

Carrico, J Bruce

From: J Bruce Carrico -FSME
Sent: Monday, March 02, 2009 10:20 AM
To: Torre Taylor
Subject: RE: question regarding the team review of NJ application
Attachments: NJ response to questions.doc; nj review - 2nd jbc cmts.wpd

Hi Torre,

Attached is my evaluation of NJ's response to the questions in NRC's letter that I believe were ones I raised. I have also attached what I had earlier passed on to Dennis/Jenny - as I mentioned, when I went through and compared my items to NJ's resolution chart just before we got together, I had marked each item with a question mark if I was unsure that my item was asked, and either ok or no depending on whether the response seemed adequate.

Bruce

From: Torre Taylor
Sent: Friday, February 27, 2009 4:48 PM
To: J Bruce Carrico
Subject: RE: question regarding the team review of NJ application

thanks Bruce - I'm running into similar difficulties in not being involved in the draft review and I have no clue what all is in the package!

From: J Bruce Carrico
Sent: Friday, February 27, 2009 4:41 PM
To: Torre Taylor
Subject: RE: question regarding the team review of NJ application

Torre

I have finished documenting the items I identified in my review of NJ's 4.3 Licensing Program package that Dennis provided to me and that Dennis, You, and I discussed a bit back. Attached is one list of items that seemed more significant to me and another that lists a few edits I noted. I'm still working my way through NRC questions/NJ responses as you requested in this email that we do - its taking a bit longer than I hoped as I had quite a few questions and its somewhat difficult as either Dennis or Jenny modified the list of items I sent them. Will try to get through it as soon a possible.

From: Torre Taylor
Sent: Wednesday, February 11, 2009 2:22 PM
To: Donna Janda; Gary Purdy; J Bruce Carrico; Sandra Gabriel; Joan Olmstead; Bruce Watson
Cc: Dennis Sollenberger
Subject: question regarding the team review of NJ application

Hello,

Good news - I'm back from being the acting TA so I'll be more involved with the NJ review now!

1. I had a question in looking at the team comments. While some members indicated that the issues raised in the January 11, 2008, letter were addressed in the final application, it wasn't so clear with others.

Dennis and I want to confirm that each team member did verify that all of the issues raised in the January 11, 2008 letter to NJ were addressed, except where noted in the comments on the final application. The ML for the January 2008 letter is: ML073331064. I've attached a copy of it as well.

Could you let us know that all issues were addressed in the final application or note what issues were not? The issues are listed by the different elements that are reviewed, so it shouldn't be hard to find your area of review. If you could just let us know what section heading, sub-heading if applicable, and item number was not addressed, that would help us out in the staff assessment.

2. Dennis and I are starting to look at the staff assessment. The team members will need to complete the assessment for their sections of review. I will be going through a draft template and inserting your names in the sections that you reviewed. These will be the sections you'll need to complete in the assessment. I will be getting that out to you soon - by early next week - so you can start looking at that.

Thanks - Torre

Torre
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Questions from 1/11/09 ltr under 4.3 that might be ones I suggested

1. Q4 - 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.

The questions I posed that might be related were:

On page 12 the provisions for temporary exemption(s) from the requirements of [NJDEP regulation or license condition seem rather unusual. While NRC has procedures, etc for granting exemptions from regulatory requirements, I'm not sure it provides for "temporary" exemptions particularly for license conditions.

On page 29 under Review of an Application for License Termination, item 3.5.1.5 states, "The licensee shall be informed that only the Radioactive Materials Section Supervisor may authorize continued use of radioactive material without a current license, i.e., grant an exemption." I'm not aware of a similar NRC policy and having the Section Supervisor grant this authorization seems somewhat contradictory to the policy stated for expired licenses on page 15 (see item 3 above).

I don't necessary see that NJ's response (item 16 in resolution chart) directly responds to my questions.

