APPENDIX G

NOTE: All areas indicated in field notes are not required to be addressed during each inspection

NOTE: Any reference to patient is intended to include human research subject

MEDICAL BROAD-SCOPE INSPECTION FIELD NOTES
Region I

Inspection Report No. 95-001

License No. 06-00817-03,04

Licensee (Name & Address):
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Docket No. 030-01244, 030-33300

Licensee Contact Mike Boban-RSO

Telephone No. 203-785-2950

Last Amendment No. 44

Date of Amendment 2/24/94

Priority: 1, 3
Program Code 2110, 3510

Date of Last Inspection 9/20-23/94
Date of This Inspection 7/31-8/2/95

Type of Inspection:

( ) Announced
(X) Routine
( ) Initial

(X) Unannounced
( ) Special
( ) Reinspection

Summary of Findings and Action:
Clear letter
( ) No violations, Clear 591 issued
( ) Violation(s), 591 issued
( ) Violation(s), Regional letter issued
( ) Followup on Previous violations

Were non-cited violations identified during this inspection? ( ) Y (X) N

Was proprietary information reviewed by or received by the inspector? (X) Y ( ) N

Inspector [signature] (Signature) Date 8/2/95

Approved [signature] (Signature) Date 8/23/95

A/S

21

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

A. Violations were identified during the last two inspections or two years, whichever is longer (X) Y ( ) N

B. Response letter(s) or 591(s) dated 10/12/94

C. Open violations from previous inspections:

Requirement	Violation	Corrective Action Taken (Y/N)	Status Open/Closed
35.25(a)	Failure to require a supervised individual to follow [illegible]	Y	C
35.59(h)	Failure to maintain records of [illegible] sealed source storage	Y	C
35.70(h)	Failure to include [illegible] in area contamination records	Y	C
NCV	Failure to label the containers of radioactive waste	Y	C
NCV	Failure to include irradiator source in inventories	Y	C
NCV	Failure to leak test irradiator source	Y	C

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

Mike Boden - RSO
Mike Vergle - Asst RSO
Phil Richardson - HP tech

V.P. → RSO → Asst RSO → HP tech

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Organizational Structure

*Mike [illegible]
Mike Vergle - ARSO
Phil Richardson - H.P. tech
*Robert Lange, M.D. - RSC Chm
Bob Varsmith - Asst. Chief tech
Nick Sandella - tech student
Valery Minicucci - tech student
Toni Benet - tech (NM)
Mark Zoari - Nuc. Card. tech
Peter Vitale - radiophysicist
Roy Weisinger - chief tech, Blood Bank
Dr. Edward Snyder - director, Blood Bank
Lorna Lowski - RN
Pat Espinoza - RCA
Khoguinder Nath, Ph.D. - Chief, Rad Phys
*Norman Roth - Sr. V.P.

\+ Individuals contacted during inspection
* Individuals present at exit meeting

1. Meets license requirements [L/C] (X) Y ( ) N
2. Multiple authorized locations of use ( ) Y (X) N
If yes, may use **ATTACHMENT A** as a guide for location(s) or lab(s) inspected and note lab numbers where violations are found. (X) N/A
3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

Nuclear Medicine consists of general nuclear medicine, Critical Care Cardiology, Nuclear Cardiology and SPECT research. The general area does 20-25 studies/day, mostly bones, lungs, HAIDA's, brains and about 10 others. There are 7 techs, 6 cameras, and 2 dose calibrators. A 3 Ci generator is received each week from Dupont and it is used as a backup for a second week.

Nuclear Cardiology has 7 techs and does mostly MUGA's and thalliums. Techs rotate through intensive care, where 3-5 patients/wk are done, mostly in their rooms.

I-131 has been used 66 times since the last inspection, 13 times > 30 mCi. Sr-89 has been used 12 times, and P-32 once.

There is also a [illegible] 1A 28, and [illegible] irradiator.

Brachytherapy consists of an HDR (~700 fractions/year), Pd-103 (~30 implants/yr), I-125 (~50 implants/yr), Ir-192 (25 implants/yr), and Cs-137 (~60 implants/yr).

B. Licensee does limited distribution of pharmaceuticals[1] under Part 35 license ( ) Y (X) N

1. Indicate type of operation:

___a. Registered or licensed with FDA as a drug manufacturer
___b. Registered or licensed with State Agency as a drug manufacturer
___c. Licensed as a pharmacy by State Board of Pharmacy
___d. Operating as a nuclear pharmacy within a Federal medical institution

2. Licensee distributes
* sealed sources ( ) Y ( ) N
* alpha and beta emitters ( ) Y ( ) N
* generators ( ) Y ( ) N
* photon emitters ( ) Y ( ) N

Remarks:

C. Research involving human subjects ( ) N/A

1. Research is conducted, funded, supported, or regulated by another Federal Agency which has implemented Federal Policy for Protection of Human Subjects[2]? [35.6] (X) Y ( ) N

If no, does licensee have license amendment authorizing human research? [35.6] ( ) Y ( ) N

2. Licensee obtains informed consent from human subjects? [35.6] (X) Y ( ) N

3. Licensee obtains approval of research activities from an Institutional Review Board? [35.6] (X) Y ( ) N

Remarks: all [redacted] metabolic studies with C-14, H-3, & SPECT,

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[1]If licensee distributes radiopharmaceuticals to several facilities, the inspector should consider the need to complete the radiopharmacy fieldnotes.

[2]Agencies: USDA, DOE, NASA, HUD, DOJ, DOD, VA, EPA, HHS, DOT, Dept. of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency, Agency for International Development, Dept. of Education, National Science Foundation

D. Radiation Safety Committee [33.13, 14, 15] ( ) N/A

1. Membership as specified [35.22(a)(1)] (X) Y ( ) N
2. Meetings held quarterly [35.22(a)(2)] (X) Y ( ) N
3. Quorums established [35.22(a)(3)] (X) Y ( ) N
4. Has sufficient authority [35.23] (X) Y ( ) N
5. Record of Committee meetings [35.22(a)(4)] (X) Y ( ) N
6. Approve/disapprove credentials of individuals prior to allowing them to work as an authorized user or authorized nuclear pharmacist [35.22(b)(2)(ii)] (X) Y ( ) N
7. Approve/disapprove applications for use [L/C] (X) Y ( ) N

Remarks:

E. Radiation Safety Officer

1. Appointed & on license [33.13, 35.21(a), L/C] (X) Y ( ) N
2. Fulfills duties per [35.21(b)] (X) Y ( ) N
3. Has sufficient authority per [35.23] (X) Y ( ) N

F. Radiation Safety Program

1. Minor changes pursuant to [35.31] ( ) N/A (X) Y ( ) N
2. Records of changes maintained [35.31(b)] (X) Y ( ) N
3. Content and implementation reviewed annually by the licensee [20.1101(c), 35.22(b)(6)] (X) Y ( ) N
4. Records of reviews maintained [20.2102] (X) Y ( ) N

G. Use by authorized individuals [L/C] (X) Y ( ) N
If no, list name/position of individual

H. Mobile Nuclear Medicine Service (X) N/A

1. Licensee operates services per [35.29, 80] ( ) Y ( ) N
2. Compliance with 20.1301 evaluated and met ( ) Y ( ) N

I. Any Amendments or Notifications since last inspection [35.13, 14] (X) Y ( ) N

Licensee has notified NRC within 30 days after RSO stops work or changes name, or mailing address changes [35.14(b)] (X) N/A ( ) Y ( ) N

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers/students per [10 CFR 19.12] (X) Y ( ) N

B. Individual's understanding of current procedures and regulations is adequate (X) Y ( ) N

C. Training program required [L/C] (X) Y ( ) N

1. If so, briefly describe training program:

2. Training program implemented (X) Y ( ) N

3. Periodic training program required (X) Y ( ) N

4. Periodic training program implemented (X) Y ( ) N

5. Records maintained (X) Y ( ) N

Remarks: Training is at least annual, and frequently more often. Most of it is done by the RSO.

