FSME Procedure Approval

Heightened Oversight and Monitoring

SA-122

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NOTE
Any changes to the procedure will be the responsibility of the FSME Procedure Contact. Copies of the FSME procedures will be available through the NRC website.

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I. INTRODUCTION

This document describes the procedures used by the Nuclear Regulatory Commission (NRC) to conduct heightened oversight or monitoring of an Agreement State program.

II. OBJECTIVES

A. To provide the guidelines that will be followed by NRC when performance weaknesses are identified in an Agreement State radiation control program that do not necessitate probation, immediate suspension, or termination of the Agreement.

B. To ensure that progress is being made to improve performance of the program relative to the areas identified as needing improvement, without degradation of other parts of the Agreement State's radiation control program.

C. To ensure an Agreement State on heightened oversight or monitoring understands the process, their role, and any actions expected of them.

D. To assist an Agreement State in restoring the radiation control program's performance to the criteria in Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP).*

III. BACKGROUND

A. Section 274j. of the Atomic Energy Act gives the Commission authority and responsibility for ensuring that Agreement State programs continue to provide adequate protection of public health and safety and are compatible with NRC's program. In cases where the Commission finds that significant program weaknesses exist regarding the adequacy and/or compatibility of the Agreement State's program, several options are available to ensure continued protection of the public.

B. If the areas needing improvement are serious enough such that the NRC determines that the program is inadequate to protect public health and safety, emergency suspension, suspension, or termination of the Agreement State program should be considered. If the areas needing improvement are not serious enough to find the program inadequate to protect public health and safety, probation, heightened oversight, or monitoring of the Agreement State program by NRC is warranted.

C. Heightened oversight is a formalized process that allows NRC to maintain an increased level of communication with an Agreement State program experiencing program weaknesses. It allows NRC to monitor the actions being taken and the implementation schedule for those actions that address the weaknesses identified in the Agreement State program. The decision to place an Agreement State program on heightened

oversight is made by the Management Review Board (MRB), based on the results of an IMPEP review, a periodic meeting (see FSME Procedure SA-116, *Periodic Meetings Between IMPEP Reviews*, for more information on periodic meetings), or other interaction with the Agreement State program. (See Section V. for criteria).

D. Monitoring is an informal process that allows NRC to maintain an increased level of communication with an Agreement State program. Monitoring is implemented in cases where weaknesses in a program have resulted in, or could result in, less than satisfactory performance for one or more performance indicators. Monitoring may be considered based on results of an IMPEP review, a followup IMPEP review, a periodic meeting, or other interaction with the Agreement State program.

IV. ROLES AND RESPONSIBILITIES

A. Management Review Board (MRB):

1. Makes the final decision on the adequacy and compatibility of an Agreement State program under IMPEP (see FSME Procedure SA-106, *The Management Review Board*, for additional information on the MRB).

2. Determines whether an Agreement State program will be placed on heightened oversight or monitoring based on the results of an IMPEP review, a periodic meeting, or other interaction with the Agreement State program.

3. Designates a period of time for the heightened oversight or monitoring process.

4. Considers improvements made by an Agreement State program and the resolution of the IMPEP review team's recommendations to determine if the heightened oversight or monitoring process should be discontinued. Results from an IMPEP review, a followup IMPEP review, or a periodic meeting will provide a basis for the decision.

5. Directs the Office of Federal and State Materials and Environmental Management Programs (FSME) to prepare a Commission paper requesting approval for an appropriate next action when an Agreement State does not correct the weaknesses that led to heightened oversight status. Options for appropriate next actions may be found in the following FSME Procedures: SA-113, *Placing an Agreement State on Probation;* SA-114, *Suspension of a Section 274b. Agreement;* or SA-115, *Termination of a Section 274b. Agreement.*

B. Director, Division of Materials Safety and State Agreements (MSSA):

1. Keeps the MRB informed of the status of Agreement State programs that are subject to the heightened oversight or monitoring process.

