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

March 17, 2016

Br.1
03011936

Health Physics Office

U.S. Nuclear Regulatory Commission, Region I
Medical Branch, Division of Nuclear Materials Safety
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Reference: U.S. Nuclear Regulatory Commission Materials License 10-12044-03, Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia 30905-5650

Dear Sir or Madam:

Please amend the referenced by-product materials license to change the designated Radiation Safety Officer. Effective April 1, 2016, Mr. Paul Gallager will succeed Major Douglas Barrickman as our Radiation Safety Officer. Mr Gallager served as the Radiation Safety Officer from June 1, 2011 until March 25, 2013. A record of his qualification and experience is already on file at your office. This request was approved by the Radiation Safety Committee.

Please amend the referenced by-product materials license to add Radioactive Seed Localization (RSL) procedures using Iodine-125 sealed sources procured from Best Medical International (Model 2301 brachytherapy seeds). NRC Form 313 and supporting documentation is attached.

Please refer any questions to Major Barrickman at (706) 787-4692.

Sincerely,

Michael A. Weber
Colonel, U.S. Army
Commanding

590661
NMSS/RGN1 MATERIALS-002

NRC FORM 313 (02-2016)
10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

# APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 02/29/2016

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

**INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.**

**APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:**

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

**ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:**

**IF YOU ARE LOCATED IN:**

**ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,**

**SEND APPLICATIONS TO:**

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

**IF YOU ARE LOCATED IN:**

**ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:**

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

**ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,**

**SEND APPLICATIONS TO:**

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

**PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.**

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [x] B. AMENDMENT TO LICENSE NUMBER 10-12044-03
- [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Department of the Army
Dwight David Eisenhower Army Medical Center
Attn: MCHF-PMS-HP, 300 East Hospital Road
Ft. Gordon, GA 30905-5660

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

See attached sheets

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Radiation Safety Officer (see attached sheets)

| BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER |
|---|---|
| (706) 787-4692 | |

BUSINESS EMAIL ADDRESS

paul.a.gallager.civ@mail.mil

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

| CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE |
|---|---|---|
| Michael A. Weber, Colonel, U.S. Army, Commanding | Michael A. Weber | 31 MAR 16 |

**FOR NRC USE ONLY**

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|---|---|---|---|---|---|
| | | | $ | | |
| APPROVED BY | | | | DATE | |

NRC FORM 313 (02-2016)

Summary of changes to the Dwight David Eisenhower Army Medical Center (DDEAMC) U.S. Nuclear Regulatory Commission license 10-12044-02 amendment revision request to current revision 45:

1. The name of the Commander was updated (see page 4).

2. Added the request for radioiodine-125 "seed" sealed sources (see pages 7, 8, and) for use in radioactive seed localization (RSL) procedures under 10 CFR 35 Subpart K for which a written directive is required (see page 11), indicated that due to device configuration and sterility issues, that the manufacturer's attestation of source activity will be decay-corrected to determine seed activity at patient implantation, and the manufacturer's leak test information will be used for determining activity prior to use as required under 10 CFR 35.67(b)(1) (see page 9). A notation was made that there is coordination between radiologists and surgeons to minimize the seed residence time (see page 9).

3. Due to a change in the command structure of the hospital, a new Deputy Commander, the Deputy Commander for Patient Services, will replace the Deputy Commander for Clinical Services as the Chairperson of the DDEAMC Radiation Safety Committee. Note that this change does not in any way reduce the level of management oversight of the DDEAMC Radiation Safety Program, but aligns it with the primary Deputy Commander responsible for the primary radioactive material use groups. Also, this Deputy Commander is not a radioactive material user (see pages 13, 14, 16, 33, and 39).

4. The addition of the Radiology Department chief as a Radiation Safety Committee member with primary responsibility for, and other radiologists as authorized users for the use of RSL under 10 CFR 35.1000 (see pages 14 and 18).

5. Added the information regarding the change of license RSO from MAJ Douglas Barrickman, who is retiring, to Mr. Paul Gallager, who was a previous license RSO for this license and remains qualified to fill that position (see page 17).

6. Added wording to clarify that only appropriate personnel who must have training required by 10 CFR 35.310 will receive that training (see page 19).

7. Added wording regarding RSL source accountability training for appropriate personnel (see page 19).

8. Added rooms to the first, second, and third floors where RSL procedure processes may occur, plus made clarification changes (plus paragraph reformatting) for better word flow regarding floor heights in the DDEAMC building (see pages 24 and 25).

9. Additional wording to add clarification, along with the addition of RSL rooms, that are "on grade" (that is, with soil and no other rooms below them) that are on the second floor are listed (see page 25).

10. Rooms that will be used for RSL seed injection that are also shielded rooms for other reasons (i.e. X-ray) are listed with descriptions of the shielding (mainly for purposes of consistency with the existing format even though shielding is not necessary from a personnel protection standpoint; see pages 26 and 27).

11. Waste control for used RSL seeds is added to the solid waste control and storage paragraph, along with the addition of the Pathology Gross Room where the RSL seeds will be temporarily stored once they are removed from excised tissue (see pages 30 and 31).

12. The addition of the storage for RSL seeds in the Gross Room is added to the description of security of radioactive material section (see page 31).

13. The liquid scintillation counter was removed from the narrative, as it is no longer being used.

14. Added information regarding the use of thin-crystal sodium iodide detectors on portable survey instruments for surveying with RSL procedure activities, clarified that G-M and pressurized ion chamber instruments are calibrated off-site, while the portable thin-crystal sodium iodide detector instruments will be calibrated in-house using a calibrated pulser since it is a count-rate instrument. Also, added the surgical-type instrument used by Surgery for seed localization is calibrated according to manufacturer's recommendations (pages 35 and 36).

15. A paragraph was added to address radiopharmaceutical dose calibrator calibration and periodic verification which was inadvertently left out of the license renewal submittal (see page 36).

16. RSL seed(s) implanted in a patient will be decay-corrected for the present activity (see page 37).

17. Wording was added in the section regarding the DDEAMC radiation safety audit program to clarify that newly-implemented" processes or programs will also be audited to ensure effective radiation safety implementation (see page 39).

18. The receipt and accountability of the RSL seeds will initially be controlled by Health Physics until all users are fully trained and experienced in the procedure, at which time the DDEAMC Radiation Safety Committee may allow direct delivery to and initial control through the Nuclear Medicine pharmacy (see page 41).

19. Radiation surveys during RSL procedures will be taken at each phase of the procedure to ensure source accountability and integrity are maintained (see page 46).

20. Indicating that RSL seeds will be manipulated with remote handling tools to reduce extremity exposure (see page 48).

21. Personnel who are in any way involved in the RSL process are trained and aware of the need for full accountability and seed integrity during all phases of the process, and what to do in the event of a seed loss or loss of seed encapsulation integrity (see page 48).

22. Personnel involved in the implanting, surgical removal, tissue sample handing, and final removal of RSL seeds are or will be trained in the identification, and actions needed for a leaking or ruptured seed, including whom to contact in such emergencies in order to obtain the necessary assistance needed to mitigate the consequences of such a situation. Also, for all emergencies, a notation that stocks of equipment and supplies are maintained to mitigate reasonable emergency situations (see page 48).

23. In the discussion of minimization of contamination, it is emphasized that vigilance during RSL seed activities is needed to prevent loss of seed integrity, and the need for rapid identification and mitigation of the loss of seed integrity if it should occur (see page 50).

24. Changed the reference in the waste management narrative for returned sealed sources from 10 CFR 35.65 to a "generic" 10 CFR Part 35 so as not to preclude the ability to return used RLS seeds to the manufacturer if we desire to in the future (see page 50).

25. Attached floorplans of radioactive material use area, to include the addition of RSL processes, are updated (pages 51 through 64).

26. Other minor typographical and grammatical changes were made throughout the document that did not substantially change the meaning of information previously listed One additional administrative change made throughout the document was for the room number of the Radioactive Waste Room, from 3E-16A to 3E-17; the change was to the room number, but there is no physical location change.

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| Response: Revision to License No. 10-12044-03 | | |

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| 8.2 | 8.2 | Item 2—Applicant's Name and Mailing Address |
| Response: Michael A. Weber<br>Colonel, U.S. Army<br>Commanding<br>Department of the Army<br>Dwight David Eisenhower Army Medical Center<br>Attn: MCHF-PMS-HP<br>300 Hospital Road<br>Ft. Gordon, GA 30905-5650 | | |

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| 8.3 | 8.3 | Item 3—Address(es) Where Licensed Material Will be Used or Possessed |

Response: Primary Location:

Dwight David Eisenhower Army Medical Center
300 Hospital Road (Building 300)
Ft. Gordon, GA 30905-5650

Additional buildings include:

Dwight David Eisenhower Army Medical Center
Department of Clinical Investigation
Building 38705
7th Avenue and 38th Street Alley
Ft. Gordon, GA 30905-5650

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| 8.4 | 8.4 | Item 4—Person to be Contacted About This Application |

Response: Contact for information on this application and any routine mailings should be made to:

Health Physics Service 3M-15
Attn: Radiation Safety Officer (MCHF-PMS-HP)
Dwight David Eisenhower Army Medical Center
300 Hospital Road
Ft. Gordon, GA 30905-5650
Voice (706) 787-4692 or (706) 787-6392
FAX (706) 787-3427

E-mail: To ensure receipt and response in a timely manner, please send to the following two e-mail addresses:

douglas.d.barrickman.mil@mail.mil

paul.a.gallager.civ@mail.mil

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| 8.5 | 8.5, 8.5.1 | Item 5—Radioactive Material / Radioactive Material - Unsealed and/or Sealed Byproduct Material |

Response: Note: This list reflects our currently licensed amounts verbatim (from the current license version, Amendment No. 45). In addition, we are now requesting to add radioiodine "seeds" (sealed sources) to conduct

| 6. Byproduct material | 7. Chemical/Physical Form | 8. Maximum Amount |
|---|---|---|
| A. Any byproduct material with atomic numbers 3 through 83 and half life less than or equal to 120 days | A. Any | A. 300 millicuries per radionuclide and 2 curies total |
| B. Any byproduct material with atomic numbers 1 through 83 | B. Sealed Sources | B. 100 millicuries per radionuclide and 2 curies total |
| C. Hydrogen 3 | C. Any | C. 100 millicuries |
| D. Carbon 14 | D. Any | D. 25 millicuries |
| E. Molybdenum 99 | E. Any | E. 11 curies |
| F. Technetium 99m | F. Any | F. 11 curies |
| G. Iodine 131 | G. Any | GI. 3 curies |
| H. Fluorine 18 | H. Any | H. 3 curies |
| I. Iodine 125 | I. Sealed Sources, Best Medical International Model 2301 brachytherapy seeds | I. 300 microcuries per source, 1.5 millicuries maximum per procedure, and 22 millicuries total (to include sources held for decay in waste) |

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| 8.5 | 8.5, 8.5.1 | Item 5—Radioactive Material / Radioactive Material - Unsealed and/or Sealed Byproduct Material |

**9. Authorized use:**

A. through H. Medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including instrument calibration; student instruction; and *in-vitro* studies.

I. For use in radioactive seed localization procedures for non-palpable lesions.

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| 8.6 | 8.5.1 | Item 5—Sealed Sources and Devices (including Ra-226 sealed sources and devices) / Unsealed and Sealed Byproduct Material |

Response: Requesting the addition of Iodine-125 seeds (sealed sources) for use in Radioactive Seed Localization (RSL) medical procedures on human patients. Therefore, we request the addition of (Authorization 6) Iodine 125 (Authorization 7) sealed sources currently manufactured by Best Medical International (I-125 Model 2301) and distributed by MPM Medical Supply with (Authorization 8) individual source activities of up to 300 microCuries each source (seed), using a per-patient limit of up to five seeds per procedure (for a total of up to 1.5 milliCuries per procedure), and a total of no more than 22 milliCuries on-hand, to include unused seed inventory and used seeds in storage for decay, based on anticipated use, (Authorization 9) for use as temporary implants to help localize non-palpable lesions.

As an important note with these devices, they are packaged with individual seeds in sterile, shielded delivery devices. They also have U.S. Food and Drug Administration approval for this use. There is no useful way to determine seed activity or conduct sealed source leak tests on these devices prior to patient use since they would then be non-sterile. Actual delivered activity will be based on the device manufacturer's attestation of activity, corrected for decay from the source calibration date. Also, these devices are only good for up to 90 days from manufacture due to sterility of the packaging; an additional leak test is not required during that time by current rules in 10 CFR 35.67(f)(5) so no additional leak test will be performed.

Also note that there is coordination between surgical staff and radiologists implanting the seeds to minimize the time between implantation and surgery, as both services are conducted at this location.

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| 8.7 | 8.5.1 | Item 5—Discrete Source of Ra-226 (other than Sealed Sources) |

Response: NONE, and none requested.

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| 8.8 | 8.5.2 | Item 5—Recordkeeping for Decommissioning and Financial Assurance / Financial Assurance and Recordkeeping for Decommissioning |
| Response: | DDEAMC does not meet 10 CFR 30.35(a) or (d) limits. Based on the criteria of radionuclides with half-lives >120 days and unsealed sources, the only two specific radionuclides we would use would be hydrogen-3 and carbon-14. Both items are under the possession limit of $10^3$ times the applicable 10 CFR 30 Appendix B limit, and their limit-ratio, when summed, is below unity.<br><br>Record Keeping for Decommissioning – appropriate records have been, and will continue to be maintained in support of future decommissioning actions. This facility routinely conducts measurements of surface contamination for unsealed sources and routine leak tests for sealed sources. Any known spills of materials are monitored for residual contamination after decontamination. | |

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| 8.9 | 8.6 | Item 6—Purposes for Which Licensed Material Will Be Used |

Response:

- 10 CFR 35.100 (Subpart D), medical use of unsealed byproduct material for any uptake, dilution, and excretion studies for which a written directive is not required.
- 10 CFR 35.200 (Subpart D), medical use of unsealed byproduct material for any imaging and localization studies for which a written directive is not required.
- 10 CFR 35.300 (Subpart E), medical use of unsealed byproduct material for the treatment of medical conditions including but not limited to hyperthyroidism, ablation of thyroid cancer metastasis, treatment of leukemia, palliation of bone pain in cancer patients, and other appropriate treatments, for which a written directive is required.
- 10 CFR 35.1000 (Subpart K), medical use of sealed sources as temporary implants to localize non-palpable lesions, for which a written directive is required.
- Unsealed byproduct material for in-vitro testing, laboratory studies, and in-vitro research.
- Sealed sources, as identified in 10 CFR 35.65, for imaging system quality verification, dose calibrator verification and calibration, other radiation measurement system verifications, and portable instrument operability checks.

NOTE: Presently, we conduct no direct research on humans with radioactive materials (that is, to assess some type of response primarily as a result of radioactive material use, such as a therapeutic action). As an ancillary requirement for other human testing that requires some type of imaging be conducted we require radiation safety review and approval. Regardless of the study performed, this process is conducted within the guidelines of approved human studies which is reviewed and controlled by the DDEAMC Institutional Review Board, and informed consent must be obtained from the patient. Where radioactive materials are used for even an ancillary requirement such as imaging studies, it is then brought to the Radiation Safety Committee for their review and approval. We will not permit the use of radioactive materials for research use unless under the auspices of the Federal Policy for the Protection of Human Subjects, in the guidelines stated in Part 35.6(b.). Furthermore, if the research is ever to be conducted in any way that is not under the auspices of the Federal Policy for the Protection of Human Subjects (such that it would fall under Part 35.6(c.) requirements), then we will apply for a specific amendment for this research prior to initiating the use of radioactive material in this research.

