



FSME STP Procedure Approval

Reviewing ~~the~~ Non-Common Performance Indicator #1 Legislation and Program Elements Required for Compatibility Requirements - SA-107

Issue Date:

~~Review~~ Expiration Date:

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NOTE

The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure Manual. These procedures were formally issued by the Office of State and Tribal Programs (STP). Any changes to the procedure will be the responsibility of the STP-FSME Procedure Contact as of October 1, 2006. Copies of STP FSME procedures will be distributed for information available through the NRC website.



Procedure Title: *Reviewing **the Non-Common Performance Indicator #1, Legislation and Program Elements Required for Compatibility Requirements***

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I. INTRODUCTION

This document describes the procedure for conducting reviews of Agreement States **radioactive materials programs** using Non-Common Performance Indicator: **#1, Legislation and Program Elements Required for Compatibility Requirements, specified in** [NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*].

II. OBJECTIVE

To ensure that an Agreement State program does not create ~~any~~ conflicts, **duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive** ~~disruptive duplication in the collective national effort to regulate materials under the Atomic Energy Act, as amended.~~

III. BACKGROUND

For Agreement State program reviews, an assessment of both adequacy and compatibility is necessary to ensure that State programs are ~~not only~~ adequate to protect public health and safety, ~~and but~~ compatible with NRC's **regulatory** program ~~as well~~. This indicator is a non-common performance indicator because it is not applicable ~~for to~~ NRC Regional offices **radioactive materials programs**.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader:

~~The team leader for the review will~~ **D**determine which team member is assigned lead review responsibility for this performance indicator. ~~The principal reviewer should meet the appropriate requirements specified in Management Directive (MD) 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.~~

B. Principal Reviewer:

- 1.** The principal reviewer for this indicator is responsible for reviewing

Reviews State legislation and regulations, program elements and other generic legally binding requirements (including license conditions); conducting staff discussions; and documenting information pertinent to the compatibility of the State and the adequacy of the authority to conduct Agreement State functions.

2. Meets the appropriate requirements specified in Management Directive (MD) 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.

V. GUIDANCE

A. Scope

1. Statutes and regulations comprise one of the basic components of an Agreement State radioactive materials program, since they provide the program's regulatory framework. A regulation, program element or generic legally binding requirements should be reviewed only as necessary to assure it meets the appropriate compatibility category.
2. Statutes Compatibility category designations can be found in OSP Procedure SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*. A regulation, program element or other generic legally binding requirements should only be adopted as necessary to meet the appropriate category.
 - a. Under Section 274 of the Atomic Energy Act of 1954, as amended, Agreement States administer regulatory programs under their own State statutes. State laws should provide specific elements of authority to the Agreement materials program.
 - b. State laws should not create duplications, gaps or conflicts in regulation, between the State and NRC, State agencies, other Federal agencies, or State and local agencies.
 - c. The State laws should not seek to regulate materials or activities reserved to NRC.

3. Regulations

- a. Each Agreement State has the responsibility to promulgate generic legally binding requirements that satisfy the compatibility requirement of Section 274 of the Atomic Energy Act of 1954, as amended. States generally fulfill that responsibility through promulgation of regulations. Because each Agreement State possesses detailed knowledge of its own requirements, Agreement States are best able to determine that their regulations or other generic legally binding requirements are compatible with NRC regulations and where there are significant differences that could affect compatibility.
- b. For regulations designated as necessary for health and safety, Agreement States are best able to determine whether those regulations or generic legally binding requirements met the health and safety designations and where there are significant differences that could affect adequacy.
- c. To assist States in promulgating compatible regulations or other generic legally binding requirements within three years of the effective date of changes in NRC regulations, NRC staff prepares and publishes a Chronology of NRC Amendments. Included in the chronology is identification of each regulation change, the specific sections modified or established by the regulation change, the effective date of the change, and the compatibility or health and safety designation.
- d. The State Regulation Status Data Sheet (SRS) for each Agreement State is also available on the FSME home page to assist States in identifying the necessary regulations or other generic legally binding requirement necessary for adequacy and compatibility.