2. Coordinates followup IMPEP reviews (see FSME Procedure SA-119, *Followup IMPEP Reviews*) of Agreement State programs.

3. Reports annually to the Commission on the status of the Agreement States, focusing on those on heightened oversight or monitoring.

4. Prepares the letter transmitting the final IMPEP report to the Agreement State when a State is placed on heightened oversight or monitoring.

5. Prepares and transmits notification of Agreement States placed on heightened oversight and monitoring to the Commissioners' assistants through the Office of the Executive Director for Operations.

6. Prepares, based on the MRB's consideration of the results of the followup review, a Commission paper requesting approval for additional actions if the Agreement State program does not address the weaknesses that led to heightened oversight status. The Commission paper will include the status of the Agreement State program, recommendations of the MRB, and any other pertinent information.

C. IMPEP Team Leader:

1. Recommends to the MRB whether an Agreement State program should be placed on heightened oversight or monitoring, based on the results of an IMPEP review or a followup IMPEP review of the Agreement State program.

2. Provides assistance and support to the Regional State Agreements Officer (RSAO) for heightened oversight or monitoring activities.

D. RSAO:

1. Leads and coordinates heightened oversight or monitoring activities with the Agreement State program management and other NRC staff.

2. Prepares minutes of all conference calls relating to the heightened oversight or monitoring process and coordinates the review of the minutes with the Agreement State program management and other NRC staff to ensure that a clear understanding of discussions were recorded. (See Appendix A for a sample conference call summary.)

3. Ensures that heightened oversight or monitoring correspondence; such as letters, conference call minutes, and e-mail messages; is entered into NRC's Agencywide Documents Access and Management System (ADAMS).

4. Participates, as a team member, on followup IMPEP reviews.

5. Recommends heightened oversight or monitoring of an Agreement State program, in

coordination with the FSME Designee, for consideration by the MRB, based on the results of a periodic meeting, an orientation meeting, or another interaction with an Agreement State program.

6. Reviews and comments on the Program Improvement Plan (see Section V.C.1.a. for further details) submitted by an Agreement State on heightened oversight.

E. FSME Designee:

1. Participates, in coordination with the RSAO, in heightened oversight or monitoring activities for assigned States.

2. Participates in conference calls for assigned Agreement States.

3. Reviews and comments on the Program Improvement Plan submitted by an Agreement State on heightened oversight.

G. Agreement State Program Manager(s):

1. Coordinates heightened oversight or monitoring activities with NRC.

2. Develops and implements a Program Improvement Plan during the heightened oversight period.

3. Prepares and submits periodic progress reports during the heightened oversight period.

4. Participates in heightened oversight or monitoring conference calls.

V. GUIDANCE

A. Heightened Oversight Criteria

1. If the MRB finds an Agreement State program is unsatisfactory for one or more IMPEP performance indicators, the MRB will consider placing the program on heightened oversight.

2. The MRB may decide to place an Agreement State program on heightened oversight based on the results of a periodic meeting or other interaction with the Agreement State program. The loss of key State personnel, a shift in resources to address specific State priorities, a pattern of weak State responses to events, or deliberate misconduct on the part of a State official could be factors in the decision process.

3. The MRB may consider heightened oversight, as opposed to probation or suspension, if senior Agreement State management makes strong commitments to improve the program. The MRB should be confident that the State is capable of

implementing those commitments and that the actions by the Agreement State will result in necessary program improvements.

4. The normal duration of the heightened oversight process is 1 year unless otherwise directed by the MRB.

B. Monitoring Criteria

1. Monitoring of an Agreement State program may be appropriate if heightened oversight is not warranted, but a program performance weakness is identified during an IMPEP review or a periodic meeting or through other information provided by an Agreement State program.

2. Monitoring may also be considered, after implementation of a Program Improvement Plan under heightened oversight, to provide continued assurance that an Agreement State maintains a fully adequate and compatible radiation control program.