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| 8.10 | 8.7 | Item 7—Individual(s) Responsible for Radiation Safety Programs and Their Training and Experience |
| Response: See responses to individual subsections, below. | | |

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| 8.10 | 8.7.1 | Item 7— Individual(s) Responsible for Radiation Safety Programs and Their Training and Experience / Executive Management oversight, control, and interaction and the general description of current Radiation Safety Program (RSP) |
| Response: The Dwight David Eisenhower Army Medical Center (DDEAMC) RSP is currently a U.S. Nuclear Regulatory Commission (USNRC)-authorized Type A specific license of broad scope. (Note that the reference to the "RSP" here and below is both to the written document describing the program and directives of the program, and the actual implementation and operation of the program, which are intrinsically linked.) The license is administered through the DDEAMC Radiation Safety Committee (RSC), as authorized by and through the DDEAMC Commander as the chief executive officer of the facility. The DDEAMC Commander retains the final authority and responsibility for the entire program. | | |

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| 8.10 | 8.7.2 | Item 7—Individual(s) Responsible for Radiation Safety Programs and Their Training and Experience / DDEAMC RSC Information |

Response: The DDEAMC Commander delegates the routine management leadership of the DDEAMC RSC to the Deputy Commander for Patient Services (DCPS), who serves as committee chair. In this capacity, the DCPS, as both a senior command staff member and medical staff member, serves as the immediate liaison between the DDEAMC Commander and the RSC. Day-to-day functional operation of the DDEAMC RSP is vested in the appointed Radiation Safety Officer (RSO), with the support of the Health Physics Office staff. The RSC provides routine review and oversight of the RSP at regular meetings (currently conducted quarterly); minutes of the meeting are then provided to the DCPS and Commander for review and approval. Typical reviews by the RSC include:

- Oversight of USNRC-licensed material for medical, research, and non-medical purposes (as well as other ionizing and non-ionizing radiation-producing devices used in the medical, dental, and veterinary treatment facilities) to ensure the DDEAMC RSP is being conducted in a safe and appropriate manner;
- Ensuring the DDEAMC As Low As Reasonably Achievable (ALARA) Program is being implemented by reviewing radiation exposure reports and doses that have exceeded any administrative action levels and that public doses are within limits;
- The implementation of new or revised USNRC (and Army and Medical Command) regulations for radioactive material;
- Radioactive material accountability, security, disposal when required, and safe use;
- Incident investigation, documentation (and if needed notification), and methods to prevent recurrence;
- Training and retraining progress, statistics, and issues;
- Equipment has and is being properly maintained in order to ensure reliability and the least amount of radiation exposure to patients, staff, and the public;
- Recommending appropriate actions to be taken when radiation protection standards are not met, and review of the results;
- Advising the DDEAMC Commander on the status, direction, and needs of the DDEAMC RSP;
- Making appropriate and necessary changes to the RSP regulation, or adding/deleting authorized users (using the methodology and criteria for approval listed below in 8.12), either within the scope of the allowances specified in the current USNRC license and 10 CFR 35.15 and 35.26, or submitting a request for license amendment through the DDEAMC Commander to the USNRC;

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| 8.10 | 8.7.2 | Item 7—Individual(s) Responsible for Radiation Safety Programs and Their Training and Experience / DDEAMC RSC Information |

- Supporting the authority, duties, and responsibilities of the RSO to properly and effectively implement the day-to-day activities of the DDEAMC RSP;
- Resolving issues brought before it by the RSO, RSC members, or members of the DDEAMC staff; and
- Ensuring the RSO conducts periodic audits of programmatic units (e.g. nuclear medicine, health physics) and a comprehensive annual audit of the DDEAMC RSP, and review of the audit results.

Any changes made to the RSP (either internally or by request to the USNRC) are documented in the RSC minutes, then implemented in appropriate regulations and procedures, followed by training of users to ensure they understand and follow any revised methods or requirements, and audited after implementation for change effectiveness. Revisions to the RSP will be in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the RSP.

The current makeup of the RSC includes, for purposes of compliance with 10 CFR 35.24(f):

- The DCPS as chairperson, who is the senior management representative, and is neither the RSO nor an authorized user;
- The RSO, who is USNRC-approved to fulfill this position;
- The chief of the Nuclear Medicine Service, as an authorized user (physician) under 10 CFR 35 Subparts D and E;
- The chief of the Radiology Department, as an authorized user (physician) under 10 CFR 35 Subpart K
- The Nuclear Pharmacist (who is administratively assigned to the Nuclear Medicine Service but is under the line authority of the Department of Pharmacy director) as an authorized user (nuclear pharmacist);
- The chief nuclear medicine technologist (as the senior technical staff representative);
- The chief of the medical research department or the director of the research building, as senior representatives of the medical research area (the Department of Clinical Investigation);
- A representative of the Nursing Service, usually the ward head nurse where inpatient ablations are housed (or a higher-level nursing supervisor of this and other wards); and
- A representative of the medical equipment servicing organization, usually the group director or other

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| 8.10 | 8.7.2 | Item 7—Individual(s) Responsible for Radiation Safety Programs and Their Training and Experience / DDEAMC RSC Information |

supervisor, who also represents the interests of contracted facility housekeeping and maintenance functions.

- The health physicist, who is a staff member in the Health Physics Office, who is an authorized user (non-medical) for control of various sources, radioactive waste, and overall radiation safety support; this is not the RSO.

These individuals cover the gamut of personnel who work with or around radioactive material at DDEAMC, and as noted, are senior experienced personnel in their specific areas of expertise. In addition to this basic group, there are other members assigned to the RSC by DDEAMC regulation who represent users of ionizing and non-ionizing radiation-producing equipment, general safety, and the Ft. Gordon RSO. This same regulation states the RSC quorum requirements – that at least half of the membership, to include the RSC chairperson and the RSO, must be present for the meeting to be an official meeting.

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| 8.11 | 8.7.3; 8.7.4 | Item 7—DDEAMC RSO: authorities, duties, responsibilities, and training and experience (including the Radiation Safety Office Staff) |

Response: The RSO (and support staff in the Health Physics Office) provide the day-to-day oversight and functional operation of the DDEAMC RSP, as stated above. To this end, the RSO is given the necessary authority and provided the resources, including equipment, supplies, support personnel and services, to fulfill the duties and responsibilities assigned to the RSO in the DDEAMC RSP. The RSP defines the authority, duties, and responsibilities of the RSO. Besides the direct interface with the RSC chair/DCPS, the RSO also has the ability to circumvent the DCPS and report directly to the DDEAMC Commander if necessary. Also, as part of the Army Medical Command structure, the RSO has the ability and requirement to communicate directly with the regional RSO and the Army Medical Command RSO, who have reporting authority to the regional medical commander and the Army Medical Commander, respectively. To conduct the necessary oversight and control of the RSP, the RSO has the authority, duty, and responsibility for the following RSP activities (and conducts these activities in concert with Health Physics staff):

- Approves the acquisition of radioactive material authorized by the RSC, and verifies that license limits will not be exceeded;
- Ensures proper and safe receipt, use, control, security, and disposal of USNRC-licensed material for medical, research, and non-medical purposes, and halts unsafe activities when identified;
- Implements and reviews the DDEAMC ALARA Program by reviewing radiation exposure reports, investigating doses that have exceeded any administrative action levels, and where appropriate, recommending actions to reduce exposures below administrative action points;
- Verifying public doses are within limits and taking appropriate action when the limits are exceeded;
- Implementing new or revised USNRC regulations, and reviewing new or revised regulations for the method of implementation for presentation to the RSC;
- Review and investigation of spills, accidents, overexposures, and similar occurrences, along with documentation of the occurrence, regulatory notification if required, and determination of appropriate methods to prevent recurrence;
- Provides appropriate (for the type and complexity of hazard) and timely training and retraining for staff;
- Verifies that appropriate administrative control documents (e.g. procedures, written directives, survey reports, audits, other programmatic records) are being created and maintained;
- Verifies equipment that is used to monitor, measure, or image radioactive material has and is being

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properly maintained;

- Advises the RSC and (through the RSC or directly to) the DDEAMC Commander on the status, direction, and needs of the DDEAMC RSP, including appropriate actions to be taken when radiation protection standards are not met;
- Preparing for, participating in, presenting, and completing actions for the RSC meetings (including preparation of minutes);
- Conducting periodic audits of programmatic units and a comprehensive annual audit of the DDEAMC RSP for presentation to the RSC; and
- Interaction with the regulatory agencies with authority for the RSP (including the Army Medical Command structure and the USNRC), along with other oversight organizations (e.g. The Joint Commission).

The experience and educational credentials of the potential RSO, prior to submission to the USNRC in a license amendment request, is reviewed by the RSC to verify regulatory compliance and to ensure likely USNRC approval as the USNRC license RSO of record. There is a concurrent request being made to replace the current RSO, MAJ Douglas Barrickman who is currently retiring, with Mr. Paul Gallager, who is a qualified RSO and was the license RSO prior to the arrival of MAJ Barrickman. Mr. Gallager will be serving as the license RSO until a qualified military officer who can serve as the RSO arrives and an amendment request is submitted for that person.

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| 8.12 | (not listed) | Item 7—Authorized Users |
| Response: All physician (nuclear medicine and radiologist as appropriate) authorized users request are required to be reviewed by the RSC to USNRC-standards stated in 10 CFR 35.13, including the submission of preceptor attestation statements and/or professional certification certificates as appropriate before being approved as a permitted authorized user at DDEAMC in the applicable use area (10 CFR 35.100/.200/.300/.1000). Non-medical radioactive material user supervisory personnel (e.g. researchers) are also required by the RSC to be approved as a non-medical authorized user, requiring an appropriate level of training and experience before granting this permission. | | |

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| 8.13 | (not listed) | Item 7—Authorized Nuclear Pharmacist |
| Response: DDEAMC is currently authorized a registered pharmacist who specializes in nuclear medicine dosage preparation. An applicant to become an authorized nuclear pharmacist is required to submit the necessary experience, preceptor attestation statements and/or professional certification information as required to USNRC standards stated in 10 CFR 35.13 before review and approval by the RSC. In addition to this qualification, nuclear medicine (physician) authorized users also supervise the authorized nuclear pharmacist. In turn, the authorized nuclear pharmacist supervises authorized nuclear medicine technologist users who assist in the nuclear pharmacy. In the absence of the authorized nuclear pharmacist, authorized nuclear medicine technologist users may, under the supervision of a nuclear medicine physician authorized user prepare nuclear medicine dosages for use. | | |

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| 8.14 | (not listed) | Item 7—Authorized Medical Physicist |
| Response: Not applicable. | | |

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| "No Response Required" under 8.32 | 8.8 | Item 8—Safety Instruction for Individuals Working In Or Frequenting Restricted Areas / Training for Individuals Working In Or Frequenting Restricted Areas (Instructions to Occupational Workers and Ancillary Personnel) |

Response: Any licensee personnel directly working with licensed radioactive material will receive initial radiation safety training ("instructions") to comply with the requirements of 10 CFR 19.12 and (as appropriate) 10 CFR 35.310. The scope of the training will be commensurate with the type and level of the hazard to which they are exposed in routine and anticipated abnormal events in their duties. Any trainee in this category will receive commensurate initial radiation safety training and also will be closely supervised (as noted above) by an experienced worker. Initial training for this group will consist of:

- Basic radiation physics for the types of materials used at DDEAMC, including basic radiation interaction with matter;
- Basic radiation biology, to discuss the various types of radiation interaction with cells and tissue;
- Relative occupational health risk comparisons;
- Understanding of radiation and radioactivity measurement units;
- Radiation protection concepts along with the ALARA concept;
- Occupational dose limits and their significance, administrative action limits, embryo/fetus limits and declaration of pregnancy;
- Radioactive material control, storage, and security, and personnel access to use areas, and as appropriate, RSL source accountability;
- Posting and labeling requirements for radioactive material and radiation areas;
- Proper use of dosimetry (when applicable);
- Proper use of shielding (where required);
- Worker's rights and access to personal information (e.g. personal dose records), information access locations, workplace responsibilities, and obligation to report unsafe or non-compliant actions;
- Regulatory requirements and issues in the conduct of their duties;
- Requirements for periodic surveys and monitoring in the workplace after radioactive material use (where applicable);
- Identification of DDEAMC radiation safety organization structure, and to whom to report any issues or

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ask any questions;

- Emergency actions and instructions (including patient care emergencies); and
- DDEAMC's radiation safety program regulation and ancillary radiation safety processes and procedures, to include the requirements for written directive (and associated procedures) and license conditions for the use of radioactive material.

In addition, Health Physics personnel will also be initially trained in the following topics:

- Patient release procedures and limitations;
- More in-depth survey and monitoring techniques;
- Decontamination and facility release procedures;
- Assessing public doses;
- Calibration and operation of instrumentation;
- Record-keeping for the radiation safety program;
- Radiation safety program surveillance and auditing procedures; and
- Health Physics procedures for the conduct of their duties.

The overall training will be geared towards and limited to DDEAMC-specific requirements and activities to the greatest extent possible. Training will be given using any combination of various presentation formats, including but not limited to face-to-face live classroom or directly supervised on-the-job training, on-line, video recordings, and paper hand-outs. The format(s) used will be appropriate to the most effective training delivery for a specific worker or work-group. Initial training will be assessed to ensure the worker has adequate understanding of the material presented so they can safely work with radioactive material without immediate supervision. In some cases, this training may include preceptor verification of the adequacy of performance instead of a formal question-answer assessment (e.g. verification of a demonstrated task). Attestation of the training by the worker or preceptor will be made in an electronic or

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written record.

Initial training for workers directly using radioactive material will occur before direct handling of materials commences except when directly-supervised hands-on training is being used. (Note that where directly supervised training of this type is necessary, it will be accomplished using ALARA concepts to prevent unnecessary radiation exposure.) Periodically, refresher training will be provided to these workers. The refresher training will be used whenever a significant change in duties, regulations, terms of the license, types of radioactive material, or operating feedback warrants this training. Otherwise, the training may include "industry experience" information (e.g. USNRC enforcement actions), generic issues, and re-emphasis of some part of the initial training that may be necessary due to infrequency of normal use, or other pertinent topics or discussion. In addition to DDEAMC-provided radiation safety refresher training, refresher training credit may be given for commensurate training for all types of authorized users they obtain as part of other professional training (e.g. physician or technologist continuing education training) with submission of proper documentation to the RSO.

Ancillary and support staff (e.g., housekeeping, security, firefighters, maintenance) are not considered radioactive material users (and are very unlikely to exceed 100 millirem per year), so an awareness type training will be provided for these personnel who do not directly work with licensed radioactive material but only have some task in areas where radioactive material is used or stored. The training will be commensurate with the duty and specific to DDEAMC operations, and will include at least:

- A general description of the potential hazards from unnecessary exposure to radioactive material and ionizing radiation;
- Identification of areas or items containing licensed radioactive material;
- How to avoid or reduce exposure from the material (e.g. basic ALARA concepts);
- Whom to contact regarding those areas for normal conditions if there are questions;
- Whom to contact regarding those areas during emergency conditions; and

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- How to contact the RSO for any type of question or concern.

