

Torre Taylor

From: J Bruce Carrico - *JBC*
Sent: Friday, February 27, 2009 4:41 PM
To: Torre Taylor
Subject: RE: question regarding the team review of NJ application
Attachments: NJ Final Licensing Doc jbc cmts.doc; NJ Editorial Comments on final Submission.doc

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
torre.taylor@nrc.gov
301-415-7900

1. BER Procedure 3.01, in item 2.2, 2nd sentence states, "The QLR/I following the guidance in N.J. A.C 7:28-4 and %1.1 (see 0 CFR 30) is responsible for... Its not clear why Part 30 is referenced.
2. BER Procedure 3.01, item 3.3.2 suggests that if an amendment request is deemed to be too broad, the application would be returned to the applicant for resubmission. I am not aware of a similar NRC policy.
3. BER Procedure 3.01, item 3.4.4 provides for a temporary exemption when a license amendment is not deemed appropriate because of the short termed nature of the exemption and where non-compliance [of an requirement?] would result in a severity level I violation. I am not aware of a similar NRC policy.
4. Attachment 2 to BER Procedure 3.01 is "Guidance/Checklist for Risk-Significant Radioactive Materials" which starts with the 15 page "Pre-licensing Working Group Response to Comments. Is it appropriate having this response document included in this package?
5. BER 3.01 Attachment 3 provides a checklist identifying when a licensing action may require an additional onsite inspection. I am not aware of a similar NRC policy.
6. The 4.3 Licensing Program package includes NJDEP-BER Procedure No. 3.03, "Review of a Request for License Termination." The information included in this procedure appears, to a large extent, related to decommissioning activities. Should this procedure be reviewed by NRC's decommission representative?
7. BER 3.03, item 3.5.1.5 indicates that NJDEP, with approval of the Commission on Radiation Protection, may authorize a licensee whose license has expired, to continue to operate under an exemption. Not sure who the "Commission on Radiation Protection" is and I am not aware of a similar NRC policy.
8. The submission includes a document which includes "Radioactive Material License Application Instructions, Rev.3, September 2008" in the heading - the 2nd and 3rd sentences indicate that regulations for licensing diffuse naturally occurring or accelerator produced radioactive material are in subchapter 4 while regulations for licensing of byproduct and source materials are found in other subchapters. This separation seems unclear given that the EPAAct of 2005 resulted in certain accelerator produced materials to now be byproduct material.
9. On page 7 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item A. Portable Gauges, it states, "Certain portable gauges may be exempt from NJDEP licensing requirements. N.J.A.C.7:-52.1 (see 10 CFR 31) provides a listing of exempt devices." I am not aware that Part 31 provides any such listing or of any exempt portable gauges (unless they consider certain 32.26 gas or aerosol detectors portable gauges).
10. On page 8 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item D. Self-shielded irradiator, it suggests that requirements for these irradiators are found in 10 CFR 36 which is not correct.
11. On page 9 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item F, it suggests that definitions and requirements for an academic, research and development, and other limited scope licenses may be found in 10 CFR 33 which is incorrect. Limited scope licenses fall under Part 30, only broad scope licenses fall under Part 33.
12. On page 9 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item G. Exempt distribution, it refers to 10 CFR 31, "General Domestic Licensing of Byproduct Material." This is the wrong reference, the correct reference is Subpart A of 10 CFR 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." I would also

- suggest that NJ add a sentence noting that only NRC issues exempt distribution licenses in the 2nd paragraph when referring readers to NUREG-1556, Vol.8.
13. On page 11 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item J. Possession for manufacturing and distribution, the 1st sentence refers to 10 CFR 32; however, possession to possess for M&D is subject Part 30, and to a large extent, the type of products identified in the bullets in this section would appear to be specifically licensed items subject to 10 CFR 30 rather than Part 32. Note that this type of licensee could also be distributing under a "G" or "E" license.
 14. On page 12 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item L. Non-Commercial Production/Distribution it references NUREG-1556, Vol. 21 but only discusses PET drugs while the NUREG is also meant to be used by applicants that may be producing other accelerator produced byproduct materials.
 15. On page 12 of this "Radioactive Material License Application Instructions, Rev.3, September 2008" document, under item R – the list requiring registration now includes 3.7MBq radium-226.
 16. The Reciprocity Application Form, under item 19, sentence a. includes, "(see 10 CFR 31)," however NRC reciprocity requirements are located at 10 CFR 150.20 not within Part 31.
 17. This mis-reference also appears in the instructions for "Report of Proposed Activities Within New Jersey Jurisdiction Boundaries ...," 2nd paragraph, 2nd sentence and under item 17 in the Note.
 18. Note that "Instructions For Completing NJRAD Form 664.." does not exactly follow NRC Form 664 guidance.
 19. Note that NJ's form, "Notice to Employees" does not contain the same (or all) information found on NRC's Form 3.
 20. The BER Section 4.3.1, Appendix B, Sample Letters includes, on page 3, a sample denial letter for insufficient information – does NJ not need to cite a regulatory basis (such as NRC would 10 CFR 2.108) or provide for hearing rights when denying an application. (Note that NRC more commonly might void and discontinue its review versus formally denying an application under perhaps similar circumstances.)

Editorial Comments on NJ Submission

1. Under 4.3.1, 3rd paragraph, 4th sentence: change “provide” to “provided”
2. BER Procedure 3.01, in item 2.2, 2nd sentence: add a space after the “)”
3. BER Procedure 3.01, in item 3.2.7: delete a space after “determines”
4. Starting on page 4 and on a number of following pages of the Security-Related Checklist, it refers to FSME/DMSSA/SSSB to obtain additional information or assistance – however I believe this function now falls within the Source Management and Protection Branch (SMPB)
5. On page 12 of the document which includes “Radioactive Material License Application Instructions, Rev.3, September 2008” in the heading, section L is underlined while the other sections are bolded and not underlined.
6. The BER Section 4.3.1, Appendix B, Sample Letters includes, on page 12, a sample letter for termination of licenses : remove “??” in the last full paragraph.
7. In BER Procedure 3.06, page 2, under section 2.0 Responsibilities: correct the word “notifying” in the 1st sentence and remove a duplicated “if” in the 2nd paragraph

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OK

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How does NJ separate DS, source, AARM from Byproduct?

OK

OK

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NRC does e-dist., NJ should state that,

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