3. The normal duration of the monitoring process is until the next IMPEP review or periodic meeting unless otherwise directed by the MRB.

C. Required Elements of Heightened Oversight and Monitoring

1. Heightened Oversight

a. State Program Improvement Plan.

The Program Improvement Plan should be comprehensive and must include actions to address the recommendations in the final IMPEP report. It must fully address the underlying causes for weaknesses and include short- and long-term corrective actions that target the identified causes. The plan must contain dates of expected actions, products to be developed or implemented, and indicate the person(s) responsible for each product. (See Appendix B for an example of a Program Improvement Plan.) The Program Improvement Plan will be reviewed by the RSAO, the FSME Designee, and any other necessary NRC staff. Preliminary review results will be discussed at the first conference call. A formal letter will be sent to the Agreement State acknowledging receipt and approval/disapproval of the Program Improvement Plan. The letter will also include any comments from the review of the Program Improvement Plan.

b. Periodic progress reports.

The reports should be brief, concise summaries of the status of State actions and include an updated Program Improvement Plan. The report and updated Program Improvement Plan should be sent to the RSAO approximately 2 weeks before the next scheduled conference call.

c. Periodic NRC/State conference calls.

i. These calls are designed to maintain open communications between the Agreement State and NRC. The calls should involve Agreement State manager(s) responsible for improving the program and the IMPEP team leader, the RSAO, the FSME Designee, and other NRC or State staff, as needed.

ii. The periodic calls normally occur bimonthly unless, otherwise directed by the MRB.

2. Monitoring

a. Under monitoring, a State does not need to prepare or submit a Program Improvement Plan or written periodic progress reports.

b. Periodic NRC/State conference calls.

i. These calls are designed to maintain open communications between the Agreement State and NRC. The calls should involve Agreement State manager(s) responsible for improving the program and the RSAO, the FSME Designee, and other NRC or State staff, as necessary.

ii. The periodic calls will occur at a frequency agreed upon by the MRB and the State.

3. Followup review by an IMPEP team.

a. The MRB will normally determine if, and when, a followup IMPEP review should be performed to evaluate State progress in resolving weaknesses. (See FSME Procedure SA-119 for additional information on followup reviews.)

b. The results of a follow-up IMPEP review may be the basis for the MRB's decision to continue or cease the heightened oversight process.

i. If the MRB finds the Agreement State program is satisfactory for all performance indicators, the MRB should consider discontinuation of the heightened oversight process.

ii. If the MRB finds the Agreement State program is improving and resolving the recommendations from the last IMPEP review but is satisfactory, but needs improvement, in one or more performance indicators, the MRB should consider taking the State off of heightened oversight and placing the State on monitoring.

iii. If the MRB finds the Agreement State program is not improving or resolving the recommendations from the last IMPEP review and is unsatisfactory for one or more performance indicators, the MRB may elect to continue the heightened oversight process or may direct FSME to prepare a Commission paper requesting approval for an appropriate next action.

D. Additional Actions for Programs Placed on Heightened Oversight or Monitoring

1. Letter Transmitting Final IMPEP Report.

   If an underlying cause of program weaknesses identified during the IMPEP review is determined to be fiscal concerns, the MRB may direct staff to include additional language in the cover letter for the final IMPEP report to bring these issues to the attention of Agreement State senior management. Fiscal concerns include budget, staffing, and resource concerns. Communication with Agreement State senior management may facilitate necessary actions to address the fiscal concerns affecting the Agreement State radiation control program.

2. If the MRB decides to place a State on heightened oversight or monitoring (or continue the State program on heightened oversight or monitoring), the MRB may consider the issuance of a letter from the Chairman or the Executive Director of Operations (EDO) to the State Governor to communicate NRC's concerns about the program. In this case, Agreement State executive- and legislative-level knowledge of performance issues faced by a program may result in the State making additional resources available to address performance weaknesses. Additionally, the letter could assist in helping the Governor better understand the importance of the Agreement between NRC and the State, the status and value of the State's radiation safety program, and help in maintaining internal State focus on the need to provide adequate funding for the Program. A letter addressed to the Governor would usually be signed by the Chairman, and be provided to the Commission for review and approval. A sample letter to the State Governor is provided in Appendix C.

