LIST OF NEWLY SUPERSEDED OR RESCINDED PUBLICATIONS DURING THE LAST TWO INDE` CYCLES

PUBLICATION NUMBER	DATE
ALLIED COMMUNICATION PUBLICATIONS (ACP)	
ACP 150(C) Authority SS/AC 150(D) JUL 87	AUG 78
ALCOHOL & DRUG ABUSE PUBLICATIONS (ALC)	
ALC PUB 15-12 Authority: RESC/PAM 25-30. SEP 87	83
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AR 37-100-87 VOL 1 Authority. SS/AR 37-100-88/89. VOL 1. JUL 87	OCT 86
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★ AR 40-37 Authority. RESC/PAM 25-30. DEC 87	JAN 77
★ AR 40-182 Authority: SS/PAM 40-16. SEP 87	AUG 83
★ AR 40-337 Authority. RESC/PAM 25-30. DEC 87	NOV 67
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AR 140-120 Authority. SS/AR 40-501. JUL 87 AR 40-501	APR 80

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AR 230-6 Authority: SS/AR 215-2 FEB 84
★ AR 600-31 Authority. SS/AR 600-8-2. OCT 87
AR 672-1 Authority SS/C11. JUN 87 TO AR 672-5-1
AR 672-6 Authority SS/C11. JUN 87 TO AR 672-5-1
★ AR 690-950-3 Authority: SS/AR 690-950. JUL 87
AR 700-42 Authority: SS/AR 750-1 MAR 83
★ AR 735-11 Authority: SS/AR 735-5. JAN 88
CHAMPUS FACT SHEETS (CH
★ CHAMPUS FS-6 Authority: RESC/PAM 25-30. DEC 87
CIRCULARS. DEPT OF ARMY
CIR 1-86-1 Authority: SS/CIR 1-87-1. AUG 87
CIR 11-85-2 Authority: EXP/AUG 87
CIR 30-85-2 Authority: EXP/JUN 87
CIR 40-85-1 Authority: EXP/SEP 87
CIR 55-86-3 Authority: SS/CIR 55-87-3. AUG 87

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ARMY REGULATION
NO. 40-37

HEADQUARTERS
DEPARTMENT OF THE ARMY
WASHINGTON, DC, 7 January 1977

MEDICAL SERVICES

LICENSING AND CONTROL OF RADIOACTIVE MATERIALS FOR MEDICAL PURPOSES

Effective 1 February 1977

This is a complete revision of AR 40-37 and reflects the current requirements of the Nuclear Regulatory Commission as published in Title 10, Code of Federal Regulations, for the use and control of radioactive materials for medical purposes worldwide. Supplementation of this regulation is prohibited, except upon approval of The Surgeon General [HQDA (DASG-HCH) WASH DC 20310]. This regulation does not apply to the USAR and NBG.

1. Purpose. The purpose of this regulation is to—

a. Prescribe policies and procedures for the use and control of radioactive materials for medical purposes.

b. Prescribe procedures for obtaining Nuclear Regulatory Commission (NCR) licenses and amendments.

c. Prescribe procedures for obtaining Department of the Army (DA) radioactive material authorizations and amendments for radioactive materials not controlled or licensed by the NRC.

d. Establish procedures for the reporting of radioactive materials used in medical programs.

2. Scope. This regulation—

a. Applies to all Army medical facilities producing, procuring, storing, possessing, shipping, transferring, using, and disposing of radioactive materials for medical purposes worldwide.

b. Does not negate or supersede any NRC or Food and Drug Administration (FDA) requirements pertaining to the control, safeguard, and use of radioactive materials for medical purposes.

*This regulation supersedes AR 40-37, 12 August 1963.

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3. Explanation of terms. Except as indicated herein, terms used in this regulation are defined in AR 310-25.

a. Accelerator produced radioactive materials. Material made radioactive incident to accelerator operation.

b. Bioassay. The determination of kinds, amounts or concentrations, and locations of radioactive materials in the human body, whether by in vivo counting (whole-body counting, selected organ counting, etc.) or by analysis and evaluation of materials excreted or removed from the human body (AR 40-14).

c. Brachytherapy. A method of radiation therapy in which an encapsulated source or group of such sources is utilized to deliver gamma or beta radiation at a distance up to several centimeters, either by surface, intracavitary or interstitial application for medical purposes.

d. Byproduct materials. Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

e. DA authorization. Authority issued to a commander of a medical facility by the Department of the Army Surgeon General (DASG) for the medical or human use of radioactive materials not subject to licensing or control by the NRC and those materials under general license pursuant to Title 10, Code of Federal Regulations (CFR), Parts 30, 31, 35, 40 and 70.

f. Depleted uranium. Source material uranium in which the radioisotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

g. Human use. The internal or external administration of radioactive materials, or the radiation therefrom, to human beings.

h. Licensed radioactive material. Byproduct, source or special nuclear material received, stored, possessed, used or transferred under a license issued by the NRC or by an agreement state.

i. Medical use. The nonhuman use of radioactive materials, or radiation therefrom, for medical research and development studies and in vitro applications not directly involving the internal or external administration of radioactive materials, or the radiation therefrom, to human beings.

j. Naturally occurring radioactive materials. Radionuclides, such as radium and radon, which are found in nature are not classified as source material.

k. Radioactive drug (radiopharmaceutical). Any substance defined as a drug in section 201 (g) (1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

l. Radioactive materials. Naturally occurring radionuclides, accelerator produced, byproduct, source, and special nuclear materials capable of emitting corpuscular or electromagnetic radiations.

m. Radiation protection officer (RPO). 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 is tasked with the supervision of the radiation protection program (AR 40-14).

n. Sealed sources. Radioactive material that is permanently enclosed in a capsule or container designed to prevent leakage or escape of the radioactive material or any of its daughter products.

o. Source materials. Uranium or thorium or any combination thereof, in any physical or chemical form; or ores that contain by weight, one-twentieth of one percent (0.05 percent) or more of uranium, thorium or any combination thereof. Source material does not include special nuclear material.

p. Special nuclear material. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235 and any other material that the NRC determines to be special nuclear material, or other material enriched artificially by any of the foregoing, but does not include source materials.

q. Specific license. An NRC license issued to the Army medical facility to possess or use byproduct, source, or special nuclear material. (Within the Army, specific licenses are not issued to an individual.)

r. Teletherapy. A method of radiation therapy in which an encapsulated source is utilized to deliver gamma radiation at a distance greater than 10 centimeters from the human body.

4. Responsibilities. *a.* The Surgeon General's (TSG) responsibilities are delineated in AR 10-5. Additionally, TSG will—

(1) Act as executive agent for all NRC license and DA radioactive material authorization applications for the medical/human use of radioactive materials. Coordinate all NRC license applications for medical purposes with the NRC.

(2) Review and approve the use of investigational radiopharmaceuticals in accordance with AR 40-7.

(3) Review and approve the use of radioactive materials in clinical investigations in accordance with AR 40-38.

(4) Review proposals for the use of human volunteers when the studies come within the purview of this regulation and AR 70-25.

(5) Plan for a long-range scientifically oriented and integrated program which incorporates realistic requirements for personnel, training, equipment, and construction of facilities for nuclear medicine services and radiation therapy.

(6) Designate a Radioisotope Committee to assess the human and medical use programs by evaluating the documentation submitted by Army medical facilities in accordance with the requirements of this regulation and other directives.

b. The US Army Health Services Command (HSC) responsibilities are delineated in AR 10-43. Additionally, the Commanding General, HSC will—

(1) Review for technical adequacy all NRC license and DA radioactive material authorization applications for medical/human use of radioactive materials at Army medical facilities under the jurisdiction of HSC.

(2) Perform, at least annually, an evaluation and survey of the health physics aspects of nuclear medicine and radiation therapy activities at Army medical facilities.

(3) Insure that all Army medical facilities under the jurisdiction of HSC comply with the requirements of this regulation and applicable Federal directives.

c. Other major Army commanders having primary responsibility for research and development projects or technical operations are responsible for insuring that commanders of all installations and activities under their jurisdiction—

(1) Possess proper authorization, including a valid NRC license or DA radioactive material authorization when applicable, prior to procuring or using radioactive materials or sources of ionizing radiation for the purpose of exposing human beings (volunteers or otherwise) to ionizing radiation.

(2) Possess proper authorization to use investigational radiopharmaceuticals (AR 40-7).

(3) Have acquired written approval from the Secretary of the Army (AR 70-25), prior to the submission of an NRC license or DA radioactive material authorization application for human use, when human volunteers are to be used as experimental research subjects.

(4) Possess adequate resources and procedures for the safe and healthful handling and control of radioactive materials.

d. Major oversea Army commanders will comply with the requirements of this regulation and the requirements of the host country as applicable.

e. The commander of each Army medical facility is responsible for all aspects of the radiation program withing his command. This responsibility includes, but is not limited to, the following:

(1) Insure that the medical facility has been designated by TSG or HSC, as appropriate, to provide nuclear medicine service and/or radiation therapy.

(2) Insure that the medical facility possesses a valid NRC license/DA radioactive material authorization for the medical/human use of radioactive materials and that the facility provides adequate support for the medical/human use to include: accommodations for the clinical care of patients; availability of suitably trained and experienced personnel; availability of essential equipment, such as handling devices, shields, measuring and monitoring instruments; and an approved current written radiation protection program for the protection of personnel and the health and safety aspects of the medical/human use of radioactive materials and radiation sources.

(3) Designate a Radiation Protection Officer (RPO) and an alternate by letter/disposition form. The RPO will be an individual other than the Chief of Radiation Therapy or Nuclear Medicine Service.

(4) Designate a Radioisotope/Radiation Control Committee.

(5) Insure that the individual users of radioactive materials within the medical facility and each radionuclide used, will be approved and controlled by the Radioisotope/Radiation Control Committee in accordance with the requirements specified in the conditions of the NRC license/DASG radioactive

material authorization and appropriate Federal directives.

(6) Review the medical/human use program and submit reports and data in accordance with this regulation and appropirate Federal directives.

(7) Insure that each human user's personnel record reflects the current qualifications and training of the individual human user, and that this information remains in the permanent portion of that file (AR 640-10).

(8) Insure that all individuals working in or frequenting a radiation controlled area are informed of the presence of radioactive materials or equipment capable of producing ionizing radiation. These individuals will be instructed in the safety precautions and procedures necessary to minimize their exposure. In addition, they will be instructed in the biological risks to embryos and fetuses from exposure to ionizing radiation (see NRC Regulatory Guide 8.13). The extent of the instruction will be commensurate with the potential radiological health protection problem in the radiation controlled area (10 CFR 19 12 and 29 CFR 1910.96).

(9) Insure compliance with the Army Safety Program (AR 385-10) and appropriate Federal and Army directives as they pertain to health and safety.

(10) Insure that no individual who is under psychiatric care, exhibits other behavioral characteristics or is on a prescribed medication, that in the opinion of a physician might impair judgment, is allowed to work with radioactive materials or radiation producing devices.

f. The Radiosotope/Radiation Control Committee will consist of the Chief of Professional Services who will act as Chairman, the Chief of Medicine, Chief of Pathology, Chief of Radiology, Chief of Nuclear Medicine Service, Chief of Radiation Therapy, and the RPO as members. A nonvoting member from the Logistics Division/Branch is mandatory. The committee should also include the senior radiopharmacist and clinical radiological physicist, when such an individual is assigned, who does not also act as RPO. A member from the nursing service, the medical facility safety officer, and other personnel who are knowledgeable in the clinical and safe use of radioactive materials may be included at the discretion of the commander. At medical facilities with limited qualified personnel, the composition of the committee will conform to the above requirement to the extent that personnel permit. Under this circumstance, an individual on the committee may serve in a dual capacity. The Radioisotope/Radiation Control Committee will—

(1) Review and grant permission for, or disapproval of, the use of radioactive material from the standpoint of radiological health and safety of the patients, working personnel, or other factors established for the medical use of these materials.

(2) Approve individual users for each type of procedure with each individual radionuclide and insure that any physician authorized to use radioactive material in humans will, at the minimum, meet the criteria specified in appendix A. Approvals will be consistent with the limits and conditions of NRC license(s) and DA radioactive material authorization(s).

(3) Approve individual pharmacists and individual compounding protocols for compounding radioactive drugs (radiopharmaceuticals) or radiopharmaceutical compounding kits for radioactive drugs to be administered to a patient.

(4) Prescribe special conditions which will include, but are not limited to: medical examination of users, requirements for bioassays, designations of controlled areas, locations where radioactive materials are used and stored, radioactive waste disposal methods, protective measures for personnel in the care of patients, quantity of radioactive material to be permitted in the work area and special procedures or work rules for uses of radioactive material.

(5) Formulate and review the training program and procedure for the safe use of radioactive materials.

(6) Receive and review records and reports from the RPO.

(7) Recommend corrective actions when indicated.

(8) Maintain records of the training and certification of approved users.

(9) Maintain data for the reports required by this regulation.

(10) Insure that the uses of radioactive materials are in consonance with sound clinical and experimental procedures.

(11) Review the reports of unusual occurrences as they pertain to the use of radioactive materials or ionizing radiation producing devices.

(12) Review the investigation of all alleged overexposures to radioactive material or ionizing

radiation.

(13) Review applications for NRC licenses and DA radioactive material authorizations.

