Gabriel, Sandra

FSME

From: Jennifer Tobin
Sent: Wednesday, November 07, 2007 5:58 PM
To: J Bruce Carrico; Dennis Sollenberger; Gary Purdy; Joan Olmstead; Bruce Watson; Donna Janda; Sandra Gabriel
Cc: Richard Turtil; Duncan White
Subject: Draft New Jersey Letter
Attachments: NJletter.doc

Team NJ,
Dennis and I have consolidated everybody's comments into one letter. We will be discussing these items and all call participants will have a chance to both request provide and provide additional supplementary information as appropriate.

Tuesday 2:00-3:30 (probably shorter, but we have the phone line for an hour and a half)
1800-638-8081
passcode (b)(2)

Ex. 2 High

Please let me know if you have any questions. Thank you for your participation in reviewing this submission.

-Jenny

Jenny Tobin
Health Physicist
FSME (301)415-2328 T8-E20
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Information in this record was deleted in accordance with the Freedom of Information Act.
Exemptions 2 High
FOIA/PA 2010-0039

C/13

November , 2007

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 completed our completeness review of the New Jersey request for an Agreement. An interoffice staff team (Review Team), identified in Enclosure 1, conducted the review. The review was based on a Commission Policy Statement that provides criteria for new agreements, and followed the 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 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 (NRC) 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 reflected in the comments documented in Enclosure 2, the Review Team identified a number of areas where additional information or documentation is needed. A response to the comments is requested.

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 members of your staff.

First, the evaluation criteria for a new Agreement requires the Program to have an adequate number of trained and fully qualified licensing and inspection staff, before the effective date of the Agreement. Although the request describes the training and qualifications process for the Program staff, it did not appear to provide specific information confirming that an adequate number of trained and qualified licensing and inspection staff would be available in the Program 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 request, the staff-needs analysis indicated that the Program will need approximately 7.2 full-time equivalents to perform licensing activities under the Agreement. However you have six qualified license reviewers, including two managers, with all six being responsible for inspections as well. The staff-needs analysis also indicated that 4.5 FTEs are needed to perform inspection facilities. We noted that the license reviewers will be responsible not only for the approximately 511 naturally occurring or accelerator-produced radioactive

materials licenses from NRC, but also the addition of approximately 492 radioactive materials (NARM) licenses that the Program has been regulating. Thus, based upon the staff-needs analysis, a total of 11.7 FTEs are needed to perform the licensing and inspection of the 1003 licenses (NARM and current NRC licensees). The six technically trained staff plus the six vacancies (when filled) may be able to meet these projections but a significant amount of time and money may be needed to recruit and train these new hires; this item is cause of great concern.

As noted in our discussion on *November 13, 2007*, NRC Region I will stop processing incoming routine licensing actions approximately one month before the effective date of the Agreement. These pending licensing actions will then be transferred to the State for action upon the effective date of the Agreement. Therefore, it is expected that the licensing staff will start with a full workload when the Agreement takes effect. In contrast, NRC Region I is planning to complete all inspections that are due now and out to at least three months beyond the anticipated effective date of the Agreement. This effectively gives the Program a three month buffer period upon assumption of regulatory authority from NRC, regarding routine inspections.

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 have taken actions to address these two significant issues including a plan to increase 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 more complex materials licenses. The initial meeting to coordinate these activities and discuss other transition issues was held on *November 13, 2007,* at 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.

The NRC staff notes that the New Jersey program proposes to use a hybrid of NRC and state licensing guides and inspection procedures. In the submitted package, there were many cases in which there was not a clear distinction as to which agency's procedures were being used since the numbering is the same. Within these documents, there are multiple citations for other procedures that need to be checked to determine that the correct requirements are being referenced.

The NRC staff notes, as it did during the *November 13, 2007*, conference call with your staff, that any memoranda of understanding (MOU) or protocol agreements that the NRC maintains with the State with respect to low-level waste disposal in New Jersey have no affect on the NRC's review of your Agreement State request or the authority that would be relinquished if the Commission approves New Jersey's request.

Enclosure 3, "Elapsed-Weeks Milestone Schedule," provides a current estimate of the timing associated with anticipated Agreement signing and its effective date. Based on the Milestone Schedule, 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, in order to meet your target date to become an Agreement State.

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,

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

Distribution: DCD (SP05)
DIR RF

DJanda, RSAO/RI
GPurdy, NSIR
JOlmstead, OGC
SGabriel, RI
JBCarrico, FSME/DMSSA
BWatson, FSME/DWMEP
DSollenberger, FSME/DMSSA

SUNSI Review Complete
☒ Publicly Available ☐ Non-Publicly Available
☒ Non-Sensitive ☐ Sensitive

Response to Incoming Document: ML Pkg.