3. Alternatively, at the State's request, the letter could be sent to senior State management in the program instead of the State Governor. Depending on the seniority of the addressee, the letter would be signed by appropriate level of NRC management. The State Liaison Officer and the RSAO will be provided a copy of the letter.

4. NRC/State management meetings.

   NRC may offer to meet with Agreement State officials to discuss State actions to improve the radiation control program.

5. NRC technical assistance.

   NRC and the Agreement States may discuss NRC technical assistance in accordance to guidance in MD 5.7, *Technical Assistance to Agreement States.*

VI. APPENDIXES

Appendix A - Sample Heightened Oversight or Monitoring Conference Call Summary
Appendix B - Sample Program Improvement Plan
Appendix C - Sample Letter from NRC's Chairman to State Governor Informing that the State has been Placed on Heightened Oversight or Monitoring Status

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program.*
2. NRC Management Directive 5.7, *Technical Assistance to Agreement States.*
3. FSME Procedure SA-106, *Management Review Board*
4. STP Procedure SA-112, *Emergency Suspension of a Section 274b Agreement*
5. FSME Procedure SA-113, *Placing an Agreement State on Probation*
6. FSME Procedure SA-114, *Suspension of a 274b Agreement*
7. FSME Procedure SA-115, *Termination of a 274b Agreement*
8. FSME Procedure SA-116, *Periodic Meetings with Agreement States Between IMPEP Reviews*
9. FSME Procedure SA-119, *Followup IMPEP Reviews*

VIII. ADAMS REFERENCE DOCUMENTS

For knowledge management purposes, all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into ADAMS are listed below.

No.	Date	Document Title/Description	Accession Number
1	2/13/04	STP Procedure SA-122	ML040620458
2	7/28/05	STP-05-061, Opportunity to Comment on Draft Revision to STP Procedure SA-122	ML052100400
3	10/5/05	STP-05-076, Final STP Procedure SA-122	ML052790422
4	10/5/05	STP Procedure SA-122	ML061730034
5	10/5/05	STP Procedure SA-122 (redline/strikeout)	ML061730038
6	10/5/05	Summary of Comments on SA-122	ML061730043
7	7/23/09	FSME-09-058, Opportunity to Comment on Draft Revisions to FSME Procedures SA-113 and SA-122	ML091910356

Appendix A

Sample Heightened Oversight or Monitoring Conference Call Summary

[STATE]: [DATE]

The minutes are presented in the same general order as the items were discussed in the meeting. The participants were as follows:

[TEAM LEADER]
[FSME MANAGER]
[LIST STATE PARTICIPANTS]

[RSAO]
[REGIONAL MANAGER]
[FSME DESIGNEE]
[LIST OTHER NRC PARTICIPANTS]

1. **Discussion of Status of Open Recommendations.**

   [LIST ACTIONS] [SUMMARIZE STATE'S ACTION TO DATE. DOCUMENT DISCUSSIONS WITH STATE REGARDING EACH ACTION]

   [LIST ACTIONS] [SUMMARIZE STATE'S ACTION TO DATE. DOCUMENT DISCUSSIONS WITH STATE REGARDING EACH ACTION]

   [LIST ACTIONS] [SUMMARIZE STATE'S ACTION TO DATE. DOCUMENT DISCUSSIONS WITH STATE REGARDING EACH ACTION]

2. **Discussion of Current Status of Program.**

   [SUMMARIZE DISCUSSION]

3. **Date for Next Conference Call (date and time).** The next call was set up for [DAY], [DATE] at [TIME].

