Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure Approval

Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements - SA-200

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NOTE

These Procedures were formerly issued by the Office of State and Tribal Programs (STP). Any changes to the procedure will be the responsibility of the FSME Procedure Contact as of October 1, 2006. Copies of FSME procedures will be available through the NRC website

I. INTRODUCTION

This procedure establishes the compatibility and health and safety components assigned to the U.S. Nuclear Regulatory Commission (NRC) regulations and program elements as determined in accordance with Management Directive (MD) and Handbook 5.9, *Adequacy and Compatibility of Agreement State Programs.*

II. OBJECTIVE

To provide guidance to the NRC staff, Agreement States, and States pursuing an Agreement State status on the compatibility and health and safety components assigned to NRC regulations and program elements.

III. BACKGROUND

A. On September 3, 1997, the Commission implemented the Policy Statement on Adequacy and Compatibility of Agreement State Programs (Policy Statement) and this associated implementing procedure, which was developed by the Joint NRC-Agreement State Adequacy and Compatibility Working Group (Working Group). The Policy Statement sets forth the approach that the Commission will use when determining which of its regulations and program elements should be adopted by an Agreement State to maintain a compatible program. The Policy Statement also specifies that an Agreement State should have legally binding requirements to maintain adequate protection of public health and safety.

B. MD 5.9 describes the criteria and process NRC staff should follow to determine which NRC regulations and program elements should be adopted by an Agreement State for purposes of compatibility as well as purposes of health and safety. In accordance with MD 5.9, each regulation and program element is analyzed and classified in a specific compatibility or health and safety component.

C. FSME Procedure SA-200 was developed for use by NRC and State staff. It identities the assigned compatibility or health and safety component for each rule and program element, as determined in accordance with MD 5.9. The component classifications are set out in individual tables as described further below.

IV. ROLES AND RESPONSIBILITIES

A. The Director, of the Division of Materials Safety and State Agreements (DMSSA), is responsible for carrying out the responsibilities outlined in MD 5.9, Section 5.9-032.

B. The Deputy Director, National Materials Program Directorate, DMSSA, is responsible for assigning a staff member to serve as the State Regulation Review Coordinator (SRRC), assisting in procedure updates, and assisting in determination of rule and program element designations in accordance with MD 5.9.

C. The SRRC is responsible for the review, evaluation and resolution of adequacy and compatibility concerns in collaboration and coordination with NRC staff members and Agreement State personnel. The SRRC also is responsible for updating this procedure at a frequency established by DMSSA management.

V. GUIDANCE

NRC staff should follow the guidance presented in MD Handbook 5.9, which describes the criteria and the process that will be used to determine the compatibility and health and safety components of NRC regulations and program elements that an Agreement State should adopt for an adequate and compatible program. In addition, the NRC staff should follow the guidance that a State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. In such cases, however, the State would need to commit to adopting the regulation, or to impose the regulation through license conditions or other legally binding means, if an application were to be received by the State.

MD 5.9, Section 5.9-03, Organizational Responsibilities and Delegations of Authority, provides that FSME in coordination with other NRC offices will review, evaluate and determine those NRC regulations that an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. In accordance with this provision, staff in FY 2002 implemented the “Compatibility Resolution (CR)” process.

During FY 2002, Agreement State and NRC staff identified concerns regarding the acceptability of differences in working between Agreement State and NRC regulations under certain compatibility designations. In some cases, staff review indicated that the compatibility comments in the regulation tables needed revision clarifying language on

acceptable differences from NRC wording, or the rules needed clarification. The former Office of State and Tribal Programs (STP) management determined that it would not be efficient and effective to wait until the next revision of this procedure to resolve these compatibility concerns, since no interpretation or implementation issues were involved. Thus staff will use the CR process to clarify or resolve minor concerns regarding the compatibility determinations of State Regulations. Significant compatibility issues will require Commission approval, and will be handled outside of the CR process. (Also see Section D.3)

The CR document will identify the issue, provide a discussion of the issue, and provide observations and/or conclusion of the staff's resolution of the issue. The CR document will be reviewed by the Standing Committee on Compatibility for consistence with MD 5.9 (see charter: ML082610634) and will require concurrence by all relevant offices. The CR will be distributed to the Agreement States and States pursuing Agreement State status, The Organization of Agreement States (OAS), the Conference of Radiation Control Program Directors, Inc. (CRCPD), and all relevant NRC staff, and will be included as Appendix B to this procedure.

