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THIRD UNITED STATES ARMY MEDICAL LABORATORY
FORT McPHERSON, GEORGIA

ADDRESS REPLY TO
COMMANDING OFFICER

23 July 1964

Mr. Nathan Bassin
Isotopes Branch
Division of Materials Licensing
United States Atomic Energy Commission
Washington, D. C. 20545

Dear Sir:

Inclosed is a copy of revised Standard Operating Procedures for Radioisotope Committee reflecting the changes outlined in your letter of 7 July 1964.

It is requested that application be amended to substitute Mercury 197 for Mercury 203 because of the lower radiation dose.

Sincerely,

William C. Butz

WILLIAM C. BUTZ
Colonel, MC
Commanding

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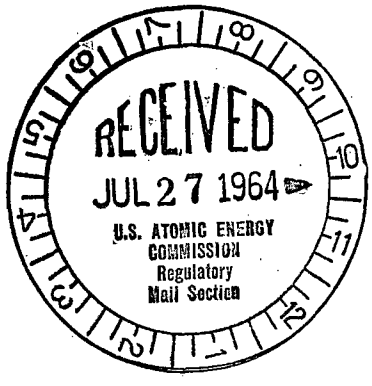

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HEADQUARTERS
THIRD UNITED STATES ARMY MEDICAL LABORATORY
Fort McPherson, Georgia

16 July 1964

STANDARD OPERATING PROCEDURES
Radioisotope Committee

1. REFERENCES:

a. AR 40-37
b. AR 40-400
c. AR 40-403
d. AR 40-414
e. AR 40-431
f. AR 40-580
g. AR 385-30
h. AR 700-323
i. AR 755-380
j. TB Med 249
k. TB Med 254
l. SB 11-206
m. CFR Title 10, Part 30

2. PURPOSE:

a. To establish uniform procedures for the use of radioisotopes in laboratory investigation and clinical diagnosis.

b. To establish adequate administrative procedures for functioning of the committee.

c. To establish adequate safety procedures for the handling, laboratory use, and clinical application of radioisotopes.

3. THE COMMITTEE:

a. Members: The Committee will consist of (1) the Commanding Officer, Third US Army Medical Laboratory, (2) Commanding Officer or a medical officer who has been approved by the Commanding Officer of the U. S. Army Hospital, Fort McPherson, (3) a Radiological Safety Officer, and (4) such other persons deemed necessary to carry out an effective program. Members will be appointed on Special Orders of this headquarters with the concurrence of parent organizations, if applicable.

b. Meetings: The Committee will meet at least once each quarter at the time and place designated by the Chairman and at other times deemed necessary by the Chairman or Safety Officer of the Committee.

c. Functions:

(1) Review and approve or disapprove the use of isotopes for specific uses within this institution and the US Army Hospital, Fort McPherson, Georgia (with the concurrence of CO, USAH, Fort McPherson, Georgia, if applicable).

This SOP supersedes HQ-D-1, 20 May 64

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(2) Prescribe special conditions which are necessary or desirable in connection with the procurement, storage, and use of radioisotopes.

(3) Appoint a Radiation Protection Officer. This officer will be the best qualified individual available. His appointment will be by Unit Orders, Third US Army Medical Laboratory, and his specific duties will be as detailed in paragraph 5, this SOP.

(4) Certify medical officers for each individual radioisotope consistent with qualifications and limitations and insure such certification is placed in user's 201 file. Each individual handling a specific isotope, i.e. I-131, will have received training at Oak Ridge Institute of Nuclear Studies, either in the six-week course or short Preclinical I and II courses in the uses of radioisotopes. Where the user has received training in the hospital in connection with residency, the Committee will review certifying statements prepared by the school to insure that a specific number of procedures on each isotope have been performed under supervision by a licensed operator. Before the clinical use of a radioisotope is undertaken, each user will receive didactic instruction and practical diagnostic uses of the particular isotope in question. The Committee will submit through channels all changes of the Radioisotope Committee and any change in appointment of Radiation Protection Officer in accordance with AR 40-37.

(5) Review records and receive reports from the Radiological Safety Officer and other individuals using radioactive materials in laboratory or clinical investigation.

(6) Recommend remedial action for persons failing to observe safety procedures established by the Radiological Safety Officer under authority of the Committee.

(7) Maintain complete records of all meetings of the Committee and all official actions taken by the Committee.