4. **Additional Topics.** [DOCUMENT ADDITIONAL DISCUSSIONS AS NEEDED]

5. **Staff's Conclusions**

Appendix B

Sample Program Improvement Plan

Note: This plan should include root causes for weaknesses and include short- and long-term corrective actions. The sample recommendations in this Appendix were identified by the Agreement State program management as root causes of the program weaknesses based on the IMPEP review. The tasks and milestones identified in the table are the short- and long-term corrective actions proposed by the Agreement State program management.

Recommendation	Tasks	Milestones	Assignments	Anticipated Completed Date	Status	Completion Date
Good performance licensee inspection extension	Develop written policy on good performance procedures	Written policy developed	Insert staff name	12/10/01	Completed	12/10/01
		Written policy reviewed	Insert manager name	12/31/01	Completed	12/31/01
		Written policy implemented	Insert staff name	1/15/02	Completed	12/31/01
		Record of adjustment made to licensee files	Insert staff name	2/28/02	Completed	5/6/02
Management measures to insure timely inspections	1. Review overdue inspection list monthly	Prioritize and assign inspections to staff	Insert manager name	12/10/01	Completed	12/08/01
		University A - Broad Licensee inspection	Insert staff name	12/31/01	Completed	12/19/01
		University B - Broad Licensee inspection	Insert staff name	12/31/01	Completed	1/25/02
		Radiographer A inspection	Insert staff name	1/31/02	Completed	2/6/02
		Irradiator Facility A inspection	Insert staff name	4/30/02	Completed	4/16/02
		Medical Broad Licensee inspection	Insert staff name	4/30/02	Completed	4/25/02
	2. Review staffing options	Create health physicist series - 5 step process	Insert manager(s) names	12/18/01	Completed (approved by legislation)	5/24/02
		Review current State Agreement Program organization structure	Insert manager(s) names	6/30/02	In process	
		Review operational processes for efficiency	Insert manager(s) names	8/31/02	In process	
		Consider contracting with private sector	Review options (Insert manager(s) names)	1/31/02	Completed	2/15/02
			Review pros & cons (Insert manager(s) names)	2/15/02	Completed	2/15/02
			Decision to proceed (Radiation Control Program Director)	2/28/02	Completed	2/28/01
			Contract approved to hire consultant	4/18/02	Completed	4/18/02

Recommendation	Tasks	Milestones	Assignments	Anticipated Completed Date	Status	Completion Date
		Consider contracts with past State employees/feds/other States	Draft letter seeking interest of past employees (Insert manager(s) names)			
			Review options (Insert manager(s) names)			
			Review pros & cons (Insert manager(s) names)			
			Response & decision to proceed			
			Draft contract (Insert manager(s) names)			
			Contract submitted to Administration for approval			
	3. Assure better communication regarding expectation of staff deliverables	Review Radiation Control Programs goals and objectives with each staff person	Finalize & send to each staff HP (Insert manager(s) names)	1/31/02 then Quarterly		
		Review status of radioactive materials program goals and objectives and revise if necessary	(Insert manager(s) names)	Quarterly		
	4. Investigate additional funding options	Revise Fees	Secure fee schedules from other States (Insert staff name)			
			Make decision on increases to fees (Insert manager(s) names)			
			Secure Technical assistance support in reviewing fees (Insert manager(s) names)			
			Draft Rules (Insert staff names)			
			Initiate Rulemaking (Insert staff names)			
			Final Rule			
			Implementation of new fees (Insert staff names)			

