February 13, 2009

E. Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
Little Rock, AR 72114

Dear Mr. McGuire:

We have reviewed your letter dated May 9, 2008 requesting approval for the production and non-commercial distribution of radioactive materials using an accelerator and the production and non-commercial transfer of Positron Emmission Tomography (PET) radioactive drugs. In order to continue our review, we will need you to submit the following additional information.

1. Scope of the Expansion

   a. Provide the number of facilities within the Department of Veterans Affairs (DVA) system that currently produce radioactive materials using an accelerator. Also, provide the number of permittees that produce Positron Emmission Tomography (PET) radioactive drugs and that non-commercially distribute PET radioactive drugs. In addition to the current number of production facilities, provide the total number of accelerator and/or PET radioactive drug facilities that will begin production in the near future (e.g., next 5 years).

   b. Describe the radionuclides and the maximum activities at each facility that are currently being produced and/or that will be produced in the near future (e.g., next 5 years).

   c. The production of radioactive materials using an accelerator generally produces long-lived (i.e., greater than 120 day half-life) activation products that may meet the quantity of material limits that require financial assurance for decommissioning. Therefore, indicate whether the DVA's current financial assurance (FA) commitment is adequate to decommission all of its facilities including the production facilities. If the current FA commitment is not adequate, provide a new financial assurance commitment containing the new cost estimate for decommissioning.

2. Regulatory Program (National Health Physics Program (NHPP))

   a. Provide information that indicates the DVA has and will continue to provide sufficient operating funds and staff to support the additional resources needed to regulate the production activities.

b. Describe the modification made by the NHPP with regards to the regulatory oversight for the production of radioactive materials using an accelerator and the production and non-commercial distribution of PET radioactive drugs. The description should address any changes to the following:

- Organization and management;
- Material control and accounting;
- Program authorities and responsibilities;
- Communications;
- Quality Control surveillance;
- Program audits;
- Procurement;
- Information dissemination;
- Document control and retrieval; and
- Other considerations essential to the successful implementation of the program.

c. Describe the procedures and criteria for ensuring that members of the NHPP staff are adequately qualified to perform the day-to-day regulatory activities involving the production of radioactive materials using an accelerator and the production and non-commercial distribution of PET radioactive drugs.

d. Describe the permitting program that will be used to authorize permittees to produce radioactive materials using an accelerator and to produce and non-commercially distribute PET radioactive drugs. The description should include the following information[1]:

- The criteria that will be used to determine if a permittee's facility and equipment is adequate to produce radioactive materials and/or PET radioactive drugs (i.e., see Section 8.9 of NUREG 1556, Vol. 21);
- The criteria that will be used for determining the radionuclides and maximum activity the permittee can produce and/or possess at any one time;
- The training and experience criteria that will be required for individuals who will work in or frequent the restricted areas within the production facility; and
- The criteria used to determine if the permittee's radiation control/safety program is adequate for the production activities.

e. Describe the inspection program that will be used for facilities that will produce radioactive materials and PET radioactive drugs.

[1] Please note that referring to NUREG-1556 guidance documents is not sufficient to respond to this request for additional information.

f. Describe the criteria that will be used to authorize permittees to non-commercially transfer PET radioactive drugs. The description should include the following information:

- The criteria that will be used to identify a consortium (i.e., see 10 CFR 30.4);
- A description of the geographical area in which the consortium members will be authorized to transfer PET drugs; and
- If noncommercial transfer of PET radioactive drugs is currently being performed, provide documentation that indicates the terms of the consortium. The documentation should demonstrate the joint ownership/sharing of the operation and maintenance cost of the PET radionuclide production facility.

g. Confirm that the DVA will not commercially distribute PET radioactive drugs. As part of this confirmation, provide the criteria to be used to distinguish non-commercial transfer from commercial distribution.

3. Permittee Requirements

a. Submit the radiation control/safety and waste management policies, procedures, directives, and/or guides that permittees will be required to use to ensure the safe use, production, storage, and transfer of radioactive materials and PET radioactive drugs.

b. Provide a description of the monitoring equipment such as counting systems, portable survey equipment, and air monitoring equipment that permittees will be required to use for surveying and monitoring production activities.

It should be noted that the DVA's amendment request was submitted in accordance with the timeline indicated in the ''Plan for the Transition of Regulatory Authority Resulting from the Expanded Definition of Byproduct Material'' (transition plan), which was noticed in the *Federal Register* (72 FR 59157) on October 19, 2007. It should also be noted that the permittees under the DVA's MML must meet the same transition plan requirements. Therefore, permittees who used, stored, produced and/or distributed PET radioactive drugs prior to November 30, 2007 and had permits that needed to be amended (e.g., needed a 10 CFR 30.32(j) authorization) should have already submitted an amendment request to the DVA's NHPP by May 30, 2008. Also, permittees who produced radioactive materials using an accelerator prior to November 30, 2007 had until December 1, 2008 to provide NHPP with a new permit application. Permittees that meet these requirements may continue their work with NARM, in accordance with NRC regulations, until the NRC makes its final decision regarding the DVA's request to produce and non-commercially transfer radioactive materials and PET radioactive drugs. All other permittees seeking authorization to produce radioactive materials using an accelerator and to produce and non-commercially transfer PET radioactive drugs must wait until the DVA's authorization is approved.

To continue review of your amendment request, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply and refer to the license, docket and control number specified below. If you have questions or require clarification on any of the information stated above, please contact Cassandra Frazier at (630) 829-9830.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Sincerely,

/RA/

Cassandra F. Frazier,
Senior Health Physicist
Materials Licensing Branch

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