From: Lanzisera, Penny
To: Mohapatra, Shashadhar M (Shashadhar.M.Mohapatra@Medstar.net)
Cc: Gaskins, Farrah; Gallaghar, Robert
Subject: Request for Additional Information for Renewal
Date: Tuesday, March 07, 2017 2:03:00 PM

MedStar Washington Hospital Center
License No. 08-03604-03
Docket No. 03001325
Mail Control No. 592388

Dear Dr. Mohapatra, in order to continue our review of your renewal request, please submit the following additional information:

1. Your application was signed by Gayle Thompson Smillie, Senior Director of Imaging. In a letter dated April 4, 2007, Catherine Monge was designated as the licensee's management representative. Please either submit a letter signed by Ms. Monge, the current management representative, indicating that management has reviewed the application and concurs in the statements and representations contained therein or designate Ms. Smillie as an additional authorized management representative, as signed by Mr. John Sullivan, President.

2. Your current mailing address includes "Administration, Room 2A2" and "-2975" as part of the zip code. Please confirm whether you wish to include this information in your mailing address. In addition, you are currently limited to use in specific rooms at 106 Irving Street, N.W. Please confirm whether you wish to continue this limitation.

3. With regards to your requested licensed material:

    a. Your current license authorizes the following for sealed sources that are not in devices:

B. Any byproduct material with atomic numbers 3 through 83
B. Sealed Sources (see Condition 12) B. xx curies
K. Hydrogen 3 K. Sealed Sources (manufacturer unknown) K. 20 microcuries
L. Carbon 14 L. Sealed Sources (manufacturer unknown) L. 4 microcuries
M. Cobalt 60 M. Sealed Sources (manufacturer unknown) M. 0.1 microcuries
N. Strontium 90 N. Sealed Sources (manufacturer unknown) N. 0.0097 microcuries
O. Technetium 99 O. Sealed Sources (manufacturer unknown) O. 0.005 microcuries
P. Cadmium 109 P. Sealed Sources (manufacturer unknown) P. 1 microcurie
Q. Iodine 125 Q. Sealed Sources (manufacturer unknown) Q. 1 millicurie
R. Iodine 129 R. Sealed Sources (manufacturer unknown) R. 0.7 microcuries
S. Cesium 137 S. Sealed Sources (manufacturer unknown) S. 30 millicuries

T. Barium 133 T. Sealed Sources (manufacturer unknown) T. 1 millicurie
U. Cerium 141 U. Sealed Sources (manufacturer unknown) U. 0.5 millicuries
V. Gd-153 V. Sealed Sources (manufacturer unknown) V. 40 millicuries
W. Thorium 230 W. Sealed Sources (manufacturer unknown) W. 1 microcurie

In addition, you requested additional radioactive material in sealed sources in your application (e.g., cesium-137). Please confirm if all these sealed sources can be consolidated in Item B and listed as follows and with a statement by you in your response that any new sources ordered will have a Sealed Source and Device Registry and will be possessed under the current possession limits of xx curies (with a possession limit provided):

B. Any byproduct material with atomic numbers 1 through 83 B. Sealed Sources (see Application dated November 1, 2016) B. xx curies

Additionally, please confirm that the Technetium-99 source may be listed with the sources above. If this source has been disposed, please provide disposal documentation. Finally, please confirm that the Thorium-230 may be listed as shown below. If this source has been disposed, please provide disposal documentation to support removal.

W. Thorium 230 W. Sealed Sources (manufacturer unknown) W. 1 microcurie

b. In section 5.a. of your application, you requested Americium 241, which is not currently listed on your license. Please provide the manufacturer and model number for the source being requested.

c. We understand that the Cobalt 60 permitted by 10 CFR 35.600 has been returned to the manufacturer. In item 6.E. you stated that Medstar Washington Hospital Center (MWHC) does not intend to reload the sources and would like to remove the device. Please provide disposal documentation, including leak test results, to support removal of the sources and the device from your license.

4. In Item 6 of your application, you request authorization for research and development, including animal studies. Additionally, in other parts of your application, you indicate that animal studies will not be performed. If licensed materials are to be used in animals, please submit:

a. a description of the animal housing facilities,
b. a description of the training that will be provided to individuals caring for animals containing licensed materials, and
c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

Appendix H of NUREG-1556, Volume 7, “Consolidated Guidance About Materials

Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" (NUREG-1556, Volume 7), addresses considerations for both laboratory animal research with licensed materials, and veterinary use of licensed materials. This guidance may be helpful to you in developing a response. You may also adopt this review process when you re-start animal studies.