A. Title 10 Code of Federal Regulations (CFR) Regulations Addressing Agreement Materials

As noted earlier, on September 3, 1997, the Commission implemented the Policy Statement. The Statement of Consideration for NRC regulations developed prior to September 3, 1997 will not contain the current compatibility designations and associated rationale for compatibility designation under the Policy Statement. For NRC rules developed after September 3, 1997, the Statements of Consideration will contain a section entitled, "Agreement State Compatibility," which will include information on NRC rule compatibility designation and rationale.

A section-by-section summary of the compatibility and health and safety categories of regulations in Title 10 of the CFR can be found on the FSME website at: http://nrc-stp.ornl.gov/regsumsheets_newregs.html. Updates to these sections will not rely on the updating of this procedure and will be done as needed.

Appendix A contains program elements that are applicable to the regulation of agreement materials. The analysis was based on the categorization criteria and processes set out in MD 5.9. Per MD 5.9 Part V program elements should be adopted within 6 months.

The Parts of 10 CFR for which tables are provided have been analyzed section-by-section; those Parts that do not have a corresponding table have been determined to address areas in which Agreement States either do not have regulatory

authority or that are applicable specifically to NRC's regulatory program and need not be addressed by an Agreement State. For the purpose of completeness, those Parts that totally address areas of exclusive NRC authority are listed in Table 1. Those Parts that generally are applicable specifically to NRC's regulatory program, but are not areas of exclusive NRC authority, are listed in Table 2. Any future changes to these determinations will be reflected in revisions to Tables 1 and 2 and to the individual section-by-section analysis tables on the website or in Appendix A, as appropriate.

Table 1
Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas of Exclusive NRC Authority
Parts 10, 11, 25, 26, 50, 51, 52, 53, 54, 55, 60, 62, 72, 73[1], 74, 75[2], 76, 81, 95, 100, 110, 140, and 160.

[1] Section 73.67 (Physical Protection of Special Nuclear Material of Moderate and Low Strategic Significance) of 10 CFR Part 73 is applicable to certain Agreement State licensees pursuant to 10 CFR 150.14. Agreement States, therefore, may wish to inform their licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws, but does not confer regulatory authority on the State in this area of exclusive NRC jurisdiction.

[2] Part 75 (Safeguards on Nuclear Material - Implementation of US/IAEA Agreement) may be applicable to certain Agreement State licensees as delineated in Section 75.2 - Scope. Agreement States, therefore, may wish to inform their licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws, but does not confer regulatory authority on the State in this area of exclusive NRC jurisdiction.

Table 2
Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas That Generally Are Applicable Only to NRC's Regulatory Program
Parts 1, 2, 4, 7, 8, 9, 12, 13, 14, 15, 16, 21,[3] 170, and 171

B. Regulation and Other Program Element Tables

1. The Regulation Review Summary Sheet Table (as described above in section V.A, the second paragraph) is divided into seven columns. These columns are: NRC Regulation Section; Section Title; State Section; Compatibility Category; Difference Yes/No; Significant Yes/No; and If Difference Why or Why Not was a Comment Generated.

   a. The "NRC Regulation Section" column contains the numbering of the regulation section as it appears in the 10 CFR.
   b. The "Section Title" column contains the section title as it appears in 10 CFR.

   c. The "State Section" will be used by NRC staff during a review of Agreement State regulations to list that State's corresponding regulation section.

   d. The "Compatibility Category" column contains compatibility or health and safety category for the regulation section that has been determined in accordance with the categorization criteria in MD 5.9.

[3] The provisions in Part 21 derive from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this Part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so.

i. Compatibility Categories & Health and Safety Identification

The key to the categories represented by either the symbols "A," "B," "C," "D," "NRC" or "H&S"[4] are as follows:

A= Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC;

B = Program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC;

C = Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met;

D= Not required for purposes of compatibility;

NRC= These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act or provisions of 10 CFR regulations. The State should not adopt these program elements;

[4]In order to be consistent with the Compatibility Categories and Health and Safety Identification provided in Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," the compatibility designation of "D/H&S" has been replaced by the designation "H&S."