2. Q6 - 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

The questions I posed that might be related were:

Starting on page 22 under Review of an Application for License Termination, although its not completely clear to me, portions the following information taken from PA report may also be applicable to NJ:

The LTP is incomplete since it does not contain provisions for implementing a number of the regulations (for example: the Timeliness Rule [30.36 (d) and 40.42 (d)]), or reviewing license termination plans and final status survey reports. These provisions are in NRC

NUREG-1757. The LTP should include these provisions or adopt the NUREG-1757 guidance.

The LTP, states that NUREG-1575 and NUREG/CR-5849 can be used in the development, implementation of the LTP and the termination of the license(s). It further states that NUREG-1727 can be used to evaluate the LTP by the Radioactive Materials Program. NUREG/CR-5849 is no longer applicable and NUREG-1727 has been superseded by NUREG-1757, and therefore the language needs to be revised accordingly.

The NJ response (item 18 in resolution chart) seems adequate.

3. Q12 - 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.

NJ's response (item 24 in resolution chart) is adequate

4. Q14 - 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.

The questions I posed that might be related were:

On page 3, third sub-bullet under the For sealed materials bullet, include "or Agreement States."

On page 3, fourth sub-bullet under the For sealed materials bullet, it only refers the applicant to confirm activities listed on "... certificate of registration issued by the NJDEP." Shouldn't this also include certificates issued by NRC or other Agreement States?

NJ's response (item 26 in resolution chart) is adequate.

5. Q15 - 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.

The questions I posed that might be related were:

On page 7 under Categories of Licensees and A. Portable Gauge, the first paragraph reads, "Certain portable gauges may be exempt from NJDEP licensing requirements. 10CFR31 provides a listing of exempt devices." Not clear what portable gauges might be exempt from licensing requirements. The regulations in 10 CFR31 apply to general licensees.

On page 7 under Categories of Licensees and A. Portable Gauge, the second paragraph, first sentence refers to "10 CFR 31.32. No such 10 CFR section exists. If this is intended to refer to 30.32, its not clear what within this section it might be referring to.

NJ's response (item 27 in resolution chart) does not appear completely adequate; NJ still refers to exempt portable gauges.

6. Q16 - 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.

My questions:

On page 10, Section H describes exempt distribution licensing criteria over which only NRC has jurisdiction

On page 12 under Possession for manufacturing and distribution, the last paragraph includes the statement, "and for distribution of items to persons exempt from license requirements is found in section H." As mentioned previously, exempt distribution is reserved to NRC.

On page 13 under Commercial Radiopharmacy, the last paragraph refers to an exempt distribution licensing activity reserved to NRC as mentioned previously.

NJ's response (item 28 in resolution chart) is adequate.

7. Q17 - 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.

The question I posed that might be related was:

On pages 7/8, its unclear what the purpose of Section C is as it does not seem to refer to any licensing guidance but instead, while mentioning authorization of sealed source device possession, it refers to NUREG-1556, Vol 3 which relates to source/device evaluation and registration which NJ has not requested.

NJ's response (item 29 in resolution chart) is adequate.

8. Q18 - 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.

The question I posed that might be related was:

On page 15 under Authorizing distribution to general licensees, should the last sentence of the first paragraph include language noting that such distribution may also be authorized by NRC or the other Agreement States?

NJ's response (item 30 in resolution chart) is adequate.

9. Q19 - 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.

The questions I posed that might be related were:

On page 17, since this document seems to be oriented to the specific license applicant, is Section R. Regarding Registration of Generally Licensed Devices Containing Greater Quantities of Certain Isotopes appropriate. Also, its confusing why the last two paragraphs and the last sentence of the first paragraph refers to g-distribution licensing.

NJ's response to my second sentence (item 31 in resolution chart) is adequate; however, not sure with regard to my first sentence.

10. Q20 - 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.

The question I posed that might be related was:

Should 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

NJ's response (item 32 in resolution chart) indicated that the only source material licensee in the State is undergoing decommissioning and that they would develop/institute if needed. Adequate?

