

MATERIALS LICENSE

Amendment No. 61

rsuant 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, 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.

<p style="text-align: center;">Licensee</p> <p>1. Department of the Army Walter Reed Army Medical Center (WRAMC)</p> <p>2. Washington, D.C. 20307-5001</p>	<p>In accordance with letter dated April 8, 1992, 3. License number 08-01738-02 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 1993</p> <p>5. Docket or Reference No. 030-01317</p>
<p>6. Byproduct, source, and/or special nuclear material</p>	<p>7. Chemical and/or physical form</p> <p>8. Maximum amount may possess a under this license <i>NRC</i></p>

A. Any byproduct material with
atomic numbers 1-83

B. Iodine 131
C. Xenon 133
D. Krypton 85
E. Gold 198
F. Phosphorus 32
G. Carbon 14
H. Iodine 125
I. Iridium 192
J. Chromium 51
K. Sulfur 35
L. Hydrogen 3
M. Molybdenum 99

N. Technetium 99m
O. Strontium 90
P. Cesium 137

Q. Gadolinium 153
R. Iodine 125

S. Iodine 125

T. Iodine 125

A. Any

B. Any
C. Any
D. Any
E. Any
F. Any
G. Any
H. Any
I. Any
J. Any
K. Any
L. Any
M. Molybdenum 99/
Technetium 99m
Generators

N. Any
O. Sealed sources
P. Sealed sources
(3M 6D6C-CA)

Q. Sealed sources
R. Sealed sources
(Norland Inst. Co.,
Model 178A591A)

S. Sealed sources
(3M Company seeds)

T. Sealed sources
(AECL Models C235 or
C324, or Amersham Corp.
Model IMC.P2)

A. 400 millicuries of each
radionuclide with a total
possession limit of 26
curies

B. 2 curies
C. 2 curies
D. 1 curie
E. 1 curie
F. 2 curies
G. 2 curies
H. 1 curie
I. 1 curie
J. 750 millicuries
K. 1 curie
L. 5 curies
M. 23 curies

N. 23 curies
O. 500 millicuries
P. 2 curies

Q. 2 curies
R. 400 millicuries

S. 500 millicuries

T. 4 sources, not to exceed
300 millicuries each

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

08-01738-02

Docket or Reference number

030-01317

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(Items 6., 7. & 8. continued)

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
U. Cesium 137	U. Sealed sources	U. 1,200 millicuries
V. Cobalt 60	V. Sealed sources	V. 500 millicuries
W. Americium 241	W. Any	W. 100 microcuries
X. Americium 241	X. Sealed sources (Monsanto Model NRC-2704)	X. 20.5 curies
Y. Nickel 63	Y. Sealed sources and foils	Y. 1 curie
Z. Iodine 129	Z. Sealed sources	Z. 1 curie
AA. Thorium	AA. Any	AA. 5 kilograms
BB. Uranium	BB. Any	BB. 50 kilograms
CC. Uranium depleted in Uranium 235	CC. Plated Metal	CC. 400 kilograms
DD. Americium 241	DD. Sealed sources	DD. 200 millicuries
EE. Cesium 137	EE. Sealed source (American Nuclear Corporation Model 127)	EE. 150 curies
FF. Cesium 137	FF. Sealed sources (3M 6D6C-CA)	FF. 50 millicuries

9. Authorized use

- A. through T. Medical research, diagnosis, and therapy; research and development as defined in 10 CFR 30.4.
- U. through Z. Research and development as defined in 10 CFR 30.4; teaching.
- AA. and BB. Teaching and laboratory research.
- CC. Shielding
- DD. Standards and reference sources.
- EE. In an Eberline Instrument Corporation Model 8150-150 CS for calibration of instruments.
- FF. Instrument calibration.

CONDITIONS

10. Location of use:

Walter Reed Army Medical Center, Washington, D. C.; WRAMC Forest Glen Section and Annex, Silver Spring, Maryland; Walter Reed Army Institute of Research Animal Holding Facility, Fort Meade, Maryland; U.S. Army Medical Laboratory, WRAMC Department of Pathology, Fort Meade, Maryland; and U.S. Army Institute of Dental Research Facility, Fort Meade, Maryland; Rickman Building, 13 Taft Court, Rockville, Maryland; Key West Research Center, 9620 Medical Center Drive, Rockville, Maryland.

11. Radiation Safety Officer: LTC Arthur G. Samiljan.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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Amendment No. 61

(Continued)

CONDITIONS

12. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee, Col. Joan T. Zajtchuk, Chairman.
- B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.2 of 10 CFR Part 35.
- C. Physicians designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR Part 35, Subpart J.
13. Experimental animals administered licensed materials or their products shall not be used for human consumption.
14. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
15. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
16. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.
17. Notwithstanding the requirements of 10 CFR 35.49 (a) and (b), the licensee may use for medical use any byproduct material or reagent kit for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND).
18. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
19. If only a single radionuclide specified in NUREG 0767, is possessed, the possession limit is the quantity specified in Schedule of Limiting Possession Limits, NUREG-0767. If two or more radionuclides are possessed, the possession limit for each is determined as follows: the sum of the quotients of the quantities possessed divided by the quantities of those radionuclides specified in the Schedule of Limiting Possession Limits, NUREG-0767 shall not exceed unity.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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(20. continued)

CONDITIONS

- B. Before disposal as normal waste, radioactive waste shall be surveyed 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.
21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the 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 than the regulations.
- A. Application dated July 18, 1979
 - B. Letter dated January 13, 1984
 - C. Letter dated May 8, 1987
 - D. Letter dated March 16, 1988
 - E. Letter dated March 28, 1988
 - F. Application dated August 5, 1988
 - G. Letter dated September 23, 1988
 - H. Letter dated July 28, 1989
 - I. Letter dated September 12, 1989
 - J. Letter dated January 19, 1990
 - K. Letter dated July 16, 1990
 - L. Letter dated March 15, 1991
 - M. Letter dated July 11, 1991
 - N. Paragraphs 4 and 5 of the letter dated April 8, 1992
 - O. Letter dated August 4, 1992

Date SEP 09 1992

For the U.S. Nuclear Regulatory Commission

By

[Signature]
Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

SEP 09 1992

Docket Nos. 030-01317
030-06895

License Nos. 08-01738-02
08-01738-03

Department of the Army
Walter Reed Army Medical Center
ATTN: Col. Donald A. Johnson, MHA, M.A.C.H.E.
Chief of Staff
Washington, D.C. 20307-5001

Dear Colonel Johnson:

Subject: Routine Inspection Nos. 030-01317/92-001 and 030-06895/92-001.

From August 11 to 14, 1992, Ms. Penny Nessen and Mr. William Davidson of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Colonel Francis O'Donnell and LTC Arthur Samiljan of your staff at the conclusion of the inspection.

Based on the results of this inspection, it appears that some of your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instruction in Appendix A.

Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Encl 9b

Your cooperation with us is appreciated.

Sincerely,

A handwritten signature in dark ink, appearing to read 'M. Shanbaky', with a stylized flourish at the end.

Mohamed M. Shanbaky, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Enclosure: Appendix A, Notice of Violation

cc:

Public Document Room (PDR)

Nuclear Safety Information Center (NSIC)

District of Columbia

State of Maryland

LTC Arthur Samiljan, Radiation Safety Officer

APPENDIX A

NOTICE OF VIOLATION

Department of the Army
Walter Reed Army Medical Center
Washington, District of Columbia 20307-5001

Docket No. 030-01317
License No.08-01738-02

As a result of the inspection conducted from August 11-14, 1992, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1992), the following violations were identified:

- A. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, from July 1, 1991, to June 2, 1992, the licensee housed iodine-131 patients in room 7437 and did not verify that radiation levels in all unrestricted areas (i.e. the hallway and the doorway) did not exist which, if an individual were continuously present in the area, could have resulted in his receiving a dose in excess of two millirems in any one hour.

This is a Severity Level IV violation (Supplement IV).

- B. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on September 13, 1991, September 25, 1991, November 25, 1991, December 6, 1991, April 23, 1992, and June 2, 1992, the licensee administered to therapy patients, 129.7, 97.5, 151, 153.1, 153, and 58.6 millicuries of iodine-131, respectively, dosages which requires hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the nuclear medicine physician who helped administer the dosages.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 35.404(b) requires, in part, that immediately after removing the last temporary implant source from a patient, the licensee make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed and retain a record of the patient survey for three years.

Contrary to the above, on November 19, 1991, and April 17, 1992, the licensee removed cesium-137 temporary implant sources from a patient, made a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources had been removed, but did not retain a record of the patient survey for three years.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Department of the Army-Walter Reed Army Medical Center is hereby required to submit to this office within thirty days of the Date of the Letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

2.

3.

NA
SSA
PRC
BRD: YES
ESTED
SEC:

4.

RAO ng-
SSN 6-0
PRC STZ
BRD: YES
ESTED
SEC: I

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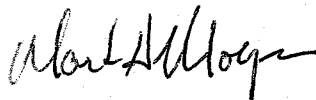
1.

