commercial land disposal site, it should submit its regulations equivalent to the regulations in 10 CFR Part 61 designated compatibility category C or H&S.

4.2.3.2 Evaluation criteria

If the State adopts the NRC regulations by reference, the State rule should disclaim any intent to regulate materials or activities over which NRC retains jurisdiction.

The State regulations or generic legally binding requirements needed for an orderly pattern of regulation, or which have particular health and safety significance, shall satisfy the criteria for compatibility category C. The criteria are given in the Handbook to MD 5.9. FSME Procedure SA-200, Appendix A, lists the equivalent NRC regulations. [1, 7, 8, 11, 32]

4.2.3.3 References

- a. Criteria Policy Statement, criteria 1, 7, 8, 11, and 32
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Title 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150
- e. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.3 Licensing Program Elements

The review team should be able to conclude that the State's technical licensing procedures will be protective of public health and safety. A State may adopt technical licensing procedures modeled on the NRC procedures, or those used by an existing Agreement State.

Nontechnical administrative procedures are usually not key contributors to program

performance. The review team usually reviews samples of these procedures. The team only needs to conclude that the State has written administrative procedures for licensing, and that they contain no obvious major defects.

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

The technical procedures address the health physics issues necessary to assure the safe storage, possession and use of the licensed materials. They do not address license fees, license file maintenance, or other materials program administrative issues.

4.3.1.1 Information needed

The State should submit its technical licensing procedures. If not part of the procedure, the State should include standard review plans, checklists, and licensing guides.

4.3.1.2 Evaluation criteria

The procedures should ensure a thorough and equitable evaluation of the application. The procedures should cover each type license (by program code) for which an NRC licensee will transfer to the State. Guidance documents, or copies of the procedures containing guidance, should be available to license applicants. [1, 13, 23]

The procedures should:

- a. address the applicant's facilities and safety equipment, training and experience in the use of the materials for the purpose requested, and proposed managerial controls; [13]
- b. provide for information exchange between the program's inspection staff and licensing staff, as appropriate; [1]
- c. specify the required qualifications of license reviewers for each license program code. Alternately, the procedures may reference a staff qualification plan.

Properly qualified persons (normally licensed physicians) must direct the medical use of materials. Qualifications should include prescribed minimum training and experience in the medical use of radioisotopes or radiation. The training requirements should be compatible to those in 10 CFR Part 35. [15]

State procedures should provide guidance for the evaluation of technical issues in license applications. The issues evaluated include: places and conditions of storage; places and conditions of use, and decommissioning of facilities and equipment. Evaluation of the places of storage and use should address environmental considerations. [13, 14]

State procedures for evaluating the conditions of storage and use should address security against unauthorized removal, and safety equipment. Procedures for evaluating the conditions of use should address the following: [13]

- a. qualification of users;
- b. licensee operating and emergency procedures;
- c. appropriate surveys;
- d. personnel monitoring under the close supervision of technically competent individuals;
- e. preparations for transport.

Procedures for evaluating decommissioning should address decontamination, disposal, and any restrictions on the future uses of the property. The procedures should also address funding and sureties. [13]

In licensing research and development, medical uses, or other activity involving multiple uses of materials, the State may issue broad scope licenses without evaluating each specific use. [13]

The team may use NRC procedures and consolidated guidance to evaluate the State procedures. However, we do not require States to adopt the NRC procedures and consolidated guidance. The State procedures should provide the same level of detail as the equivalent NRC procedure. They should address all significant technical issues.

4.3.1.3 References

- a. Criteria Policy Statement, criteria 1, 13, 14, 15, 20, and 23
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. FSME Procedure SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions*

- d. NUREG-1556, *Consolidated Guidance About Materials Licenses* (all volumes)
- e. Decommissioning specific: MARSSIM, DG-4006, NUREG-0241, NUREG-5849

4.3.2 Procedures for the Evaluation of Radiation Safety Information on Sealed Sources and Devices(SS&D), and Registration for Distribution

Sealed sources, and devices containing sealed sources, are commonly manufactured in one jurisdiction and used in others. Because of the transboundary implications, safety evaluations of the sources and devices should be conducted according to similar procedures nationwide.

4.3.2.1 Information Needed

The State should submit its procedure for evaluating radiation safety information on SS&D.

If the State will use contractor assistance in the evaluation, its procedures for the quality assurance of contractor performance should be submitted.

4.3.2.2 Evaluation Criteria

The State procedures should be essentially identical to the equivalent NRC procedures with respect to: [13]

- a. technical issues evaluated;
- b. technical criteria used to decide the adequacy of the safety information provided;
- c. use of a concurrence review;
- d. content and format of the registration sheets.

