

Synthes

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CC: _____

From: Meredith Hans /
Elliott Gruskin

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REMARKS: Urgent For your review Reply ASAP Please comment

Reference mail number 141323

Please see attached corrected license application, per your request.

Elliott Gruskin

Elliott Gruskin
VP Biomaterials R&D
Synthes

141323
NMSS/RGN1 MATERIALS-002

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5. RADIOACTIVE MATERIAL

Radioisotope	Chemical/Physical Form	Maximum Possession Limit
H-3	Liquid	100 millicuries
C-14	Liquid	50 millicuries
P-32	Liquid	25 millicuries
S-35	Liquid	25 millicuries
I-125	Liquid	25 millicuries

6. PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Licensed materials will be used in biomedical research and development. The research will utilize licensed materials as biomarkers in various studies. No animal or human use studies will be conducted.

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

RADIATION SAFETY OFFICER

Dr. Meredith Hans will serve as the Radiation Safety Officer on this license. As can be seen on her Curriculum Vitae (attached) she has extensive experience working with unsealed sources of radioactive materials in research laboratories. In addition, Synthes has established a consulting relationship with the Radiation Safety Academy division of Dade Moeller & Associates, Gaithersburg, MD, giving her access to the Academy's four certified health physicists should any questions or concerns arise. They are Mr. Ray Johnson, CHP, PE, Dr. Alan Fellman, CHP, Mr. Sean Austin, CHP, and Ms. Kelly Austin, CHP. These individuals have combined experience exceeding 70 years involving use of unsealed byproduct material in biomedical research facilities.

As RSO, Dr. Hans will perform all applicable duties and responsibilities as outlined in NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

AUTHORIZED USERS

In addition to the RSO, the following individuals will be Authorized Users, i.e., authorized to work unsupervised and to supervise others with radioactive materials - Doug Buechter, Melissa Brown, Shane Woods, and Lisa Hughes. These individuals, along with the RSO, will be responsible for the research performed under this license. Copies of their resumes (partial) and a table are attached, emphasizing experience with the types of research proposed under this license. Absent appropriate training and experience, prior to requesting

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status as an AU, newly proposed AUs will sit for radiation safety training which will cover the following topics:

- Radiation Protection Principles
- Characteristics Of Ionizing Radiation
- Units Of Radiation Dose And Quantities
- Radiation Detection Instrumentation
- Biological Hazards Of Exposure To Radiation
- Review Of Procedures Describing Work With Licensed Materials

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Authorized Users and other laboratory personnel will occupy the laboratories and other areas where licensed material will be utilized and stored.

At a minimum, the RSO will have received 40-hours of radiation safety officer training or have at least six months of experience working with licensed radioactive material in a research setting. Authorized Users named on the license will have demonstrated radiation safety training and experience working with comparable types of radioactive materials as those proposed in this application. Other individuals with access to the posted areas will have previously had or will be provided initial radiation safety training by either the RSO or arranged for by the RSO. The training will be held prior to initiating work with licensed materials and will be commensurate with the individual's potential for work with and exposure to radioactive materials. Training will cover the same topics noted in Item 7 for authorized users, and will include a review of specific procedures including contamination control techniques, disposal of radioactive waste, and other appropriate topics related to the utilization of radioisotopes in biomedical research.

Training will be provided prior to an individual's work with licensed material. Annual refresher training will also be provided. Radiation safety awareness training may also be provided to ancillary personnel. Documentation of training will be maintained by the RSO.

9. FACILITIES AND EQUIPMENT

As shown in the attached sketch, licensed materials will be used in a restricted portion of the Synthes Biomaterial's facility. Radioisotopes will be stored and used in the R & D Laboratory within the Synthes, USA Development Center. The door to the lab will be posted with a 'CAUTION RADIOACTIVE MATERIALS' posting and a copy of the NRC 'Notice To Employees.' A fume hood located in the portion of the lab designated for radioisotope work will be utilized for work with any potentially volatile materials such as unbound I-125. It, too, will be labeled 'CAUTION RADIOACTIVE MATERIALS' and will be considered a part of the restricted area. A sketch of the room may be found in the attachment identified as R & D Laboratory. Personal belongings such as coats, lunches, etc. will not be allowed in

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these areas. All research with licensed material will be done in this posted laboratory. Work surfaces where licensed materials are used will be covered with absorbent paper. Vials and other materials posing external radiation hazards will be shielded, as appropriate, with lead or other suitable materials.

Synthes personnel have card key access to the facility building. The doors to the posted laboratory and the waste storage area will be locked at all times. Card key access to these rooms will be provided to authorized persons.

