



DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
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6470
Ser OM/ 09852

02 JUL 1997

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM
INFORMATION NOTICE 97-07

Ref: (a) OPNAVINST 6470.3
(b) BUMEDINST 6470.20

Encl: (1) NEHC Nuclear Medicine Inspection Field Notes
(2) List of 1997 NAVENVIRHLTHCEN Information Notices

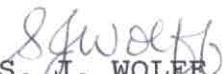
1. Reference (a) requires that Navy Environmental Health Center (NAVENVIRHLTHCEN) perform inspections at commands holding NRMPs. Enclosure (1) will be used by NAVENVIRHLTHCEN personnel to conduct these inspections.

2. Reference (b) requires that each permittee be audited annually by an individual independent of the program. The audit shall not be conducted by the incumbent Radiation Safety Officer (RSO) or an authorized user on the facility permit. Enclosure (1) shall be used to document these audits and a copy shall be forwarded to NAVENVIRHLTHCEN in accordance with reference (b).

3. When an RSO is to be replaced, the prospective RSO shall complete a relief audit using enclosure (1). The completed checklist shall be forwarded to NAVENVIRHLTHCEN as an enclosure to the amendment request to change the RSO.

4. Enclosure (1) is a list of all NRMP Information Notices issued during calendar year 1997. Copies of letters listed in this enclosure are available from NAVENVIRHLTHCEN.

5. You may contact the Radiation Health Team for more information at DSN 864-5575 or (757)363-5575, by fax to DSN 565-9481 or (757)445-9481, or by e-mail at wolffs@ehc50.med.navy.mil.


S. J. WOLFER
By direction

Distribution:
All hospital RSOs

Copy to:
CNO(N455)
BUMED(MED-211)
NSHS Bethesda, MD (Attn: Clinical Nuclear Medicine School)
NAVUSEAMEDINSTITUTE Groton, CT

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Note: Italicized sections indicate that the inspection item can be best evaluated by observation of a procedure or through interviews with appropriate personnel, vice the conduct of a detailed administrative review.

1. INSPECTION HISTORY () N/A - Initial inspection

A. Deficiencies were identified during the last inspection or three years () Y () N

B. Response letter(s) dated _____

C. Deficiencies from previous inspections:

Requirement:

Deficiency:

Corrective actions:

Status:

Requirement:

Deficiency:

Corrective actions:

Status:

Requirement:

Deficiency:

Corrective actions:

Status:

Requirement:

Deficiency:

Corrective actions:

Status:

D. Explain any previous deficiencies not corrected or repeated () N/A

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Organizational Structure

+ Individuals contacted during inspection

1. Meets functional requirements () Y () N
2. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

B. Radiation Safety Committee

1. Membership as specified [35.22(a)(1)] () Y () N
2. Meetings held quarterly [35.22(a)(2)] () Y () N
3. Quorums established [35.22(a)(3)] () Y () N
4. Records maintained [35.22(a)(4)] () Y () N
5. ALARA program review [35.20(c)]
 - a. Review of byproduct material used () Y () N
 - b. Occupational doses () Y () N
 - c. Changes in procedures () Y () N
 - d. Continuing education and training () Y () N
6. Has sufficient authority [35.23](a)] () Y () N
7. Established in writing [35.23(b)] () Y () N
8. Documents approval/disapproval of individuals prior to allowing them to work as an authorized user [35.22(b)(2)(ii)] () Y () N

C. Radiation Safety Officer

1. Appointed in writing [35.21(a), 900] () Y () N
2. Fulfills duties [35.21(b)] () Y () N
3. Has sufficient authority [35.23] () Y () N

D. Radiation Safety Program

1. Minor changes pursuant to [35.31] () Y () N
2. Records of changes maintained [35.31(b)] () Y () N

3. Content and implementation reviewed annually by the RSC and management [20.1101(c), 35.22(b)(6)] () Y () N
4. Records of reviews maintained [20.2102] () Y () N
5. Annual external NRMP review [BUMEDINST 6470.20] () Y () N
6. Semi-annual external radiation health program audits [NAVMED P-5055] () Y () N

E. Use by authorized individuals [NRMP]

Compliance is established by meeting at least one criteria under each category.