11. Q21 - 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."

The question I posed that might be related was:

Should also include procedures and guidance similar to NUREG-1556 Vol 21, Possession Licenses For Production Of Radioactive Material Using An Accelerator to address this activity.

NJ's response (item 33 in resolution chart) only discusses PET, does not address other uses such as production.

12. Q23 - 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.

The questions I posed that might be related were:

On page 15, item the Environmental Radiation Bureau Chief may approve continued operation under the authority, of any license for which the renewal application was

submitted after the license's expiration date. I'm not aware NRC has similar procedures or such a policy.

On page 29 under Review of an Application for License Termination, item 3.5.1.5 states, "The licensee shall be informed that only the Radioactive Materials Section Supervisor may authorize continued use of radioactive material without a current license, i.e., grant an exemption." I'm not aware of a similar NRC policy and having the Section Supervisor grant this authorization seems somewhat contradictory to the policy stated for expired licenses on page 15 (see item 3 above).

It doesn't appear to me that NJ's response (item 34 in resolution chart) really addresses the issues raised. NJ indicates that it included a reference to 30.36, but (if I understand it correctly) this provision only - and automatically - applies to possession of contaminated materials possessed due to decommission activities. NJ's statements seemed to suggest that they might provide an exemption to having a valid license that would allow the former licensee to continue to possess and use radioactive materials just as it had under its now inactive license.

13. Q24 - 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.

The question I posed that might be related was:

The form did not seem to include sections 5 and 6 included in the letter.

NJ's response (item 36 in resolution chart) is adequate.

The following items located in the Licensing Guidance Document need clarification:

- ?1. On page 2, regarding Reciprocity Application, it states, "Refer to §4.2 for recognition of licenses from other jurisdictions. See section on reciprocity for further information." A section on reciprocity was not found.
- ?2. On page 2, under Completing License Application Form, fourth bullet, change "require" to "required."
- Ok3. On page 3, under Item Number 5, first bullet, last sub-bullet, its unclear what categories 10 CFR 30 refers to in "Use categories in §4.7(b) and or 10 CFR 30."
- ?no4. On page 3, second sub-bullet under the For sealed materials bullet, requests that the applicant identify the serial number for each sealed source and device requested. Noting that the State refers applicants to NRC's NUREG-1556 series, this information is not requested in the NUREGs.
- ok5. On page 3, third sub-bullet under the For sealed materials bullet, include "or Agreement States."
- ok6. On page 3, fourth sub-bullet under the For sealed materials bullet, it only refers the applicant to confirm activities listed on "... certificate of registration issued by the NJDEP." Shouldn't this also include certificates issued by NRC or other Agreement States?
- ?No7. On page 5, under Item Number 10, it instructs applicants to "Include copies of all documents relating to radiation protection procedures and control measures (e.g. emergency procedures, spill control, surveys performed and their frequency, etc.)" and also refers them to "section 8.10 of your license category's license application guidance." However, NRC's NUREG-1556 series generally does not expect such specific details from applicants.
- no8. On page 7 under Categories of Licensees and A. Portable Gauge, the first paragraph reads, "Certain portable gauges may be exempt from NJDEP licensing requirements. 10CFR31 provides a listing of exempt devices." Not clear what portable gauges might be exempt from licensing requirements. The regulations in 10 CFR31 apply to general licensees.
- Ok9. On page 7 under Categories of Licensees and A. Portable Gauge, the second paragraph, first sentence refers to "10 CFR 31.32. Not such 10 CFR section exists. If this is intended to refer to 30.32, its not clear what within this section it might be referring to.
- ?10. On page 7 under Sealed Sources, the first sentence suggests that "sealed source" is defined in 10 CFR 31.4 which is incorrct. Assume they mean to refer to 30.4. Also in the second sentence it states, "byproduct material or NARM" which are the same under

the new definitions.

