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JUL 31 1985

Molecular Genetics, Inc.
ATTN: Andrea Fell-Moody
10320 Bren Road East
Minnetonka, MN 55343

Gentlemen:

We have reviewed your application dated March 12, 1985 requesting renewal of License Number 22-18862-01 and find that we will need additional information as follows:

✓ 1. H-3 Bioassays

Please indicate that if you intend to use hydrogen-3 in quantities above 0.1 of the levels in Table 1 of the Guidelines For Bioassay Requirements for Tritium, that you will perform bioassays as described in the guide.

2. Personnel Instruction

- ✓ a. Specify the frequency at which the instructions to personnel described in your application on page 27 will be given. As a minimum, training should be given initially upon employment and annually thereafter.
- ✓ b. It appears that the training program described in page 27 of your application is intended for individuals who work directly with radioactive material. In addition, ancillary personnel (clerical, receiving, 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. This instruction should be given both initially and annually thereafter on a refresher basis. This training should include the topics specified in 10 CFR 19.12 (enclosed).

3. Laboratory Surveys

- ✓ a. In addition to performing surveys after each experiment, investigators should perform surveys at least weekly when millicurie quantities are used and at least monthly when microcurie quantities are used. Modify your survey program to include these recommended frequencies.
- ✓ b. Modify your survey program to include that records will be maintained of the survey results.

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- c. Specify the frequency at which the RSO or her designee will perform laboratory surveys. These surveys should be performed at least every three months.
- d. Modify your decontamination limits to indicate a more descriptive disintegrations per minute (dpm) rather than counts per minute (cpm). In addition, you may find 100cpm/100cm² difficult to maintain. A level of 200 dpm/100cm² above background may be more appropriate.
- e. Modify the survey program to include surveys of all receipt, storage and waste areas by the RSO at least every three months.
- f. Describe your procedures for complying with Section 20.1(c), Section 20.103, and Section 20.106 of 10 CFR Part 20 for procedures such as protein iodinations and tritium labeling experiments that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys (e.g., environmental or breathing zone), frequency of surveys, and the individuals who will perform the surveys (e.g., Radiation Safety Officer or investigator), equipment to be used, and the procedures for evaluating the results. Refer to Section 20.201 for a definition of "surveys".

4. Package Receipt Procedures

- a. Please describe the training provided to the receiving personnel who perform wipe tests on packages containing radioactive material. Describe how the wipe is taken and how it is analyzed.
- b. Describe the instructions given to receiving personnel in case a package appears to be damaged or leaking. This should include the immediate steps taken to limit exposure and contamination of personnel and subsequent notification of RSO.
- c. Modify your package opening procedures to include that each person opening a package will carry out the following:
 - i. Gloves shall be worn to prevent hand contamination;
 - ii. For all packages containing millicurie quantities or more of high energy beta or gamma emitting radionuclides survey the packages at 3 feet and record. If >10mR/hr, stop and notify RSO. Measure the surface exposure rate and record. Notify RSO if >200mR/hr.

- iii. For all packages, wipe external surface of the final source container. Check wipes as appropriate for radionuclide and take precautions against the spread of contamination as necessary.
- iv. Monitor all packing material and packages for contamination before discarding.
- v. Maintain records of the results of checking each package.

5. RSO Duties

Submit a description of the duties and responsibilities of your radiation protection officer. The typical duties of a radiation protection officer would be:

- a. To ensure that the use of radioactive material is by or under the direct supervision of individuals specifically listed on your license.
- b. To ensure that all users (where appropriate) wear personnel monitoring equipment when using radioactive materials.
- c. To ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.
- d. To perform routine confirmatory inspections of all laboratories using or storing radioactive materials.
- e. To ensure that the terms and conditions of your license are met, and that all required records are maintained.

6. Individual Users

- a. Each user of radioactive material must show training and experience with the types and quantities of radionuclides that they wish to use. The types of radionuclides are low energy beta emitters (H-3), high energy beta emitters (P-32), gamma emitters (Cr-51), and radioiodine. Several individuals listed in your application have requested radionuclides with which they do not appear to have experience. Specifically, M.S. Collett and M. Lum wish to use chromium-51 and show no experience with gamma emitters of similar energy. W. DeLorbe and S. Halling requested use of iodine-125 and show no previous experience with radioiodine. M. Walbuki-Bunoti does not show experience with phosphorus-32 or the high energy beta emitters.
- b. For each of these individuals, submit documentation of additional experience with these radionuclides. Alternatively, they may elect to use these radionuclides under the supervision of another individual until they have gained experience.

As discussed in our telephone conversation on July 23, 1985, vanadium-48 is an accelerator produced radionuclide and as such is not under the jurisdiction of the NRC. You should contact your state department of health to determine any state requirements regarding this material.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 78517.

Sincerely,

Original Signed By
Evelyn R. Matson
Materials Licensing Section

Enclosures:

1. Regulatory Guides 8.20 and 10.8
2. 10 CFR Part 19
3. Guidelines for Bioassay
Requirements for Tritium

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Matson/cm
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