Sollenberger, Dennis

FSME

From: J Bruce Carrico
Sent: Wednesday, October 24, 2007 2:03 PM
To: Dennis Sollenberger; Jennifer Tobin
Subject: New Jersey Review
Attachments: nj review - jbc cmts.wpd

Attached are my comments regarding the licensing aspects of the NJ submission.

G/15

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. Also do not find a form comparable to NRC form 241.

2. On page 2, under Completing License Application Form, fourth bullet, change "require" to "required."

3. 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."

4. 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.

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

6. 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?

7. 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.

8. 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.

9. 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.

11. 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 Fixed gauge, the first sentence refers to 10 CFR 31 which is applicable to general licensees; however, this section, which also references NUREG-1556, Vol 4, seems instead to oriented to specifically licensed guages.

13. 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.

14. On page 9 under Academic, research and development and other programs of limited scope including gas chromatographs and X-ray flourescence 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.

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

16. 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.

17. 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.

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

19. 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 Sates?

20. 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.

21. 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 1 under Purpose, the form linked under item 1.3.1 is different than the application form provided in the file "Licensing forms.xls."

2. 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.

3. 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.

4. 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.

5. 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.

6. 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).

7. While item 3.2.1 on page 3 provides that a reviewer may conduct a visit with the applicant if needed to clarify information, there do not seem to be any procedures requiring pre-licensing visits.

Comments on New Jersey's G registration letter and form

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

Comments on New Jersey's Licensing Forms

1. The Application for Radioactive Materials License form includes items for exempt distribution (6H) and what appears to be general license registration (6R). New Jersey will not have exempt distribution authority and 6R does not seem appropriate to be on this form.