1. Authorized User [35.13(b)] () Y () N
 - a. Certified by organization in 35.910, 920, 930, 940, 950, 960 () Y () N
 - b. Identified on NRC or Agreement State license or NRMP () Y () N
 - c. Listed on facility permit () Y () N
 - d. Documented approval by RSC [35.22(b)(2)(ii)] () Y () N
2. Radiation Safety Officer [35.13(c)] Listed on facility permit () Y () N

F. Amendments since last inspection [35.13] List changes: () Y () N

G. Notifications since last inspection [35.14] () Y () N

1. Permittee has provided appropriate documentation to NEHC for authorized user no later than 30 days after the individual starts work [35.14(a)] () Y () N
2. Permittee has notified NEHC within 30 days after authorized user or RSO stops work or changes name [35.14(b)] () Y () N
3. Their user list matches NEHC () Y () N

3. TRAINING

A. Instructions to workers [19.12] () Y () N

1. Informed of storage, use, or transfer of radioactive material in restricted areas () Y () N

2. Instructed of the health problems associated with such exposure to radioactive material or radiation, procedures to minimize exposure, and in the functions of protective devices employed () Y () N
 3. Instructed in and instructed to observe the NRC Regulations for the protection of personnel from radiation exposures () Y () N
 4. Instructed to report to the licensee any condition which may cause a violation of regulations or unnecessary radiation exposure () Y () N
 5. Instructed in the response to warnings () Y () N
 6. Advised of radiation exposure reports that may be requested () Y () N
- B. Individual's understanding of current procedures and regulations is adequate () Y () N

List personnel interviewed and areas:

- C. Training program IAW permit application () Y () N
1. Briefly describe training program:
(Who, when, how)
 2. Initial/periodic training program implemented () Y () N
 3. Complete records maintained () Y () N
(Date, duration, place, instructor, subjects covered, attendees' names)
- D. Supervision of individuals by authorized user in accordance with [35.25] () Y () N
1. Supervised individuals are instructed in preparation of material, principles and procedures for radiation safety and QMP as appropriate [35.25(a)(1), 35.25(b)(1)] () Y () N
 2. Permittee periodically reviews supervised individuals use of material and records kept to reflect use [35.25(a)(3)] () Y () N
- Method of review:
3. Authorized user periodically reviews work and records of work of supervised individuals as it pertains to preparing byproduct material [35.25(b)(3)] () Y () N
- Method of review:
- E. Inpatient therapy training; Safety instruction [35.310, 410] () N/A
1. Control of patient & visitors () Y () N
 2. Contamination and waste () Y () N
 3. Size/appearance of sources () Y () N
 4. Handling/shielding of sources () Y () N
 5. RSO notification in emergency or death () Y () N
 6. Records maintained [35.310(b), 410(b)] () Y () N
 7. All patient care personnel involved are trained () Y () N
 8. Training timely to therapy () Y () N

F. Revised Part 20

Workers cognizant of requirements for:

1. Radiation Safety Program [20.1101] () Y () N
2. Annual dose limits [20.1301, 1302] () Y () N
3. 10% monitoring threshold [20.1502] () Y () N
4. Dose limits to embryo/fetus and declared pregnant worker [20.1208] () Y () N
5. Procedures for opening packages [20.1906] () Y () N
6. Sewer disposal limits [20.2003] () Y () N
(If applicable)

