

Gabriel, Sandra

FSME

From: Chon Davis
Sent: Monday, January 14, 2008 1:54 PM
To: J Bruce Carrico; Bradley Jones; Kathaleen Kerr; Patricia Holahan; Dennis Sollenberger; Jennifer Tobin; Gary Purdy; Joan Olmstead; RidsFsmeOd Resource; Duncan White; Bruce Watson; Brian Holian; Donna Janda; Sandra Gabriel
Subject: 01/11/2008 Paul Baldauf Ltr Re: NRC Completeness Review of the New Jersey Application to Become an Agreement State.
Attachments: Baldauf Letter re NJ Agreement.pdf

The attached document has been added to ADAMS and may be found at ML073331064.

Date: January 11, 2008
ADAMS ML Number: ML073331064
LETTER TO: Mr. Paul Baldauf, Assistant Director
FROM: Charles L. Miller
SUBJECT: Paul Baldauf Ltr Re: NRC Completeness Review of the New Jersey Application to Become an Agreement State
TICKET NO.: Not Ticketed DATE SIGNED: 01/11/08

Chon F. Davis
U.S. Nuclear Regulatory Commission
FSME
301-415-7278

January 11, 2008

Mr. Paul Baldauf, Assistant Director
Radiation Protection Programs
Department of Environmental Protection
P. O. Box 415
Trenton, NJ 08625-0415

Dear Mr. Baldauf:

We have finished our completeness review of New Jersey's request to become an Agreement State in accordance with Section 274b of the Atomic Energy Act, as amended. A U.S. Nuclear Regulatory Commission (NRC) interoffice review team (identified in Enclosure 1) conducted the review following the guidance of an NRC Commission Policy Statement that provides criteria for new agreements and the NRC Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, and Handbook, *Processing an Agreement*.

The review was conducted to determine whether the proposed New Jersey Radiation Protection Program (hereafter, the Program) met the evaluation criteria for an Agreement Program that is adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission materials program. The review team found that the request provided information on all major program elements and reflected significant New Jersey staff effort. However, as commented in Enclosure 2, the review team identified a number of areas where additional information is needed. We request a response to the comments.

For your reference, the comments are correlated to the pertinent sections of your request and the pertinent sections of the FSME Procedure SA-700 Handbook.

Among the comments, two significant issues of concern to the NRC are the staffing level of the Program and the training and qualifications of the staff. The issues are discussed below and have been discussed by the NRC staff in telephone conversations with you and your staff.

First, the evaluation criteria for a new Agreement require that the Program have an adequate number of trained and qualified licensing and inspection staff before the effective date of the Agreement. Although the request describes the training and qualifications process for the proposed program staff, it does not appear to provide specific information confirming that an adequate number of these staff members would be on board at the time the Agreement is signed. The distribution of licensing and inspection staff qualifications should be reasonably matched to the workload for the categories of licenses to be transferred from the NRC before the Agreement is signed.

Second, in your draft request, the staff-needs analysis indicated that the proposed program will need approximately 7.2 full-time equivalents (FTE) to perform licensing activities and 4.5 FTE to perform inspection activities for a total of 11.7 FTE. However, you currently have six staff, including managers, conducting these activities for your current licensees for naturally-occurring and accelerator-produced radioactive materials (NARM). The proposed program staffing plan has six vacancies that will need to be filled and the individuals trained in order for the Program to have sufficient qualified staff to implement the proposed Agreement State program.

As noted, during our discussion on November 13, 2007, the State will receive a number of pending licensing actions when the Agreement goes into effect, and the licensing staff will start with a normal workload. Consequently, the State needs a sufficient number of qualified reviewers the day the Agreement goes into effect.

Based on our review of the request, we conclude that the Program may not be adequately staffed to assume the regulatory authority being requested until: (1) the distribution of licensing and inspection staff qualifications is reasonably matched to the workload for the categories of licensees that will be transferred; and (2) the licensing group is fully staffed with individuals qualified according to your training and qualification procedures.

