file

SEP 3 1985

St. Joseph's Hospital
ATTN: Lee Jaeger
Assistant Administrator
700 Broadway
Ft. Wayne, IN 46802

Gentlemen:

We have reviewed your letter received July 1, 1985 requesting an amendment to renew your Byproduct Material License Number 13-00418-02 and find that we will need additional information as follows:

1. Please note that 10 CFR Part 35 has been revised effective October 12, 1982. This revision requires a representative of the nursing staff to be on the Medical Isotopes Committee. In view of this new requirement, you should appoint a member of your nursing staff to your Medical Isotopes Committee immediately.

2. Thyroid uptake can occur by breathing volatile iodine which is released when the cap is first removed from vials containing therapeutic liquid iodine-131. Personnel should be instructed to wear gloves and to open the vials in a fume hood or to take alternative precautionary measures.

   A bioassay program should be established for personnel who handle therapeutic liquid iodine-131. As a minimum, thyroid counts should be obtained approximately twenty-four (24) hours after exposure. Refer to the enclosed bioassay guide.

   Submit the precautionary measures and the bioassay procedures that you will follow.

3. Your updated list of instrumentation should include a dose calibrator. Please specify the manufacturer's name and model number of the instrument used at your facility.

4. Please supplement your package opening procedures to include instructions to verify that the contents of the packages agree with the packing slip and label on the bottles received. Submit your revised procedures.

5. Please submit a copy of your ALARA Program as requested in NRC's June 16, 1980 letter (copy enclosed). If you have chosen to adopt the Model ALARA Program attached to the June 16 letter, you may simply do the following:

   a. Fill in the blanks on the first page of the program.

   b. Have a representative of your management sign the program on the last page.

   c. Submit the signed Model ALARA Program.

   Once submitted and accepted by our office, your program will be incorporated as a condition of your NRC license.

6. In support of adding gadolinium-153 and iodine-125 sealed sources for use in bone mineral analyzers, please submit responses to the following items:

   a. Identify the names of the individuals who will use or supervise the use of the source/device. For individuals who are not authorized for one or more of the groups, submit their training and experience.

   b. Specify the manufacturer and model number of both the gadolinium-153 and iodine-125 sources and the manufacturer and model number of devices in which they will be contained.

   c. Specify the title and training of the individuals who will be responsible for installing and removing the gadolinium-153 and iodine-125 sources from the devices. Each individual who will perform these operations should be trained by the manufacturer at the time of installation.

   d. Submit specific procedures that will be followed when installing or removing the gadolinium-153 and iodine-125 sources from the device. You may submit copies of the manufacturer's recommended procedures for each source.

   e. State the method for disposing of your sealed sources that have decayed or that are no longer needed.

   f. Specify who will perform the servicing and maintenance of the bone mineral analyzers involving the source holder and/or shutter mechanism. We recommend that such services be performed by the manufacturer or by other persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State.

   g. Describe your procedures for assuring that the bone mineral analyzer and source are secured at all times against unauthorized use or removal.

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 79265.

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
Cassandra McDonald
Materials Licensing Section

Enclosures:
1. Regulatory Guide 8.20
2. ALARA letter June 16, 1980

RIII
9/4/85
McDonald/cm
08/29/85

CONVERSATION RECORD

TIME 2:25 pm. DATE August 22, 1985

TYPE ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☑ INCOMING ☒ OUTGOING

Location of Visit/Conference:

ROUTING	
NAME/SYMBOL	INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
John Helmer (RSO)	St. Joseph's Hosp Ft. Wayne IND.	(219) 425-3977

SUBJECT

Renewal Appl. Date Received July 1, 1985

SUMMARY

Ltr. referenced old renewal application & supplement letters (e.g., Jan. 28, 1975, Sept. 26, 1975 & Aug 8, 1977).

Question: Should renew request reference newer renewal request dated Jan. 29, 1980 & ltr. Mar 28, 1980

Answer: yes, previous ltrs. are incorrect.

ACTION REQUIRED

Review license referencing ~~license~~ renewal application dated Jan. 29, 1985 and ltr. dated March 28, 1980.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
CASSANDRA MCDONALD		8/22/85

ACTION TAKEN

SIGNATURE	TITLE	DATE