Because ancillary and support staff will not to be routinely involved with direct exposure to radioactive material, for some groups initial training will occur at periodic intervals (at least one training opportunity per year) as these personnel are available to receive the training. This is necessary since DDEAMC does not administratively control all groups (e.g. Ft. Gordon Fire Department) or due to routine turnover of various contracted personnel. Contracted housekeeping staff receives orientation and periodic refresher training that contains radiation safety segments (which currently includes training information prepared by DDEAMC Health Physics staff). In any case there is little likelihood that an untrained or inexperienced person in either category will be dealing alone with radioactive material in their duties since they would be supervised by or teamed with a co-worker who has had the training and is experienced in the handling of situations where radioactive material may be encountered. Emergency responders (i.e. firefighters), consistent with their other training where hazardous material may be present, will be informed to exit the area after lifesaving and stabilization occurs, and will be directly guided by the RSO or designee for any follow-on activity where licensed materials may be a hazard.

The initial and periodic refresher training presentation formats for ancillary and support staff will consist of any of the format methods described earlier for direct radioactive material user training formats. The training will not have a formal assessment process (e.g. no written test), but the key points will be kept to a minimum to ensure trainees understand and retain the key material presented. If or when conditions change that requires these types of personnel to have more detailed training and consequently the understanding and retention of concepts presented, then the type of assessment will be changed accordingly (inclusion of a written test or demonstration of skills, etc.). In all cases of training, however, each trainee will be required to attest to having received and understood the material. The frequency of retraining will be contingent on the group being trained and their specific responsibilities. In no case will it be less frequently than biennially for any group. Typically, it will be more often than this, especially where changes occur or operating experience dictates the need for updating information to a group.

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Qualifications of trainers: Individuals who will prepare or conduct the radiation safety training are experienced staff in the Health Physics Service at DDEAMC, to include the RSO. The staff has significant experience in the field of radiation safety; for example, at the time this application was prepared two staff members are qualified and experienced RSOs with master's degrees in the field of radiation safety. The combined radiation safety experience of the staff is in excess of seventy person-years among four persons at this time. All have had experience presenting radiation safety training, to include the preparation and delivery of this training to various types of trainees (from physicians to technical medical staff to custodial). Each staff member brings unique experiences and skills to the training arena, in order to provide any specific trainee with the necessary information that trainee will need in order to properly, safely, and compliantly work with or around radioactive material.

Revisions to radiation safety training: As necessary and appropriate (due to changes in regulations, requirements, operating experience, new processes or practices, etc.) it will be necessary to revise training to ensure the training is effective and appropriate for workers to adequately understand the tasks and requirements to protect themselves and to safely and effectively work with radioactive material. Therefore, it is requested that DDEAMC, as directed and approved by the RSC and RSO, be able to change and implement revised training whenever necessary. The revised training will be prepared, conducted, and evaluated as discussed above for our existing training.

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Response: DDEAMC current radioactive material storage and use locations are as follows:

Building 300 (main hospital building):

First Floor:
1L-06 (Gross Room)

Second Floor:
Rooms 2M-04 (Nuclear Medicine Imaging Suite), 2M-05 (Nuclear Pharmacy), 2R-01 (PET-CT Room), 2R-02 (Toilet), 2R-04 (SPECT-CT Room), 2R-06 (PET Pharmacy, PET Dosing Area and Quiet Room), 2P-19 (Stress Test Room), 2Q-14 (CT Scan Room), 2R-32 (Stereotactic Breast Biopsy Room), 2R-33 (Ultrasound Scan Room 1), 2R-34B (Ultrasound Scan Room 2), and 2R-34A (Ultrasound Scan Room 3)

Third Floor:
Rooms 3I-07 (Health Physics Laboratory-Source Storage Room and Counting Room), 3E-17 (Radioactive Waste Storage Room), 3G-19 (Interventional Radiology Procedure Room "X-ray"), 3P-11 (OR #2), 3P-12 (OR #3), 3P-14 (OR #4), 3P-16 (OR #5), 3P-18 (OR Suite 1), 3P-19 (OR #8), 3P-23 (OR #7), and 3P-23 (OR #6)

Ninth Floor:
Room 9C-39, Inpatient Radionuclide Therapy Room

Building 38705:
Room 116 (Radioisotope Lab)

Building 300 (main hospital building) information:
Currently, the DDEAMC building (300) radioactive material use and storage areas are directly supporting Nuclear Medicine modalities (regular uptake and imaging) plus inpatient radioiodine therapy sequestration, RSL-related processes, along with supporting activities provided by Health Physics (radioactive waste

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decay storage, radioactive source storage, and radioactive material counting rooms for contamination control swipe analysis). Specific modalities used by Nuclear Medicine include normal uptake measuring (e.g. radioiodine percentage), nuclear camera imaging (e.g. bone scans), and SPECT-CT imaging (using the CT for attenuation correction and detailed radiographic imaging). In 2009, DDEAMC added PET-CT as a modality; this included a shielded dose verification area with a dosing/quiet room, plus the shielded PET-CT room. In 2016 DDEAMC requests to add RSL processes (including the source injection into the lesion, surgical removal of the source and lesion, and separation of the source from the lesion with temporary source storage) in several locations to support the overall RSL process.

General Information: inside the DDEAMC building, the floor-to-floor height on the first four floors is 15 feet and for floors five and above is 11 feet, all with a nominal 10 inch floor thickness throughout.

Areas that have structural shielding:

2M-05 (Nuclear Pharmacy)
3/32" lead to 7' 0" height (walls and doors), plus supplemental shielding in source storage areas in cabinetry (1/8" in the refrigerator and 1" in all other radioactive material storage cabinets), and inherent shielding in floors and ceilings from structural concrete, along with distance to nearest receptor. The cabinets where radioactive material is stored are commercially-made nuclear medicine cabinetry (currently Biodex) with smooth, impervious tops, mainly stainless steel. Aside from generator elution, currently most actual radiopharmaceutical preparation is conducted in laminar-flow hoods with filtered recycled airflow; interior surfaces are stainless steel. Floors are a sealed vinyl material over concrete. Walls are normal painted gypsum board. A laboratory chemical fume hood is also located here with air exhausted to the environment (see below). No special general room air filtration control is provided apart from the localized air control measures noted.

(Note: Rooms 2R-01, 2R-02, 2R-04, 2R-06, 2P-19. 2Q-14, 2R-32, 2R-33, 2R-34A, and 2R34B are on grade level, even though they are on the second floor. This is due to the design of the hospital and the local topography; the hospital is built into the side of a hill, and the first, and portions of the second and third floors are under the ground surface. Also, the second and third floors are wider and longer than the

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first, and fourth through fifteenth floors.)

2R-01 (PET-CT Room)

1/4" lead to 7' 0" height (walls, doors, and viewing window) and inherent shielding in ceilings from structural concrete, along with distance to nearest receptor. Floors are linoleum tiles over concrete. Walls are normal painted gypsum board. No special general room air filtration control is provided.

2R-02 (Toilet used by PET-CT patients)

1/16" lead to 7' 0" height (west, north, and east walls and both doors) and 1/4" lead to 7' 0" height (south wall). Floors are linoleum tiles over concrete. Walls are normal painted gypsum board. No special general room air filtration control is provided.

2R-04 (SPECT-CT Room)

1/16" lead to 7' 0" height (walls, doors, and viewing window) and inherent shielding in ceilings from structural concrete, along with distance to nearest receptor. Floors are linoleum tiles over concrete. Walls are normal painted gypsum board. No special general room air filtration control is provided.

2R-06 (PET Pharmacy, PET Dosing Area and Quiet Room)

3/4" lead to 7' 0" height (walls and doors), plus supplemental shielding in source storage areas in cabinetry (1/4" to 1"), and inherent shielding in ceilings from structural concrete, along with distance to nearest receptor. The cabinets where radioactive material is stored are commercially-made nuclear medicine cabinetry (currently Biodex) with smooth, impervious tops. Any actual radiopharmaceutical preparation is conducted on the surface of these counters. Floors are linoleum tiles over concrete. Walls are normal painted gypsum board. No special general room air filtration control is provided.

2Q-14 CT Scan Room

This room is proposed for use with RSL source injection procedures. This is the primary computed tomography system, and has lead shielding to a height of 7 feet-0 inches from the floor, with a thickness of 1.6 millimeters (approximately 1/16 inch).

2R-32 Stereotactic Breast Biopsy Room

This room is proposed for use with RSL injection procedures. This room, as originally installed in the original hospital layout of 1975, was part of a proposed radiation therapy suite of rooms; this room was a regular radiology room. This room was lined with 3.2 millimeter (approximately 1/8 inch) thick lead shielding. Currently it is used for mammography imaging and for stereotactic breast biopsy procedures (both units are in the same room, but only used one at a time). The shielding extends to at least 7 feet – 0 inches from the floor.

Ultrasound Scan Rooms 2 (2R-34B) and 3 (2R-34A)

This room is proposed for use with RSL injection procedures. This was a single large room that was sub-divided into two smaller rooms to support additional ultrasound locations. As noted above, this suite was originally designed and installed to support radiation therapy procedures. This room was originally designated to become a cesium teletherapy room. Walls are nominally 46-inch thick concrete; vertical extension is to at least 7 feet – 0 inches above floor level.

Interventional Radiology Procedure Room (X-ray) 3G-19

This room is proposed for use with RSL implantation procedures. This room is a large shielded location with a bi-plane fluoroscopy system. The shielding is 3.2 millimeters (3/16 inches) thick and extends to a height of 7 feet – 0 inches above the floor.

9C-39 (In-patient radiopharmaceutical therapy room)

Room 9C-39 is a single room with commode, shower, and lavatory. This room has shielding to a height of 6 feet from the floor along the wall between the bathroom and a hallway-accessible closet and also along a portion of the room entrance-way; the lead thickness is 1/4". No other walls are shielded.

This concludes the listing of areas that have structurally-shielded radioactive material use areas.

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Areas without structural shielding:
Rooms 2M-04 (Nuclear Medicine Imaging Suite), 2P-19 (Stress Test Room), 3I-07 (Health Physics Laboratory-Source Storage Room and Counting Room), and 3E-17 (Radioactive Waste Storage Room)
No general lead shielding is provided in these areas. When necessary, supplemental lead shielding is used to provide localized shielding in and around trash and linen containers from the inpatient therapy room during decay for dose rate reduction. Lead shielding is provided in the Health Physics Laboratory for source storage areas, not primarily for dose reduction purposes but to provide low-enough background to count various low-level radioactive samples (primarily swipes) to meet necessary detection limits on counting equipment. Floors are linoleum tiles over concrete. Walls are normal painted gypsum board. No special general room air filtration control is provided.

Areas adjacent to Radioactive Material Areas
With the exception of adjacent rooms that are accessible from the internal areas of 2M-04 (Nuclear Medicine Imaging Suite) and 2M-05 (Nuclear Pharmacy), all other areas are considered "uncontrolled" for exposure limits (i.e. are limited to 0.1 rem per year as required by 10 CFR 20.1301). These uncontrolled areas include offices, laboratories, corridors, conference rooms, storage rooms, rest rooms, maintenance shops, the morgue, patient rooms, and linen storage. Surveys are conducted periodically to measure and ensure that an individual located in these areas, based on their normal occupancy, will not be able to exceed the 0.1 rem per year limit for a member of the public.

Inpatient therapy room information:
The only inpatient radiopharmaceutical therapy currently conducted at DDEAMC uses licensed materials in dosages that do not meet the limits for immediate release under 10 CFR 35.75 for uses authorized under 10 CFR 35 Subpart E. For inpatient "extended" (at least overnight) stays or for where nursing care will be needed, a specific room is utilized to house the inpatient. Room 9C-39 is a single room, with its own commode, lavatory sink, and shower. This room is controlled by the RSO (through the Health Physics staff) for purposes of radiation and contamination control. Access to this room, when a therapy inpatient is not in the room, is controlled by Health Physics. (The only other organization that has access to this room is the DDEAMC Security Office, who has a master key to access the room only for emergency conditions.) When a patient is in the room, control of the room is shared directly by RSO/Health Physics and the ward

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nursing staff attending the patient. Unless the patient is a "medically-fragile" patient (e.g. elderly, with dementia, or has secondary medical conditions requiring regular nursing care), no one is allowed to enter the room except in the event of an emergency or with a Health Physics escort. Patients are counseled prior to dose administration that visitors are normally are not allowed for the duration of their stay unless with the RSO/Health Physics permission; minors, or pregnant or lactating individuals will not be allowed to visit at any time. This room has shielding to a height of 6 feet from the floor along the wall between the bathroom and a hallway-accessible closet and also along a portion of the room entrance-way; the lead thickness is 1/4". Additionally, adjacent patient rooms are vacated for at least part of the period a therapy patient is in 9C-39. The shielding and these administrative actions are sufficient to ensure patients and visitors in adjoining areas will not exceed the limits in 10 CFR 20. Subpart D. When a therapy patient has been released (according to 10 CFR 35.75 requirements), the room is locked and controlled by Health Physics until decontamination or radiological decay occurs. Housekeeping staff are not allowed access until the results of radiological surveys indicate the room is at approved release levels. This room is also utilized for non-radiological therapy patients between radiopharmaceutical therapy inpatients. One other location, the PET Quiet Room (a shielded room as previously discussed) is utilized for temporary inpatient therapy stays for medium dosages of radioiodine (less than 55 milliCuries) for thyroid ablations. Typically a patient is able to be dosed and released to meet 10 CFR 35.75 requirements within a weekday work shift. If the patient cannot be released within the work shift, they will be transferred to 9C-39 for an overnight stay. This area is then decontaminated and surveyed to ensure it meets approved radiological release limits.

Liquid waste systems

DDEAMC disposes of small activity amounts of radionuclides (within certain criteria as described) in the sanitary sewage system in accordance with 10 CFR 20.2003. Presently, small amounts of short half-life radionuclides from nuclear medicine testing are disposed when necessary. We also utilize this method for disposal of any low-activity carbon-14 wastes used for nuclear medicine testing. All releases through RSC-approved "dump sinks" are required to be tallied by the responsible group (in units of activity by radionuclide at the time of disposal into the sink), which is reviewed quarterly by the RSO. This information is reviewed by the RSC and documented as part of the RSC minutes supplemental information.

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Airborne vent systems

The nuclear pharmacy has a laboratory fume hood hooked to the main hospital air exhaust system plenum. This plenum air is exhausted to the environment through a roof access vent on top of the main hospital building above the 15$^{th}$ floor. Any potential volatile radioactive materials are released to the environment for further dispersion and dilution from this elevated point. Any actual release, though not directly monitored, is likely to be very low activity and an annual calculation of releases of all types of radioactive materials is estimated to ensure compliance with 10 CFR 20.1301(e), in order to comply with 40 CFR 190. Currently, the COMPLY computer code from the U.S. Environmental Protection Agency is used to conduct the annual airborne effluent calculation. This information is reviewed by the RSC and stored as part of the RSC minutes supplemental information.

Solid waste control and storage

All short half-life (≤120 days) radioactive waste (to include known-to-be contaminated items from dose preparation and administration areas) is initially kept locally in the Nuclear Medicine pharmacies in shielded storage for initial decay or for used RSL "seeds" in a holding container in the "Gross Room" in Pathology. When lower radiation levels have been reached or periodically for used RSL "seeds," these materials are transferred to Health Physics for final decay-in-storage and then eventual disposal when released as non-radioactive waste items under 10 CFR 35.92 requirements. Material with half lives >120 days (e.g. calibration and reference sources) are transferred to Health Physics, where they are either returned to the manufacturer for disposal or stored for disposal through a licensed waste processing facility (contracted through the U.S. Army Material Command radioactive waste processing office). Spent molybdenum/technetium generators are initially held by Nuclear Medicine for several weeks for decay, and then transferred to Health Physics for additional decay and return to the vendor for recycling (using hazardous material transportation procedures for this purpose).

