

October 13, 1998

MS 16
Q5

Reference: Mail Control Number 125935

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06-30469-01
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Dear Ms. Ullrich:

This is in response to your letter of September 15, 1998, requesting additional information about my application for a Nuclear Regulatory Commission license. Each point below addresses the item of the same number in your letter.

1. Training Program Description

The training program will provide orientation for all new employees as part of overall health and safety program. All personnel will receive instruction before performing duties with or frequenting areas where licensed materials are used. The content of training will be directed to authorized users, support groups, and affected workers. Topics included, depending on job requirements, will be:

- characteristics of ionizing radiation
- modes of exposure – internal and external
- dose equivalent estimates
- protective measures – time, distance, shielding
- radiation effects – acute, chronic
- contamination control, protective clothing, workplace safety procedures
- radiation monitoring programs
- warning signs, alarms, controls
- emergency procedures
- responsibilities – workers, RSO, organization

Periodic refresher training will be provided as necessary or at intervals of not greater than 1 year. Orientation will also be provided as necessary for outside contractors and emergency response personnel.

2. Description of Duties of Radiation Safety Officer

The duties of the RSO will involve licensing and regulatory compliance, safety evaluations, personnel training, radioactive material procurement and control, radiation

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safety surveys, dosimetry and bioassay services, waste disposal, recordkeeping, audits and inspections.

- a. To assess radiological hazards, and prescribe and ensure the implementation of, appropriate radiation safety precautions.
- b. To ensure that the use of licensed material is by or under the direct supervision of individuals specifically listed on your license.
- c. To ensure that all users (where appropriate) wear personnel monitoring equipment when using licensed materials.
- d. To ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.
- e. To perform routine inspections of all laboratories using or storing licensed materials.

3. Survey Monitor

Though we will still use the Technical Associates Model TBM-3S, a Ludlum Measurements (Sweetwater, TX) Model 44-3 Low Energy Gamma Scintillator Probe (designed to work in concert with the Model 3 Survey Meter) has been ordered. The scintillator is a 2.5 cm diameter, 1 mm thick thallium-doped sodium iodide crystal [NaI(Tl)] with an efficiency (4π geometry) of 19% for ^{125}I . The recommended energy range is 10-60 keV, appropriate for ^{125}I energies (predominant radiation emission K_{α} X-ray of 27 keV; secondary emissions are K_{β} X-ray of 31 keV and γ of 35 keV).

4. ^{125}I Procedures

Handling procedures for volatile radioiodine were originally written for a previous version of the handbook intended for a more diverse company. Item 5 of the application was correct in requesting only non-volatile iodine-125, as we do not intend to work with volatile compounds or perform iodinations. Procedures still in place would be:

- a. A mandatory radiation survey (personal and work area) and wipe test for radioactive contamination after each use.
- b. Bioassays (thyroid scan) required for individuals working with millicurie quantities of radioiodine at three-month intervals or after each millicurie use, whichever is more frequent.
- c. Storage of millicurie quantities of radioiodine will be in vented hoods.
- d. Dry runs of each new procedure will be required before the addition of radioactivity. The RSO will also be present during new procedures.

5. ^{32}P Procedures

- a. Appropriate low density shielding will be used for personal protection, such as $\geq 1/4$ " Plexiglas or acrylic plastic. This will minimize Bremsstrahlung radiation formation from the interaction of high-energy β particles ejected from ^{32}P with dense (high Z number) nuclei involved in shielding.
- b. A mandatory radiation survey (personal and work area) and wipe test for radioactive contamination after each use.
- c. Extremity monitors (finger badges) will be required for procedures involving one millicurie or more of ^{32}P .
- d. Dry runs of each new procedure will be required before the addition of radioactivity. The RSO will also be present during new procedures.
- e. Eye protection will be required for procedures involving ≥ 10 mCi.

6. Routine Survey Program

In order to assess the levels of contamination in a lab, surveys must be completed on a regular and ongoing basis. Results of the survey are then compared to action levels for remediation, and areas are decontaminated, if needed. Action levels are from "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," U.S. Nuclear Regulatory Commission, Division of Fuel Cycle, Medical, Academic, and Commercial Use Safety; April 1993.

Surveys with probes appropriate for both isotopes under consideration will be performed at least as frequently as monthly in all areas designated for radionuclide use. If isotopes are used within any single month period, surveys will be undertaken immediately after each usage as well. This will include wipe tests of all work surfaces, shielding, and other areas in which licensed material was used or transported. Wipe tests will be carried out according to the "Guidelines for Decontamination..." document above. Amounts above background will be brought immediately to the attention of the RSO. Records will be kept in a logbook at the workbench and be reviewed by the RSO at least monthly.

