DEPARTMENT OF THE ARMY
U.S. ARMY HEALTH PROFESSIONAL SUPPORT AGENCY
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

March 22, 1989

Preventive and Military
Medicine Consultants Division

U.S. Nuclear Regulatory Commission
Region IV
Nuclear Materials Safety Section
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Dear Sir:

Enclosed are two copies of a request for amendment to Byproduct Material License Number 42-01368-01, Brooke Army Medical Center, Fort Sam Houston, Texas.

Recommend approval.

Sincerely,

Charles E. Day III

Charles E. Day, III
Lieutenant Colonel, U.S. Army
Radiological Hygiene Consultant

Enclosure

462483

DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234

REPLY TO
ATTENTION OF:

HSHE-MP (385-11m)

06 MAR 1989

Robert N. Cherry, Jr.
~~MAJ, MS HSCL-P~~, RC 7 Mar 89
Radiation Protection Staff Officer

MEMORANDUM THRU: Commander, U.S. Army Health Services Command, ~~Fort Sam Houston, TX 78234-6200~~

FOR: HQDA, ATTN: DASG-PSP-E, Washington, DC 20310-2300

SUBJECT: Request for Amendment to U.S. Nuclear Regulatory Commission (USNRC) Byproduct Material License

1. Reference. USNRC Byproduct Material License Number 42-01368-01.

2. Request that the maximum possession limits for Technetium-99m and Molybdenum-99 be raised from 10 Curies each to 15 Curies each. This request is based on the manufacturer's difficulty in supplying 6.62 Curie generators. This action would permit procurement of the next larger size.

FOR THE COMMANDER:

JAMES L. ROSENGREN
Captain, MS
Chief, Administrative Services

MAR 27 1989

FEE EXEMPT

DEPARTMENT OF THE ARMY
BROOKE army MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234

REPLY TO
ATTENTION OF:

HSHE-MP (385-11m)

06 MAR 1989

Robert N. Cherry, Jr.
~~MAJ, MS~~ ~~HSCL-P~~, RC 7 Mar 89
Radiation Protection Staff Officer

MEMORANDUM THRU: Commander, U.S. Army Health Services Command, ~~ATTN: HSCL-P~~, Fort Sam Houston, TX 78234-6200

FOR: HQDA, ATTN: DASG-PSP-E, Washington, DC 20310-2300

SUBJECT: Request for Amendment to U.S. Nuclear Regulatory Commission (USNRC) Byproduct Material License

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FOR THE COMMANDER:

JAMES L. ROSENGREN
Captain, MS
Chief, Administrative Services

RECEIVED
MAR 27 1989

462483

DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200

REPLY TO
ATTENTION OF:

HSHE-MP (385-11j)

30 NOV 1987

MEMORANDUM THRU: Commander, U.S. Army Health Services Command, ATTN: HSCL-P, Fort Sam Houston, TX 78234-6000

2 Dec 87

FOR: HQDA, ATTN: DASG-PSP-E, Washington, D.C. 20310-2300

SUBJECT: Request for Amendment to U.S. Nuclear Regulatory Commission (USNRC) Byproduct Material License

1. Reference USNRC Byproduct Material License Number 42-01368-01.

2. Request that the license referenced above be amended to include an additional 150 Kg of Uranium (depleted in Uranium-235). Said material is used for shielding purposes in Technetium Generators procured from Medi-Physics.

FOR THE COMMANDER:

Karen L Wisentaner
KAREN L. WISENTANER
Captain, MS
Chief, Administrative Services

Copy sent to DCS

461788

DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200

REPLY TO
ATTENTION OF:

HSHE-MP

SUBJECT: Amendment of USNRC License

THRU: Commander
U.S. Army Health Services Command
ATTN: HSCL-P
Fort Sam Houston, TX 78234-6000

7 Dec 86

TO: HQDA (DASG-PSP-E)
Washington, DC 20310-2300

1. USNRC Byproduct Materials License No. 42-01368-03 authorizes possession and use of 2,500 curies of Cesium - 137 for the irradiation of biological materials in an Isomedix, Inc. Gammator Model M38-2 Irradiator. This license expires on 31 January 1987. In lieu of renewal it is requested that this license be terminated, and that all activities authorized by this license be transferred by amendment to USNRC Broad Scope Medical License No. 42-01368-01. This action is requested in order to consolidate the administrative requirements for management of radioactive materials at this medical center.

2. The following information is provided in support of this application.

a. BAMC Memo 40-72, which is referenced in both licenses mentioned above, reflects our current radiation protection program. A copy of this document is provided as enclosure 1.

b Enclosure 2 contains extracts from AR 40-37 which are referenced in BAMC Memo 40-72.

c. Current operating procedures for the Gammator are at enclosure 3.

d. The individual responsible for the radiation safety program, and the point of contact for this application is CPT John C. Weiser. CPT Weiser can be reached at (512) 221-4181 or FTS 746-4181.

3. If amendment of License No. 42-01368-01 is deemed inappropriate, then it is requested that this letter be handled as an application for renewal of License 42-01368-03.

3 Encls

FEE EXEMPT

MICHAEL R. ANTOPOL
Colonel, MC
Deputy Commander for
Clinical Services

46133

*BAMC Memo 40-72

DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
Fort Sam Houston, Texas 78234

MEMORANDUM
No. 40-72

18 June 1982

Medical Services
RADIATION PROTECTION PROGRAM

1. PURPOSE. To establish radiation protection policy and procedures to meet Federal and DA regulatory requirements and to keep personnel exposures to ionizing radiation as low as reasonably achievable. References are:

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*Supersedes BAMC Reg 40-72, 24 October 1977, with changes 1 - 5, and BAMC letter, AFZG-MDZ, dated 25 January 1980, subject: As Low As reasonbaly Achievable (ALARA) Program, and inclosure thereto.

Encl 1

a. BAMC Reg 15-1, Hospital Boards, Committees, and Councils.

b. AR 40-5, Health and Environment.

c. BAMC Memo 40-9, Pregnancy Surveillance Program.

d. AR 40-14, Control and Recording Procedures for Occupational Exposures to Ionizing Radiation.

e. BAMC Memo 40-32, Human Use of Ionizing Radiation from X-Ray, Radium, and Radionuclides.

f. AR 40-37, Licensing and Control of Radioactive Materials for Medical Purposes.

g. BAMC Command Policy 43, Utilization of Pregnant X-Ray Technicians and Other Radiation Workers.

h. AR 340-18-6, Maintenance and Disposition of General Personnel Management and Safety Functional Files.

i. AR 385-11, Ionizing Radiation Protection.

j. TM 3-220, Chemical, Biological, and Radiological (CBR) Decontamination.

k. TM 3-261, Handling and Disposal of Unwanted Radioactive Material.

l. TB 43-180, Calibration Requirements for the Maintenance of Army Material.

m. TB MED 521, Management and Control of Diagnostic X-Ray, Therapeutic X-Ray, and Gamma-Beam Equipment.

n. Code of Federal Regulations, Title 10, Energy. "Chapter 1 - Nuclear Regulatory Commission."

(1) Part 19, Notices, Instructions, and Reports to Workers; Inspections.

(2) Part 20, Standards for Protection Against Radiation.

(3) Part 21, Reporting of Defects and Noncompliance.

(4) Part 31, General Domestic Licenses for Byproduct Material.

(5) Part 35, Human Uses of Byproduct Material.

o. Code of Federal Regulations, Title 21, Food and Drugs. "Subchapter J - Radiological Health."

(1) Part 1003, Notification of Defects or Failure to Comply.

