



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

DEC 18 2010

Eduard Kotlyarov, M.D.
Radiation Safety Officer
Pontiac Osteopathic Hospital
50 North Perry Street
Pontiac, MI 48058

Dear Dr. Kotlyarov:

This refers to the letter dated September 21, 2010, with attachments, requesting the addition of materials in 10 CFR 35.400 to your NRC byproduct materials license no. 21-04081-03.

We are unable to approve your request at this time because the information in the above letter was insufficient to complete our review. Please provide the information described in this letter and indicated on the attached excerpts from Appendix C, NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses - Program-Specific Guidance About Medical Use Licenses," in accordance with the following guidance.

If you wish to pursue this request, please submit the following information as a written, currently signed and dated response, addressed to my attention, and reference it as "additional information to control number 573580" to facilitate proper handling in our office.

As we cannot amend your license at this time, we are voiding your request by taking it out of our active database until we receive an adequate written response from you concerning the items below. In voiding your request, please note that this action is without prejudice to resubmission.

If you have any questions or require clarification on any of the information stated above, you may contact me directly at (630) 829-9841. My fax number is (630) 515-1078.

1. In order to consider your request to add materials in 10 CFR 35.400 to your license you must provide a list of the specific radionuclides you want to become authorized for, including, for each, the manufacturers' names and model numbers for all sealed sources and a possession limit. We must be able to verify each sealed source by its manufacturer and model number in the Sealed Source and Device Registry (SSDR). Your vendors can provide you with this information.

Please refer to the NUREG 1556, Vol. 9, Rev. 2 above and to section 8.6 and Table C.2, Items 5 and 6, attached. This guidance document should have been sent to you as a hard copy already and it is available on our website at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>

2. Please note that we will be unable to name an Authorized Medical Physicist (AMP) to your license for manual brachytherapy only as one is not required unless a strontium-90 ophthalmic applicator is requested and listed on your license.

E. Kotlyarov

3. Your proposed facility diagrams for the manual brachytherapy program were inadequate. Please provide appropriate diagrams based upon the NUREG guidance document and section 8.16, Item 9 and Table C.3 Item 9, excerpts attached. Please do not submit blueprints or copies of blueprints.
4. Please confirm that all other radiation safety program elements currently in the license will be extended to include the manual brachytherapy program also.
5. Please confirm that you, as the RSO for the manual brachytherapy program, will receive appropriate training in the radiation safety aspects of similar types of byproduct material use for which you will be assuming responsibility, with a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e).
6. Please provide the name, telephone number and fax number of at least one person whom we may contact if additional information is required during the review process. I checked our records and discovered that we did not have this information for your license, especially the fax number.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-04081-03

Docket No. 030-02041

Enclosure:

Excerpts from NUREG 1556, Vol. 9, Rev. 2