Security of radioactive materials

Security of radioactive materials is accomplished through a combination of engineered controls and administrative actions. To comply with 10 CFR 20 Subpart I requirements, licensed materials must be under the direct control of an authorized user unless it is stored in a code- or key-controlled location. These areas are the nuclear or PET pharmacy, the Pathology Gross Room (for temporary storage of used

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RSL seeds removed from excised tissue), the Health Physics Laboratory-Source Storage Room and Counting Room, and the Radioactive Waste Storage Room. When radioactive material is in these storage areas, access doors must be locked when no authorized person is present (or a small locked, shielded, and labeled storage container for the temporary storage of RSL seed is used in the Gross Room). Also, the SPECT-CT unit has an installed, machine-controlled source for performing daily quality control checks; this area is also locked when no one is immediately present. Locks for these areas include code-type cipher locks (to facilitate easy resets when personnel change) or locks which have limited access to other groups (e.g. security). Delivery of radioactive material by common carrier or by a vendor courier requires delivery directly to the authorized use location (the preferred location) or the warehouse (as a back-up in the event the preferred location is not open), both of which are secure locations. After-hours deliveries must be routed to the central entrance, where a security officer will escort the delivery person and place the item in the secure nuclear medicine suite.

Building 38705 (Clinical Investigation [CI]) information:

Radioisotope Laboratory (Room 116)

The CI laboratory building has one general-purpose biomedical laboratory dedicated to unsealed in-vitro type radioisotope use. Laboratory work will be conducted on regular laboratory-type furniture with sealed tops. Absorbent material with a liquid-impervious backing will be required for all bench-top experiments to minimize the spread of contamination into surfaces. In Room 116, the floors are linoleum tiles over concrete, walls are painted gypsum board, and the ceiling is a drop-in type with an above plenum space. There is a standard chemical ventilation hood that exhausts directly to the outside located in Room 116. This room has a sink and running water, but the sink is not approved by the RSC as a radioisotope disposal sink at this time. This room has hallway and building-exterior walls and has other laboratories in adjacent rooms. Building 38705 is a single-story structure on a concrete slab. Anticipated work in this building will be with in-vitro biomedical experiments using typical labeled beta-emitting and gamma-emitting radionuclides in activities ranging from several hundred microCuries up to a few milliCuries per experiment. As noted, each worker will be required to be adequately trained before being allowed to work with radioactive material. Also, for any research activity that may require complex techniques, an experienced

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Health Physics staff member may be assigned to cover the work when it is being conducted. When significant amounts of radioiodine are used in an experiment (> 500 microCuries per operation), thyroid bioassay of laboratory workers using radioiodine will be required. Any step that could cause volatilization of radioiodine is required to be conducted in an operating laboratory fume hood.

Liquid waste systems

DDEAMC plans to dispose of small activity amounts of radionuclides into the sanitary sewage system from this facility, to include the disposal of any short half-life materials and hydrogen-3 or carbon-14 wastes meeting the criteria as described in 20.2003, if these radionuclides. A designated "dump sink" will be identified by the RSC and disposal by this method will be required to be tallied by the responsible group (in units of activity by radionuclide at the time of disposal into the sink), which will be reviewed quarterly by the RSO. This information will then be reviewed by the RSC and included as part of the RSC minutes supplemental information.

Security of radioactive materials

Security of radioactive materials is accomplished through a combination of designed controls and administrative actions. To comply with 10 CFR 20 Subpart I requirements, licensed materials must be under the direct control of an authorized user unless it is stored in a code- or key-controlled location. First, the entire building is a code-secured area, as entrance doorways require individualized access via the DDEAMC smart badge. Anyone not authorized for this building via their badge will be required to be admitted only by a building occupant for authorized reasons. Next, the radioactive material use room in this building is considered a storage and use area for radioactive material. When radioactive material is in the storage area, access doors must be locked when no one is present. Delivery of radioactive material by common carrier or by a vendor courier requires delivery directly to this building (the preferred location) or the hospital central warehouse (as a back-up in the event the preferred location is not open), both of which are secure locations. After-hours deliveries must be routed to the central entrance, where a security officer will escort the delivery person and place the item in the secure nuclear medicine suite until proper delivery can be accomplished.

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Drawings with scale

See Appendix A for this information.

Method to control facility use changes (by the RSO and RSC)

The RSO is the day-to-day point of contact for all radiation safety issues at DDEAMC. This is a dedicated position, staffed by an experienced health physicist, presently supported by a staff of other experienced health physicists who have extensive knowledge of the history and activity of the DDEAMC RSP. (Actual combined staff "person-years" of experience within the current DDEAMC RSP is in excess of twenty years.) Facility Management personnel are also long-term experienced DDEAMC staff members, so a well-developed relationship is in place with excellent rapport between them and the RSO/Health Physics staff. Nuclear Medicine and Clinical Investigation management are also long-term experienced DDEAMC staff members and members of the RSC. Furthermore, the RSC chairperson (who is also the DCPS and a high-level management member) would also know about any planned facility changes. Therefore, any proposed changes are normally identified early in the development cycle and necessary radiation safety considerations (e.g. shielding, source-term reduction, waste handling, etc.) are incorporated into the change.

At this point the proposed change is brought to the attention of the RSC for review and approval. Any changes deemed to not require a license amendment (10 CFR 35.13 but with the exemptions listed 10 CFR 35.15) will then be recorded and the change implemented. Otherwise, if a license amendment is required, the license amendment request as approved by the RSC will be administratively handled by the RSO, through the DDEAMC Commander to request the amendment. In summary, facility changes with radiation safety implications are adequately identified and controlled at DDEAMC. Furthermore, it is requested that the RSC be able to continue to exercise the autonomy needed to designate new and

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| discontinue unneeded radioactive material use areas in the designated buildings as deemed necessary for the safe and efficient operation of the DDEAMC RSP. | | |
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| 8.17 | 8.10.2 | Item 9—Radiation Monitoring Instruments |

Response: DDEAMC currently uses a variety of radiation monitoring instrumentation, with the capability to monitor radiation levels, fixed-plus-transferable contamination levels, and transferable contamination levels. Adequate quantities of these instruments are available for personnel who must use these instruments to measure and quantify ionizing radiation levels in their workplace, and detect and quantify any unsealed radioactive material on surfaces (i.e. radioactive contamination) that may be present in their workplace. The various instrumentation used provides us with the capability of monitoring any type of radioactive material used at DDEAMC. In addition, there are adequate numbers of the various types of portable survey instruments to conduct all required monitoring even when instruments sent off for calibration, Instrumentation include the following types:

Fixed instrumentation

- Sodium iodide detector based gamma counting system for swipe samples (measuring transferable contamination) or other small-volume samples that may need to be measured, with very low activity levels. This system is used in order to meet assorted RSP monitoring levels for compliance with USNRC and USDOT requirements. This system also has limited gamma energy peak identification capabilities (multi-channel analyzer).
- Uptake measurement probe and counter, used to measure low-activity radioiodine in the thyroid. By Army Medical Command radiation safety procedures, we are obligated to do a thyroid bioassay measurement of certain individuals who participated in the preparation or administration of large-activity radioiodine therapy dosages. This system is used to conduct this measurement. It is also used as a back-up system for the Nuclear Medicine Uptake Probe system in case their system is inoperable. The particular system is currently a multi-channel analyzer, but we also have the equipment to conduct this measurement via a single-channel analyzer.

Portable survey instrumentation

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- Geiger-Mueller (G-M) battery-powered survey instruments, with detection ranges from 0.01 mR/hr to 15 mR/hr (general radiation fields) and 0-50,000 counts per minute (near-contact surface readings for measuring fixed-plus-transferable radioactivity levels). Other G-M battery-powered survey instruments are used exclusively as screening instruments for locating any surface radioactivity contamination on floors, walls, work areas, etc.
- Portable battery-powered pressurized ion chamber radiation field measurement instruments, with detection ranges from 0.001 mR/hr to 5,000 mR/hr.
- Portable battery-powered combination G-M survey instrument combined with cesium iodide detector and processor that is able to provide isotopic identification of photon-emitting radionuclides (multi-channel analyzer); used for screening only.
- Portable battery-operated survey instrument equipped with thin-crystal sodium-iodide detectors for surveying after RSL procedures.

Method of calibration

Radiation monitoring instruments will be calibrated by a person trained and authorized to perform survey meter calibrations.

- All G-M and pressurized ion chamber portable survey instruments (except as noted) are calibrated by the U. S. Army Test, Measurement, and Diagnostic Equipment (TMDE) Activity. Currently, this is the Secondary Reference Nucleonics Laboratory, in Anniston, AL. The portable G-M survey/multi-channel analyzer instrument is calibrated at the manufacturer, or at a manufacturer-authorized calibration facility. All such facilities are USNRC or agreement state-licensed facilities authorized for instrument calibration.
- The RSL portable survey instrumentation will be calibrated locally, using the RSO-approved survey instrument calibration method. This will be accomplished by first using a pulser device (calibrated by the TMDE Activity noted above) following survey-instrument manufacturer's recommended procedures since it is not an exposure-rate instrument, but a count-rate instrument. Functional verification of each instrument, which includes the thin-crystal sodium iodine detector, is conducted immediately following calibration using a dedicated (to the instrument) check source that is used for functional verification of instrument operability before each use.

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- The surgical-type instrument used for locating the seed(s) will be calibrated according to the instrument manufacturer's recommendations.
- All fixed instrumentation is calibrated locally.
  - All counters are evaluated to determine the statistical detection limit to ensure necessary limits can be met for samples analyzed in the device (package and surface swipes on packages and leak tests).
  - For the gamma counter (and well counter when used), after normal machine-run checks of high voltage and window energy and width, sources of various gamma energies with known activity rates are used to determine system response efficiencies (energy-efficiency), to then analyze an unknown radioactivity sample in order to quantify the sample activity.
  - Radiopharmaceutical dose calibrators are calibrated and verified according to manufacturer's recommendations, either using their direct procedures or using national standard practices.
  - Both radioiodine uptake probes are used in slightly different ways because of the method of detection they use, although baseline test parameters (high voltage setting, window energy and width, repeat count variability limits) are the same. In nuclear medicine, the sample activity is determined in the dose calibrator, and then verified in the proper geometry for the thyroid as having the same activity; it is then administered to the patient and after an uptake period is counted again (after appropriate decay correction) to determine the uptake percentage, a key indicator of thyroid function. For the post-administration in-vivo bioassay, operability checks, background-based statistical detection limit verifications, and detection system efficiency and energy-window measurements using a "mock iodine" source are made, then actual bioassay measurements are taken and for any measurements above the detection limit a determination of the thyroid activity and organ dose are calculated.

Instrument/system/procedural change control assurance

We request the right to replace and to upgrade our radiation monitoring instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used. The RSO is the day-to-day point of contact for all radiation safety issues at DDEAMC. This is a dedicated position, staffed by an experienced health physicist, presently supported by a staff of other experienced health physicists

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| who have extensive knowledge of the history and activity of the DDEAMC RSP, as discussed earlier. Therefore, the staff members are adequately qualified, by operational health physics experience, to understand the unique needs of the licensed program at DDEAMC regarding the use of radiation monitoring instruments. Changes in instrument or counting systems will be consistent with the present or projected needs of the RSP. Procedures controlling the selection, use, and calibration are under the authority and direction of the RSO as the subject matter expert in this area. The RSO reports this information to the RSC for information and for concurrence. Furthermore, it is requested that the RSO, under the authority of the RSC, be able to continue to exercise the autonomy needed to revise, update, refine, and improve procedures associated with the radiation monitoring instrumentation as deemed necessary for the safe and efficient operation of the DDEAMC RSP. | | |

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| 8.18 | (not listed) | Item 9—Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material |
| Response: Only gamma and beta-emitting unsealed byproduct materials are used at this time. Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. | | |

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| 8.19 | (not listed) | Item 9—Therapy Unit – Calibration and Use |
| Response: Aside from unsealed therapy doses (that would otherwise be measured in a dose calibrator or obtained from a material provider in a unit dose), no other radiotherapy utilizing radioactive material is conducted in this facility. RSL "seeds" are not considered therapy; however, source decay corrections will be used from manufacturer-supplied data to verify source activity that is recorded at the time the source(s) is (are) implanted in patient. | | |

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| 8.20 | (not listed) | Item 9—Other Equipment and Facilities |
| Response: The current facility detail for radionuclide therapy and PET radionuclide receiving, use, storage, and disposal areas is described in detail in Item 9—Facilities and Equipment. | | |

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| 8.21 | 8.10 | Item 10—Radiation Protection Program / Radiation Safety Program |
| Response: See responses to individual subsections, below. | | |

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| 8.22 | (not listed) | Item 10—Safety Procedures and Instructions |
| Response: Not applicable to this program, as no external source therapy is conducted nor is there PET drug production. | | |

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| (not listed). | 8.10.1 | Item 10—Audit Program |

Response: As noted above in Item 7—Individual(s) Responsible for Radiation Safety Programs and Their Training and Experience / DDEAMC RSC Information and Item 7—DDEAMC RSO: authorities, duties, responsibilities, and training and experience, DDEAMC has an active management oversight program for the DDEAMC RSP. The RSC has an expectation of being provided a full review of the DDEAMC RSP at each quarterly meeting, which is provided by the RSO through the assistance of the Health Physics service staff. This report provides not only successes and accomplishments, but also statistical reporting information, and most importantly, problems and weaknesses in the RSP plus corrective actions taken by the RSO or planned (for RSC approval) to prevent recurrence. Also as noted, the RSC chairperson is the DCPS, an executive staff member with direct-reporting requirements to the DDEAMC Commander. Therefore, as noted, the RSP and its activities have top-level review and oversight.

On nearly a daily basis, some member of the Health Physics group (or in the case of Health Physics users, the RSO or senior staff member) reviews workers and work in radioactive material use areas for conformance to DDEAMC requirements for safe use. Quarterly, the RSO (or a designated senior member of the Health Physics staff) conducts a comprehensive audit of all radioactive material users at DDEAMC. This audit includes review of records, review of the work areas, and worker task reviews. A summary of each audit is provided to the RSC and the complete audit information included in as part of the RSC minutes. Whenever a process or program is newly-implemented or revised, audits will be conducted to focus on the process or program to ensure the effectiveness of the implementation are evaluated.

In addition to the internal audits conducted by RSO and Health Physics staff, periodic outside audits of the RSP are conducted. These include a no-less-often-than triennial comprehensive program audit from the Regional Medical Command Radiation Safety Consultant. All RSC minutes prepared, along with supporting documentation, are submitted after minutes approval to the Regional Consultant for review, as a means for a more timely independent review of the DDEAMC RSP.

