Sollenberger, Dennis

From: Jennifer Tobin
Sent: Monday, October 22, 2007 3:00 PM
To: Sandra Gabriel
Cc: Dennis Sollenberger
Subject: Re: New Jersey regulations

Sandy,
I'm glad that you found it to be somewhat helpful. I think it would be helpful to the state if you could highlight some of the ones that are most easily identifiable/important if you have the time right now to do so (if not, you could always hold off until the next round....whatever you prefer).

I'm sorry to say that there isn't an organized structure to how items related to NJ are put into ADAMS. Since the work is done across branches and divisions here in headquarters, different technical support assist the technical staff so everything is put in separately. I agree with you, it would be nice to have "one-stop shopping" and I'll check into what kind of effort it would take to put it in a package together.

-Jenny

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>>> Sandra Gabriel 10/22/2007 1:14:16 PM >>>
Thank you. After taking a quick look through these, I have an improved understanding of some of the mixed regulatory references in the Agreement Request. Can also see that a number of items in the licensing section in the draft request will need to be updated to be consistent with the revised NJ regs. Would you like me to try to identify those that are easily identifiable?

Also: I have not been able to identify an organizational structure for the way in which documents related to the NJ Agreement have been placed in ADAMS. Is there an ADAMS folder or package where the team can look to easily find these documents.

thanks.

>>> Jennifer Tobin 10/22/2007 11:45 AM >>>
Sandy,
Thank you very much for sending in your comments, I'm incorporating them into the completeness review letter, I'll let you know if I have any questions. The NJ regulations can be found within the review package in ADAMS at ML071630325. I hope you find that helpful.

Please let me know if there's anything else that I can help you with. Your speedy work is greatly appreciated!

-Jenny

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N/6

>>> Sandra Gabriel 10/20/2007 6:19:03 PM >>>
General comments

I found no major "deal-breakers," though I share your concerns about numbers of hired/trained/knowledgeable staff (particularly in medical) and the need to designate staff breakdown for licensing vs. inspection.

Overall, this draft request is significantly more complete than Pennsylvania's, and looks pretty good. My impression is that efforts to combine existing NJ procedures/forms with NRC information need to be refined a bit to make processes less cumbersome and inconsistent. I tried to walk through the procedures and forms from 2 perspectives: as a licensee and as a license reviewer, and wasn't totally sure of what I was expected to do in either case.

Some relatively picky comments are listed below. I have placed a * at the beginning of the comments I consider to be most significant.

I have been unable to locate the proposed NJ regulations, limiting me somewhat in my review. For example, NJ's equivalent to Part 35, is there a direct adoption of Part 35 by reference, or are Part 35 elements incorporated into the existing NJ reg? It's difficult to evaluate if some of the procedures/forms make sense without knowing whether NJ retained their current, prescriptive requirements, or if they have removed those and directly incorporated Part 35.

NJ needs to update procedures and forms to correct typos and to doublecheck regulatory references and requirements for accuracy. I won't go into a full list of errors/inconsistencies that I've found, but here are two quick examples from the document called "Radioactive Material License Application Instructions." (a) On the bottom of page 10, the example of information that physicians may submit in lieu of documentation of training and experience does not fully meet minimum NRC requirements. (b) First full paragraph of page 13 references 10 CFR 32.11 rather than 31.11 (the correct reference for in vitro test kits).

*As mentioned by Bruce Carrico during Wednesday's call, while NJ apparently does not intend to evaluate sealed sources and devices, their procedures have some confusing references related to NUREG-1556, Vol. 3. Item C in the categories of licensees (listed on form NJRAD-313 and on page 7-8 of the "Radioactive Material License Application Instructions") is titled "Sealed Source," and seems to hold the place of NUREG-1556, Vol. 3 for evaluation of sealed sources and devices. However, the text of page 7-8, refers to Vol. 3 as providing "assistance to applicants on submitting requests to NJDEP to possess sealed sources and devices...." Perhaps we can clarify that the licensing guidance for possession of sealed sources is provided in other 1556 volumes, depending on the nature of the licensee's proposed use of the sources, and that Vol. 3 refers only to evaluation and registration. Also in the license application instructions, at the top of page 4, last bullet item under "For sealed materials", says "Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by the NJDEP. Not sure what is "certificate of registration issued by NJDEP."