(2) Part 1020, Performance Standards for Ionizing Radiation Emitting Products.

p. Code of Federal Regulations, Title 29, Labor. Part 1910, Occupational Safety and Health Regulations.

q. US Nuclear Regulatory Commission Regulatory Guides.

(1) Number 8.9, Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program.

(2) Number 8.13, Instruction Concerning Prenatal Radiation Exposure.

(3) Number 8.20, Applications of Bioassay for I-125 and I-131.

(4) Number 8.23, Radiation Safety Surveys at Medical Institutions.

(5) Number 8.26, Applications of Bioassay for Fission and Activation Products.

(6) Number 10.8, Guide for the Preparation of Applications for Medical Programs.

r. National Council on Radiation Protection and Measurements (NCRP) Reports.

(1) Number 37, Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides.

(2) Number 40, Protection Against Radiation from Brachytherapy Sources.

2. APPLICABILITY. This memorandum applies to all personnel and activities assigned or attached to BAMC. It also applies to personnel and activities at the Institute of Surgical Research (ISR) with regard to radioactive materials used under provisions of licenses or authorizations issued by the Nuclear Regulatory Commission (NRC) or DA to BAMC.

3. RESPONSIBILITIES.

a. Radiation Control Committee (RCC). See BAMC Reg 15-1 and paragraph 4f, AR 40-37.

b. Health Physics Officer (HPO). If considered qualified by the RCC, the HPO will be designated in writing as the Radiation Protection Officer (RPO) for BAMC. A person may be considered qualified for designation as RPO if he or she is certified by the American Board of Health Physics or the American Board of Radiology in Radiological Physics or is eligible for such certification. Responsibilities of the RPO are listed in Appendix B, AR 40-37. In addition, the HPO will:

(1) Provide health physics support to DENTAC, Ft Sam Houston, to ISR, and to the Military Enlistment Processing Station (MEPS), San Antonio.

(2) Provide personnel dosimetry services.

(3) Provide a radioactive waste disposal service.

(4) Design or review plans for design or modification of diagnostic x-ray, therapeutic x-ray, and gamma-beam therapy facilities and of other facilities where ionizing radiation sources are used or stored.

(5) Provide training required by 10 CFR 19 and 29 CFR 1910.

(6) Perform annual radiation protection surveys of x-ray systems and other sources of machine-produced radiation in accordance with TB MED 521 and 21 CFR 1020.

(7) Post and maintain notices required by 10 CFR, Parts 19 and 21.

(8) Maintain a health physics reference library and make available to appropriate personnel copies of references not available through normal distribution channels which are required for compliance with this memorandum.

c. Physicians authorized as principal users by the RCC (physician-user).

(1) See paragraphs 4h(1) through (4), AR 40-37, for responsibilities of the physician-user. These responsibilities may be delegated to physicians who are in training under the supervision of the physician-user. "Supervision" means that the physician-user has adequately instructed the physician(s)-in-training in the specific human use and has ascertained that they are receiving training in the safe use of these materials and of radiation in or on humans. It also means that the physician-user periodically reviews the work of those supervised and assures himself or herself that proper medical records are made of each use. It does not mean that the physician-user is necessarily present for each radiopharmaceutical or radiation administration.

(2) See paragraphs 4i(1) through (5), AR 40-37, for activities which may be delegated to properly trained technicians, technologists, or other paramedical personnel under the physician-user's direction.

d. All principal users.

(1) Will use ionizing radiation sources only in accordance with stipulations of BAMC RCC authorizations (see 17 below) and applicable regulations.

(2) Have primary responsibility for insuring that persons under their supervision receive radiation safety training appropriate for their jobs.

(3) Will report violations or suspected violations of applicable radiation safety directives to the HPO.

(4) Will provide radiologically safe work environments for persons under their supervision (see 25e below).

e. Radiation workers (persons occupationally exposed to radiation).

(1) Will work in a radiologically safe manner to protect themselves, other workers, patients, and the general public.

(2) Will report radiologically unsafe working conditions to supervisors or the HPO.

(3) Will provide off-duty occupational radiation exposure information to the HPO at least once percalendar quarter.

f. Activity RPO. An Activity RPO may be designated in writing for an activity, department, service, or area. This person will have sufficient authority, training, and experience to perform the duties of an Activity RPO. Within his or her activity, department, service, building, or area, the Activity RPO will:

(1) Be a point-of-contact for the HPO.

(2) Implement the radiation protection program in accordance with this memorandum and other applicable directives, under the guidance and supervision of the HPO.

4. CALIBRATION OF RADIATION SURVEY METERS. The HPO will insure that all survey meters are calibrated at least once every 12 months. Generally, calibration will be done by the Metrology Section, Sacramento Army Depot. Army requirements for survey meter calibration are in TB 43-180.

5. EXCEPTIONS. Exceptions to this memorandum may be granted on a case-by-case basis by the HPO provided that such exceptions do not endanger personnel or property and do not violate Federal, DA, or HSC regulations, NRC license conditions, or DA radiation authorization conditions. An exception granted by the HPO will be reviewed by the RCC at its next meeting.

6. HUMAN USE OF IONIZING RADIATION. See BAMC Memo 40-32.

7. DEFINITIONS. Terms used in radiation protection are defined in AR 40-14 and AR 40-37.

8. PERSONNEL DOSIMETRY PROGRAM. Army maximum permissible exposure standards are in AR 40-14. Federal maximum permissible exposure standards are in 10 CFR 20 and 29 CFR 1910. The personnel dosimetry program will be in accordance with AR 40-14.

a. The HPO will determine which persons will be issued which types of dosimeter using the guidelines in AR 40-14 and the following:

(1) A whole-body film badge will be issued to each person who is likely to exceed more than 62.5 millirem whole-body dose equivalent in a calendar quarter. Further, anyone who is issued an extremity personnel dosimeter will also be issued a whole-body film badge.

(2) Film badges to monitor exposure to the head and neck (collar badges) and to the hands and forearms (wrist badges) will be issued to persons who are likely to exceed 5 percent of the applicable radiation protection standard.

(3) Thermoluminescent-dosimeter (TLD) ring badges will be issued to those persons routinely handling brachytherapy sources and syringes

containing radiopharmaceuticals. They may also be made available to those persons whose hands are routinely in or near primary fluoroscopic x-ray beams when wrist badges would interfere with clinical performance.

(4) Other persons not included above may be issued personnel dosimeters at the discretion of the HPO.

b. Each activity (e.g., service or clinic) routinely receiving personnel dosimetry service will designate a person who will collect, exchange with Health Physics, and reissue personnel dosimeters at each monthly exchange time.

c. BAMC-issued personnel dosimeters will not be worn at facilities other than those of BAMC, ISR, DENTAC (Ft Sam Houston), or MEPS (San Antonio), except as authorized by the HPO.

d. Radiation workers will not wear personnel dosimetry devices while undergoing medical or dental diagnostic or therapeutic treatment with ionizing radiation.

e. Persons beginning or ending personnel dosimetry service at BAMC will report to the Health Physics Office, Headquarters, BAMC, Room B-13, Building 1029, during normal duty hours with their Medical Records for processing.

9. BIOASSAY PROGRAM. The Bioassay program will be in accordance with AR 40-14 and NRC Regulatory Guides 8.9, 8.20, and 8.26.