D. Supervision of individuals

1. Supervised individuals[3] are instructed in preparation of material, principles and procedures for radiation safety and QM Program as appropriate [35.25(a)(1), 35.25(b)(1)] (X) Y ( ) N

2. Licensee periodically reviews supervised individuals use of material and records kept to reflect use [35.25(a)(3)] (X) Y ( ) N

3. Authorized nuclear pharmacist or user periodically review work and records of work of supervised individuals as it pertains to preparing byproduct material [35.25(b)(3)] ( ) N/A (X) Y ( ) N

Remarks:

E. Therapy training

1. Safety instruction [35.310, 410, L/C]

a. Control of patient and visitors (X) Y ( ) N

b. Contamination and waste (X) Y ( ) N

c. Size/appearance of sources ( ) N/A (X) Y ( ) N

d. Handling/shielding of sources ( ) N/A (X) Y ( ) N

e. RSO notification in emergency or death (X) Y ( ) N

f. Records maintained [35.310(b), 410(b)] (X) Y ( ) N

2. Manufacturer's instructions available and followed [35.59(a), 400] (X) Y ( ) N

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[3]Applies to individuals that receive, possess, use, transfer, or prepare byproduct material for medical use under supervision of authorized nuclear pharmacist or user.

3. Training for operating and emergency procedures for HDR Remote Afterloaders ( ) N/A (X) Y ( ) N

F. Revised Part 20

Workers cognizant of requirements for:

1. Radiation Safety Program [20.1101] (X) Y ( ) N
2. Annual dose limits [20.1301, 1302] (X) Y ( ) N
3. New forms 4 and 5 ( ) N/A (X) Y ( ) N
4. 10% monitoring threshold [20.1502] (X) Y ( ) N
5. Dose limits to embryo/fetus and declared pregnant worker [20.1208] ( ) N/A (X) Y ( ) N
6. Grave Danger Posting [20.1902] (X) N/A ( ) Y ( ) N
7. Procedures for opening packages [20.1906] ( )N/A (X) Y ( ) N
8. Sewer disposal limits [20.2003] ( ) N/A (X) Y ( ) N

NOTE: Deficiencies in Section 3.F, while not always a violation, should be brought to the attention of licensee management at the exit meeting and in the cover letter transmitting the inspection report or NOV.

Remarks:

4. FACILITIES

A. Facilities as described in license application (X) Y ( ) N

B. Storage areas

1. Materials secured from unauthorized removal or access [20.1801] (X) Y ( ) N
2. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802] (X) Y ( ) N
3. Licensee uses process or other engineering controls for airborne concentrations, internal exposures in restricted areas, and volatiles/gases in storage [20.1701, 1702, 35.90] (X) Y ( ) N
4. Maintenance program implemented for engineering controls (negative pressure, ventilation rates, filter changes, etc.) [35.205(e), L/C] (X) Y ( ) N

C. Describe any Self-contained dry-source-storage irradiators [Part 36] and/or survey instrument calibrators (model, radionuclide, activity, use, etc) (X) N/A

1. Maintenance of safety-related components performed by authorized persons [L/C] ( ) Y ( ) N
2. Access to keys and/or material controlled [20.1801, 1802, L/C] ( ) Y ( ) N
3. Access to high/very high radiation areas controlled [20.1601, 1602, L/C] ( ) Y ( ) N
4. Adequate protection of shield integrity, fire protection [L/C] ( ) Y ( ) N

Remarks:

5. EQUIPMENT

A. Dose calibrator - Photon-emitting radionuclides

1. Possessed and used [35.50(a)] (X) Y ( ) N
2. Constancy [35.50(b)(1)]
   a. Performed daily prior to use (X) Y ( ) N
   b. Dedicated check source used (X) Y ( ) N
3. Accuracy [35.50(b)(2)]
   a. Performed at installation and annually (X) Y ( ) N
   b. At least 2 sealed sources used (X) Y ( ) N
4. Linearity [35.50(b)(3)]
   a. Performed at installation and quarterly thereafter (X) Y ( ) N
   b. Includes range between 30 uCi and the highest dosage administered (X) Y ( ) N
5. Geometric Dependence [35.50(b)(4)]
   a. Performed at installation or relocation (X) Y ( ) N
   b. Includes range of volumes and volume configurations used (X) Y ( ) N
6. Dosage readings over 10 uCi mathematically corrected for geometry or linearity errors greater than + or - 10% (X) N/A ( ) Y ( ) N
7. Repaired or replaced when constancy or accuracy errors exceeded + or - 10% (X) N/A ( ) Y ( ) N
8. Approved procedures followed [35.22, 25, L/C] (X) Y ( ) N
9. Records maintained and include identity of the individual performing the test. [35.50(e)(2)] (X) Y ( ) N

Remarks: 2 dose calibrators in general N.M., 1 in intensive care, and 1 in Nuclear Cardiology

B. Instrumentation - Alpha- or beta-emitting radionuclides ( ) N/A

1. List type of equipment used to assay alpha and beta particles:
   Sr-89 assayed in dose calibrator by established procedures

2. Licensee has procedures for use of instrumentation [35.52(b)] (X) Y ( ) N

3. Accuracy, linearity and geometric dependence tests are performed prior to initial use, periodically, and following repair, if applicable[4] [35.52(b)(1), L/C] (X) Y ( ) N

4. Instruments are checked for constancy and proper operation at the beginning of each day of use [35.52(b)(2), L/C] (X) Y ( ) N

5. Appropriate action taken when calibration errors in excess of limits are identified [L/C] (X) Y ( ) N

6. Records maintained [L/C] (X) Y ( ) N

Remarks:

C. Licensee uses generators (X) Y ( ) N

1. Each eluate/extract used for radiopharmaceuticals tested for Mo-99 breakthrough (X) Y ( ) N

2. No radiopharmaceuticals <u>administered</u> with Mo-99 concentrations over 0.15 uCi per mCi of Tc-99m (X) Y ( ) N

3. Records maintained [35.204(c)] (X) Y ( ) N

D. Syringes properly labeled and shielded [35.60] (X) Y ( ) N

E. Vials kept in a shield [35.61(a)] (X) Y ( ) N

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

Remarks:

6. <u>MATERIALS</u>

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

B. Licensee administers alpha- or beta-emitting radionuclides (X) Y ( ) N

If yes,

1. Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [35.53(b)] (X) Y ( ) N

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[4]Linearity and geometric dependence tests are not applicable if liquid scintillation is used. Linearity is not applicable if sodium iodide is used.