5. In Item 6 of you application, you request authorization for research in humans. Please address the following:

    a. 10 CFR 35.6 states, in part, "A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research." Indicate if research involving human subjects and byproduct material at your institution is conducted, funded, supported or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. If not, (1) describe the type of research, radionuclide(s), chemical/physical form and activity; (2) state the sponsor(s) of the research; and (3) identify the appropriate reviewing and approving committees (e.g., Institutional Review Board and Radiation Safety Committee).

    b. Regardless of whether or not research involving human subjects and byproduct material at your institution is conducted, funded, supported or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects, 10 CFR 35.6 requires that at a minimum, prior review and approval of the research activities by an Institutional Review Board and informed consent from the human subjects be obtained. Confirm that, prior to performing research on human subjects, you will obtain (1) review and approval of the research activity by an Institutional Review Board; and (2) informed consent from each research subject.

6. Pursuant to 10 CFR Part 33, you have requested a Type A specific license of broad scope authorizing possession and use of any byproduct material, with atomic numbers from 1 to 83, for research and development activities as well as for activities authorized by 10 CFR Part 35. In order to be approved for this type of license, you will need to provide additional information as requested in NUREG-1556, Volume 11, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Licenses of Broad Scope" (NUREG-1556, Volume 11).

    a. In accordance with Section 8.7.1 of NUREG-1556, Volume 11, provide a description or an organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the Radiation Safety Committee (RSC). The chart submitted with your application does not include the RSC.

    b. In accordance with Section 8.7.2 of NUREG-1556, Volume 11:

        i. Indicate whether the RSC's duties include a review of all incidents

involving radioactive material.

ii. Provide criteria for selecting members of the RSC, including which members are **required** for a quorum and the minimum number of members that will constitute a quorum. Section 8.7.2, "Radiation Safety Committee" of NUREG-1556, Volume 11 contains information on the duties and responsibilities of the RSC and may be helpful to you in developing your response. Please note also that, in accordance with 10 CFR 35.24(f), your RSC must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer (RSO), a representative of the nursing service, a representative of management who is neither an authorized user nor the RSO, and other members as appropriate. Your proposed membership does not include a member from research. Please confirm that if non-medical research use is re-started, that a member will be added to your RSC.

iii. Describe the detailed information provided to the RSC for approval of users. For instance, indicate whether detailed training is documented on forms, such as the NRC Form 313 for authorized medical users, medical physicists, and nuclear pharmacists. Also, confirm that the minimum training and experience criteria your RSC will use to permit individuals to work as authorized nuclear pharmacists, authorized medical physicists (AMP), or authorized users (AU), as defined in 10 CFR 35.2, will be equivalent to that detailed in the current 10 CFR Part 35 (not Subpart J). For nonmedical AUs, describe the criteria used by the RSC for approval of new users and the documentation obtained for the RSC's review. For instance, indicate whether a Bachelor's degree is required and if the radiation safety training will require "hands-on" experience with the isotopes requested for use.

iv. Submit a description of the RSC program for review of protocols/permits issued to AUs. For example, the types and quantities of licensed material, a description of the experimental protocol and maximum quantities used at one time, a description of the clinical trial, the facilities and equipment proposed, the operating or handling procedures, the types of surveys and frequency required, the training of supervised individuals who will work under the protocol, potential exposure pathways, and appropriate shielding should be addressed during protocol review. Your application must provide sufficient detail to assure that the RSC evaluations are sufficient in scope and depth to satisfy 10 CFR Part 33.

v. In your application you describe a permit renewal process. Please indicate how often this process will be performed.

vi. Describe the criteria your RSC will use to approve new uses in medical areas, including Nuclear Medicine and Radiation Oncology. For instance will the criteria used for approval of your current facilities and as described in NURG-1556, Volume 9, be used?