10. PREGNANCY SURVEILLANCE. Radiation dose equivalent to the fetus will be kept below 0.5 rem for the duration of the gestation period.

a. A female radiation worker with a confirmed pregnancy and her supervisor will notify the HPO about the pregnancy as soon as possible. A mutually convenient time for an appointment between the radiation worker and the HPO will be arranged for consultation regarding health physics aspects of the pregnancy. The HPO will review the radiation exposure relative to her pregnancy and provide instruction concerning prenatal radiation exposure, in accordance with AR 40-5, 10 CFR 19, and 29 CFR 1910. Copies of BAMC Memo 40-9, BAMC Command Policy 43, and NRC Regulatory Guide 8.13 will be provided to the radiation worker.

b. The HPO will provide a DF to the radiation worker's supervisor to indicate that the required consultation took place and what further actions, if any, will be taken.

11. ACCOUNTABILITY AND INVENTORY OF IONIZING RADIATION SOURCES. The HPO is responsible for the physical inventory and accountability of all radioactive materials and ionizing radiation producing devices in accordance with the provisions of Federal and DA regulations. The HPO shall insure that the total inventory of any radioisotopes on hand at any one time does not exceed the possession limitations imposed for that isotope by the applicable NRC license or DA radiation authorization. To do this, the HPO may assign maximum possession limits to users of radioactive material.

a. Each user shall insure that the total inventory of any radioisotope on hand at any one time in his or her activity is within the maximum possession limits assigned to his or her activity by the HPO.

b. A physical inventory will be conducted quarterly under the supervision of Health Physics Office personnel. Each user of radioactive material shall maintain a current inventory of radioactive material within the user's control. A written report detailing the amount of radioactive material received, used, disposed, and on hand will be submitted to the HPO within 5 days after the end of each quarter by the user.

c. Machines and devices which produce ionizing radiation shall be registered with the HPO. The HPO shall physically inventory these machines semi-annually.

12. PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL.

a. Only activities (e.g., services, departments) authorized by the RCC to use radioactive materials may submit a purchase request for radioisotopes. The HPO shall provide Logistics Division with a list of activities authorized to purchase radioactive materials. In addition, the HPO shall have the authority to approve all purchase requests for radioactive materials prior to purchase.

b. A system for ordering and receiving radioactive materials will be established and maintained by each authorized activity. The system will consist minimally of the following:

(1) Ordering of routinely used materials.

(a) Written records that identify the isotope, compound, activity levels, supplier, etc., will be used.

(b) The written records will be annotated when opening or storing a radioactive shipment.

(2) Ordering of specially used materials (e.g., therapeutic uses).

(a) A written request will be obtained from the physician who will perform the procedure. In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

(b) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

(c) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

(3) It is essential that written records be maintained for all ordering and receipt procedures. See AR 340-18-6 for filing procedures. In the case of special orders, the physician's written request and appropriate

shipping/receipt records will be referenced and dose assayed prior to its administration.

d. During off-duty hours, the Administrative Officer of the Day (AOD) or Non-Commissioned Officer of the Day (NCOD) will accept delivery of radioactive packages in accordance with the procedures outlined in the sample DF in Figure 1. The HPO will insure that current copies of the DF are in the AOD and NCOD instruction books. The ISR Activity RPO will provide the HPO a copy of instructions similar to those in Figure 1 which are applicable for receipt of radioactive packages at ISR during off-duty hours.

13. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL. Users will consult with the HPO about interpretations of 10 CFR 20.205 and this paragraph whenever in doubt, to preclude violation of 10 CFR 20.205.

a. Only the Health Physics Office, Nuclear Medicine Service, Department of Clinical Investigation, Department of Pathology and Area Laboratory Services (Building 2630), ISR (Building 2653), Radiation Therapy Service, and Blood Donor Center (Building 1126) are authorized to receive packages from shippers. In the event a package is erroneously received by Logistics Division, the person in charge of the receiving area shall immediately notify the addressee (during duty hours) or the AOD during non-duty hours. The addressee shall be responsible for obtaining the packages and complying with the provisions of this paragraph.

b. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in 10 CFR 20.205. They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during normal duty hours or within 18 hours if received after normal duty hours, in accordance with 10 CFR 20.205(a) through (c).

c. Shipments of isotopes containing radioactive material in other than liquid form (including molybdenum-99/technetium-99m generators) need not be monitored in accordance with 10 CFR 20.205(a) through (c) if the total activity of the shipment is less than the Type A quantity specified in 10 CFR 20.205. Any shipment whose activity is less than the exempt quantity is exempt from the requriements of 10 CFR 20.205. Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfer-35, or iodine-125, and packages containing only radionuclides with half-lives of less than 30 days and a total quantity not exceeding 100 millicuries are also exempt from the requirements of 10 CFR 20.205. Otherwise, all shipments of liquids greater than the exempt quantities as specified in 10 CFR 20.205 will be tested for leakage.

d. Surveys shall be performed on all incoming packages not exempt from the provisions of 10 CFR 20.205. Written records of such surveys shall be maintained by the receiving activity. These records will contain the information indicated on the sample record in Figure 2. In the event that the survey indicates removable contamination in excess of 0.01 microcurie per 100 square centimeters or an external radiation level in excess of 200 millirem per hour at the surface or 10 millirem per hour at three feet from the external surface of the package, the receiving activity shall notify

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL	SUBJECT
HSHE-MP	Receipt of Packages Containing Radioactive Material

TO AOD
Nursing Supervisor, BP
CQ, Dept of Pathology & ALS

FROM Health Physics Off

DATE 26 November 1985

CMT 1

CPT Weiser/jw/4181

1. This DF establishes guidelines for receipt of packages containing radioactive material during non-duty hours.

2. Federal regulations require that, if a package is wet or appears to be damaged, it must be accepted by the addressee. In such circumstances:

a. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

b. Immediately notify one of the following individuals: SSG Rook, 661-9428; SSG Forster, 828-3463; or CPT Weiser, 494-0485.

3. Federal regulations also require that all packages received after duty hours must be monitored within 18 hours of receipt. Packages received after 1400 on days preceding a duty day require no special notifications. When packages are received at any other time, the appropriate Activity RPO (ARPO) listed below should be notified during normal waking hours.

a. DPALS ARPO: CPT Williams, 824-5881

b. Radiation Therapy ARPO: MAJ Bice, 661-0191

c. Nuclear Medicine ARPO: MAJ Landry, 1-885-7726

4. The person receiving the shipment will make note of the isotope and amount as indicated on the package label and deliver the package as follows:

a. Packages addressed to DPALS, Building 2630, should be delivered there by the commercial carrier to the CQ for that building on Monday-Friday 0730-2300. Packages received at other times will be delivered to the Beach Pavilion Clinical Laboratory, where they will be held until they can be delivered to the DPALS CQ. The DPALS CQ will place these packages in the Nuclear Chemistry Section Laboratory.

b. Packages addressed to the Radiation Therapy Service will be accepted by the Administrative Officer of the Day (AOD), taken to room 10A Main Hospital, and placed on the laboratory counter.

c. Packages addressed to the Institute for Surgical Research (ISR), should be delivered by the commercial carrier to the ISR CQ in Building 2653.

d. All other packages will be taken to the Nuclear Medicine Service at Beach Pavilion and left on the steps leading to the Nuclear Pharmacy at the rear of the clinic.