For additional criteria, see the IMPEP SS&D indicator (non-common performance indicator 2) in MD 5.6, Handbook (dated February 26, 2004 or later).

The review team may use NRC's consolidated guidance about applications for SS&D evaluation and registration in NUREG-1556, Volume 3, as a guide.

4.3.2.3 References

- a. Criteria Policy Statement, criterion 13
- b. NUREG-1556, *Volume 3, Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*
- c. FSME Procedure SA-108, *Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program*

4.3.3 Procedure for Conducting the Evaluation of a Regulatory Program for a Low-level Radioactive Waste (LLRW) Land Disposal Site

The regulatory program for a commercial land disposal site for LLRW has significant health and safety implications. It requires substantial resources beyond those needed for conducting routine licensing evaluations and inspections. If the State will regulate a site, it should have the resources and procedures to conduct a site license evaluation and inspection program, even if NRC will transfer an established site.

If NRC will not transfer a licensed site or an application for a site license, and there is no reasonable expectation of an application for a license being submitted in the foreseeable future, the State may assume the authority without having the resources and procedures in place. In this case, information showing that the State has the authority to acquire the resources and adopt appropriate procedures before undertaking the evaluation of an application, accompanied by the conceptual description of the program, is sufficient.

4.3.3.1 Information Needed

The State should submit a concise description of its program for regulating a commercial land disposal site. The description should include a discussion of the resources available to the program. The State should also submit its procedures for conducting the technical licensing evaluation and inspection program.

If the State proposes to use contractor assistance in the evaluation, procedures for the quality assurance of contractor performance should be submitted.

4.3.3.2 Evaluation Criteria

The State procedures should contain the same level of detail as the NRC procedures in NUREG-1199, 1200, and 1274. However, we do not require the procedures to be identical if they address all significant objectives. The State procedures should be consistent with the NUREG with respect to the following: [9, 13]

- a. technical issues evaluated;
- b. qualifications of the personnel performing evaluations;
- c. assuring the quality of the licensing action;
- d. inspection procedures, including security-related inspections.

4.3.3.3 References

- a. Criteria Policy Statement, criteria 9 and 13
- b. NUREG-1199, *Standard Format and Content for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility*, NUREG-1200, *Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility*, NUREG-1300, *Environmental Standard Review Plan for the Review of a License Application for a Low-Level Waste Disposal Facility*, NUREG-1274, *Review Process for Low-Level Radioactive Waste Disposal License Applications Under Low-Level Radioactive Waste Policy Amendments Act*.
- c. FSME Procedure SA-109, *Reviewing the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program*.

4.3.4 Procedure for Conducting the Evaluation of a Regulatory Program for 11e.(2) Byproduct Material including Uranium or Thorium Milling Facilities

The regulatory program for 11e.(2) byproduct material including a uranium or thorium milling facility has significant health and safety implications. It requires substantial resources beyond those needed for conducting routine licensing evaluations and inspections. If the State will regulate a site, it should have the resources and procedures to conduct a site evaluation and inspection, even if NRC will transfer an established site.

If NRC will not transfer a licensed site or an application for a site license, and there is no reasonable expectation of an application for a license being submitted in the foreseeable future, the State may assume the authority without having the resources and procedures in place. In this case, information showing that the State has the authority to acquire the resources and adopt appropriate procedures before undertaking the implementation of a program, accompanied by the conceptual description of the program, is sufficient.

4.3.4.1 Information Needed

The State should submit a concise description of its program for regulating 11(e).2 byproduct

material. The description should include a discussion of the resources available to the program. The State should also submit its procedures for conducting the technical licensing evaluations and inspections.

If the State will use contractor assistance in the evaluation, it should submit procedures for assuring the quality of contractor performance.

4.3.4.2 Evaluation Criteria

The State procedures should contain the same level of detail as the equivalent NRC procedures. However, we do not require the procedures to be identical to ours if they address all significant technical issues. The State procedures should be consistent with the NRC procedures with respect to the following: [35]

- a. technical issues evaluated;
- b. qualifications of the personnel performing evaluations;
- c. assuring the quality of the licensing action;
- d. inspection procedures, including security-related inspections

4.3.4.3 References

- a. Criteria Policy Statement, criterion 35
- b. NRC Uranium Recovery Program Policy and Guidance Directives
- c. FSME Procedure SA 110, *Reviewing the Non-Common Performance Indicator, Uranium Recovery Program*

4.3.5 Procedures for Assuring the Technical Quality of Licenses

Secondary review of license applications adds value to, and helps assure the integrity of, the application evaluation process. Peer and supervisory review are commonly used. Larger programs may use a committee to conduct reviews of selected application evaluations recently completed. Other forms of effective quality assurance are acceptable.