DOCUMENT NAME:

ML

OFFICE	DILR/ILB	DMSSA/SAISB	Technical Editor	FSME/DMSSA/SAISB	FSME/DMSSA: D
NAME	JTobin	DSollenberger	CPoland	DWhite	JRSchlueter
DATE	11/ /07	11/ /07	11/ /07	11/ /07	11/ /07

OFFICE	OGC	RI/DNMS:D	NSIR/DSP:D	FSME:D	
NAME	FXCameron	BEHolian	PKHolahan	CLMiller	
DATE	11/ /07	11/ /07	11/ /07	11/ /07	

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STATE OF NEW JERSEY
REVIEW TEAM

Jenny Tobin, Office of Federal and State Materials and Environmental Management Programs (FSME)	Team Leader Regulatory Elements Legal Elements Staffing and Training
Dennis Sollenberger, Office of Federal and State Materials and Environmental Management Programs (FSME)	Team Leader Program Organization Staffing and Training
Joan Olmstead Office of the General Counsel	Legal Elements Regulatory Elements Enforcement
Bruce Carrico, FSME	Licensing Elements
Sandra Gabriel, Region I	Licensing Elements
Donna Janda, Region I	Inspections Enforcement
Bruce Watson, FSME	Decommissioning
Gary Purdy, Office of Nuclear Security and Incident Response	Events and Allegation Elements

ENCLOSURE 1

Enclosure 2

STATE OF NEW JERSEY
FORMAL REQUEST COMMENTS

After conducting the detailed review of the New Jersey Agreement proposed request, 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 NRC staff to conduct a detailed review. The State should provide information on how the State resolves interpretations of state law including accommodating future NRC amendments, and in the Administrative Procedures Act to explain the State's rulemaking process. The State also needs to address the eight comments raised in NRC's August 9, 2006 letter to Patricia Gardner regarding their proposed legislation.

4.1.2 Organization of the Proposed Program

1. On page 20 of the Brief History of the Program, New Jersey mentions one of the MOUs entered into with NRC but does not include the specific language of this legally binding document as part of the New Jersey package.

2. The New Jersey organizational charts do not show the link between the Governor and the State program director. The information about the linkage may be addressed in either graphic or text format.

3. The Bureau of Environmental Radiation description does not identify which section would be responsible for the low-level waste program (licensing, inspection and other actions) yet states that the program will be developed if New Jersey is designated as a host state.

4. The Bureau's description includes several statements about support for other State organizations for activities (licensed contaminated sites, LLW activities, radioactive materials discharges) that will be assumed under the Agreement with NRC. The description should clearly state which organization within the State is responsible and include the expected resources in the estimate for taking on the new responsibilities.

5. The Program description does not mention which organization is responsible for the Enforcement Program. A brief statement and reference where the detailed program description is located 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, a brief description should be submitted to include support for hearings, regulation support, escalated enforcement, and other legal support.

4.1.3 Content of Agreement

1. A brief description/introduction needs to be added 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 low level radioactive waste. The description should also state the New Jersey does not intend to assume responsibility for 11e.(2) byproduct material or the evaluation of sealed sources and devices. 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 has addressed 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 submitted in 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 (IAEA 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.

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 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 volume(s). 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 NJ checklist. This list includes certain items that the NUREG-1556 checklists do not require to be submitted.

3. Procedure BER 2.01 does not indicate the time length of licenses and how to determine the expiration date.

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. For temporary exemption from NRC regulations incorporated by reference, the NRC needs to be consulted.

5. Attachment BER 2.02-2, titled "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 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, titled "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, titled "License Termination", provided a list of references, however it did not include some recent NRC guidance:

   a. NUREG-1757, Vol. 1, "Consolidated NMSS Decommissioning Guidance, Decommissioning Process for Materials Licensees" or a State equivalent. NUREG-1757 vol. 1 replaces NUREG 1727, NUREG 1549 and NUREG/BR-0241. 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.

7. BER 2.03, titled "Review of an Application for License Termination", needs to contain the specific radiological criteria for terminating a license (corresponding to 10 CFR 20.1402-1404).

8. BER 2.03, titled "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 and 20.1404 respectively).

9. The procedures need to describe the way in which the program will address the handling of security-related, sensitive unclassified non-safeguards information (SUNSI), as described in RIS 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 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 website.

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 was not submitted with the package.

14. In "Licensing Guidance" on page 4, the third and forth 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 and 31.32 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 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 page 7/8, 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 licenses (which are not addressed in the NUREG-1556 series) including standard review plans, checklists and licensing guides.

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" pages 12 and 29 provide for temporary exemptions from the requirements of NJDEP regulations or license conditions. This practice is not compatible with NRC methodology and needs to be removed.

23. 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." This practice is not compatible with NRC methodology and needs to be removed.

24. 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.

25. 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 NRC's IMPEP 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 change in RSO as 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 IP 87126 Industrial/Academic/Research Programs and IP 87130 Brachytherepy Programs were not included in the draft package and involve New Jersey specific program codes and thus need to be submitted in the final submission.

2. The following inspection procedures (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. 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. The inspection procedures submitted did not include a list of NJDEP's field and laboratory instrumentation or instrument calibration for review.

4. The inspection procedures did not include procedures covering Section 11(e).2 byproduct material as described in SA-700 Handbook, Section 4.4.1.2. a.-c.

5. NJDEP MC 2800 and several inspection procedures 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.

6. Inspection Procedure 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.

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 needs 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 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 initial qualify a sufficient number of staff to cover the licensing, inspection, rulemaking and other areas for the materials program. This has been one of the major sticking points in prior experience with States seeking an Agreement. 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. The NRC may want to meet with New Jersey and go over the detailed training records identified in the Formal Qualifications Plan that support the summary sheets.

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 inspection procedures. This document provides the policy for follow-up inspections to events and enforcement actions.

2. Although the NJEMS data base 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.

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

1. New Jersey document, "BER-RM-03 THE NUCLEAR MATERIALS EVENT DATABASE" 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 proved 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 were 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 1of 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 the *January 26, 2007,* letter have been resolved, and New Jersey's commitment to address the staff level and 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 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
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
EDO signs paper	2	23 + Hold
Commission SRM approving Agreement	4	27 + Hold
Signing of Agreement	4	31 + Hold
Effective Date of Agreement	To Be Determined	

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

Enclosure 3