NRC FORM 699 (03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 06/12/2015

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Alan M. Jackson, M.S., CHP, Radiation Safety Committee Chairperson	05/12/2015	☐ E-MAIL ☑ TELEPHONE
E-MAIL ADDRESS: alanj@rad.hfh.edu	TELEPHONE NUMBER: (313) 911-6273	☐ INCOMING ☑ OUTGOING

ORGANIZATION	DOCKET NUMBER(S)
Henry Ford Hospital	030-02043
LICENSE NUMBER(S)	CONTROL NUMBER(S)
21-04109-16	586401

SUBJECT

Our review of your March 17, 2015, license renewal application. Additional information is requested by August 12, 2015. Please email your response as pdf attachment to sara.forster@ nrc.gov, or send via FAX to (630) 515-1078.

SUMMARY AND ACTION REQUIRED:

Please provide information noted below. Respond via a signed & dated cover letter, using typed 8.5" x 11" sheets. Refer to NUREG 1556, Vol. 11, "Program-Specific Guidance About Licenses of Broad Scope," at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v11/, when responding. Please call or email me with any questions.

ADDITIONAL INFORMATION NEEDED:

1. Please provide the licensee name to be listed in Item 1 to the license. If the licensee's name has changed from "Henry Ford Hospital" as listed on the previous amendment to the license, please explain the change, including to confirm that the change is not a transfer of control.

2. Please confirm that you are retracting the request to use radioactive materials at temporary jobsites. Our office understands that a similar request to conduct this type of work may be submitted at a later date, based on additional licensee review.

3. RADIOACTIVE MATERIALS AUTHORIZATIONS: Please confirm the NRC's understanding, based on the conversation, that:

(3.1) You have requested to revise the 0.6 curie possession limit for any form of yttrium-90, not strontium-90.
(3.2) You wish to revise the single-source iridium-192 possession limit. Include the revised single-source possession limit and confirm that no single source will exceed 11 curies at installation.
(3.3) You wish to reduce possession limits, if applicable. Note that reducing possession limits for certain long-lived radionuclides - especially tritium, gadolinium-153, and strontium-90 - may also reduce and/or remove the requirement to submit Decommissioning Financial Assurance (DFA) to the NRC.
(3.4) Submit revised DFA reflecting changes to licensee name, locations of use, and/or authorized materials, as needed.

NAME OF PERSON DOCUMENTING CONVERSATION

Sara A. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, IL 60532; (630) 829-9892

SIGNATURE: Sara A. Forster 6/12/2015

CONVERSATION RECORD (continued)

A. Jackson C/N 586401

SUMMARY AND ACTION REQUIRED - ADDITIONAL INFORMATION NEEDED (Continued from page 1):

4. RADIATION SAFETY COMMITTEE (RSC) REVIEW & APPROVAL: Please clarify the following as outlined below:

(4.1) AUTHORIZED USERS (AUs): Please resubmit the criteria the RSC uses to review and approve each type (i.e. - 35.100, 35.200, 35.600, Y-90 microsphere for human use, irradiator, non-human, etc.) of AU. Include the minimum training and experience as well as commitments that must be made, prior to the RSC approving a new AU for radioactive materials use under the license. For non-human use, include any required hands-on training and/or radiation safety courses (such as meeting the criteria outlined for AUs in NUREG 1556, Vol. 7, p. 8-17). For the required evaluation of new irradiator operators, please explain what constitutes "demonstrating the competency" as discussed in the application. Also for irradiator AUs, please discuss whether such individuals may be approved to conduct non-routine or other maintenance under the request.

(4.2) AREAS OF USE (AOUs): Please explain how the RSC approves each AOU (i.e. - for HDR, research irradiator, animal facility, etc.).

(4.3) AUTHORIZATIONS TO USE RADIOACTIVE MATERIALS: Please explain how the RSC approves an AU to use radioactive materials in an AOU. Include considerations such as safety equipment, security, monitoring requirements, emergency procedures, personnel, possession limits, approved uses, facility adequacy, and other factors used when reviewing and approving a request.

