FILE COPY

MAR 28 1985

Defiance Hospital, Inc.
ATTN: Mike Reichfield
Acting Administrator
1206 E. Second Street
Defiance, OH 43512

RE: Your Application Dated May 11, 1984 For Renewal Of License Number 34-15654-01

Gentlemen:

In order to complete our review and issue your license amendment, you will need to submit additional information on and/or clarification of the following items:

INSTRUMENT CALIBRATION

1. You have referenced License Number 34-13011-05 (Medical College of Ohio) as the outside firm responsible for your survey instrument calibrations. However, License Number 34-13011-05 has not been approved by the NRC or an equivalent Agreement State for the calibration of survey instruments of other client licensees. Either the Medical College will need to obtain a license for such services or you will need to submit alternate procedures. If you intend to have an outside firm calibrate your survey meters, you should contact the firm to determine if procedures for operating a commercial calibration service have been filed with the NRC.

2. You have indicated the the Xenogard (or equivalent) air monitor will be used each day xenon is used in the department and during each ventillation study and the results recorded. Please submit your procedures for calibration and the frequency of calibration of the Xenogard (or equivalent) monitoring system.

DOSE CALIBRATION

Item 10, page 3 of your application, states that in the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the reliance upon the manufacturer's assay of precalibrated activities. It is the Commission's position that precalibrated doses prepared outside the licensee's facility (by a Commercial Nuclear Pharmacy) must be physically assayed by the licensee intending to administer the dose, prior to actual administration. Please modify your procedures and confirm that all patient doses will be physically assayed prior to administration.

PROCEDURES AND PRECAUTIONS FOR USE OF XENON-133

1. Your emergency procedures should be modified to evaluate the contaminated area for a period of time approximating ten room changes or until a proper survey has been performed to ensure that xenon-133 air concentrations have reached levels equivalent to 1 X 10-5 microcuries/milliliter. Please modify your procedures accordingly.

2. Your calculations for air concentrations in restricted areas are based upon a 600 cfm exhaust and a single camera room air supply of 550 cfm. However, the diagram presented in Item 11 of your application specified an air supply of 1,095 cfm, which indicates a positive room pressure. Please clarify. If the exhaust found in the ventillation hood is to be used in your calculations, please submit procedures used to ensure maximum utilization of this system for room exhaust during xenon procedures.

SURVEY METERS

It appears that you receive all of your radiopharmaceuticals from Syncor and do not need to be reauthorized to possess and use a Mo-99/Tc-99m generator. Please confirm if we are correct. If we are not and you wish to continue authorization to possess and use such a generator, you will need to obtain a survey meter with a range at least equivalent to 1 R/hr. Please indicate the manufacturer's name, model number and the highest level range of the survey meter you intend to use.

AREA SURVEYS

You have indicated that area surveys and wipe tests will be performed weekly or in any case where contamination is suspected. Please modify your procedures to be at least equivalent to those outlined in Appendix I of Regulatory Guide 10.8 (Revision 1) dated October, 1980 (enclosed). Also, please submit your procedures for analyzing area wipe tests. If access to an instrument (e.g., solid scintillation counter) sufficiently sensitive to detect 200 dpm/100 cm^2 is limited, you may assay your area wipe samples with your GM survey meter provided you submit the following information:

a. State the sensitivity of the instrument in cpm or mR/hr.

b. State the efficiency of the instrument for common medical isotopes.

c. Confirm that the wipes will be counted in a low background area.

d. Confirm that the beta shield (if present) will be removed from the probe before counting the wipes.

e. Describe the optimum counting geometry for the particular instrument and confirm that you will adhere to it.

f. State the instrument response time and the equilibration time that you will allow for counting each wipe.

g. Confirm that your action level will be any instrument response greater than background.

PROCEDURES FOR SAFELY OPENING PACKAGES

Item 14 of your application states that a wipe of the external surface of each lead container will be made and the reading will be recorded. Please submit your procedures for analyzing the wipe samples and your action levels for decontamination.

PERSONNEL MONITORING DEVICES

In your application dated May 11, 1984 you indicated that ICN personnel monitoring devices would be used. However, an exchange frequency was not indicated. Please submit the exchange frequency of your personnel monitoring devices. We recommended exchange on a monthly basis.

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 77113.

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

Sincerely,

Original Signed By
J.R. Madera
Materials Licensing Section

Enclosure: Regulatory Guide 10.8

RIII

Madera/cm
03/27/85