WestVirginiaUniversityHospitals

April 17, 2012

Docket No. 030-20233 License No. 47-23066-02
Control No. 576453

Tara Weidner, Health Physicist
United States Nuclear Regulatory Commission-Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406

SUBJECT: Response to U.S. NRC E-mail request, on March 22, for additional information

Dear Ms. Weidner:

This packet is in reference to your e-mail request for additional information dated March 22, 2012.

If you have any further questions or concerns regarding our responses please feel free to contact Radiation Safety Department at 304-293-1554.

Sincerely,

Stephen E. Tancin
Vice President, Ancillary and Support Services

Nasser Razmianfar
Director and Radiation Safety Officer

Enclosure

Hospital Administration
Ruby Memorial Hospital
West Virginia University Children's Hospital
Jon Michael Moore Trauma Center
Chestnut Ridge Center

Phone: 304-598-4200
www.health.wvu.edu

PO Box 8059
Morgantown, WV 26506-8059

"With regards to your locations of use, "

Please disregard listing on Room B816. It is encompassed in the Health Sciences Center South Building currently listed on our license.

"With regards to the licensed material requested, "

1. A) the list of all specifically licensed sealed sources currently in our possession (> 1mCi) and for sources above the millicurie ranges

Isotope	Model#	Manufacturer
31 X Gd-153 *1	A-3410/A3432	Eckert & Ziegler

*1 Gd-153 for use in Ccams for patient attenuation.

Isotope	Model#	Manufacturer
4 X Ge-68 *2	PET-180/1 /PET-20C19/1	Sanders Medical
3 X Ge-68 *3	CS-27/LS-LA/11797/11798	Siemens

*2 and *3 Gd-68 for use as a reference for PET/CT Scanner and as a reference in a dose calibrator

Isotope *4	Model#	Manufacturer
Co-57	BM06E-57	RAD Qual, LLC
Co-57	BM101-10	RAD Qual, LLC
Co-57	MED-3727	Eckert & Ziegler
Co-57	RU-057-5M	Eckert & Ziegler
Co-57	BM1005/71204010	RAD Qual, LLC
Co-57	RV-057-5M	Eckert & Ziegler
Co-57	MED3709	Eckert & Ziegler

*4 all the listed Co-57 is used for dose calibrator and Flood sources

Sealed Sources above the millicurie Ranges

Isotope	Model#	Manufacturer
Co-60	AB ELEKTA MODEL 43047	GENERAL ELECTRIC CO.
Ir-192	VS 2000	VARIAN MEDICAL SYSTEMS

At this time, we don't possess Alpha sealed sources. And we confirm that Table 6. Item B may be reduced to 100 millicuries per sources and 1.5 Curies total.

2. A. Iridium-192 in Item 6.E, after every usage, was shipped out/returned to the company. Currently we don't have Ir-192 of Item 6.E in our possession. However, we are requesting to keep it in our license for a future use.

   B. Americium-241, Item 6.O. is not in our possession. Discussed with former RSO's, believed it was shipped in the early 1990's.

3. We wish to continue to be authorized to use these materials under our specific license as written on current license
4. We confirm that we possess VariSources iX HDR- Ir-192.

"With regards to individuals responsible for the Radiation Safety Program,"

"Executive Management:"

1. Executive management is made aware of the results of periodic audits and the annual program review primarily through participation/attendance of the quarterly Radiation Safety Committee (RSC) meetings during which quarterly and annual reports are reviewed and discussed by members. The individual, at the senior management level, who is responsible for the oversight of the facility's radiation safety program is a permanent member of the RSC and attends the quarterly meetings. If s/he cannot attend a suitable representative attends in their stead.
2. An organizational chart can be found as an attachment to this document.