H&S[5] = Program elements identified by H&S in the Comment column are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

[ ] = A bracket around a category means that the Section may have been adopted elsewhere and it is not necessary to adopt it again.

e. The "Difference Yes/No" column will be used by NRC staff during a review of Agreement State regulations to state whether the corresponding Agreement State regulation is or is not different from NRC's regulation.

f. The "Significant Yes/No" column will be used by NRC staff during a review of Agreement State regulations if the Different Yes/No column contains a Yes. This column will determine whether the difference found in the Agreement regulation is in accordance with the Compatibility Category assigned to the regulation.

g. The "If Difference Why or Why Not was a Comment Generated" column will state what the difference is and whether or not that difference is in accordance with the regulation's Compatibility. If the difference makes the regulation non-Compatible, NRC staff will also list what changes are needed to make the Agreement State regulation compatible.

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[5]An NRC program element that is not required for compatibility. This element should be adopted by Agreement States because of a particular health and safety role in the regulation of Agreement material. If the essential objectives of the program element were not adopted, it could result directly (i.e., two or fewer failures) in an exposure to an individual in excess of the basic radiation protection standards. The concept embodied by "two or fewer failures" is that if the essential objectives of the program element were not adopted and implemented, then an event could occur that would not have taken place were the essential objectives adopted. This alone or in conjunction with, at most, one other event could result in exposure of an individual in excess of limits set by basic radiation protection standards. (Management Directive 5.9., Handbook, Part II, Section E)

h. In using the regulation tables, staff should be aware of the following points:

i. The following sections are found in multiple Parts of 10 CFR: *Purpose, Scope, Interpretations, Communications, OMB Approval, Violations, Criminal Penalties* and *Inspections*. They are all essentially identical from Part to Part. These requirements are not required for either compatibility or health and safety reasons. The State may elect to adopt similar sections based on its requirements;

ii. Unless otherwise indicated in the tables, the compatibility category or identification of health and safety significance applies to the entire section of the Part. See, for example, the table for 10 CFR Part 20, Section 20.2003, where individual paragraphs are assigned different components.

2. The Program Element Table is divided into three columns. These columns are: Program Element; Required For; and Comments. As directed by the Commission in Staff Requirements Memorandum, SECY-93-349-Draft Policy Statement for Agreement State Adequacy and Compatibility, dated April 21, 1994, the program elements identified in the table are consistent with the common and non-common performance indicators identified in Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Staff should use Management Directive 5.6 along with other IMPEP guidance document in the review of these program elements.

a. The Program Element column describes the program element.

b. The Required For column provides whether the program element is required for purposes of adequacy or compatibility.

c. The Comment column contains the rationale and supporting information as to why a program element was designated as being required for either compatibility or adequacy.

C. Reviews

1. The SRRC will review and revise these procedures, as needed, in accordance with MD 5.9.

2. The SRRC will recommend to the Director of DMSSA the cycle for review and update of this procedure taking into consideration periodic updates to incorporate new final rules or program elements adopted by the Commission. The revision of this procedure will also take into consideration any changes of designation of current NRC regulations and program elements.

3. Significant revisions to this procedure will be distributed for review and comment to FSME staff, NMSS, OGC, the Agreement States, States pursuing Agreement State status, OAS and CRCPD. A review and comment period of at least 30 days will be provided.

4. The SRRC will review and address any comments provided on the revisions. Any significant comments will be coordinated with management and staff as appropriate.

D. Approvals

1. Approvals of designations of final regulations developed after September 3, 1997 will be done in accordance with MD 5.9 and MD 6.3, *The Rulemaking Process.*

2. Approvals of revisions to designations established during the efforts of the Joint NRC/Agreement State Working Group which was implemented on September 3, 1997, will be made by FSME management. As needed, staff will seek input from NMSS, OGC, and Agreement States.

3. Approvals of revisions to designations of rules developed after the implementation of the Policy Statement in September 3, 1997, will be submitted to the Commission for approval. The rules developed after September 1997, were developed in accordance with MD 5.9, and MD 6.3, *The Rulemaking Process,* which included Commission review and approval and public notice in the *Federal Register*; thus, it is essential to obtain Commission approval of these revisions.

VI. APPENDICES

Appendix A - Program elements
Appendix B - Compatibility Resolutions

VII. REFERENCES

1. STP Procedure SA-201, *Review of State Regulatory Requirements*

2. Title 10, Code of Federal Regulations

3. Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*

4. *Final Policy Statement on Adequacy and Compatibility of Agreement State Programs*, dated September 3, 1997

5. Management Directive 6.3, *Rulemaking Process*

6. Management Directive 5.6, "*Integrated Materials Performance Evaluation Program (IMPEP)*

VIII. ADAMS Reference Documents

For knowledge management purposes, listed below are all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into the NRC's Agencywide Document Access Management System (ADAMS).