4.3.5.1 Information Needed

The State should submit its procedures that address peer review, supervisory review, and any other method to assure the quality of licensing actions.

4.3.5.2 Evaluation Criteria

The State should have written licensing procedures that provide some form of review for licensing quality. We do not prefer a particular form or method. The procedures should reflect the organization of the State program and any special requirements of State law. [1, 13]

4.3.5.3 References

- a. Criteria Policy Statement, criteria 1, and 13
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. FSME Procedure SA-104, *Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program*

4.3.6 Administrative Licensing Procedures

The routine operation of the program requires administrative processing of licenses beyond the technical evaluations. Written procedures describing the administrative processing steps are useful to assure that all procedural requirements are completed. They may become critical if there is an unexpected turnover of senior staff.

Generally, NRC transfers to the State those NRC licenses that the State will regulate. The State recognizes the transferred NRC licenses, including licenses under timely renewal, as State licenses. Those licenses continue in effect until they are replaced by State issued licenses. The State may propose an alternative to transferring licenses, if desired.

4.3.6.1 Information Needed

The State should submit its administrative procedures for licensing. The procedures should address the following:

- a. receipt of licensing actions;
- b. assignment of licensing actions to technical evaluators;
- c. license document preparation;
- d. tracking of action progress;
- e. the signing of completed licenses;

- f. transmittal of the signed license to the licensee;
- g. license file maintenance.

The State should submit procedures for assuring the continued validity of licenses affected by the Agreement. If NRC will transfer its licenses to the State, the State should have procedures to receive, store, and regulate the licenses as State licenses. If an alternative to transferring licenses is proposed, appropriate procedures should be submitted. In either case, the transfer should produce the least interference with licensed activities or the processing of license applications that is practical.

4.3.6.2 Evaluation Criteria

The State should have program specific written procedures to guide licensing program staff. The procedures should reflect the program organization and any special requirements of State law (i.e., who can sign licenses). Since these procedures do not require a thorough review, the team may review a selected sampling of the procedures instead. [1]

The State must provide procedures for the continued operation of transferred NRC licensees. [25]

4.3.6.3 References

- a. Criteria Policy Statement, criteria 1 and 25

4.4 Inspection Program Elements

A State may adopt technical inspection procedures modeled on IMC 2800, or the procedures of an existing Agreement State.

Nontechnical administrative procedures, such as a procedure for assigning inspections to inspectors, are usually not key contributors to program performance. The review team usually reviews samples of these procedures. The team only needs to conclude that the State has written administrative procedures for inspections, and that they contain no obvious major defects.

4.4.1 Procedures for Inspecting Facilities Where Radioactive Material Is Stored or Used

The technical inspection procedures should address the scheduling of inspections and the different kinds of inspections (i.e., routine, reactive, reciprocity, security, etc.). They should also address the performance of inspections. The technical procedures should not address administrative matters, such as inspection fees.

The technical procedures should address the form and guidance for inspection reports. They should also address giving notice to the licensee of whether or not it is in compliance.

The technical procedures should address field instrumentation and laboratory analysis. Calibration and quality assurance should be included.

4.4.1.1 Information Needed

The State should submit inspection procedures, including inspection report formats, checklists, status reports, etc. Procedures submitted should cover all NRC license program codes of licensees that will transfer to the State.

The State should also submit its priority schedule for inspections by program code and its schedule for reciprocity inspections.

4.4.1.2 Evaluation Criteria

The State should perform inspections following written procedures that address inspection activities appropriate to the category of licensee being inspected. [1]

The State should relate inspection frequency to the amount and kind of material and type of operation licensed. Routine, initial, and reciprocity inspections should not be less frequent than NRC inspections as listed in IMC 2800. [16]

Inspection procedures should provide for information exchange between the inspection staff and the licensing staff, as appropriate. [1]

The procedures should provide guidance on the use of both field and laboratory instrumentation to ensure the licensee's control of materials and to validate the licensee's measurements. The State should submit a list of its instrumentation for review. The procedures should include instrumentation calibration. [16, 36]

If the Agreement covers Section 11(e).2 byproduct material, the procedures should also: [36]

- a. provide the capability for quantitative and qualitative analysis of radionuclides associated with natural uranium and its decay chain, primarily; U-238, Ra-226, Th-232, Pb-210, and Rn-222, in a variety of sample media such as will be encountered from an environmental sampling program;
- b. provide analysis and data reduction from laboratory analytical facilities within 30 days of submittal. State acceptability of quality assurance (QA) programs should also be established for the analytical laboratories;

- c. provide arrangements for a large number of samples in a variety of sample media resulting from a major accident to be analyzed in a time frame that will allow timely decisions to be made regarding public health and safety.