(8) Render reports to inspecting agencies as required by law and/or by Army Regulations, and cooperate fully with these agencies when inspections are made by them.

d. Training and Experience for Medical Users of Byproduct Material:

(1) General Training:

(a) General training in basic radioisotope handling techniques will include:

1. Principles and practices of radiological health safety.

2. Radioactivity measurements, standardization, and monitoring techniques and instruments.

3. Mathematics and calculations basic to the use and measurement of radioactivity.

4. Biological effects of radiation.

5. Experience in the use of byproduct material for the types and quantities for which the application is being made.

(b) Clinical radioisotope training consists of:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis.

2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data.

3. Physicians will have adequate period of training, either through completion of basic course in radioisotope techniques given at Oak Ridge Institute of Nuclear Studies or equivalent training within a hospital or university medical center.

(2) Specific Training:

(a) Category I - Diagnostic procedures such as Iodine 131 uptake, Chromium 51 blood volume, Cobalt 60 or 58 as Labeled Vitamin B12 for diagnosis of pernicious anemia.

1. For diagnostic uses of all radioisotopes, thirty hours of training in basic radioisotope handling techniques will be required.

2. Active participation in the performance of five uptake studies, three dilutions and three excretions.

3. No therapeutic uses of radioisotopes will be undertaken.

(b) Indications for Uses of Radioisotopes

Iodine 131 will be used for diagnosis of thyroid function, uptake and thyroid scan; Iodinated Human Serum Albumin for blood volume determination or brain tumor localization; Hippuran for ranograms and kidney scan; Rose Bengal for liver function studies and liver scan; Labeled Fats for fat absorption studies; Cholografin for gallbladder and bile duct function; Iodine 125 for diagnosis of thyroid function; Chromium 51 for blood volume studies in the form of Sodium Chromate; Cobalt 57, 58 and 60 in the form of Cyanocobalamin in the study of pernicious anemia; Iron 59 as Ferric Chloride used for iron turnover studies. Limitation of dosage will be in accordance with paragraph 5(a), Form AEC 313a of basic application for byproduct material license.

4. SAFETY: The following safety procedures are hereby established for the guidance of the Committee, except when these procedures are contrary to safety procedures established by the Atomic Energy Commission or other competent authority.

a. Dosimetry Requirements:

(1) All persons engaged in the use of ionizing radiation will utilize film packet dosimeters. Other dosimeters which will enhance the completeness of the dosimetry problem will be employed as deemed necessary by competent medical authority.

(2) All persons exposed to ionizing radiation other than therapeutic or diagnostic radiation will utilize dosimeters except when the potential radiation is negligible and exemption from use is authorized by The Surgeon General, US Army.

b. Dosimeters:

(1) Only dosimeters capable of measuring radiation with an accuracy of 10% or better in the average energy ranges normally encountered in the use of sources of ionizing radiation will be used.

(2) The film packet dosimetry service for Army installations is provided by the Signal Corps in accordance with SB 11-206, and will be employed solely except in unusual circumstances as approved by the Chief Signal Officer.

c. Monitoring Period:

(1) Packet chambers and self-reading dosimeters will be charged and read at least every two days.

(2) Film packets will be worn for periods compatible with the potential hazards involved, but in no case longer than 4 weeks. Exposed film packets will be dispatched by the most direct means to the developing and evaluating agency.

d. Records: Dosimetry Records will be maintained in accordance with AR 40-431. All entries in Column "Dose" will be made in "rem" units except for low order exposure for which "rad," "rep" and "roentgen" are considered equivalent. Where the entry in the "Dose" column is greater than 0.1 "rem" in one calendar week, a brief explanation of the probable cause of over-exposure will be attached to DD Form 1141.

e. Storage Area:

(1) Standard radiation warning signs as described in AR 385-30 will be posted in conspicuous places where radiation is present. Radiation levels will be indicated on warning signs.

(2) Storage area will be considered a restricted area.

(3) Only authorized personnel will be allowed to enter the storage area. Individuals will not be permitted to remain in the storage area long enough to exceed the maximum permissible exposure.

(4) Personnel monitoring devices will be used when entering the storage area.

(5) All isotopes on hand will be stored in a locked vault lined with lead bricks. Isotopes in fluid state as concentrates will be handled by remote control and by the use of shielded dose cups. Disposal of isotopes with short half-lives will be through a sanitary sewerage system after ten half-lives have passed. Sealed sources of radioisotope will not be opened.