5. TRAINING: Please resubmit your training program to include the initial and refresher training requirements for each type of worker. Include the minimum training criteria required for initial approval of each group of individuals permitted to work with radioactive materials or in areas where materials may be used or stored. This criteria should include the initial training format and components, how adequacy is assessed, what is included in refresher training, and the frequency at which refresher training must be completed. At a minimum, provide responses for the following types of workers:

(5.1) AUs - HUMAN USE (10 CFR Parts 35.100, 35.200, 35.300, 35.400, 35.600 and 35.1000 - yttrium-90 microspheres), AUTHORIZED MEDICAL PHYSICISTS (AMPs), and AUTHORIZED NUCLEAR PHARMACISTS (ANPs): Confirm that all approved AUs (including HDR operators required to be trained in accordance with 10 CFR 35.610), AMPs and ANPs will meet the Training and Experience criteria outlined in Title 10 of the Code of Federal Regulations Part 35. In addition for 10 CFR 35.1000 - yttrium-90 microspheres use authorized under the license, confirm that AUs will meet the training and experience criteria outlined in the most recent revision to the 10 CFR 35.1000 guidance document, "Microsphere Brachytherapy Sources and Devices." Note that the most recent version of this document was published in June 2012, and may be found at the NRC website, http://www.nrc.gov/materials/miau/med-use-toolkit.html#other.

(5.2) AUs - HUMAN USE - OTHER MEDICAL DIAGNOSIS, THERAPY AND RESEARCH of radionuclides with atomic numbers 1 through 83 and 88, inclusive: Please describe the training and experience required for AUs using radioactive materials in or on human beings, outside the bounds of subitem 5.1, above.

(5.3) AUs - NON-HUMAN USE and SELF-SHIELDED IRRADIATOR AUs: Please describe the initial and refresher training required for each approved AU.

(5.4) RADIATION WORKERS: Please describe how an individual is initially approved, and how that worker is evaluated to be permitted to work under the supervision of an AU. See also NUREG 1556, Vol. 7, Appendix J.

(5.5) SELF-SHIELDED IRRADIATOR OPERATORS: Please describe how an irradiator operator is initially approved for work, the scope of work such an individual may be approved to do, and how that worker is evaluated in order to be permitted to work under the supervision of an AU.

(5.6) ANCILLARY PERSONNEL: Please describe job duties and access privileges for individuals in this category, including a description of training requirements to be allowed to complete these duties in and out of the physical presence of a supervising AU and/or Radiation Worker.

CONVERSATION RECORD (continued)

A. Jackson C/N 586401

SUMMARY AND ACTION REQUIRED - ADDITIONAL INFORMATION NEEDED (Continued from page 1):

6. FACILITIES: Your application included a list of facilities but was unclear as to the activities conducted at each facility. Please explicitly list activities to be conducted at each facility (e.g. 35.200 , 35.600 (HDR), AN 1-83, J.L. Shepherd irradiator, etc.). For any 35.200 use, please indicate whether any PET use may be authorized by the RSC at that location. In addition, please provide additional facility details as noted:

   (6.1) DIAGRAMS: Please provide sample in-vitro, non-human use research lab, and animal research facility diagrams and resubmit diagrams on pages 49 (blood bank irradiator); 51 (research irradiator); 53 (nuclear medicine); 59 (hot lab); 60 (radiopharmacy reference); 94 (waste), etc., of the application noting what is above, below, and adjacent to that area. Each diagram should show dimensions or be drawn to scale, and include key elements such as secure access doors, sinks, fume hoods, refrigerators, freezers, other radioactive materials storage, work areas, or waste holding areas. Please also clarify the West Grand Boulevard diagram on page 37 of the application by identifying buildings where material may be used or stored.