The procedures should provide the notice to the licensee in a short period, usually within 30 days after the inspection. [18]

The team may use NRC inspection procedures as guidance to evaluate the State inspection procedures. The State procedures should provide approximately the same level of detail as the equivalent NRC procedure. However, the procedures are not required to be uniform if they address all significant technical issues. We do not require States to adopt the NRC procedures.

4.4.1.3 References

- a. Criteria Policy Statement, criteria 1, 16, 18, and 36
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. FSME Procedures SA-101, *Reviewing the Common Performance Indicator, Status of Materials Inspection Program*; and SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections*
- d. NRC Inspection Manual Chapters 1220, 2800, and 2801
- e. NRC Inspection Procedures 87101 through 87120, and others as appropriate

4.4.2 Procedures for Assuring the Technical Quality of Inspections and Inspection Reports

Secondary review of inspection reports adds value to, and helps assure the integrity of, the inspection process. Peer and supervisory review are commonly used. Larger programs may use a committee to conduct reviews of selected inspections recently completed. Other forms of effective quality assurance are acceptable.

4.4.2.1 Information Needed

The State should submit its procedures addressing peer review, supervisory review, and any other method to assure the quality of inspections and inspection reports.

4.4.2.2 Evaluation Criteria

The State should also have written procedures to guide program staff. We do not prefer any

particular form or method. The procedures should reflect the organization of the State program and any special requirements of State law. [1, 16]

4.4.2.3 References

- a. Criteria Policy Statement, criteria 1, and 16
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. FSME Procedure SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections*
- d. NRC Inspection Manual Chapter 2800

4.4.3 Administrative Procedures for Inspections

The routine operation of the program requires administrative processing of an inspection report after the inspector has written it. Written procedures describing the administrative processing steps are useful to assure that all procedural requirements are completed. They may become critical if there is an unexpected turnover of senior staff.

4.4.3.1 Information Needed

The State should submit its inspection program administrative procedures.

4.4.3.2 Evaluation Criteria

The State should have program specific written procedures. The procedures should reflect the organization of the State program and any special requirements of State statute (i.e., public disclosure or confidentiality). [1]

Since these procedures do not require a thorough review, the team may review a selected sampling of the procedures instead.

4.4.1.3 References

- a. Criteria Policy Statement, criterion 1
- b. NRC Inspection Manual Chapter 2800 and 2801

4.5 Enforcement Program Elements

A State may adopt enforcement procedures modeled on the NRC procedures, or those used by another Agreement State. The routine procedures include a notice of the violation to the licensee. Escalated enforcement procedures supplement routine enforcement procedures, and are for serious or repeated violations.

4.5.1 Routine Enforcement Procedures

Routine enforcement procedures describe the actions the program takes in response to a violation of a regulatory requirement that is not serious in nature, and is not a repeated violation.

4.5.1.1 Information Needed

The State should submit its procedures for routine enforcement.

4.5.1.2 Evaluation Criteria

The State should have procedures for assuring the fair and impartial administration of regulatory law. They should scale the actions to the seriousness of the violation. [23]

The procedures should establish standard methods of communicating sanctions to the licensee. The State should give written notice using standardized wording and format. Legal counsel should review the wording and format. [18]

The procedures should include a means for tracking the completion of enforcement actions. [1]

4.5.1.3 References

- a. Criteria Policy Statement, criteria 1, 18, and 23
- b. NUREG-1600, *NRC Enforcement Policy*
- c. NRC Inspection Manual Chapter 2800 and 2801

4.5.2 Escalated Enforcement Procedures

For serious or repeated violations of regulatory requirements, the program should use escalated enforcement. Escalated enforcement actions usually supplement the routine actions. Escalated enforcement actions may include:

- a. administrative or civil monetary penalties;
- b. the modification, suspension, or revocation of the license;

c. referral for criminal prosecution.

4.5.2.1 Information Needed

The State should submit its procedures for escalating enforcement actions.

4.5.2.2 Evaluation Criteria

The State should scale the sanctions in escalated enforcement cases to the seriousness of the violation. The sanctions should be more severe than routine enforcement. [23]

The procedures should address notifying the licensee of proposed escalated enforcement actions. The notice should be written, using standard wording and format when practical. [18, 19]

The enforcement program element manager, or higher, should sign notices of escalated enforcement. [23]

Escalated enforcement actions should be coordinated with legal counsel. [19]

4.5.2.3 References

- a. Criteria Policy Statement, criteria 18, 19, and 23
- b. NUREG-1600
- c. NRC Inspection Manual Chapter 2800 and 2801

4.6 Technical Staffing and Training Program Elements

The State should adopt technical staffing standards similar to NRC's standards. The State may adopt training and qualification procedures modeled on NRC's procedure in IMC 1246, or on the report of the OAS/NRC working group.