5. DUTIES AND RESPONSIBILITIES OF THE RADIOLOGICAL SAFETY OFFICER: Operating under the authority of Federal Law, pertinent Army Regulations, and the authority of the Committee, he will:

a. Review all plans for the proposed use of radioisotopes from the standpoint of radiological safety and make appropriate recommendations to the individual users and the Medical Committee on Radioisotopes.

b. Review all requisitions for radioisotopes in order to insure that a suitable storage area exists for the quantities and activities involved.

c. Arrange for procurement, calibration, and maintenance of survey instruments as needed for the performance of his duties.

d. Survey incoming shipments of radioisotopes and supervise the storage and distribution of such shipments.

e. Survey storage and working areas as frequently as he considers necessary. Conduct wipe test and/or leak test when required.

f. Instruct laboratory personnel concerning approved practices in preparing dilutions of radioisotopes and in their storage and detection. Specifies prohibited practices such as use of mouth suction in pipetting solutions, eating, drinking, or smoking in a room where radioisotopes are handled, etc.

g. Require the posting of warning signs in areas in which radioisotopes are stored or used.

h. Determine radiation exposure potentials under working conditions and recommend time limits of personnel exposure and minimum working distances.

i. Supply personnel monitoring devices (film badges, dosimeters, etc.) to individuals engaged in work with radioactive materials in this institution, require wearing of same during all times of potential exposure, collect and forward to the US Army Lexington Signal Depot for evaluation, and have recorded the findings on DD Form 1141 maintained for each such individual.

j. Supervise decontamination of all spills or personnel contamination.

k. Supervise disposal of all radioactive waste.

l. Supervise the maintenance of complete records of the receipt, storage, transfer, and disposal of radioisotopes in this institution.

m. Report any unusual incidents such as over-exposure, a spill, a loss of radioactive substance, or other accident.

n. Render a report at each meeting of the Medical Committee on Radioisotopes of all current authorizations to procure isotopes for uses other than in humans and of all pending applications for such authorizations and to render such report at any time upon the request of the Chairman.

o. Examine rate of flow of air in fume hoods used for preparation of solutions of radioactive elements to assure compliance with minimum requirements of the Atomic Energy Commission in this regard.

6. RADIATION SAFETY PROCEDURES FOR USERS:

a. In handling, all isotopes, upon receipt from vendor or producer, will be taken into custody, inventoried, and dosage entered into master file inventory record. Sealed sources will be tested for leakage or contamination. Monitoring of storage area by Radiation Safety Officer will be maintained. If greater than 0.005 mc is detected, a report should be filed within five days with the Director of Licensing and Regulation, Atomic Energy Commission, Washington, D. C.

b. Isotopes, i.e. Iodine 131, should be retained in lead brick-sealed vault until the expiration of ten half-lives. If capsules are not used, they should be destroyed by washing down sanitary sewerage system.

c. All radioisotopes will be procured in precalibrated individual doses and stored behind lead shields within locked safety vault.

d. During administration of dosage to patients, rubber gloves will be worn.

e. Preparation room, storage room and diagnostic room will be monitored daily after administration of isotopes.

f. Uptake equipment and portable survey meter will be checked daily and calibrated monthly.

g. All radioisotope handlers will be issued film badges which will be developed on a monthly basis and exposure entered into the handler's file.

h. Permanent records on all radioisotope shipments, dosage administered, and waste disposal will be maintained. Solid wastes and unused precalibrated, empty isotope containers will be disposed of in labeled waste containers. Contaminated instruments (syringes, etc.) will be stored to background within locked safe until the isotope has reached background levels.

7. OPERATIONAL PROCEDURES:

a. All medical isotopes will be requisitioned through Supply Section, Third US Army Medical Laboratory, Fort McPherson, Georgia. This requisition will then be processed through the Supply Section, Fort McPherson Army Hospital. Upon arrival of the item requisitioned, it will be taken to the Radiation Protection Officer who will immediately make and record an inventory of the specific isotope or isotopes procured and enter them in the register. The isotopes will then be placed in security.

b. All clinical uses will be under the supervision of medical officers who have been certified by the Radioisotope Committee as an individual user for the procedure involved. Appropriate dosage will be recommended in each case before it is administered.

c. All isotopes which have not been used will be destroyed by washing the same down the sink following the expiration of ten half-lives.

d. The work area will be posted with AEC regulations and secured at all times when not in use.

e. The quarterly report of the activities of the Radioisotope Committee will be submitted on a quarterly basis to The Surgeon General. This report will record the minutes of each Radioisotope Committee meeting, certification of each new member of the Radioisotope Committee, and will include data on the training and experience on all medical officers who are users. It will reflect the quantities of radioisotopes procured and disposed of during the period in storage, list procedures with dosage of each radioisotope used during the period, and provide information on unsolved problems and needed support to be rendered by The Surgeon General.

FOR THE COMMANDER:

William P. Thompson

WILLIAM P. THOMPSON
CWO, USA
Adjutant