2594

VETERANS ADMINISTRATION
HOSPITAL
4101 WOOLWORTH AVENUE
OMAHA, NEBRASKA 68105

IN REPLY REFER TO: 636/151C

September 6, 1979

Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and Material Safety
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Control No. 97365

Dear Mr. Lamastra:

With reference to your letter of August 21, 1979, the following additional information is supplied for the renewal of our Material License No. 26-00138-10.

1. Your assumption concerning our institutions need for byproduct material is correct. However, as will be explained in item 8 below, there will be no need for 10 curies of tritium. 50 millicuries of tritium will be sufficient. Please add "as needed" as the maximum possession limit for Item 6a Group VI.

2. Radioactive drugs and biologicals used in Group I thru VI as outlined in 10 CFR 35 will only be procured from vendors whose product is manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA.

   At the present time there are no plans for using "radioactive drugs for certain research uses" as described in 21 CFR 361.1 but if the need develops the FDA regulations will be strictly followed.

   All radioactive drugs and biologicals are approved by the Radiation Safety Officer, or his delegate, before they are ordered and it will be his responsibility to see that FDA regulations are complied with.

3. A 5 millicurie cobalt-57 source with an accuracy of $\pm$ 5% has been purchased to perform the daily consistency and annual energy check of the dose calibrator. Item 10a of our original application contains the following error: ^{137}Cs 81 mCi should be 81 µCi.

4. Veterans Administration Medical Center Memorandum No. 115-1 has been amended to include Robert L. Gradoville, Administrative Assistant to the Chief of Staff, as a member of the Radioisotope and Radiation Safety Subcommittee. See attachment 1.

7910150249

"To care for him who shall have borne the battle, and for his widow, and his orphan." – ABRAHAM LINCOLN

5. Substitute the enclosed attachment 2 "Procedures for Opening Packages Containing Radioactive Material" for page 1 of Item 14 of the original application dated November 11, 1978. The amended page 1 contains the modifications mentioned in your letter.

6. Substitute the General Rules for the Safe Use of Radioactive Materials as outlined in Appendix G Regulatory Guide 10.8 for item 15a of the original application dated November 11, 1978.

7. The following procedures will be used for complying with Sections 20.1 (c), 20.103, and 20.106 of 10 CFR Part 20.

   All experiments that may release volatile or gaseous radioactive material such as in tritium labeling or protein iodinations will only be carried out in the radioisotope hood in room R-225 or R-325. Each of these hoods has their own prefilter and HEPA filter, and an air flow of at least 920 CFM with the hood open one foot.

   a. Tritium labeling will be done in a closed system to insure that no tritium is released during the labeling procedure. In addition, an Atomic Accessories Model TS-M-91-B Tritium monitor will be used to monitor the breathing zone in order to assure that no tritium is released and a water bubbler used to take a continuous air sample from the hood duct. Surveys will be performed by the Radiation Safety Officer or his designate and assay of the environmental samples will be carried out in a liquid scintillation counter. Since labeling experiments are done infrequently, the above monitoring will be carried out only during the time that the labeling experiment is being performed.

   b. Protein iodinations will be carried out in the radioisotope hood in R-225 (described above). During the time that the iodination is being performed (usually not more than 10 minutes twice a month) the following types of surveys will be carried out.

      1) Environmental - Monitoring will be accomplished by taking a continuous air sample from the hood duct. The sampling device will consist of a pump, a flow meter, an inline filter holder and charcoal filter paper which will remove better than 75% of iodine vapors. At the completion of the iodination procedure the filter paper will be removed and counted in a Nuclear Measurements Corp. Model PCC-IIT Gas Flow Counter calibrated for ^{125}I. Due to the naturally occurring radon and thoron gases in the atmosphere, and their particulate daughters being carried directly or indirectly on other dusts, the sample will be counted

4 hours (C_1) and 24 hours (C_2) after sampling. The long lived activity count rate (Cll in counts/min) may then be determined from the following formula:

$$Cll = \frac{C_2 - 0.271\ C_1}{0.729} \quad cpm$$

By use of appropriate conversion factors the counts per minute will be converted to µCi/ml.

2) Breathing zone monitoring will be carried out by means of a portable air sampler such as the Atomic Accessories Model MS 343 with the filter holder attached to the lapel of the individual doing the iodination. Charcoal filter paper as described above will be used. Evaluation of the filters will also be as described above. Surveys will be performed by the Radiation Safety Officer or his designate.

All iodinations will be done in a charcoal filtered mini-hood within the large hood. This mini-hood will have a 1 cubic foot working volume, a replaceable activated charcoal filter with a minimum of 1 inch thickness, and a blower capable of pulling 100 cubic feet per minute.

8. Delete the 10 curie amount of tritium. This was a carry over from a previous license and there are no plans to use that amount. 50 millicuries will be sufficient.

9. Since the surgeon who requested the irradiation of gold grains for therapeutic procedures left the Omaha VA Hospital before he was able to carry out the treatment, the technique has never been performed. We included the procedure in the license application since we were licensed for it in our previous license and the possibility of using the procedure in the future has not been completely ruled out. We have no objection to your not including it in our license at the present time and would appreciate your keeping the proposal in our file so that if the occasion arises we can obtain the Food and Drug Administrations approval, submit evidence to your office that all FDA requirements are complied with, and request that you add the procedure to our license.