5. Only persons authorized by the ARPO will be allowed to open packages containing radioactive material.

HSHE-MP CMT 1
SUBJECT: Receipt of Packages Containing Radioactive Material

6. Federal regulations require that a copy of this DF be retained in the BAMC AOD and DPALS CQ Books.

JOHN C. WEISER
CPT, MS
Health Physics Officer

CF:
Indiv Conc (1 ea)

BAMC Memo 40-72

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. PO Number: _____ Survey Date: _____

   Time: _____ Surveyor: _____

2. CONDITION OF PACKAGE:

   _____OK _____Punctured _____Status _____Wet _____Crushed _____ Other:

   _____

3. RADIATION UNITS OF LABEL: _____ Units (mR/h)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mR/h

   b. 3 feet from surface _____ mR/h

5. DO PACKING SLIP AND VIAL AGREE?

   a. Radionuclide _____ yes _____ no, difference _____

   b. Amount _____ yes _____ no, difference _____

   c. Chemical form _____ yes _____ no, difference _____

6. WIPE RESULTS FROM:

   a. Outer _____ CPM; converted to _____ DPM/100 cm^2

   b. Final source container _____ CPM; converted to _____ DPM/100 cm^2

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/h, CPM

8. DISPOSITION OF PACKAGE AFTER INSPECTION _____

9. IF HPO/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED: _____

_____

Signature Date

Figure 2

the HPO immediately. The HPO shall perform notifications required by 10 CFR 20.205, if appropriate.

e. For all packages, the following additional procedures for opening packages will be carried out:

(1) Put on gloves to prevent hand contamination.

(2) Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify the HPO.

(3) If the package is not exempt from 10 CFR 20.205 (see 13b and c above), measure exposure rate at 3 feet from the package surface and record. If the exposure rate is greater than 10 milliroentgens per hour, stop procedure and notify the HPO. It is recommended that this step be followed for exempt packages also.

(4) If the package is not exempt from 10 CFR 20.205, measure surface exposure rate and record. If the exposure rate is greater than 200 milliroentgens per hour, stop procedure and notify the HPO. It is recommended that this step be followed for exempt packages also.

(5) Open the package with the following precautionary steps:

(a) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

(b) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip and label on bottle. In the case of special orders (e.g., therapy doses), also compare with physician's written request.

(c) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

(d) Check that the shipment does not exceed possession limits.

(6) If the package is not exempt from 10 CFR 20.205, wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record the amount of removable activity. If the removable activity is in excess of 100 disintegrations per minute per 100 square centimeters, stop procedure and notify the HPO. Take precautions against the spread of contamination as necessary.

(7) Monitor the packing material and packages for contamination, as appropriate, before discarding.

(a) Treat contaminated packing material as radioactive waste.

(b) If packing material is not contaminated, obliterate radiation labels before discarding in regular trash.

14. SHIPMENTS OF RADIOACTIVE MATERIAL. No one will ship radioactive material held under authority of NRC licenses or DA radiation authorizations without prior concurrence of the HPO. The HPO will insure that the shipper complies with all applicable directives before dispatch of the shipment is permitted.

15. TRANSFERS OF RADIOACTIVE MATERIAL BETWEEN ACTIVITIES.

a. Except for individual diagnostic dose and BACTEC transfers, all transfers between activities will have prior approval of the HPO. BAMC Form 739 (see Figure 3) will be used to document transfers. Appropriate changes to inventories will be made.

b. The activity from which the transfer is made will insure that appropriate precautions are taken. The HPO will provide guidance as necessary.

c. Normally, two persons will accompany any radioactive material during its movement. In case of an accident or spill, one person will stay with the material to protect passersby while the other notifies the HPO and takes other appropriate action. Corrective actions (decontamination, repackaging, etc.) will be the responsibility of the activity from which the transfer is made but will be under the supervision of the HPO.

16. DISPOSAL OF RADIOACTIVE WASTE.

a. Release to the sanitary sewerage system.

(1) No radioactive material will be released into the sanitary sewerage system unless it is readily soluble or dispersable in water and approval has been given by the HPO. In granting approval for release into the sanitary sewerage system, the HPO has sole authority to:

(a) Designate the sinks to be used. These sinks will be designated as "hot sinks" and will be appropriately labeled or marked, as indicated by the HPO. The HPO will be notified before any maintenance or repair (e.g., by plumbers) is done on any hot sink so that it may be surveyed.

(b) Prescribe daily and annual limits within the limits of 10 CFR 20.303 on the amount and types of radioactive waste disposed of in this manner for each hot sink.

(2) The using activity will maintain a record for each hot sink identifying the radionuclides disposed and date disposed, activity, cumulative activity for the calendar year to date for each radionuclide disposed in that hot sink, and identification of the person making the disposal (e.g., initials). This record (e.g., log book) will remain near the hot sink for easy access by both disposing activity personnel and the HPO. Upon removal from active use, the record will be forwarded to the HPO and filed in accordance with AR 340-18-6.

(3) Excreta from patients undergoing medical diagnosis or therapy with radioactive material (e.g., iodine-131 radiotherapy treatment of the thyroid) are exempt from the limitations of 10 CFR 20.303 to the extent

RADIOACTIVE MATERIALS MOVEMENT
WITHIN BROOKE ARMY MEDICAL CENTER

BAMC Memo 40-72

For use of this form, see BAMC Memo 40-72; the proponent is the Health Physics Officer.

DETAILS OF MOVEMENT

(Except for individual diagnostic doses and BACTEC, radioactive materials movements between BAMC activities must have prior approval of the Health Physics Officer.)

1. TO:	2. FROM:

3. Description of Material

a. Container (box, bag, etc)	b. Contents (syringes, tubes, etc)	c. Isotope, form, activity	d. Radiation levels (mR/h)		(For Health Physics Use)
			At surface	At 3 feet	
(1)					
(2)					
(3)					
(4)					
(5)					
(6)					
(7)					
(8)					
(9)					
(10)					

4. Remarks or special precautions

5. Signature and position of shipper	Date
6. Signature and position of receiver	Date

Completed copies of this form will be provided to (1) Shipper, (2) Receiver, and (3) Health Physics Officer (if not shipper or receiver) and will be kept under file number 608-11 (AR 340-18-6).

BAMC Form 739 NS
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Figure 3.

they are disposed of in the sanitary sewerage system. However, spills or incontinence may result in radioactive contamination which must be carefully and adequately cleaned up (see 19 below). Also, treat laboratory samples from such patients as radioactive material; the HPO will be consulted in such circumstances.

b. Release of radioactive gases to the atmosphere.

(1) No radioactive material will be released to the atmosphere for disposal unless approval has been given by the HPO. The HPO will not give approval unless calculations based on air flow rate surveys and the rate of radioactivity released demonstrate compliance with 10 CFR 20.106.

(2) Chief, Preventive Medicine Activity, will insure that semiannual ventilation surveys are conducted in all areas where radioactive gases are used. The number of air changes, room pressures, amounts of fresh air, and diagrams of areas surveyed will be reported. Survey results will be provided to the chief of the service responsible for surveyed area. The HPO will be provided a copy of the results of each survey.

c. Other radioactive waste. The HPO will operate a radioactive waste disposal service for waste which is not disposed of as specified in 16a or b above.

(1) Periodically, Health Physics personnel will pick up properly packaged waste from users.

(2) Users are responsible for:

(a) Segregation and packaging of waste generated by their activities as directed by the HPO.

(b) Identifying the contents of their waste, to include radioisotope, approximate activity, and date.

(c) Completing BAMC Form 739 to accompany the transfer.

(3) Radioactive waste collected by the HPO will either be held for decay until it can be disposed of as ordinary waste or held until it is shipped to a radioactive waste burial site. Shipment of radioactive waste will be in accordance with TM 3-261 (which specifies compliance with NRC and Department of Transportation regulations and with Army Armament Materiel Readiness Command instructions).

17. AUTHORIZATIONS FOR USE OF IONIZING RADIATION SOURCES.

a. General.