4.3.1

The Tables of Contents for Procedures BER 2.01, 2.02, and 2.06 each include a listing for "Environmental Radiation Bureau Chief" however the procedures do not include a corresponding section.

*In procedure BER 2.01, Review of Application, section 3.2.2 states "the application should be reviewed against the checklist/suggested format in the appropriate NUREG-1556 volume(s). 3.2.4 states "the reviewer shall assure that the review of the application includes the following commonly missed items," which are then included on an NJ checklist. This list includes certain items that the NUREG-1556 checklists do not require to be submitted. "Radioactive Materials License Application Instructions" also seem to refer to a mix of NJ forms/guidance and NRC NUREG-1556, however the NUREG-1556 checklists are not mentioned. I'm somewhat confused about exactly what a licensee is expected to submit; is the expectation that they will submit everything in the NJ guidance plus everything in the 1556 guidance?

Procedure BER 2.01 does not indicate term of licenses (e.g., how to determine expiration date).

Attachment BER 2.01-4 is titled "Temporary Exemption from DEP Regulation or License Condition." What are NJ procedures for determining acceptability of and granting exemptions? For temporary exemption from NRC regulations incorporated by reference, is NRC consulted?

Attachment BER 2.02-2, Sample Renewal Letter for 90 day Notification, directs the licensee to submit a complete new application on form NJRAD-313. However, procedure BER 2.02 also refers to "expedited renewal," using form NJRAD-102 (which appears to be essentially the same as the current NJ renewal form). [Sample Letter for Expired License, Att. BER 2.02-1 presents the option of the "renewal certification process," which seems to be the same as "expedited renewal," however it does not specifically reference form NJRAD-102.] If expedited renewal will be an option for non-expired licensees, how will they know this? [note: current NRC regional practice is to do what NJ refers to as "renewal in entirety"]

*License Termination, BER 2.03 provides a list of references, however it does not appear to include a major NRC reference, NUREG-1757, Vol. 1, "Consolidated NMSS Decommissioning Guidance, Decommissioning Process for Materials Licensees." Does NJ intend to follow this document, for example, to establish decommissioning groups and determine the criteria to be used to evaluate a licensee's decommissioning actions? (e.g., in BER 2.03 step 3.2.2 to determine potential risk of residual radioactive contamination and to determine the adequacy of the licensee's information submitted in step 3.4.1.5).

*NJ should also describe the way in which they will address the information provided in RIS 2005-31 (control of SUNSI) and prelicensing guidance [as this is an evolving area, could commit to following the then-current guidance].

Without access to the proposed NJ regs, I don't know if they include the equivalent of 35.1000 licensing of emerging medical technologies. If NJ recognizes 35.1000, ask them to describe the criteria they will use for licensing (for example, following the then-current guidance posted on the Medical Uses Licensee Toolkit page of the NRC website).

4.3.5

In the "Licensing Quality Assurance" section of the draft request, "4.3.5 Licensing Quality Assurance" describes both supervisory review of all actions and a detailed audit procedure that seems to be taken from the IMPEP procedure SA-104. There is no indication of the procedure the supervisor will use to review all actions. The detailed procedure does not indicate the frequency at which the audit will be performed and who will perform it. [There is no specific requirement for such a detailed audit program. One alternative might be for NJ to remove the "Purpose" and "Procedure" sections of the detailed procedure, and state that the review of all actions performed by the supervisor will include all of the items in the section of the detailed procedure headed: "To determine the technical quality of licensing actions, the principal reviewer should evaluate the following:..."]

4.3.6

In the "Licensing Adminstrative Procedures" section of the draft request, the document "checklist charts.doc" includes several forms that don't seem directly related to licensing. However, the first of these forms does partially address NRC "Processing an Agreement" section 4.3.1.2.b "provide for information exchange between the programs' inspection staff and licensing staff as appropriate." NJ should update this form, "Checklist for Determining When a Significant Licensing Action Has Taken Place That May Require An Additional Onsite Inspection," to include change in RSO as a licensing change that merits consideration of an additional inspection. NJ should also describe the procedure for inspection staff to exchange information with licensing staff, for example, if an inspector identifies an issue that needs to be resolved as part of a licensing action.

Thank you for the opportunity to submit these comments.