G. HAZARDOUS MATERIALS TRANSPORTATION TRAINING
(49 CFR 172.700-704)

1. All personnel involved with RAM transfers trained [172.702(a)] () Y () N
2. Training includes: [172.704(a)]
 - a. Regulations 49 CFR 171-173 () Y () N
 - b. Identification of RAM () Y () N
 - c. Function-specific training () Y () N
 - d. Safety training
 - (1) Emergency response () Y () N
 - (2) Self-protection () Y () N
 - (3) Accident avoidance () Y () N
3. Training within 90 days of employment or job change [172.704(c)] () Y () N
4. Training repeated every 3 years [172.704(c)] () Y () N
5. Training records include: [172.704(d)]
 - (1) Name () Y () N
 - (2) Topic outline () Y () N
 - (3) Date, location, trainer () Y () N
 - (4) Certification of training and testing () Y () N
6. Records maintained for 3 years [172.704(d)] () Y () N

4. FACILITIES

- A. Facilities as described in permit application () Y () N
- B. Storage areas
 1. Materials secured from unauthorized removal or access [20.1801] () Y () N

2. *Permittee controls and maintains constant surveillance of permitted material not in storage [20.1802]* () Y () N
5. EQUIPMENT
- A. Dose calibrator for photon-emitters
1. Possessed and used [35.50(a)] () Y () N
 2. *Constancy [35.50(b)(1)]*
 - a. *Performed daily* () Y () N
 - b. *Dedicated check source used* () Y () N
 3. *Accuracy [35.50(b)(2)]*
 - a. *Performed at installation and annually* () Y () N
 - b. *At least 2 sources used* () Y () N
 4. *Linearity [35.50(b)(3)]*
 - a. *Performed at installation and quarterly thereafter* () Y () N
 - b. *Includes range between 30 uCi and the highest patient dosage administered* () Y () N
 5. *Geometry Dependence [35.50(b)(4)]*
 - a. *Performed at installation or relocation* () Y () N
 - b. *Includes range of volumes and volume configurations used (Syringes, vials, etc.)* () Y () N
 6. *Dosage readings mathematically corrected for geometry or linearity errors greater than ±10% [35.50(d)]* () Y () N
 7. *Repaired or replaced when constancy or accuracy errors exceeded ±10% [35.50(d)]* () Y () N
 8. *Procedures followed [35.21, 35.25, NRMP]* () Y () N
 9. *Records maintained and include identity of technician [35.50(e)]* () Y () N
- B. Permittee uses generators () Y () N
1. *No radiopharmaceuticals administered with Mo-99 over 0.15 uCi per mCi of Tc-99m [35.204(a)]* () Y () N
 2. *Each eluate for patient use tested for Mo-99 breakthrough [35.204(b)]* () Y () N
 3. *Records maintained [35.204(c)]* () Y () N
- C. *Syringes properly shielded [35.60(a)]* () Y () N
- D. *Syringes properly labeled [35.60(b)]* () Y () N
- E. *Vials kept in a shield [35.61(a)]* () Y () N

F. Vial shields labeled [35.61(b)] () Y () N

6. MATERIALS

A. Permittee measures activity of each dosage of photon-emitting radionuclide prior to use [35.53(a)] () Y () N

B. Permittee administers beta emitters () Y () N
If yes,

1. Permittee receives unit doses and relies on assay data supplied by manufacturer [35.53(b)] () Y () N

2. Permittee measures by direct measurements and/or calculation each dose prior to use [35.53(b)] () Y () N

List method:

C. Unsealed materials used are
1. Obtained from manufacturer or properly licensed organization () Y () N
AND/OR

2. Prepared by physician user or individual under the supervision of an authorized physician user [35.920] [35.100(b), 35.200(b), 35.300(b)] () Y () N