"Radiation Safety Committee:"

1. A list of the current members of the RSC follows, including several senior research staff:
   a) Vice President (Executive Mgt), Hospital Administration
   b) Vice President (Executive Mgt), HSC Administration
   c) Director/RSO, Radiation Safety Department
   d) Professor/Researcher, Chemistry
   e) Director, Clinical Services
   f) Technologist, Jefferson Memorial
   g) JD, Legal Services/Risk Management
   h) Professor/Researcher, Neurobiology & Anatomy
   i) MD, Nuclear Medicine/PET Center
   j) Coordinator, Nursing Education
   k) Manager, Nursing/8 East
   l) RN/Manager, Oncology 9/West
   m) Professor/Researcher, Physiology & Pharmacology
   n) Medical Physicist, Radiation Oncology
   o) MD and Chair, Radiation Oncology
   p) MD, Radiation Oncology
   q) Director, Radiology
   r) Administrative Director, Research & Graduate Studies
   s) Manager, Ruby Day Surgery
2. We confirm that final approval of new uses, users, and facilities will be provided by the RSC.
3. Information provided to the RSC for approval of users is as follows:

a) As stated in our Radiation Safety Manual: "An applicant must show that they fulfill the pertinent training and experience requirements in 10 CFR 35. These include board certification or specific training in relevant radioisotope handling techniques and appropriate clinical experience. Applicants should support their training and experience history with a preceptor statement from their training institution."

We confirm that medical users will be required to meet the training and experience requirements in 10 CFR Part 35 and on the NRC's website for emerging technologies.

b) For an individual to become an Authorized User, the person must have completed Radiation Safety training provided by the Radiation Safety Department. The provided Authorized Radiation User training consists of the following topics:

- Radiation Basics and Radiobiology
- Surveying and Monitoring
- Lab Protection
- Purchasing
- Nuclear Gauges and Irradiators
- Laboratory Inspection
- Obtaining and Maintaining an Authorization
- Training of Laboratory Personnel
- Overview of Radioactive Waste Disposal Procedures

Prospective Authorized Users must also have ample experience before the Radiation Safety Committee will authorize his or her use of radioactive materials or radiation producing devices. The Authorized User (or Prospective Authorized User) must file an application that meets the requirements of this section. The application process includes a technical review of qualifications by the Radiation Safety Department staff, who will make a recommendation to the Radiation Safety Officer. This recommendation will be reviewed by the Radiation Safety Officer and if deemed appropriate forwarded to the Radiation Safety Committee for consideration. Authorized Users must complete Radiation Safety training prior to assuming duties with or working in the vicinity of radioactive materials. In addition to the initial Radiation Safety training, Authorized Users must attend training whenever there is a significant change in duties, regulations, or the terms of the license AND must complete Radiation Safety refresher training annually in order to maintain his/her authorization status.

Authorized User application evaluations include the following:

a.) Identification and review of the types and proposed uses of all radiation sources in the application form. The review and subsequent permit approval is based on the radioactivity used at one time or the design parameters of the radiation producing device. Requests that include possession of radionuclides will consider the amount used at one time, with possession limits that are adequate to cover laboratory operations. In addition, the applicant must agree to abide by all policies and procedures for acquisition, use, storage and disposal of radioisotopes.

b.) The Prospective Authorized User must be a full time staff member demonstrating the appropriate education, training, and practical experience commensurate with the radiation sources to be used. Prospective Authorized Users who wish to be approved by a radiation safety committee must submit a statement from a sponsoring faculty member that he or she is the appropriate principal investigator and is granted full responsibility for the laboratory

c.) The Radiation Safety Officer will review the application and may suggest changes. The application will then be considered at the next meeting of the appropriate radiation safety committee which may accept the proposal or suggest changes necessary for approval.

d.) Applicants must give pertinent information about their training and experience, a protocol for the proposed project and a description of their laboratory. Current policy requires that a prospective radionuclide user demonstrate his or her knowledge of radiation protection practices by successfully completing a short examination. An investigator may arrange to take the exam at any time by calling the Radiation Safety Department.

e.) A representative of the Radiation Safety staff may wish to interview the applicant or inspect the laboratory before radionuclide use is permitted. This will assure that the laboratory is properly set up, that acceptable monitor and survey instruments are available, and that required notices are posted

4. In order to use radioactive material for human use not exempted by the State of West Virginia, an individual must first be approved as an Authorized User by the appropriate radiation safety committee. The RSC is responsible for insuring that radioactive materials are used safely and in compliance with ALARA. This is accomplished, in part, by formal review of a written permit application for the proposed radioisotope use. The application describes the isotope(s), amount(s), facilities, experimental procedures, hazards, precautions and the qualifications of the applicant.