   (6.2) RADIATION SAFETY COMMITTEE REVIEW CRITERIA: Please resubmit the table on page 42 of the application to clarify the basis for creating the table and to include radium-223 and radium-226 considerations. For Table 9.D. on page 44 of the application, please indicate whether these requirements are meant to apply to 10 CFR Part 35 radioactive materials uses. If so, please confirm that in cases where Part 35 has a more restrictive requirement than Table 9.D., requirements in 10 CFR Part 35 will be followed. Finally, for areas where PET radioactive materials will be used or stored, please describe the shielding and safety evaluation that will be conducted by the RSC prior to approving the use of PET materials in an area.

7. RADIATION SAFETY PROGRAM:

   (7.1) Please describe any changes to HDR operating procedures that the RSC would allow, and how such changes would be reviewed and approved.

   (7.2) Confirm that the licensee will follow 10 CFR 35.643, 35.633, and 35.2632, for all HDR use of radioactive materials.

   (7.3) For microsphere brachytherapy use described on page 93 of the application; please confirm that the RSC requires use of 10 CFR 35.1000 guidance in review and approval of AUs and any use will be in accordance with that guidance. Also, provide confirmation that each item outlined in the 10 CFR 35.1000 guidance will be followed.

   (7.4) Please describe the methodology and tactics used to complete RSO Audits, as described on pages 15 and 126 of the application to include the types & frequencies of monitoring, and how results will be evaluated and addressed.

   (7.5) Please describe any instrument calibrations the licensee will perform in accordance with page 127 of the application. Please confirm that that the licensee may be calibrating dose calibrators, and that the licensee will not be conducting any survey meter calibrations. Also, confirm that the NUREG 1556, Vol. 11, Appendix O procedure will be followed or otherwise describe the licensee's instrument calibration program.

   (7.6) Confirm that sealed source inventories will be conducted at intervals not to exceed 6 months.

   (7.7) Concerning, material procurement described on page 128 of the application, please discuss how the RSC will review and approve procedure changes and describe how material will be transferred from dock to end users, including receipt criteria.

   (7.8) Please confirm that the NUREG 1556, Vol. 11, Appendix R and S procedures will be followed for the licensee's conduct of leak tests (if, per page 128 of the application, leak tests will be completed in house), and surveys (per pages 129-130 of the application). In the alternative, describe the licensee's leak testing and survey procedures.

8. WASTE PROGRAM: Please confirm that the procedure in NUREG 1556, Vol. 11, Appendix T will be followed. In the alternative, please describe the licensee's waste program.

AU TRAINING & EXPERIENCE CRITERIA TO CONSIDER

NRC believes that to demonstrate adequate training and experience the AU should have (1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles
- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used)
- Hands-on Use of Radioactive Materials.

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested, but it should cover the subjects stated.

An AU is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high energy beta emitters.

Response from Applicant: Provide the following:

- Name of each proposed AU with the types and quantities of licensed material to be used
- Information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.

TRAINING TOPICS, CRITERIA, METHODOLOGY, AND FREQUENCY TO CONSIDER

Radiation Safety Training Topics

This Appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be provided by providing a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

Frequency of Training

A. Before assuming duties with, or in the vicinity of, radioactive materials

B. Whenever there is a significant change in duties, regulations, or the terms of the license

C. Annually (refresher training).

General Information

A. Radiation safety

1. radiation vs. contamination
2. internal vs. external exposure
3. biological effects of radiation
4. ALARA concept
5. use of time, distance, and shielding to minimize exposure.

B. Regulatory requirements

1. RSO
2. material control and accountability
3. personnel dosimetry
4. radiation safety program audits
5. transfer and disposal
6. record keeping
7. surveys
8. postings

9. labeling of containers
10. handling and reporting of incidents or events
11. licensing and inspection by NRC
12. need for complete and accurate information
13. employee protection
14. deliberate misconduct.

Licensee-Specific Program Elements

A. Authorized users and supervised users.

B. Ordering and receiving radioisotopes.

C. Applicable regulations and license conditions.

D. Areas where radioactive material is used or stored.

E. Potential hazards associated with radioactive material in each area where the individuals will work.

F. Appropriate radiation safety procedures.

G. Licensee's in-house work rules. (For instructions on laboratory safety and uses of radioisotopes, see Section IV.)

H. Each individual's obligation to report unsafe conditions to the RSO.

I. Appropriate response to spills, emergencies or other unsafe conditions.

J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable.

K. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

L. Emergency procedures:

1. RSO name and telephone number
2. immediate steps to prevent or control spread of contamination
3. clean-up instructions, decontamination.

M. Survey program:

1. survey instrument accessibility
2. who is responsible
3. types, contamination and area
4. frequency
5. levels of contamination
6. personnel, hands, shoes
7. records.

N. Waste

1. liquid
2. solids
3. sanitary sewer
4. burial (transfer to low level waste repository)
5. storage
6. decay-in-storage
7. waste storage surveys
8. incineration
9. records.

O. Dosimetry

1. whole body
2. extremities
3. lost or replacement badges and dose assessment
4. bioassay procedures
5. records.

P. Instrumentation

1. survey meters-use, calibration frequency, use of check sources
2. analytical instruments-gas chromatographs, liquid scintillation counters.

Q. Procedures for receiving packages containing radioactive materials.

1. normal
2. off-duty
3. notification of user and RSO
4. security
5. exposure levels
6. possession limit
7. receipt of damaged packages.

R. Procedures for opening and examining packages

1. leakage and contamination
2. monitoring packages
3. monitoring packing materials
4. gloves
5. transferring material to users.

S. Animal experiments

1. description of facilities
2. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
3. security.

T. Sealed sources

1. leak test requirements
2. inventory requirements
3. exempt quantities
4. records.

U. Other topics, as applicable

V. Question and answer period.

For Laboratory Safety and Use of Radioisotopes

A. Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per experiment, etc.

B. Protective clothing and what laboratory apparel to wear and what equipment to use.

C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or gloveboxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma emitting licensed materials are handled.

D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.

E. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.

F. Decontamination procedures to use and whom to contact in case of an emergency.

G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.

H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.

I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.

K. Records to be maintained on use and disposal of licensed materials.

L. Prohibition of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are used.

FACILITIES CRITERIA TO CONSIDER

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that an ARDL licensee will use or otherwise have available. Not every ARDL applicant will need to address each topic in its application.

- 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 application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- 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 and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- 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.

  Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR 20, Appendix B.
  Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.

- 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.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- 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.
- 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.
- 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.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- 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.
- 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.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H.

10 CFR 35.1000 GUIDANCE FOR MICROSPHERES

Microsphere Brachytherapy Sources and Devices

REVISED JUNE 2012

Questions should be directed to: Ashley Cockerham (240) 888-7129 or
MedicalQuestions.Resource@nrc.gov

Licensing Guidance – TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres

Yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy. Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." Consistent with the direction in 10 CFR 35.1000, the NRC has evaluated these devices and determined that licensees must use Y-90 microspheres in accordance with the following requirements, which will be incorporated into the license either through license condition or through incorporation by reference to licensee submittals that include commitments consistent with these requirements. Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in 10 CFR Part 35, Subparts A, B, C, L, and M.

Training and Experience

NRC has determined that individuals meeting the guidance provided in both A and B below will be considered qualified and can be authorized for the use of Y-90 microspheres. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

The authorized user for Y-90 microspheres (AU):

A)

1) Is identified as an authorized user for medical uses in 10 CFR 35.400, "Use of sources for manual brachytherapy," or for medical uses in 35.300, "Use of unsealed byproduct material for which a written directive is required," that includes categories 1, 2, and 3 as listed in 10 CFR 35.390(b)(1)(ii)(G) on one of the following licenses or permits that permit the medical use of byproduct material: A Commission or Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State specific licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee; or
2) Meets the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490; or