D. Isotope, chemical form, quantity and use as authorized [31.11, 35.400, 500, NRMP] () Y () N

E. Are materials actually used under 31.11 ? () Y () N

F. Observe use of radiopharmaceuticals [Reg Guide 10.8, Appendix I]

1. Protective clothing worn () Y () N

2. Personnel routinely monitor their hands () Y () N

3. No eating/drinking in use or storage areas () Y () N

4. No food, drink, or personal effects in use/storage areas () Y () N

5. Proper dosimetry worn () Y () N

6. Radwaste disposed in proper receptacles () Y () N

- G. Sealed source leak tests and inventories
(Includes brachytherapy sources)
1. Leak test performed [35.59(b)] () Y () N
 2. Leak test records in microcuries [35.59(d)] () Y () N
 3. Inventoried quarterly [35.59(g)] () Y () N
 4. Inventory performed promptly at the storage area after removing sources from a patient and includes required information [35.406(a)] (brachytherapy) () Y () N
 5. Records maintained & signed by RSO [35.59, 35.406] () Y () N

7. RADIATION SURVEYS

A. Survey instruments used

1. Appropriate and operable [35.120, 220, 320, 420] () Y () N
(0.1-100 mR/hr and 1-1000 mR/hr)
2. Calibrations [35.51(a,b)]
 - a. Before first use, annually & after repairs () Y () N
 - b. Approved calibration procedure followed to include check source reading determination [35.51(a)(3)] () Y () N
 - c. Within 20% in each scale or decade of interest [35.51(b)] () Y () N
3. Records maintained 3 years [35.51(d)] (calibration certificate) () Y () N
4. Source-checked each day of use [35.51(c)] () Y () N
5. AN/PDR-27 apparent exposure rate procedures available and followed
 - a. Recorded on meter () Y () N

B. Radiation surveys performed

1. Daily in all areas where radiopharmaceuticals are prepared or administered [35.70(a)] () Y () N
2. Weekly in all areas where radiopharmaceuticals or waste is stored [35.70(b)] () Y () N
3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered or stored [35.70(e)] () Y () N
4. Quarterly in brachytherapy source storage area [35.59(h)] () Y () N

- C. Trigger levels [35.70]
1. Established [35.70(d)&(g)] () Y () N
 2. Exceeded () Y () N
 3. Corrective action taken/documentated [35.21(b)(1)] () Y () N
- D. Techniques can detect 0.1 mR/hr, 2000dpm [35.70(c)&(f)] () Y () N
1. *Swipe counting method:*
- E. Complete records maintained [35.70(h)] () Y () N
(Date, map, trigger level, mR/hr or dpm/100 sq cm, instrument, initials)
- F. Protection of members of the public
1. Adequate surveys to demonstrate that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year [20.1302(a)&(b)] () Y () N
 2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] () Y () N
 3. Records maintained indefinitely [20.2103, 2107] () Y () N
8. PATIENT RELEASE () N/A
- A. Individuals released when TEDE less than 0.5 rem [35.75(a)] () Y () N
 - B. Instructions on ALARA provided to individuals when TEDE exceeds 0.1 rem [35.75(b)] () Y () N
 - C. Instructions to breast-feeding women include required information [35.75(b)] () Y () N
 - D. Release records maintained if 35.75(c) criteria are met [35.75(c)] () Y () N
 - E. Records of instructions given to breast-feeding women maintained, if required [35.75(d)] () Y () N

9. RADIOPHARMACEUTICAL THERAPY () N/A
- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release and contamination controls [35.315(a)] () Y () N
- B. Dose rate surveys and contamination surveys [35.315(a)(4), (7)] () Y () N
- C. RSO promptly notified if patient died or had a medical emergency [35.315(b)] () Y () N
10. BRACHYTHERAPY () N/A
- A. Safety precautions implemented to include patient facilities, posting, stay times, and area radiation level surveys [35.415] () Y () N
- B. Patients surveyed immediately after implant [35.406(c)] () Y () N
- C. Patients surveyed immediately after removing the last temporary implant source [35.404(a)] () Y () N
- D. Records maintained [35.404(b), 406(d), 415(a)(4)] () Y () N
- E. Manufacturer's instructions available and followed [35.59(a), 400] () Y () N
11. RADIOACTIVE WASTE
- A. Disposal
1. Decay-in-storage () N/A
- a. Approved [20.2001, 35.92] () Y () N
- b. Procedures followed [35.92] () Y () N
- c. Labels removed or defaced [20.1904, 35.92] () Y () N
- d. Records contain all required information [35.92(b)] () Y () N
(Date of disposal, date placed in storage, radionuclides, instrument, background, dose rate, name of individual)