To evaluate some complex cases, the staff may need to be supplemented by consultants or staff from other State agencies.

4.6.1 Technical Staff Organization

The State should conduct an analysis of the expected workload, and establish an appropriate staffing plan. The analysis should consider the number, distribution, and sizes of the licensees that will transfer under the Agreement. Sample forms for a staffing analysis are in handbook Appendix B.

The staffing analysis should also consider if the State will: evaluate the radiation safety information on SS&D containing materials and register the sealed sources or devices for distribution; license a LLRW commercial land disposal site; license uranium or thorium recovery facility subject to the requirements of UMTRCA; license major manufacturers, universities with major research programs, or other large scale materials users; or will need to perform increased controls inspections on affected licensees.

4.6.1.1 Information Needed

The State should submit its program staffing plan, including organization charts. The staffing plan should show the number of staff members assigned to specific responsibilities, such as license review and inspection and for each major category of licensee. It should estimate the workload for the licensees that will transfer, and the other duties of the program.

4.6.1.2 Evaluation Criteria

The State is not required to use the sample forms in handbook Appendix B. If used, the State should modify the forms as needed to reflect the mix of license programs that the State will regulate.

The State must staff the program with enough qualified personnel. The staff must consist of at least two technical staff. [20]

We have no criteria for the number of staff required, but the experience of existing Agreement States should be considered. Depending on training and experience, Agreement State programs typically employ one to 1.5 technical staff members per 100 active licenses. Waste disposal sites or uranium mills require additional staff. The distribution of staff should be based on workload estimates that are consistent with NRC and other Agreement State programs experience. [20, 34]

The State workload estimate should be based on the State's organization, policies, practices, and procedures. The State should not create a staffing plan based solely on the NRC staffing plan. [20]

4.6.1.3 References

- a. Criteria Policy Statement, criteria 20 and 34
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. FSME Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training*

4.6.2 Formal Qualification Plan

The ability to conduct an effective material program depends on having enough trained and experienced staff members. Since retirements and other normal events cause the departure of staff members, there must be a plan for staff replacement.

4.6.2.1 Information Needed

The State should submit its position descriptions, and its plan for the formal qualification of technical staff members.

4.6.2.2 Evaluation Criteria

Each technical staff position should require a bachelor's degree in the physical or life sciences, or engineering. An equivalent combination of education and experience may substitute for the degree. [20]

The program should have a written qualification plan. It should address job specific training and experience. The plan should specify the qualification procedures, including times for completing requirements. It should address the credentialing of individuals qualified to work independently. The plan should provide for interim qualification and certification by the State program Director or designee. [20]

The plan should meet the training and qualification requirements in the NRC/OAS working group recommendations. IMC 1246 may be used as general guidance. [20]

4.6.2.3 References

- a. Criteria Policy Statement, criterion 20
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. NRC Inspection Manual Chapter 1246
- d. NRC/OAS Training Working Group, *Recommendations for Agreement State Training Programs*, STP All-Agreement States Letter SP-97-087⁶

⁶Available at the STP Internet website www.hsr.gov/nrc/home.html; click on "NRC-State Letters," then search for "087" in 1997 Letters

e. FSME Internal Procedure SA-103

4.6.3 Qualifications of Current Technical Staff

The program staff qualifications should cover both routine functions and emergency cases. The distribution of staff qualifications and the distribution of licensees transferred should match. For example, there should be enough inspectors qualified to inspect industrial radiography licensees that a backlog of industrial radiography inspections will not develop.

4.6.3.1 Information Needed.

The State should submit the resume of each current member of the technical staff. The resume should, as a minimum, show the educational level, experience, and any speciality training. For staff members admitted into training courses not yet completed, submit the course name or description and scheduled dates.

For each current staff member, identify the individual's qualifications (including interim qualifications) under the State's written qualification plan.

4.6.3.2 Evaluation Criteria.

Except for some junior positions, all staff members should meet the program's own qualification requirements. [20]

The review team may consider the State's experience working with NRC inspectors and license reviewers. It may also consider experience regulating non-Agreement materials and machine-produced sources of radiation. [20]

4.6.3.3 References

- a. Criteria Policy Statement, criterion 20
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. NRC Inspection Manual Chapter 1246

4.7 Event and Allegation Response Program Elements

A State may adopt event and allegation response procedures modeled on NRC procedures, or those used by another Agreement State. The procedures for reporting events to NRC should be modeled on FSME Procedure SA-300.

4.7.1 Procedures for Responding to Events and Allegations

The program must have written procedures for responding to materials events within the State. The response capability may be part of another organization, such as a response organization for fixed nuclear facilities. However, it is still part of the materials program under the Agreement. The program should also have written procedures for reporting events to NRC and to the Nuclear Materials Events Database (NMED).