We understand that you are taking actions to address these two significant issues including a re-evaluation of the staffing analysis and increased interactions on licensing and inspections between NRC Region I staff and New Jersey staff in the upcoming months. These interactions should provide your staff with additional knowledge and experience on the more complex NRC materials licenses. The initial telephone conference to coordinate these activities and discuss other transition issues was held on November 13, 2007, at the NRC Region I office. It is my understanding that the meeting was productive, and NRC and New Jersey staffs are working together on these issues.

In addition, the NRC staff review of the draft package identified that New Jersey proposes to use a mix of NRC and State guidance documents to implement the licensing and inspections programs. A number of the documents in the draft package were not clear on which agency's procedures were to be implemented. Therefore, New Jersey should review their proposed procedures and guidance documents to ensure that the references and citations are accurate and that the documents represent a coherent regulatory program. This issue needs to be addressed before the submittal of the final package.

Enclosure 3, "Elapsed-Weeks Milestone Schedule," provides a current estimate of the timing associated with anticipated Agreement signing and its effective date. Based on that schedule, in order to meet your target date to become an Agreement State, the comments identified in Enclosure 2 must be resolved, and your commitment to address the staff level and distribution concerns discussed above must be received by November 7, 2008.

P. Baldauf

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If you have any questions about the review, the information needed, or steps involved in processing the Agreement, please contact me at (301) 415-7197, or Ms. Jenny Tobin, team leader for the New Jersey Agreement Review Team, at (301) 415-2328.

Sincerely,

/RA George Pangburn for/

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:

1. State of New Jersey Review Team
2. State of New Jersey Formal Request Comments
3. Elapsed-Weeks Milestone Schedule

P. Baldauf

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Distribution: DCD (SP05)

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NUCLEAR REGULATORY COMMISSION
INTEROFFICE REVIEW TEAM FOR THE
STATE OF NEW JERSEY AGREEMENT REQUEST

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Office of Nuclear Security
and Incident Response

Events and Allegation Elements

STATE OF NEW JERSEY FORMAL REQUEST COMMENTS

After conducting the completeness review of the New Jersey request for an Agreement, received October 3, 2007, the Review Team has the following comments:

Section 4.1 Legal Elements

4.1.1. Statutory Authority

1. The draft request contained most of the information needed to enable Nuclear Regulatory Commission (NRC) staff to conduct a detailed review. Per the Administrative Procedures Act, the State should explain the State's rulemaking process including information on how the state resolves interpretations of State law. The explanation should address how the State's rulemaking process accommodates future NRC amendments. The State also needs to address the eight comments raised in NRC's August 9, 2006 letter to Patricia Gardner, Manager, New Jersey Bureau of Environmental Radiation regarding the State's proposed legislation.

4.1.2 Organization of the Proposed New Jersey Program

1. On page 20 of the Brief History of the Proposed New Jersey Program (hereafter, the Program), the State mentions one of the Memoranda of Understanding (MOUs) entered into with NRC but does not include the specific language of this legally binding document as part of the New Jersey package. If there are any MOUs that will be inspected by or will impact the proposed 274b. Agreement, please provide a description of the MOU and the impact.
2. The New Jersey organizational charts do not show the link between the Governor and the State program director. Please provide information about the linkage in either graphic or text format.
3. The Bureau of Environmental Radiation description does not identify which organizational unit would be responsible for the low-level waste (LLW) program (licensing, inspection and other actions) if New Jersey is designated as a host State. Please clarify which organizational unit is responsible for the LLW program.
4. The Bureau's description includes several statements about support for other State organizations that would oversee regulatory activities if New Jersey enters into Agreement with the NRC (e.g., licensed contaminated sites, LLW activities, radioactive materials discharges). The description should clearly state which organizations within the State are responsible for each activity and detail the expected additional resources needed.

5. The Program description does not mention which State organization would be responsible for the various program elements such as the enforcement program. A brief statement of the program elements, and where they are located in the organization, as well as referencing the location of the detailed program description in the package should be included in the formal application. The proposed program should be the roadmap for the package linking the Program responsibilities to the detailed subprogram descriptions. Therefore, references to the rest of the package would make the document easier to navigate and would ensure every subprogram is addressed.
6. The Program description does not include information on the legal support to the program. Please briefly describe planned legal support for activities such as hearings, regulations, and escalated enforcement.