2. Other disposal methods () N/A
Describe:
3. Improper/unauthorized disposals () Y () N
[20.2001]
4. Records maintained indefinitely () Y () N
[20.2103(a), 2108]
- B. Effluents
1. Release to sanitary sewer [20.2003] () Y () N
- a. Material is readily soluble or readily dispersible () Y () N
[20.2003(a)(1)]
- b. Monthly average release concentrations do not exceed App. B, Table 2 values () Y () N
- c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [20.2003] () Y () N
- d. *Methods for determining compliance:*
2. Waste incinerated () Y () N
(Not authorized)
3. Air effluents less than 10 mrem constraint limit [20.1101] () Y () N
4. Effluent data to NEHC as required [20.2203(a)] () Y () N
- C. Waste storage
1. *Protection from elements and fire* () Y () N
2. *Control of waste maintained [20.1801]* () Y () N
3. *Containers properly labeled and area properly posted [20.1902, 1904]* () Y () N
4. *Package integrity adequately maintained* () Y () N
- D. Records of surveys and material accountability are maintained [20.2103, 2108] () Y () N

12. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- A. Describe how packages are received and by whom: () N/A
- B. Written package opening procedures established and followed [20.1906(e)] () Y () N
- C. All incoming packages with a DOT label wiped, unless exempted (gases and special form) [20.1906(b)(1)] () Y () N
- D. Incoming packages surveyed [20.1906(b)(2)] () Y () N
- E. Monitoring in (C) and (D) performed within time specified [20.1906(c)] () Y () N
- F. Transferree's license on file [30.41] () Y () N
- G. All packages surveyed before shipment [20.1501(a), 49 CFR 173.475(i)] () Y () N
- H. Records of surveys and receipt/transfer maintained[20.2103(a), 30.51] () Y () N
- I. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] () Y () N
- J. RSO reviews all shipments, incoming or outgoing, after April 97 [NEHC letter of 11 April 1997] () Y () N

13. TRANSPORTATION

(10 CFR 71.5(a) and 49 CFR 171-189) () N/A

- A. Permittee shipments are:
() delivered to common carriers
() transported in permittee's vehicle
() no shipments since last inspection
- B. Permittee returns radiopharmacy doses () Y () N
1. Permittee assumes shipping responsibility () Y () N
2. If NO, describe arrangements made between permittee and radiopharmacy for shipping responsibilities:

- C. Packages () N/A
1. Authorized packages used [173.415, 416] () Y () N
 2. Performance test records on file () Y () N
 - a. DOT-7A packages [173.415(a)] () Y () N
 - b. Special form sources [173.476(a)] () Y () N
 3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity (in Tbq), and Hazard Class [172.403, 173.441] () Y () N
 4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee) [172.301, 306, 310, 312, 324] () Y () N
 5. Closed and sealed during transport [173.475(f)] () Y () N
- D. Shipping Papers () N/A
1. Prepared and used [172.200(a)] () Y () N
 2. Proper {Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)} [172.200-204] () Y () N
 3. Readily accessible during transport [177.817(e)] () Y () N
14. PERSONNEL RADIATION PROTECTION
- A. Permittee performed exposure evaluation [20.1501, 1502] () Y () N
- B. Permittee implemented ALARA program [35.20, 20.1101(b)] () Y () N
- C. External Dosimetry () N/A
1. Permittee monitors workers [20.1502(a)] () Y () N
 2. Supplier _____
Frequency _____
 3. Supplier is NVLAP-approved [20.1501(c)] () Y () N
 4. Dosimeters exchanged 6-7 weeks [NAVME P-5055, para 6-5] () Y () N

