Molecular Genetics Inc

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August 20, 1985

Ms. Evelyn R. Matson
Materials Licensing Section
U.S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Ms. Matson:

In reference to your letter dated July 31, 1985, concerning our renewal application, Control Number 78517, the following additional information is provided:

1. H-3 Bioassays

Presently our level of H-3 use is less than 10% of the levels in Table 1 of the Draft Regulatory Guide, "Applications of Bioassay for Tritium". If, in the future, our use of H-3 increases to greater than 10% of the levels in Table 1 we will perform bioassays as described in the guide.

2. Personnel Instruction

a. Employees will receive the training described on page 27 of our application initially upon employment and annual update training will be provided thereafter.

b. Our receiving personnel attend the same training sessions as our laboratory personnel since this person has a scientific background. Other ancillary personnel who frequent restricted areas will receive initial and annual update training. Instruction will include identification of areas where radioactivity is stored and used, health hazards associated with overexposure to radiation, procedures to minimize exposure to radioactive materials, and procedures in case of emergency.

3. Laboratory Surveys

a. Radiation surveys will be conducted by the investigator after each experiment, or at least weekly when millicurie quantities are used, or at least monthly when microcurie quantities are used.

b. & c. The Radiation Safety Officer (RSO) will conduct radiation surveys at least every two months and will maintain records of the survey results.

d. We will continue to decontaminate surfaces when levels reach 100 cpm or greater. It has been our experience that we have been able to maintain this level. Since our scintillation counter prints out in cpm and it would be too time-consuming to convert each sample result to dpm, we would prefer to continue to describe contamination limits in terms of cpm.

e. The RSO will conduct surveys of receipt, storage, and waste areas monthly.

f. Iodine-125 is used in a chemical hood with the exhaust air passing through a charcoal filter. Hood face velocity is at least 80 fpm. One millicurie of ^{125}I is the maximum amount being used for iodinations. The iodine removal efficiency of the charcoal filter is 99.994%. A worse case of 1 mCi being released into the hood, with an air exhaust volume from the hood being 733 cfm, and filter efficiency of 99.994% would result in 2.8×10^{-9} uCi of I-125 released per milliliter of air. However, this procedure is presently conducted 10 times per year at most and with the hood running 24 hours/day, we would be in compliance with Section 20.106 of 10 CFR, Part 20 and would not exceed the limits of Appendix B, Table II when averaged over one year.

We do not use tritium in volatile form and therefore, release of gaseous tritium would not be an issue.

4. Package Receipt Procedures

a. Receiving personnel have viewed the training programs described on page 27 of our application. Receiving personnel have been instructed by the RSO on wipe test procedures. All radioisotope shipments are wipe tested according to the following procedure: i) Gloves must be worn when monitoring packages. ii) Using a Whatman No. 1 dry filter paper, wipe all sides of the outside of the package. iii) Completed wipe test samples are to be counted in a liquid scintillation counter on the wide open channel. iv) If removable radioactive contamination in excess of 0.01 uCi (22,000 dpm) is found, notify the RSO immediately.

b. If a package appears to be damaged or leaking, receiving personnel are instructed to do the following: i) Place leaking package in a plastic bag and restrict access to the area. ii) Check for personnel contamination and decontaminate, if necessary. iii) Notify RSO immediately.

c. Receiving personnel monitor all packages containing millicurie quantities or more of high energy beta or gamma emitting radionuclides. Packages are surveyed at 3 feet and results are recorded. If radiaiton levels are in excess of 10 mR/hr, the package is held in receiving and the RSO notified immediately. The external surface exposure rate is also measured and results are recorded. If radiation levels are in excess of 200 mR/hr, the package is held in receiving and the RSO notified immediately.

The investigator who ordered the material will open the radioactive package and wipe test the final source container. Wipes will be counted in a liquid scintillation counter. If contamination is found, the investigator will take necessary precautions to prevent the spread of contamination. Wipe test results will be recorded on the "Radioisotope Shipment Receipt" form.

The investigator will also monitor all packing material and packages for contamination before discarding.

5. The following are the duties and responsibilities of the Radiation Protection Officer:

a. Obtain necessary permits and licenses for use and disposal of radioisotopes. Ensure that terms and conditions of license are met and that all required records are maintained.

b. Perform routine surveys of all laboratories where radioactive material is used or stored. Ensure that areas are decontaminated to below established limits.

c. Ensure that the use of radioactive material is by or under the direct supervision of individuals specifically listed in our license.

d. Ensure that all individuals wear appropriate personnel monitoring devices when using radioactive material.

e. Ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.

6. Individual Users

In our renewal aplication we did not request that M.S. Collett be authorized to use chromium-51. M. Lum will use chromium-51 under the direct supervision of an authorized user of Cr-51. W. DeLorbe and S. Halling will use iodine-125 under the direct supervision of an authorized user of I-125. M. Wabuki-Bunoti is no longer with our company and we request that his name be withdrawn from the list of authorized users. We request that Peter Sadowski, Ph.D. be continued as an authorized user of Cr-51. This radioisotope was left off of our renewal request under item 3, page 3. Dr. Sadowski has had three years of experience working with Cr-51 and is an authorized user of Cr-51 under our present license.

Please contact me if you need any further information.

Sincerely,

Andrea Fell-Moody

Andrea Fell-Moody
Radiaton Protection Officer