4.1.3 Content of Agreement

1. Please add a brief description/introduction to this section stating New Jersey's intent to include authority over 11e.(1), 11e.(3), and 11e.(4) byproduct material, source material, certain quantities of special nuclear material, and the commercial disposal of LLW. The description should also state that New Jersey does not intend to assume responsibility for 11e.(2) byproduct material or the evaluation of sealed sources and devices (SS&D). Additionally, the information on the bottom of page 3 includes only 11.e(1) byproduct material. The information regarding Agreement material needs to be consistent throughout the sample agreement.

4.2 Regulatory Requirements Program Elements

1. The draft request contained the same regulations that were commented on in NRC's letter dated August 3, 2007 to Patricia Gardner. New Jersey should submit a revised regulation section that addresses the 25 comments in the previous letter. The changes should be made to meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental management Programs (FSME) Procedure SA-200.
2. The previously submitted proposed regulations did not include provisions for the Increased Controls that the NRC has issued (by NRC Order EA-05-090) to certain licensees possessing risk-significant sources (International Atomic Energy Agency Category 1 and 2 radioactive material). New Jersey needs to include these requirements (e.g. sample license conditions or other legally binding requirements) as part of their regulatory framework.
3. New Jersey needs to have a process to adopt the new NARM rules and any other amendments that would become effective prior to August 2009. The application should describe how New Jersey will avoid an NRC licensee from having the "whiplash" effect due to different regulatory agencies.

4.3 Licensing Program Elements

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

1. The Tables of Contents for Procedures Bureau of Environmental Radiation (BER) 2.01, 2.02, and 2.06 each include a listing for "Environmental Radiation Bureau Chief" however the procedures do not include a corresponding section.
2. In procedure BER 2.01, "Review of Application," section 3.2.2 states, "the application should be reviewed against the checklist/suggested format in the appropriate NUREG-1556, "Consolidated Guidance about Materials Licenses," volume(s)." Section 3.2.4 states, "the reviewer shall assure that the review of the application includes the following commonly missed items," which are then included on a New Jersey checklist. This list includes certain items that the NUREG-1556 checklists do not require to be submitted.
3. Procedure BER 2.01, "Review of Application for License or Amendment Request," does not indicate the time length of licenses and how to determine the expiration date. It is not clear if New Jersey is using a 10-year or 5-year license.
4. Attachment BER 2.01-4, titled "Temporary Exemption from DEP Regulation or License Condition," does not include a method for determining the acceptability of and the granting of exemptions. Please describe what is meant by a "Temporary Exemption" system of exemptions.
5. Attachment BER 2.02-2, "Sample Renewal Letter for 90-day Notification," directs the licensee to submit a complete new application on form NJRAD-313. However, procedure BER 2.02, "Review of Application for Renewal of a Specific License," also refers to the use of the "expedited renewal," (form NJRAD-102) but appears to be essentially the same as NJRAD-313. Attachment BER 2.02-1, "Sample Letter for Expired License," presents the option of the "renewal certification process," that appears to be the same as "expedited renewal." However, BER 2.02-1 does not specifically reference form NJRAD-102. New Jersey needs to add a standard methodology for licensees to determine when the expedited renewal is an option.
6. BER 2.03, "License Termination," provided a list of references, however it did not include some recent NRC guidance:
 - a. NUREG-1757, Vol. 1, 2 and 3, "Consolidated Decommissioning Guidance," or a State equivalent. NUREG-1757 replaces NUREG 1727, "NMSS Decommissioning Standard Review Plan," NUREG 1549, "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination," and NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees." This procedure needs to include a standard methodology to establish decommissioning groups and determine the criteria to be used to evaluate a licensee's decommissioning actions.
 - b. NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination."