The following information is submitted in addition to the above requested information.

Item 18 Since much of the work utilizing byproduct material at the VA Medical Center is combined University of Nebraska VA Medical Center research, negotiations are underway between the University of Nebraska, who hold a State of Nebraska broad scope license #02-01-03 with a condition for disposal by incineration or burying,and the State of Nebraska Division of Radiological Health to enable the University to accept our long-lived waste for disposal. If this can be worked out some of our waste will be transferred to

the University for disposal. If approval can not be granted for the above disposal a commercial waste disposal firm will be contracted with in the future. At that time the commission will be notified for approval prior to letting the contract.

Item 20 Sources containing byproduct material and used for Bachytherapy as licensed under Group VI of 10 CFR 35 may at times be brought in and used on a VA patient in the VA Medical Center Surgery suite by a University of Nebraska College of Medicine Radiotherapist. Since the therapy is done on a contract basis the sources will be procured and remain the possession of the University of Nebraska Medical Center under their license with the State of Nebraska. The Radiotherapist from the University of Nebraska College of Medicine will be responsible for determining the patient dosage, determining the radiation dose to the extremities of the personnel handling the sealed sources, maintaining source accountability, etc. However, during the implants the VA Medical Center Radiation Safety Officer will also be in the operating suite to assure the safety of VA personnel. Immediately after the implant has taken place, the Omaha VA Medical Center Radiation Safety Officer will be responsible for assuring that the procedures described in Appendix L of Regulatory Guide 10.8 are followed. The University of Nebraska Medical Center Radiotherapist will be approved as a user by the Omaha VA Medical Center Radiation Safety Committee.

As per your recent telephone conversation with A. J. Blotcky we would appreciate your sending him information on disposal of waste by incineration.

T. P. MULLON
Director

Attachment 1

Veterans Administration Medical Center
Omaha, NE 68105

MEMORANDUM NO. 115-1
July 8, 1976
Amendment NO. 2
September 5, 1979

RADIOISOTOPE AND RADIATION SAFETY SUBCOMMITTEE

Under Paragraph 3 a, PROCEDURE:, Members, add as a member

R. L. Gradoville, Hospital Administration

T. P. MULLON
Director

DISTRIBUTION:
All Service Chiefs and Sections
All Committee Members

Item 7a
September 5, 1979

Attachment 2

2594

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Use the following procedures in conjunction with Table I to determine what action should be taken.

1. Visually inspect all packages for any sign of damage (e.g., wetness, crushed, etc.). If damage is noted stop procedures and notify Radiation Safety Officer.

2. Measure the surface exposure rate of all packages regardless of whether the isotope is a gamma or a weak beta emitter. If the package contains a weak beta emitter and the exposure rate indicates the possible presence of a gamma emitter or the surface exposure rate is > 200 mR/hr, stop procedures and notify the Radiation Safety Officer.

3. When package monitoring is indicated from Table 1, do it as soon as possible after a package is delivered, but in all cases no later than three hours after delivery if received during normal working hours, or within 18 hours of delivery, if received after normal working hours. A record must be kept showing the results of all package monitoring.

4. Put on gloves.

5. If the radioactivity in the shipping container does not exceed the amount listed in Column I of Table I, open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packing material). Remove the radioisotope from the box and monitor the box and the packing material for contamination before discarding.

   a. If contaminated, treat as radioactive waste.

   b. If not contaminated, obliterate radiation labels before discarding in regular waste.

6. If the radioactivity in the shipping container exceeds the amount listed in Column I of Table I, wipe-test the outside of the package, place swipes in glassine envelopes and deliver to Radiation Safety Officer (SW-2) for counting in Gas Flow Counter. If contamination exceeds 22,000 dpm per $100cm^2$, the Radiation Safety Officer will notify the last delivery carrier and the Nuclear Regulatory Comission (NRC). Wipe-testing is not required for gases or if the amount if equal to or less than that in Column I.

7. If the amount is greater than that in Column 2 (Type A quantities) measure the external radiation levels and wipe-test the outside of the package. If the surface reading is greater than 200mrem/hr. or if the reading at three feet is greater than 10mrem/hr., notify the Radiation Safety Officer who will notify the final delivery carrier and the NRC.

8. If the package requires action as described in paragraph 6 or 7, but does not indicate reportable removable contamination or external exposure, open and monitor as described in paragraph 5 above.

VETERANS ADMINISTRATION
HOSPITAL
4101 WOOLWORTH AVENUE
OMAHA, NEBRASKA 68105

November 11, 1978

IN REPLY
REFER TO: 636/151

ADCMD for Operations (115)
Veterans Administration Central Office
810 Vermont Avenue, N.W.
Washington, D. C. 20420

SUBJ: Renewal of byproduct license of broad scope #26-00138-10

1. Enclosed please find the original and one copy of the application for renewal of our byproduct material license #26-00138-10 which expires December 31, 1978.

2. If this meets with your approval, will you please forward the original and one copy to the Radioisotopes Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555.

T. P. MULLON
Director

Enclosure

James Smith M D

NOV 20 1978
NOV 20 1978

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

FEE EXEMPT

COPIES SENT TO OFF. OF
INSPECTION AND ENFORCEMENT

23365

"To care for him who shall have borne the battle, and for his widow, and his orphan."— ABRAHAM LINCOLN