- D. Internal Dosimetry () N/A
1. Permittee required to bioassay
[20.1502] () Y () N
Periodicity:
 2. *Briefly describe permittee's program for
monitoring and controlling internal
exposures [20.1701, 1702]:*
 3. Are rooms at negative pressure
[35.205(b)] () Y () N
 4. Has spilled gas clearance time been
calculated [35.205(c)] () Y () N
- E. TLD Reports
1. Reviewed by RSO () Y () N
Frequency:
 2. Inspector reviewed personnel monitoring records
for period _____ to _____
 3. Prior dose determined for individuals
likely to receive doses [20.2104] () Y () N
 4. Maximum TEDE noted _____
 5. Permittee sums internal and external
[20.1202] () Y () N
 6. TEDEs within limits [20.1201] () Y () N
 7. NAVMED forms used and current
[20.2104(d), 2106(c)]
 - a. NAVMED FORM 6470/10 () Y () N
Complete: () Y () N
 - b. NAVMED FORM 6470/115 () Y () N
Complete: () Y () N
 8. Worker declared her pregnancy in
writing during inspection period
(review records) () Y () N
If yes, permittee in compliance with
[20.1208] and () Y () N
Records maintained [20.2106(e)] () Y () N
- F. Records of exposures, surveys, monitoring,
and evaluations maintained
[20.2102, 2103, 2106, 35.205(d), 315(a)(8)] () Y () N

15. MISADMINISTRATIONS AND RECORDABLE EVENTS () N/A

- A. If misadministrations or recordable events have occurred since the last inspection, evaluate the incident(s) and the permittee's QMP.

16. INDEPENDENT MEASUREMENTS

A. Survey instrument Serial No. Last calibration

- B. Inspector's measurements were compared to permittee's () Y () N

C. Describe the type, location, and results of measurements:

17. NOTIFICATION AND REPORTS

- A. Permittee in compliance with [19.13, 30.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20) () Y () N

- B. Permittee in compliance with [20.2201, 20.2202, 20.2203, 30.50] (theft or loss, incidents, overexposures and high radiation levels) () Y () N

- C. Permittee aware of NEHC phone number () Y () N

- D. Permittee in compliance with [20.2203] (Constraint on air emissions) () Y () N

18. POSTING AND LABELING

- A. Current NRC-3 "Notice to Workers" posted [19.11] () Y () N

- B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, and permit documents are posted or a notice indicating where documents are is posted [19.11, 21.6] () Y () N

- C. Other posting and labeling per [20.1902, 1904]
and the permittee is not exempted by
[20.1903, 1905] () Y () N

19. RECORDKEEPING FOR DECOMMISSIONING

- A. Records of information important to the safe
and effective decommissioning of the
facility maintained in an independent and
identifiable location until permit
termination [30.35(g)] () Y () N

- B. Records include all information outlined in
[30.35(g)] () Y () N
(spills, maps, pipes, etc.)

20. INFORMATION NOTICES

- A. All NEHC Information Notices, received by
the permittee () Y () N

- B. Permittee took appropriate action in
response to Notices received () Y () N

21. SPECIAL PERMIT CONDITIONS OR ISSUES () N/A

- A. Special permit conditions or issues to be reviewed:

B. Evaluation:

22. DEBRIEF WITH PERMITTEE STAFF () Y () N

Items discussed:

Individuals present:

23. CONTINUATION OF REPORT ITEMS

24. DEFICIENCIES AND OTHER ISSUES

Note: Briefly state (1) the requirement and (2) how and when the permittee violated the requirement. For non-cited deficiencies, indicate why the deficiency was not cited.

25. PERFORMANCE EVALUATION FACTORS

- A. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight () Y () N
- B. RSO too busy with other assignments () Y () N
- C. Insufficient staffing () Y () N
- D. Radiation Safety Committee fails to meet or functions inadequately () Y () N
- E. Inadequate audits () Y () N

Remarks (consider above assessment and/or other pertinent PEFs)

END