- c. NUREG 1501, "Background as a Residual Radioactivity Criterion for Decommissioning," to support section 1.5.1 of BER 2.03.
7. BER 2.03, "Review of an Application for License Termination," needs to contain the specific radiological criteria for terminating a license (corresponding to Title 10 of the Code of Federal Regulations (CFR) sections 20.1402-1404).
 8. BER 2.03, "Review of an Application for License Termination," needs to address criteria for license termination under restricted use and alternate criteria for license termination (corresponding to 10 CFR 20.1403, "Criteria for License Termination under Restricted Conditions," and 20.1404, "Alternate Criteria for License Termination," respectively). If the State is not going to allow restricted release, it should explain how the Program will address the situation where a licensee is not capable of meeting unrestricted release requirements.
 9. The procedures need to describe how the Program will address the handling of security-related, sensitive, unclassified, non-safeguards information (SUNSI), as described in Regulatory Issue Summary 2005-31.
 10. The procedures need to describe the Program practices for pre-licensing activities with licensees. Note: the NRC is in the process of developing further guidance on these activities; a commitment to present guidance needs to be included in the formal submission.
 11. As adopted by reference, New Jersey regulations recognize 10 CFR 35.1000 and thus a procedure is needed to specify the criteria licensing emerging medical technologies. The current NRC guidelines refer to changing guidance posted on the Medical Uses Licensee Toolkit page of the NRC web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.
 12. In "Licensing Guidance" on page 2, it states "Refer to §4.2 for recognition of licenses from other jurisdictions. See section on reciprocity for further information." However, a section on reciprocity was not included.
 13. In "Licensing Guidance," a New Jersey equivalent of NRC form 241, "Report of Proposed Activities in Non-Agreement States," was not submitted with the package.
 14. In "Licensing Guidance" on page 4, the third and fourth sub-bullets under the "For Sealed Materials" bullet, needs to recognize the SS&D authority of other Agreement States in addition to the NRC's authority.
 15. In "Licensing Guidance" on page 7 under Categories of Licensees, A Portable Gauge, incorrect references to 10 CFR 31, "General Domestic Licenses for Byproduct Material," and 31.32, which does not exist, are cited. The procedure is not clear as to what portable gauges may be exempt from licensing requirements.
 16. In "Licensing Guidance" on pages 10, 12 and 13, there are descriptions of exempt distribution; this language should be omitted since only the NRC has this authority.

Exempt distribution licenses are also included on the "Licensing Forms" and need to be removed because the NRC has jurisdiction for this activity.

17. In "Licensing Guidance" on pages 7 and 8, Section C should not be included in the final package since New Jersey is not intending to include SS&D authority in the Agreement.
18. In "Licensing Guidance" on page 15, the last sentence of the first paragraph should also indicate that the general licensee could be authorized by the NRC or other Agreement States.
19. In "Licensing Guidance" on page 17, the last two paragraphs of section R refer to general licensees. This document provides guidance for specific licensees and so this language should not be included here.
20. The New Jersey submission needs to include technical licensing procedures for 10 CFR Part 40, "Domestic Licensing of Source Material," licenses (which are not addressed in the NUREG-1556 series) including standard review plans, checklists and licensing guides. This could be geared to the types of source material licensees currently in the State.
21. The New Jersey submission needs to include procedures and guidance similar to NUREG-1556 volume 21, "Possession Licenses for Production of Radioactive Material Using an Accelerator."
22. In Attachment BER 2.01-4 "Licensing SOP," page 15 item 3.14, it states, "that the Environmental Radiation Bureau Chief may approve continued operation under the authority of any license for which the renewal application was submitted after the licensee's expiration date." Please explain what New Jersey proposes (e.g. enforcement discretion) and what legal mechanism would be used to implement a legally binding requirement on the expired license holder.
23. Specific procedures requiring pre-licensing visits were not included in the submission. "Licensing SOP" in item 3.2.1 on page 3 provides for the case that a reviewer may conduct a visit with the applicant if needed to clarify information. The NRC is currently evaluating the pre-licensing visit procedure and New Jersey should follow NRC practice in existence at the time of the formal submission.
24. The General Licensing registration letter does not include sections 5 "Certification and Signature" and 6 "Devices Not Subject to Registration" as indicated on the registration form.