3) Is an interventional radiologist who meets the training and experience guidelines as follows:

i)

a) American Board of Radiology certification in diagnostic radiology and subspecialty certification in interventional radiology; or

b) Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology; and

ii) has 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received in accordance with Item A.3.i. in:

a) Radiation physics and instrumentation;

b) Radiation protection;

c) Mathematics pertaining to the use and measurement of radioactivity;

d) Radiation biology; and

iii) has work experience under the supervision of an AU for Y-90 microspheres or training provided by a Y-90 microsphere manufacturer representative involving:

a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;

c) Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site;

d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;

e) Using administrative controls to prevent a medical event involving the use of byproduct material (Appendix S to NUREG-1556, Volume 9 provides additional guidance on this subject);

f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures (Appendix N to NUREG-1556, Volume 9 provides additional guidance on this subject. The procedures should address any special circumstances that may be encountered, such as electrostatic charge of microspheres and proper survey instrument and survey technique for beta emitters); and

g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and

B) has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. The additional Y-90 microsphere specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by either:

pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status; or

pathway 2) a Y-90 microsphere manufacturer. The clinical use experience should include at least three supervised hands-on *in-vitro* simulated cases for each type of Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized.

The applicant must submit documentation for the above training and experience. For individuals obtaining clinical use experience under pathway 1 above, this documentation includes the clinical use cases. For individuals obtaining clinical use experience under pathway 2 above, this documentation includes the *in-vitro* simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally for pathway 2, the licensee's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.

In addition, the applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

If the NRC staff revises the training and experience criteria, physicians who were authorized for the medical use of a specific type of Y-90 microsphere under these criteria or previous criteria, do not have to meet the revised criteria for that type of microsphere.

Leak Tests

Leak tests are not required for Y-90 microspheres based on the criteria in 10 CFR 35.67(f).

CONFIRM ALL MICROSPHERE USE WILL BE PER STATEMENTS ON pp. 4 to 5 of this guidance document.

License Commitments - Written Directives, Inventory, Patient Release, Labeling, & Medical Event Reporting

The applicant shall commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

- For the purpose of written directives and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose.
- The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the prescribed dose/activity; the manufacturer; and, if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis."
- The written directive should specify the maximum dose(s)/activity(ies) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).
- Administration of Y-90 microspheres must be performed in accordance with the written directive. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.
- The licensee shall record the administered dose/activity delivered to the primary treatment site and to the other specified site(s). If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who made the assessment, the date, and the signature of an AU for Y-90 microspheres, if terminated due to stasis.
- The licensee shall commit to following the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternative methods.
- The semi-annual physical inventory of microsphere aggregates (e.g. vials) should include:
  1) the radionuclide and physical form; and
  2) unique identification of each vial in which the microspheres are contained; and
  3) the total activity contained in each of the vial(s); and
  4) the location(s) of the vial(s).

- The licensee shall retain each semi-annual physical inventory record for three years.
- The licensee should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75.
- The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:
  1) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
  2) Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).
- The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:
  1) the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
  2) the administration of Y-90 microspheres results in a dose
     a) that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or
     b) that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or
     c) to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the written directive
- Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Notes to Licensees

Team Approach

Microsphere brachytherapy treatment is usually conducted using a multi-disciplinary team approach. The AU should consult, as necessary, with individuals with expertise in:

- Cancer management (e.g. radiation or medical oncology)
- Catheter placement

- Radiation dosimetry
- Safe handling of unsealed byproduct material

One individual may satisfy more than one of the listed areas of expertise.

Notification for AUs

NRC recognizes that if an AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres and is currently listed on a Commission or Agreement State medical use license or permit for a specific type of microsphere, the AU should be allowed to work under a different license for the medical use of the same type of microsphere. A limited specific medical use applicant initially applying for authorization for the medical use of Y-90 microspheres or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU to work at its facility without the need to request an additional license amendment, provided the following conditions are met:

1) the AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres; and
2) the AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee; and
3) the licensee provides NRC a copy of the license or permit on which the AU was originally listed for the specific microsphere use; and
4) the licensee provides documentation to NRC for each AU of the above listed conditions no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific type of microsphere.

If this authorization is approved, these notification conditions will be incorporated as license conditions in the licensee's license.