(14) Meet at least quarterly and at the call of the Chairman to review the medical/human use of radioactive materials, the effectiveness of the radiation protection program and to consider special cases or problems.

(15) Maintain written records of actions taken by the committee.

g. The RPO's duties and responsibilities are outlined in appendix B. The RPO will exercise staff supervision over the overall radiation protection program for the MEDCEN/MEDDAC.

h. The certified (approved) user(s) of radioactive materials in or on humans for diagnostic, therapeutic or investigationl purposes will be a physician approved by the Radioisotope/Radiation Control Committee. No certified (approved) physician may delegate to another physician who is not under the direct supervision of the certified (approved) user the following:

(1) The approval of procedures involving the administration of radiopharmaceuticals to patients or the application of ionizing radiation to patients from a teletherapy machine, brachytherapy sources, or an eye applicator.

(2) The prescription of the radiopharmaceutical or source of ionizing radiation and the dose or exposure to be administered.

(3) The determination of the route of administration.

(4) The interpretation of the results from diagnostic procedures in which radiopharmaceuticals are administered.

i. The certified (approved) user(s) may authorize nuclear medicine technicians to perform the following:

(1) Preparation and quality control testing of radiopharmaceuticals and sources of ionizing radiation.

(2) Measurement of radiopharmaceutical doses prior to patient administration.

(3) Use of appropriate instrumentation for the collection of data to be used by the physician.

(4) A technician will not administer by injection a therapeutic dose of radioactive material to a patient.

(5) The administration of radiopharmaceuticals and radiation from radioactive materials to patients within limits established within this regulation or otherwise permitted under applicable Federal directives.

NOTE: Whenever a technician or other paramedical personnel administers a radiopharmaceutical to a patient by injection, a physician, not necessarily a physician certified (approved) by the Radioisotope/Radiation Control Committee, shall be immediately accessible.

5. Reporting requirements. The following report will be prepared: Radioisotopes in Human Use Activities, RCS MED-197. Commanders of each Army medical facility having authorization to use radioactive materials in humans will prepare the report covering the period of each calendar quarter. The report will be in narrative form and will be submitted through command channels to TSG [HQDA (DASG-HCH), WASH DC 20310] within 30 days following the close of the report period and will contain at least the following information:

a. Copy of the minutes of each Radioisotope/Radiation Control Committee meeting, including a record of all actions taken by the committee. Special care will be taken to include formalized actions that certify (approve) each individual human user for each new use of radioactive materials.

b. Copy of the training and experience record of each individual who is an approved human user of radioactive materials (Form NRC-313a, page 3) or who is appointed as RPO and alternate RPO. After initial record is submitted, subsequent reports will include any changes in qualifications or in certification during the report period.

c. Notification of all changes in membership of Radioisotope/Radiation Control Committee, RPO and alternate RPO. Each new member of the Radioisotope/Radiation Control Committee will be documented as to medical specialty, specific training, and clinical experience with radioactive materials, as applicable.

d. Number of diagnostic procedures categorized as: function studies, imaging (scan) studies, in vitro studies; and number of therapeutic procedures, to include the radiopharmaceutical(s)/ionizing radiation source(s) used.

e. Information on unsolved problems, unusual occurrences, accidents, new or improved developments or comments on the support rendered by higher headquarters.

6. Applications for NRC licenses. *a.* Application for byproduct material licenses for medical or human use will be submitted on Form NRC-313

and Form NRC-313a through command channels to TSG [HQDA (DASG-HCH) WASH DC 20310]. These forms will be prepared in accordance with appendix C. Applications for source and special nuclear material will be in accordance with 10 CFR, Parts 40 and 70, respectively. Sufficient copies of the application will be submitted (signed and dated) so that five copies are received by TSG [HQDA (DASG-HCH) WASH DC 20310].

b. Renewals or amendments of an NRC license will be requested in the same manner as the original application. Requests for renewal and amendments will be submitted on Form NRC-313 for byproduct material and Form NRC-2 for source material through command channels to TSG [HQDA (DASG-HCH) WASH DC 20310]. Requests for renewals will be submitted so as to arrive at TSG [HQDA (DASG-HCH) WASH DC 20310] not later than 60 days prior to the expiration date.

c. Direct communication with the NRC is not authorized, except to comply with the requirements of 10 CFR, Parts 2, 19, 20, 30, 35, 40, and 70, and respond to inquiries initiated by the NRC. Information copies of all such communication will be forwarded through command channels to TSG [HQDA (DASG-HCH) WASH DC 20310].

7. DA radioactive materials authorization. *a.* DA radioactive materials authorization is required for Army medical facilities to produce, procure, receive, own, possess, use, store or transfer accelerator produced materials, and radium or radon sources for medical purposes, as well as all NRC generally licensed radioactive materials.

b. DA radioactive materials authorization is required for the medical/human use of radioactive materials when such materials are used or stored at Army medical installations and activities located in oversea commands.

8. Applications for DA radioactive materials authorization. *a.* Applications for DA radioactive materials authorization for medical purposes will be submitted on DA Form 3337 through command channels to TSG [HQDA (DASG-HCH) WASH DC 20310]. DA Form 3337 will be prepared in accordance with appendic C and is available through normal publications supply channels. Sufficient copies of the application will be submitted (signed and dated) so that three copies are received by TSG [HQDA (DASG-HCH) WASH DC 20310]. The application will contain essentially the same supporting documentation as required for an NRC license application.

b. Renewals or amendments of an authorization will be requested in the same manner as the original application. Requests for renewal will be submitted on DA Form 3337 through command channels so as to arrive at TSG [HQDA (DASG-HCH) WASH DC 20310] not later than 60 days prior to the expiration date.

9. Use of radioactive material for in vitro testing. *a.* Commanders possessing an NRC license which authorizes in vitro testing will use the radioactive material only in the locations described in the application for the NRC license. If it is desired to perform in vitro testing in other locations, an application to amend the current NRC license will be submitted.

b. Commanders desiring to use only limited quantities of byproduct materials for in vitro testing will prepare Form NRC-483 in accordance with appendix C. Sufficient copies of the application will be submitted (signed and dated) through command channels so that four copies are received by TSG [HQDA (DASG-HCH) WASH DC 20310]. (See CFR 31.11 concerning information relating to this type of general license.)

c. Individual qualifications and training requirements for in vitro testing are specified in paragraph A-1, appendix A.

10. Control of needles and syringes. Needles and syringes will be secured in both used and unused conditions. Used needles and syringes will be either held for decay of the radioactive material and then disposed of in an acceptable manner (TB MED 291) or disposed of as radioactive waste.

11. Night vision adaptometers. Night vision adaptometers will be procured, handled, leak tested, and controlled as specified in AR 40-61 and SB 8-74.

12. Consent by nonmilitary patients to medical care. *a.* A nonmilitary individual may not be furnished medical care in any Army medical treatment facility without either his or her consent or the consent on his or her behalf in accordance with applicable local laws or the order of a court having jurisdiction over both the individual and the medical facility concerned. An express consent involves an interchange of language by which the patient or person authorized to act on his or her behalf specifically states that his or her consent is given to the proposed medical care.

b. A written consent will be recorded on SF 522,

Clinical Record - Authorization for Administration of Anesthesia and for Performance of Operations and Other Procedures, when nonmilitary patients (both inpatients and outpatients) are involved in all therapeutic procedures where radioactive material or radiation therefrom is used in their treatment or therapy (AR 40-3).

13. Calibration of eye applicators. Eye applicators used in the treatment of humans, which contain radioactive material, will be recalibrated at least once every 3 years.

14. Report of unusual occurrence. This report will be prepared when a patient is involved in an unusual occurrence as it pertains to the use of radioactive material or radiation sources in accordance with current Army directives. These reports will be reviewed by the Radiosotope/Radiation Control Committee

15. Accidents and injuries. Accidents and injuries will be reported as soon as possible in accordance with AR 385-40.

16. References. *a.* AR 10-5, Department of the Army.

b. AR 10-43, US Army Health Services Command.

c. AR 40-2, Army Medical Treatment Facilities General Administration.

d. AR 40-3, Medical, Dental, and Veterinary Care.

e. AR 40-5, Health and Environment.

f. AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances.

g. AR 40-14, Control and Recording Procedures for Occupational Exposure to Ionizing Radiation.

h. AR 40-38, Clinical Investigation Program.

i. AR 40-61, Medical Logistics Policies and Procedures.

j. AR 40-400, Patient Administration.

k. AR 55-55, Transportation of Radioactive and Fissile Materials Other than Weapons.

l. AR 70-25, Use of Volunteers as Subjects of Research.

m. AR 200-1, Environmental Protection and Enhancement.

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

o. AR 340-18-9, Maintenance and Disposition of Medical Functional Files.

p. AR 385-10, Army Safety Program.

q. AR 385-30, Safety Color Code Markings and Signs.

r. AR 385-40, Accident Reporting and Records.

s. AR 640-10, Individual Military Personnel Records.

t. AR 755-15, Disposal of Unwanted Radioactive Material.

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

v. TM 5-838-2, Medical Facility Design—Army.

w. TM 38-740, The Army Maintenance Management System (TAMMS).

x. TM 55-315, Transportability Guidance for Safe Transport of Radioactive Materials.

y. TM 743-200, Storage and Materials Handling.

z. TB MED 291, Guidance for Inventory, Control and Accountability of Drugs and Injection Devices of Potential Abuse at Medical Treatment Facilities Worldwide.

aa. TB 38-750-2, Implementing Instructions for the Army Integrated Equipment Record Maintenance Management System (TAERS) for Army Medical Service Units and Activities.

ab. TB 43-180, Calibration Requirements for the Maintenance of Army Materiel.

ac. TB 700-1, Construction and Materiel Schedule for Military Medical and Dental Facilities.

ad. SB 8-74, Adaptometer, Radioactive Plaque, Night Vision, NSN 6515-00-382-1000, NRC, License No. 37-11831-01.

ae. Title 10, CFR, Chapter I, Atomic Energy Commission [Volume 40 Federal Register (FR), 8774, 3 March 1975, abolished the Atomic Energy Commission and created the Nuclear Regulatory Commission].

af. Title 21, CFR, chapter I, Food and Drug Administration, Department of Health, Education and Welfare.

ag. Title 29, CFR, chapter XVII, Occupational Safety and Health Administration, Department of Labor.

ah. Title 42, CFR, chapter I, Public Health Service, Department of Health, Education and Welfare.

ai. Title 49, CFR, Section 173.397, Contamination Control.

aj. Volume 40 FR, 31308, 25 July 1975 and Volume 40 FR 44543, 29 September 1975.

*ak. NRC Licensing Guide for Broad Medical Licenses.

*al. NRC Licensing Guide for Preparation of Applications for Medical Programs.

*am. NRC Licensing Guide for Teletherapy Programs.

*an. NRC Regulatory Guide 7.3, Procedures for Picking Up and Receiving Packages of Radioactive Material.

*ao. NRC Regulatory Guide 7.4, Leakage Tests on Packages for Shipment of Radioactive Materials.

*ap. NRC Regulatory Guide 8.13, Instruction Concerning Prenatal Radiation Exposure.

*aq. National Council on Radiation Protection and Measurement (NCRP) Reports No. 10, 30, 37, 40 and 41.

ar. American National Standards Institute (ANSI) Standards N.5.2 - 1963 and N 44.2 - 1973.

as. DA Form 2791-R, Radioactive Materials Movement—Shipment/Receipt (LRA).

at. DA Form 3337, Application for DA Radioactive Material Authorization or Permit.

au. DA Form 3862, Controlled Substances Stock Record.

av. DA Form 4574-R, Radiopharmaceutical Stock Record.

aw. Form NRC-2, Application for Source Material License.

ax. Form NRC-313, Application for Byproduct Material License.

ay. Form NRC-313a, Application for Byproduct Material License - Medical Supplement A - Human Use.

az. Form NRC-483, Registration Certificate - In Vitro Testing with Byproduct Material Under General License.

*NRC publications referenced in this regulation which are not available to users may be obtained on request from HQDA (DASG-HCH) WASH DC 20314.

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

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–3*a* 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 treat

minimum of 3 years experience.

(b) Beta particle applications for the treatment of superficial eye disease. Active practice in therapeutic radiology or ophthalmology and experience in the therapeutic use of beta particles (rays) or soft x-rays. Active participation in the treatment of at least three patients with superficial eye diseases.

c. Treatment of patients with teletherapy machines.

(1) Each individual user of a teletherapy machine for the treatment of humans will be a physician.

(2) The physician will have at least 3 years experience in therapeutic radiology or therapeutic roentgenology, including deep therapy techniques conducted at a medical institution approved or accredited by the American Board of Radiology.

NOTE: If the user is certified by the American Board of Radiology in Radiology, Therapeutic Radiology, or Therapeutic Roentgenology, then the following statement will be entered on the license application, "Byproduct material will be used by, or under the supervision of, a physician who is certified by the American Board of Radiology in Radiology, Therapeutic Radiology, or Therapeutic Roentgenology, and designated by the Radioisotope/Radiation Control Committee." If the physician is not certified as indicated above, the physician's training and experience, including training and experience in deep therapy techniques, will be included with the NRC license application.

A-4. Nuclear Medicine Technician Training.

a. The certified (approved) human user of radioactive material will insure that each technician has received training in the following subjects prior to performing duties as described in paragraph A-4.

(1) General characteristics of radiation and radioactive materials.

(2) Physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used in the nuclear medicine service.

(3) Mathematics and calculations basic to the use of the radiopharmaceutical prescribed and measurements of activity and the units of exposure, dose, and dose equivalent.

(4) Principles and practices of radioisotope handling and radiation protection.

(5) Use of radiation instrumentation for measurement and monitoring, including operating procedures, calibration of instruments, limitations of instruments, operational performance of instrumentation, and quality control procedures.

(6) Biological effects of ionizing radiation.

(7) Maintenance of logs and records as required for the receipt, use, and disposal of radioactive material and radioactive waste.

(8) Federal directives, Army regulations and local SOP concerning radiation protection and emergency procedures.

NOTE: An individual who has completed the nuclear medicine training course HM-8416 or equivalent, as determined by the Chief of Nuclear Medicine, will be deemed to satisfy the above training requirements.

b. The Chief of Nuclear Medicine Service will insure that technicians receive appropriate training to maintain proficiency in the field of nuclear medicine technology, additional training when new duties are added, and will maintain records of such training. He will document participation in in-service education, on-the-job training, outside workshops, institutes, etc.

NOTE: The Chief of Nuclear Medicine Service will insure that no individual who is under psychiatric care, exhibits other behavioral characteristics or is on a prescribed medication, that in the opinion of a physician might impair judgment, is allowed to work with radioactive material or administer radioactive material to a patient.

A-5. Radiation therapy technician training.

a. The certified (approved) human user of a teletherapy machine will insure that each therapy technician has completed the Radiographic Procedures (Basic) Course (313-91P20), which is an approved program in Radiologic Technology by the Council on Medical Education of the American Medical Association, or equivalent training, as determined by the Chief of Radiology, and has knowledge of the following prior to performing independent therapy procedures.

(1) General characteristics of radiation and the principles of radiation protection.

(2) Mathematics and calculations basic to the treatment of patients.

(3) Use of radiation instrumentation for measurement and monitoring of radiation.

(4) Biological effects of ionizing radiation.

(5) Units of activity, exposure, dose, and dose equivalent.

(6) Techniques to be used and precautions to be

observed in the storage, preparation, use, and maintenance of brachytherapy sources.

(7) Maintenance of utilization logs for radiation therapy machines and brachytherapy sources.

(8) Federal directives, Army regulations and local SOP concerning radiation protection and emergency procedures.

NOTE: The supervisory therapy technician will be an individual who is a graduate of a program in Radiation Therapy Technology approved by the Council on Medical Education of the American Medical Association, and has knowledge as described in paragraph A–5a, this appendix, or has the equivalent of such education and training, as determined by the Chief of Radiation Therapy. This individual will be present during the treatment of a patient by a student technician.

b. The Chief of Radiation Therapy will insure that technicians receive appropriate training to maintain proficiency in the field of radiation therapy, additional training when new duties are added, and will maintain records of such training. He/she will document participation in inservice education, on-the-job training, outside workshops, institutes, etc.

NOTE: The Chief of Radiation Therapy will insure no individual who is under psychiatric care, exhibits other behavioral characteristics or is on a prescribed medication, that in the opinion of a physician might impair judgment, is allowed to work with radioactive material or treat a patient with a teletherapy machine.

A–6. Radiopharmacist training. *a.* A radiopharmacist/nuclear pharmacist will be registered and competent in the preparation, handling, storage, dispensing, disposition and pharmacology of radioactive drugs.

b. The Radioisotope/Radiation Control Committee will insure that each radiopharmacist has received adequate training and experience prior to performing duties assigned and procedures described in this regulation.

c. Training in the practice of radiopharmacy will include experience and education in clinical radiopharmacy and a working knowledge of the following:

(1) Nuclear and radiation physics and instrumentation.

(2) Health physics and radiation protection.

(3) Radiation biology and biophysics.

(4) Mathematics and calculations of activity and radiation dose.

(5) Nuclear medicine procedures, radiation instrumentation for measurement, calibration and limitation of instruments, and quality control procedures.

(6) Physical, chemical and pharmaceutical characteristics of radiopharmaceuticals.

(7) Compounding radiopharmaceuticals and radiopharmaceutical kits.

(8) Nuclear pharmacy jurisprudence.

(9) Maintenance of logs and records as required for the receipt, preparation, dispensing and disposal of radiopharmaceuticals.

(10 Federal directives, Army regulations and local SOP concerning radiation protection and emergency procedures.

d. The Chief of Pharmacy or the Chief of Nuclear Medicine Service will insure that radiopharmacists receive appropriate training to maintain proficiency in the field of radiopharmacy, additional training when new duties are added, and will maintain records of such training. He/she will document participation in inservice education, on-the-job-training and outside workshops, institutes, etc.

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 385-80).

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.

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APPENDIX C
INSTRUCTIONS FOR COMPLETING NRC AND DA FORMS
(Item Numbers Keyed to Format Block Numbers of Forms NRC–313, 313a, 483 and DA Form 3337)

C–1. Form NRC-313 (Application for Byproduct Material License) and DA Form 3337 (Application for DA Radioactive Material Authorization or Permit).

a. Item 1(a)—Name and Street Address of Applicant. Enter name and address of the Army medical facility. The use of APO numbers on NRC forms for OCONUS Army medical facilities is not permitted.

b. Item 1(b)—Street Address(es) at which Byproduct Material or Radioactive Material Will be Used. Self-explanatory. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use.

c. Item 2—Department(s) to Use Byproduct Material or Radioactive Sources. List all departments and services where byproduct material may be used.

d. Item 3—Previous License Number(s) or DA Authorization/Permit Number(s). Self-explanatory.

e. Item 4—Individual User(s). Enter statement, "Use will be by or under the supervision of a physician for human use or individual for medical use approved by the Radioisotope/Radiation Control Committee." Acceptable training and experience is specified in appendix A for routine medical/human use and Appendix A and D for nonroutine human use.

f. Item 5—Radiation Protection Officer. Enter statement "The Radiation Protection Officer (RPO) and an alternate will be designated by the Commander." The RPO and alternate will be technically qualified by virtue of education, training and professional experience in the assay of radioisotopes and in radiological health and safety to insure a capability commensurate with the assignment and his duties are specified in appendix B. The RPO will be an individual other than the Chief of Nuclear Medicine Service or Radiation Therapy.

g. Item 6(a) (b)—Radioactive Material. Enter the group(s) of desired radiopharmaceuticals from 10 CFR 35.100. If radioactive material or procedures are not listed in the above reference then complete documentation must be submitted to support the rationale (see app D). The dosage range should not exceed that listed in Appendix E and will not exceed the dosage range recommended by the manufacturer.

NOTE: For nonhuman use state the chemical and physical form and possession limit for each radionuclide. If the material is in the form of a sealed source, state the name of the manufacturer, model number, and maximum activity of the source(s).

h. Item 7—Describe Purpose for Which Byproduct Materials or Sources will be used. Enter statement, "See Supplement A (Form NRC-313a)," if the radioactive material is for human use. Otherwise, the purpose for which the material is to be used.

i. Item 8—Type of Training and Item 9—Experience with Radiation. Initially the training and experience of the members of the Radioisotope/Radiation Control Committee, the RPO, and the alternate will be submitted. Subsequent changes in personnel who are members of the committee will not require an amendment to the license, but will be reported through command channels to TSG [HQDA (DASG-HCH) WASH DC 20310] as an inclosure to RCS MED-197.

j. Item 10—Radiation Detection Instruments. List all radiation monitoring or measuring instruments that are available. The list will include instruments used for measuring uptake and imaging of the radioactive material, assaying biological specimens, and making radiation protection surveys. List manufacturer's name and model number of each instrument, the number of each instrument available, type of radiation detected (beta, gamma, etc.), the window thickness (mg/cm^2), sensitivity (mR/hr, R/hr or cpm), and the use (measuring, monitoring or surveying).

k. Item 11—Methods, Frequency, and Standards Used in Calibrating Instruments Listed in Item 10. All radiation survey instruments used directly in

the radiation protection program for health and safety monitoring of radioactive materials will be calibrated every 3 months and after each instrument servicing or repair (AR 40-5 and TB 43-180). All pocket chambers and dosimeters used in the radiation protection program for health and safety monitoring of personnel will be calibrated every 6 months (AR 40-5 and TB 43-180). Calibration check on instruments used for uptake, scans, or imaging procedures will be accomplished each day the equipment is used (42 CFR 74.27).

NOTE: The daily performance checks for gamma cameras should include an evaluation of intrinsic, collimator and spatial-volume resolution and uniformity-field linearity. The daily performance checks for rectilinear scanners should include an evaluation of collimator and spatial-volume resolution.

Instruments used in radiation therapy to measure the exposure, dose, or dose rate to patients during therapeutic procedures, will be calibrated at least annually, and after each instrument servicing or repair. The uncertainty of measurement shall be within 2 percent for each energy used. Records of such calibration will be retained in accordance with AR 340-18-6 and AR 340-18-9, as applicable.

NOTE: Radiation sources used in the calibration of radiation detecting and measuring instrumentation shall be traceable to the National Bureau of Standards. Survey instruments should be calibrated at two points on each scale.

l. Item 12—Film Badges, Dosimeters and Bioassay Procedures. The film badge is the primary dosimetric device used in the Army (AR 40-14 and SB 11-206). In addition to the whole-body badge, a wrist badge will be provided to all personnel who elute generators, prepare diagnostic and therapeutic doses, or handle brachytherapy sources (AR 40-14 and NCRP Report No. 40). A bioassay program will be established for personnel who use unsealed radioactive materials. The frequency of bioassay will be commensurate with the activity and chemical form used, the relative hazard of the radionuclide, the procedures followed, and the equipment used which makes it possible for radioactive material to be ingested, inhaled, or absorbed into the body (AR 40-5, AR 40-14, and NCRP Report No. 30).

NOTE: Bioassay studies of occupationally exposed personnel will be performed when there is believed to be reasonable risk of internal radiation hazard. As a minimum, the type of bioassay, frequency, and action levels are as follows:

(1) Any individual who at one time handles more than 5 millicuries of unsealed high-specific activity iodine-123, iodine-125, or iodine-131, shall have the total radioactive iodine content (microcuries) of the thyroid gland measured using an uptake probe system. This will be done under the supervision of the Chief, Nuclear Medicine Service, within 96 hours after each work period for intermittent exposure and monthly for continuous exposure. A total thyroid radioactive iodine content equal to or greater than 0.1 microcuries will require further investigation by the RPO. Thyroid gland radioactive iodine content will also be determined, under the supervision of the Chief, Nuclear Medicine Service, in any occupationally exposed individual suspected of accidental ingestion or inhalation of radioactive iodine. This will be done within 96 hours of the accidental exposure. A total thyroid radioactive iodine content in excess of 0.14 microcuries will result in the individual being removed from duties involving radioactive iodine exposure until the thyroid iodine content has dropped to 0.05 microcuries.

(2) In the case of uncontained tritium labeled organic compounds, urinalysis by liquid scintillation counting will be effected weekly whenever the amount used in a single procedure is greater than 10 millicuries. Any urinalysis revealing in excess of 25 microcuries/liter in a 24-hour urine collection will result in the individual being removed from duties involving tritium exposure until the urine concentration has dropped to 5 microcuries/liter, as revealed by subsequent liquid scintillation tests.

(3) Additional bioassay procedures will be accomplished as specified in appropriate regulations, directives, NRC licenses, or DA radioactive material authorizations. Results of bioassay studies will be recorded in the health record (AR 40-14).

m. Item 13—Facilities and Equipment. Describe in sufficient detail information about the facilities and equipment to determine their adequacy. Describe the use of shielded syringes and auxiliary shielding. For handling low to moderate levels of radioactive materials, the average velocity through the window of the hood should be 100 linear feet per minute with the hood window/door in the operating position (AR 40-5 and NCRP Report No. 30). Radioisotope laboratories in medical facilities

should meet the requirements of ANSI Standard N5.2-1963 (ISO R1710), NCRP Report No. 30 and TM 5-838-2.

NOTE: Syringe shields should be used during the preparation and administration of patient doses.

n. Item 14—Radiation Protection Program. Prepare a detailed written radiation protection program which is current (dated and authenticated) and describes procedures by which responsible persons are promptly notified of receipt of radioactive material, methods of control, functions and membership of the Radioisotope/Radiation Control Committee, as well as operations which include emergency procedures (see Appendix F), procurement, use and disposal of radioactive materials. Individual names will not be used in the development of this document but responsibilities will be assigned by military or civilian position. The document which describes the function and membership of the Radioisotope/Radiation Control Committee should also state how many or which members of the committee constitute a quorum, and whether unanimous committee approval is required for authorization of users.

NOTE: The Radioisotope/Radiation Control Committee for Army medical facilities will perform the functions of the Ionizing Radiation Control Committee required by AR 40-14. Considerable time and correspondence have been occasioned in the past review of license and authorization applications due to a lack of program coordination or documentation in the following areas:

(1) Leak Tests. Leak tests are required for all sealed sources containing 100 microcuries or more of beta-gamma emitting material other than hydrogen or 10 microcuries or more of alpha emitting material, with a physical half-life greater than 30 days and in any form other than gas every 6 months. If the sealed source is in storage and is not being used, such sources will be tested for leakage prior to use or transfer. Each source designed for the purpose of emitting alpha particles will be wipe tested every 3 months. The RPO will be responsible for the performance of leak tests. Procedures for performing the leak tests will be provided and an instrument with the capability of detecting 0.005 microcuries of activity must be available (NCRP Report No. 40 and ANSI Standard N44.2-1973). If the leak test reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at a rate of 0.0001 microcuries or more per 24 hours, remove the source from use (10 CFR Parts 20 and 35) and notify proper authorities (AR 385-40).

(2) Dose Calibration. Procedures and equipment will be available to determine the activity of the radiopharmaceuticals to be administered to patients. A dose calibrator or other suitable instrument will be used to assay the activity of the radiopharmaceutical prior to administration. The procedures will be adequate to insure that the error is no greater than 10 percent.

NOTE: The dose calibrator will be calibrated with radioactive standards over the entire range of activities, volumes and energies for which the instrument is to be used. This calibration will be accomplished at least annually and after each maintenance action. A performance test for stability/consistency will be made with a reference source at least once each day the dose calibrator is used. Describe methods for such calibration and performance tests in the application. Maintain records of instrument calibration and performance testing (AR 340-18-9).

(3) Training Program. Describe the training program for personnel who are involved in or associated with the use of radioactive materials. Include the form of training (formal course work, lectures, etc.) the duration of training, and the subject matter included (see app. A).

(4) Volatile and Gaseous Radioactive Materials. Describe procedures and equipment used to control and monitor the release of volatile and gaseous radioactive materials to controlled and noncontrolled areas. Submit calculations to show that such releases are as low as practicable and in compliance with 10 CFR 20.1(c), 20.103 and 20.106. Radiation accidents/incidents and accidental releases will be reported in accordance with AR 385-40, 10 CFR 20.403 and 20.405. The vapor emissions from gas chromatographs containing radioactive material should be vented to a fume hood or to the outside environment, not to the laboratory atmosphere.

(5) Radiopharmaceutical Quality Control. Describe control procedures for insuring assay, identity, sterility, and nonpyrogenicity of radiopharmaceuticals used in humans when not obtained from a supplier who manufactures a product under approved quality controls. Describe radiometric methods for Tc-99m activity and Mo-99 breakthrough contamination and insure that eluates will

not be used if there is more than 1 microcurie of Mo-99 per millicurie of Tc-99m or more than 5 microcuries of Mo-99 per administered dose of Tc-99m.

(6) Logs and Records. The RPO should maintain a centralized system of records for procurement, receipt, use, transfer, disposal, surveys, leak tests, personnel monitoring, inventories and all other records associated with the use of radioactive materials/radiation sources in accordance with AR 340-18-6.

(a) Radiopharmaceutical Inventory Records. Nuclear Medicine Service will maintain an inventory of each radiopharmaceutical received, used, lost through radioactive decay or disposal. In addition, records will be maintained showing the supplier, lot number, date of administration, name of requesting physician, identity and activity of the radiopharmaceutical, and identity of the recipient. DA Form 4574-R (fig. 1, located at the end of the regular size printed pages, (Radiopharmaceutical Stock Record) will be used for this purpose and maintained in accordance with AR 340-18-9. DA Form 4574-R will be locally reproduced on 10½ by 8 inch paper printed head to foot (front and back print alike). Medical facilities, utilizing large numbers and amounts of radioactive materials and having machine data processing capability, may use this capability provided at least all information required is included in the program.

(b) Inventory and leak test records will be maintained on a consecutive entry log and the removable activity will be recorded in microcuries. DA Form 3862 (Controlled Substances Stock Records) may be adapted for this purpose. DA Form 3862 is available through normal publications supply channels. Medical facilities, utilizing large numbers and amounts of radioactive materials and having machine data processing capability, may use this capability provided at least all information required is included in the program (see AR 40-61).

(c) Instrument logs will be maintained indicating calibration and maintenance (TM 38-750 and TB 38-750-2).

(7) Posting of Notices to Workers.

(a) Current copies of 10 CFR, Parts 19 and 20; 29 CFR, Part 1910; copies of NRC licenses and DA radioactive material authorizations; SOP and notices of violations will be posted. If posting of these documents is not practicable, a notice may be posted which describes the documents and states where they may be examined (10 CFR 19.11).

(b) Current copies of Form NRC-3 (Notice to Employees) will be posted wherever individuals work in or frequent any portion of a controlled area (10 CFR 19.11 and 29 CFR 1910.96).

(8) Signs, Labels, and Barriers.

(a) Radiopharmaceuticals will be labeled with a radiation warning sticker. The following information will be included on the sticker. the name of the supplier, lot number, radionuclide, activity, date of assay, and volume or concentration.

(b) The radioactive material storage area will be neat, segregated by type and secured when not attended. Radioactive materials will be shielded and so stored that the radiation level at any accessible location does not exceed 2 mR/hr. All radioactive material storage areas will be posted in accordance with 10 CFR 20.203 and 20.204; and AR 385-30.

(9) Marking Controlled Areas. Any area where radioactive materials are used or stored and the exposure rate is in excess of 2 mR/hr will be considered to be a controlled area and will be posted in accordance with 10 CFR 20.203 and 20.204; and AR 385-30.

(10) Instructions to Nurses and Other Personnel. A detailed SOP will be prepared concerning the care and handling of patients who are undergoing therapy with sealed or unsealed radioactive material (NCRP Reports No. 37 and 40).

(11) Shipment and Receipt of Radioactive Material. DA Form 2791-R is not required to document the receipt of radiopharmaceuticals provided other suitable records are maintained. however, the preparation of DA Form 2791-R is required for the receipt of other radioactive materials and the shipments thereof as specified in AR 55-55 and TM 55-315. Surveys will be performed as specified in 10 CFR 20.205. See NRC Regulatory Guides 7.3 and 7.4.

(a) The pickup of radioactive material will be accomplished as soon as practicable (if possible within 2 or 3 hours) after receiving notification by the carrier that the material is available for pickup.

(b) A package arriving at the consignee's facility during normal duty hours will be monitored for leakage and radioactive contamination within 3 hours. (Monitoring at time of receipt is preferred.)

(c) Packages arriving during nonduty hours will be monitored within 18 hours of receipt. (Monitoring at time of receipt is preferred.)

(d) The outer and inner surfaces of each pack-

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age/container will be monitored while it is being opened and before the packaging of the contents are removed from the unpacking location.

(e) Each medical facility will establish and maintain written procedures for safely opening packages containing radioactive material and shall assure that such procedures are followed, and that due consideration is given to special instructions for the type of package being opened.

(12) Radiation Surveys. Includes an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other radiation sources. The evaluation will include exposure-rate measurements and smear (wipe) tests to determine the amount of removable/transferable contamination. Acceptable levels of contamination are specified in appendix G. When appropriate, concentrations of radioactive materials in air and water will be determined (10 CFR 20.103 and 20.106). Records of such surveys will be maintained.

(a) Radiation surveys will be made periodically during the procedure by the technician, before leaving the controlled area and at end of each day (NCRP Reports No. 10 and 30). The technician will monitor his hands and clothing prior to leaving any potentially radioactively contaminated area.

(b) The RPO will make monthly surveys where radioactive materials are used and stored (10 CFR 20.201).

NOTE: If radioactive materials are to be used in animals, then a description of the animal housing facilities, a copy of instructions provided to animal handlers for the handling of animals, animal waste and carcasses, and for cleaning and decontamination of animal cages, and procedures for insuring that animal rooms will be secured unless attended by authorized users of radioactive material will be included with the application.

o. Item 15—Radioactive Waste Disposal.

(1) The conventional disposal as nonradioactive material is authorized when the material has been controlled through the period of radioactive decay to a normal background surface exposure and/or activity. This procedure is recommended for medical facilities with adequate local storage and for materials which have a short physical half-life to decay to background level within less than 12 months.

(2) Unwanted radioactive materials with radioactive waste will be transferred to an NRC licensed disposal facility for ultimate disposal (AR 200-1, AR 755-15 and TM 3-261).

(3) Radioactive waste will not be incinerated or buried, except at an NRC licensed disposal facility.

(4) Release of radioactive materials into the sanitary sewerage system will be in accordance with 10 CFR 20.203, AR 200-1 and AR 755-15. Records will be maintained identifying the radionuclide, activity, the date of disposal, and cumulative activity as of any date for each radioactive disposal sink. All sinks that are routinely used for the disposal of liquid waste will be posted (29 CFR 1910.96).

(5) All "empty" radioactive material containers, having background radiation levels, may be discarded as nonradioactive waste provided that the radiation warning labels are removed or defaced before discarding.

(6) The instruments used and the procedures followed for the monitoring of trash for radioactivity before disposal will be sufficient to insure that no detectable radioactivity remains. When large containers full of radioactive waste material are monitored, low levels of activity in the center of the container may not be detected.

(7) Radioactive materials will be stored in closed containers. Each container having radioactive material stored therein will be labeled (AR 385-30 and AR 55-55) and, if applicable, a radioactive waste container log maintained for each container.

(8) Records will be maintained for the disposal of all radioactive material, 10 CFR 20.401 and 30.51, as specified in AR 340-18-6.

p. Item 16—Certificate or Statement. The NRC license or DA radioactive material authorization is always for the Army medical facility; therefore, all copies will be signed by or for the Commander after approval by the Radioisotope/Radiation Control Committee.

NOTE: Normally only a single byproduct, source or special nuclear material license or DA radioactive material authorization is issued to an installation/activity to cover the use of radioactive materials for medical purposes; however, a separate application will be submitted for kilocurie sources used in teletherapy or gamma irradiation devices/facilities.

C–2. Form NRC-313a (Application for Byproduct Material License-Medical—Supplement A—Human Use).

a. Item 1(a)—Using Physician's Name and Item 1(b)—Name and Address of Applicant Enter the name and address of the medical facility.

b. Items 2 and 3. Enter statement, "Not Applicable."

c. Item 4. Attach a description of the using physician training and experience in the use and handling of radioactive materials.

d. Items 5(a), (b) and (c)—Describe purpose for which radioactive material will be used, chemical form to be administered and proposed dosage range for each specific condition to be diagnosed or treated (see Appendix E). Any dosage which exceeds the recommended dosage level must be explained. Documentation will be provided the local Radioisotope/Radiation Control Committee which discusses the rationale for the higher dosage and calculations of the absorbed dose to the whole-body and critical organs.

e. Item 6—Investigative Proposal for Experimental and Nonroutine Use (see app D).

f. Item 7—If Byproduct Material will not be Obtained in Pre-Calibrated Form, describe Identification, Processing and Standardization Procedures. See paragraph 1n(5) of this appendix.

g. Item 8—The Proposed Use of Byproduct Material has been approved by Medical Isotope Committee. Enter "yes."

h. Item 9(a) and (b)—Hospital Facility for Individual Practice Use Only Enter "yes."

i. Form NRC 313a, page 3. This form or similar local form will be completed and submitted for each individual who has adequate training and experience (app. A) to use radioactive materials in humans and has approval by the Radioisotope/Radiation Control Committee. Resubmission of page 3 addressed to TSG [HQDA (DASG–HCH) WASH DC 20310] is required when an individual is certified for a new procedure or a new radionuclide. The resubmission does not require an amendment of the NRC license.

C–3. Form NRC–483 (Registration Certificate—In Vitro Testing with Byproduct Material under General License).

a. Enter name and address of installation or activity.

b. Enter location of use. Same as above.

c. A statement will be made that the installation or activity has appropriate radiation measuring instruments to perform the in vitro tests and that tests will be performed only by persons who have had adequate training and experience in the use of such instruments and the handling of radioactive materials (see para 9).

d. Prepare an SOP for the control and safe use of radioisotopes for in vitro studies and describe procedures by which responsible persons are promptly notified of receipt of radioactive material, methods of control, as well as survey procedures, posting of radiation caution signs, records of receipt, use, and disposal of radioactive material, and emergency procedures (see app. F).

e. Describe the physical facilities and equipment, including radiation measuring instruments used to carry out in vitro test procedures.

NOTE: A medical facility [illegible] material for in vitro testing under the [illegible] tion Certificate will not possess, use or [illegible] one time or any one location a total activity of iodine-125, iodine-131, iron-59 or other [illegible] emitting byproduct material in excess of [illegible] curies or no more than 100 microcuries of [illegible] or no more than 1000 microcuries [illegible] tritium without a specific NRC license.

f. Since the registration certificate [illegible] Army medical facility, all copies will be [illegible] for the Commander and submitted through command channels to TSG [HQDA (DASG–HCH) WASH DC 20310].

APPENDIX D
NONROUTINE HUMAN USE OF RADIOACTIVE MATERIALS

D-1. Experimental and nonroutine human use of radioactive materials include all those uses not specified in appendix E and/or 10 CFR 35.100. Those radiopharmaceuticals to be used for diagnostic or therapeutic purposes for which a "Notice of Claimed Investigational Exemption for a New Drug (IND)" has been accepted by FDA in accordance with 21 CFR Part 310, will be used in accordance with the manufacturer's instructions and the protocol will be approved prior to use as specified in paragraph D-4. Nonroutine human use will be classified into one of two phases of development:

a. Clinical research applies to a new use of radioactive material in humans. Little or nothing is known about the procedure and little or nothing has been published on the subject. The basis for proceeding with the new use in humans is derived from knowledge obtained from animal studies. This phase of development includes the initial introduction into humans and initial trials on a limited number of patients.

b. Clinical evaluation applies to the planned testing of a new diagnostic or therapeutic procedure in an appropriate series of control and diseased humans. The procedure and results of clinical research will ordinarily have been reported in the literature or at meetings. If adequate information has not been published, the applicant should have spent sufficient time with those who developed the test to be thoroughly familiar with the details.