2. Licensee measures by direct measurements or combination of measurement and calculation each dosage of alpha or beta-emitting radionuclide prior to medical use [35.53(b)] (X) Y ( ) N

C. Unsealed material used under 35.100,200,or 300 are [35.100(b), 35.200(b), 35.300(b):
(1) Obtained from manufacturer or properly licensed organization AND/OR (X) Y ( ) N
(2) Prepared by authorized nuclear pharmacist or physician user or individual under the supervision of a authorized nuclear pharmacist or physician user (X) Y ( ) N

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

Remarks:

E. Use of RAM [L/C]

1. Protective clothing worn (X) Y ( ) N
2. Personnel routinely monitor their hands (X) Y ( ) N
3. No eating/drinking in use/storage areas (X) Y ( ) N
4. No food, drink, or personal effects kept in use/storage areas (X) Y ( ) N
5. Proper dosimetry worn (X) Y ( ) N
6. Radwaste disposed in proper receptacles (X) Y ( ) N
7. No pipetting by mouth (X) Y ( ) N

F. Radioisotopes are used in research in accordance with current procedures [L/C] (X) Y ( ) N

G. Leak tests and Inventories

1. Leak test performed on sealed sources and brachytherapy sources [35.59(b)] (X) Y ( ) N
2. Leak test records in microcuries (X) Y ( ) N
3. Inventory of sealed sources and brachytherapy sources performed quarterly [35.59(g)] (X) Y ( ) N
4. Inventory performed promptly at the storage area after removing sources from a patient to ensure all sources taken from the storage area are returned [35.406(a)] (X) Y ( ) N
5. Records maintained and signed by RSO [35.59, 406] (X) Y ( ) N

Remarks:

7. RADIATION SURVEYS ( ) N/A

A. Survey instruments

1. Appropriate operable survey instrumentation possessed [35.120, 220, 320, 420, L/C] or available [35.520, L/C] ( ) N/A (X) Y ( ) N
2. Calibrations [35.51(a), (b)]

   a. Before first use, annually & after repairs (X) Y ( ) N
   b. Approved calibration procedure followed to include check source reading determination [35.51(a)(3), L/C] (X) Y ( ) N
   c. Within 20% in each scale or decade of interest [L/C] (X) Y ( ) N

3. Records maintained [35.51(d)] (X) Y ( ) N
4. Source-checked each day of use [35.51(c)] (X) Y ( ) N

B. Radiation surveys performed

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

C. Trigger levels [35.70(d), (g)]

1. Established (X) Y ( ) N
2. Exceeded (X) Y ( ) N
3. Corrective action taken and documented (X) Y ( ) N

D. Techniques can detect 0.1 mR/hr, 2000dpm [35.70] (X) Y ( ) N
E. Records maintained [35.70(h), L/C] (X) Y ( ) N
F. Protection of members of the public

Note: See IN 94-09 for updated guidance on conflicts between Parts 20 and 35.

1. Licensee made adequate surveys to demonstrate either (1) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (2) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] (X) Y ( ) N
2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] (X) Y ( ) N
3. Records maintained [20.2103, 2107] (X) Y ( ) N

G. **Describe licensee's survey requirements for research areas** ( ) N/A

Most respondents N.M. as survey requirements are the same as N.M. The RIAEB was not inspected.

H. Research areas surveyed as required [20.1501(a), L/C] (X) Y ( ) N
I. Research area survey records maintained [20.2103, L/C] (X) Y ( ) N

Remarks:

8. 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), L/C] (X) Y ( ) N
B. Area dose rate surveys and room contamination surveys [35.315(a)(4), (7)] (X) Y ( ) N
C. Release of patients containing radiopharmaceuticals meets <5 mR/hr @ 1m or <30 mCi [35.75] (X) Y ( ) N
D. RSO promptly notified if patient died or had a medical emergency [35.315(b)] (X) N/A ( ) Y ( ) N

Remarks:

9. BRACHYTHERAPY ( ) N/A

A. Safety precautions implemented to include patient facilities, room posting, stay times, and area radiation level surveys [35.415, L/C] (X) Y ( ) N
B. Patients surveyed immediately after implant [35.406] (X) Y ( ) N
C. Release of patients with permanent implants meets <5 mR/hr @ 1m [35.75] ( ) N/A (X) Y ( ) N

D. Patients surveyed immediately after removing the last temporary implant source (required for all manual, LDR, MDR, and HDR therapies) [35.404(a)] ( ) N/A (X) Y ( ) N
E. Records maintained [35.404(b), 406(d), 415(a)(4)] (X) Y ( ) N

Remarks:

10. RADIOACTIVE WASTE ( ) N/A

A. Disposal

1. Decay-in-storage ( ) N/A

a. Approved [20.2001, 35.92, L/C] (X) Y ( ) N
b. Procedures followed [35.92, L/C] (X) Y ( ) N
c. Labels removed or defaced [20.1904, 35.92] (X) Y ( ) N

2. Special procedures performed as required [L/C] (X) Y ( ) N
3. Liquid scintillation (LS) media and animal carcasses per [20.2005] ( ) N/A (X) Y ( ) N
4. Improper/unauthorized disposals [20.2001] ( ) Y (X) N
5. Records maintained [20.2103(a), 2108, L/C] (X) Y ( ) N

B. Effluents ( ) N/A

1. Release into sanitary sewer [20.2003] (X) N/A ( ) Y ( ) N

a. Material is readily soluble or readily dispersible [20.2003(a)(1)] ( ) Y ( ) N
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(a)] ( ) Y ( ) N
d. Procedures to ensure representative sampling and analysis implemented [20.1501, L/C] ( ) Y ( ) N

2. Release into septic tank [20.2003] (X) N/A ( ) Y ( ) N

a. Within unrestricted limits [App B,Table 2] ( ) Y ( ) N

3. Waste incinerated (X) N/A

a. License authorizes [20.2004(a)(3)] ( ) Y ( ) N
b. Licensee directly monitors exhaust ( ) Y ( ) N
c. Airborne releases evaluated and controlled [20.1501, 1701] ( ) Y ( ) N

Remarks:

4. Control of air effluents and ashes [20.1201, 1301, 1501, 2001, L/C] {See also IP 87102, RG 8.37} (X) Y ( ) N

a. Compliance with air emissions requirements in Part 20:

Licensee has demonstrated compliance with air emission requirements in 10 CFR Part 20 (X) Y ( ) N

Basis for compliance determination (check one or more; provide basis below)