B. Evaluation Procedures

1. The principal reviewer should refer to Part III, Evaluation Criteria, of MD 5.6, *Integrated Materials Performance Evaluation Program*, for specific evaluation criteria.
2. Any changes to State legislation *since the last IMPEP review* affecting the radiation control program should be reviewed.

3. The status of all regulations adopted in the radiation control program or other generic legally binding requirements since the last IMPEP review, as well as **the status of** any regulations currently in the rulemaking process, should be ~~noted~~**determined**.
4. The principle reviewer should complete as much of the ~~review~~**work to determine the status of the Agreement State's rules** prior to the on-site ~~visit~~**portion of the review**. This work should be coordinated with the State Regulation Review Coordinator (SRRC), State Agreement and Industrial Safety Branch (SAISB), Division of Material Safety and State Agreements (DMSSA).
5. The status of the State's regulations and other generic legally binding requirements should be discussed with the appropriate Regional State Agreements Officer (RSAO) and the SRRC.

C. Review Guidelines

1. **A copy of the SRS for the State from the Office of Federal and State Materials and Environmental Management Programs (FSME) home page will be included in the IMPEP questionnaire for the State to review, verify as correct, and update the information since the last IMPEP review. The response generated by the State to relevant questions in the IMPEP questionnaire should be used to focus the review.**
2. **Information from the IMPEP questionnaire on legislation, regulations and other program elements required for compatibility should be used by the principal reviewer as a starting point for discussions with the State. A printout of the State's regulation status from the Regulation Assessment Tracking System (RATS) should be obtained from the Office of State Programs (OSP).**
- ~~3. The status of the State's regulations and other generic legally binding requirements should be discussed with the appropriate Regional State Agreements Officer (RSAO).~~

3. Findings

- a. **A "satisfactory" finding may be appropriate in the following circumstances:**

- i. If the State program has no significant changes to the statutes affecting the program's regulatory authority, no overdue regulations, legally binding requirements or other program elements, and meets all the other evaluation criteria for this performance indicator in MD 5.6, the review team should recommend to the MRB that the State's performance with respect to this indicator, be found satisfactory.
- ii. If the State program has adopted all but a few essential regulations or other program elements, and meets all the other evaluation criteria for this performance indicator in MD 5.6, the review team should consider recommending to the MRB that the State's performance with respect to this indicator, be found "satisfactory." One or a combination of the following circumstances may pertain to regulations or program elements that have not been adopted and should be considered in reaching a proposed finding recommendation:
 1. Compatibility significance of the rules.

For example, the adoption of the "Transportation Requirements," Part 71 is more significant than "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments and the State has postponed adoption of the less significant rule.
 2. Rules not needed at the time of the review.

For example, a State may not have issued any licenses for well logging licensees so that "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment is not necessary at this time. The State has postponed adoption.
- iii. If the State program has no overdue regulations or other program elements, at the time of the onsite review, but

experienced difficulties during the review period adopting regulations within the three-year period, the review team should consider whether the State's performance with respect to this indicator, be found "satisfactory" or "satisfactory but needs improvement." The review team will need to consider in their evaluation of this performance indicator the root cause of the delay in promulgation of regulations, the State managements' actions which addressed and corrected the problem and the compatibility significance of the regulations or elements. For example, a State could experience significant staff loss, which the State managed and recovered from through hiring, training and prioritizing workload such that at the time of the onsite review, all regulations had been promulgated and the root cause for the delay has been addressed to ensure that the State would not experience the same difficulty in the future.