The program should have written procedures for responding to allegations of violations of regulatory requirements. The program does not need to have criminal investigatory capability within the program or its parent agency. If it does not, then it should have procedures for contacting appropriate authorities when needed.

4.7.1.1 Information Needed

The State should submit its procedures for responding to events and allegations.

4.7.1.2 Evaluation Criteria

Event response procedures should be consistent with, but need not be identical to NRC procedures. The procedures should address the following: [1, 11]

- a. immediate response and actions to mitigate an event;
- b. follow-up inspections and enforcement actions;
- c. notifications to licensing staff;
- d. reports to the incident file;
- e. notifications to other affected licensees of generic problems.

Allegation procedures should address response, follow-up and closeout. They should also provide for protection of the identity of a person making an allegation when requested. The procedures should also provide for the protection of other sensitive information. [1, 11]

4.7.1.3 References

- a. Criteria Policy Statement, criteria 1 and 11
- b. NRC Management Directive 8.8, *Management of Allegations*
- c. NRC Inspection Manual Chapter 1300 through 1303, and 1330
- d. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- e. FSME Procedure SA-105, *Reviewing Common Performance Indicator #5, Response to Incidents and Allegations*
- f. FSME Procedure SA-300, *Reporting Material Events*
- g. FSME Procedure SA-400, *Management of Allegations*

4.7.2 Procedures for Identifying Significant Events and Allegations, and for Entering Same into the Nuclear Materials Events Database

NRC has established a database (NMED) of materials events, including incidents, accidents, and medical misadministrations. The States must report to NMED all events that NRC regulations (or equivalent State regulations) require the licensees to report.

4.7.2.1 Information Needed

The State should submit its procedures for generating event reports. It should also submit its procedures for entering reports in the NMED database.

4.7.2.2 Evaluation Criteria

The State procedures should assign responsibility for the completion of the reports, and for assuring the quality of the reports. They should specify times for completion of the reports and submitting them to NRC. The procedures should provide guidance for identifying abnormal occurrences. [1, 11]

The procedures should contain criteria for identifying reportable events. They should guide forwarding reports (notification, follow up, and closeouts) to NRC for inclusion in NMED. The State procedures should be consistent with the STP Procedure SA-300 Handbook, *Nuclear Material Event Reporting in the Agreement States*. [1, 11]

4.7.2.3 References

- a. Criteria Policy Statement, criteria 1 and 11
- b. FSME Procedure SA-300 Appendix, *Handbook on Nuclear Material Event Reporting in the Agreement States*

Glossary

CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors, Inc.
DG	Draft regulatory guide
DNMS	Division of Nuclear Materials Safety (NRC regional organization units)
EPACT	Energy Policy Act of 2005
FSME	Office of Federal and State Materials and Environmental Management Programs
FTE	Full Time Equivalent of personnel effort
IMC	NRC Inspection Manual Chapter
IP	NRC Inspection Procedure
LLRW	Low-Level Radioactive Waste
MD	NRC Management Directive
DMSSA	Division of Materials Safety and State Agreements
MOU	Memorandum of Understanding
NMED	Nuclear Materials Event Database
NMSS	NRC Office of Nuclear Materials Safety and Safeguards
NARM	Naturally occurring or accelerator produced materials
NRC	United States Nuclear Regulatory Commission
SA	FSME Agreement States Procedure
SSR's	<i>Suggested State Regulations</i> , published by the CRCPD
OGC	NRC Office of the General Counsel
RSAO	Regional State Agreements Officer (NRC staff)
UMTRCA	Uranium Mill Tailings Radiation Control Act of 1978, as amended

Definitions

As used in this document:

Act - means the Atomic Energy Act of 1954, as amended.

Commission - means the United States Nuclear Regulatory Commission

Civil penalty - means a monetary fine imposed and collected by the materials program, or by apparent agency. Also known as an "administrative fine."

Generic legally binding requirement - means a legally enforceable statement, limited in the extent of its application, that implements or interprets law or describes procedural requirements, and that is adopted in accordance with the administrative procedures of the promulgating jurisdiction. Examples are license conditions or orders. Generic legally binding requirements differ from regulations in that they are directed to a specifically identified constituency. To be considered generic, however, the requirements should be made effective upon all members of any class of licensees or other persons upon which a regulation would have effect.

License - includes registrations, permits, and certifications.

License application - means the formal request for a new license, a license renewal, or a license amendment, as appropriate, made in accordance with the administrative licensing procedures of the jurisdiction.

Materials - generally means byproduct, source, and special nuclear materials, as defined in the Act. However, if appropriate to the context, it may include naturally occurring or accelerator produced radioactive materials, if such radioactive materials are regulated by the same program designated to regulate byproduct, source, and special nuclear materials under the agreement.