c. You have submitted various procedures for Beta-Cath, Radioactive Seed Localization (RSL), and Microsphere use. These procedures should be approved by your RSC instead of prescriptively tied to your license. Provide the criteria that will be used by the RSC to approve uses, training for authorized personnel, procedures, and facilities and equipment for all emerging

technologies authorized pursuant to 10 CFR 35.1000. For instance, will the criteria published by NRC for emerging technologies be adopted by your RSC? The "Emerging Technologies and 10 CFR 35.1000 Table" on the NRC public website at http://www.nrc.gov/materials/miau/med-use-toolkit.html may be helpful in designing your criteria. In addition, please note that your microsphere guidance, conventional brachytherapy, and high dose rate brachytherapy procedures refer to "Radiation Oncologist" and your RSL guidance refers to Radiologist in several places without clarification if these are the AUs. Please clarify if these are AUs. It is not necessary to re-submit the procedures in your response. Finally, please note that the procedure entitled "Radiation Safety Procedure During Y-90 Microsphere Treatment" appears to be incomplete in Item 1.ii. For instance the last part of the last sentence appears to apply to the prior sentence.

d. In accordance with Section 8.7.3 of NUREG-1556, Volume 11:

   i. Provide a copy of senior management's current written statement of delegation of authority to the RSO. The statement submitted in your application is dated May 14, 2002, and signed by Michael H. Covert, President. The current president is John Sullivan. Please send an updated Delegation of authority issued by the current licensee management representative; either Ms. Catherine Monge, Vice President, or Mr. John Sullivan, President. This statement should include the requisite authority to communicate with and direct personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material. Appendix J of NUREG-1556, Volume 11 contains a model delegation of authority and may be helpful to you in developing your response. In addition, if management will delegate authority to the RSO for submission of NRC license amendments on their behalf, please provide a copy of this delegation.
   ii. Confirm that the RSO's responsibilities will not be delegated to another individual. While other individuals may assist in the tasks and duties associated with managing the radiation safety program, the responsibility for these tasks/duties should not be transferred.
   iii. Confirm that the RSO will attend all RSC meetings whenever possible and that meetings will be missed rarely. In the event that a meeting will be missed, describe the mechanism for informing the RSO of the decisions reached during the meeting.

e. The NRC will provide even greater flexibility to Type A Broad Scope licensees to make some programs changes and changes to procedures specifically identified in documents which were previously approved by the Commission and incorporated into the license, without prior Commission approval. If you would like authorization for this flexibility, confirm that:

   i. Changes to your program and procedures will be limited to the following areas: radiation safety training; audit program; radiation monitoring instruments; material receipt and accountability; occupational dose; safe use of radionuclides; and survey/leak test program. In addition, state that

you will apply for, and receive an amendment to your license prior to implementing any other programmatic or procedural changes.

ii. The proposed revision will be documented, reviewed, and approved by the your RSC in accordance with established procedures prior to implementation.

iii. The revised program will be in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.

iv. Your staff will be trained in the revised procedures prior to their implementation.

v. Your audit program will evaluate the effectiveness of the change and its implementation.

7. In accordance with Section 8.8 of NUREG-1556, Volume 11, describe your radiation safety training program, and refresher training, for each group of workers (such as nonmedical AUs, laboratory supervisors and technicians; incinerator operators, waste compactor operators, and purchasing department personnel receiving licensed material; housekeeping, nursing, security, and other ancillary personnel; the radiation safety office staff; etcetera). Include the topic(s) covered, qualification(s) of the instructor(s); method of training; method for assessing the success of the training, and the frequency of training and refresher training. Alternately, you may identify an applicable model training program, (such as that in Appendix J of NUREG-1556, Volume 7) and submit a statement that this training program will be implemented.

8. In Item 10.2, you describe the use of contractor staff in medical areas and indicate that "adequate mechanisms for oversight will be in place." Please describe these mechanisms and confirm that the licensee accepts responsibility for all activities conducted by contractor staff.

9. In addition to the information provided in response to question 6 above and in accordance with Section 8.9 of NUREG-1556, Volume 11, describe the criteria the RSC will use to review and approve facilities and equipment. In your application, your outline three classifications of laboratories (Type A, Type B, and Type C); however additional information is necessary as noted below. Appendices K and L of NUREG-1556, Volume 11 and Appendix K of NUREG-1556, Volume 7 contains guidance which may be helpful in developing your response. Your description should include:

    a. the method of classifying laboratories based on types, quantities, and toxicity of the byproduct material requested to be used;

    b. confirmation that security mechanisms will be reviewed during authorization;

    c. sample diagrams for each classification scheme that considers radiation safety of workers and proximity to unrestricted areas, and ventilation if radioactive materials may become airborne;

