

*file*

JUL 18 1985

Boehringer Mannheim Diagnostics, Inc.  
ATTN: Iva Sue Smith  
Manager, Regulatory Affairs  
9115 Hague Road  
Indianapolis, IN 46250

We have reviewed your application dated June 17, 1985 requesting a new license and find that we will need additional information as follows:

1. After reviewing Patricia Ann Jamison's resume, it is not clear that she has sufficient training and experience to function as radiation protection officer. Please clarify by submitting the following information:
  - a. Describe the type (on-the-job or formal course work) location and the number of hours of training for each of the following topics:
    - (i) principles and practices of radiation protection;
    - (ii) radioactivity measurements, and monitoring techniques;
    - (iii) mathematics basic to use and measurement of radioactivity; and
    - (iv) biological effects of radiation.
  - b. Describe the individual's experience handling radioactive material including (i) the specific isotope handles, (ii) maximum quantities handled and (iii) type of use. The qualifications, training, and experience should be commensurate with the material and its use as proposed in your application.
2. In addition to Ms. Jamison's training, you must provide the names and training of each person who will use or directly supervise the use of radioactive material. For each approved individual user describe their training as requested in Item, 1.a. and b. above.
3. Radiation workers (technologists, etc.) must receive instruction as specified in 10 CFR 19.12 (enclosed). Note that many of these items pertain to circumstances at your particular institution; therefore, you may not assume that this instruction has been adequately covered by prior occupational training, Board certification, etc. Please outline and submit your program for providing the necessary instruction. This instruction should be given both initially and annually thereafter on a refresher basis.

8509110207 850801  
REG3 LIC30  
13-24532-01 PDR

4. Ancillary personnel (clerical, 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.
5. Describe your procedures for disposing of short-lived radioactive waste material. These procedures should include the following:
  - a. Radioactive waste to be disposed of shall be held for decay a minimum of ten half-lives.
  - b. Prior to disposal as normal waste, radioactive material shall be monitored to determine that its radioactivity cannot be distinguished from background with an instrument capable of detecting small quantities of the radionuclide involved. All radiation labels will be removed or obliterated.
  - c. Records of survey results and identification of instrument used shall be maintained.

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 79281.

Sincerely,

Original Signed By  
Evelyn R. Matson  
Materials Licensing Section

RIII

*ERM*  
Matson/cm  
07/17/85