From: Lanzisera, Penny
Sent: Monday, June 20, 2011 1:57 PM
To: sgregoire@nmcinc.org
Subject: Request for Additional Information

Licensee: Northwestern Medical Center
License No. 44-16669-02
Docket No. 03038450
Mail Control 575133

Dear Ms. Gregoire,

As per our telephone conversation on June 17, 2011, we need the following additional information to support your request for a new NRC license:

1. Please indicate whether any other entity currently uses radioactive material at your address of use.
2. Please confirm the requested licensed material (e.g., TC-99m and Tl-201 only or 35.200) and use (cardiology only or any 35.200 nuclear medicine use).
3. Please indicate whether PET radionuclides will be used, and if so, please provide shielding evaluations for areas of use. In addition, please provide the manufacturer name and model number for any sealed sources that do not meet the criteria in 10 CFR 35.65 (e.g., greater than 30 mCi).
4. Please note that NRC regulations do not recognize assistant RSOs.
5. It appears that Drs. Savard and Dr. Gonzalez may be consultants. Please provide the following information:

    a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

    b. Describe the relationship that will exist between the consultant-RSO and the consultant-Authorized User(AU) and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

    c. Identify other commitments of the consultant-RSO and consultant-AU for other NRC or Agreement State licensed facilities, along with a description of how the individual will allocate time to permit the performance of their duties as described in the regulations. State the consultant-RSO's and consultant-AU's minimum amount of on-site time (hours per week).

    d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

    e. Describe the overall availability of the consultant-RSO and consultant-AU to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO or AU to arrive at the facility in the event of an emergency or questions that require their presence.

6. Provide documentation to support that Dr. Gonzalez is licensed to practice medicine in Vermont.
7. NRC's recent licensing guidance NUREG-1556, Volume 9, does not require the submittal of detailed procedures, but instead requests commitments from licensees to develop, document, and maintain various procedures. This allows licensees the flexibility to update their procedures as necessary. Therefore, your detailed procedures submitted in Sections 8, 10, 11, 12, and 13 were not reviewed in detail and will not become a condition of your NRC license. Detailed procedures will be reviewed during inspections. However, during a cursory review of the submitted procedures, it was noted that some items were incomplete (e.g., dose calibrator testing procedures) or contained questionable statements (e.g., do not call RSO for a contaminated packaging). The NUREG provides several NRC approved procedures that licensees may choose to adopt or model their own procedures after. Please confirm that you will review the NUREG and revise any existing procedures, as necessary. Additionally, please confirm the following:

    a. "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

    b. "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

    c. "When administering dosages of alpha-emitting unsealed byproduct material pursuant to 10 CFR 35.300, in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j); dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." Alternatively, you may confirm that alpha byproduct material will not be used.

    d. "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

    e. "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

    f. "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

    g. "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

    h. "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with10 CFR 20.1101, that also

meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

8. Please submit facility diagrams indicating the position of each area of use and storage and describe the type, dimensions, and thickness of shielding that you will use for these areas. If the waste storage area is not located within your main department, describe how you will secure the material. In addition, please describe any additional shielding used in radiopharmaceutical preparation and dispensing areas (e.g., lead glass L-block, specifically designed PET shielding, etc.). Finally, identify adjacent areas from use and storage locations, including areas above/below, and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.
9. Please provide a description of instruments used for area radiation level surveys and contamination monitoring.

You may fax the response to my attention to 610-337-5269. Please reference Mail Control No. 575133 in your response.

Sincerely,

Penny Lanzisera
US NRC, Region 1