Questions from 1/11/08 Letter under Section 4.3
Remaining Questions from Reviewer

NOTE: a few of the questions in 1-6 below are on list that I emailed on 2/27/09

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.

   Original question reviewer had:

   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 see that NJ's response (item 16 in crosswalk) directly responded to questions.

2. 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.

   Original question reviewer had:

   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, it's not clear what within this section it might be referring to.

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

M/32

3. 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.

Original question reviewer had:

> 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, it's 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 crosswalk) is adequate; however, not sure with regard to my first sentence.

4. 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.

Original question reviewer had:

> 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 crosswalk) indicated that the only source material licensee in the State is undergoing decommissioning and that they would develop/institute if needed.

5. 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."

Original question reviewer had:

> 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 crosswalk) only discusses PET, does not address other uses such as production.

6. 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.

Original question reviewer had:

> 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 that NJ's response (item 34 in crosswalk) 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.

Additional Questions Received from Reviewer

1. 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 EPAct of 2005 resulted in certain accelerator produced materials to now be byproduct material.

2. 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.

   Self-shielded irradiators are regulated pursuant to 10 CFR Part 30. Part 36 is not a correct reference.

3. 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.

4. 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.

   Basic question is if this item is referring to end user of a product authorized for exempt distribution or if it is intended for the distributor. If it is for the distributor, that is done per part 32. If it is the end user, it is in part 30. Also, if it is for the end user, we recommend deleting the last paragraph of this section, and clarifying in the 1st paragraph that this is after initial distribution.

   Also, we recommend a statement along the lines that exempt distribution is authorized by NRC and that possession is authorized by NJ.

5. 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.

   This ties in to question 4 as well. Item J regarding possession for manufacturing and distribution refers to Part 32 – it should actually be Part 30/ NJ's subchapter

51 for the possession part of the activity. Part 32/NJ equivalent would be for the distribution.

We are not sure that it is clear that exempt distribution is authorized only by NRC.

6. 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.

   This paragraph should include Ra-226 at 3.7 MBq. We did see it on NJ's form for registration.

7. 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.

   This 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.

   This regulation reference should be to the part 150.20 equivalent – we think subchapter 62 – in a few places in the form and in the instructions.

8. Note that NJ's form, "Notice to Employees" does not contain the same (or all) information found on NRC's Form 3.

9. 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.)

   This is letter for terminating review for non-response. We just wanted to check that you have a similar regulatory basis as 10 CFR 2.108.

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