___(1)	Measured concentrations of radionuclides in air effluents are below Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr)	
_✓_(2)	Bounding calculations show that air effluents could not exceed Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr)	
_✓_(3)	Dose modeling shows that dose equivalent to the individual likely to receive the highest dose does not exceed 10 mrem/yr	
_✓_(4)	Licensee does not possess sufficient radioactive material to exceed Part 20 requirements	

Basis for Determination: ~~Discussion that they comply with EPA requirement at level 1 and are not required to report~~

b. Description of effluent program

1.	Monitoring system hardware adequate	(✓) Y ( ) N
2.	Equipment calibrated as appropriate	(✓) Y ( ) N
3.	Air samples/sampling technique (i.e. charcoal, HEPA, etc.) analyzed with appropriate instrumentation	(✓) Y ( ) N

Remarks: Consists only of hood for I-131 process; generator production has been discontinued

C. Waste Management ( ) N/A

1.	Waste compacted	( ) Y (X) N
2.	Storage area(s)	( ) N/A
a.	Protection from elements and fire [L/C]	(X) Y ( ) N
b.	Control of waste maintained [20.1801]	(X) Y ( ) N
c.	Containers properly labeled and area properly posted [20.1902, 1904]	(X) Y ( ) N
d.	Package integrity maintained [L/C]	(X) Y ( ) N

3. Packaging, Control and Tracking [App. F.III] [20.2006(d)]

Note: The licensee's waste is likely to be Class A.

a.	Not packaged for disposal in cardboard or fiberboard boxes [61.56(a)]	( ) Y ( ) N
b.	Liquid wastes solidified, i.e., less than 1% freestanding liquid, and void spaces minimized [61.56(a), (b)]	( ) Y ( ) N

c. Does not generate harmful vapors [61.56] ( ) Y ( ) N

d. Structurally stable (will maintain its physical dimensions and form under expected disposal conditions) [61.56(b)] ( ) Y ( ) N

e. Packages properly labeled [App. F.III.A.2] ( ) Y ( ) N

f. Licensee conducts a QC program to ensure compliance with [61.55, 56] and includes management evaluation of audits [App. F.III.A.3] ( ) Y ( ) N

g. Shipments not acknowledged within 20 days after transfer are investigated and reported [App. F.III.A.8] ( ) N/A ( ) Y ( ) N

4. Transfers to land disposal facilities (X) N/A

a. Transferred to person specifically licensed to <u>receive waste</u> [30.41, 20.2001(b)] ( ) Y ( ) N

b. Each shipment accompanied by a manifest prepared as specified in Section I of Appendix F [20.2006(b) and App. F.III.A.4] ( ) Y ( ) N

c. Manifests certified as specified in Section II of Appendix F [20.2006(c)] ( ) Y ( ) N

D. Records of surveys and material accountability are maintained [20.2103, 2108] (X) Y ( ) N

Remarks:

11. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

A. Describe how packages are received and by whom [33.13, L/C] Nuclear Medicine couriers are escorted to the [illegible] by security, who [illegible] the [illegible] material and [illegible] brought to the Radiation Safety Office ( ) N/A

B. Written package opening procedures established and followed [20.1906(e)] (X) Y ( ) N

C. All incoming packages with a DOT label <u>wiped</u>, unless exempted (gases and special form) [20.1906(b)(1)] (X) Y ( ) N

D. Incoming packages surveyed [20.1906(b)(2), L/C] (X) Y ( ) N

E. Monitoring in (C) and (D) above performed within time specified [20.1906(c)] (X) Y ( ) N

F. Transfer(s) between licensees performed per [30.41] ( ) Y (X) N

G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i), L/C] (X) Y ( ) N

H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51] (X) Y ( ) N

I. Transfers within licensee's authorized users or locations performed as required [L/C] ( ) N/A (X) Y ( ) N

J. Arrangements made for packages containing quantities of radioactive material in excess of Type A quantity [20.1906(a)] (X) Y ( ) N

K. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] (X) Y ( ) N

Remarks:

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

A. Licensee shipments are:

(X) delivered to common carriers
( ) transported in licensee's own private vehicle
( ) both
( ) no shipments since last inspection

B. Licensee returns radiopharmacy doses ( ) N/A ( ) Y (X) N

1. Licensee assumes shipping responsibility ( ) Y ( ) N
2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages

1. Authorized packages used [173.415, 416] ( ) N/A (X) Y ( ) N
2. Performance test records on file (X) N/A

a. DOT-7A packages [173.415(a)] (X) Y ( ) N
b. Special form sources [173.476(a)] ( ) Y (X) N

3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441] (X) 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] (X) Y ( ) N
5. Closed and sealed during transport [173.475(f)] (X) Y ( ) N

D. Shipping Papers ( ) N/A

1. Prepared and used [172.200(a)] (X) 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] (X) Y ( ) N
3. Readily accessible during transport [177.817(e)] (X) Y ( ) N

Remarks:

13. PERSONNEL RADIATION PROTECTION

A. Licensee performed exposure evaluation [20.1501] (X) Y ( ) N
B. Licensee incorporated ALARA considerations in the Radiation Protection Program [35.20, 20.1101(b)] (X) Y ( ) N

C. External Dosimetry ( ) N/A

1. Licensee monitors workers [20.1502(a), L/C] (X) Y ( ) N
2. External exposures account for contributions from airborne activity [20.1203] (X) N/A ( ) Y ( ) N
3. Supplier Landauer Frequency monthly
4. Supplier is NVLAP-approved [20.1501(c)] (X) Y ( ) N
5. Dosimeters exchanged at required frequency [L/C] (X) Y ( ) N

D. Internal Dosimetry ( ) N/A

1. Licensee monitors workers [20.1502, L/C] (X) Y ( ) N
2. Briefly describe licensee's program for monitoring and controlling internal exposures [20.1701, 1702, L/C]:
3. Aerosols and gases sampled [20.1204, 35.205] (X) Y ( ) N
4. Monitoring/controlling program implemented (includes bioassays) [35.205(d), 315(a)(8), L/C] (X) Y ( ) N
5. Respiratory protection equipment [20,1703] ( ) Y (X) N

E. Reports

1. Reviewed by RSO Frequency annually
2. Inspector reviewed personnel monitoring records for period 8/1994 to 1995
3. Prior dose determined for individuals likely to receive doses [20.2104] (X) Y ( ) N
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organ(s) _____
6. Maximum CEDE 330 mrem/yr 4210 mrem/gestation
7. Licensee sums internal and external [20.1202] (X) Y ( ) N
8. TEDEs and TODEs within 20.1201 limits (X) Y ( ) N
9. NRC forms or equivalent [20.2104(d), 2106(c)]

   a. NRC-4 (X) Y ( ) N Complete: (X) Y ( ) N
   b. NRC-5 (X) Y ( ) N Complete: (X) Y ( ) N

10. Worker declared her pregnancy in writing during inspection period (review records) ( ) N/A (X) Y ( ) N
    If yes, licensee in compliance with [20.1208] (X) Y ( ) N
    and records maintained (X) Y ( ) N

F. Who performed any PSEs at this facility (number of people involved and doses received) [20.1206, 2104(b), 2105, 2204] (X) N/A