Memorandum of Understanding - means any formal statement of cooperation between agencies. The term "Letters of Agreement" is equivalent.

Procedure - means a written statement delineating the steps in an activity, may include "policy" statements.

Program - means the organization within a jurisdiction that is specifically dedicated to the regulation of materials. It may be a separate organizational unit, or a subunit of an organization with wider responsibilities. It may also consist of the sum of the materials program elements distributed over several organizations. The NRC materials program consists primarily of FSME and the DNMS of each region, but includes the support activities provided by other NRC Offices as required.

Radiation - means ionizing radiation only.

Regulation - means a legally enforceable statement of general applicability that implements or interprets law or describes procedural requirements, and that is adopted in accordance with the administrative procedures of the promulgating jurisdiction. The term "rule" is equivalent.

Appendix A

Cross Index Table

Section	Program Element	Information from State	Criteria number ^(a)	References
4.1	Legal Elements			
4.1.1	Statutory Authority	Sections of State Law that authorize the program and the Agreement	1, 9b, 12, 13, 17, 19, 21, 23, 24, 27, 28, 29, 30, and 31	Suggested State Legislation; Statement of Principles and Policy for the Agreement State Program
4.1.2	Program Organization	Detailed narrative description of radiation protection program	1, 24, and 33	Program descriptions from IMPEP reports; MD 5.9; and SA-200 Appendix B
4.1.3	Content of Agreement	Proposed Agreement	26, and 27	MD 5.8
4.2	Regulatory Elements			
4.2.1	Radiation Protection Standards	State standards for protection against radiation	2, 3, 4, 5, 6, 9a, 11, and 22	MD 5.9; SA-200 Appendix A; 10 CFR Parts 20, 30, 35, 40, 61, 71, and 150; SSR's
4.2.2	Transboundary Requirements	State regulations with significant transboundary implications	6, 9a, and 10	MD 5.9; SA-200 Appendix A; 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150; SSR's

Section	Program Element	Information from State	Criteria number ^(a)	References
4.2.3	Orderly Pattern of Regulation or Health and Safety Significance	State regulations that apply the essential objectives of NRC regulations designated category C or H&S	1, 7, 8, 11, and 32	MD 5.9; SA-200 Appendix A; 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150; SSR's
4.3	Licensing Program			
4.3.1	Materials licensing	Licensing Program description and procedures; licensing guides	1, 13, 14, 15, 20, and 23	MD 5.6; SA-104; NUREG-1556 series; MARSSIM, DG-4006, NUREG-0241, NUREG-5849
4.3.2	SS&D Safety Evaluations	SS&D Program description and procedures	13	NUREG-1556, Volume 3
4.3.3	Low-level Waste Site Licensing	LLW Program description and procedures	9, and 13	NUREG-1199, NUREG-1200, NUREG-1300, NUREG-1274
4.3.4	Uranium or Thorium Mill Licensing	11e.(2) Program description and procedures	35	NRC Uranium Recovery Program Policy and Guidance Directives
4.3.5	Licensing Quality Assurance	Procedures for review of licensing quality	1, and 13	MD 5.6; and SA-104
4.3.6	Licensing Administrative Procedures	Procedures for processing licensing actions	1, and 25	

Section	Program Element	Information from State	Criteria number ^(a)	References
4.4	Inspection Program			
4.4.1	Inspection Procedures	Inspection Program description, inspection procedures and guides, report formats, inspection frequency	1, 16, 18, and 36	MD 5.6; SA-101 and 102; IMC 1220 and 2800; IP 87101 thru 87120
4.4.2	Inspections Quality Assurance	Procedures for review of inspection quality	1, and 16	IMC 2800; MD 5.6 and SA-102
4.4.3	Inspection Administrative Procedures	Procedures for processing & filing inspection reports	1	IMC 2800
4.5	Enforcement Program			
4.5.1	Routine Enforcement Procedures	Enforcement program description and procedures for routine enforcement actions, notice of violation letters	1, 18, and 23	NUREG-1600 and IMC 2800
4.5.2	Escalated Enforcement Procedures	Procedures for escalated enforcement actions, procedures for legal assistance	18, 19, and 23	NUREG-1600 and IMC 2800
4.6	Technical Staff			