The Radiation Safety Officer may grant temporary approval pending review by the committee. A prospective Authorized User must submit an application for the use of radiopharmaceuticals to the Radiation Safety Department. An applicant must show that they fulfill the pertinent training and experience requirements in 10 CFR 35 Subpart J. These include board certification or specific training in relevant radioisotope handling techniques and appropriate clinical experience. Applicants should support their training and experience history with a preceptor statement from their training institution. Prior to being designated as an any AU PI, the candidate must demonstrate to the RSO knowledge and capability in radiation safety fundamentals and the requirements and procedures established in the WVU Hospitals manual, policy and procedures and relevant SOP's.
The RSO reviews with AU PI candidates the requirements set forth in this manual, relevant SOP's, and the RM license during the application process. Explicit radiation safety procedures for each research experiment or operation are tailored to the experiment and are established by the AU PI prior to its implementation. Where appropriate, the guidance and requirements presented in radiation safety shall be incorporated into experimental protocols to assure the safe handling of RAM. The uniqueness of an experiment may require modification of these procedures. Accordingly, the AU PI should consult the RSO for technical guidance and to determine the proper methods for safely handling and disposing of RAM, while maintaining the experimental objectives.

The use of all experimental techniques on humans involving radioactive material or otherwise is governed by the WVU Institutional Review Board (IRB). All experimental procedures involving radiation exposure must also be approved by the Human Use of Radiation and Radionuclides committee. Protocols which involve procedures which are in clinical practice or have been approved by the Human Use committee may be approved by the Radiation Safety Officer. The Human Use committee has adopted the radiation exposure limits for all research subjects which are required for FDA studies per 21CFR 361.1(b)(3)(i & ii).

5. The Facility and Equipment have been designed to adequately protect health, minimize danger to life and property, minimize the likelihood of contamination, and keep exposures to workers and the public ALARA as required under 10 CFR 30.33(a) and/or 35.18(a). West Virginia University Hospitals, Inc demonstrates that all facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the types and quantities of radioactive materials to be used. Facilities and equipment n is also designed to control exposure ranging from a vial that contains licensed material, to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but also limit access and secure the source. All facilities that will be used as a radiation area is reviewed and approve by RSC and RSO before it used for its safety and security.

WVU Hospitals, Inc does not classify laboratories based on type, toxicity and quantity of byproduct material being requested. All radiation areas (RAM labs) are restrictive areas. Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials.

The following shall be posted with the radiation symbol and a "Caution - Radiation Area" sign: any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05mSv (5 mrems) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates. High Radiation Area shall be posted with the radiation symbol and a "Caution - High Radiation Area" sign: any area, accessible to individuals, in which radiation levels could result in an excess of 1 mSv (100 mrems) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates and also Very High Radiation Area shall be posted with the radiation symbol and a sign bearing the words "GRAVE DANGER, VERY HIGH RADIATION AREA": any area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Grays (500 rads) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. Airborne Radioactivity Area: shall be posted with a "Caution - Airborne Radioactivity Area" sign: a room, enclosure or area in which airborne radioactive materials exist in concentrations -

1. In excess of the derived air concentrations (DACs) specified in Appendix 16.7, or,
2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

Once Authorization approval has been granted, Principle Investigators must set up their labs following Radiation Safety Department Guidelines. A member of the Radiation Safety Department shall be contacted to assist the Authorized User in lab setup. All labs where radioactive materials will be utilized shall meet the following general criteria for authorization as an "active" lab. The physical requirements.

1. Floors: smooth and continuous surfaces are recommended; tiles and so forth are acceptable if cracks are filled with wax.