G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, 35.205(d), 315(a)(8), L/C] (X) Y ( ) N

Remarks:

14. MISADMINISTRATIONS AND RECORDABLE EVENTS None

A. If misadministrations or recordable events (defined in 35.2) have occurred since last inspection, evaluate the incident(s) and the licensee's quality management program (QMP) using the existing guidance. [Reference TI 2800/025 and IP 87103]

1. Event date _____ Information Source _____
2. Notifications

NRC Ops Center	( ) Y ( ) N	Region	( ) Y ( ) N
Referring Physician	( ) Y ( ) N	Patient	( ) Y ( ) N
In writing	( ) Y ( ) N		

If notification did not occur, why not:

3. Written Reports [35.33]

a. Submitted to Region within 15 days ( ) Y ( ) N
b. Copy to patient within 15 days ( ) Y ( ) N

B. Records maintained [35.33(b)] ( ) Y ( ) N

Remarks:

15. NRC INDEPENDENT MEASUREMENTS

A. Survey instrument	Serial No.	Last calibration
Ludlum 14C	9656	6/20/95

B. Inspector's measurements were compared to licensee's (X) Y ( ) N
C. Describe the type, location, and results of measurements:
0.03-0.7 mR/hr in common areas, 0.2 mR/hr in hot lab, 0.1-0.3 mR/hr at control panel for HVAC, 0.01 mR/hr around incubator, 0.03 mR/hr at base of lead shield storage area, 2 mR/hr next to shield, 0.6 mR/hr at shield.

16. NOTIFICATION AND REPORTS

A. Licensee in compliance with [19.13] (reports to individuals, public and occupational, monitored to show compliance with Part 20) ( ) None (X) Y ( ) N

B. Licensee in compliance with [20.2201] (theft or loss) (X) None ( ) Y ( ) N

C. Licensee in compliance with [20.2202] (incidents) ( ) None (X) Y ( ) N

D. Licensee in compliance with [20.2203] (overexposures and high radiation levels) (X) None ( ) Y ( ) N

E. Licensee aware of NRC Ops Center phone number (X) Y ( ) N

17. POSTING AND LABELING

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

B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted or a notice indicating where documents can be examined is posted [19.11, 21.6] (X) Y ( ) N

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

Remarks:

18. 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 license termination [30.35(g)] (X) Y ( ) N

B. Records include all information outlined in [30.35(g)] (X) Y ( ) N

Remarks:

19. BULLETINS AND INFORMATION NOTICES

A. Bulletins, Information Notices, NMSS Newsletters, etc., received by the licensee (X) Y ( ) N

B. Licensee took appropriate action in response to Bulletins, Generic Letters, etc. (X) Y ( ) N

Remarks:

20. SPECIAL LICENSE CONDITIONS OR ISSUES ( ) N/A

A. Special license conditions or issues to be reviewed: [illegible handwriting]

B. Evaluation: [illegible handwriting] written procedures

21. DEBRIEF WITH LICENSING STAFF

Inspection findings discussed with licensing staff (X) N/A ( ) Y ( ) N

Items discussed:

22. CONTINUATION OF REPORT ITEMS

[illegible] as of 1/13, [illegible]

23. VIOLATIONS, NCVs, AND OTHER ISSUES

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

None

24. EPA REFERRAL FORM

EPA referral form for air effluents sent to appropriate EPA regional office per IP 87102 ( ) Y (X) N

If no, explain: [illegible]

25. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) Yale-New Haven Hospital, 20 York Street, New Haven, Connecticut 06504

Inspector Richard R. McKinley

Inspection Date 7/31/95 – 8/3/95

A. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ( ) Y (X) N

B. RSO too busy with other assignments ( ) Y (X) N

C. Insufficient staffing ( ) Y (X) N

D. Radiation Safety Committee fails to meet or functions inadequately ( ) Y (X) N

E. Inadequate consulting services or inadequate audits ( ) Y (X) N

F. Financial Instability ( ) Y (X) N

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

Regional follow-up on above PEFs citations:

END

ATTACHMENT A
LABORATORY INSPECTION FIELD NOTES

1. Date _____ Authorized User(s) _____

2. Location(s) Building _____ Room(s) _____
3. Person(s) Contacted _____

4. Describe scope of lab use (Nuclides, form, frequency, purpose, etc):

5. Training
   - A. Frequency: _____ Conducted by: _____
   - B. Individuals interviewed understand safety practices ( ) Y ( ) N

Remarks:

6. Surveys
   - A. Types of surveys performed (daily, weekly, monthly, etc.)
   - B. Instrumentation properly calibrated and used ( ) Y ( ) N
   - C. Efficiency of counting system determined ( ) Y ( ) N
   - D. Hood airflow adequate and checked as required ( ) N/A ( ) Y ( ) N
   - E. Records maintained: trigger levels established, area diagram, instrument used, individual performing survey, results in proper units, decontamination performed as necessary, etc.) ( ) Y ( ) N
   - F. Inspector surveyed ( ) Y ( ) N
     Results satisfactory ( ) N/A ( ) Y ( ) N

Remarks:

7. Receipt and Transfer
   - A. Incoming packages properly surveyed ( ) Y ( ) N
   - B. Interlaboratory transfers performed as specified in the license ( ) N/A ( ) Y ( ) N
   - C. Records maintained ( ) Y ( ) N

Remarks:

8. Personnel Dosimetry
   - A. Appropriate dosimetry assigned and worn ( ) N/A ( ) Y ( ) N
   - B. Results available to lab personnel ( ) Y ( ) N
   - C. Bioassays performed ( ) N/A ( ) Y ( ) N

Remarks:

9. Handling Waste

A.	Procedures followed		( ) Y ( ) N
B.	Proper storage (area, containers, labeling, etc.)		( ) Y ( ) N
C.	Liquid/solid waste disposal		( ) Y ( ) N
D.	Incineration	( ) N/A	( ) Y ( ) N
E.	Compaction	( ) N/A	( ) Y ( ) N
F.	Sewer discharge	( ) N/A	( ) Y ( ) N
G.	Records maintained		( ) Y ( ) N

Remarks:

10. Inventory conducted ( ) N/A ( ) Y ( ) N
Records Maintained ( ) Y ( ) N

Remarks:

11. Storage and use of RAM

A.	Adequate method to prevent unauthorized access	( ) Y ( ) N
B.	Condition of areas acceptable	( ) Y ( ) N
C.	Personnel wear disposable gloves and protective clothing while handling material	( ) Y ( ) N
D.	Hands monitored after procedures or before leaving	( ) Y ( ) N
E.	No eating, drinking, or smoking in use/storage areas	( ) Y ( ) N
F.	No food, drink, or personal items stored in use/storage areas	( ) Y ( ) N
G.	Use of shielding/distance while using/storing material	( ) Y ( ) N
H.	RAM is under surveillance and control when not in storage in an unrestricted area	( ) Y ( ) N

Remarks:

12. Posting and Labeling

A.	NRC-3 "Notice to Workers"	( ) Y ( ) N
B.	Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures for Part 21, and license documents or a notice indicating where documents can be examined	( ) Y ( ) N
C.	Other posting and labeling requirements met	( ) Y ( ) N

Remarks:

13. Violations Observed

END

ATTACHMENT A

QUALITY MANAGEMENT PROGRAM (QMP)

QM FIELD NOTES

1. GENERAL

A. Facility name(s): Yale - New Haven Hospital
B. License number(s): 06-00312-0304
C. Docket number(s): 030-01744 030-33300
D. Last inspection date(s): 4/20-23/94
E. Current inspection date(s): 7/31/95 8/3/95
F. Most recent QMP and certification received by NRC [35.32(e), (f)(2)] Date: 10/25/94

2. PREPARATION

A. Be familiar with the submitted QMP and any modifications in preparation for inspection of the licensee's implemented QMP. Familiarization should focus upon awareness of the submitted program in order to compare the written program with the program as implemented.

