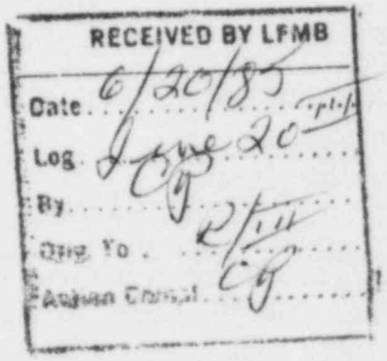
34-2672

St. Vincent Medical Center



May 31, 1985

Mr. Bruce Mallett
License Division
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 61037

RE: ATTACHED LETTER REGARDING RENEWAL OF NRC LICENSE #34-01216-03

Dear Mr. Mallett:

Please note in the attached letter of May 17, 1985, from Ms. Evelyn R. Matson that alternate adequate procedures must be submitted for the requested changes in performing dose calibrator accuracy and constancy tests. I have also attached the pertinent sections of our license and the letter dated August 1, 1984.

Since time-activity curves are derived using decay factors, I am not sure what alternate adequate method could be proposed. For each standard source, I will provide the technologist with a table of decay factors versus time for the appropriate day, then, the technologist will multiply the original source activity by the appropriate decay factor to arrive at the activity of the standard source on that day. That activity will then be compared to the reading obtained in the dose calibrator for +/- 5% agreement.

The purpose of using the decay tables to arrive at standard source activity benchmark values instead of the semilogarithmic plots recommended by Regulatory Guide 10.8 (Appendix D, Section C, #4) is simplicity. Our technologists prefer recording actual values and then calculating to ensure that the +/- 5% agreement exists, rather than plotting those values on semilogarithmic scale, and reading benchmark activities from the semilogarithmic plot. Please be assured that this requested change pertains only to the determination of the benchmark standard source activities and to the recording of measured standard source activity data. The standard sources will still be counted in the dose calibrator as indicated in Appendix D.

In addition, please clarify that Item 5b in our letter of August 1, 1984, is indeed acceptable by the NRC.

Thank you, Mr. Mallett, for your cooperation in clarifying this matter. Your assistance is highly valued.

Sincerely,

Kathryn J. Williford, M.S.
Medical Radiation Physicist

KJW/cah

Attach.

St. Vincent Medical Center

August 1, 1984

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Request for Renewal
Byproducts Materials License
34-01216-03
Expiration Date August 31, 1984

Dear Sirs;

Please renew the above noted Byproduct Materials License under the conditions present in the current license and supporting documents as follows:

1. Application dated	October 27, 1978	(Amendment No.31)
	January 15, 1979	(Letter)
2. Letters dated	October 10, 1979	(Amendment No.32)
	August 21, 1981	(Amendment No.33)
	August 21, 1981	(ALARA Program)
	January 14, 1982	(Amendment No.33)
	October 20, 1982	(Amendment No.34)
	January 18, 1983	(Amendment No.35)
	June 14, 1983	(Amendment No.36)
	August 1, 1983	(Amendment No.37)

The following letters have been superseded in part by the June 14, 1983 communication and Amendment No 36:

October 20, 1982	(Amendment No.34)
January 18, 1983	(Amendment No.35)

St. Vincent Medical Center will continue to operate in accordance with the above noted documents and applicable NRC regulations and license conditions.

At this time, St. Vincent Medical Center requests that the following revisions be made in the current documents:

1. Change of Licensee's Name
   The Licensee Name should be changed from St. Vincent Hospital and Medical Center, Department of Nuclear Medicine to St. Vincent Medical Center, Department of Nuclear Medicine.

CONTROL NO. 79143

JUN - 7 1985

2pp.

2213 Cherry Street, Toledo, Ohio 43608-2691 419/259-4098

2. Addition of Authorized Users for Group VI Material only:
   Marsa, G.W., M.D.
   Mah, Chun Il., M.D.
   Zeidner, Steven, M.D.
   Mueller, William K., M.D.
   Eggleston, William D., M.D.

   Each of the above noted requested Authorized Users are currently authorized for Group VI material use under N.R.C. Materials License No. 34-15184-01 for Flower Hospital, 5200 Harroun Road, Sylvania, Ohio, 43560. The supplements A and B for each individual are therefore currently on file with the N.R.C.

3. Deletion of Authorized User:
   Please delete R.M. Stankey, M.D. as an Authorized User under our license.

4. Change in Medical Isotope Committee Membership:
   Please amend membership of Medical Isotope Committee in accordance with Attachment #1 to this letter.

5. Change in Methods of Calibration of Dose Calibrator:
   a. Instrument Constancy and Instrument Accuracy may be evaluated against an activity of isotope(s) used derived using either a table of decay factors or an activity vs. time semilogrithmic plot.

   b. Instrument linearity may be evaluated either by the method noted in Appendix D Section 2.E in Regulatory Guide 10.8 or with the use of a Linearity Test Kit, using a series of filters as described in Attachment #2 of this letter.

6. The company supplying our radioisotope doses and removing unused doses and spent syringes is Syncor, Inc., Toledo, Ohio. N.R.C. License No. 34-16654-01MD.

Enclosed please find a check in the amount of $580.00 for the License Renewal Fee, under 10CFR170.31.7C.

All correspondence regarding this request for Byproduct Materials License Renewal should be directed to K.J. Williford, Radiation Physicist, St. Vincent Medical Center, 2213 Cherry Street, Toledo, Ohio, 43608.

Sincerely,

Allen B. Johnson
Executive Administrator

CONTROL NO. 9143

ABJ/jfp

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

MAY 17 1985

St. Vincent Medical Center
Department of Nuclear Medicine
ATTN: K. J. Williford, M.S.
Radiation Physicist
2213 Cherry Street
Toledo, OH 43608-2691

Gentlemen:

Enclosed is Amendment No. 39 renewing your NRC License No. 34-01216-03 in accordance with your request.

Please note that Condition 19. has been added to your license requiring the performance of bioassays on individuals who handle therapeutic quantities of liquid iodine-131. Also note that we have not approved the procedures for performing dose calibrator constancy and accuracy tests as described in your letter dated August 1, 1984. You may submit alternate adequate procedures if you wish to have these conditions modified or deleted.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address.

5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

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CONTROL NO. 19143

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 34-01216-03

Docket or Reference number 030-02672

Amendment No. 39

16. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.

17. Patients containing Iodine 131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.

18. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.

    B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

19. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

20. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated October 27, 1978; letters dated January 15, 1979, October 10, 1979, August 21, 1981, January 14, 1982, January 18, 1983, June 14, 1983 and August 1, 1984 (except Item 5.A.); and ALARA Program dated August 21, 1981. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

MAY 17 1985

Date [redacted]

By Evelyn R Matson
Materials Licensing Section, Region III

CONTROL NO. 9445

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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

Sincerely,

Evelyn R Mateon
Materials Licensing Section

Enclosure(s):
1. Amendment No. 39
2. Regulatory Guide 8.20