PURDUE
UNIVERSITY

RADIOLOGICAL & ENVIRONMENTAL MANAGEMENT

July 22, 2013

U.S. Nuclear Regulatory Commission
Region III Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352
Attn: Ms. Cassandra Frazier

Dear Ms. Frazier:

This submission is a response to your telephone request for further information for Purdue University Broad Scope License 13-02812-04 for use of Cd-109 in human research studies.

For clarity, a previous submission is included (without attachments) with additional information requested provided in italics in sections 1.1, 1.3, 1.4 (pictures of the shutter), 2.3, and 2.6.

Please contact me if further information is required at 765-494-2350. Thank you for your prompt consideration of this amendment.

Sincerely,

James F. Schweitzer
Radiation Safety Officer

550 Stadium Mall Drive ■ West Lafayette, IN 47907-2051 ■ (765) 494-6371 ■ Fax: (765) 494-7403

1. Request for Additional Information

1.1 Please clarify why on Page 2 it is stated that the source used for the research will have a maximum activity of 300 mCi when the Russian certificate as well as Purdue letter dated December 22, 2011, list only 135 mCi. Please explain the apparent discrepancy.

The request for 300 mCi is for future needs- we intend to use a source up to this maximum activity. The request for 135 mCi is to cover the source which is currently in possession.

We confirm that 135 mCi will be the maximum activity of the source.

1.2 Please demonstrate that the Purdue University Institutional Review Board's approval is sufficient for conducting research involving human subjects (Page 2).

The Purdue Institutional Review Board (IRB) routinely approves the use of human research subjects in social science, biomedical, and community research. The number of protocols reviewed on an annual basis exceeds 2000. The IRB has regularly reviewed the use of ionizing radiation (machine produced radiation) for research protocols. In cooperation with the Radiation Safety Committee, the IRB evaluates the risk to the subjects and ensures that the risk is appropriately communicated to the individuals participating in these research projects. Any questions regarding the magnitude of the radiation dose are resolved prior to commencement of the research.

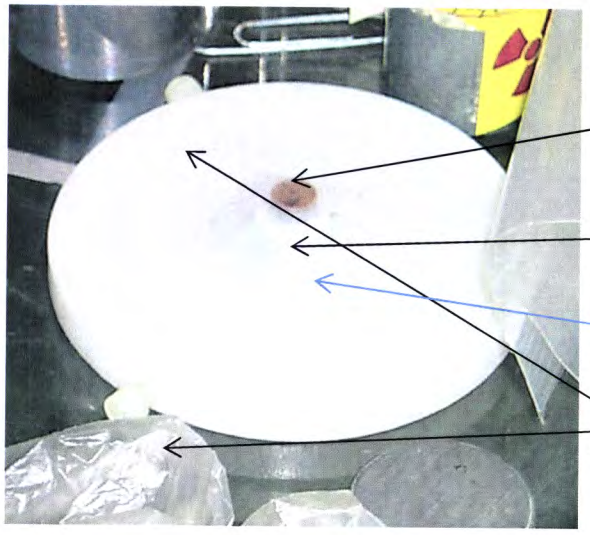
1.3 *Please explain the role and relevance of the "courtesy" review made by the Indiana University School of Medicine.*

We believed that additional review by a broad scope medical license would provide additional assurance that doses and protocol were consistent with practices that would occur at a medical licensee.

We will follow the recommendation of the IU IRB/RSC on the consent form as recommended. The calculated skin dose will be discussed in the consent form.

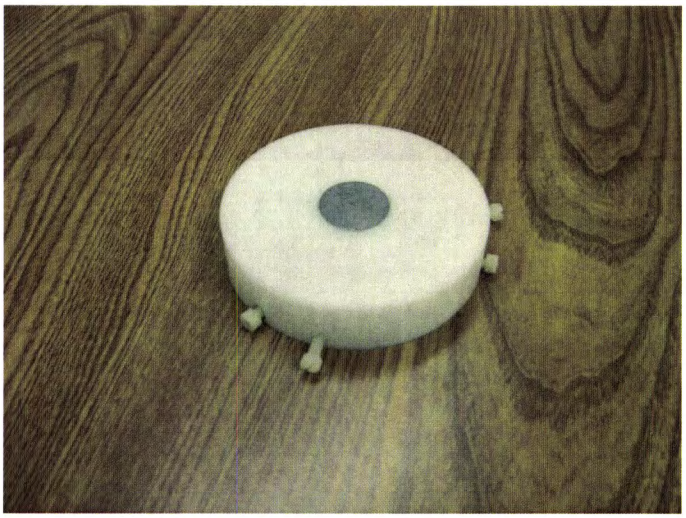
1.4 Please provide a description of the components, in terms of physical design, used to mount the source in front of the HPGe detector (Page 2).