2. Walls, ceiling and woodwork: non-porous surfaces should be washable.
3. Ventilation: labs with more than 10 microcuries of radionuclides should have hoods with face velocities of at least 100 linear feet per minute when the sash is at working height and individual exhaust air filters.
4. Equipment: suitable monitoring and measuring equipment for the radionuclides and activities used must be available.
5. Benches: should have non-porous tops with no sharp corners. Use of absorbent paper and strippable paint is recommended.
6. Monitoring: appropriate monitoring for the radionuclides used will be required. This will generally consist of a check of the area with a survey meter or wipe tests taken throughout the area. These surveys must be carried out on each day when radionuclides are used; monthly surveys are required even if no radionuclides are used. Results of these surveys must be recorded and be available for inspections.
7. Shielding: the requirement of shielding will be decided based on the kind of isotopes being used. WVU Hospitals, Inc requires labs that use high energy beta emitters to use Plexiglas and lead blocks for gamma emitters.
8. Hood: any lab that uses volatile material or iodination shall have approved hood. An approved hood shall have an air flow of at least 100 linear FPM when the sash is at working height. This will be checked by a representative of the Radiation Safety office before being put into use and at least annually thereafter.

Essentially, Radiation Safety Committee will be using the following criteria's as a bench mark in reviewing and approving facilities and equipments in West Virginia University Hospitals, Inc:

I. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.

II. Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces. Surfaces should be smooth and non-porous, to facilitate decontamination.

III. Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

IV. Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.

V. Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

VI. A particular sink should be designated however, it is the policy of WVU Hospitals Inc not to dispose any liquid radioactive waste to the sanitary sewerage system.

VII. Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.

VIII. Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

IX. Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
X. Designated areas should be provided for coats and personal belongings, to avoid contamination.
XI. Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
XII. Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
XIII. Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
XIV. The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
XV. If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H.
XVI. If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204.

6. For current types of facilities described in this application, the RSC will review future facilities against criteria used for currently approved facilities.
7. We confirm that the RSC duties and responsibilities will include:
    a. Review and approval of permitted program and procedural changes prior to implementation;
    b. Implementation of program and procedural changes;
    c. Audit of licensed operations to determine compliance; and
    d. Taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.
8. When approving uses, training for authorized personnel, and facilities for emerging technologies licensed under 10 CFR 35.1000, the RSC will review applicable sections of the "Licensing Guidance for 10 CFR 35.1000 Sealed Sources and Devices" in order to design criteria for approval.
9. The committee's duties include a review of all incidents involving radioactive material. This is addressed during committee meetings during the review of quarterly and annual reports in which there are sections specifically addressing incidents.

"Radiation Safety Officer:"