No.	Date	Document Title/Description	Accession Number
1	02/06/01	Final STP Procedure SA-200	ML010580517
2	10/25/02	STP-02-075, Opportunity to Comment on Draft Revisions to STP Procedure SA-200	ML022980631
3	10/08/04	Final STP Procedure SA-200	ML042820600
4	10/08/04	Resolution of Comments	ML042820609
5	03/22/05	Final STP Procedure SA-200	ML050770486 (pkg. ML51030417)

PROGRAM ELEMENTS

PROGRAM ELEMENT	REQUIRED FOR	COMMENTS
Legislation and Legal Authority	Adequacy	See discussion in Adequacy Section of Policy Statement
• Regulations	Compatibility or Health and Safety	See Regulation Tables for 10 CFR Parts on the FSME website at: http://nrc-stp.ornl.gov/regsumsheets_newregs.html.
• Guidance documents and interpretations	D	
Licensing	Adequacy	See discussion in Adequacy Section of Policy Statement
• Reciprocal recognition of licenses	C	This program element has significant effects on the regulation of agreement materials on a national basis. However, States should be provided flexibility for the type of license and time period recognized under reciprocity. Although there are transboundary implications, there is not a necessity for all States to be identical, such as would be required by a classification of "B."
• Written procedures	C	
• Maintenance of records, especially for decommissioning	C	
• Inspection and licensing files	C	
Inspection and Enforcement	Adequacy	See discussion in Adequacy Section of Policy Statement
• Written procedures	C	

PROGRAM ELEMENT	REQUIRED FOR	COMMENTS
• Radiological laboratory support	D	
• Instrumentation	D	
Personnel	Adequacy	See discussion in Adequacy Section of Policy Statement
• Qualification procedures	C	There should be minimum education and experience requirements for all technical personnel in RCPs nationwide. Flexibility is provided to allow for different State administrative requirements.
Response to Events and Allegations	Adequacy	See discussion in Adequacy Section of Policy Statement
• Written procedures	C	
• Major incident investigation procedures	C	Need to prevent gaps in reporting effectiveness of national program
• Procedures for investigation of “wrongdoing”	C	
Sealed source and device program	Adequacy	Non-common performance indicator
• Standard review plan	C	
• Format and content of registration certificates	B	Need to have national consistency so that all RCPs can rely on the specific information included in these documents.
• Inclusion of Information in the National SS&D registry	B	Need to have national consistency so that all RCPs can rely on the specific information included in these documents
• Written procedures	C	

PROGRAM ELEMENT	REQUIRED FOR	COMMENTS
Low level waste	Adequacy	Non-common performance indicator
• Written procedures	C	
Uranium recovery	Adequacy	Non-common performance indicator
• Written procedures	C	
• Exchange of information	C	Necessary for effective regulation of agreement materials on a national basis; necessary for effective review of NRC and Agreement State programs for agreement material with respect to protection of public health and safety.
• Event reporting	C	See previous comment. In addition, Agreement State event reporting to NRC is mandatory as directed by the Commission in a Staff Requirements Memorandum dated June 30, 1997. Failure to comply with this provision can serve as a basis alone for a finding of "not compatible."
• Legal assistance	D	
• Technical advisory committees	D	
• Technical assistance and support	D	
• Program funding, including program support services	D	
• Organization, management & location of radiation control program	D	

Compatibility Resolution Documents

CR - 02-01

10 CFR 34.20 COMPATIBILITY RESOLUTION REQUIREMENT TO USE COLLIMATORS IN INDUSTRIAL RADIOGRAPHY

ML091180090

CR - 02-02

10 CFR 34.13(h) COMPATIBILITY RESOLUTION QUALIFICATIONS OF INDIVIDUALS PERFORMING LEAK TESTING

ML022380136

CR-05-01

10 CFR 31.6 and 10 CFR 150.20 Compatibility Resolution on Reporting Requirements for Persons who are Generally Licensed to Service and Install GL Devices

ML052030548

CR-06-01

10 CFR 31.6 Compatibility Resolution Clarification of Offshore Waters

ML062330056

CR-08-01

10 CFR 35.491 Compatibility Resolution on Training for Ophthalmic Use of Strontium-90

ML080630478