- b. A "satisfactory, but needs improvement" finding may be appropriate in the following circumstances:
 - i. If the State program has not adopted several essential regulations, or other program elements, the review team should consider whether to recommend to the MRB that the State's performance with respect to this indicator, be found "satisfactory but needs improvement" or be found "unsatisfactory." For a finding of "satisfactory but needs improvement," one or a combination of the following circumstances may pertain to regulations or program elements that have not been adopted:
 1. Compatibility significance of the rules.

For example, the adoption of the "Transportation Requirements," Part 71 is more significant than "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments and the State has postponed adoption of the less significant rule.
 2. Rules not needed at the time of the review.

For example, a State may not have issued any licenses for well logging licensees so that “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment is not necessary at this time. The State has postponed adoption.

3. Status of draft regulations within the State’s administrative procedures

A State has experienced difficulties adopting regulations within the three-year period, but the State has drafted regulations and begun the process of promulgating the necessary regulations.

- ii. For the review team to consider that the State is in the process of promulgating the necessary regulations, the State should have completed draft regulations and the draft regulation package should be either out for public comment, or within the State’s administrative procedures for final promulgation to be given consideration for a “satisfactory but needs improvement” finding.
- iii. Essential regulations are usually considered Category A or B as defined in FSME Procedures SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*.

- c. A “unsatisfactory” finding may be appropriate in the following circumstances:

- i. If the State program has not adopted over ten regulations or other program elements required for compatibility, has experienced difficulties or has often been unable to adopt regulations during the review period, the review team should consider whether the State’s performance with respect to this indicator, be found unsatisfactory or satisfactory but needs improvement.

- ii. If a State has not begun drafting regulations or has only an internal draft package that has not been transmitted for external review by stakeholders in the promulgation process, the review team should give consideration for an unsatisfactory finding.

D. Review Details.

For ~~legislation and program elements required for compatibility requirements~~, the principal reviewer should evaluate and document the review of the following:

1. Legislation that affects the radiation control program, including any legislation that has been passed since the last review, that affects the State's authority to:
 - a. Promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety.
 - b. License, inspect, and enforce legally binding requirements such as regulations and licenses.
2. State statutes are consistent with Federal statutes, as appropriate.
3. The State has adopted legally binding requirements, regulations, and other program elements in accordance with MD 5.9, *Adequacy and Compatibility of Agreement State Programs*, and the current revisions of ~~OSPFSME~~ Procedures SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*, and SA-201, *Review of State ~~Regulatory~~ Regulations or Other Generic Legally Binding Requirements*.
4. The State has existing legally enforceable measures in place such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health and safety in the regulation of agreement material.
5. The State's administrative rulemaking process allows for the adoption of regulations in an appropriate amount of time and includes sufficient period(s) for public comment.
6. All regulations required for purposes of compatibility or health and safety

are adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of NRC's final rule. The FSME's OSP's Chronology of Amendments is a list of NRC regulation amendments including the NRC effective date. The most recent chronology can be found on the OSPFSME home page (<http://nrc-stp.ornl.gov/>) under Agreement State Letters. Use the examples in Appendix A as a sample format for listing regulation amendments in IMPEP reports.

7. The status of any regulations currently in the rulemaking process.
8. There is sufficient **full-time equivalent** (FTE) in the program dedicated to regulation adoption and oversight.
9. **The State Programs** submits proposed regulations or other generic legally binding requirements following the guidance in OSPFSME Procedure SA-201, *Review of State Regulatory Regulations or Other Generic Legally Binding Requirements*. Specifically, draft rules **and generic legally binding requirements** are sent to DMSSAOSP for review and comment.
10. Other program elements that have been designated as necessary for maintenance of an adequate and compatible program are adopted and implemented within 6 months following NRC designation.
11. **The State has implemented legally binding requirements, regulations, and other program elements in accordance with MD 5.9, Adequacy and Compatibility of Agreement State Programs and the current revisions of FSME Procedures SA-200, Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements.**

E. Discussion of Findings with State.

The reviewer should follow the guidance given in OSPFSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussion of technical findings with reviewers, supervisors, and **management managers**.