Packages with licensed materials will be delivered to Synthes Biomaterials at the address indicated on this license application. A sketch of the Synthes, Biomaterials Development Center may be found as an attachment. All packages will be delivered directly to the loading dock and moved into the laboratories posted for work with radioactive materials. Office workers will be provided radiation safety awareness training such that they are able to recognize packages with licensed material. They will be instructed to immediately notify the RSO, an AU, or a worker trained to work in the posted laboratory upon arrival of licensed material. Within not more than three business hours of receipt of licensed material, the RSO or his/her designee will perform the required package survey measurements detailed in the Radiation Safety Manual package receipt procedure. The licensed material will be placed in an appropriately labeled, locked refrigerator, freezer, or cabinet in the posted laboratory.

Dry radioactive waste (e.g., lab diapers, gloves, paper towels, etc.) generated in the posted laboratory will be placed in labeled waste containers lined with labeled plastic bags for either decay-in-storage or transfer to a licensed radioactive waste broker. When waste containers are full, waste will be transferred into storage in the waste storage area. Soluble liquid radioactive waste will be collected in plastic containers known as "carboys." Liquid waste will either be discharged to the sanitary sewer in the posted laboratory or taken to the waste storage area and held for either decay-in-storage or transfer to a licensed radioactive waste broker.

The facility as constructed coupled with the activity limits requested will be sufficient to ensure that the dose to individual members of the public from licensed operations will not exceed the limits of 10 CFR 20.1301 (0.1 rem in a year and no more than 0.002 rem in any one hour).

10. RADIATION SAFETY PROGRAM (see attached Radiation Safety Manual)

A. Audit Program.

The licensee will maintain a radiation safety program as outlined in NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. As a part of the safety program, the licensee will review the content and implementation of its radiation safety program bi - annually to ensure:

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- a) compliance with NRC and DOT regulations and the terms and conditions of the license,
- b) occupational doses and doses to members of the public are ALARA, and
- c) records of audits and other reviews of program content are maintained for 3 years.

Audits will be conducted bi-annually according to the outline of Appendix L, NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

B. Instruments

Synthes Biomaterials will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary.

Several types of radiation detectors will be routinely used. Contamination monitoring will be performed with pancake GM detectors (Ludlum model 43-9 or equivalent) or thin window, thin crystal NaI detectors (Ludlum model 44-1 or equivalent) coupled to a ratemeter (Ludlum model 3 or equivalent). Dose rates will be determined with a NaI detector (Ludlum model 44-2 or equivalent) or energy compensated GM detector coupled to an appropriately calibrated ratemeter or with a portable ion chamber, pressurized ion chamber, or tissue equivalent plastic scintillator. A liquid scintillation counter for analyzing alpha, beta, and gamma radioactivity will be used for detection and contamination monitoring.

Detector/ratemeter pairs will be calibrated annually at a licensed calibration facility. Calibration records will be maintained by the RSO.

If any need for contamination monitoring is warranted in the case of fire, accident, or incident involving licensed materials, additional instruments and procedures will be obtained as appropriate from facilities such as the Radiation Safety Academy and RSO, Inc., located in Gaithersburg, MD and Laurel, MD, respectively.

C. Material Receipt and Accountability

The licensee will maintain comprehensive records of all receipts, transfer, or disposal of licensed material to ensure cradle to grave accountability. Licensed materials will be maintained in a secure area, i.e., the posted laboratory will be locked at all times. Material record-keeping will enable the RSO to demonstrate compliance with the license activity limits at all times. Physical inventories of all licensed material possessed will be conducted at intervals not to exceed six months. [Note: No sealed sources (except exempt quantity check sources) will be possessed under this license.] Inventory records will ensure that the possession limits stated in the license are not exceeded.

Inventory records will include:

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1. Decay corrected quantities of licensed material in source vials.
2. Activity present in samples and labeled compounds.
3. Activity in storage in the waste storage area.
4. Date of the inventory.
5. RSO Signature.

D. Occupational Dose

We will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG - 1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope,' dated December 1999.

Appropriate dosimeters will be procured from a National Voluntary Laboratory Accreditation Program (NVLAP) approved dosimetry vendor. They will be furnished to the RSO who will issue dosimeters to the appropriate personnel who work with licensed materials. We anticipate providing both whole body and extremity dosimeters (ring badges) to personnel.

If internal exposure to any licensed material is suspected because of fire or other incident, then bioassay samples will be collected. Estimates of committed effective dose equivalent (CEDE) will be based on the urinalysis data. If in response to suspected intake of radioiodine, thyroid scanning may be implemented instead of urinalysis. Routine bioassay monitoring will not be required unless quantities of materials used exceed limits established in the Radiation Safety Manual.

E. Safe Use Of Radionuclides and Emergency Procedures

The licensee has developed, and will implement and maintain operating procedures for the safe use of licensed materials, including security of materials and emergency response procedures. Procedures are consistent with guidance contained in Appendix P, NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Procedures may be revised only if 1) the changes are reviewed and approved by the RSO in writing; 2) the licensee staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do not degrade the effectiveness of the program.

F. Surveys

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. No sealed sources will be listed on the license; therefore, leak tests will not be required.

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11. WASTE MANAGEMENT

We will use the Decay-In-Storage model waste procedures that are published in Appendix T to NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.