Each year, the RSO conducts a comprehensive year-wide roll-up assessment of the quarterly audit results for the previous calendar year for RSP for presentation. This consolidated assessment is used to better review any negative trends and ensure corrective actions taken to findings have been successful in preventing recurrence. Also, annually the RSC reviews the air effluent public dose and the sewerage

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| releases for the previous calendar year to ensure they comply with Part 20 and license requirements.<br><br>Audit Program change control assurance:<br>Changes in the frequency, depth of review, and audit area focus will be consistent with the present or projected needs of the RSP. Procedures controlling the audit program are primarily under the authority and direction of the RSO, but ultimately are reviewed and controlled by the RSC. Furthermore, it is requested that the RSO and RSC be able to continue to exercise the autonomy needed to revise, update, refine, and improve procedures associated with the audit program as deemed necessary for the safe and efficient operation of the DDEAMC RSP. | | |

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| (not listed) | 8.10.3 | Item 10—Material Receipt and Accountability |

Response: The DDEAMC RSC requires approval for all radioactive material purchases; this is administratively controlled by the RSO. Any purchaser must have the appropriate experience and training as described earlier as well as an approved use for the material. Purchases are approved and receipt of material tracked by the RSO to ensure material has been received.

Unsealed Source Control:

The largest user of radioactive material (in terms of total radioactivity) is the Nuclear Medicine Service. Unsealed radiopharmaceutical sources and generators are received directly there (via special courier or common carrier), received by their personnel with the appropriate actions for material receipt as stated in 10 CFR 20.1906. The material is logged into a computer tracking system in order to efficiently track dosages received and administered to patients. The system is tied to the dose calibrators to provide direct input of the measured radioactivity value, as well as to decay-correct doses for these short half-life materials. This system is especially useful for tracking the use of individual doses taken from bulk technitium-99m generator elutions.

As noted earlier, to date, no radioactive material has been used in the Clinical Investigation area. However, when any use starts there, they will be responsible for obtaining RSO approval for each request, having the material received there (with 10 CFR 20.1906 actions fulfilled), and the use and disposal method logged while in their possession.

All Sources Other-Than-Unsealed Control:

All other sources (to include any source not intended for routine use as an unsealed source), to include various quality control, check sources for instruments, and other miscellaneous sources (e.g. chemical agent detector ionization sources in manufactured homeland defense-type devices) are received through Health Physics (regardless of the end-user). Health Physics then ensures these devices are inventoried periodically, leak-tested when necessary, and sent for proper disposal when no longer needed (discussed below). RSL "seeds" will be delivered directly to Health Physics during the roll-out of the RSL procedure program to ensure full control and accountability of these sources; as experience is gained by users and compliance with program requirements are verified, the DDEAMC RSC may allow direct delivery of the devices to the Nuclear Medicine pharmacy, who will then receive, control, and distribute the devices.

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| (not listed) | 8.10.3 | Item 10—Material Receipt and Accountability |

Receipt of Radioactivity:
Material received from origins outside of DDEAMC, that have been delivered through regulated transportation (i.e. special courier or common carrier) are required to be "received" using procedures prepared by the individual authorized organizations and approved by the RSO that meet the requirements of 10 CFR 20.1906. Records of the receipt are kept as required in order to track material use and disposal, and for inventory control.

Security of radioactive material:
This item was discussed earlier, by building-specific requirements.

Radioactive Material Receipt and Accountability Program change control assurance:
Changes in the specifics of the radioactive material receipt and accountability program will be consistent with the present or projected needs of the RSP. Procedures controlling the radioactive material receipt and accountability program are primarily under the authority and direction of the RSO, but ultimately are reviewed and controlled by the RSC. Furthermore, it is requested that the RSO and RSC be able to continue to exercise the autonomy needed to revise, update, refine, and improve procedures associated with radioactive material receipt and accountability as deemed necessary for the safe and efficient operation of the DDEAMC RSP.

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| 8.23 | 8.10.4 | Item 10—Occupational Dose |

Response: All current radioactive material users at DDEAMC are monitored with external personal dosimeters. These workers are monitored with dosimeters to measure "whole body" dose. As necessary, due to the potential for elevated exposure to the hands, one (or two) extremity dosimeter(s) is (are) issued to some workers. Declared pregnant workers, if continuing to work in restricted areas, are assigned an additional dosimeter to evaluate fetal dose. Doses from previous employment and concurrent employment at other facilities are also evaluated. The requirements for dosimetry assignment are specified by Army-wide regulation. Note that nursing staff who are assigned to the ward where in-patient ablations occur are currently not routinely monitored with dosimetry, since historical monitoring information did not support continued issuance of dosimetry, and a determination was made in 2012 to discontinue regular dosimetry issuance since nursing staff do not enter into close proximity to in-patients during ablation procedures. In the event of a medically-fragile patient needing closer nursing support, consideration of dosimetry issuance will be made based on the specific needs in that situation where issuance of such dosimetry is determined to be "likely" as listed in 10 CFR 20.1502.

Dosimeters used: All dosimeters used in the facility are obtained from the central Army Dosimetry Center laboratory, a NVLAP-accredited facility for the exposure types encountered at DDEAMC. This accreditation is periodically reviewed by the RSO to ensure it remains appropriate to our dosimetry needs.

As previously noted, some personnel also receive periodic thyroid uptake measurements following the preparation and administration of therapeutic-level I-131 dosages. Aside from this process, no other specific internal uptake and dose assessments are identified as being routinely needed. (Currently no Xe-133 is being used and limited aerosolized lung scans with Tc-99m are performed.) However, this does not preclude the need for off-normal conditions that could necessitate the need for some form of specialized bioassay for a worker. In such cases, the RSO will identify the need for specialized bioassay, notify the Army Medical Command Radiation Safety Consultant of the need, and then coordinate the specific bioassay measurement process that would need to be conducted through the U.S. Army Public Health Command's Health Physics support office.

Any new process or program that will utilize radioactive materials will be analyzed to determine the need for, and if needed, the type of dosimetry required in order to properly monitor workers for exposure to

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| 8.23 | 8.10.4 | Item 10—Occupational Dose |
| ionizing radiation as required by 10 CFR 20 regulations and U.S. Army regulations.<br><br>Occupational Dose Monitoring and Control and Dosimetry Program change control assurance:<br>Procedures controlling the selection, use, and measurement of radiation doses are under the authority and direction of the RSO. Furthermore, it is requested that the RSO be able to continue to exercise the autonomy needed to revise, update, refine, and improve procedures associated with the occupational dose monitoring and dosimetry program as deemed necessary for the safe and efficient operation of the DDEAMC RSP. | | |

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| (not listed) | 8.10.5 | Item 10—Public Dose |

Response: The DDEAMC RSO conducts multiple assessments of public dose, to inform the RSC of compliance with requirements in 10 CFR 20 Subpart D. These assessments include:

- Prospective calculations of any new exposure processes, or changes to existing exposure processes, to ensure that the likelihood of exceeding a public dose limit will not occur.
- On-going measurements of actual exposure processes, with periodic radiation level measurements using calibrated radiation monitoring instruments and documented surveys of the levels.
- Retrospective annual assessments of radioactivity receipts and possible releases to airborne effluents (10 CFR 20 Appendix D) using approved calculational methods to determine doses from potential airborne releases.
- Retrospective assessments, if and when needed, following any incident that may result in public dose (e.g. a major spill of licensed material in an unrestricted area).
- Adherence to DDEAMC and section procedures for the control and storage of radioactive material.
- Careful determination of release criteria and patient instruction for in-patient radionuclide therapy patients (10 CFR 35.75) to ensure the release of these patients does not cause unnecessary public dose.

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| 8.24 | 8.10.7 | Item 10—Area Surveys / Surveys |

Response: DDEAMC conducts surveys in and around radioactive material use and storage areas that were developed to implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70 to:

- Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 1 mSv per year (100 millirem/year) and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour from licensed operations;
- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 10 CFR 20.1201;
- Control and maintain constant surveillance over licensed material that is not in storage, and secure licensed material from unauthorized access or removal;
- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in 10 CFR 20.1101; and
- Verify that sealed sources do not emit radioactivity in excess of levels allowed in 10 CFR 35.67.

These include surveys of ionizing radiation levels, measurement of fixed and transferable contamination, measurements of certain worker thyroids for radioiodine uptake, and calculations based on other measurements of radioactivity that may be placed in sanitary sewerage or emitted through building exhaust to the air. Surveys are conducted as follows:

- Radiation levels are assessed at least daily when radionuclide work is conducted during that day in dose preparation and administration areas.
- Radiation surveys are conducted during each RSL procedure phase (implanting, surgical removal, post-removal handling and pathology tissue manipulation) until full source accountability is achieved and source integrity is ensured;
- Radiation and contamination levels are surveyed at least weekly in all use and storage areas.
- Ambient radiation levels are surveyed at least quarterly in areas surrounding use and storage areas.
- Leak tests for sealed sources as identified in 10 CFR 35.67 or as specified in license requirements at no less than the minimum frequency stated to the necessary detection level.

Surveys will be made as needed following known or suspected spills or other incidents, radioiodine

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| 8.24 | 8.10.7 | Item 10—Area Surveys / Surveys |

bioassays following large therapy dosage administrations, in support of routine maintenance or facility rework in use areas, and as otherwise deemed to be needed by the RSO.

Radiological Hazard Survey Program and Sealed Source Leak Test change control assurance:

Changes in the radiological hazard survey program or sealed source leak test procedures will be consistent with the present or projected needs of the RSP. Procedures controlling the type, frequency, detail, and documentation of these activities are under the authority and direction of the RSO by authority of the RSC, to whom reports of these surveys are given. Furthermore, it is requested that the RSO and RSC be able to continue to exercise the autonomy needed to revise, update, refine, and improve procedures associated with the radiological hazard survey program and sealed source leak test process as deemed necessary for the safe and efficient operation of the DDEAMC RSP.

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| 8.25, 8.26 | 8.10.6 | Item 10—Safe Use of Unsealed Licensed Material, and Spill/Contamination Procedures / Safe Use of Radionuclides and Emergency Procedures |

Response: DDEAMC has developed, implemented, and maintains procedures for the safe use of sealed and unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301, to include the safe and effective response to spills of licensed material. As discussed earlier, all users of radioactive material must either be experienced users or be under the direct supervision of an experienced user while gaining experience, knowledge, and understanding of the safe use of both sealed and unsealed radioactive material. As part of the initial and continuing training, users are required to know the requirements for procedures to use, store, secure, and dispose of radioactive material items in order to keep their exposure and public exposure to a minimum as well as meet regulatory requirements. Appropriate stocks of equipment and supplies to mitigate reasonable emergency situations are maintained for use.

Written procedures currently exist and will continue to be maintained that include:

- the need to wear protective items to prevent skin and personal clothing contamination (which is also required for blood-borne pathogen protection and infection control);
- the need for shielding adjuncts (e.g. syringe and vial shields, RSL procedure use of remote handling devices) use to reduce extremity exposure;
- the need for workers to monitor themselves for contamination at certain times when using unsealed radioactivity sources;
- the need for workers involved in all phases of RSL procedures (including implanting, surgical removal of lesions and seeds, and post-surgical handling of tissues with seeds until seeds are removed from the tissue and are placed in temporary waste storage) to ensure seeds are fully accounted for and that there has not been any loss of integrity of a seed that may release radioactive material either into the patient or cause workplace contamination, and for actions that must be promptly taken to mitigate those issues.
- actions to be taken in the event of spills of radioactivity, loss of material, leaking or ruptured RSL seeds in a patient or in a tissue sample, deceased patients who received radiopharmaceuticals for diagnosis or therapy, or significant emergencies where radioactive material use/storage areas are involved; and
- to whom and how contact will be made in an emergency.

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|---|---|---|
| 8.25, 8.26 | 8.10.6 | Item 10—Safe Use of Unsealed Licensed Material, and Spill/Contamination Procedures / Safe Use of Radionuclides and Emergency Procedures |
| Safe Use of Radioactive Material, Radionuclides, and Spill/Contamination/Emergency Procedures change control assurance:<br>Changes in procedures for the safe use of radioactive material and for spill/contamination/emergency procedures will be consistent with the present or projected needs of the RSP. Procedures controlling the type, frequency, detail, and documentation of these activities are under the authority and direction of the RSC through the DDEAMC procedure change control process . Furthermore, it is requested that the RSC be able to continue to exercise the autonomy needed to revise, update, refine, and improve procedures associated with the safe use of unsealed licensed material, radionuclides, and associated spill/contamination/emergency procedures as deemed necessary for the safe and efficient operation of the DDEAMC RSP. | | |

| NUREG-1556 Vol. 9 | NUREG-1556 Vol. 11 | Item # and Subject |
|---|---|---|
| 8.27 | (not listed) | Item 10—Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources |
| Response: No radiotherapy devices with sealed radioactive material are used in this facility. | | |

| NUREG-1556 Vol. 9 | NUREG-1556 Vol. 11 | Item # and Subject |
|---|---|---|
| 8.28 | (not listed) | Item 10—Minimization of Contamination |

Response: As discussed earlier in the various descriptions of our DDEAMC facilities, our radiological survey practices, our safe use of unsealed licensed material, our spill/contamination procedures, and our waste management practices, the RSC requires an aggressive contamination control program at DDEAMC in order to reduce the unnecessary exposure of patients, staff, and the environment. Key items in ensuring radiological contamination is minimized includes:

- Training for all personnel using unsealed sources includes the need to immediately mitigate a spill, that is, any radioactive material outside the intended work area, as well as request Health Physics assistance to survey the area.
- Appropriate use of protective barriers (absorbent pads with liquid-impervious backing) where useful, practical, and radiological contamination is most likely.
- The use of radiological material that has a short half-life when possible.
- Frequent radiological surveys to identify potential contamination.
- Allowing only experienced personnel to conduct work with unsealed licensed material, or to directly supervise inexperienced personnel while they gain experience.
- Vigilance during the conduct of RSL actions to prevent loss of RSL seed integrity, but also to rapidly identify and mitigate any loss of RSL seed integrity.
- Adherence to DDEAMC and section procedures for the control and storage of radioactive material.
- The authority given to the RSO to discontinue any operation that can cause significant radiological risk to patients, staff, or the facility.

| NUREG-1556 Vol. 9 | NUREG-1556 Vol. 11 | Item # and Subject |
|---|---|---|
| (not listed) | 8.10.8 | Item 10—Transportation |

Response: DDEAMC currently ships radioactive material in the following circumstances:

- To return spent technetium generators to the manufacturer for reuse;
- To return sealed sources no longer needed or usable (due to decay) to the manufacturer for disposal;
- To transfer materials between Building 38705 and Building 300 when any radioactive material work should commence there;
- In support of samples containing radioactive material, if this should become necessary; and
- Shipment of radioactive waste to a licensed processor (if not accomplished through a broker contracted by the Army Materiel Command which is the normal process).