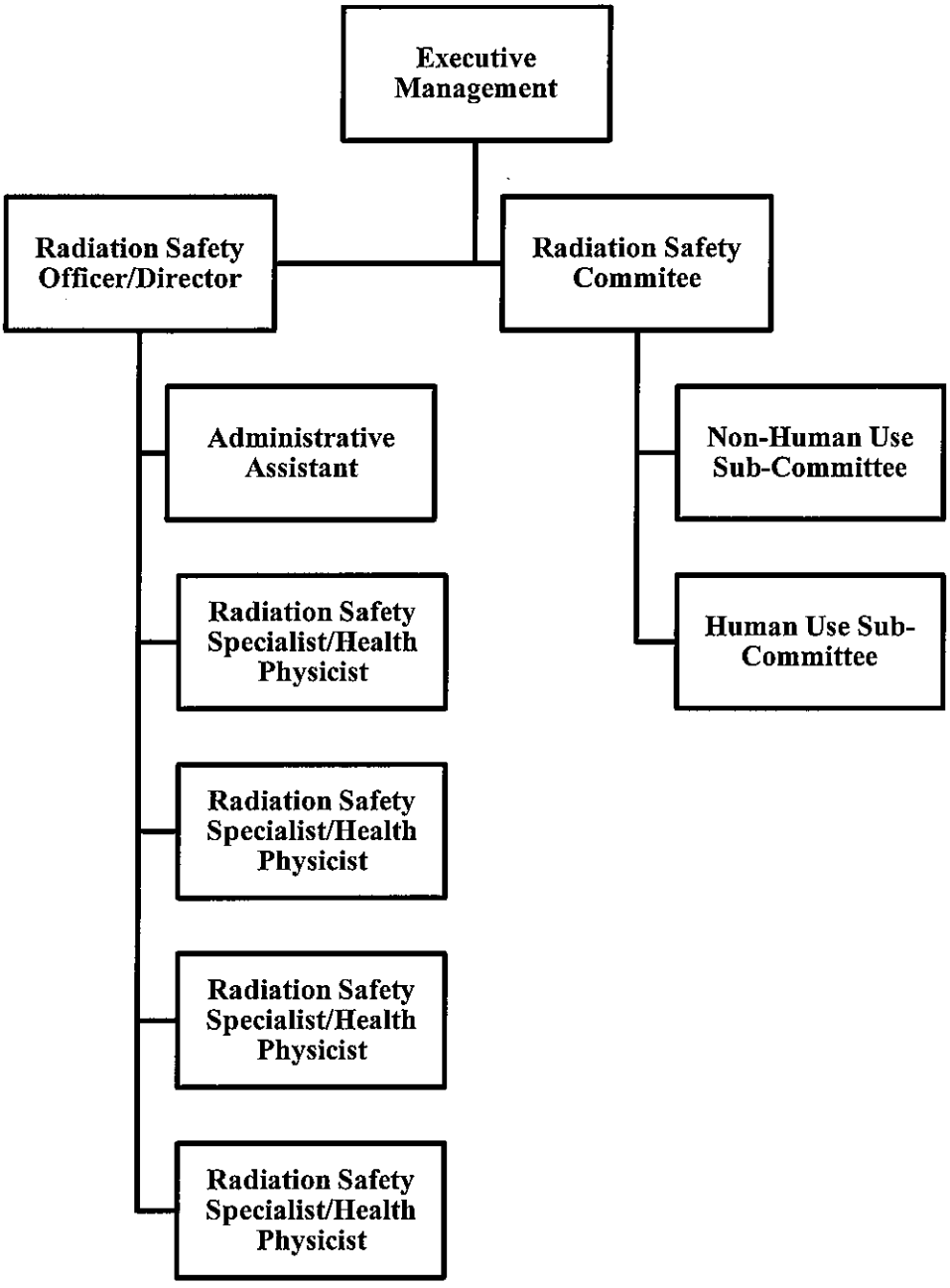
1. A Delegation of Authority for our Radiation Safety Officer signed by executive management is attached.
2. We confirm that the RSO's responsibilities will not be delegated to another individual.
3. We confirm that the RSO will attend all RSC meetings whenever possible and that meetings will be missed rarely. In the event that a meeting will be missed, the chair of the committee will direct the meeting and all minutes will be provided to the RSO for review.

"Training Program:"

1. Training is provided by either approved Authorized Users or designees of the Radiation Safety Officer such as members of the Radiation Safety Department staff. All training materials have either been developed or reviewed/approved by the RSO.
2. Following training required prior to work with license material, individuals are tested on the training material and must pass the evaluation with a proficiency of 80% or greater.

West Virginia University Hospitals-Radiation Safety Department

Organizational Chart Summarizing Management Structure



WestVirginiaUniversityHospitals

MEMORANDUM

To: All Authorized Users

From: Stephen L. Tancin
Vice President, Ancillary & Support Services

Date: April 12, 2012

Re: Delegation of Authority for Radiation Safety Officer

In order to fulfill all United States Nuclear Regulatory Commission (USNRC) requirements for the renewal of West Virginia University Hospital Inc. Type A Broad Scope license for radioactive materials, the following Delegation of Authority for the current Radiation Safety Officer must be furnished to the USNRC and available to all affected employees.

Nasser Razmianfar has been appointed as WVU Hospitals, Inc. Radiation Safety Officer (RSO) since June 2000 and is responsible for ensuring the safe use of byproduct material. He is responsible for administration of the radiation safety program; identifying radiation safety problems; initiating, determining root causes, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of byproduct material.

The RSO shall insure that radiation safety activities are being performed safely according to approved policies and procedures, and all regulatory requirements are met. He shall have full access to all activities involving the use of byproduct material.

The RSO has the authority to immediately stop any operations involving the use of radioactive material in which health and safety may be compromised or may result in non-compliance with USNRC requirements. The RSO is hereby delegated the authority necessary to meet these responsibilities.

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 will not be transferred.

Stephen L. Tancin
Vice President, Ancillary & Support Services
WVU Hospitals, Inc.

cc: Nasser Razmianfar, Director and Radiation Safety Officer
Darlene Headley, Director, Radiology/Radiation Oncology
Geraldine Jacobson, MD, Professor and Chair, Radiation Oncology
Radiological Safety Committee

Hospital Administration

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