

MAY 06 1985

Frank S. Lisella, Ph.D.
Director, Office of Biosafety
Centers for Disease Control
DHHS, PHS
1600 Clifton Road, N.E.
Atlanta, GA 30333

Gentlemen:

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING A MATERIAL LICENSE
APPLICATION (REFERENCE: 18444, 030-04001)

This refers to your application dated November 19, 1984 for renewal of License Number 10-06772-01. As discussed with Paul Simpson during our phone conversation on April 17, 1985, your file has recently been transferred to the Region II office in Atlanta for licensing purposes, and after an initial review of your renewal application, it has been determined that additional information for the following items is needed:

1. Item 3 (Form NRC 313) - A clear and specific descriptive address for the Lawrenceville facilities. This should be a street number, building name, or other similar description of the physical location rather than a P. O. Box number.
2. Under Item 8 (Training for individuals working in or frequenting restricted areas) - A more definitive description of your training program to include such factors as:
 - A. Qualifications of instructors;
 - B. An outline showing major items to be covered and the amount of time for each;
 - C. The frequency training is to be given (initial or periodic refresher);
 - D. The method used to verify trainee competence (for example, a quiz). Include a sample if a quiz is given.
 - E. Records maintained.
3. Under Item 11 (Waste Management) - A complete description of your procedures for handling, storing and disposing of each type of radioactive waste generated in your operations. Specific NRC requirements are set forth in 10CFR20.301, 20.302, 20.303, 20.305, 20.306, and 20.311. Please note that certain procedures (i.e., incineration) are prohibited except as specifically approved by NRC pursuant to 20.106(b) and 20.302. Based on this, we are unsure of your reference to incineration.

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4. Draft Radiation Safety Manual (pages 40-41, surveys) - Please clarify types of surveys to be performed. Distinguish between surveys performed by OBS and those required to be performed more routinely by the authorized users. Also, specify what records will be maintained. Enclosed are three pages for reference on recommended frequency and type of surveys for different operations.
5. Draft Radiation Safety Manual - If researchers use animals, do you have procedures for the researchers and/or animal caretakers to follow (such as, in caring for the animals, cleaning the cages, handling of excreta and carcasses, etc.) If so, these procedures should be in the Radiation Safety Manual.

We note that the Radiation Safety Manual provided with your renewal application is in draft form, and we are unable to ascertain that it represents existing CDC policy. Furthermore, several key radiation safety items have not been adequately addressed as noted above. The document submitted to us is reviewed for compliance with NRC regulations and guidance and, if acceptable, will be referenced in your license. Once this is done you must adhere to its provisions.

If any information in the application dated November 19, 1984 needs updating, please submit those changes. Provide two copies of your reply and reference Mail Control Number 18444. Our review of your application will continue upon receipt of the above information. If you should have any questions, do not hesitate to contact me at 221-2675.

Sincerely,

Carol A. Connell
Radiation Specialist
Nuclear Materials Safety Section

Enclosure:
Referenced pages

RII *CAC*
CConnell:nw
5/3/85

RII *JPP*
JPPotter
5/3/85