Shipments of these materials are accomplished only through regulated means as identified in 10 CFR Part 71 and 49 CFR Subchapter C. Personnel who make these shipments are required to be trained for both 10 CFR Part 71 and 49 CFR Subchapter C.

| NUREG-1556 Vol. 9 | NUREG-1556 Vol. 11 | Item # and Subject |
|---|---|---|
| 8.29 | 8.11 | Item 11—Waste Management |

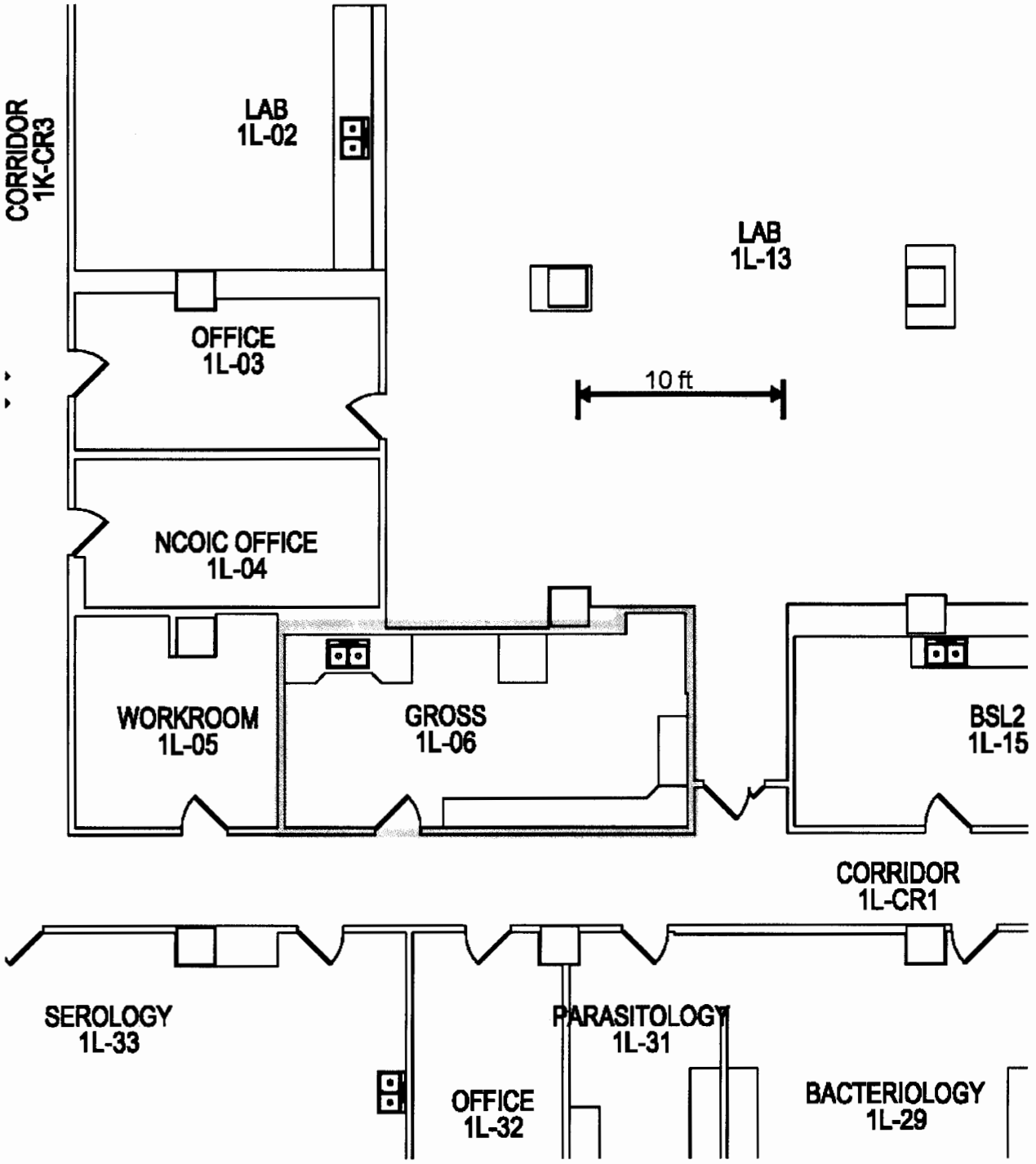
Response: DDEAMC currently utilizes a combination of practices for waste disposal and has developed, implemented, and maintain written waste disposal procedures for licensed material, in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and of 10 CFR 35.92. These include:

- Decay in storage for radioactive materials that have a half-life less than 120 days, followed by disposal using appropriate waste types following monitoring to ensure no reading above ambient background, using the most sensitive instrument available, is made and documented (10 CFR 35.92);
- Sink disposal into the sanitary sewerage for certain water soluble/dispersible small activity wastes, but not to exceed monthly/annual limits as specified in 10 CFR 20.2003 and our license;
- Return to the manufacturer for sealed sources used under 10 CFR Part 35 and for spent technetium generators;
- Waste from *in-vitro* kits (under 10 CFR 31.11) are disposed in normal waste;
- Long (>120-day) half-life material that is not otherwise returned to the manufacturer for disposal is otherwise treated as radioactive waste and handled accordingly, and disposed through U.S. Army Materiel Command-contracted waste pick-ups and transfer to a licensed waste processing facility; and
- Disposal of animal carcasses and liquid scintillation counting media as non-radioactive that meet the limitations of 10 CFR 20.2005 (when this may become necessary if this type of work is conducted in our research building).

At this time, no other type of waste handling or processing is anticipated.

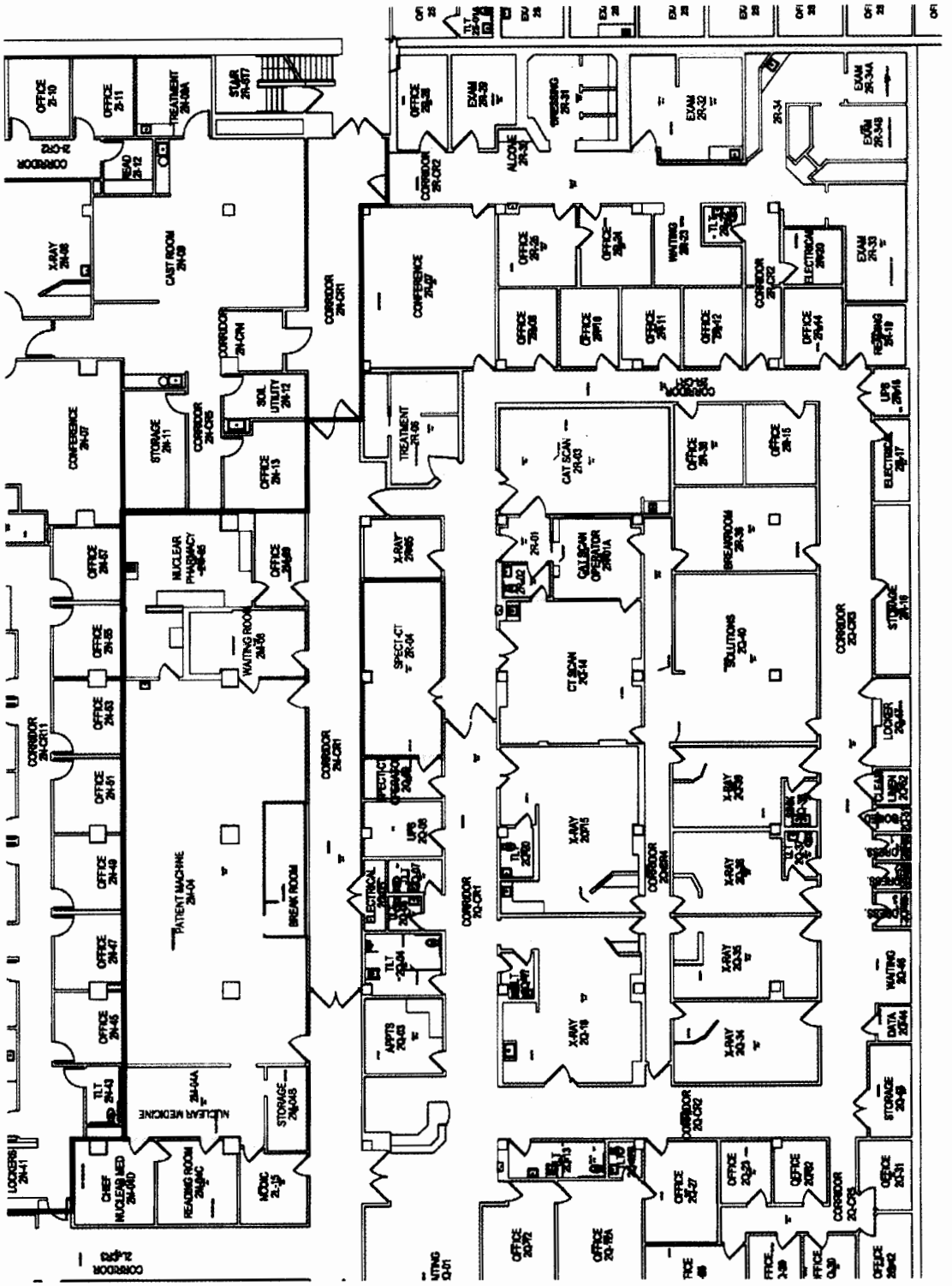
Appendix A: Drawings to Scale of Radioactive Material Use Area

**Building 300 First Floor with Radioactive Material Areas**

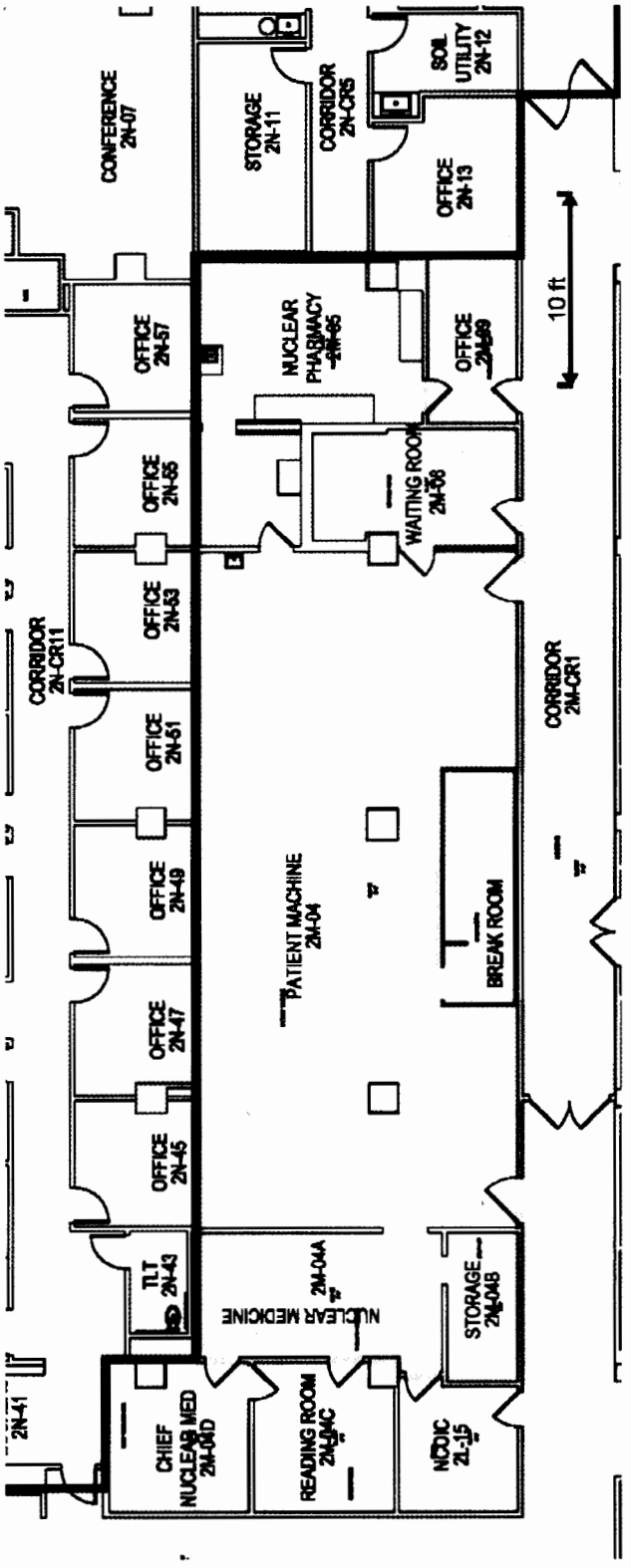


## Building 300 Second Floor with Radioactive Material Areas

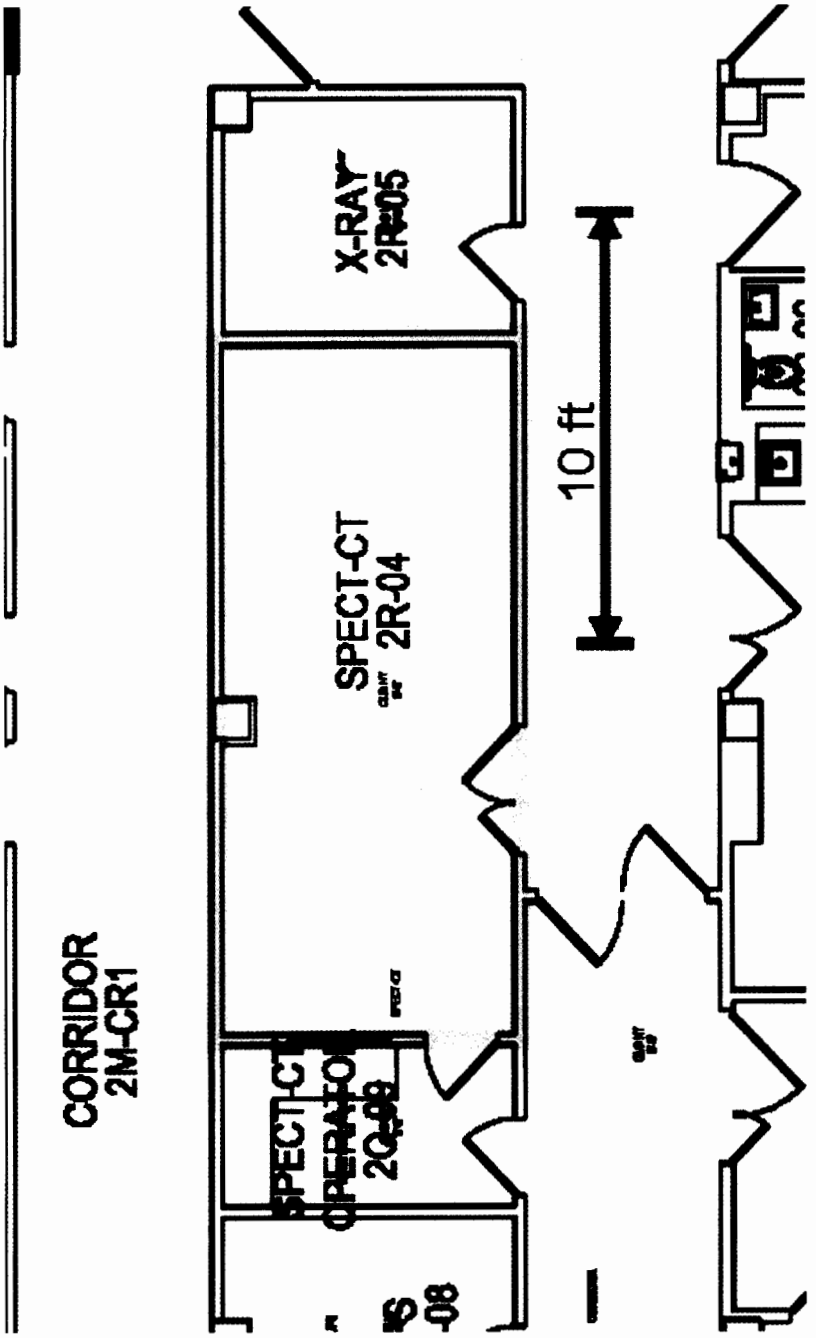
B300/F2-0 Showing Full Radioactive Material Area Layout