COLINS, Cyn
SSN 228-68
PROGRAM START
BRIEFED: YES
ESTIMATED DUE
SECTION: Viru

MEMORANDUM FOR RECORD

SUBJECT: Spill, Nuclear Medicine Clinic

1. On 22 September 1989 SGT Moyes and SPC Ward of the Walter Reed Health Physics Office responded to a telephonic message from MAJ Minton of the Nuclear Medicine Clinic at 0900 in regard to a spill. Upon arrival information was gathered from MAJ Minton that the spill had occurred at 0300 and was a flood containing 5 μ Ci 99Tc. Information provided said that Edith Lima-Brown had dropped the flood, and fell in the liquid. She changed clothes and put her contaminated clothes and shoes in a bag. The spill was cleaned and covered. At the completion of that morning's shift, Ms Brown had taken her clothing and shoes home with her. At this point SFC Bautista was informed that these items must be retrieved. A survey was conducted and re-covered. The specimens were returned to the Health Physics Office and tested. Results showed that the spill area was still highly contaminated. SFC Bautista was notified that the area must be cleaned again.
2. Upon the 2nd arrival, the floor was found uncovered. SSG Dunkle claimed that the area was cleaned, and their survey instrument did not detect any contamination. A second survey was conducted and our instrument detected a high amount of radiation. We were also informed by SFC Bautista that they could not get in contact with Ms Brown because they did not have a current telephone number or address for her. Therefore the uniform and shoes were unable to be retrieved. The second survey was completed and the floor was re-covered before returning to the Health Physics Office. The second survey yielded results that were almost identical to those of the first survey.
3. At this point we were unable to contact Nuclear Medicine due to it being late Friday afternoon and the staff had already left for the weekend.

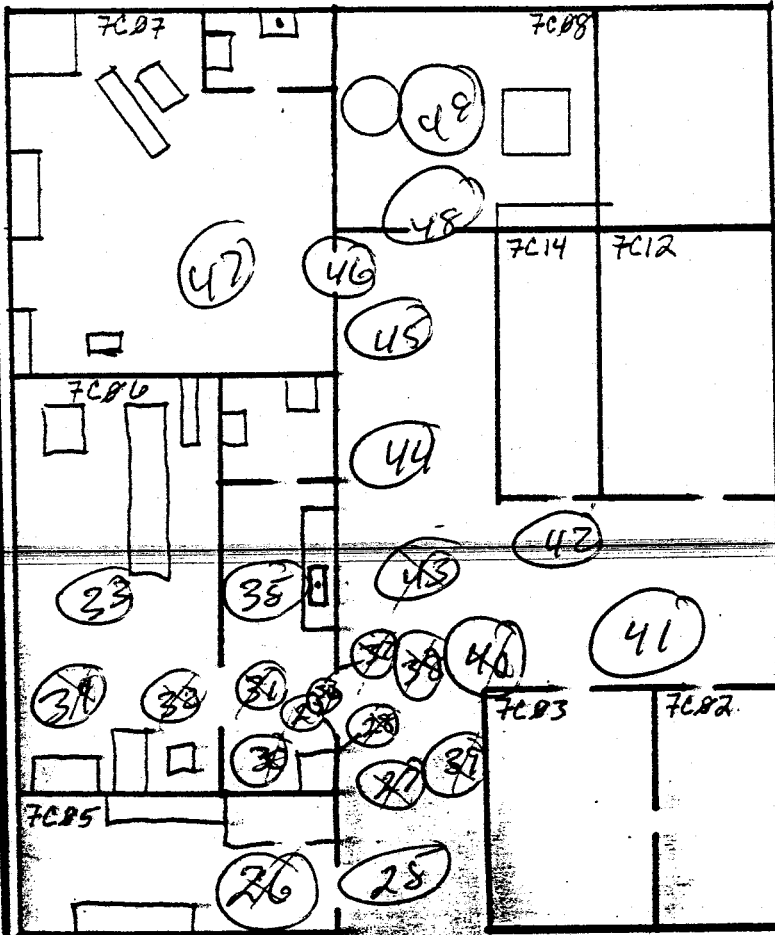


MARK A. MOYES
SGT, USA
Operations Section
WRAMC Health Physics Office

HEALTH PHYSICS LABORATORY SURVEY

PRINCIPAL USER: ANDERSON, JAY H. COL.		AUTH. NO: H274	SURVEYOR(S): Ward/Moyes	DATE: 22 Sep 89
ORGANIZATION: NUCLEAR MEDICINE SERVICE			SURVEY METER: L3	METER MODEL:
BUILDING NO: 2	ROOM NO: SUITE D	PHONE NO: 576-0177	SN: 12565 11928	CAL DUE: 11-20-90