Section	Program Element	Information from State	Criteria number ^(a)	References
4.6.1	Technical Staff Organization	Staffing plan	20, and 34	MD 5.6; SA-103; recent Agreement State application
4.6.2	Formal Qualification Plan	Formal qualification plan for technical staff	20, and 34	MD 5.6; IMC1246 or NRC/OAS Training Working Group Recommendations for Agreement State Training Programs
4.6.3	Current Technical Staff Qualifications	Resumes or CV's of current technical staff	20, and 34	MD 5.6; IMC1246; recent Agreement State application
4.7	Event & Allegation			
4.7.1	Event & Allegation Response Procedures	Program description and procedures for responding to incidents and allegations	1, and 11	MD 5.6 and 8.8; SA-105 and 300; IMC 1300 - 1303, 1330
4.7.2	Event Reporting Procedures	State NMED reporting procedures	1, and 11	SA-300 Appendix; Handbook

(a) See section 2.2.1

Appendix B
Staffing Analysis Forms

Staff Need / Resource Analysis

Instructions

Address all Major Program Areas. Note that the following is representative and may not be a complete list of technical staff activities for any particular program.

A. Need Analysis

1. In the Licensing and Inspection Program Areas: For each License Category, enter the number of licenses (not licensees) your program will have. See the sample "NEED ANALYSIS" form, attached.
2. Estimate the average number of licensing actions (new, renewal, amendments, and terminations) you expect to receive per year per license in that category. For estimate assistance, talk to your NRC Region and the existing Agreement States about their experience.
3. Estimate the number of staff days you need to process an average action.
4. Multiply the estimates in steps 2 and 3 to derive an estimate of the number of staff days you will need to process the expected licensing actions for that category.
5. Repeat steps 2, 3 and 4 for inspections. Include reactive inspections, and consider preparation, travel, on-site, and report writing time.
6. Conduct a similar analysis for the other Major Areas of your Program. You should consider: regulation development; decommissioning (including Complex decommissioning sites); response to incidents and allegations; contingencies and unanticipated work; and supervisory functions (including inspector accompaniments).

B. Resource Analysis

1. Enter staff member ID in blank boxes on top row. See the sample "RESOURCE ANALYSIS" form, attached.
2. In the Licensing and Inspection Program Areas: For each License Category the individual is qualified to inspect, enter the number of days the individual will be available for inspections of those licensees.

3. For each License Category the individual is qualified to review licenses, enter the number of days the individual will be available for reviewing actions of those licensees.
4. For each License Category, sum the days available over all inspectors and enter on the Balance Analysis. Sum the days available over all license reviewers and enter on the Balance Analysis.
5. Conduct a similar analysis for the other Major Program Areas.

C. Balance Analysis

1. In the Licensing and Inspection Program Areas: For each License Category, compare the estimated number of days needed and days available for licensing and inspections. The number of days available **must be at least equal** to the number of days needed.
2. In the other Program Areas: For each Program Area, compare the estimated number of days needed and days available. The number of days available **must be at least equal** to the number of days needed.

STAFF NEEDS ANALYSIS⁷

License Category	Number of Licenses	Licensing actions / yr	Staff days per action	Licensing staff days	Inspections per year	Staff days / inspection	Inspection staff days
Academic							
Broad Scope Academic							
Nuclear Med - Uptake, etc							
Nuclear Med - Imaging							
Nuclear Med - therapy							
Bone Mineral							
Brachytherapy							
Teletherapy							
Medical - Broad Scope							
Nuclear Pharmacy							
Fixed Gauge							
Portable Gauge							
Industrial - other							
Broad Scope Industrial							
Industrial Radiography							
Well Logging							
LLRW broker							
LLRW site							
U recovery							
SS&D							

⁷The Category of Inspections includes Security Inspections

STAFF RESOURCE ANALYSIS⁸

Staff Member											Total	
License Category	Insp	Lic	Insp	Lic								
Academic												
Broad Scope Academic												
Nuclear Med - Uptake, etc												
Nuclear Med - Imaging												
Nuclear Med - therapy												
Bone Mineral												
Brachytherapy												
Teletherapy												
Medical - Broad Scope												
Nuclear Pharmacy												
Fixed Gauge												
Portable Gauge												
Industrial - other												
Broad Scope Industrial												
Industrial Radiography												
Well Logging												
LLRW broker												
LLRW site												
U recovery												
SS&D												

⁸The Category of Inspections includes Security Inspections

STAFF BALANCE ANALYSIS⁹

License Category	Inspection staff days		Licensing staff days	
	Needed	Available	Needed	Available
Academic				
Broad Scope Academic				
Nuclear Med - Uptake, Dilution, and Excretion				
Nuclear Med - Imaging				
Nuclear Med - Therapy				
Bone Mineral Analysis				
Brachytherapy				
Teletherapy				
Medical - Broad Scope				
Nuclear Pharmacy				
Fixed Gauge				
Portable Gauge				
Industrial - other				
Broad Scope Industrial				
Industrial Radiography				
Well Logging				
LLRW broker				
LLRW site				
U recovery				
SS&D				

⁹The Category of Inspections includes Security Inspections