(1) Radioactive material at BAMC is held, used, and disposed of in accordance with applicable Federal and DA regulations and under terms of NRC licenses or DA radiation authorizations. The BAMC RCC has been delegated authority by the NRC and OTSG to approve (with review by the Executive Committee) uses and users of radioactive material within regulatory limits.

(2) The RCC also has been delegated authority to approve uses and users of other ionizing radiation sources (e.g., x-ray systems, electron microscopes). Use and user approval authority for ionizing radiation sources, other than radioactive material, orthovoltage x-ray therapy systems, and the linear accelerator, is delegated to supervisors, with review by the RCC as it deems necessary.

(3) Physicians authorized by the RCC to be principal users of radioactive material listed in group VI, 10 CFR 35.100, are hereby authorized as principal users of the orthovoltage therapy x-ray system and the linear accelerator.

b. Explanation of terms.

(1) Human use. The internal or external administration of radioactive materials or ionizing radiation to human beings.

(2) Principal user. A person who, by virtue of training and experience, has been authorized by the RCC to use ionizing radiation for a given purpose.

(3) User's certificate. A document indicating RCC authorization of a principal user and the uses to which that person may put ionizing radiation at BAMC.

c. Procedures for obtaining authorization from the RCC to use ionizing radiation. The HPO will provide forms and assistance to applicants as necessary.

(1) For human use, the petitioning principal user will prepare in final form, and provide to the HPO, the following documents.

(a) BAMC Form 176, Request for Approval to Use Radioactive Materials. See Figure 4 for sample form.

(b) Form NRC-313M-Supplement A, Training and Experience Authorized User or Radiation Safety Officer. Submit one form for each pirncipal user named on BAMC Form 176.

(c) Form NRC-313M-Supplement B, Preceptor Statement. Submit one form for each principal user named on BAMC Form 176.

(d) Protocol. See Appendix D, AR 40-37, for guidance in preparing protocols for nonroutine human use of radioactive materials. A protocol generally will not be required for those uses of radioactive material listed in 10 CFR 35.31, 10 CFR 35.100, or Appendix E, AR 40-37, or for routine human use of the orthovoltage x-ray system or the linear accelerator.

(2) For other uses, the petitioning principal user will prepare in final form, and provide to the HPO, the following documents.

(a) Bamc Form 176.

(b) Form NRC-313M-Supplement A. Submit one form for each principal user named on BAMC Form 176.

REQUEST FOR APPROVAL TO USE RADIOACTIVE MATERIALS

THRU: RPO, BAMC TO: Chairman, Radioisotope Committee	FROM: (Principal user & organizational element)

PROPOSED USE (Group uses as Diagnostic, Therapeutic, Research, Clinical investigation, Animal studies or In Vitro)

Radionuclide	Chemical and/or Physical Form	USE*	Max Dose	Maximum on Hand

(Signature of Principal User)

*Submit separate protocol for each radioisotope procedure except for routine diagnostic procedures listed in 10 CFR 35.100

RADIOISOTOPE COMMITTEE APPROVAL

Approved: Chairman, Radioisotope Committee	Approved by Subcommittee	Authorization No

SPECIAL INSTRUCTIONS

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Figure 4.

(c) Protocol. A protocol must be submitted for each use named on BAMC Form 176, except for those uses of radioactive material listed in 10 CFR 31.11.

(3) The HPO will review the application for completeness, appropriateness, and radiation protection adequacy. The HPO will request additional information and survey the proposed facilities, as necessary. As Recorder of the RCC, the HPO will make copies of the completed application and distribute them to the RCC members for their review prior to the next RCC meeting.

(4) The RCC will evaluate the application with regard for completeness, appropriateness, radiation protection adequacy, and training and experience of principal users (see 17f below). Protocols will be evaluated to determine medical acceptability of procedures with regard to personnel exposures. Protocols inv lving the use of human subjects as volunteers will also be evaluated by the Human Use Committee (see BAMC Reg 15-1). The RCC may then approve or disapprove the application or may ask for clarification or further information before making a decision.

d. Amendments to authorizations. Before a principal user may deviate from uses and procedures approved by the RCC, he or she will obtain an amendment to the authorization by submitting documentation to the HPO which adequately describes the proposed changes. Procedures in 17c(3) and (4) will then be followed.

e. Annual review. The HPO will review current authorizations at least once a year. The results of this review, to include recommendations for renewal, nonrenewal, or amendment, will be presented to the RCC.

f. Acceptable Training and Experience.

(1) For human uses of ionizing radiation.

(a) Acceptable training and experience for those human uses of radioactive material listed in 10 CFR 35.100 and Appendix E, AR 40-37, are listed in Appendix A, NRC Regulatory Guide 10.8, and paragraphs A-1 through A-3, Appendix A, AR 40-37.

(b) Acceptable training and experience for human uses of the orthovoltage and linear accelerator therapeutic x-ray systems is similar to that listed in paragraph 5, Appendix A, NRC Regulatory Guide 10.8.

(c) Acceptable training and experience for those human uses, by a physician, of radioactive material listed in 10 CFR 35.31, is listed in paragraph A-1, Appendix A, AR 40.37.

(d) Acceptable training and experience for non-routine human use of radioactive material is discussed in paragraph D-2, Appendix D, AR 40-37. Appendix A, NRC Regulatory Guide 10.8, and Appendix A, AR 40-37, may be used as guides in assessing training and experience for non-routine human use.

(2) For other uses of radioactive material. Acceptable training and experience is listed in paragraph A-1, Appendix A, AR 40-37.

g. Radioactive calibration and reference standards. Principal users are hereby authorized use of sealed sources up to 3 millicuries as calibration or reference standards. Use of radioactive material (to include flood phantoms) by principal users in the Nuclear Medicine Service to check and calibrate cameras and other devices and to calibrate dose calibrators in accordance with Section 2, Appendix D, NRC Regulatory Guide 10.8, is also hereby authorized.

18. GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIALS. The rules in Appendix G, NRC Regulatory Guide 10.8, will be followed. Principal users will include these rules, appropriately modified as determined by the HPO to suit each situation, in their SOPs.

19. EMERGENCY PROCEDURES FOR SPILLS. The procedures in Appendix H, NRC Regulatory Guide 10.8, will be followed. Principal users will include these procedures in their SOPs. The SOPs will also contain the office telephone number of the HPO (221-4181/4231) and instructions to notify the AOD (221-2141) after duty hours o that the HPO or alternates may be contacted as necessary.

20. LEAK TESTING SEALED SOURCES. Leak tests are required for sealed sources containing more that 100 microcuries of beta-gamma emitting material, except tritium, or more than 10 microcuries of alpha-emitting material. Leak tests are not required if the radioactive material has a half-life shorter than 30 days or is a gas. Leak tests are not required for sources in storage by the HPO, but such sources will be leak tested immediately upon removal from storage as necessary. The HPO is responsible for performing leak tests. Criteria for leak testing follow:

a. Leak tests, when required, will be perforemd at 6-month intervals, except that sources of alpha-emitting radioisotopes will be tested at 3-month intervals.

b. If a source requiring leak testing is supplied with a certificate from the vendor indicating that a leak test has been made within six months (three months for alpha-emitting sources), the source need not be retested until six months (three months for alpha-emitting sources) after the date of the last test and may be issued for immediate use.

c. If no documentary evidence is available to substantiate that a given source has been leak tested within six months (three months for alpha-emitting sources), the source will not be issued until it has been leak tested and the results evaluated.

d. The minimum detectable activity for each leak test will be less than 0.001 microcurie.

e. Sealed sources will be considered contaminated if a leak test removes 0.005 microcurie or more of radioactive material, except for the teletherapy source and radium sources. The action level for the teletherapy source is 0.05 microcurie. For radium sources, leakage of radon gas in escess of 0.001 microcurie in 24 hours is considered excessive.

f. All sealed sources found to be excessively contaminated will be immediately withdrawn from use by the HPO, who will determine whether

or not the source is leaking. If it is leaking, it will be resealed or disposed. The HPO will also prepare any required reports.

g. The HPO will be notified prior to fabrication of a sealed source so that the required leak testing may be accomplished.

21. REPORTING OF DEFECTS AND NON-COMPLIANCE. All alleged defects and items of non-compliance involving radiation will be reported to the HPO. The HPO will begin an investigation within one duty day after the report and take immediate corrective action if warranted. The HPO will report the defect or item of alleged non-compliance, along with an evaluation and recommendation to the RCC, upon termination of the investigation. If the RCC finds that the defect or item of non-compliance exists or existed and constitutes a significant safety hazard, the Chariman of the RCC and the HPO will inform the Commander of the provisions of 10 CFR 21 or 21 CFR 1003 for reporting such defects and items of non-compliance. At the direction of the Commander, the HPO will make the appropriate notifications.

22. AREA SURVEY PROCEDURES (RADIOACTIVE MATERIAL).

a. Frequencies of surveys.

(1) All elution, preparation, and injection areas will be surveyed daily with an appropriate low-range survey meter and decontaminated, if necessary. The daily survey results need not be recorded, although it is recommended. These surveys are the responsibility of the user.

(2) Laboratory areas where only small quantities of radioactive material are used (such as in in-vitro testing) will be surveyed monthly by the HPO.

(3) Waste storage areas and all other laboratory areas will be surveyed weekly by the HPO.

(4) Unrestricted areas will be surveyed quarterly by the HPO to verify that radiation and radioactive material are adequately confined to restricted areas.

b. The weekly, monthly, and quarterly surveys will consist of:

(1) A measurement of radiation levels with a survey meter sufficiently sensitive to detect an exposure rate of 0.1 milliroentgen per hour.

(2) A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 disintegrations per minute per 100 square centimeters for the contaminant involved.

c. A record will be kept of all survey results, including negative results. It will be filed in accordance with AR 340-18-6. The record will include:

(1) Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

(2) Name of person conducting the survey.

(3) Drawing of area surveyed, identifying relevant features such as active storage areas. active waste areas, etc.

(4) Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

(5) Detected contamination levels, keyed to locations on drawing.

(6) Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

d. Radioactive contamination guides are given in Appendix G, AR 40-37. The sample checklist in Appendix B of NRC Regulatory Guide 8.23 will be used as guidance for surveyors.

e. In general, the user who causes contamination is responsible for decontamination. The HPO will provide supervision and assistance, as necessary. The principal user is responsible for providing resources for decontamination operations. If necessary, the HPO will coordinate with other activities to secure the needed resources. Guidance for decontamination operations is contained in many publications, including TM 3-220.

23. RADIOPHARMACEUTICALS. Chief, Nuclear Medicine Service, has primary responsibility for the preparation and dispensing of radiopharmaceuticals intended for use in humans. The Radiopharmacist is responsible to Chief, Nuclear Medicine Service, for the preparation, manufacture, and dispensing of radiopharmaceuritals. Radiopharmaceuticals will be prepared in accordance with accepted pharmacy proactice, an determined by the Radiopharmacist and approved by the RCC.

a. Only the Nuclear Medicine Service shall manufacture, prepare and dispense radiopharmaceuticals intended for administration to humans. Radiopharmaceuticals compounded at BAMC will not be used in or on humans until their pharmaceutical quality and assay have been established. They will not be dispensed except for use at BAMC by users approved by the RCC.

b. The Radiopharmacist, in collaboration with the Chief, Nuclear Medicine Service, will establish specific procefures for the compounding of each radiopharmaceutical. The procedures will be approved by the RCC.

24. HEALTH PHYSICS ASPECTS OF PATIENT CARE.

a. Patients containing more than 30 millicuries of iodine-131 or gold-198, as determined by the HPO, will not be discharged.

b. Generally, guidance contained in NCRP Reports Number 37 and Number 40 will be followed.

c. The HPO will be notified by the Nuclear Medicine Service or the Radiation Therapy Service at least 24 hours in advance of each intended

therapeutic administration of radioactive material (except teletherapy) which requires hospitalization. Transportation of the therapeutic radioactive material to the site of administration will be coordinated with the HPO.

d. Generally, radiation safety procedures for therapeutic use of radiopharmaceuticals will be as in Appendix K, NRC Regulatory Guide 10.8. However, note that, generally, patient excreta will be disposed of as indicated by 16a(3) above.

e. Generally, radiation safety procedures for therapeutic use of sealed sources (brachytherapy) will be as in Appendix L, NRC Regulatory Guide 10.8.

25. PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AS LOW AS REASONABLY ACHIEVABLE (ALARA).

a. Purpose. To describe the BAMC program for intaining occupational exposures to ionizing radiation as low as reasonably achievable (the ALARA Program).

b. Policy.

(1) Brooke Army Medical Center is committed to the program described in this paragraph for keeping exposures (individual and collective) as low as reasonably achievable. In accord with this commitment, the administrative organization for radiation safety is described below. The organization will include the RCC and HPO.

(2) An annual review of the radiation safety program, including the ALARA Program, will be performed. It shall include reviews of operating procedures and exposure records, records of inspections, and consultations with the radiation protection staff or outside consultants. It will generally be performed concurrently with the Health Services Command Annual General Inspection (AGI) and US Army Environmental Hygiene Agency (USAEHA) radiation protection survey.

(3) Modifications to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost is considered to be unjustified. Documentation will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended by qualified experts but not implemented, documentation will be prepared to describe the reasons for not implementing them.

(4) In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the total of all doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

c. Radiation Control Committee.

(1) Review of proposed users and uses.

(a) The RCC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he or she has applied to insure that the applicant will be able to take appropriate measures to maintain exposures ALARA.

(b) When considering a new use of byproduct material, the RCC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to insure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his or her proposed use.

(c) The RCC will insure that the user justifies his or her procedures and that doses will be ALARA (individual and collective).

(2) Delegation of authority.

(a) Authority is delegated to the HPO for enforcement of the ALARA concept.

(b) The RCC will support the HPO in those instances where it is necessary for the HPO to assert authority. When the HPO is overruled, the RCC will record the basis for its action in the minutes of its quarterly meeting.

(3) Review of ALARA programs.

(a) The RCC will encourage all users to review current procedures adn develop new procedures as appropriate to implement the ALARA concept.

(b) The RCC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigation Levels in the table in 25g below are exceeded. This will normally be done at the quarterly meeting using information provided by the HPO. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see 25g below).

(c) The RCC will evaluate BAMC's overall efforts for amintaining exposures ALARA on an annual basis. This review will include the efforts of the HPO, authorized users, and workers, as well as those of Command. The review may be accomplished by evaluation of the AGI and USAEHA radiation protection survey findings.

d. Health Physics Officer.

(1) Annual and quarterly review.

(a) Annual review of the radiation safety program. The HPO will perform an annual review of the radiation protection program for adherence to ALARA concepts. This may be done concurrently with the AGI and USAEHA radiation protection surveys. Reviews of specific procedures may be conducted on a more frequent basis.

(b) Quarterly review of occupational exposures. The HPO will review at least quarterly the external radiation exposure of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of 25g below.

(c) Quarterly review of records of radiation level surveys. The HPO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

(2) Education responsibilities for ALARA program.

(a) The HPO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(b) The HPO will insure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy.