ROOM SKETCH



QUESTIONS

	YES	NO	N/A
1. POSTING FORMS, SIGNS, AND LABELS			
A. NRC FORM 3			
B. NOTICE TO EMPLOYEES			
C. 10 CFR 19, 20, AND 21			
D. CAUTION RADIOACTIVE MATERIAL (CRM)			
1) ENTRANCE			
2) STORAGE AREAS			
3) WORK AREAS			
4) WASTE STORAGE AREAS			
E. CAUTION (HIGH) RADIATION AREA			
F. CAUTION AIRBORNE RADIOACTIVITY			
G. RADIOACTIVE WASTE WASH SINK (RWS)			
1) RWS LABEL			
2) SHELLFISH WARNING			
3) MAINTENANCE WARNING			
H. RADIOACTIVE REFRIGERATOR (RSR)			
1) CRM			
2) NO FOOD OR BEVERAGE ...			
3) MAINTENANCE WARNING			
I. RADIOACTIVE FREEZER (RSF)			
1) CRM			
2) NO FOOD OR BEVERAGE ...			
3) MAINTENANCE WARNING			
J. RADIOACTIVE CENTRIFUGE			
1) CRM			
2) MAINTENANCE WARNING			
K. NO EATING, DRINKING, OR SMOKING			
2. COPY OF AUTHORIZATION AVAILABLE			
3. TERMS AND CONDITIONS AVAILABLE			
4. CONDITION #2 FOLLOWED			
5. CONDITION #3 FOLLOWED			
6. CONDITION #4 FOLLOWED			
7. USER SURVEY LOG AVAILABLE			
8. SURVEY INSTRUMENT			
9. RWS LOG			

Highest Readings: mR/hr
CPM

COMMENTS:

SMEAR ANALYSIS

- ☐ ALL SMEARS SHOW LESS THAN 100 DPM OF REMOVABLE CONTAMINATION
- ☒ ALL SMEARS SHOW LESS THAN 100 DPM OF REMOVABLE CONTAMINATION EXCEPT:

SMEAR	DPM	SMEAR	DPM	SMEAR	DPM
26	Tc 99	610 dpm	29	Tc 99	1290 dpm
27	Tc 99	264 dpm	30	Tc 99	1288 dpm
28	Tc 99	1770 dpm	31	Tc 99	1222 dpm

TYPE OF ANALYSIS:

- ☒ AUTO GAMMA
- ☐ LIQUID SCINTILLATION

ANALYSIS PERFORMED BY: *W. J. Anderson*

COMMENTS:

DATE OF ANALYSIS:

32 Tc 99 584 dpm

34 Tc 99 638 dpm

36 Tc 99 15410 dpm

37 Tc 99 5872 dpm

38 Tc 99 698 dpm

39 Tc 99 1810 dpm

40 Tc 99 1760 dpm

43 Tc 99 228 dpm

*Reviewed on 26 Sept 89
all clear*

ACTION REQUIRED: ☒ YES ☐ NO

ACTION TAKEN:

25 Sept 89 Suite D

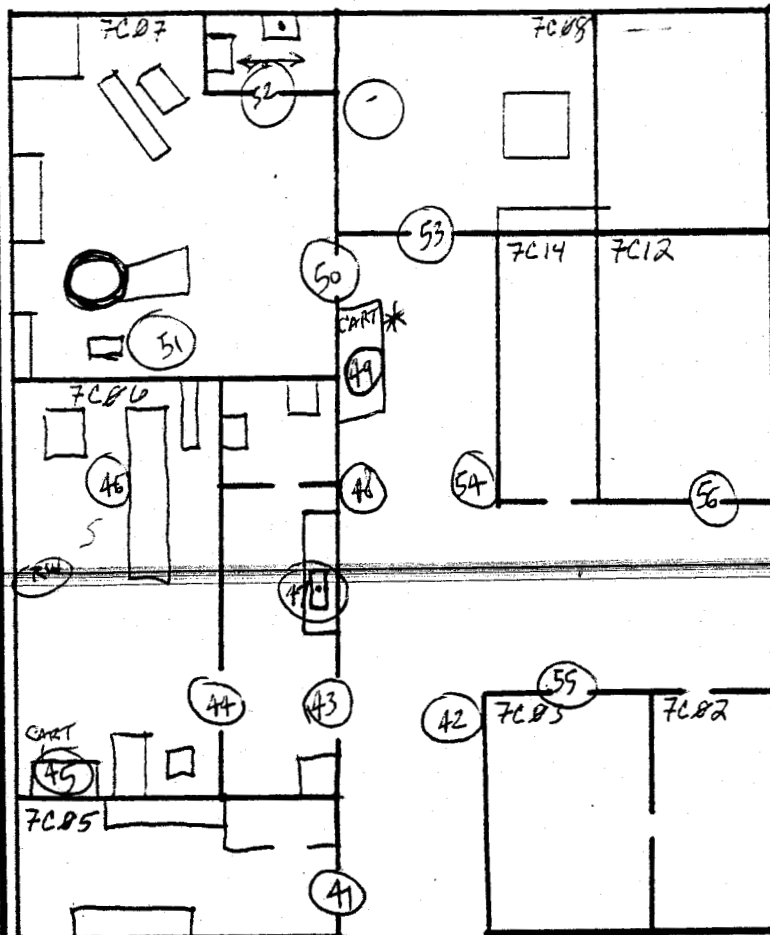
Reviewed: 1

W. J. Anderson

HEALTH PHYSICS LABORATORY SURVEY

PRINCIPAL USER: ANDERSON, JAY H. COL.		AUTH. NO: H274	SURVEYOR(S): FONTANE	DATE: 26 SEP 89
ORGANIZATION: NUCLEAR MEDICINE SERVICE			SURVEY METER: L	METER MODEL: 3
BUILDING NO: 2	ROOM NO: SUITE D	PHONE NO: 576-0177	SN: 12005	CAL DUE: 16 FEB 90

ROOM SKETCH



Highest Reading ~~100~~ CPM

SMEAR ANALYSIS

- ☒ ALL SMEARS SHOW LESS THAN 100 DPM OF REMOVABLE CONTAMINATION
☐ ALL SMEARS SHOW LESS THAN 100 DPM OF REMOVABLE CONTAMINATION EXCEPT:

SMEAR	DPM	SMEAR	DPM	SMEAR	DPM

TYPE OF ANALYSIS:

- ☒ AUTO GAMMA
☒ LIQUID SCINTILLATION

ANALYSIS PERFORMED BY: *JS*

COMMENTS:

DATE OF ANALYSIS:

OCT 02 1989

QUESTIONS

	YES	NO	N/A
1. POSTING FORMS, SIGNS, AND LABELS			
A. NRC FORM 3	<input type="radio"/>	<input type="radio"/>	
B. NOTICE TO EMPLOYEES	<input type="radio"/>	<input type="radio"/>	
C. 10 CFR 19, 20, AND 21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
D. CAUTION RADIOACTIVE MATERIAL (CRM)			
1) ENTRANCE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) STORAGE AREAS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) WORK AREAS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) WASTE STORAGE AREAS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
E. CAUTION (HIGH) RADIATION AREA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F. CAUTION AIRBORNE RADIOACTIVITY	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
G. RADIOACTIVE WASTE WASH SINK (RWS)			
1) RWS LABEL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) SHELLFISH WARNING	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) MAINTENANCE WARNING	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
H. RADIOACTIVE REFRIGERATOR (RSR)			
1) CRM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) NO FOOD OR BEVERAGE ...	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) MAINTENANCE WARNING	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I. RADIOACTIVE FREEZER (RSF)			
1) CRM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) NO FOOD OR BEVERAGE ...	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) MAINTENANCE WARNING	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
J. RADIOACTIVE CENTRIFUGE			
1) CRM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) MAINTENANCE WARNING	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
K. NO EATING, DRINKING, OR SMOKING	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. COPY OF AUTHORIZATION AVAILABLE	<input type="radio"/>	<input type="radio"/>	
3. TERMS AND CONDITIONS AVAILABLE	<input type="radio"/>	<input type="radio"/>	
4. CONDITION #2 FOLLOWED	<input type="radio"/>	<input type="radio"/>	
5. CONDITION #3 FOLLOWED	<input type="radio"/>	<input type="radio"/>	
6. CONDITION #4 FOLLOWED	<input type="radio"/>	<input type="radio"/>	
7. USER SURVEY LOG AVAILABLE	<input type="radio"/>	<input type="radio"/>	
8. SURVEY INSTRUMENT	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. RWS LOG	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

COMMENTS:

STRETCHER
 * CART - PREVIOUSLY USED TO PLACE SMOKERS, WHEELCHAIR

ACTION REQUIRED: ☒ YES ☒ NO
 ACTION TAKEN:

Reviewed: *JS*