The source is mounted in a plastic holder- it is currently secured by tape. A set screw will be installed to hold the source in position during use. The plastic holder is then secured to the face of the germanium detector crystal by set screws.

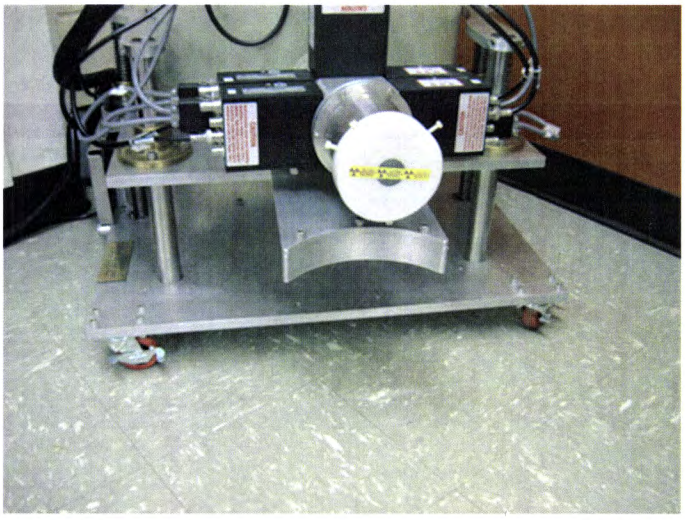


Below are pictures of the system:

The source holder (left without source) and the shutter or shield that will be in place when not acquiring data.



Source shutter (cover) in place. Center portion is approximately 3 mm thickness of lead which attenuates greater than 99% of photons.



Source holder and shutter mounted to Germanium detector

2. Request for Additional Information Regarding Appendix F

2.1 Please provide procedure/s for conditions of normal operations. Please provide the procedures in the traditional procedure format.

See Attachment A.

2.2 Please provide emergency procedures in the traditional procedure format for handling the requested quantity of radioactive material in unsealed form (as specified in NUREG-1556, Vol. 3, Rev. 1, Section 5.1.3). The document is accessible on the NRC website at www.nrc.gov.

See Attachment B.

2.3 Please provide documentation to show that the licensee staff is qualified by training and experience to safely use and handle the requested quantity of radioactive material in unsealed form (as specified in NUREG-1556, Vol. 3, Rev. 1, Section 5.1.3).

The researcher has extensive experience with handling this type of source. The source has been successfully used without incident for over 10 years at other institutions. Although the source has not received evaluation under SSDR it is designed by the manufacturer (and has been leak tested) to contain the radioactive material. The source is additionally contained within a capsule with a screw-top lid. The source will be stored and used in only one area at Purdue University under normal environmental conditions. This area can be quickly isolated to prevent the spread of any contamination if a breach of the source occurred.

In addition the radiation safety staff has an RSO who is a Certified Health Physicist with over 25 years of experience. There are also health physicists and technicians (experience from 3-19 years) who have had experience in handling radioactive materials and responding to spills. The radiation safety office has radiation detection equipment such as portable meters, liquid scintillation counters, and gamma spectroscopy for responding to any incident.

Additionally a physician who meets the qualifications under 10 CFR 35.590 will serve as mentor for this research, review procedures, and monitor any adverse effects from the research. Dr. Arthur Ko is affiliated with Arnett IU Health (Lafayette, IN NRC License No. 13-32087-01) and IU Methodist/IU Health (Indianapolis, IN (NRC License No. 13-02752-03). We will follow guidance in NUREG 1556 Vol 9 for use of the source in research.

2.4 Please describe how the source will be removed from secure storage (Section 10.2).

The source is maintained in a Plexiglas lockbox in a locked room. The source is also has a lead cover to attenuate the low energy gammas emitted by the source. The source when in use is always mounted in the plastic source holder. The plastic source holder is retrieved from the lockbox and mounted to the face of the Germanium detector crystal by handling the plastic source holder. Care is taken to avoid placing fingers too near the source to keep finger doses ALARA.

2.5 Please explain how the source is mounted in the source housing; provide drawings, description and dimensions, and the material of construction for the components (Section 10.3).

The source upon receipt is placed in a tungsten capsule with a screw-top lid with a copper window. The capsule serves two purposes: to attenuate lower energy x-rays

which are not useful for measurements (allows 88 keV photons to escape through copper window) and to protect the thin source window from physical damage. It is then mounted in a plastic holder which provides a way to mount the source in a stable and reproducible geometry to the face of the germanium detector. See Figures 1 and 2.

2.6 Please describe whether the beam is always 'on'. If not, describe how shielding or shutter use is accomplished.

While measurements are not being taken, the source will be shielded by an iron or lead shutter which will be placed in front of the source and removed by hand. This shutter is currently under design. It will be fabricated to ensure that the shutter can be manipulated without placing the fingers in the beam. Once measurements are complete or are suspended, the source will be placed back in the lockbox.

The shutter is shown in the response to question 1.4. During the measurement process the principal investigator or designee will be present at all times. There is no hazard from the equipment if an individual were to tamper with the device (e.g. high voltage); however, each subject will be observed and instructed not to touch any equipment. The liquid nitrogen dewar which is required for operation will be filled only when no research subjects are present. There is no hazard to the research subjects during operation.

2.7 Please specify the labeling that will be used to identify the source holder and the source storage container. Please describe the locations, materials of construction, and method of attachment for the labels (Section 10.4).

The labels that will be used are standard "Caution Radioactive Materials" labels (see Figure 3). The label will include the nuclide and activity. The labels will be made of commercially available adhesive paper. Since the system will never be used in harsh environments the labels will be durable and last for the life of the source. The labels will also be inspected by radiation safety staff when the source is inventoried on a semi-annual basis. Labels that become worn or degraded will be replaced at that time.

2.8 Please quantify the term "source holder would minimize impact". Also, please describe what is meant by the terms "plastic holder" and "source holder" (Section 10.5)

If the source were to be dropped the metal source capsule would prevent a direct impact to the source itself. This would reduce the likelihood that the source window would be damaged by dropping. It would also be very likely that the plastic holder would hit the floor and the source or source holder would not directly impact the floor, again this would be expected to prevent damage to the source.

2.9 Please describe actions to be taken if the source dislodged from the source holder when dropped (Section 10.5).

The actions to be taken in case of a dropped source are in the operating procedures (Section 5):

1. If at any time the source or source assembly is dropped the data acquisition should cease to verify that the source has retained its integrity:
    a. Retrieve the source/source assembly with tongs and place in shielded storage container.
    b. Ask any other personnel to move at least 2 meters from the area while you perform a survey of the area with a GM meter or NaI scintillation meter.

c. If levels are greater than 2 times background notify the Radiation Safety Officer (RSO) for assistance. Ensure that all personnel and subjects are surveyed for contamination prior to leaving the area.
d. The source must be leak tested before placing back in service.

2.10 Please describe how the researcher would verify integrity of the source (e.g., leak testing visual inspection) as well as the pass/fail criteria for integrity testing.

A visual inspection would be performed and any visual damage of the source would be immediate cause for termination of any activities. If a source is dropped our procedures require that a leak test (wipe test) be performed and if removable activity exceeds 0.005 microcuries the source will be taken out of service.

2.11 Please provide Table 2 for maximum exposure a rate which are referenced in Section 10.6, but is missing from the document package that we received.

Table 2 is attached.

2.12 Since there will be no formal quality control or assurance programs, please indicate if the source was leak-tested upon arrival to the facility. Also, please indicate if a leak-test will be performed at six month intervals.

The source was leak tested prior to shipment at the manufacturing facility. The source will also be tested upon arrival and at six-months intervals.

3.1 Please clarify the term "The source...will be manufactured..." Is the source not at your location now? How and where were the radiation profile measurements taken (referenced in Appendix F, Section 10.6) if the source is still to be manufactured?

We currently are in possession of a source that was manufactured in 2010. The measurements were taken with this source. Due to decay the source must be replaced at regular intervals, so we anticipate replacing this source within the next few years.

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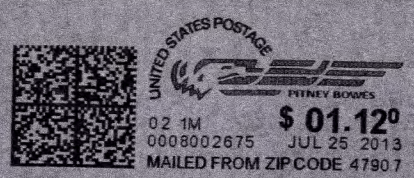

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