(3) Cooperative efforts for development of ALARA procedures. Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(a) The HPO will be in close contact with all users and workers in order to develop ALARA procedures for working with ionizing radiation sources.

(b) The HPO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage use of these procedures.

(4) Reviewing instances of deviation from good ALARA practices. The HPO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the HPO will require changes in the program to maintain exposures ALARA.

e. Users.

(1) New procedures involving potential radiation exposures.

(a) The potential authorized user will consult with the HPO during planning for using radioactive materials or ionizing radiation sources for a new procedure.

(b) The authorized user will evaluate all procedures before using radioactive materials to insure that exposures will be kept ALARA. This may be enhanced through the applications of trial runs.

(2) Responsibility of authorized users to persons under his or her supervision.

(a) The authorized user will explain the ALARA concept and his or her commitment to maintain exposures ALARA to all persons under his or her supervision.

(b) The authorized user will insure that persons under his or her supervision who are subject to occupational radiation exposure are trained and educated in good health physics practives and in maintaining exposures ALARA.

f. Radiation Workers.

(1) The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

(2) The worker will know what recourses are available if he or she feels that ALARA is not being promoted on the job.

g. Establishment of Investigational Levels. Investigational Levels are established for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the HPO. The Investigational Levels adopted are listed in the following table. These levels apply to the exposures of individual workers.

TABLE. Investigational Levels.

	Investigational Levels (millirems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads.	125	375
2. Hands and forearms; feet and ankles.	1875	5625
3. Skin of whole body.	750	2250

(1) Quarterly exposure of individuals to less than Investigational Level I. Except when deemed appropriate by the HPO, no further action will be taken in those cases where an individual's exposure is less than the table values for Investigational Level I.

(2) Personnel exposure equal to or greater than Investigational Level I, but less than Investigational Level II. The HPO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the

first RCC meeting following the quarter when the exposure was recorded. No action related specifically to the exposure is required unless deemed appropriate by the RCC or the HPO. The RCC will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the RCC minutes.

(3) Exposure equal to or greater than Investigational Level II. The HPO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation and actions taken, if any, will be presented to the RCC at the first RCC meeting following completion of the investigation. The details of these reports will be recorded in the RCC minutes. Committee minutes will be sent to the BAMC Executive Committee for review, in accordance with BAMC Reg 15-1. The minutes will be made available to NRC inspectors for review at the time of the next NRC inspection.

(4) Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in the table.

(a) In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

(b) The RCC will review the justification for, and will approve all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in 25g(3) above will be followed.

The proponent of this memorandum is the Health Physics Officer, BAMC. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications) to Commander, BAMC, ATTN: AFZG-MDZ-HP, FSHTX 78234.

FOR THE COMMANDER:

ROBERT Y. TANAKA
MAJ, MSC
Adjutant General

DISTRIBUTION:
A plus
50 to 16

APPENDIX A
TRAINING AND EXPERIENCE FOR MEDICAL/HUMAN USES OF RADIOACTIVE MATERIALS

A-1. Basic radioisotope handling techniques. *a.* Individuals using radioactive materials will have at least 40 hours of training and a working knowledge.

(1) Principles and practices of radiation protection.

(2) Radioactivity measurements, standardization, monitoring and survey techniques, and instrumentation.

(3) Mathematics, calculations basic to the use and measurement of radioactivity, basic nuclear physics, and radiation protection.

(4) Biological effects of ionizing radiation.

(5) Federal directives, Army regulations and local standing operating procedures (SOP) concerning the health physics and safety aspects of the control and handling of radioactive materials.

b. The individual user should have experience in the use of radioactive material of the types and quantities for which the application is being made, or equivalent experience.

A-2. Clinical radioisotope training. *a.* Supervised examination of patients to determine the suitability for radioisotope diagnosis or treatment and recommendation on dosage to be prescribed.

b. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the absorbed dose, related measurements and plotting, and interpretation of data.

c. Management of patients who have been administered diagnostic or therapeutic quantities of radioactive material.

d. Discussion and study with preceptor case histories to establish the most appropriate diagnostic or therapeutic procedure, limitation, and contraindication.

NOTE: The Chief of Nuclear Medicine Service should have at least 700 hours of clinical radioisotope training in a residency program, formal training courses, and collaboration in a human use program using radioactive materials.

A-3. Individual qualification criteria for the diagnostic or therapeutic use of radioactive materials and sealed sources. *a.* To qualify as adequately trained for the diagnostic procedures in Groups I, II, and III a physician background will include—

(1) Forty hours of training in basic radioisotope handling techniques as specified in paragraph A-1.

(2) Five hundred hours of clinical radioisotope training in residency, formal training course, or collaboration in an institutional program using radioactive materials as specified in paragraph A-2.

b. In addition to the qualifications described in A-3a above, a physician desiring to perform therapeutic procedures using radioactive materials will have the specific training described below:

(1) For Group IV.

(a) Iodine-131 for treatment of hyperthyroidism/cardiac conditions. Clinical experience in the diagnosis of thyroid function and active participation in the treatment of 10 patients.

(b) Phosphorus-32 for treatment of polycythemia vera, leukemia and/or bone metastases. Clinical experience in the treatment of three patients with one of these conditions.

(c) Colloidal phosphorus-32 for intracavitary treatment. Clinical experience in the treatment of three patients.

(2) For Group V.

(a) Iodine-131 for the treatment of thyroid carcinoma. Clinical experience in the diagnosis of thyroid function and treatment of hyperthyroidism/cardiac dysfunction and active participation in the treatment of three patients with thyroid carcinoma.

(b) Colloidal gold-198 for intracavitary treatment. Clinical experience in the treatment of three patients.

(3) For Group VI.

(a) Brachytherapy sources for interstitial, intracavitary, or surface treatment of cancer. Active practice in therapeutic radiology with a

Encl 2

DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200

Standing Operating Procedure

26 March 1985

OPERATING AND SAFETY PROCEDURES FOR THE GAMMATOR M-38 IRRADIATOR

Table of Contents

1. General

a. The Gammator M-38 shall be used (operated) only by or under the direct supervision of individuals designated by the Brooke Army Medical Center Radiation Control Committee.

b. The authorized principal user is directly responsible for the control and safe use of this irradiator and will designate individuals to operate the M-38.

c. The M-38 shall be used exclusively for the irradiation of blood products and for medical research.

2. Definitions

Because the precise meaning given to one or more critical terms frequently determines the interpretation of a statement, the following definitions are given for key words and phrases as they are used in this document:

a. "Shall" - denotes the ensuing recommendation is necessary or essential to meet the currently accepted standards of radiation protection.

b. "Should" - (is recommended) - indicates advisory recommendations that are applied when practicable.

c. "Explosive" - refers to materials (either solids or liquids, mixtures or single compounds) which undergo rapid chemical reaction, producing heat, gas, and pressure.

This SOP supersedes SOP dated 1 May 81 all provisions of which are contained herein.

Encl 3

d. "Flammable" - refers to materials capable of being easily ignited; preferred to "inflammable", because of the possible ambiguity of the in prefix..

e. "Individual" and/or "Operator" - indicates a person designated by the authorized principal user to operate the Gammator M-38.

f. "Emergency" - denotes an unforeseen combination of circumstances (e.g., failure of an interlock or safety device, fire, ruptured or leaking source, etc.) that may pose a threat to personnel or property.

3. Responsibilities

a. The authorized principal user:

(1) Insuring that the M-38 is operated in accordance with the conditions of the Nuclear Regulatory Commission license issued to BAMC.

(2) Instructing individuals in safe operating procedures in accordance with the instructions outlined herein. He shall promulgate rules for working safety, including any restrictions of the operating technique.