4.3.5 Procedures for Assuring the Technical Quality of Licenses

1. In the "Licensing Quality Assurance" section of the draft request, "4.3.5 Licensing Quality Assurance" describes both supervisory review of all actions and a detailed audit procedure that appears to be taken from the FSME Integrated Materials Performance Evaluation Program Procedure SA-104. There is no indication of what procedure the supervisor will use to review all actions. The detailed procedure does not indicate the

frequency at which the audit will be performed and who will perform it. Although there is no specific requirement for such a detailed audit program, the "Purpose" and "Procedure" sections of the detailed procedure are misleading and could be amended to state that the review of all actions performed by the supervisor will include all of the items in the section of the detailed procedure headed: "To determine the technical quality of licensing actions, the principal reviewer should evaluate the following..."

4.3.6 Administrative Licensing Procedures

1. The first of the forms in the "checklist charts.doc" document needs to be updated to read "Checklist for Determining When a Significant Licensing Action Has Taken Place That May Require an Additional Onsite Inspection," and needs to include that a change in the radiation safety officer is a licensing change that merits consideration of an additional inspection.
2. The New Jersey program needs a procedure for inspection staff and licensing staff to exchange information.

4.4 Inspection Program Elements

4.4.1 Procedures for Inspecting Facilities Where Radioactive Materials Are Stored or Used

1. The guidelines provided in Inspection Procedure (IP) 87126, "Industrial/Academic/Research Programs," and IP 87130, "Brachytherapy Programs," were not included in the draft package. As these involve New Jersey specific program codes, they need to be in the final submission.
2. The following IPs were referred to in the draft package but were not submitted. Note: these appear to be NRC procedures but that fact is not communicated in the submission.
 - a. IP 87103 "Inspection of Materials Licensees Involved in an Incident or Bankruptcy"
 - b. Manual Chapter (MC) 2602 "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"
 - c. IP 84750 "Radioactive Waste Treatment and Effluent and Environmental Monitoring"
 - d. IP 86740 "Inspection of Transportation Activities"
 - e. IP 84850 "Radioactive Waste Management – Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61"
 - f. IP 84900 "Low Level Radioactive Waste Storage"
 - g. IP 87102 "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"
 - h. IP 83822 "Radiation Protection"
3. New Jersey Department of Environmental Protection (NJDEP) MC 2800 and several IPs discuss the Nuclear Materials Management and Safeguards System (NMMSS) database, which is not a program under Agreement State authority. New Jersey should delete all references to NMMSS from its Agreement request. However, New Jersey could encourage their licensees to fulfill their obligation to report to NMMSS.

4. IP 87104 titled, "Decommissioning for Materials Licensees," should add the requirement to verify that the licensee is in compliance with the Waste Acceptance Criteria for the burial site(s) where the licensee is planning to dispose of the decommissioning waste. This requirement should be included in Appendix A, Section b-4.
5. Several IPs state that certain activities, such as non-routine maintenance or sealed source replacement, which are typically performed by individuals (e.g., service providers) authorized by NRC or an Agreement State, must be authorized by the NJDEP. New Jersey should revise its IPs to include activities performed by service providers who are authorized by NRC, NJDEP, or another Agreement State.

4.6 Technical Staffing and Training Program Elements

4.6.1 Technical Staff Organization

1. The staffing analysis provided in the formal request does not include a program staffing plan showing the number of staff members assigned to specific responsibilities, such as license review and inspection for each major category of licensee. New Jersey would need to include this information in the formal request for an Agreement.

4.6.3 Qualifications of Current Technical Staff

1. The training records of the New Jersey personnel include a majority of "on the job" training (OJT) without further documentation about what might be included in the training. Further details concerning specific tasks and functions are needed about these activities to ensure the applicability of the OJT to the operations of the program.
2. The Formal Qualification Plan is comprehensive but its criteria may be difficult for New Jersey to meet before the effective date of the Agreement. New Jersey should provide an additional description of how the program will initially qualify a sufficient number of staff to cover the licensing, inspection, rulemaking and other areas for the materials program. The final package needs to have clear information on what training has been accomplished to meet course work specified in the qualification plan and that the current staff (at the time the Agreement goes into effect) are capable of conducting all aspects of the program.
3. The training records sheet, used to summarize the individual staff training to date, does not match the Formal Qualifications Plan. The sheets should also include documentation of management approval that the staff member has actually successfully completed the qualification element.

4.7 Event and Allegation Response Program Elements

4.7.1 Procedures for Responding to Events and Allegations

1. The guidance document regarding follow-up inspections, "NJDEP Inspection Manual Chapter 2800," is not clear as to use of IPs. This document provides the policy for follow-up inspections to events and enforcement actions. However, it is not clear what inspection procedures will be used for follow-up inspections.
2. Although the New Jersey Emergency Management System database is used to notify the licensing staff of events, no procedures were found to notify other affected licensees of generic problems.
3. In guidance document, "SOP RR-101 Notification, Initial Response and Mobilization," section 2.3 states, "Check to see if the nuclides involved are Nuclear Regulatory Commission (NRC)-regulated materials (Attachment RR101-3). If this is true, contact the NRC using Attachment RR101-4 for phone numbers and attachment RR101-5 for a phone log." The purpose of this notification is not clear in that response capability is not addressed.
4. In guidance document, "SOP RR-101 Notification, Initial Response and Mobilization," Attachment RR101-3 "NRC AND/OR STATE REGULATED MATERIAL" should be updated to indicate that NRC regulates naturally occurring or accelerator-produced radioactive materials.

4.7.2 Procedures for Identifying Significant Events and Allegations, and for Entering Reports into the Nuclear Material Events Database

1. New Jersey document, "BER-RM-03 THE NUCLEAR MATERIALS EVENT DATABASE" (NMED) details procedures for entering data into the NMED database. The document contains numerous typographical errors that make the document confusing and difficult to use. Examples of the errors are provided below:
 - a. Section 1.2 references documents that were not provided in the Agreement package (e.g., BER-ER-5.03 and BER-ER-6.10).
 - b. It appears that a global search and replace was used to change NRC to DEP. There are many instances where NRC is the correct acronym. The document should be reviewed to ensure that the change was correct.
 - c. Part of Section 2.6 is missing. The document should be reviewed to ensure that Section 2 is complete.
 - d. The document uses Commonwealth instead of State.
 - e. Attachment 2, Footnote 4, the sample fax is located in Exhibit 1 not Table 1 of SA-300.

- f. Attachment 2, Footnote 6, the minimum basic event information is located in Section 2 not Section 3 of SA-300. Attachment 1 to the document also provides the minimum basic event information.

ELAPSED-WEEKS MILESTONE SCHEDULE*

The following events will not start until the U.S. Nuclear Regulatory Commission (NRC) sends an acknowledgment letter to the New Jersey Program confirming that all the Review Team's comments documented in this letter have been resolved, and New Jersey's commitment to address the staff level and staff distribution concerns discussed in that letter has been received.

Event	Event Time (Weeks)	Elapsed Times (Weeks)
Team completes Notation Vote Commission Paper, including Draft Staff Assessment and <i>Federal Register</i> (FR) Notice	2	2
NRC offices concur on Commission Paper	3	5
EDO sends Paper to Commission	2	7
Commission gives notation vote	2	9
First publication in FR	1	10
Public comment period ends	4	14
Review team analyzes comments; completes final assessment and Commission Paper	4	18
HOLD, IF NECESSARY, PENDING COMPLETION OF STAFF HIRING AND QUALIFICATION BY NEW JERSEY	Hold	18 + Hold
NRC offices concur on final assessment and paper	3	21 + Hold
Executive Director for Operations signs paper	2	23 + Hold
Commission Staff Requirements Memorandum approving Agreement	4	27 + Hold
Signing of Agreement	4	31 + Hold
Effective Date of Agreement	To Be Determined	

*** Assumes that all significant issues, including hiring sufficient qualified staff and addressing any public comments, are resolved.**