3. MODALITIES

A. Identify licensee procedures and attach appropriate inspection module(s):

Module:

1.	NaI I-125 or I-131 > 30 µCi and/or Therapeutic radiopharmaceutical other than NaI	(X) Y ( ) N
2.	High-Dose-Rate Remote Afterloading Brachytherapy	(X) Y ( ) N
3.	All Other Brachytherapy	(X) Y ( ) N
4.	Strontium-90 eye applicator	(X) Y ( ) N
5.	Teletherapy	( ) Y (X) N
6.	Gamma Stereotactic Radiosurgery	( ) Y (X) N
7.	Event (misadministration or other)	( ) Y (X) N

4. SAMPLING (Inspector random sample of each modality)

Total Written Directives	Minimum Target Sample
1 to 5	All
5 to 100	5
> 100	5%

		Total Written Dir.	Target Sample	Number Reviewed
1.	NaI I-125 or I-131 > 30 µCi	66	5	13
2.	Therapeutic Radiopharmaceutical other than NaI	12	5	5
3.	HDR remote afterloading brachytherapy	21	10	10
4.	Other brachytherapy	113	6	13
5.	Sr-90 eye applicator	0	0	0
6.	Teletherapy			
7.	Gamma Stereotactic Radiosurgery			

A/6

31

If two (2) or more written directives are incomplete or missing, the review must be expanded to assess whether this is an isolated occurrence or represents a substantial failure of the QMP.

MODULE 1

GREATER THAN 30 MICROCURIES NaI I-125 or I-131 AND RADIOPHARMACEUTICAL THERAPY

1. **GENERAL**

A. Facility name: Yale - New Haven Hospital
B. License number(s): 06-228/9-07
C. Docket number(s): 030-01244

2. **SAMPLING** (Inspector random sample of each modality)

Total Written Directives	Minimum Target Sample
1 to 5	All
5 to 100	5
> 100	5%

	Total Written Dir.	Target Sample	Number Reviewed
1. NaI I-125 or I-131 > 30 µCi	66	5	13
2. Therapeutic Radiopharmaceutical other than NaI	12	5	5

If two (2) or more written directives are incomplete or missing, the review must be expanded to assess whether this is an isolated occurrence or represents a substantial failure of the QMP.

3. **SUPERVISION**

A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] (X) Y ( ) N
List individual(s) found to be inadequately trained:

4. **NaI I-125 or I-131 > 30 µCi** ( ) N/A

OBJECTIVE 1

		Number Missed
A.	A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] (X) Y ( ) N	
B.	Written directives, as applicable, contain required dosage information [35.2] (X) Y ( ) N	
C.	Exceptions to written directives are documented [footnote to 35.32(a)(1)] (X) N/A	
1.	Written revisions ( ) Y ( ) N	
2.	Oral revisions ( ) Y ( ) N	
3.	Oral directives ( ) Y ( ) N	

OBJECTIVE 2

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] (X) Y ( ) N _____

Remarks:

OBJECTIVE 3 (Does not apply)

OBJECTIVE 4

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] (X) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Dosage measured prior to administration (X) Y ( ) N
2. Dosage confirmed just prior to administration (X) Y ( ) N

C. Record of administration maintained in auditable form [35.32(d)(2)] (X) Y ( ) N _____

Remarks:

OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)] (X) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y (X) N
   Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y (X) N
3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y (X) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] (X) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause (X) Y ( ) N
2. Identify corrective action to prevent recurrence (X) Y ( ) N
3. Retain a record of items 1 and 2 (X) Y ( ) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)]( ) Y (X) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

Remarks:

5. Therapeutic Radiopharmaceutical other than NaI ( ) N/A

OBJECTIVE 1

A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] (X) Y ( ) N _____

B. Written directives, as applicable, contain required information, radiopharmaceutical, dosage, and route of administration [35.2] (X) Y ( ) N _____

C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] (X) N/A

1. Written revisions ( ) Y ( ) N _____
2. Oral revisions ( ) Y ( ) N _____
3. Oral directives ( ) Y ( ) N _____

OBJECTIVE 2

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]: (X) Y ( ) N _____

Remarks:

OBJECTIVE 3 (Does not apply)

OBJECTIVE 4

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] (X) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Dosage measured prior to administration (X) Y ( ) N
2. Radiopharmaceutical, dosage and route of administration confirmed immediately prior to administration (X) Y ( ) N

C. Record of administration maintained in auditable form [35.32(d)(2)] (X) Y ( ) N _____

Remarks:

OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)] (X) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y (X) N
   Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y (X) N
3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y (X) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] (X) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause (X) Y ( ) N
2. Identify corrective action to prevent recurrence (X) Y ( ) N
3. Retain a record of items 1 and 2 (X) Y ( ) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

Remarks:

6. **PERIODIC REVIEWS OF THE QMP**

A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] (X) Y ( ) N
   Date of last review: 6/22/95

B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] (X) Y ( ) N

The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide

8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the events were isolated N/A( ) Y ( ) N

D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] (X) Y ( ) N

E. Based on evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] ( ) Y (X) N

F. Modifications sent to NRC within 30 days [35.32(e)] ( ) Y ( ) N (X) N/A

G. Records of reviews including evaluation and findings maintained for at least 3 years [35.32(b)(3)] (X) Y ( ) N

7. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

8. Time spent completing this module: 2 hours

	I-131	Sr-89	P-32
1993	62	5	1
1994	73	10	1
1995	46	7	0

MODULE 2

HIGH-DOSE-RATE REMOTE AFTERLOADING BRACHYTHERAPY

1. SUPERVISION

A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] (X) Y ( ) N
List individual(s) found to be inadequately trained:

2. OBJECTIVE 1

Number Missed

A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] (X) Y ( ) N _____

B. Written directives contain required information, isotope, treatment site, & total dose [35.2] (X) Y ( ) N _____

C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] (X) N/A

1. Written revisions ( ) Y ( ) N _____
2. Oral revisions ( ) Y ( ) N _____
3. Oral directives ( ) Y ( ) N _____

Remarks:

3. OBJECTIVE 2

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] (X) Y ( ) N _____

Remarks:

4. OBJECTIVE 3

A. Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives [35.32(a)(3)] (X) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Check of dose calculations by an authorized user or a qualified person under supervision

of an authorized user who whenever possible did not make the original calculations (X) Y ( ) N

2. Performing acceptance testing (based on licensee's specific needs & applications) on each treatment planning or dose calculating computer program that could be used for dose calculations (X) Y ( ) N

3. Other, describe:

Remarks:

5. OBJECTIVE 4

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] (X) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Plan of treatment prepared in accordance with the written directive (X) Y ( ) N
2. Person administering therapy treatment confirms the prescribed radioisotope, site, & total dose (X) Y ( ) N
3. Dwell times and positions verified prior to start of treatment (X) Y ( ) N
4. Verify source position using dummy sources or fixed geometry applicators prior to inserting sealed sources (X) Y ( ) N
5. Prompt record by the authorized user, of the treatment parameters and signing or initialing patient's chart or appropriate record (X) Y ( ) N
6. Other, describe:

C. Record of administration maintained in auditable form [35.32(d)(2)] (X) Y ( ) N _____

Remarks:

6. OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)] (X) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y (X) N

Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y (X) N

3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y (X) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] (X) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause (X) Y ( ) N
2. Identify corrective action to prevent recurrence (X) Y ( ) N
3. Retain a record of items 1 and 2 (X) Y ( ) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

Remarks:

7. PERIODIC REVIEWS OF THE QMP

A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] (X) Y ( ) N
Date of last review: 11/95

B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] (X) Y ( ) N

The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

C. If review identified recordable events or misadministrations, not previously identified, the review was expanded by the licensee to ensure the events were isolated NA ( ) Y ( ) N

D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] (X) Y ( ) N

E. Based on evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] ( ) Y (X) N

F. Modifications sent to NRC within 30 days [35.32(e)] ( ) Y ( ) N (X) N/A

G. Records of reviews including evaluation and findings maintained for at least 3 years [35.32(b)(3)] (X) Y ( ) N

8. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

9. Time spent completing this module: 1.5 hours

MODULE 3

BRACHYTHERAPY
(OTHER THAN HDR REMOTE AFTERLOADING)

1. SUPERVISION

A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] (X) Y ( ) N
List individual(s) found to be inadequately trained:

2. OBJECTIVE 1

Number Missed

A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] (X) Y ( ) N _____

B. Written directives contain required information [35.2]:

1. Prior to implantation: radioisotope, number of sources, and source strengths (X) Y ( ) N _____
2. After implantation & prior to completion of procedure: radioisotope, site, total source strength & exposure time (or total dose) (X) Y ( ) N _____

C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] ( ) N/A

1. Written revisions (X) Y ( ) N 1
2. Oral revisions ( ) Y ( ) N _____
3. Oral directives ( ) Y ( ) N _____

Remarks:

3. OBJECTIVE 2

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] (X) Y ( ) N _____

Remarks:

4. **OBJECTIVE 3**

A. Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives [35.32(a)(3)] (X) Y ( ) N ____

B. Procedures **may** include: **(not requirements)**

1. Check of dose calculations by an authorized user or a qualified person under supervision of an authorized user who whenever possible did not make the original calculations (X) Y ( ) N
2. Performing acceptance testing (based on licensee's specific needs and applications) on each treatment planning or dose calculating computer program that could be used for dose calculations (X) Y ( ) N
3. Other, describe:

Remarks:

5. **OBJECTIVE 4**

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] (X) Y ( ) N ____

B. Procedures **may** include: **(not requirements)**

1. Plan of treatment prepared in accordance with the written directive (X) Y ( ) N
2. Person administering treatment confirms prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, & total dose (X) Y ( ) N
3. Verify source position using dummy sources or fixed geometry applicators prior to inserting sealed sources (X) Y ( ) N
4. Prompt record by the authorized user, of the number of sources, the actual loading sequence of sources implanted (location of each sealed source in a tube, tandem, or cylinder) and signing or initialing the patient's chart or appropriate record (X) Y ( ) N
5. Ensure that source will not move or dislodge while implanted (X) Y ( ) N
6. Inspect implanted sources (X) Y ( ) N
   Frequency: Prior to
   Inspecting individual trained (X) Y ( ) N
7. Other, describe:

C. Record of administration maintained in auditable form [35.32(d)(2)] (X) Y ( ) N ____

Remarks:

6. OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)] (X) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y (X) N
Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y (X) N

3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y (X) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] (X) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause ( ) Y (X) N
2. Identify corrective action to prevent recurrence ( ) Y (X) N
3. Retain a record of items 1 and 2 ( ) Y (X) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

Remarks:

7. PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] (X) Y ( ) N
Date of last review: 1/95

B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] (X) Y ( ) N

The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of

10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the events were isolated NA ( ) Y ( ) N

D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] (X) Y ( ) N

E. Based on evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] ( ) Y (X) N

F. Modifications sent to NRC within 30 days [35.32(e)] ( ) Y ( ) N (X) N/A

G. Records of reviews including evaluation and findings maintained for at least 3 years [35.32(b)(3)] (X) Y ( ) N

8. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

9. Time spent completing this module: 2 hours

	Pd-103	I-125	Ir-192	Cs-137
1994	30	35	4	60
1995	8	33	2	32

MODULE 4

STRONTIUM-90 EYE APPLICATORS

1. **SUPERVISION**

A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] ( ) Y ( ) N
List individual(s) found to be inadequately trained:

2. **OBJECTIVE 1**

Number Missed

A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] ( ) Y ( ) N _____

B. Written directives contain required information, source strength, site, & exposure time or total dose [35.2] ( ) Y ( ) N _____

C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] ( ) N/A

1. Written revisions ( ) Y ( ) N _____
2. Oral revisions ( ) Y ( ) N _____
3. Oral directives ( ) Y ( ) N _____

Remarks:

3. **OBJECTIVE 2**

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] ( ) Y ( ) N _____

Remarks:

4. **OBJECTIVE 3**

A. Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives [35.32(a)(3)] ( ) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Plan of treatment prepared in accordance with the written directive ( ) Y ( ) N

2. Assess quantity of material remaining after decay (decay chart or other method)
3. Other, describe: ( ) Y ( ) N

Remarks:

5. **OBJECTIVE 4**

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] ( ) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Method used to time the administration
2. Person administering treatment confirms the prescribed site and the total dose, or source strength and exposure time ( ) Y ( ) N
3. Other, describe: ( ) Y ( ) N

C. Record of administration maintained in auditable form [35.32(d)(2)] ( ) Y ( ) N _____

Remarks:

6. **OBJECTIVE 5**

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)] ( ) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y ( ) N
Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y ( ) N
3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y ( ) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] ( ) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause ( ) Y ( ) N
2. Identify corrective action to prevent recurrence ( ) Y ( ) N

MODULE 5

TELETHERAPY

1. SUPERVISION

A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] ( ) Y ( ) N
List individual(s) found to be inadequately trained:

2. OBJECTIVE 1

Number Missed

A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] ( ) Y ( ) N _____

B. Written directives contain required information, total dose, dose per fraction, site, & overall treatment period [35.2] ( ) Y ( ) N _____