Change in Physical Conditions of Use

If the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate, the limited specific medical use licensee should request an amendment for the new conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of Other Y-90 Microspheres

The SSD safety evaluation for a specific manufacturer's Y-90 microspheres does not cover the use of any other Y-90 microspheres, including the preparation of Y-90 on other microspheres by a commercial nuclear pharmacy, the medical use licensee's authorized nuclear pharmacist, or a physician authorized user qualified to prepare radioactive drugs. The medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSD safety evaluation for a given manufacturer's Y-90 microsphere delivery system does not cover the use of that manufacturer's Y-90 microspheres with another manufacturer's delivery system or the use of another manufacturer's Y-90 microspheres with the given manufacturer's delivery system. Before authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres.

TheraSphere® Use Outside Humanitarian Device Exemption (HDE) Restrictions

The MDS Nordion TheraSphere® Y-90 microspheres are approved by the U.S. Food and Drug Administration (FDA) under the provisions of a "Humanitarian Device Exemption" (HDE No. H9800006), which includes unique restrictions on the medical use of the devices. Nothing in the NRC license relieves the licensee from complying with those FDA requirements.

If the Institutional Review Board that is required to approve and monitor the use of the MDS Nordion TheraSphere® Y-90 microspheres determines that the particular use of TheraSphere® Y-90 microspheres is for research purposes, the licensee must meet the requirements in 10 CFR 35.6, "Provisions for research involving human subjects." (Note: One of the conditions of approval for an HDE is that there be an Institutional Review Board initial review and approval before a humanitarian use device is used at a facility, as well as continuing review of its use.)

Revision of Y-90 Microsphere Radiation Safety Programs to Conform to Changes in This Licensing Guidance

The above licensing guidance may be revised as additional experience is gained regarding the medical use of TheraSphere® and SIR-Spheres® Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in this guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform with the revised provisions.

An applicant initially applying for authorization for the medical use of TheraSphere® and SIR-Sphere® Y-90 microspheres, or a licensee applying for an amendment to conform with revisions may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

1) the revision is in compliance with the regulations; and
2) the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Web site; and
3) the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
4) the affected individuals are instructed on the revised program before the change is implemented; and
5) the licensee will retain a record of each change for five years; and
6) the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

Waste Disposal Issues

In March 2007 NRC staff issued an Information Notice (IN 2007-10) to alert all medical licensees of the presence of radioactive contaminants and possible disposal issues with the two variations of commercially available Y-90 labeled microspheres, TheraSphere® and SIR-Spheres®. Depending on the contaminants, licensees may need to:

- hold the remaining microspheres longer in decay-in-storage in accordance with 10 CFR 35.92; or
- return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- transfer the microspheres to an authorized recipient.

IN 2007-10, *Yttrium-90 TheraSpheres® and SIRSpheres® Impurities*, is available on the NRC public website at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2007/in200710.pdf.

Forster, Sara

From: Forster, Sara
Sent: Friday, June 12, 2015 2:32 PM
To: AlanJ@rad.hfh.edu
Subject: Additional Information Request for Henry Ford Hospital (etc.) renewal, NRC Lic. No. 21-04109-16
Attachments: 02110.586401.21-04109-06 telecon signed.pdf

Dear Mr. Jackson:

See the attached file for additional information needed to complete the review of the renewal application for NRC Lic. No. 21-04109-16. Note that the attached phone conversation record requests additional information on or before close of business on August 12, 2015. Additional guidance may be found in, either NUREG 1556, Vol. 5, "Program Program-Specific Guidance About Self-Shielded Irradiator Licenses;" NUREG 1556, Vol. 7, "Program Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope;" NUREG 1556, Vol. 9, Rev. 2, "Program Program-Specific Guidance About Medical Use Licenses;" or NUREG 1556, Vol. 11, "Program-Specific Guidance About Licenses of Broad Scope," which may be found, respectively, at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v5/;
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/;
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/; or
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v11/.

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have.

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment