MATERIALS LICENSE

Amendment No. 24

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated August 1, 1996
1. Department of the Army Dwight D. Eisenhower Army Medical Center	3. License Number 10-12044-03 is amended in its entirety to read as follows:
2. ATTN: HSHF-HP Fort Gordon, Georgia 30905-5650	4. Expiration Date July 31, 2003 (extended)
	5. Docket or Reference No. 030-11936 (10-12044-04)

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Iodine 131	C. Any unsealed form for preparation and administration as specified in 10 CFR 35.300	C. 111 gigabecquerels (3 curies)
D. Any byproduct material with a half-life less than 120 days except iodine 131	D. Any form for uses described in 10 CFR 35.300 initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.	D. As needed, not to exceed 3.7 gigabecquerels (100 millicuries) per container
E. Any byproduct material identified in 10 CFR 35.500	E. Any diagnostic sealed source identified in 10 CFR 35.500 and registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	E. As needed (See Item 9.E)
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. As needed

d1

M120

License Number 10-12044 03

Docket or Reference Number 030-11936

Amendment No. 24

MATERIALS LICENSE
SUPPLEMENTARY SHEET

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
G. Any byproduct material with atomic numbers 3 - 83, inclusive, with a half-life less than 120 days	G. Any	G. Not to exceed 925 megabecquerels (25 millicuries) per nuclide
H. Any byproduct material with atomic numbers 3 - 83, inclusive, with a half-life equal to or greater than 120 days	H. Any	H. Not to exceed 925 gigabecquerels (25 millicuries) per nuclide
I. Hydrogen 3	I. Any	I. 1.85 gigabecquerels (50 millicuries)
J. Hydrogen 3	J. Foil and/or plated source in a detector cell registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	J. 18.5 gigabecquerels (500 millicuries)
K. Nickel 63	K. Foil and/or plated source in a detector cell registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	K. 11.1 gigabecquerels (300 millicuries)
L. Cesium 137	L. Sealed sources	L. 4837 terabecquerels (131 curies)
M. Americium 241	M. Sealed sources	M. 1.11 gigabecquerels (30 millicuries)
N. Gadolinium 153	N. Sealed sources (North American Scientific Model MED 3601)	N. Not to exceed 11.1 gigabecquerels (300 millicuries) each, 37 terabecquerels (1 curie) total
O. Cesium 137	O. Sealed sources (CEA-ORIS-LAPIB Model 437C)	O. 188.7 terabecquerels(5100 curies), not to exceed 62.9 terabecquerels (1700 curies) per source
P. Cesium 137	P. Sealed sources	P. 18.5 gigabecquerels (500 millicuries)

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 10-12044-03

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9. Authorized Use:

A. Medical use described in 10 CFR 35.100
B. Medical use described in 10 CFR 35.200
C. and D. Any radiopharmaceutical therapy approved in §35.300
E. Medical use described in 10 CFR 35.500
F. *In vitro* studies
G.- I. For possession and use in *in vitro* testing, laboratory studies, and research including animal studies.
J.- K. For possession and use of foil and/or plated source in a detector cell (registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation) for use in compatible gas chromatographs for sample analysis.
L. Two sealed sources for use in J.L. Shepherd Model 89 shielded calibration unit for the calibration of instruments.
M. For use in anatomical markers and instrument calibration.
N. For possession and use in an ADAC Vantage Nonuniform Attenuation Correction System for imaging purposes. For storage in a shipping cask pursuant to source exchange.
O. For possession and use in a Compagnie ORIS Industrie Model IBL-437C self-contained irradiator for in vitro irradiation of blood, blood products, cells and tissues.
P. For possession and use in the calibration of instruments.

CONDITIONS

10. Location for use: Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia

11. Radiation Safety Officer: CPT Michael A. Tressler
Alternate Radiation Safety Officer: SFC John R. Olson.

12. A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

13. Sealed sources containing licensed material shall not be opened by the licensee.

License Number
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030-11936

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MATERIALS LICENSE
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CONDITIONS

Continued -

14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or
(ii) they contain only a radioactive gas; or
(iii) the half-life of the isotope is 30 days or less; or
(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
(v) they are not designed to emit alpha particles, are in storage, and are not being used.

However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Materials Licensing/Inspection Branch, 101 Marietta Street N.W., Suite 2900, Atlanta, Georgia, 30323-0199. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

15. Maintenance, repair, cleaning, replacement and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 10-12044-03

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CONDITIONS

Continued -

16. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by the NRC.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

17. The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every six months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).

18. The device manufacturer's Instruction Manual for the International CIS Model IBL-437C irradiator shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

19. The licensee shall not perform repairs or alterations of the International CIS Model IBL-437C irradiator or the J.L. Shepherd Model 89 shielded calibration unit involving removal of shielding or access to the licensed material. Removal replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

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

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

B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

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

D. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

License Number 10-12044-03

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

CONDITIONS

Continued -

21. In addition to the possession limits in item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

22. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities listed in Condition 10 pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

23. Except as specifically provided otherwise in the license and as provided in 10 CFR 35.51, the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive that the regulations.

A. Application dated December 14, 1992 [renewal application]

B. Letters dated:

1. May 25, 1993 [change of RSO and Alternate RSO]
2. July 15, 1993 [supplemental information]
3. May 5, 1994 [change of RSO and Alternate RSO]
4. June 7, 1995 [change of RSO, change in waste storage room]
5. July 21, 1995 w/endorsements [change of Alternate RSO]
6. April 4, 1996 [Add ADAC device]
7. August 1, 1996 [Change bioassay program]

C. Reference March 1, 1996 letter from NRC on extension of expiration date per 10 CFR 30.36.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

DATE OCT 10 1996

BY David J. Collins

Region II, Division of Nuclear Materials Safety
101 Marietta Street, N.W., Suite 2900
Atlanta, Georgia 30323-0199

N:\MLICENSE\10-12044.A24

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO
ATTENTION OF

October 2, 1996

Preventive Medicine
and Wellness Division

U.S. Nuclear Regulatory Commission
Region II
202 Marietta Street, N.W.
Suite 2900
Atlanta, Georgia 30323

Dear Sir or Madam:

The enclosure is a request to amend the Nuclear Regulatory Commission license for Dwight David Eisenhower Army Medical Center (NRC By-Product Material License No. 10-12044-03).

If I can be of any further assistance please do not hesitate to call me at (210) 221-6612.

Sincerely,

Eric G. Daxon, PhD, CHP
Colonel, U.S. Army
Radiation Protection Staff
Officer

Enclosure

Copy Furnished:

Commander, U.S. Army Center for Health Promotion and Preventive Medicine, Attention: MCHB-MR-HM, 5158 Blackhawk Rd, Aberdeen Proving Ground, Maryland 21010-5422 (with enclosure)
Commander, Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia 30905-5650 (withcut enclosure)

Retain w docket

CONVERSATION RECORD

TIME | DATE

TYPE ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference: Army

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU: Eisenhower Med Ctr

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO:

SUBJECT: Iodines

Fort Gordon GA

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Bioassay req'd for 10% Rg 8.20 Table 1 values. OK

Req'd bioassay ~~not~~ acceptable — should ~~to~~ say >30mCi

OK to 8.20 conforms to Rg 4.9 guidelines

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
David Collins	David J. Collins	8/28/96

ACTION TAKEN

SIGNATURE	TITLE	DATE

DEPARTMENT OF THE ARMY
HEADQUARTERS DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON, GEORGIA 30905-5650

July 25, 1996

Health Physics Office

U. S. Nuclear Regulatory Commission, Region II
101 Marietta Street, N. W.
Suite 2900
Atlanta, Georgia 30323

Dear Sir:

Enclosed is a courtesy copy of our request to amend Nuclear Regulatory Commission License Number 10-12044-03. The original has been forwarded to you through required military channels. This copy, however, is forwarded to you to allow timely review.

Sincerely,

Michael A. Tressler
Captain, U. S. Army
Chief, Health Physics Office

DEPARTMENT OF THE ARMY
HEADQUARTERS DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON, GEORGIA 30905-5650

MCHF-HP (385-11m)

2 Aug 96

MEMORANDUM FOR Headquarters, U. S. Army Medical Command, ATTN: MCHO-CL-W, 2050 Worth Road, Fort Sam Houston, TX 78234-6000

SUBJECT: Request for Amendment to Nuclear Regulatory Commission License Number 10-12044-03, Dwight David Eisenhower Army Medical Center, Fort Gordon, GA 30905-5650

1. Enclosed is our letter to the U. S. Nuclear Regulatory Commission (NRC), Region II, requesting that our NRC License Number 10-12044-03 be amended to replace the current bioassay program with the enclosed bioassay program.

2. Following the review of our request, please forward the request to the NRC, Region II, office. A preaddressed envelope is enclosed for your convenience.

3. POC regarding this amendment to NRC License No. 10-12044-03 is CPT Tressler at COMM (706) 787-4692/6392, DSN 773-4692/6392.

FOR THE COMMANDER:

Encl

for Esther M. Prior
ROBERT W. PRIOR
Chief, Administrative Services

Encl

DEPARTMENT OF THE ARMY
HEADQUARTERS DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON, GEORGIA 30905-5650

Health Physics Office

1 Aug 96

SUBJECT: Request for Amendment to Nuclear Regulatory Commission License Number 10-12044-03, Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia 30905-5650

U.S. Nuclear Regulatory Commission, Region II
101 Marietta Street, N. W.
Suite 2900
Atlanta, Georgia 30323

Dear Sir:

Request that Nuclear Regulatory Commission (NRC) License Number 10-12044-03 be amended to replace the previous bioassay program with the enclosed bioassay program. This change is requested as the previous program is believed to be more restrictive than necessary. The previous program declared action levels and time periods for bioassays that were too labor intensive. Furthermore, the previous program included equipment specific steps for calibration and measurement that are made obsolete with a new biossay instrument.

The Radiation Safety Committee approved this request on July 24, 1996. The point of contact regarding this amendment for NRC License No. 10-12044-03 is Captain Tressler, (706) 787-4692/6392.

Sincerely,

Stephen N. Xenakis
Brigadier General, U. S. Army
Commanding

Enclosure

Personnel Bioassay Program

Personnel at Dwight D. Eisenhower Army Medical Center, Fort Gordon will implement and follow these provisions based on guidelines published in Regulatory Guide 8.20, "Applications of Bioassay for I-131," September 1979, and in Regulatory Guide 8.9, " Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," July 1993.

THYROID BIOASSAY FOR I^{131}

1. PURPOSE: This SOP defines the policies and procedures of Health Physics, Dwight David Eisenhower Army Medical Center (DDEAMC) in reference to the thyroid bioassay program for I^{131}, to include: equipment operation, quality control measures, investigational limits, frequency, and bioassay procedures.

2. SCOPE: This SOP is applicable to all personnel who may process or have been exposed to quantities of I^{131} in excess of the quantities listed in Table 1. The quantities shown in Table 1 apply to both the quantity handled at any one time or integrated as the total amount of activity introduced over any 3-month period.

Table 1
Activity Levels Above Which Bioassay for I^{131} is Necessary

FORM	TYPE OF OPERATION	VOLATILE	BOUND TO NONVOLATILE AGENT
Sealed	Any	1 mCi	10 mCi
Unsealed	Processes in Open Room	0.1 mCi	1 mCi
Unsealed	Processes Within Fume Hood	1 mCi	10 mCi
Unsealed	Processes Within Glovebox	10 mCi	100 mCi

3. RESPONSIBILITIES:

a. Chief, Health Physics -- Maintains a functioning and ongoing bioassay program available to those personnel who use radioactive iodine.

b. Principal Authorized Users -- Enforce the participation at the required frequency of all personnel who have performed iodination procedures or could have possibly been exposed to such procedures.

c. Radiation Workers -- Will ensure that proper procedures are followed, to include use of protective equipment when performing iodination procedures.

d. Dosimetry Custodian -- Forwards all bioassay results to Redstone Arsenal, Alabama. The

form appearing in Appendix A or similar form may be used.

e. Head Nurse, 9W -- Selects personnel from 9W to be bioassayed based on contact with ablation patients. Also selects personnel on a random basis to ensure no accidental uptakes have occurred.

4. PROCEDURES:

a. Baseline bioassays will be performed on all newly arriving personnel to 9W, Health Physics, and Nuclear Medicine.

b. Periodic bioassay measurements shall be scheduled based on the unlikely exposure of an individual that could result in internal deposition of radioactive material.

(1) Thyroid ablation procedures using unsealed/unbound I^{131} require bioassay measurement of workers' thyroids within 72 hours (but not sooner than 24 hours) of potential exposure.

(2) Other special bioassay monitoring shall be determined by the RPO and conducted at established frequencies.

c. Termination bioassays should be performed when an individual is no longer subject to the bioassay program because of termination of employment or change in employment status. Termination bioassay measurements should be made, when practicable, to ensure that any unknown intakes are quantified.

5. ACTION LEVEL:

a. IAW the ALARA (As Low As Reasonably Achievable) Program, evaluation and investigation limits have been established to ensure the thyroid burden remains ALARA. When an individual's thyroid burden exceeds prescribed limits, an ALARA investigation will be conducted by Health Physics and the supervisors of the individual concerned.

b. A Level I (formal) evaluation for very small intakes (> 0.02 ALI) will be conducted when the thyroid burden exceeds 0.133 μCi for I^{131}.

c. A Level II (formal) investigation for intakes (> 0.1 ALI) will be conducted when the thyroid burden exceeds 0.665 μCi for I^{131}. Restriction of workers exceeding Level II investigation levels for work involving unsealed or unbound iodine shall be determined and implemented by the RPO as appropriate.

d. Other special evaluations shall be conducted by the RPO as appropriate based on the isotope, levels of activity, potential for intake, and data trends. Intakes exceeding 0.02 ALI and 0.1 ALI shall be trigger points for Level I evaluations and Level II investigations respectively.

6. PROBE CALIBRATION

a. DAILY, BEFORE BIOASSAYS ARE PERFORMED

1. Laboratory background in the bioassay channel must be measured over a period equal to the actual thyroid measurement period.

2. Equipment efficiency must also be calculated by measuring a Ba^{133} source. The measured counts per minute is divided by Ba^{133}'s known disintegrations per minute to determine efficiency.

b. MONTHLY: A chi square test will be performed monthly.

7. THYROID MEASUREMENT: Thyroid measurements will be performed IAW manufacturer's specifications.

8. RECORDING DATA

a. Calculate the minimum detectable activity (MDA) in µCi.

b. If personnel exceed MDA, Whole Body Committed Effective Dose Equivalent (CEDE) and Thyroid Dose must be calculated and reported.

DEPARTMENT OF THE ARMY
HEADQUARTERS DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON, GEORGIA 30905-5650

APPENDIX A (SAMPLE FORM TO AIRDC)

MCHF-HP

10 January 1996

MEMORANDUM FOR US Army Ionizing Radiation Dosimetry Center, US Army TMDE Activity, ATTN: AMSMI-TMDE-SR-D, Bldg 5417, Redstone Arsenal, AL 35898-5400

SUBJECT: Bioassay Results

1. The following personnel were potentially exposed to NaI-131 and were bioassayed IAW Reg Guide 8.20.

STAFF MEMBER	SSN	ABLATION DATE	BIO DATE	µCi I - 131	DOSE WB	DOSE THY

2. MDA is x.xx nCi.

3. POC is 2LT Gumboc at (706) 787-4692 or DSN 773-4692.

MICHAEL A. TRESSLER
CPT, MS
Radiation Protection Officer