7. Decontamination Procedures

If a spill has occurred, it should be determined if it is a minor or major spill. For ^{32}P , a minor spill is defined as less than 10 mCi, and a major spill as equal to or greater than 10 mCi; for ^{125}I , a minor spill is less than 1 mCi, and a major spill is equal or greater than 1 mCi.

Minor Spill Procedure

1. Notify personnel in the area that a spill has occurred.
 2. Prevent the spread by covering the spill with a suitable absorber.
 3. Decontaminate (see procedure below).
 4. Contact RSO.
 5. Records – retain survey information with the contamination survey records for review.
- If the spill is reportable, submit a written report to the RSO within 7 days describing the

incident including actions to be taken to prevent the recurrence.

Major Spill Procedure

1. Clear the area – notify personnel in the proximity of the spill to vacate the area.
2. Prevent the spread by covering the spill with a suitable absorber, but do not attempt to clean it up. Confine the movement of potentially contaminated personnel to prevent spread.
3. Shield the source if it can be done without further contamination or significantly increasing radiation exposure.
4. Contact the RSO.
5. Secure the area as practical to restrict entry.
6. If personnel contamination is suspected or discovered, identify the contaminated area(s) with a survey meter. See below for decontamination procedure.
7. Decontamination of area and equipment should be undertaken under the supervision of the RSO.
8. Submit a written report to the RSO within 7 days describing the incident including actions to be taken to prevent the recurrence.

Decontamination Procedure

1. Preliminary survey – draw a floor plan of the area indicating areas where surveys were performed and the results of the surveys.
2. Wear protective clothing and use remote handling equipment as appropriate. Absorb liquids with absorbent paper or other suitable absorbent. Place contaminated materials into receptacles or bags designated for radioactive waste.
3. Ensure that the levels remaining are in compliance with the values specified in the table below.

Personnel Decontamination Procedure

If the spill is on intact skin, flush thoroughly and then wash with mild soap and lukewarm water for at least three minute. Rinse thoroughly. Contaminated clothing should be removed and saved for further evaluation by the RSO.

Acceptable surface contamination levels are as follows:

Nuclides	Average ^{b, c, f}	Maximum ^{b, d, f}	Removable ^{b, e, f}
I-125	100 dpm/ 100cm ²	300 dpm/ 100cm ²	20 dpm /100cm ²
β or γ emitters (nuclides with decay modes other than α emission or spontaneous fission; i.e., P-32)	5,000 dpm βγ/ 100cm ²	15,000 dpm βγ/ 100cm ²	1,000 dpm βγ/ 100cm ²

^a From "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," U.S. Nuclear Regulatory Commission, Division of Fuel Cycle, Medical, Academic, and Commercial Use Safety; April 1993.

^b As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

^c Measurements of average contamination should not be averaged out over more than 1 square meter. For objects of less surface area, the average should be derived for each object.

^d The maximum contamination level applies to an area of not more than 100 cm².

^e The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When

removable surface contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

^f The average and maximum radiation levels associated with surface contamination resulting from β emitters should not exceed 0.2 mrad/hr at 1 cm and 1.0 mrad/hr at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

8. Animal Carcasses

The descriptions of animal carcasses were left in the handbook in error. The section has been removed. We do not intend to perform any live animal experimentation, either with or without radioactivity.

9. Waste Disposal

Disposal to sanitary sewer was inadvertently omitted from Item 11 of the application. It is our intention to eliminate some low level, large volume liquid wastes in this manner per 10 CFR 20.2004. We will utilize Method 2, "Filtration and Radiometric Analysis of Suspended Solids," described in NRC Information notice 94-07 (January 1994); either ASTM Method D 1888-78 or APHA Method 7110. The physical state of all compounds released will not be precisely known, as ^{125}I will be incorporated into a variety of protein molecules and ^{32}P will be incorporated into many different nucleic acid moieties, or released as inorganic phosphate or ^{32}P -labeled nucleoside triphosphate. Amounts released will be strictly monitored to remain in compliance with 10 CFR 20 Appendix B, Table 3, Release to Sewers values. These are expressed as average monthly concentrations and are listed as $2 \times 10^{-5} \mu\text{Ci/ml}$ for ^{125}I , and $9 \times 10^{-5} \mu\text{Ci/ml}$ for ^{32}P . Water bills for the building will be used to provide the average monthly water usage for the calculation of concentration released. A sample calculation follows.

Quarterly water usage = 137,000 ft^3 for Q1 (Source: Water Company)

$$\text{Quarterly water usage} = \frac{137,000 \text{ ft}^3 \times (2.54 \text{ cm} / \text{in} \times 12 \text{ in} / \text{ft})^3}{1000 \text{ cm}^3 / \text{l}} = 3,879,000 \text{ l H}_2\text{O}$$

Annual water usage = Quarterly water usage x 4 quarters/year x 1000 ml/l
= 3,879,000 l x 4 x 1000
= 15,516,000,000 ml/year H_2O

10 CFR 20 - Standards for Protection Against Radiation [July 31, 1998]
Appendix B - Table 2 Effluent Concentrations/Column 3 Releases to Sewer
 ^{125}I monthly average concentration limit = $2 \times 10^{-5} \mu\text{Ci/ml}$

Maximum Permissible Release to Sewers on an Annual Basis

$$\begin{aligned} & (\text{annual water usage}) \times (\text{maximum release concentration}) \\ & = 15,516,000,000 \text{ ml/year H}_2\text{O} \times 2 \times 10^{-5} \mu\text{Ci/ml} \\ & = 310,320 \mu\text{Ci} \\ & = 310 \text{ mCi} \end{aligned}$$

For DIAGNOSTIC ONCOLOGY, at the above water usage level, the maximum permissible release to sewers would be 310 mCi ^{125}I in soluble form with a maximum release of 25.8 mCi in any given month.

- a. No compaction will take place. If decay-in-storage material accumulates sufficiently to warrant transfer to a burial site, it will be shipped as is, not compacted.
- b. No volatile compounds will be used and no airborne releases will be undertaken.

10. Isotope Ordering and Receipt Procedures

Licensed materials will be ordered only through the Radiation Safety Officer. The RSO will track amounts of licensed material in use and in decay-in-storage to ensure that possession limits will not be exceeded. There is no delivery after hours; at the end of the business day the outer doors of the facility are locked and no one is available to accept packages. Either the RSO or an authorized user will be present at delivery of all shipments of licensed materials to immediately and personally convey it to secured storage. This will ensure that radiation levels in unrestricted areas of the company will not result in doses to individuals in excess of those specified in 10 CFR 20,1301(a). The package will be surveyed and wipe tested within three hours of receipt. Licensed material will be kept locked up when not in use. When in use, it will be under control of an authorized user.

11. Radiation Safety Handbook Status

Given the choices in Item 11 of your letter, I would prefer to submit the Radiation Safety Handbook as a reference for specific procedures referred to in items of my license application. Therefore, only changes made in the referenced procedures would require amendment of the license.

12. Radiation Safety Handbook Corrections

- c. All corrections pertaining to TEDE and ALI were updated as detailed in your letter to accurately reflect the 1994 revision of 10 CFR Part 20.
- d. Connecticut is now correctly identified as a non-agreement state. Byproduct material is defined and the NRC is specified as the regulatory agency in the state of Connecticut.
- e. Additional posting of notices requirements from §19.11
Current copies of the following documents will be prominently posted:
Title 10 CFR Part 19 – Notices, Instructions, and Reports to Workers: Inspection and Investigations
Title 10 CFR Part 20 – Standards for Protection Against Radiation
The US NRC license and associated documents and amendments
Any notice of violation involving radiological working conditions
NRC Form 3 – Notice to Employees (August 1977)
No specific State of Connecticut regulations apply in addition to the above labeling requirements.
- f. Limits for removable contamination have been revised to match the US NRC document "Guidelines for Decontamination of Facilities and

Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," April 1993.

- g. **References to a "Radiation Safety Staff" or "Radiation Safety Office" have been deleted. There is only a single RSO, with two additional authorized users (one has been hired since the original submission of the application; please see the additional attached Supplement A – Training and Experience: Authorized User or Radiation Safety Officer**
- h. **Deregulated scintillation waste and animal carcasses – These references were left over from a previous version of the handbook intended for a more diverse company. There will be no animal studies involving radioisotopes; indeed, we have no intention of performing experimentation on live animals of any kind.**
- i. **Sewer disposal of LLRW – The definition has been changed to "readily soluble, or readily dispersible biological material, in water". I assume that you meant to refer to item 9.a of your letter of September 15th, not 8.a, concerning disposal. Please see item 9.a of this letter for a complete response.**
- j. **The DAC values for chromium-51 were removed, as it is not an isotope under consideration by this application. The values for phosphorus-32 were added for completion of the table.**
- k. **The reference to additional waste containers was removed as it refers to containers for waste disposal materials and methods not covered by this application.**
- l. **Appendices IV through VIII, "General Handling Precautions..." prepared by NEN, were removed. They were intended only as additional technical information for workers, not as requirements for persons working with licensed materials.**

If you require any addition information to continue review of the application, please do not hesitate to contact me at [203] 881-1032 x102. I look forward to hearing from you at your earliest possible convenience.

Sincerely,



Steven P. Piccoli, Ph.D.
Chief Operations Officer

Enclosures:
Additional form "Supplement A"
Radiation Safety Handbook – Revised October 1998