Recommendation	Tasks	Milestones	Assignments	Anticipated Completed Date	Status	Completion Date
		Redirect Radiation Control Program funds	Draft legislation (Insert manager(s) names)			
			Introduce Legislation (Insert manager(s) names)			
			Approval by Legislation			
Staff training plan development	1. Develop Radiation Control Program tracking sheets	Prepare chart indicating past and needed training of each health physicist (HP)	(Insert manager name)			
	2. Seek/apply for necessary training	Apply for future courses, complete necessary in-house travel forms	(Insert manager(s) and staff names)			
	3. Develop criteria for HP series progression	Review criteria developed by other States	(Insert manager(s) names)			
	4. Define criteria for progression up ladder	Draft and decide on criteria	(Insert manager(s) names)			
Address staff turnover	Review enhancement possibilities	Introduce HP series	Explore other States' HP series job description (Insert manager(s) names)			
			Draft necessary job description			
			Write justification for review			
			Review, revise, and submit (Insert manager(s) names)			
		Introduce a workforce development plan	(Insert manager(s) names)			
Examine and change business processes and organization of the Radiation Control Program to improve the effectiveness and efficiency of the	1. Work with the advisory committee in pursuing recommendations for improvements as noted in rad material survey	Review options with advisory committee. Proceed as directed				
	2. Track with the NRC	Schedule telephone conference with NRC				

Recommendation	Tasks	Milestones	Assignments	Anticipated Completed Date	Status	Completion Date
program	bi-monthly regarding status of this "Improvement Plan"	Prepare Program Improvement Plan status report	(Insert manager(s) names)	every 2 months	On going	
Develop and implement an action plan to adopt NRC regulations in accordance with current policy on adequacy and compatibility	Rule Revision	Convert existing rules to Word and proof	(Insert staff names)			
		Review existing rules for changes	(Insert staff names)			
		Determine necessary revisions	(Insert staff names)			
		Draft rules for compatibility	(Insert staff names)			
		Submit rules for public comment	(Insert staff names)			
		Rules issued for 60 days comment period and transmitted to NRC for review	(Insert staff names)			
		Comments resolved and transmitted for final issuance	(Insert staff names)			
		Final regulations sent to NRC for final review	(Insert manager(s) names)			

Appendix C

Sample Letter from NRC's Chairman to State Governor Informing that the State has Been Placed on Heightened Oversight or Monitoring Status

The Honorable [NAME]
Governor of [STATE]
[ADDRESS]

Dear Governor [LAST NAME]:

On [DATE], the State of [STATE] entered into an Agreement with the U.S. Nuclear Regulatory Commission (NRC). Under this Agreement, the NRC relinquished its authority to regulate certain Atomic Energy Act (Act) materials, pursuant to Section 274 of the Act, and the State of [STATE], as an Agreement State, assumed that authority. Under Section 274j. of the Act, NRC has an oversight responsibility to review Agreement State Programs periodically for adequacy and compatibility with the national program. This review is conducted under NRC's Integrated Materials Performance Evaluation Program (IMPEP).

In accordance with these oversight responsibilities, on [LAST IMPEP REVIEW DATE], the NRC staff conducted an IMPEP review of the [STATE] Agreement State Program that is administered by the [STATE PROGRAM ADMINISTERING AGREEMENT STATE PROGRAM].

On [DATE], the NRC's Management Review Board (MRB) met to consider the proposed IMPEP report on the [STATE] Agreement State Program. The MRB found the [STATE] program [FINDING]. Because of the significance of the findings, the MRB determined that the [STATE] program should undergo a period of heightened oversight. Heightened oversight is an increased monitoring process used by NRC to follow the progress of improvement needed in an Agreement State Program.

The IMPEP review noted that the underlying root causes of the identified weaknesses are [UNDERLYING CAUSES]. The Commission appreciates the commitment senior [STATE AGENCY] management expressed during the MRB meeting and their efforts to address the identified weaknesses in order to operate an adequate and compatible program.

I want to assure you that the Commission supports the objectives of the [STATE] Agreement State Program. The NRC will continue to work closely with [STATE RADIATION CONTROL PROGRAM/STATE AGENCY]. Your continued support for the program will help ensure that the necessary resources to achieve a fully satisfactory program are available. I would be pleased to discuss this matter with you or your staff in further detail if you desire.

Sincerely,

[CHAIRMAN]