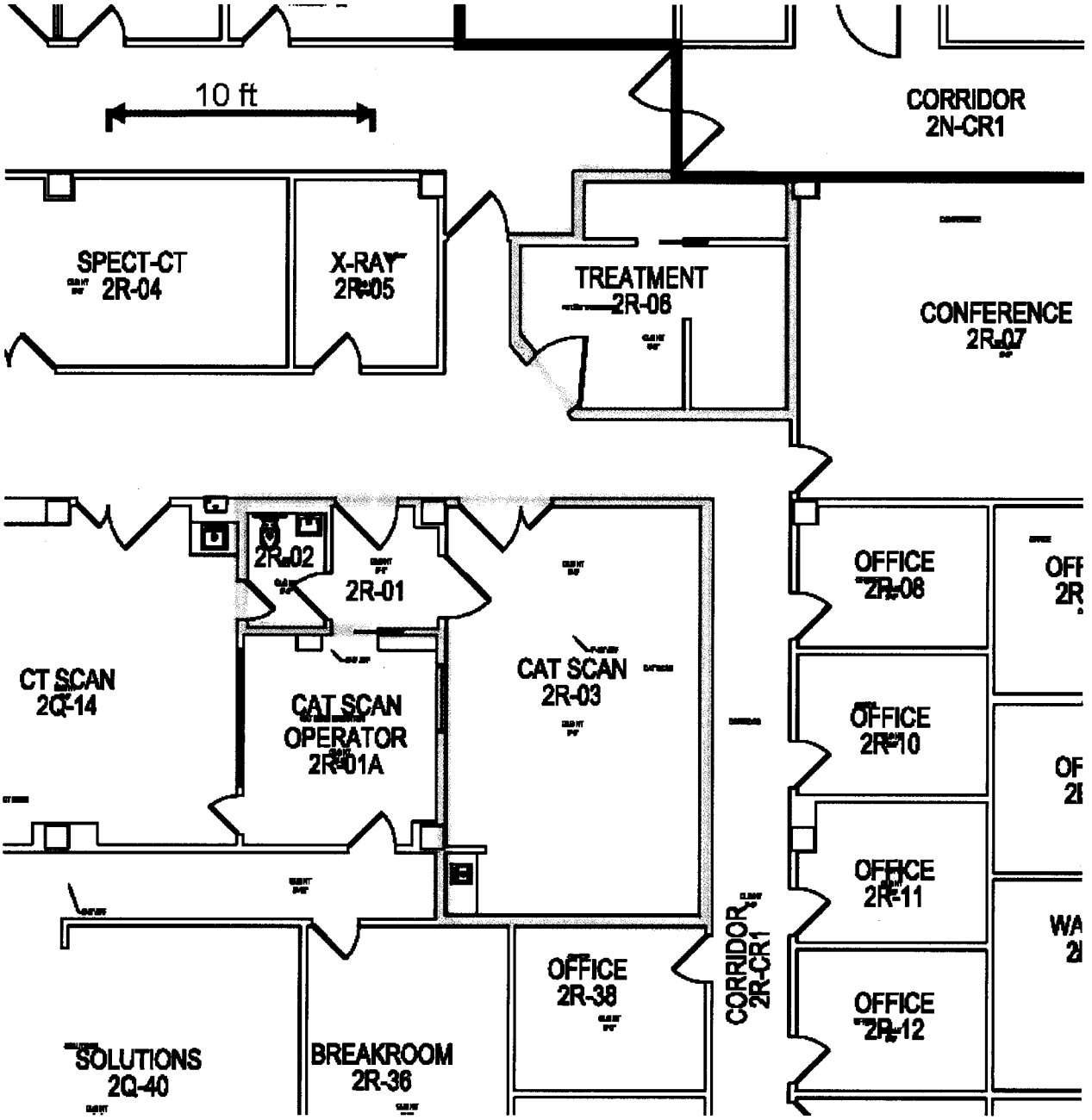
B300/F2-1 Zoom of Nuclear Medicine Area Detail