D-2. The clinical research phase of experimental or nonroutine medical use of radioactive material is normally limited to licensees who have personnel with broad experience in the clinical use of radioactive material and who have appropriate facilities and equipment available to conduct research. Research should be pursued by groups of competent investigators representing different disciplines rather than by single individuals. The individual physician will not be designated on the license as the authorized user, but should normally have broad and varied experience in the use of radioactive materials and in clinical research investigation.

D-3. The clinical evaluation phase of experimental or nonroutine medical use of radioactive material is normally limited to licensees under the supervision of an individual physician with broad experience in clinical evaluation and the use of radioactive materials, and under the guidance of a Radioisotope/Radiation Control Committee representing a number of disciplines.

D-4. Applications for experimental or nonroutine uses of radioactive materials in humans will be reviewed by the Radioisotope/Radiation Control Committee and the Clinical Investigation and the Human Use Committees (AR 40-38) before submitting applications through command channels to TSG [HQDA (DASG-HCH) WASH DC 20310]. Applications must be supported by a research protocol which includes—

a. Title of study.

b. The purpose for conducting the study. Indicate whether the study is to be clinical research or clinical evaluation and explain why.

c. The plan of investigation in sufficient detail to permit a critical evaluation of the methods for conducting the experiments and the controls established.

d. A statement as to whether any planned complementary drug or radiopharmaceutical administration is contemplated in conjunction with the study.

NOTE: (1) The pharmacological dose/amount of active ingredient or combination of active ingredients to be administered will be known not to cause any clinically detectable pharmacological effect in human beings.

(2) The total amount of active ingredients including the radionuclide will be known not to exceed the dose limitation applicable to the separate administrations of the active ingredients excluding the radionuclide.

e. A statement about the expected fate of the radioisotope administered and if the procedure is for therapy, a statement about the expected effects.

f. If the application is for clinical research, an outline of related work conducted by the applicant or others in laboratory animals and in humans, including data on localization, effective half-life, radiation dosage and dosage to the critical organ and whole-body. If no work has been conducted in animals, explain why. Pertinent references and a brief abstract prepared by the applicant of published or unpublished material should be submitted. (The brochure of a commercial supplier is not a satisfactory authority for this purpose. It is not necessary to include reprints of references with the application.)

g. If the application is for clinical evaluation, pertinent references and a brief abstract prepared by the applicant of published or unpublished material, including information on localization, effective half-life, and radiation dosage. (The brochure of a commercial supplier is not a satisfactory authority for this purpose. It is not necessary to include reprints of references with the application.)

h. A description of the human subjects to be studied:

(1) Persons without manifest disease - number, method of selection, age range.

(2) Persons with manifest disease - number, nature of pathology, method of selection, age range.

(3) Pregnant women will ordinarily be excluded from any test not involving the condition of pregnancy itself. Specify whether or not pregnant women will be tested and, if so, explain why.

i. Confirmation that consent of human subjects, or their representatives, will be obtained to participate in the investigation except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects (AR 40-38).

j. The dose range (microcuries or millicuries) to be administered and the method of administration.

k. Calculations of the radiation doses delivered to the whole-body and to the critical organ(s). The calculations will contain information about—

(1) The expected effective half-life in various organs.

(2) The relationship between the retained radioactivity and the permissible body burden for radiation workers (except for therapy).

(3) The rationale for using the dose selected.

(4) The radiation dose due to other simultaneous or accompanying radioactive material tests or x-ray procedures which may be administered.

(5) Assumptions made in performing the radiation dose calculations.

(6) The possibility of followup studies will be included in the dose calculations.

NOTE: The dose/amount of radioactive material to be administered will be such that the individual receives the smallest radiation dose which is practical to perform the study.

(1) Under no circumstances will the radiation dose to an adult human volunteer from a single biochemical, physiological, pathophysiological or endocrinological study or cumulatively from a number of such studies conducted within a single year be recognized as permissible if such dose exceeds the following:

(a) Whole-body, active blood-forming organs, lens of the eye, and gonads:

Single dose . . . . . 3 rems
Annual and total dose commitment . 5 rems

(b) Other organs:

Single dose . . . . . 5 rems
Annual and total dose commitment 15 rems

(2) For a research subject under 18 years of age at last birthday, the radiation dose will not exceed 10 percent of that set forth in (1) above.

l. A statement of the institutional resources available to support the study including—

(1) Physical facilities and equipment especially suited for the study under consideration.

(2) Availability of clinical material.

(3) Types of consultation or collaboration available including the name of the sponsor of the study if other than the applicant.

m. Qualifications of the individual physician who will be responsible for the study, including a summary of research training and experience and pertinent training or experience in the use of radioactive materials.

n. Estimated time needed to complete the study.

o. A schedule for reporting results of the study and an outline of the type of information to be included in the report. The schedule can be in terms of time intervals or number of subjects studied. If studies are to be long range, interim reports will be provided.

D–5. Army medical facilities issued an NRC broad specific license for medical research, diagnoses and therapy will, in addition to complying with the requirements stated in this regulation, comply with

the requirements of 21 CFR 361.1 as added effective 25 July 1975 (40 FR 31308), officially corrected 29 September 1975 (40 FR 44543); AR 40-7, AR 40-38 and AR 70-25; and other applicable Federal directives.

NOTE: The duties and responsibilities of the Radioactive Drug Research Committee may be performed by the Clinical Investigation Committee if properly constituted and approved as required by 21 CFR 361.1.

APPENDIX E
LIST OF WELL ESTABLISHED PROCEDURES CURRENTLY AUTHORIZED FOR CLINICAL STUDIES

GROUP I. Diagnostic Studies Involving Measurements of Uptake, Dilution and Excretion

Radionuclide	Chemical Form	Use	Recommended Dosage Range
Iodine-131	Sodium Iodide	Thyroid uptake	Up to 5 microcuries
		Thyroid uptake (suppression test)	Up to 50 microcuries
Iodine-123*	Sodium Iodide	Thyroid uptake	Up to 100 microcuries
Iodine-125	Sodium Iodide	Thyroid uptake	Up to 25 microcuries
Iodine-131	Iodinated human serum albumin (IHSA)	Blood and blood plasma volume cardiovascular function, and protein turnover	Up to 20 microcuries
Iodine-125	IHSA	Blood and blood plasma volume cardiovascular function, and protein turnover	Up to 20 microcuries
Iodine-131	Rose Bengal	Liver function	Up to 100 microcuries
Iodine-125	Rose Bengal	Liver function	Up to 50 microcuries
Iodine-131	Labeled Fats or Fatty Acids	Fat absorption	Up to 100 microcuries
Iodine-125	Labeled Fats or Fatty Acids	Fat absorption	Up to 100 microcuries
Iodine-131	Labeled iodopyracet, Sodium iodohippurate, Sodium diatrizoate, Diatrizoate methylglucamine, Sodium diprotrizoate, Sodium acetrizoate, or Sodium iothalamate	Kidney function	Up to 50 microcuries
Iodine-125	Labeled iodopyracet, Sodium iodohippurate, Sodium diatrizoate, Diatrizoate methylglucamine, Sodium acetrizoate, or Sodium iothalamate	Kidney function	Up to 50 microcuries
Cobalt-57*	Labeled cyanocobalamine	Intestinal absorption studies	Up to 0.5 microcuries
Cobalt-58	Labeled cyanocobalamine	Intestinal absorption studies	Up to 0.5 microcuries
Cobalt-60	Labeled cyanocobalamine	Intestinal absorption studies	Up to 0.5 microcuries
Chromium-51	Sodium chromate	Determination of red blood cell volume and studies of red blood cell survival time	Up to 150 microcuries
Chromium-51	Labeled human serum albumin	Gastrointestinal protein loss studies	Up to 75 microcuries

*Accelerator produced.

Radionuclide	Chemical Form	Use	Recommended Dosage Range
Iron-59	Chloride, Citrate or Sulfate	Iron turnover studies	Up to 35 microcuries
Potassium-42	Chloride	Potassium space determinations	Up to 40 microcuries
Sodium-22*	Chloride	Sodium space determinations	Up to 40 microcuries
Sodium-24	Chloride	Sodium space determinations	Up to 100 microcuries
Technetium-99m	Pertechnetate	Blood flow studies	Up to 20 millicuries
Mercury-197	Chlormerodrin	Kidney function studies	Up to 200 microcuries

*Accelerator produced

GROUP II. Diagnostic Study Involving Imaging and Tumor Localization

Radionuclide	Chemical Form	Use	Recommended Dosage Range
Iodine-131	Sodium Iodide	Thyroid imaging	Up to 100 microcuries
Iodine-125	Sodium Iodide	Thyroid imaging	Up to 100 microcuries
Iodine-123*	Sodium Iodide	Thyroid imaging	Up to 2 millicuries
Iodine-131	IHSA	Brain tumor localizations Cardiac imaging	Up to 500 microcuries,
Iodine-131	Macroaggregated iodinated human serum albumin	Lung imaging	Up to 300 microcuries
Iodine-131	Colloidal (microaggregated) iodinated human serum albumin	Liver imaging	Up to 300 microcuries
Iodine-131	Rose Bengal	Liver imaging	Up to 300 microcuries
Iodine-131	Iodopyracet, Sodium iodohippurate, Sodium diatrizoate, Diatrizoate methylglucamine, Sodium diprotrizoate, or Sodium acetrizoate	Kidney imaging	Up to 250 microcuries
Iodine-131	IHSA	Placenta localization	Up to 5 microcuries
Chromium-51	Sodium chromate	Spleen imaging	Up to 300 microcuries
Chromium-51	Human serum albumin	Placenta localization	Up to 10 microcuries
Gold-198	Colloidal form	Liver imaging	Up to 200 microcuries
Mercury-197	Chlormerodrin	Kidney and brain imaging	Up to 200 microcuries
Selenium-75	Selenomethionine	Pancreas imaging	Up to 250 microcuries
Strontium-85	Nitrate or chloride	Bone imaging	Up to 100 microcuries
Fluorine-18	Sodium fluoride	Bone imaging	Up to 4 millicuries
Technetium-99m	Pertechnetate	Brain imaging (static) Brain imaging (dynamic)	Up to 10 millicuries
Technetium-99m	Pertechnetate	Thyroid imaging	Up to 10 millicuries
Technetium-99m	Pertechnetate	Salivary gland imaging	Up to 10 millicuries
Technetium-99m	Pertechnetate	Placenta localization	Up to 1 millicuries
Technetium-99m	Sulfur colloid	Liver, spleen, imaging	Up to 6 millicuries
Technetium-99m	Sulfur colloid	Bone Marrow imaging	Up to 12 millicuries
Technetium-99m	Macroaggregated human serum albumin	Lung imaging	Up to 5 millicuries
Gallium-67*	Citrate	Tumor and abcess localization	Up to 5 millicuries
Phosphorus-32	Sodium phosphate	Eye tumor localization	Up to 500 microcuries
Ytterbium-169	DTPA	Cisternography	Up to 2 millicuries

*Accelerator produced

GROUP III. Special Diagnostic Uses of Radiopharmaceuticals

Radionuclide	Chemical Form	Use	Recommended Dosage Range
Xenon-133	Gas or in saline	Perfusion study Lung ventilation studies	Up to 15 millicuries Up to 30 millicuries
Technetium-99m	Diethylenetriamine pentoacetic acid (DTPA) (Fe)	Kidney imaging with renal flow	Up to 15 millicuries
Technetium-99m	DTPA (Sn)	Kidney imaging with renal flow	Up to 15 millicuries
Technetium-99m	DTPA	Kidney functioning with renal flow	Up to 15 millicuries
Technetium-99m	Dimercaptasuccinic acid (DMSA)	Kidney imaging	Up to 15 millicuries
Technetium-99m	DTPA (Sn)	Brain imaging	Up to 25 millicuries
Technetium-99m	Human serum microspheres	Lung imaging	Up to 5 millicuries
Technetium-99m	Polyphosphates	Bone imaging	Up to 15 millicuries
Technetium-99m	Stannous Pyrophosphates	Bone imaging	Up to 15 millicuries
Technetium-99m	Distannous etidronate	Bone imaging	Up to 15 millicuries
Indium-111*	DTPA	Cisternography	Up to 2 millicuries
Indium-111*	Chloride	Malignant neoplasm and bone marrow imaging	Up to 3 millicuries
Indium-113m	Chloride	Blood pool imaging with placenta localization	Up to 5 millicuries

*Accelerator produced.

GROUP IV. Therapeutic Uses Not Requiring Hospitalization

Radionuclide	Chemical Form	Use	Recommended Dosage Range
Iodine-131	Sodium Iodide	Hyperthyroidism Cardiac Dysfunction	Up to 30 millicuries per dose.
Phosphorus-32	Soluable phosphate	Treatment of Polycythemia vera	Up to 3 millicuries per dose. Total up to 10 millicuries
Phosphorus-32	Soluable phosphate	Treatment of Bone metastases	Up to 7 millicuries per dose. Total up to 20 millicuries
Phosphorus-32	Soluable phosphate	Treatment of Leukemia	Up to 1 millicuries per dose. Total Up to 10 millicuries
Phosphorus-32	Collodial chromic phosphate	Intracavitary treatment of malignant effusions	Up to 20 millicuries

GROUP V. Therapeutic Uses Requiring Hospitalization

Chemical Form	Use	Recommended Dosage Range
Colloid	Intracavitary treatment of malignant effusions	Chest-P.C. up to 125 millicuries. Abdomen up to 200 millicuries
Iodide	Treatment of thyroid carcinoma	Up to 200 millicuries per dose. Total. Up to 600 millicuries

Therapeutic or Diagnostic Use of Sealed Beta Particle and Gamma Ray Sources

Chemical Form	Use
Sealed source	Bone mineral analysis
Sealed source	Bone mineral analysis
Sealed source (Needles and cells)	Topical, interstitial or intracavitary therapy of cancer
Sealed source (Needles and cells)	Topical, interstitial or intracavitary therapy of cancer
Sealed source (Needles and cells)	Topical, interstitial or intracavitary therapy of cancer
Seeds	Interstitial treatment of cancer
Seeds	Interstitial treatment of cancer
Seeds	Interstitial treatment of cancer
Seeds	Interstitial treatment of cancer
Seeds and Wires	Interstitial treatment of cancer
Seeds	Interstitial treatment of cancer
Ophthalmic applicator	Treatment of superficial eye conditions
Sealed source	Teletherapy
Sealed source	Teletherapy

APPENDIX F
EMERGENCY PLANNING FOR LABORATORIES USING RADIOACTIVE MATERIALS

F-1. Minor Spills Involving No Radiation Hazards to Personnel. *a.* Notify all persons in the room and area at once.

b. Notify the RPO immediately.

c. Survey all personnel before they become dispersed and change clothing as necessary.

d. Permit only the minimum number of persons necessary to deal with the spill into the area.

e. Confine the spill immediately.

(1) Liquid spills.

(a) Don protective lab coat.

(b) Don protective gloves.

(c) Drop absorbent paper on spill.

(2) Dry spills.

(a) Don protective lab coat.

(b) Don protective lab gloves.

(c) Water may be used to decontaminate except where chemical reaction with water would then generate an airborne hazard. Oil should be used.

f. Plan decontamination action.

g. Prepare a report of the incident and submit through the RPO to the Radioisotope/Radiation Control Committee.

F-2. Major Spills Involving Radiation Hazards to Personnel. *a.* Notify all persons not involved in the spill to vacate the room or area at once. Limit the movement of displaced persons to confine the spread of radioactive contamination.

b. Notify the RPO immediately.

c. If the spill involves a liquid and the hands are protected, right the container; otherwise use a handling tool, stick or other appropriate device.

d. If the liquid radioactive contamination is on the skin, flush thoroughly with water.

e. If the liquid radioactive contamination is on the clothing, remove outer or protective clothing at once.

f. Turn off all ventilation.

g. Monitor all persons involved in the spill.

h. Permit no person to resume work in the room or area without the approval of the RPO.

i. Prepare a report of the incident and submit through the RPO to the Radioisotope/Radiation Control Committee.

F-3. Accidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors and Gases. *a.* Notify all persons to vacate the room or area immediately.

b. Hold breath, close air vents and turn off ventilation.

c. Vacate the room or area. Seal off the room or area, if possible.

d. Notify the RPO at once.

e. Ascertain that all doors giving access to the room are closed. Post radiation warning signs or guards to prevent opening of the doors until the RPO arrives.

f. Identify to the RPO all known or suspected individuals who may have inhaled radioactive materials.

g. Monitor all persons involved in the incident.

h. Permit no person to resume work in the room or area without the approval of the RPO.

i. Prepare a report of the incident and submit through the RPO to the Radioisotope/Radiation Control Committee.

F-4. Injuries to Personnel Involving Radiation Hazards. *a.* Notify the RPO immediately.

b. Notify the Chief of Nuclear Medicine or the Chief of Radiology immediately.

c. Wash minor wounds immediately under running water while spreading the edges of the wound.

d. Permit no person involved in the radiation injury to return to work without the approval of the attending physician and the RPO.

e. Prepare a report of the incident and submit through the RPO to the Radioisotope/Radiation Control Committee.

F-5. Fires or Other Major Emergencies. *a.* Notify all persons in the room and building at once.

b. Notify the Fire Department, RPO and other facility safety personnel immediately.

c. Attempt to put out the fire by approved means if there is no immediate radiation hazard.

d. Avoid the spreading of radioactive contamination or passing contaminated equipment into clean areas.

e. Monitor all personnel involved in the incident.

f. Permit no person to return to work within the room or area without the approval of the RPO.

g. Prepare a report of the incident and submit through the RPO to the Radioisotope/Radiation Control Committee.

Note: Decontamination operations and radiation surveys and monitoring of contaminated personnel and equipment should be performed under the supervision of the RPO.

APPENDIX G RADIOACTIVE CONTAMINATION GUIDES

Contaminated Items and Indications for Action	Fixed (F) or Removable (R)	Dpm per 100 cm²	Contamination Level: Alpha Dpm per 100 cm²	Contamination Level: Beta-gamma* mrad/hr 2.54 cm	Dpm per 100 cm²	Method of Measurement
1. Clothing, including shoes:						
a. Personal. Should be replaced, decontaminated or stored for decay if above:	F	200		0.2		Probe
	R		None		None	Smear†
b. Anticontamination.						
(1) General. Should be replaced and/or decontaminated, if above:	F	1000		0.2		Probe
	R		200		1000	Smear†
(2) Laundry. Should not be released to public laundry if above	F	200		0.2		Probe
	R		50		200	Smear†
(3) Respirators. Should be decontaminated after use if above:	F	200		1.0‡		Probe
	R		None		None	Smear‡
2. Containers. Prior to nonradioactive use, should be decontaminated if above:	F	200		0.2		Probe
	R		None		100	Smear†
3. Laboratories and Work Areas:						
a. Noncontrolled Area. Require controls and posting or decontamination if above:	F	200		0.2		Probe
	R		20		100	Smear†
b. Controlled Areas:						
(1) Hoods:	F	1000		2.0		Probe
	R		200		2000	Smear‡
(2) Glove Boxes:	F	5000		2.5		Probe
	R		1000		5000	Smear†
(3) Workbench Surface:	F	1000		0.5		Probe
	R		200		1000	Smear†
4. Skin:						
a. Body. Continue decontamination if above:	F	200		0.06		Probe
	R		None		None	Smear†
b. Hands. Continue decontamination if above:	F	400		0.1		Probe
	R		None		None	Smear†
5. Vehicles/Radioactive Containers:						
a. Used in controlled area. Should be decontaminated if above:	F	—§		2.0§		Probe
	R		2200§		22,000§	Smear†
b. Used in noncontrolled area. Should be decontaminated if above:	F	—§		0.5§		Probe
	R		220§		2,200§	Smear†
6. Equipment:						
a. Used in controlled area. Should be decontaminated if above:	F	5000		2.0		Probe
	R		1000		10,000	Smear†
b. Used in noncontrolled area. Should be decontaminated if above:	R	500		0.2		Probe
	F		100		1,000	Smear†

* Measured through not more than 7 milligrams per square centimeter of total absorber and averaged over not more than 1 square meter.
† The amount of removable/transverable radioactive material as determined by wiping/smearing 100 square centimeters with filter or soft absorbent paper, applying moderate pressure and assessing the amount of radioactive material on the wipe/smear with an appropriate instrument with known efficiency.
‡ In contact with any outside surfact of Respirator/Mask.
§ Based on 49 CFR 173.397 or Graziano's Tariff.

U.S. GOVERNMENT PRINTING OFFICE: 1977— 241-379:30918

7 January 1977 AR 4

The proponent agency of this regulation is the Office of the Surgeon General. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) direct to HQDA (DASG-HCH) WASH DC 20310.

By Order of the Secretary of the Army:

BERNARD W. ROGER
General, United States A
Chief of Staff

Official:

PAUL T. SMITH
Major General, United States Army
The Adjutant General

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RADIOPHARMACEUTICAL	MANUFACTURER	DATE	Label or Item Space
	LOT NUMBER	EXPIRATION DATE	

NUMBER	PATIENT NAME	PROCEDURE	DATE	TIME	ASSAY (mCi/ml)	PATIENT DOSE		BALANCE REMAINING (ml)	PRESCRIPTION NUMBER	ADMINISTERED BY (initials)
						ACTIVITY (mCi)	VOLUME (ml)			

DA FORM 4574-R, 1 NOV 76

Figure 1.

ARMY REGULATIONS
No. 40-37

HEADQUARTERS,
DEPARTMENT OF THE ARMY
WASHINGTON, D.C., *12 August 1963*

MEDICAL SERVICE

RADIOISOTOPE LICENSE PROGRAM (HUMAN USE)

Section I. GENERAL

1. Purpose and scope. *a. Purpose.* These regulations—

(1) Prescribe policies and procedures for the human use radioisotope license program.

(2) Establish the procedure for the reporting of radioisotopes in human use activities.

(3) Furnish guidance to major oversea commanders whose medical treatment facilities outside the United States are authorized to operate human use radioisotope programs without the requirement for a license from the U.S. Atomic Energy Commission.

b. Scope. These regulations—

(1) Apply to all Army medical treatment facilities located in a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(2) Apply to major oversea commanders as follows:

(*a*) Applies to installations and activities assigned to major oversea commanders which are located in an area which falls under AEC jurisdiction.

(*b*) Major oversea commanders will adopt such portions of these regulations for installations and activities outside the United States as are necessary to insure the continuity of professional qualifications and maintenance of current documentation of the training and experience of the individual radioisotope user. (This official record of professional qualifications must be acceptable to The Surgeon General and the U.S. Atomic Energy Commission when an individual is reassigned to the United States or that geographical area where radiological byproduct materials are licensed by the U.S. Atomic Energy Commission.)

(3) Do not apply to the use of equipment generating ionizing radiation by electrical means for diagnostic or therapeutic procedures. The provisions of TB MED 62 (*Diagnostic X-Ray Protection*) apply for use of diagnostic X-ray equipment.

2. Definition of terms. For the purpose of these regulations, the following definitions apply—

a. Byproduct materials. Means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear materials.

b. Special nuclear material. Plutonium, uranium 233, uranium enriched in the isotope 235, or

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any other material which the U.S. Atomic Energy Commission determines to be special nuclear material.

c. Sealed sources. Any radioactive material that is inclosed, or is to be used in, a container in a manner intended to prevent leakage of the radioactive material or any of its daughter products.

d. Human use. The internal or external administration of radioactive material (byproduct material or otherwise) or the radiation therefrom, to human beings.

e. License. A license issued by the U.S. Atomic Energy Commission.

3. Responsibilities. *a. The Surgeon General.* The Surgeon General is responsible for staff supervision of this program and administrative approval of licenses pertaining to human use of radioactive material. He will specifically—

(1) Designate medical treatment facilities authorized to use radioisotopes for human use and provide diagnostic and/or therapeutic radioisotope services.

(2) Provide policy guidance and advisory support to Army medical treatment facilities.

(3) Review all license applications for human use of radioisotopes.

(4) Maintain a current list of approved individuals (users) and radioisotopes for which the users are approved.

(5) Plan for a long-range scientifically oriented and integrated program which incorporates realistic requirements for training, construction, and equipment.

(6) Perform, at least on an annual basis, a survey of all aspects of radioisotope activities at licensed medical treatment facilities.

(7) Appoint a Radioisotope Committee to assess the program by evaluating the minutes in the letter reports of medical treatment facilities using radioisotopes, submitted in accordance with paragraph 4, survey reports and other available data.

b. Major overseas commanders. ZI army commanders, Commanding General, Military District of Washington, U.S. Army; Commanding General, U.S. Army Materiel Command, and other separate commanders having primary responsibility for research and development projects, or technical operations. These commanders will be responsible for insuring that commanders of all installations and activities under their jurisdiction—

(1) Are provided with the proper authorization, including valid AEC license when applicable, prior to procuring or using radioactive material or sources of ionizing radiation for the purpose of radiation exposure of human beings (volunteers or otherwise), associated with military projects.

(2) Are provided with adequate means and procedures for safe handling of radioactive materials.

(3) Have acquired a written approval from the Secretary of the Army (AR 70–25, 26 March 1962), prior to the submission of license application for human use, when volunteers are to be used as experimental research subjects.

c. The commander of each medical installation or treatment facility. This commander is responsible for all aspects of the radiation program within his command. This responsibility includes, but is not limited to, the following:

(1) Insure that the medical treatment facility concerned has been assigned the mission by The Surgeon General to provide diagnostic and/or therapeutic radioisotope services.

(2) Insure that the medical treatment facility as the applicant for an AEC license, or as a licensed medical treatment facility provides adequate support for the human use activity to include—accommodations for clinical care of patients; availability of suitably trained and experienced personnel; availability of proper equipment such as handling devices, shields, measuring and monitoring instruments; and standardized operating procedures for the protection of health and safety in all aspects of the medical treatment facility operation.

(3) Appoint a radioisotope committee which will be designated as user on the license of the medical treatment facility.

(4) Insure that the individual users of radioisotopes within the facility and each ra-

dioisotope used will be approved and controlled by the Radioisotope Committee as the licensed user in accordance with requirements as specified in licensing procedures and regulations of the U.S. Atomic Energy Commission (title 10, Code of Federal Regulations and RC–12 "The Medical Use of Radioisotopes—Recommendations and Requirements by the Atomic Energy Commission").

(5) Review radioisotope program and submit reports and data in accordance with paragraph 4.

(6) Insure that each user's 201 file reflects current qualifications of the individual user, and that this information remains a permanent portion of that file.

(7) Performs within reason or permits the U.S. Atomic Energy Commission to perform such tests or inspections as the Commission deems appropriate or necessary for the administration of their regulations on radioisotopes.

d. Radioisotope Committee. This committee will consist of the Chief of Medicine, the Chief of Pathology, the Chief of Radiology, the Chief of the Radioisotope Clinic, and a radiation protection officer or health physicist. A nonvoting member of supply and service is mandatory. Others may be included at the discretion of the medical treatment facility commander. At medical treatment facilities with limited qualified personnel, the radioisotope committee will conform to stated composition to the extent that personnel permit. Under this circumstance, one individual on the committee may serve in a dual capacity. This committee will have the following responsibilities:

(1) Review and grant permission for, or disapproval of, the use within the medical treatment facility of byproduct material from the standpoint of radiological health and safety and other factors established for medical use of these materials.

(2) Certify individual users for each type of procedure with each individual radioisotope and insure that a copy of such certification is placed in the appropriate users' 201 file.

(3) Prescribe special conditions which may be necessary to include, but not limited to, medical examinations, additional training, designation of radiation areas, location of radioisotope use, waste disposal method, and protective measures for personnel in care of patients.

(4) Review records and receive reports from the radiological protection officer or other individuals responsible for health and safe practices.

(5) Recommend corrective actions when indicated.

(6) Keep an official record of its actions.

(7) Maintain current records of the training of approved users, documenting the qualifications and limitations of each.

(8) Maintain data for the report required by paragraph 4.

4. Reporting requirements. The following reports will be prepared:

a. Radioisotopes in Human Use Activities, RCS MED–197. Commanders of each medical treatment facility located in the United States and the Commonwealth of Puerto Rico having diagnostic or therapeutic radioisotope service will prepare the report covering the period of each calendar quarter. Report will be in narrative form and will be dispatched through command channels to The Surgeon General, Department of the Army, ATTN: MEDPS–PO, Washington, D.C., 20315, by the 15th working day following the close of the report period and will contain at least the following information:

(1) Copy of the minutes of each radioisotope committee meeting, including a record of all actions taken by the committee. Special care should be taken to include formalized actions that—

(*a*) Certify each individual for each new use of radioisotope.

(*b*) Appoint a radiation protection officer.

(2) Copy of the training and experience record of each individual who is an approved user of radioisotopes (AEC Form 313a, page 3) or appointed a radiation protection officer. After initial record is submitted, subsequent report will include any changes in qualifications or in certification during the report period.

(3) Notification of all changes in membership of radioisotope committee. Each new member of the radioisotope committee will be documented as to specific training and experience.

(4) Quantities of radioisotopes procured, used (exclusive of volunteer RD activities), and disposed of during the period and in storage end of period.

(5) List of procedures with dosage for each radioisotope used during the period, that varies from the dosage range listed in table I of the appendix.

(6) Information on unsolved problems, new or improved developments, or comments on the support rendered by The Surgeon General.

b. Radioisotopes in Human Use—Volunteer RD activities, RCS MED–198. Indviduals or the commanders designated as a licensee for a research and development project which utilizes any radioisotopes in human use volunteer activities located in the United States and the Commonwealth of Puerto Rico on completion of the project will prepare a final narrative report consisting of—

(1) The human use component of the project to include, but not be limited to, a description of the volunteers, as to source, age, sex, and number.

(2) Procedures used.

(3) Dosages involved, and

(4) Evaluation of the total integrated lifetime dose received by each individual prior to and following the experiment. Report will be submitted through command channels to The Surgeon General, ATTN: MEDPS–PO, Department of the Army, Washington, D.C., 20315, within 45 calendar days after completion of the project.

5. License applications. Applications for byproduct material license for human use will be submitted on AEC Form 313 (Application for Byproduct Material License, Supplement A—Human Use) in sufficient numbers so that six copies (all signed and dated) are received by The Surgeon General.

a. Class II medical installations and activities will submit such applications direct to The Surgeon General, ATTN: MEDPS–PO.

b. Class I medical installations will submit applications through command channels to The Surgeon General, ATTN: MEDPS–PO.

c. Commanders responsible for specific research and development projects which require licenses involving the human use of radioactive materials, that are disassociated from medical treatment facilities, patient care, or diagnostic or therapeutic care, will submit license applications through command channels to The Surgeon General, ATTN: MEDPS–PO. Adequate supporting documentation covering the training and experience of personnel involved, SOPs, plans, and other pertinent data is essential to process the application. Direct correspondence with the Atomic Energy Commission in license applications is not authorized, except to reply to correspondence initiated by AEC; information copies of all such correspondence will be forwarded by the commander concerned to The Surgeon General, ATTN: MEDPS–PO. The use of improper channels will result in considerable delay since AEC will return the application to the applicant pursuant to agreement with The Surgeon General. Guidance to the applicant in completing license application is provided in section II.

6. Procurement of Atomic Energy Commission regulations and forms. Supplies of the Atomic Energy Commission regulations and blank forms pertaining to the use and licensing of byproducts, special nuclear or source material may be obtained upon request from the U.S. Atomic Energy Commission, Division of Licensing and Regulation, Washington, D.C., 20545.

ARs

Section II. INSTRUCTIONS FOR COMPLETING LICENSE APPLICATIONS

(Item numbers keyed to format block numbers of AEC Forms 313 and 313a)

7. Form AEC 313 (Application for Byproduct Material License).

a. Item 1(a)—Name and Street Address of Applicant. Enter name and address of facility.

b. Item 1(b)—Street Address(es) at Which Byproduct Materials Will Be Used. Self-explanatory.

c. Item 2—Department To Use Byproduct Material. List all departments where isotopes may be used.

d. Item 3—Previous License Number(s). Self-explanatory.

e. Item 4—Individual User(s). Enter statement, "Users will be approved by the Radioisotope Committee."

f. Item 5—Radiation Protection Officer. Enter statement, "This officer will be appointed by the Radioisotope Committee." This officer will be the best qualified individual available and his duties are to be specifically assigned. Subsequent changes in personnel must be reported to The Surgeon General in accordance with provisions of paragraph 4, giving qualifications of the replacement.

g. Item 6(a)—Byproduct Material. Enter statement "See inclosure ------." List of acceptable radioisotopes for human use, see table I.

h. Item 6(b)—Chemical and/or Physical Form and Maximum Number of Millicuries of Each Chemical and/or Physical Form that You will Possess at Any One Time. Enter any item which has been established by adequate medical research and can be supplied by an approved medical drug corporation. Each isotope should be included in and not exceed that quantity listed in table I unless previously licensed or justified through correspondence with The Surgeon General, ATTN: MEDPS-PO.

i. Item 7—Describe Purpose for Which Byproduct Materials will be Used. Enter statement "See supplement A (Form AEC 313a)."

j. Item 8—Type of Training and *Item 9—Experience With Radiation.* Initially the training of the members of the Radioisotope Committee will be submitted. Subsequent changes in personnel of isotope committee will not require an amendment to license but must be reported to The Surgeon General giving qualifications of the replacement. See paragraph 4.

k. Item 10—Radiation Detection Instruments. List available instrumentation. Sophisticated instruments of a medical diagnostic type must be available. Survey instruments of a low-level capability must also be present for conducting surveys of the clinic for contamination. These survey instruments must be calibrated at least every 6 months and after each maintenance procedure or battery change. The calibration should include a check of at least 2 points on each scale. Use of check sources included with instruments does not constitute a calibration. High range instruments must be available for high level gamma emitters such as Gold 198 and Iodine 131 (IM-108, not acceptable).

l. Item 11—Method, Frequency, and Standards Used in Calibrating Instruments Listed Above, Item 12—Film Badges, Dosimeters, and Bio-Assay Procedures Used, and *Item 13—Facilities and Equipment.* Self-explanatory.

m. Item 14—Radiation Protection Program. A detailed standard operating procedure will be submitted describing method- of control, functions, and membership of the Radioisotope Committee, operation of radioisotope procurement, use and disposal, protection program and control. Individual names will not be used in the development of this SOP but responsibilities must be assigned by military or civilian position. Considerable time and correspondence have been occasioned in the past reviews of license applications due to lack of program coordination or documentation in the following areas:

(1) *Wipe testing.* This is required on all sealed sources every 6 months. A person must be designated by position who will be responsible for the performance of the wipe test. He must have adequate training and knowledge to know how to perform such a test safely. Procedures for performing the test must be given and an instrument with the capability of detecting 0.005 microcuries of activity must be available for counting. Strontium 90

beta applicators are considered as sealed sources.

(2) *Logs and records.*

(*a*) AEC Form 3 (Notice to Employees—Standards for Protection Against Radiation) must be posted in a conspicuous location.

(*b*) AEC Form 4 (Occupational External Radiation Exposure History) and Form 5 (Current Occupational External Radiation Exposure) must be maintained. This record should also be entered on DD Form 1141 (Record of Exposure to Ionizing Radiation) in accordance with AR 40–431.

(*c*) The license and the facility SOP must be posted or readily available.

(*d*) Inventory must be maintained of each radioisotope received, used, lost through decay, or disposed of. Periodic inventory balance will be determined at frequent intervals, depending upon the magnitude of the half-life of the isotope in use, such as monthly for Iodine 131. DA Form 8–212 (Narcotic and Controlled Drug Record) may be adapted for this purpose.

(*e*) Wipe-tests records will be kept on a consecutive entry log and the removable activity must be recorded in microcuries.

(*f*) Instrument logs must be maintained indicating calibration and maintenance.

(*g*) Results of surveys must be maintained.

(3) *Signs, labels, and barriers.* Isotopes must be labeled with the radiation sticker of yellow and magenta, and the isotope and activity as of a certain date per cc or unit must be recorded on the label. The storage area should be neat and segregated by type. Gamma emitting isotopes must be so stored that the radiation level at the edge of the storage area does not exceed 2 mr/hr. A large sign "Caution—Radioactive Material" must be posted at the storage area (Title 10, Code of Federal Regulations (part 20), and AR 385–30).

(4) *Marking controlled area—when Gamma emitters are used for therapy.* Any activity in excess of 2 mr/hr in a potentially occupied area is considered to be a controlled area and will be marked with appropriate signs or symbols ((3) above). The radiation at the skin surface of the patient will be measured and recorded so that nursing and other appropriate personnel can be properly advised regarding instituting their activities in close association with the patient. Nurses and others caring for this type of patient should be informed of the hazards of radiation and monitored by film badges or dosimeters. Visitors should be warned of the radioactive material and should be restricted to an area below 2 mr/hr. Lead shielding may be required. If the dose rates in rooms adjacent to the patient are equal to, or above 2 mr/hr, these rooms should not be occupied by patients.

n. Item 15—Waste Disposal. Wastes may be disposed of by holding and permitting complete decay, then disposal of the no longer active material. Liquid wastes may be disposed of through the sanitary sewer providing the requirements of the Code of Federal Regulations, title 10, part 20, are met. Solid radioactive wastes cannot be buried or burned without special permission. Disposal should be in accordance with AR 755–380. Title 10, part 20, Code of Federal Regulations states that AEC approval must be granted before disposal of radioactive material by incineration. To secure approval, the applicant must provide the following information:

(1) The type, quantity, and chemical form of byproduct material to be incinerated.

(2) The method of measurement of, or estimation of, the concentration of radioactive material in the effluent at the point it leaves the stack.

(3) Methods of control to insure that particulates and concentrations of radioactive materials are not released which could result in exposures of individuals in excess of the levels set forth in AEC's "Standards for Protection Against Radiation," Part 20.

(4) The height of the incinerator stack, expected dilution factors (if necessary) and the height of and distance to buildings in the surrounding area.

(5) The procedures which will be followed to prevent overexposure of personnel dur-

ing all phases of the operation, particularly the instructions given to the persons handling the combustibles and the ashes.

(6) The method for disposing of contaminated ash. An example of an approved action is as follows:

Example: The anticipated activity to be used at any one time for metabolism studies will not exceed 30 microcuries of Carbon 14. Waste inherent in such experimental procedures will include for the most part absorbent paper used to contain accidental spills and that paper used for wiping pipette tips, etc. At times laboratory animal carcasses will be included in this type of radioactive waste particularly desirable to incinerate.

Combustion will take place in a closed brick-type furnace at the sewage plant using both methane from sewage gas and natural gas. The temperature ranges from 1200° to 1400° F. and will remain constant for a period of nearly 24 hours to insure complete combustion. The radioactive waste will be mixed with both dry and wet nonradioactive waste in sufficient volume so that concentrations of effluents will not exceed the amount as specified in the National Bureau of Standards Handbook 53 or part 20, appendix B, table II, Code of Federal Regulations. However, the anticipated activity to be incinerated should not exceed a total of 5 to 10 microcuries per week except for an occasional small animal carcass. Depending on the activity of the waste, incineration will occur once weekly.

o. Item 16—Certificate. The license is always for the facility, therefore all copies will be signed either by the commandant or executive officer.

8. Form AEC 313a (Application for Byproduct Material License—Supplement A—Human Use). *a. Item 1(a)—Using Physician's Name* and *Item 1(b)—Name and Address of Applicant.* Enter the facility, name, and address.

b. Item 2—License of the Using Physician and *Item 3—A Statement of the Using Physician's Clinical Radioisotope Experience.* Enter statement, "Not applicable."

c. Items 4(a), (b), (c), and (d)—Proposed Diagnosis or Treatment. This should be completed for all accepted isotopes and uses.

d. Item 5—Proposed Dosage Schedule. Proposed dosage range for each specific condition to be diagnosed or treated is listed in table I. Any dosage which exceeds accepted dosage levels must be fully explained. Local radioisotope committee will not approve dosage levels in excess of published levels without prior approval of The Surgeon General.

e. Item 6—If Byproduct Material Will Not Be Obtained in Pre-Calibrated Form . . .. Describe Identification, Processing, and Standardization Procedures. Self-explanatory.

f. Item 7—The Proposed Use of Byproduct Material Has Been or Will Be Approved by the Medical Isotope Committee. Enter Statement, "Yes."

g. Item 8—Hospital Facilities for Individual Practice Use Only. Enter statement, "Not Applicable."

h. AEC Form 313a, page 3. This form will be completed and submitted on all individuals and demonstrate approval by the Radioisotope Committee. Resubmission of page 3 addressed to The Surgeon General (par. 4), is required when the individual is certified in a new use of, or a new radioisotope. The resubmission does not require an Atomic Energy Commission amendment to the license.

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MILITARY PUBLICATIONS

INDEX OF ADMINISTRATIVE PUBLICATIONS

(Army Regulations, Special Regulations, Circulars, Pamphlets, Department of the Army Posters, Commercial Traffic Bulletins, Military Traffic Management Bulletins, Joint Chiefs of Staff Publications, General Orders, and Bulletins)

Current as of 2 July 1964

CHANGE No. 4

HEADQUARTERS
DEPARTMENT OF THE ARMY
WASHINGTON, D.C., *9 July 1964*

DA Pam 310-1, 24 December 1963, is changed as follows:

1. Army Regulations (AR) and Special Regulations (SR).

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NO.	DATE	TITLE, DISTRIBUTION, CHANGES
		ADMINISTRATION
1-11‡	17 Jan 58	Army management structure. [C] Changes 1, 3-4, 7-10
1-18‡	20 Feb 64	Military conferences and other activities having international implications (reports control symbol OSD-1084) (R1)). [E plus GENMISH (5)]
1-20‡	19 Feb 64	Legislative liaison. [D; NG & USAR. D]
1-25‡	29 Apr 64	United States—Canadian Defense Development Sharing Program. [C]
1-37‡★	28 May 64	Utilization of resources for support on Non-Army agencies (reports control symbol CSGPA-657 (R1)). [D]
1-38‡	Jan 64	Defense Utilization Manual. [D] Change 1★
1-40‡	24 Oct 63	Visits to installations, activities, and units within CONUS and to oversea areas. [C] Change 1★
1-110	28 Jun 61	Contracting for management advisory services and operations research studies and projects. [C; NG D] Changes 1-2★
1-251‡	30 Nov 61	Army data processing systems program [C; NG & USAR C] Changes 1-3★
		ORGANIZATION AND FUNCTIONS
10-7	26 Jun 63	United States Continental Army Command. [C, NG D] Change 1★
10-8	27 Apr 62	[Delete entry]
10-11‡	31 Dec 63	United States Army Materiel Command [C, NG D]
10-14‡★	15 Jun 64	Logistics headquarters. [C; NG D, USAR C]
10-16‡	8 Jan 64	United States Army Nuclear Weapon Systems Surety Group [C, NG: C]
(C) 10-122‡★	13 May 64	United States Army Security Agency (U) [D]
10-130‡	17 Dec 63	United States Army Strategy and Tactics Analysis Group. [D]
		ARMY PROGRAMS
(S) 11-12	26 Apr 60	Priorities for supply and oversea command levels (U) [D] Change 2
11-14‡	7 Jan 63	Materiel readiness [A, NG & USAR, A]
11-15	11 Apr 56	Troop bases (reports control symbol CSGPA-381) [E] Changes 1-2
11-20‡★	28 May 64	Army cost reduction program [B, NG & USAR D]
		BOARDS COMMISSIONS, AND COMMITTEES
15-1‡	21 Jun 63	Committee management. [D NG.D] Change 1
AR 15-22‡★	18 May 64	Nuclear Weapon Accident Investigation Board (CONUS) [D, NG & USAR D]
15-160‡	26 Mar 64	Department of the Army procedures in processing disability cases under Chapter 61 Title 10, United States Code [E, NG: D]
		INSPECTIONS AND INVESTIGATIONS
20-1‡	27 Jun 63	Inspector General activities and procedures [A, NG & USAR, A] Change 1
		MILITARY JUSTICE
22-15‡	20 Nov 63	Nonjudicial punishment. [A, NG & USAR A] Change 1★
22-45‡	19 Feb 64	Report of summary and special court-martial cases (reports control symbol JAG-2 (R3)). [C; NG: D]
		WELFARE, RECREATION, AND MORALE
28-12‡	20 Nov 63	The Army Entertainment Program Theatre Arts Scholarship Plan [A]
28-62	12 Jun 59	Army and Air Force Motion Picture Service [D, NG D] Changes 3, 5-7★
28-63	13 Nov 59	Operation of Army, and Air Force theaters [C, NG, D] Changes 1-2
28-73	23 Dec 63	United States Army Chorus [A]
28-95‡★	2 Jun 64	Army flying club program. [C, NG, D, USAR C]

This change supersedes C 3, 21 May 1964.

NO.	DATE	TITLE, DISTRIBUTION, CHANGES
		FOOD SERVICE
30-30‡	20 Jan 64	Meal rates for field and garrison ration messes. [A, NG & USAR: A]
		SUBSISTENCE SUPPLY
31-60‡★	2 Jun 64	Operational rations. [A, NG: C]
31-61‡★	2 Jun 64	Submission and approval of issue factors, determination of requirements, and preparation and processing of requisitions. [C]
31-100‡	21 Aug 63	Subsistence supplies authorized for issue and sale in commissaries and commissary stores. [D]
31-200‡	4 Apr 61	Army commissary operating procedures. [A, USAR: A] Changes 1-4
		CLOTHING AND TEXTILE MATERIEL
32-5‡	17 Dec 63	Introduction of new clothing and textile items into Department of Defense supply system. [D]
32-15	28 Nov 55	[Delete entry]
		FINANCE AND FISCAL
35-14‡	31 Jan 63	Reimbursement for accessorial charges. [C] Changes 2-3
35-19‡★	28 May 64	Financing costs of transportation of AAFES and AAFMPS materiel to and from Army and Air Force oversea organizations. [C, NG D]
35-227	19 Jul 57	[Delete entry]
35-232‡	12 Feb 64	Funding for commercial line haul transportation within CONUS under the appropriation "Operation and Maintenance, Army". [C; NG D]
35-247‡★	18 May 64	Military compensation rate tables [C; NG: D]
35-251	22 Jun 59	Appropriation and fund accounting reports compiled by accounts offices. [C; NG, D] Changes 1-5, 7-9, 11
35-273	20 Jul 60	Accounting policy and procedures for intragovernment intradefense, and intradepartment transactions. [C, NG, C] Changes 1-3
35-275	25 Nov 57	[Delete entry]
35-285	24 Apr 58	[Delete entry]
		AUDIT
36-20‡	21 Jan 64	U.S. General Accounting Office audits. [C]
		FINANCIAL ADMINISTRATION
37-10‡	21 Jan 64	Internal review. [C; NG; D]
37-15‡	10 Jan 64	Budget procedures. [C, NG & USAR, C] Changes 1-3★
37-21	25 Jan 60	Prerequisites for recording obligations. [C; NG C] Changes 1, 3-4, 6
37-40‡	28 Apr 63	Army production base support program report (reports control symbol CSGLD-1123. [E] Change 1★
37-63‡	28 Feb 58	Working capital funds—Army stock fund uniform accounting and reporting criteria for home offices. [C (CONUS), NG; D] Changes 4-5, 7
37-76‡	30 Dec 63	Financial reports for Department of Army Industrial Fund [C] Change 1
37-80‡★	1 May 64	Financing, funding, accounting, and reporting for Military Assistance Sales to eligible foreign countries and international organizations. [D]
37-81	15 Nov 62	Financing, funding, accounting, and reporting for the Military assistance Grant Aid Program. [DA Changes] 1-3
37-82‡	31 Jan 63	Financing accounting, control, and reporting of military procurement by the Federal Republic of Germany. [D] Change 1
37-100‡★	15 Jun 64	The Army Management Structure (Fiscal Code). [C NG: C]
37-102‡	12 Jun 57	Army Fiscal Code. [C; NG: C] Changes 1-34
37-102-5‡	27 Sep 63	Finance and accounting for installations, Department of Defense fiscal code. [C; NG: C] Changes 1-2
37-103‡	6 Dec 56	Finance and accounting for installations disbursing operations. [C; NG & USAR C] Changes 1-49★
37-104‡	2 Dec 57	Finance and accounting for installations, pay and allowances of military personnel. [A, NG & USAR A] Changes 1-85★
37-105‡	6 Sep 57	Finance and accounting for installations, civilian pay procedures. [C, NG: C] Changes 1-16
37-105-2‡	26 Dec 63	United States General Accounting Office Salary Table No 42 [C; NG C] Change 1
37-106‡	9 May 58	Finance and accounting for installations—travel and transportation allowance [B, NG C] Changes 1-20★
37-115‡★	15 Jun 64	Accounting for special post engineer projects. [C, NG: C]
37-335‡	11 Dec 62	Financial accounting and reporting for Army excess inventory and sales of surplus and foreign excess personal property [C, NG: D] Changes 1-2
		MEDICAL SERVICE
40-1	4 Nov 60	Composition, mission, and functions of the Army Medical Service [A, NG & USAR: A] Changes 3-4, 7-8
40-3‡	26 Mar 62	Medical, dental and veterinary care. [A, NG & USAR A] Changes 1-10
40-4‡★	15 May 64	Army Medical Service facilities [A; NG; C; USAR: A]
40-5‡★	*10 Apr 64*	*Preventive medicine. [A, NG: A]*
(C) 40-11‡	21 Jan 64	Emergency medical situation report (U) (reports control symbol MED 202). [D (CONUS), NG: D (CONUS)]
40-13‡	29 Jan 64	Radiological emergency medical teams. [D, NG & USAR D]
40-18‡	26 Feb 64	Evaluation of commercial items of medical, dental, veterinary, and other materiel at Army Medical Service facilities. [D, USAR: D]
40-19‡	20 Feb 64	Sterilizing medical, surgical, and dental materiel. [A, NG B USAR A]
40-20‡★	25 May 64	Evacuation of patients. [A; NG D; USAR A]
40-30‡	10 Dec 63	*Medical service for dependents in the Metropolitan area of Washington [10 copies Each DA Form 12-9 account in MDW area]*
40-37‡★	12 Aug 63	Radioisotope license program (human use). [C]
40-56	8 Dec 59	[Delete entry]
40-219‡	2 Mar 64	Professional specialty board certification. [B; NG, D]
40-330‡★	19 May 64	Rates for Army Medical Service activities for fiscal year 1965. [C]
40-332‡★	19 Jun 64	Preparation of DD Forms 7 and 7A for billing purposes. [C; NG: D]
40-501‡	5 Dec 60	Standards of medical fitness. [A; NG & USAR. A] Changes 1-13★
40-535‡★	15 May 64	Worldwide Aeromedical evacuation. [A; NG: D; USAR: A]
40-562‡	10 Dec 63	Immunization requirements and procedures. [A; NG & USAR: A]
40-685	18 Dec 50	[Delete entry]
		TRANSPORTATION AND TRAVEL
55-16‡	9 Jan 63	Movement of cargo by air and surface—including less than release quantity and parcel post shipments. [C; NG: D] Change 1
55-27‡	15 Nov 63	Vehicle movement schedule (reports control symbol DD-DSA (M) 238 (DTMS)) [D, NG, D]
55-35‡	11 Jun 62	Utilization of cargo trailers in roll-on/roll-off service. [D] Change 1
55-42‡	16 Apr 62	Shipment of household goods and personal baggage. [C; NG, D] Changes 1-5
55-44‡	5 Feb 64	Policy and reporting incident to labor disputes affecting transportation. [C]
55-46	16 Nov 59	Travel of dependents and accompanied military and civilian personnel to, from, or between oversea areas. [A, NG D] Changes 1-6, 9-12
55-52‡	23 Mar 64	Reports of peacetime and mobilization movement requirements for bulk (unpackaged) petroleum, chemicals, acids, and gases Peacetime RCS DD-DSA (Q) 208 (DTMS)—Mobilization RCS DD-DSA(A)209(DTMS). [E (CONUS)]
55-60‡	21 Oct 63	Official table of distances Continental United States, Alaska, Hawaii, Canada, Canal Zone, Central America, Mexico and Puerto Rico. [C; NG, C]. Changes 1★
55-113‡	14 Feb 64	Movement of units within Continental United States. [C (CONUS); USAR A]