VI. APPENDIXES

A. ~~Sample~~ List of **NRC Amendments to 10 CFR Regulations for Adoption by**

Agreement States

B. Frequently Asked Questions

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*.
2. Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*.
3. Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.
4. ~~OSP~~FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
5. ~~OSP~~FSME Procedure SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*.
6. ~~OSP~~FSME Procedure SA-201, *Review of State ~~Regulatory~~ Regulations or Other Generic Legally Binding Requirements*.

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	6/17/99	SP-99-040, Opportunity to Comment on Draft Revisions to OSP Procedure SA-107	ML
2	1/7/00	Final OSP Procedure SA-107	ML
3		FSME-07-0XX, Opportunity to Comment on Draft Revisions to FSME Procedure SA-107	ML0
4		Summary of Comments on SA-107	ML0
5		Final FSME Procedure SA-107	ML0

Appendix A

~~Sample List of NRC Amendments to 10 CFR Regulations for Adoption by Agreement States~~

The following is a list of the NRC amendments issued since 1991 that need to be addressed during IMPEP reviews in rulemakings or by adopting alternate legally binding requirements. Use the following format for listing regulation amendments in IMPEP reports:

- ~~“Emergency Planning Rule,” 10 CFR Parts 30, 40, and 70 amendments (54 FR 14051) that became effective on April 7, 1990.~~
- “Standards for Protection Against Radiation,” 10 CFR Part 20 amendment (56 FR 23360) that became effective June 20, 1991. ~~The Agreement States were expected to promulgate their regulations no later than January 1, 1994.~~
- “Safety Requirements for Radiographic Equipment,” 10 CFR Part 34 amendment (55 FR 843) that became effective January 10, 1991.
- “Notification of Incidents,” 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 64980) that became effective on October 15, 1991.
- “Quality Management Program and Misadministrations,” 10 CFR Part 35 amendment (56 FR 34104) that became effective January 27, 1992 .
- “Licensing and Radiation Safety Requirements for Irradiators,” 10 CFR Part 36 amendment (58 FR 7715) that became effective July 1, 1993.
- “Definition of Land Disposal and Waste Site QA Program,” 10 CFR Part 61 amendment (58 FR 33886) that became effective July 22, 1993.
- "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993.
- “Uranium Mill Tailings: Conforming to EPA Standards,” 10 CFR Part 40 amendment (59 FR 28220) that became effective July 1, 1994.
- “Timeliness in Decommissioning of Materials Facilities,” 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994.
- “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use,” 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, **and 59 FR 65243 and 60 FR 322**) that became effective January 1, 1995.

Appendix A (Continued)

- “Frequency of Medical Examinations for Use of Respiratory Protection Equipment,” 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995.
- m“Low-Level Waste Shipment Manifest Information and Reporting,” 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. ~~The Agreement States were expected to promulgate their regulations no later than March 1, 1998 so that NRC and the State would require this national system to be effective at the same time.~~
- “Performance Requirements for Radiography Equipment,” 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724) that became effective April 1, 1996.
- “Termination or Transfer of Licensed Activities: Record Keeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1996.
- “Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act,” 10 CFR Part 20 amendment (61 FR 65120~~19~~) that became effective January 9, 1997.
- “Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997.
- “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.
- “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 2894~~78~~)

Appendix A (Continued)

that became effective June 27, 1997.

- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.
- “Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea,” 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.
- “Deliberate Misconduct by Unlicensed Persons,” 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.
- “License for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections,” 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.
- “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 393477 and ~~63 FR~~ 45393) that became effective October 26, 1998.
- “Transfer for Disposal and Manifest; Minor Technical Conforming Amendments,” 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998.
- “Radiological Criteria for License Termination of Uranium Recovery Facilities,” 10 CFR Part 40, Appendix A (64 FR 17506) that became effective June 11, 1999.
- “Respiratory Protection and Controls to Restrict Internal Exposures,” 10 CFR Part 20 amendment (64 FR 54543 and 55524) that became effective February 2, 2000.
- “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR 39 amendment (65 FR 20337) that became effective May 17, 2000.
- “New Dosimetry Technology,” 10 CFR 34, 36, and 39 amendments (65 FR 63750) that became effective January 8, 2001.
- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001.
- “Revision of the Skin Dose Limit,” 10 CFR 20 amendment (67 FR 16298) that became effective April 5, 2002.

