

File

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Incell Corporation
ATTN: John P. Earle, Ph.D.
Senior Staff Scientist
P.O. Box 11596
Milwaukee, WI 53211

RE: Application for NRC License Dated January 31, 1985, Control No. 78331

Gentlemen:

We have reviewed your application and find we need the following:

1. It appears that you will be using microcurie amounts of phosphorus-32 and sulfur-35 for in vitro studies. Please specify the average amounts of hydrogen-3, carbon-14, and iodine-125 that will be used for in vitro studies.

For each radioisotope requested, specify the average activity you will use for in vivo studies.

If you will be using millicuries amounts of phosphorus-32 per study, please submit procedures for handling this material. We recommend that your procedures include the following:

- a. The use of low atomic number shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum.
 - b. A mandatory radiation survey and wipe test procedures after each use.
 - c. The use of finger type extremity monitors.
 - d. The use of a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the Radiation Protection Officer be present during new procedures.
 - e. The use of eye protection for procedures that involve 10 millicuries or more.
2. We recommend you add an additional individual as a supervisor/user on the license. Individuals not listed on the license may only use radioactive materials under the supervision of the supervisor/user. If the supervisor/user is on vacation or leaves the program, the use of radioisotopes must be stopped. To add another individual as a supervisor/user, send a copy of their training and experience with radioactive materials.

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3. Regarding your request to transport radioactive samples to the University of Wisconsin at Milwaukee, we need the following:
 - A. Submit a letter from the Radiation Safety Committee at the University of Wisconsin at Milwaukee stating that they will allow you to transport radioactive samples to their facility.
 - B. Will radioactive samples be transferred from Incell to the University and the samples disposed of by the University, or will the samples be returned to Incell for disposal?
 - C. Who will transport the radioactive samples? If individuals not listed on the license transport samples, specify the training and instructions they will receive. The following subjects should be discussed in the training program: emergency procedures to follow in case of an accident, contamination control of packages, securing packages during transport, safe handling of packages, etc.
4.
 - A. During our discussion on April 19, 1985, it was our understanding that your survey meter will be calibrated by the manufacturer or by individuals specifically authorized to perform survey meter calibrations. Please confirm.
 - B. State the calibration frequency for the liquid scintillation counter.
5. Describe your procedures for handling and disposal of radioactive waste. Clarify the method of waste collection from individual users to the waste storage area.
6. Describe what areas will be included in your radiation surveys. All areas where radioactive material is used should be surveyed. Radiation surveys should also include waste and storage areas.
7. Describe your procedures for ordering radioactive materials. As a minimum, procedures for ordering radioactive material should indicate the individual responsible for:
 - (A) ordering all radioactive material.
 - (B) ensuring that the requested materials and quantities are authorized by the license.
 - (C) ensuring the possession limits are not exceeded.
 - (D) keeping written records identifying the isotope compound, activity levels, supplier, etc.

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8. Describe your procedures for examining incoming packages for leakage, contamination or damage, and for safely opening packages in accordance with Section 20.205 of 10 CFR Part 20. It is recommended that, as a minimum, these include instructions to wear gloves, monitor the packages before opening, and a wipe test of the final source container.
9. If other individuals will use radioactive materials under the supervision of the authorized user, written safety instructions should be prepared and furnished to these persons and/or posted in work areas. Please confirm that safety instructions will be prepared and distributed or posted and the following subject areas will be addressed:
 - a. Outline control procedures for obtaining permission to use radioactive materials at your institution; give limitations on quantity to be handled per student or allowed per experiment.
 - b. Explain what laboratory apparel to wear and what safety equipment to use (e.g., use of laboratory coats, gloves, and remote pipetting devices).
 - c. Prescribe limitations and conditions on handling liquid or loose (unencapsulated or dispersible) radioactive materials and what laboratory equipment to use in working with them. For example, explain when materials and operations should be confined to radiochemical fume hoods or gloveboxes and explain what shielding or remote handling equipment is to be used when hard beta- or gamma-emitting materials are handled.
 - d. Instruct the user about routine survey and monitoring procedures for each contamination control zone.
 - e. Instruct the user about movement of materials between rooms, halls, or in corridors, if applicable.
 - f. Explain requirements for storage of materials and labeling of containers and how areas will be identified where radioactive materials are used. Explain where and how contaminated articles and glassware are to be handled and stored.
 - g. Specify personnel monitoring devices to be used, where to obtain them, and instructions given on recording exposure results or properly turning in personnel monitoring devices for processing at appropriate intervals.
 - h. Instruct the user in waste disposal procedures to follow in the laboratory, including limitations for disposal of liquid or solid wastes by the user and procedures to use for waste storage within each laboratory.
 - i. Explain what records are to be kept for the use and disposal of materials.
 - j. Describe contamination control procedures, including restrictions against smoking and consumption of food and beverages.

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10. Specify the type of personnel dosimeter you will use (thermoluminescent dosimeters or film badges). Specify the frequency of exchange and evaluation.
11. It is not clear if your training program will include ancillary personnel. Ancillary personnel (clerical, nursing, housekeeping, security, etc.) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. Outline your method to assure that these employees receive the necessary instructions. Confirm that this instruction will be given both initially and annually thereafter on a refresher basis.

We will continue our review of your application upon receipt of this information. Please send a copy of your response and refer to Control No. 78331

Sincerely,

Original Signed By
William P. Reichhold
Materials Licensing Section

Enclosure: Appendix D, Section 1

RIII

Reichhold/cm
04/30/85