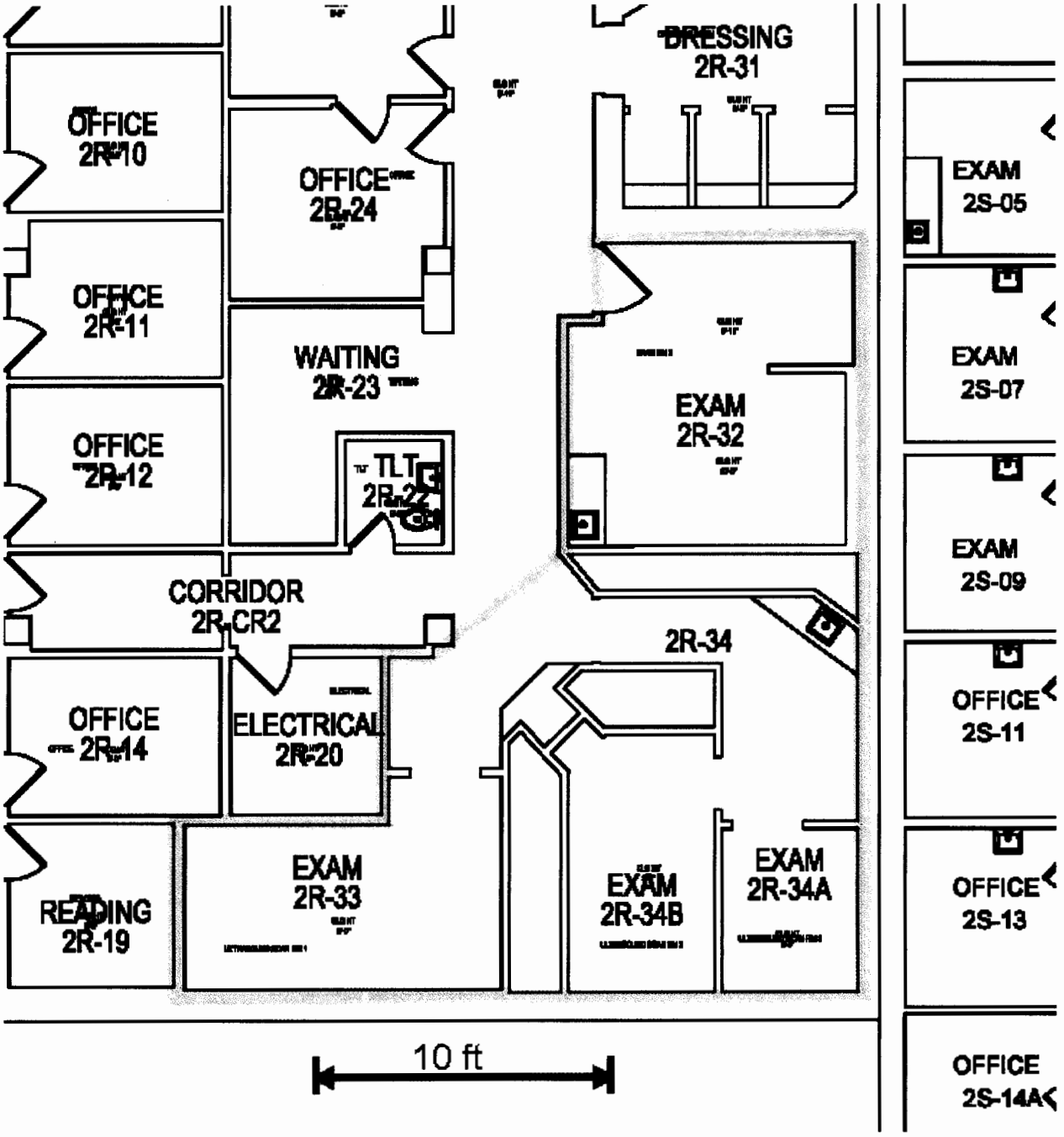
B300/F2-2 Zoom of SPECT-CT Room



B300/F2-3 Zoom of PET-CT Room Enclave

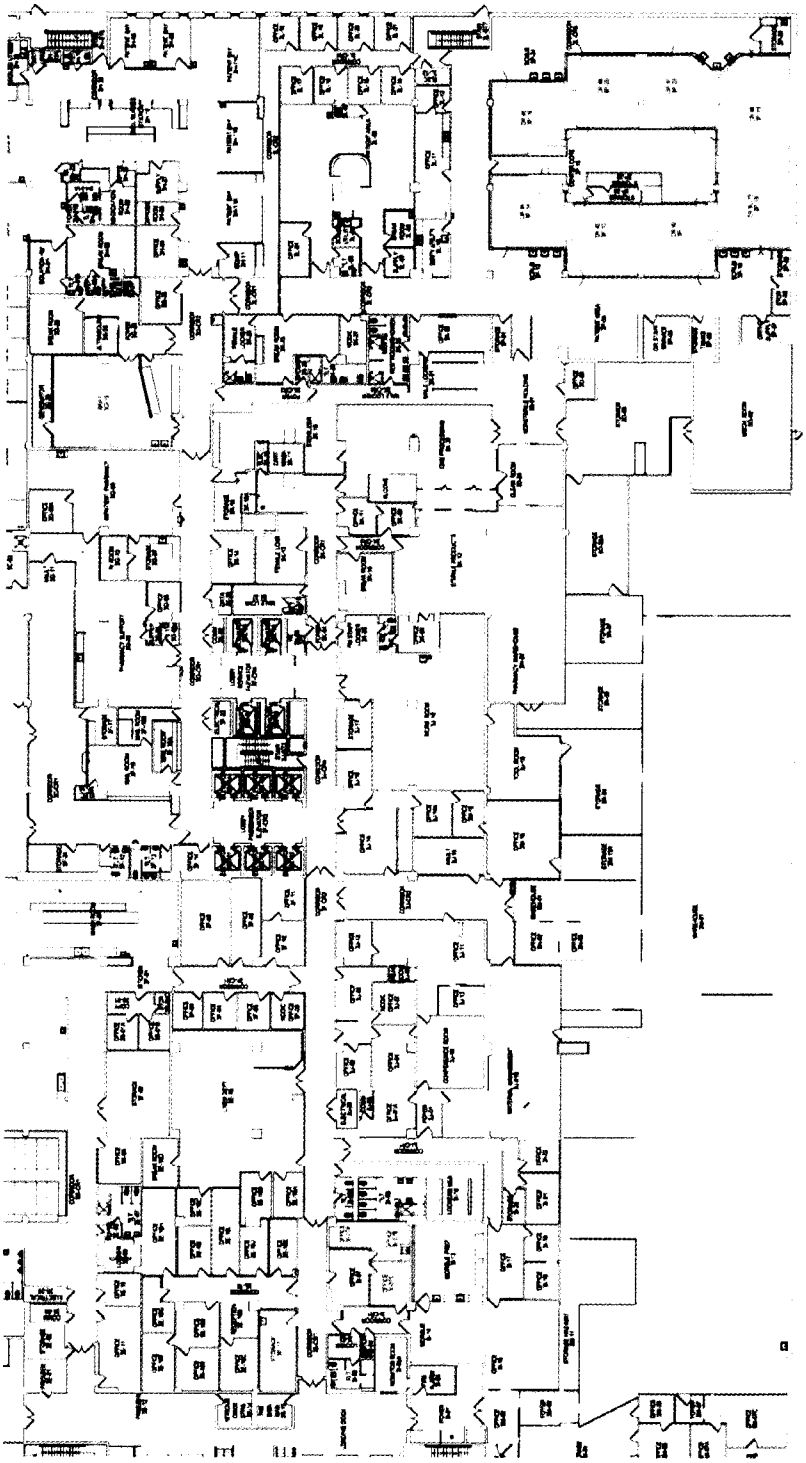


B300/F2-4 Zoom of Stereotactic Breast Biopsy and Ultrasound Rooms

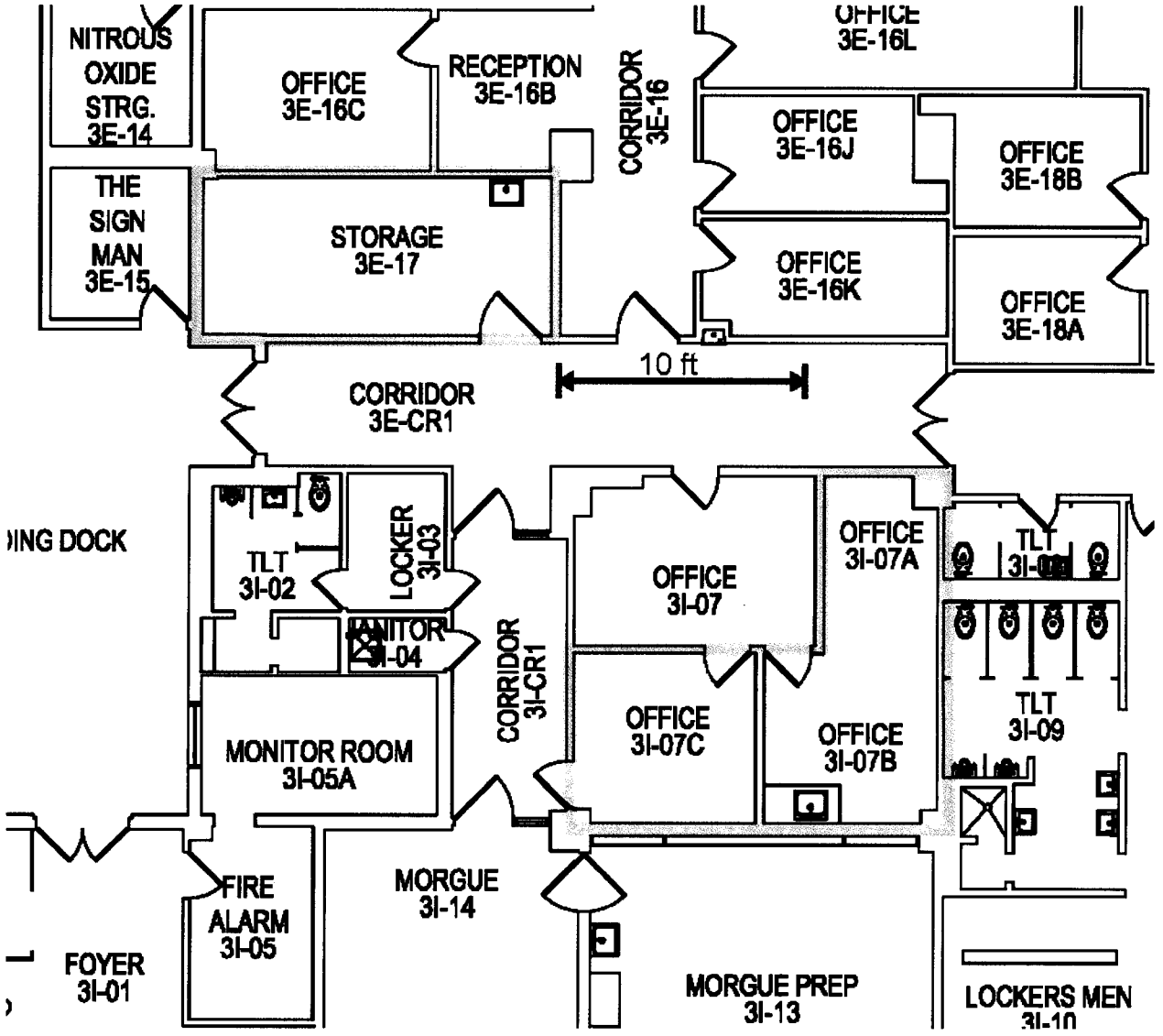


## Building 300 Third Floor with Radioactive Material Areas

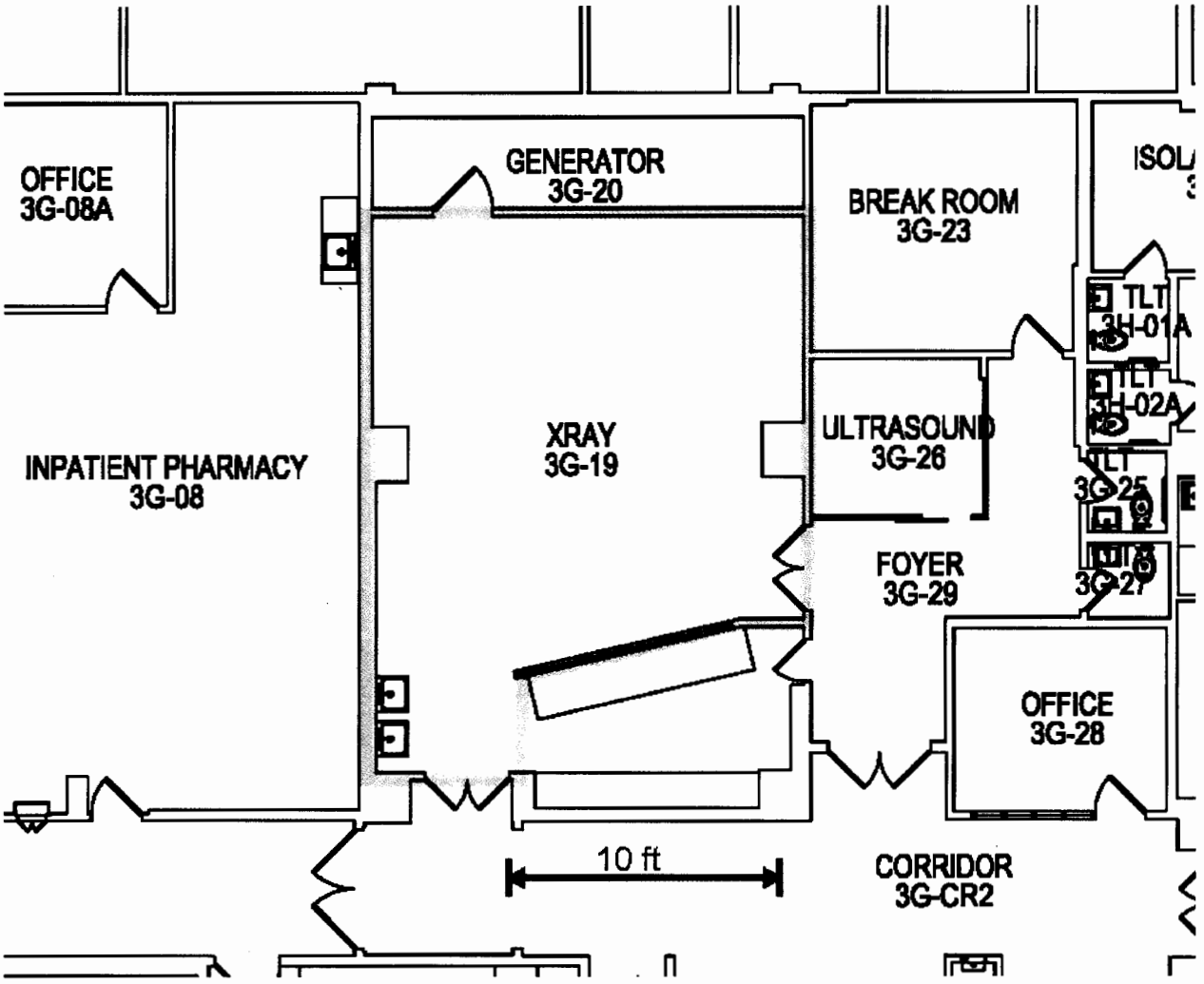
B300/F3-0 Showing Full Radioactive Material Area Layout



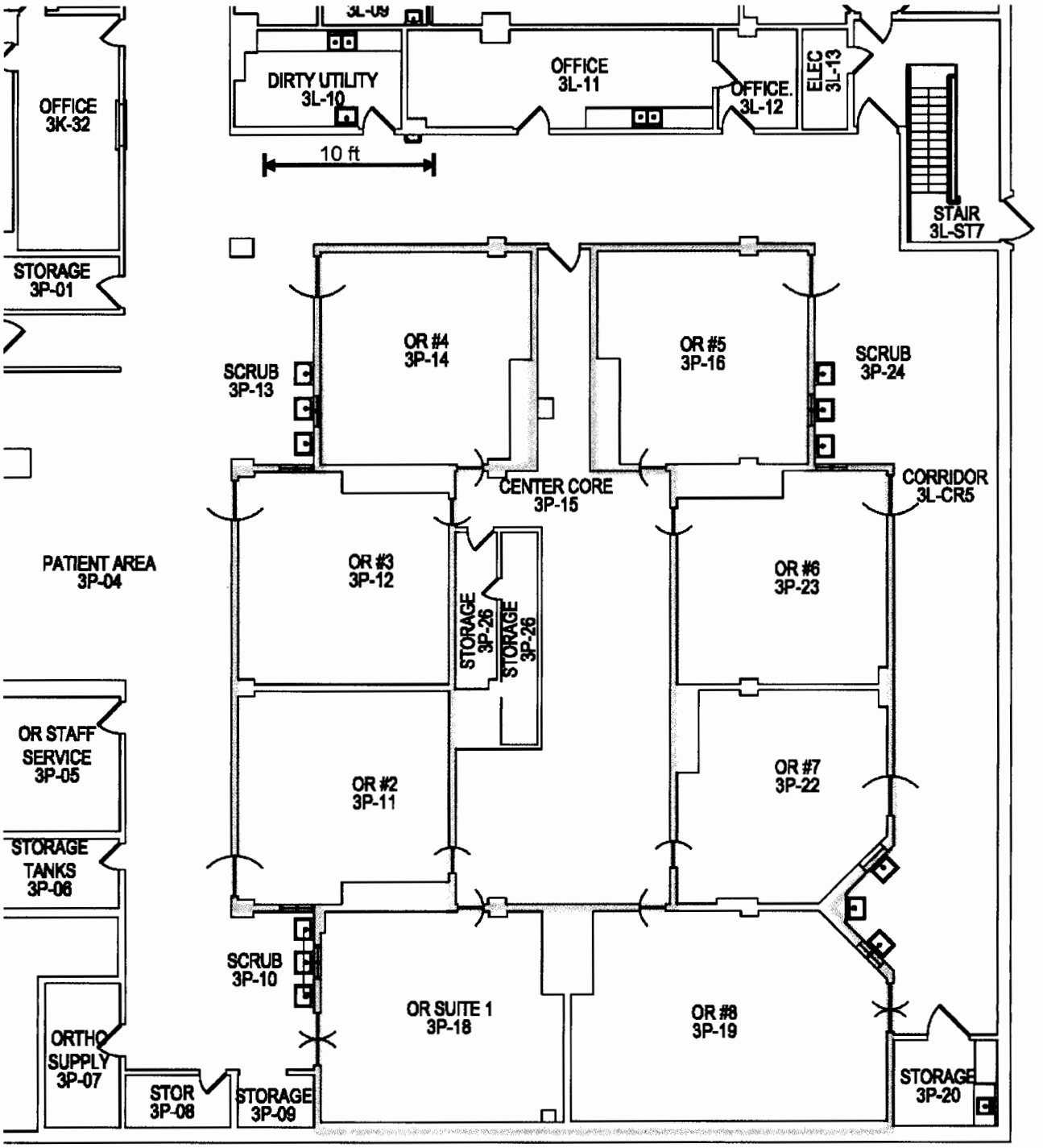
B300/F3-1 Zoom of Health Physics Lab and Waste Storage Areas



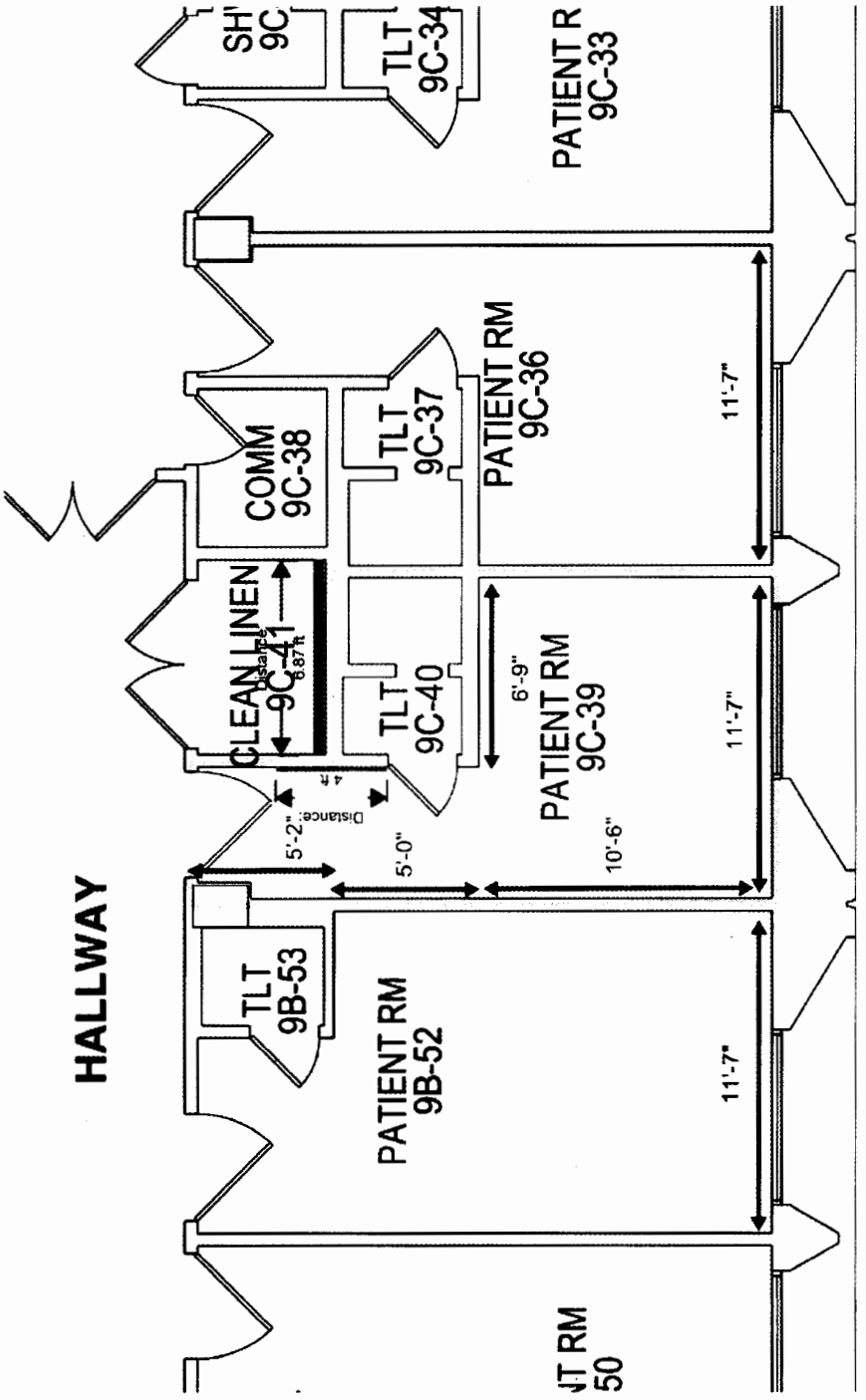
B300/F3-2 Zoom of Interventional Radiology Procedure Room



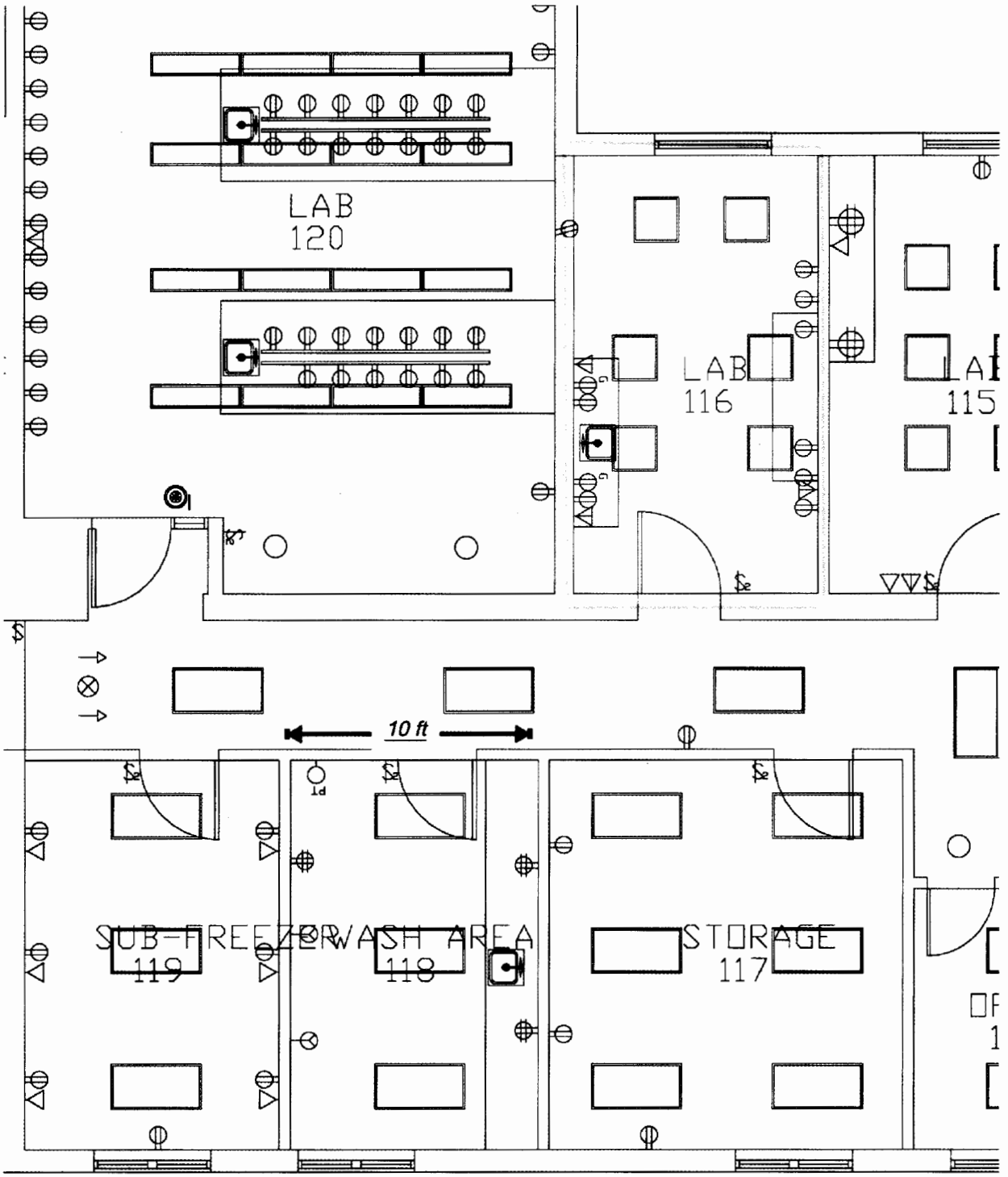
B300/F3-3 Zoom of Operating Room Enclave



## Building 300 Ninth Floor In-Patient Ablation Therapy Room



## Building 38705 Clinical Investigation Research Area



This is to acknowledge the receipt of your letter/application dated 03/17/2016, and to inform you that the initial processing which includes an administrative review has been performed.

10-12044-03 (Amendment)

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 590661
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader.