

June 17, 1985

Crittenton Hospital
ATTN: Michael Chopp, Ph.D.
1101 W. University Drive
Rochester, MI 48063

License No. 21-13562-01

Gentlemen:

We have reviewed your application dated January 10, 1985 requesting renewal of License No. 21-13562-01 and find that we will need additional information as follows:

1. Your application requests the use of Group V and VI procedures; however, none of the physicians listed on the current license have been given authorization to perform these procedures. In order to be added for Group V (including Iodine-131 for treatment of thyroid carcinoma) and Group VI procedures, a physician must demonstrate his/her training and experience with these procedures. For a description of the required experience refer to the enclosed Federal Register Notice. Please clarify your intentions regarding Group V and VI procedures.
2. Regarding the Group VI sealed sources now in your possession, please provide the following:
 - a. Describe the total activity presently in your possession;
 - b. Describe the storage facilities for the sources including shielding, security and a diagram.

Without an authorized physician on the license for Group VI sources, we can authorize them for storage only until you have such a physician authorized.

3. In order to be authorized to use xenon-133 gas submit the following:
 - a. The ventilation diagram previously submitted is confusing and difficult to follow; therefore, please submit a simplified diagram of just the hot lab and imaging room showing the location of all exhaust and supply vents.
 - b. All areas where xenon-133 is used or stored must be maintained under negative pressure where the exhaust rate exceeds the supply rate by at least 10 percent. Submit documentation of air flow rates that

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demonstrates that you have currently established this required ventilation.

- c. Describe further the recirculation of exhausted air. Include in your description where the recirculated air goes, the extent of its dilution and calculations showing that all areas receiving the air meet the limits for xenon-133 in an unrestricted area.
 - d. Describe the immediate area around the point of release for the air exhausted from the hot lab and camera room. Include in your description distance to nearest air intake, window, etc.
 - e. Describe how you will use the G-M survey meter to determine that the xenon-133 charcoal trap is effectively trapping the xenon-133 gas. Describe your criteria for determining when the trap is saturated.
 - f. Modify your procedures to include measuring air flow rates in the hot lab and camera room at a frequency not to exceed six months.
4. Specify the frequency at which you will provide training to ancillary personnel who may enter restricted areas or come into contact with radioactive material. As a minimum, training must be given initially upon assumption of their duties and at least annually thereafter.
 5. In the interest of providing a complete renewal of the license without potentially confusing references to previously submitted documents, please submit a complete description of your ordering and receiving procedures for packages containing radioactive material. Please refer to Appendix E of Regulatory Guide 10.8 (enclosed).
 6. In addition to the above, submit your area survey procedures. They should be at least equivalent to those in Appendix I of Regulatory Guide 10.8.
 7. Submit your ALARA program. You may refer to the model program in Appendix O, Regulatory Guide 10.8 or submit an equivalent program. Please include concurrence by the hospital administration.
 8. Submit procedures to be followed when patients treated with 8 millicuries or more of iodine-131 or phosphorus-32 are hospitalized. As a minimum, you should include the items addressed in Item 19 of Regulatory Guide 10.8 on page 10.8-10.

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

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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 78142.

Sincerely,

Original Signed By
Evelyn R. Matson
Materials Licensing Section

Enclosure: Regulatory Guide 10.8

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Matson/jl
6/14/85