- ok11. On pages 7/8, its unclear what the purpose of Section C is as it does not seem to refer to any licensing guidance but instead, while mentioning authorization of sealed source device possession, it refers to NUREG-1556, Vol 3 which relates to source/device evaluation and registration which NJ has not requested.
- ?12. On page 8 under Self-shielded irradiator, the first sentence indicates that 10 CFR Part 36 contains requirements for licensing these irradiators which is incorrect. See 36.1.
- ?13. On page 9 under Academic, research and development and other programs of limited scope including gas chromatographs and X-ray fluorescence analyzers, the first sentence indicates that definitions and requirements for these activities are found in 10 CFR Part 30 which is completely accurate - no such definitions and only general regulations regarding byproduct material.
- No14. On page 10, Section H describes exempt distribution licensing criteria over which only NRC has jurisdiction.
- ?no15. On page 11 under Broad Scope, its not clear what's the basis for statements in the second paragraph. I was unable to find anything similar in NUREG-1556, Vol 11 by conducting a text search on the first sentence of this paragraph.
- Ok16. On page 12 under Possession for manufacturing and distribution, the last paragraph includes the statement, "and for distribution of items to persons exempt from license requirements is found in section H." As mentioned previously, exempt distribution is reserved to NRC.
- ok17. On page 13 under Commercial Radiopharmacy, the last paragraph refers to an exempt distribution licensing activity reserved to NRC as mentioned previously.
- ok18. On page 15 under Authorizing distribution to general licensees, should the last sentence of the first paragraph include language noting that such distribution may also be authorized by NRC or the other Agreement States?
- ?ok19. On page 17, since this document seems to be oriented to the specific license applicant, is Section R. Regarding Registration of Generally Licensed Devices Containing Greater Quantities of Certain Isotopes appropriate. Also, its confusing why the last two paragraphs and the last sentence of the first paragraph refers to g-distribution licensing.
- Ok?/no?20. Should 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. Should also include procedures and guidance similar to NUREG-1556 Vol 21, Possession Licenses For Production Of Radioactive Material Using An Accelerator to address this activity.

Comments on New Jersey's Licensing SOP

- ?1. On page 7 under Checklist for review of license application, item g suggests that applicants should discuss records. However, most NUREG-1556 series guides do not expect applicants to provide detailed explanations with regard to records.
- ?2. On page 12 the provisions for temporary exemption(s) from the requirements of [NJDEP regulation or license condition seem rather unusual. While NRC has procedures, etc for granting exemptions from regulatory requirements, I'm not sure it provides for "temporary" exemptions particularly for license conditions.
- ??no3. On page 15, item the Environmental Radiation Bureau Chief may approve continued operation under the authority, of any license for which the renewal application was submitted after the license's expiration date. I'm not aware NRC has similar procedures or such a policy.
- ok4. Starting on page 22 under Review of an Application for License Termination, although its not completely clear to me, portions the following information taken from PA report may also be applicable to NJ:

The LTP is incomplete since it does not contain provisions for implementing a number of the regulations (for example: the Timeliness Rule [30.36 (d) and 40.42 (d)]), or reviewing license termination plans and final status survey reports. These provisions are in NRC NUREG-1757. The LTP should include these provisions or adopt the NUREG-1757 guidance.

The LTP, states that NUREG-1575 and NUREG/CR-5849 can be used in the development, implementation of the LTP and the termination of the license(s). It further states that NUREG-1727 can be used to evaluate the LTP by the Radioactive Materials Program. NUREG/CR-5849 is no longer applicable and NUREG-1727 has been superseded by NUREG-1757, and therefore the language needs to be revised accordingly.

- ?5. On page 29 under Review of an Application for License Termination, item 3.5.1.5 states, "The licensee shall be informed that only the Radioactive Materials Section Supervisor may authorize continued use of radioactive material without a current license, i.e., grant an exemption." I'm not aware of a similar NRC policy and having the Section Supervisor grant this authorization seems somewhat contradictory to the policy stated for expired licenses on page 15 (see item 3 above).

Comments on New Jersey's G registration letter and form

ok1. The form did not seem to include sections 5 and 6 included in the letter.