

DONNA:

Comments on Section 4.4, Inspection Program Elements, NJDEP Formal Application

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

Review Team Comments:

- NJDEP Inspection Procedure (IP) 87131, Nuclear Medicine Programs, Written Directive Required, which was previously submitted with the draft application, was not submitted with the formal application. As IP 87131 involves a New Jersey specific program code, it must be submitted for review. As an alternative, if no major revisions have been performed on IP 87131 submitted with the draft application, New Jersey can commit to using the IP 87131 which was previously submitted.

____ **NOTE: this procedure was provided via an email from Pat Gardner. DONE.**

- NJDEP Manual Chapter 2800, Materials Inspection Program, does not describe the inspection program for licensees with permanent field offices. New Jersey must submit for review a description of this inspection program. Section 07.04.b.1-b.3 of NRC Manual Chapter 2800 contains a description of an inspection program for licensees with permanent field offices which may be helpful in your response.

____ **Pending**

- Section 03.01.b.1 of NJDEP IP 87132 references 10 CFR 643, 647, and 657, which appear to be typographical errors. The correct references should be 10 CFR 35.643, 35.647, and 35.657.

____ **Pending.** Just need to let NJ know for their correction.

4.4.2 Procedures for Assuring the Technical Quality of Inspections and Technical Reports

- No comments

4.4.3 Administrative Procedures for Inspections

- No comments

Comments on Section 4.5, Enforcement Program Elements, NJDEP Formal Application

4.5.1 Routine Enforcement Procedures

- No comments

4.5.2 Escalated Enforcement Procedures

- No comments

SANDRA:

NJ DEP resolution of NRC comments from 1/11/08:

The issues regarding licensing elements appear to be resolved, except for the following (note: The numbering of NJDEP procedures appears to be somewhat different in draft vs. final requests. Procedures that began with 2 the draft request now appear to begin with 3. As a result, some of the "State Responses" reference outdated procedure numbers.):

Item #14: See comments under "Instructions for Completing Initial Application," below. (formerly called "Licensing Guidance"?) **(Q. 2 of 1/08 letter)**

Item #21: NJ response states that NJDEP views all information concerning radioactive material licensees' activities as a domestic security issue, therefore it is exempted from OPRA requirements to provide information to the public and there is no need for a procedure regarding withholding of information. The response does not address whether NJ will mark outgoing documents, such as licenses and correspondence, to indicate that they are security-related and not to be released to the public. **Q.9 of 1/08 letter)**

Item #27: References to NRC regulations in the "State Response" for this item are not fully correct, but appear to be corrected in the "Instructions for Completing Initial Application." [Note the typo in the first NJAC reference in this section of the "Instructions....;" should be N.J.A.C. 7:28-52.1] **(Q. 15 of 1/08 letter)**

_____ above are pending

"Instructions for Completing Initial Application" per item 14/Q2 above

It is still unclear whether licensees are to follow the instructions in this document or the NUREG-1556 guidance, or both. In some cases the instructions conflict with the NUREG-1556 guidance. Will NJDEP accept use of the checklists in the NUREG-1556 volumes? [these are designed for use by both licensees and license reviewers]

In addition, NUREG-1556, Vol. 9, Rev. 1 has been superseded by Rev. 2; the reference and the link to the NRC website should be updated. Will NJDEP accept use of the Form 313A series and guidance, for medical use licensees to submit qualifications for proposed authorized individuals? If so, it might be helpful to state this and provide the link(s) to the NRC website. Also, NUREG-1556, Vol. 13 has been superseded by Rev. 1; the reference and link to the NRC website should be updated.

Page 2 instructs applicants not to submit copies of NRC or NJDEP licenses. While NJDEP will certainly have access to copies of its own licenses, there are likely to be many situations in which it is most expeditious for applicants to include copies of NRC licenses in order to verify previous authorizations of authorized individuals.

_____ above are pending; discuss with NJ

BER 3.01, Att 2, Comments after Pilot Rev 6

This is not pertinent as a procedure (it presents the response of the Pre-Licensing Working Group to Agreement State comments during the pilot) and may be removed.