- “Medical Use of Byproduct Material,” 10 CFR 20, 32 and 35 amendments (67 CFR 20249) that became effective October 24, 2002.
- “Financial Assurance for Materials Licensees,” 10 CFR 30, 40, and 70 amendments (68 FR 57327), that became effective on December 3, 2003.
- “Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments,” 10 CFR 71 amendments (69 FR 3698), that became effective on October 1, 2004.
- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR 30 amendments (70 FR 2001) that became effective July 11, 2005.
- “Medical Use of Byproduct Material - Recognition of Specialty Boards,” 10 CFR 35 amendments (70 FR 16336; 71 FR 1926) that became effective April 29, 2005.
- “Increased Controls for Risk-Significant Radioactive Sources” (NRC Order EA-05-090), (70 FR 72128). Agreement States issued legally binding requirements satisfying the requirements of NRC Order by December 15, 2005.
- “Minor Amendments - Parts 20, 30, 32, 35, 40, and 70," 10 CFR 20, 30, 32, 35, 40, and 70 amendments, (71 FR 15005) that became effective March 27, 2006.

Appendix B

Frequently Asked Questions

- Q. Can the review team make a preliminary finding of compatibility for the overall program, if the finding for this performance indicator is satisfactory with recommendations for improvement.
- A. The review team should make a recommendation for an overall finding of compatibility if the State is found satisfactory or satisfactory but needs improvement for this performance indicator and no other compatibility issues have been identified in other performance indicators. If the team finds a State unsatisfactory for this performance indicator, the recommended finding to the Management Review Board should be not compatible.
- Q. If a State has adopted legally binding requirements instead of a regulation, do we still require the State to adopt the regulation in order to be considered satisfactory for this indicator?
- A. Implementation of a NRC regulation through a legally binding requirement is an acceptable approach and if the legally binding requirement is issued within 3 years, the State should be considered as meeting requirement for this regulation.
- Q. If a State adopts legally binding requirements, is it necessary for NRC to review the requirement before NRC considers the requirement acceptable?
- A. Agreement States should submit legally binding requirements in accordance with FSME Procedure SA-201 for review. If a State has issued legally binding requirements, but has not sought NRC review, the review team should make a recommendation to the State to provide all legally binding requirements for NRC review, but the State should be given credit for addressing the requirement.
- Q. If the Agreement State staff has just begun work on drafting the necessary regulations, however State management has not received the completed package. Can the review team give the State credit for being in the process of promulgating the regulations?
- A. For the review team to consider the State in the process of promulgating the necessary regulations, the State should have completed draft regulations and the draft regulation package should be either out for public comment or within the State's administrative procedures for final promulgating.
- Q. The review team has found that the State had not promulgated "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 393477 and 63 FR 45393) and

“Transfer for Disposal and Manifest; Minor Technical Conforming Amendments,” 10 CFR Part 20 amendment (63 FR 50127). Although both of these regulations revise regulations that have been identified as Category A and B, would these be considered essential regulations for determining the finding for this performance indicator.

- A. Minor revisions and clarifications to Category A or B regulations are normally not considered as critical as the initial revision to the regulations.
- Q. The review team has found that the State had promulgate an amendment in accordance with NRC’s policies and procedures, however the State is not implementing the compatible requirement or is interpreting the requirements differently than NRC in the licensing program.
- A. The review team should identify the issue associated with the implementation to both the State and the Management Review Board as a compatibility issue.