(3) Insuring that these instructions and references contained in paragraph 6 are available at the M-38 unit at all times.

(4) Promptly reporting to the BAMC Health Physics Officer (221-4181), any source malfunction, incident or other unplanned occurrence that could result in an unsafe condition or exposure of personnel.

b. BAMC Health Physics:

(1) Conducting routine radiation protection surveys and inspections.

(2) Providing technical assistance as required.

c. Individual Operators:

(1) Being familiar with the content of this SOP and other regulations as may be prescribed by the authorized principal user.

(2) Operating the unit in accordance with the operation and safety procedures delineated in this SOP.

(3) Recording all pertinent information in the operating log maintained by the authorized principal user.

(4) Locking the M-38 unit and insuring that the key is properly secured to prevent unauthorized use.

(5) Reporting promptly to the authorized principal user all malfunctions, incidents and any other unplanned occurrences that could result in an unsafe condition or exposure of personnel.

4. Operating Procedures

a. Automatic Time Mode (up to 9999.9 minutes)

(1) Check to be sure that the Gammator line cord is plugged into a 110 VAC receptacle and that the sample is in a suitable container or holder.

(2) Position the sample to be irradiated on the turntable.

(3) Turn power on using the key switch. White, Power On Indicator and Green, Load Position Indicator should be on.

(4) Push turntable switch on if dose rate averaging is desired. The auto turntable pilot light should be on.

(5) Insure dose rate indicator is set at 100.

(6) Set the timer for the desired time interval.

(7) Swing the rotor handle to the left. The Green, Load Position light will go out. Upon reaching the position coinciding with the dose rate setting, micro switch trips energizing the magnetic break, turning on Red, Irradiate Position pilot light, and activating impulse transmitter to start timer.

(8) At the end of the time interval the break is de-energized. Irradiate position pilot light is automatically turned off and the rotor is returned to the load position by a controller mechanism. Upon reaching load position, the Green, Load Position pilot light will go on.

NOTE: If desired, the timer may be bypassed by pressing the time bypass switch prior to positioning the sample in the radiation field. The sample will remain in the irradiation position until the switch is pressed off returning the sample to the load position.

(9) After sample has been irradiated, sample is removed, the unit is locked in the off position, and the key is secured.

5. Safety/Emergency Procedures

a. The M-38 shall be operated as described in the operator's manual and in accordance with this Standing Operating Procedure (SOP).

b. Emergency procedures (see Annex A of this Standing Operating Procedure).

c. No individual shall undertake repair, perform any maintenance, or make any changes in or on the M-38 without prior approval of the authorized principal user and the Health Physics Officer, BAMC.

d. Under no circumstances shall explosive material be irradiated in the M-38.

e. Health Physics, BAMC, shall perform leak tests, periodic inspections, and radiation protection surveys as required by USNRC Byproduct Material License No. 42-01368-03.

f. An operating log shall be maintained by the authorized principal user.

g. Key Control: Operating keys shall be handled under direct supervision of the authorized principal user approved by BAMC Radiation Control Committee. The principal user is responsible for assuring proper key control and security.

6. References

a. Isomedix Inc., Instruction Manual and Owner Guide Model M Gammator.

b. Nuclear Regulatory Commission Byproduct Material License No. 42-01368-03.

APPENDIX B
RADIATION PROTECTION OFFICER

B-1. The RPO is an individual designated by the commander to provide consultation and advice on the degree of hazards associated with radiation and the effectiveness of the measures to control these hazards. In addition, he will supervise the radiation protection program (AR 40-14).

B-2. Organizationally, the RPO will be in a position wherein he can effectively advise the commander and the radiation workers on all matters pertaining to radiation protection.

B-3. Responsibilities of the RPO will include, but not be limited to:

a. Providing the commander, Radioisotope/Radiation Control Committee and radiation workers with advice and assistance on all matters pertaining to radiation protection. This includes instructing and training of workers (users) and visitors in the safe use of protective equipment and radiation producing devices (AR 40-5 and AR 40-14).

b. Providing guidance on types of protective clothing and equipment required and its proper use (AR 40-5).

c. Reviewing radiological operations to determine compliance with regulations and approved procedures.

d. Reviewing or preparing SOP for operations involving sources of ionizing radiation prior to approval by the Radioisotope/Radiation Control Committee (AR 40-5).

e. Reviewing and approving the procurement of all radioactive material and radiation producing devices.

f. Insuring that proper personnel monitoring devices are used and that necessary bioassays are performed and required records are maintained of the results (AR 40-5 and AR 40-14).

g. Insuring that radiation survey/detection instruments used in radiation protection are properly calibrated and are available to radiation workers (AR 40-5 and TB 43-180).

h. Insuring that all radiation shields, containers and handling equipment are maintained in satisfactory condition (AR 40-5).

i. Insuring the proper posting of any radiation warning signs (AR 385-30).

j. Maintaining a current inventory of radioactive materials and a registry of radiation producing devices.

k. Maintaining the required radiation protection records (AR 340-18-6).

l. Conducting a physical inventory of radioactive materials at least once every 3 months.

m. Performing radiation surveys and leak tests or insuring that such surveys and leak tests are performed. The accuracy of tests and surveys, if performed by others, remains the responsibility of the RPO (AR 40-5).

n. Evaluating the hazard potential and adequacy of protective measures for existing and proposed operations (AR 40-5).

o. Monitoring incidents wherein unusual levels of radiation or radioactive contamination are suspected (AR 40-5).

p. Insuring that all radioactive materials are properly used, stored, handled, shipped and disposed of in accordance with applicable directives (AR 40-5).

q. Formulating and implementing the radiation protection program.

r. Investigating radiation accidents/incidents and overexposures to determine the cause and taking steps to prevent recurrence (AR 40-5 and AR 40-14).

s. Terminating a project or procedure involving the use of radioactive material or radiation producing device which is found to be a threat to health or property.

B-4. The RPO will act as executive agent for all NRC licenses and DA radioactive material authorizations for the possession, use and storage of radioactive material.

B-5. The RPO should be a member of the following installation/activity committees if such committees have been established (the name of the committees may vary):

a. The Radioisotope/Radiation Control Committee (AR 40-14).

b. The reactor Safeguards Committee (AR 385-30).

c. The Safety and Health Committee (AR 385-10).

d. The Accelerator Facility Safety Committee.

e. The Human Use Committee, if radioactive material is used (AR 40-38).

f. The Clinical Investigation Committee, if radioactive material is used (AR 40-38).

g. The Radioactive Drug Research Committee.

DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES

26 March 1985

ANNEX A

EMERGENCY PROCEDURES FOR THE GAMMATOR M-38

1. In the event of an emergency, malfunction, or other unusual occurrence, the following individuals shall be notified as soon as possible after the M-38 has been turned off:

a. Fire Department (if appropriate) - Telephone #17

b. The Authorized Principal User

c. Health Physics Officer - Telephone #'s 221-4181/4231

d. Safety Officer - Telephone #'s 221-6084/3710

e. AOD, BAMC (after duty hours) - Telephone # 221-5711

The senior individuals at the site shall clear the area of personnel and restrict access to the area until relieved by competent authority.

2. The Health Physics Officer will determine the presence of a radiation hazard as soon as possible. There is little likelihood of radiation hazard unless the temperature of the source shield reaches the melting point of lead (621°F). Water should be sprayed on the source shield if there is a possibility of the temperature reaching this value.

3. Following an emergency the M-38 shall not be operated until an inspection and radiation protection survey has been conducted by BAMC Health Physics.