_____ this has been removed per previous conversations with NJ

BER 3.04 and 3.07: Time frames for completion of review of licensing actions

Time frames for completion of review of licensing actions appear to differ in BER 3.04, section 3.1 (90 days for completion of licensing action, with deficiencies issued by day 45) and BER 3.07, section 3.0C, which says the objective is to issue licensing actions within 45 days and deficiency letters within 30 days (with clock re-starting after receipt of response).

_____ 3.04 is prioritization of licensing and general license registration actions. This has a default of 90 days. 3.07 is licensing administrative procedures and has the objective stated above. These should be consistent.

Technical Staffing and Training, Formal Qualification Plan:

Medical Qualification Journal references to program code 2100 should be corrected to 2110 for medical institution, broad.

The submitted qualification journals for current staff appear to list certain accompaniments with NJ inspectors as fulfilling training requirements. Not sure this should be considered acceptable for complex programs, without consideration for the NRC-licensed aspects of the program? For example, a medical broad license accompaniment is listed for one individual (Jack Tway), when this licensee does not hold an NRC medical broad license.

_____ Pending. Dennis and I have looked at. The program code should be corrected.

_____ Need to check again re: the medical broad license accompaniment – licensee not being an NRC Broad license. Is overall comment that the NJ staff may not be getting the inspection accompaniment that they need at the right complexity?

GARY:

Comments on NJ Application Section 4.7

The following event response procedures (from 4.7.1.2) appear to be missing from application:

- notifications of licensing staff
- notifications to other affected licensees of generic problems

Additionally, the following guidance should be added to the application.

- Response to radioactive material incidents that do not require activation of the incident response plan. Specifically guidance regarding the need for a reactive/special inspection should be developed.

____ **Dennis and I did discuss with NJ and got revised paragraphs**

____ **Pending Gary's review and ok.**

- Follow-up actions and action levels for radiation exposures associated with materials incidents involving members of the public
- Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)
- Response to Transportation Accidents Involving Radioactive Materials

MC 2800 references the use of Management Directive 8.10, "NRC Medical Event Assessment Program." Does NJ have a medical consultant program?

____ **Need to discuss above with NJ with exception of 3rd bullet.**

(b)(5)

EXS
Attorney
Client
Privilege

BRUCE Watson: Decommissioning – no comments

BRUCE Carrico: Licensing element

Bruce had several areas marked – mostly edits, some appeared to be incorrect regulatory references.

Notes from our meeting:

1. Q. 4 in 1/08 letter – regarding exemptions. Comment is that we usually see this with medical only and don't use temporary exemptions routinely. He didn't see anything in the application that changed or expanded.
 - a. Torre note: they said that they added the 2 paragraphs (on p. 6 of 6 in BER 3.01, 3.4.3 and 3.4.4. I'm not sure what was in draft application.
2. Q. 15 in 1/08 letter (row 27) – we had a question regarding references to 10 CFR 31 and 31.32 and what portable gauges may be exempt from licensing requirements. Bruce still has question on this. NJ answer was to say certain portable gauges may be exempt – Section 52 or 10 CFR 30 provides a listing of exempt devices for further clarification.
 - a. Tabbed in volume 2 of 4 – have to look at Section 52 – their regulations. I'm not finding it.
3. Q. 21 in 1/08 ltr 9row 33 in crosswalk) – limited to PET. Vol. 21 was not limited to PET – dealt with production using an accelerator.
 - a. Torre note based on 1/08 ltr – noncommercial distribution will only be PET I believe. The production will be others.

____ **Need to verify with state**

4. Q. 22 in 1/08 ltr (row 34 in crosswalk) – Bruce can't find what they referenced. Related to statement about continued operation under the authority of any license for which renewal application was submitted after expiration date.
- a. Torre – can't find 7:28-51. Can't find BER 2.02, page 15, item 3.14.

___ check this

___ Need to look at specifics to see if need corrections from State.

___ Summary: no issues that would hold up Agreement

TORRE AND DENNIS: Staffing and Training; Program Organization

Reviewed staffing and training – appears to be adequate. Staffing is increased; folks have training and plans for additional training. Courses are correct ones.

___ Need to check against 1/08 deficiency letter

___ Need to continue review of Program Organization – believe it's ok, but need to check against 1/08 deficiency letter.