    d. locations of facilities designed or established for special uses (such as laboratories using greater than 10 millicuries per experiment, nuclear pharmacies, iodination/tritiation laboratories, unsealed alpha laboratories, animal facilities, incinerators, compactors, large quantity/high activity processing

facilities, instrument calibration facilities, waste handling or processing facilities, long-term waste storage facilities, etcetera) and the procedures for Radiation Safety Committee review of such facilities and significant changes or modifications to such facilities,

e. the criteria the Radiation Safety Committee will use to determine if special facilities or equipment are required, such as: use of fume hood, glove box, etcetera when working with volatile radioactive materials; use of remote handling equipment when working with high-activity sources; the types of storage containers and/or shielding for high-energy beta-emitting or gamma-emitting radionuclides.

Please note that Figure 1 of Attachment 6 appears to indicate that the location currently used for radioactive waste storage will become a "Building Site." Please confirm if this area will no longer be used for radioactive waste storage and in fact is the location for a new building. If this is the location for a new building, please provide the notification required by 10 CFR 30.36 (d). In addition, please describe how the area will be evaluated to ensure compliance with 10 CFR 20.1402 and provide documentation of the results of the radiological assessments that show compliance with 10 CFR 20.1402.

10. In accordance with Section 8.10.1 of NUREG-1556, Volume, 11:

    a. describe the mechanism(s) that will be used by executive management to ensure that adequate oversight of the radiation safety program is exercised, including the role of the RSC in the oversight mechanisms.

    b. describe the audit mechanism(s) that will be implemented by the RSO or other responsible individual(s) to determine user compliance with NRC regulations, the license, the requirements of Radiation Safety Committee approvals, and good health physics practices.

11. In accordance with Section 8.10.2 of NUREG-1556, Volume 11:

    a. describe the criteria that will be used by the RSC to review and approve radiation monitoring instrumentation and to assure that appropriate radiation monitoring equipment will be used during licensed activities.

    b. Submit your instrument calibration procedures and specify the frequency of instrument calibration, or state that your instruments will be calibrated by the instrument manufacturer or a person specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform instrument calibration. If you intend to calibrate your own instruments, you may commit to implementing the model procedure in Appendix O of NUREG-1556, Volume 11; with an identification of the source(s) used. In addition, please describe the criteria used by the RSC for approving individuals performing meter calibrations. Finally, confirm that the lower limit of detection will be determined for instrumentation used in quantitative sampling and analysis.

12. In accordance with Section 8.10.3 of NUREG-1556, Volume 11, describe your

administrative procedures and other provisions to assure (1) control of procurement and use of licensed material; (2) inventory, control and accounting of licensed material; and (3) security of licensed material from unauthorized removal from the place of storage (10 CFR 20.1801) and in unrestricted areas (10 CFR 20.1802). In addition, submit your procedures for transfer and transportation of licensed material between AUs at your facility, and your procedures for transfer and transportation of licensed material to other licensees. Describe your program to control such transfers, including update of material inventory and audits of users' procedures.

13. In accordance with Section 8.10.6 of NUREG-1556, Volume 11, provide your general rules for safe use of radioisotopes, and your procedures in case of emergencies involving licensed materials. You may commit to implementing the model procedures in Appendix R of NUREG-1556, Volume 11. You should also consider if additional safety procedures should be implemented for such activities as handling millicurie quantities of phosphorus-32, iodinations or other radio-labeling procedures, handling of animals that contain licensed materials, etcetera.

14. In accordance with Section 8.10.11 of NUREG-1556, Volume 11, submit your procedures to evaluate external and internal radiological hazards. You may state that you will implement the model procedures contained in Appendix S of NUREG-1556, Volume 11. Your survey program should include:

    a. correlating the survey frequency for research laboratories to the hazard using a scheme such as that found in Appendix K of NUREG-1556, Volume 11, or Appendix Q of Volume 7 and correlating medical area surveys using a scheme such as that found in NUREG-1556, Volume 9. Survey procedures should consider the areas to be surveyed, the types and levels of radiation and contamination considered to be acceptable, and provisions for maintaining records of surveys.

    b. the types and frequencies of confirmatory surveys and monitoring that will be performed by the RSO and staff in both unrestricted and restricted areas, and the types and frequencies of routine surveys and monitoring that will be performed by AUs and radiation workers.

    c. criteria for monitoring to assess internal dose, which may be required for certain uses of material under your license. This may include surveys for airborne licensed materials such as breathing zone and general work area air sampling and direct or indirect bioassay measurements.

    d. criteria for assessing dose from skin contamination incidents.

    e. criteria for surveys and sampling to ensure compliance with 10 CFR 20.1302 for releases of licensed materials in gaseous or liquid effluents to unrestricted areas. This may include hood and room ventilation air flow rate measurement and air sampling, stack effluent sampling, sampling of releases to rivers or privately owned sanitary sewerage treatment facilities or septic tanks.

    f. criteria for surveys and sampling to ensure compliance with 10 CFR Part 20, Subpart K, and other waste disposal requirements of the license. This may

include surveys or sampling of releases into public sanitary sewerage, other specific wastes, and surveys of materials stored for decay.

g. action limits for all surveys, and the actions to be taken when these limits are exceeded.

In addition, please note that License Condition 14 is no longer necessary as the regulations related to external exposures were clarified in questions and answers found in NUREG 1736.

15. If you plan to release facilities and equipment for unrestricted use, describe the criteria you will use to determine the types of surveys you will require and the criteria you will use to determine if levels of residual radioactivity are acceptable. Facilities to be released for unrestricted use must meet the NRC criteria specified in Subpart E of 10 CFR Part 20. Equipment to be released may meet the criteria in the NRC "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material". Describe the administrative procedures for review and approval of survey results by the Radiation Safety Officer or the Radiation Safety Committee prior to release of facilities or equipment. Additional guidance for surveys to be performed prior to release of facilities may be found in NUREG-1757, “Consolidated Decommissioning Guidance.”

16. In accordance with NUREG-1556, Volume 11, submit your leak test procedures. You may commit to implementing the model leak test program in Appendix T of NUREG-1556, Volume 11. If you elect to have another person perform leak tests, submit the name of the person and the applicable U.S. Nuclear Regulatory Commission or Agreement State license number.

17. In accordance with Section 11 of NUREG-1556, Volume 11, provide your procedures for waste collection, storage, and disposal. Describe any significant radioactive waste treatment procedures that will be performed at your facility, such as compaction, evaporation, solidification, liquid scintillation vial crushing, etcetera. Model waste procedures provided in Appendix T of NUREG-1556, Volume 7, may be helpful in developing your response. Confirm if you want to be authorized to perform decay-in-storage of non-medical waste, in addition to medical waste.

18. For any therapy and PET facilities, provide the information described below for shielding. Drawings should be to scale, and the scale, plane, and elevation indicated.

    a. Diagrams for each dedicated remote afterloader room, including location of doors, windows, conduits, and viewing ports.

    b. Location, distance, room numbers, and principal use of each adjacent room or area (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below. Indicate whether each room or area is restricted or unrestricted as defined in 10 CFR 20.1003.

    c. Shielding calculations, with information about type, thickness and density of all shielding materials, including walls, floor, ceiling and viewing ports (if applicable) to enable independent verification of shielding calculations. For HDR facilities,

include information on the maximum “on time” per hour and per week and occupancy factors used for all adjacent areas. Shielding calculations must demonstrate compliance with 10 CFR 20.1301.

d. For HDR facilities, describe other radiation producing equipment housed within the same or adjacent rooms, (e.g., linear accelerator, orthovoltage machine) and mechanisms in place to ensure no two radiation producing machines can be used simultaneously.

e. For HDR facilities, indicate the location of area radiation monitoring equipment, that indicates the presence of radiation to an individual entering the treatment room.

f. Confirm that subsequent diagnostic and therapy facilities approved by the RSC will be similar to those described here.

g. Please note that in your application, you reference Lab #4; however, Figure 9 does not include this lab. In addition, the diagram for the Cath Lab Radiation Storage room was not included in your application attachments. You are not required to submit these diagrams, but should ensure that your files include this information.

19. With regards to your brachytherapy procedures:

a. 10 CFR 35.643(d) lists the minimum requirements for spot checks for licensees authorized to use a remote afterloader unit for medical use. Please confirm that your HDR spot-checks will be performed in accordance with nationally recognized standards and will include all items listed in the regulations.

b. Your High Dose Rate (HDR) Brachytherapy Implants procedure refers to second independent physics checks. Please describe if these checks are done by two different individuals or if done by two different methods.

c. Indicate if second independent checks are performed of written directives or treatment plans for conventional brachytherapy; and if so, how.

d. In Attachment “B” for conventional brachytherapy, the prescription form does not include documentation of the expected time of removal of sources. Please clarify how total prescribed dose is verified.

e. The Post Treatment Surgical Considerations for microspheres include values of “<20 mSv patient skin surface dose rate” for special handling, “exceeds 50 uSv/hr” for labeling of a container with an explanted liver, and “15-20 uSv” for when no extremity monitors are needed. Please provide the reference for these values.

f. Please describe the emergency response equipment available for manual brachytherapy. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radioactive materials labels.

20. 10 CFR 35.12 requires that licensees submit detailed facility and equipment descriptions for remote afterloader units. Please provide a description of the following:

    a. Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;

    b. Area radiation monitoring equipment and its location;

    c. Viewing and intercom systems;

    d. Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;

    e. Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons;

    f. Emergency response equipment (e.g., shielded container large enough to accommodate all applicators, long-handled tongs, and wire cutters).

21. In accordance with Section 8.20 of NUREG-1556, Vol.9, please address the following with respect to your HDR:

    a. Confirm that only authorized, trained persons will have access to the facility/HDR keys.
    b. Confirm that the HDR will not be used in pulsed mode.

22. In accordance with 10 CFR 35.610 please confirm that the following with respect to your HDR:

    a. Your training program will include initial and annual training on operating instructions, and drills of the emergency procedures and that those in attendance include AMPs, AUs, and all individuals who operate the unit.

    b. In accordance with 10 CFR 35.610(a)(4)(ii), confirm that you will modify your emergency procedure to include “posting” the treatment area in the event the source does not retract to minimize the risk of inadvertent exposure. In addition, confirm that your procedures will: (i) specify the individual(s) responsible for implementing each step of the emergency plan, (ii) describe the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure, (iii) include the names and telephone numbers of AUs, AMPs, and the RSO, and (iv) describe bringing the patient into the Trilogy room for source removal and describe the shielding available in this room for ensuring that public dose limits and occupational dose limits are maintained.

    c. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an un-retracted or stuck HDR source.

23. In accordance with 10 CFR 35.615 please confirm the following with respect to your HDR:

    a. That an AU and an AMP will be physically present during the initiation of every treatment.

    b. That an AMP and an AU or a physician under the supervision of the AU who has been trained in the operation and emergency response of the unit is physically present throughout the treatment.

    c. The Radiation Safety Officer will be notified of any death or medical emergency.

24. With regard to your patient release calculations and instructions provided in accordance with 10 CFR 35.75, please provide the following clarifications:

    a. Provide the reference to support the formula used for Tositumomab study patients.
    b. Provide the rationale to support use of 14.3 mrem/hour-meter for thyroid patient release and 25 mrem/hour-m for Tositumomab study patients used in Section IV.

25. Section 10.4 “Sealed Sources Leak Test Procedure” discusses the use of sealed sources or devices received from the vendor without prior NRC or Agreement State review and registration. Please confirm that should you take possession of sealed sources or devices that have not been reviewed by the NRC or an Agreement State and registered on the Sealed Source and Device Registry you will perform a review of the source(s) or device(s) that includes sufficient information as described in 10 CFR 32.210 (c).

26. Your irradiator was added to your license in 2005. The supporting documentation that you submitted with your application which discusses the irradiator is the original information submitted in 2005. Please confirm that the location, and commitments remain unchanged. In addition, please submit the following statements:

    a. Before being named as the RSO, future RSOs will have successfully completed training described in Appendix G in NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses.’

    b. Before using licensed material, AUs will receive the training described in Appendix G in NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses.’

    c. We will ensure that each area where a self-shielded irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and

control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.

d. We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's (or distributor's) written recommendations and instructions.

e. Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one 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 Criteria in the section entitled "Radiation Safety Program Occupational Dose" in NUREG - 1556, Vol. 5.

In addition, in Item 10, the irradiator procedures indicate that area monitors would be “placed for a reasonable period of time.” Please provide the results of your area monitoring and indicate if monitoring is still conducted.

Please contact Farrah Gaskins at 610-337-5143 or Robert Gallaghar at 610-337-5182 with questions on this request for additional information. We will continue our review of your license renewal upon receipt of the response to this request. Please reference Mail Control No. 592388 in your response.

Sincerely,
Penny Lanzisera
Senior Health Physicist
U.S. NRC, Region I