C. Exceptions to written directives documented [footnote to 35.32(a)(1)] ( ) N/A

1. Written revisions ( ) Y ( ) N _____
2. Oral revisions ( ) Y ( ) N _____
3. Oral directives ( ) Y ( ) N _____

Remarks:

3. OBJECTIVE 2

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] ( ) Y ( ) N _____

Remarks:

4. OBJECTIVE 3

A. Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives [35.32(a)(3)]( ) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Check of dose calculations by an authorized user or a qualified person under supervision

of an authorized user who whenever possible did not make the original calculations ( ) Y ( ) N

2. Performing acceptance testing (based on licensee's specific needs and applications) on each treatment planning or dose calculating computer program that could be used for dose calculations ( ) Y ( ) N
3. Determining transmission factors for beam modifying devices before first use and after replacement of the source ( ) Y ( ) N
4. Output measurements for treatment parameters not addressed in the most recent full calibration ( ) Y ( ) N
5. Checking dose calculations administration in fractions (procedure should include consideration of number of fractions and specified time within which the check should be performed) ( ) Y ( ) N
6. Other, describe: ( ) Y ( ) N

Remarks:

5. OBJECTIVE 4

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] ( ) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Plan of treatment prepared in accordance with the written directive ( ) Y ( ) N
2. Person administering treatment confirms the written directive and plan of treatment. At a minimum, the verification of treatment site and dose per fraction ( ) Y ( ) N
3. Other, describe:

B. Record of each administration or fraction maintained in auditable form ( ) Y ( ) N _____

6. OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)] ( ) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y ( ) N
Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y ( ) N

3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y ( ) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] ( ) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause ( ) Y ( ) N
2. Identify corrective action to prevent recurrence ( ) Y ( ) N
3. Retain a record of items 1 and 2 ( ) Y ( ) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y ( ) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y ( ) N

Remarks:

7. PERIODIC REVIEWS OF THE QMP

A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] ( ) Y ( ) N
Date of last review: _____

B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] ( ) Y ( ) N

The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the events were isolated ( ) Y ( ) N

D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] ( ) Y ( ) N

E. Based on the evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] ( ) Y ( ) N

F. Modifications sent to NRC within 30 days [35.32(e)] ( ) Y ( ) N ( ) N/A

6. Records of reviews including the evaluation and findings maintained for at least 3 years [35.32(b)(3)] ( ) Y ( ) N

Remarks:

8. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

9. Time spent completing this module:_____hours

3. Retain a record of items 1 and 2 ( ) Y ( ) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y ( ) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y ( ) N

Remarks:

7. PERIODIC REVIEWS OF THE QMP

A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] ( ) Y ( ) N
Date of last review:_____

B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] ( ) Y ( ) N

The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the events were isolated ( ) Y ( ) N

D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] ( ) Y ( ) N

E. Based on evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] ( ) Y ( ) N

F. Modifications sent to NRC within 30 days [35.32(e)] ( ) Y ( ) N ( ) N/A

G. Records of reviews including evaluation and findings maintained for at least 3 years [35.32(b)(3)] ( ) Y ( ) N

8. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

9. Time spent completing this module:_____hours

MODULE 6

GAMMA STEREOTACTIC RADIOSURGERY

1. SUPERVISION

A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] ( ) Y ( ) N
List individual(s) found to be inadequately trained:

2. OBJECTIVE 1

Number Missed

A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] ( ) Y ( ) N _____

B. Written directives contain required information, target coordinates, collimator size, plug pattern, and total dose [35.2] ( ) Y ( ) N _____

C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] ( ) N/A

1. Written revisions ( ) Y ( ) N _____
2. Oral revisions ( ) Y ( ) N _____
3. Oral directives ( ) Y ( ) N _____

Remarks:

3. OBJECTIVE 2

A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] ( ) Y ( ) N _____

Remarks:

4. OBJECTIVE 3

A. Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives [35.32(a)(3)] ( ) Y ( ) N _____

B. Procedures may include: (not requirements)

1. Check of dose calculations by an authorized user or a qualified person under supervision

of an authorized user who whenever possible did not make the original calculations ( ) Y ( ) N

2. Performing acceptance testing (based on licensee's specific needs and applications) on each treatment planning or dose calculating computer program that could be used for dose calculations ( ) Y ( ) N
3. Plan of treatment prepared in accordance with the written directive ( ) Y ( ) N
4. Imaging and localization precision assured ( ) Y ( ) N

   a. Stereotactic frame aligned and affixed ( ) Y ( ) N
   b. Imaging films correctly centered & labeled ( ) Y ( ) N

5. Verify correct helmet & plug pattern selected ( ) Y ( ) N
6. Verify computer generated dose calculations were correctly entered into unit and that the computer print out shows correct data for the patient were used in the calculations ( ) Y ( ) N
7. Other, describe:

Remarks:

5. <u>OBJECTIVE 4</u>

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] ( ) Y ( ) N _____

B. Procedures <u>may</u> include: <u>(not requirements)</u>

1. Check of treatment parameters by an authorized user or a qualified person under supervision of an authorized user who whenever possible did not make the original calculations ( ) Y ( ) N
2. Verify stereotactic frame coordinates on the patient's skull match the plan of treatment ( ) Y ( ) N
3. Person administering treatment confirms prescribed target coordinates, collimator size, plug pattern, and total dose prior to administration ( ) Y ( ) N
4. Prompt record of treatment parameters and signing or initialing of the patient's chart or appropriate record ( ) Y ( ) N
5. Other, describe:

B. Record of administration maintained in auditable form [35.32(d)(2)] ( ) Y ( ) N _____

Remarks:

6. OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)] ( ) Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y ( ) N
   Dates of events:
2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y ( ) N
3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y ( ) N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] ( ) Y ( ) N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause ( ) Y ( ) N
2. Identify corrective action to prevent recurrence ( ) Y ( ) N
3. Retain a record of items 1 and 2 ( ) Y ( ) N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y ( ) N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y ( ) N

Remarks:

7. PERIODIC REVIEWS OF THE QMP

A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] ( ) Y ( ) N
   Date of last review: _____

B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] ( ) Y ( ) N

   The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the

events were isolated ( ) Y ( ) N

D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] ( ) Y ( ) N

E. Based on the evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] ( ) Y ( ) N ( ) N/A

F. Modifications sent to NRC within 30 days [35.32(e)] ( ) Y ( ) N ( ) N/A

G. Records of reviews including evaluation and findings maintained for at least 3 years [35.32(b)(3)]: ( ) Y ( ) N

8. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

9. Time spent completing this module:_____hours

MODULE 7

MEDICAL EVENTS AND MISADMINISTRATIONS

1. **GENERAL**

A. Modality of event or misadministration:_____
B. Therapeutic or diagnostic event:_____
C. Date of event:_____
D. Date of discovery:_____
E. Identified by:_____
F. Licensee implemented a QMP for this modality [10 CFR 35.32] ( ) Y ( ) N

2. **TRAINING AND SUPERVISION**

A. Supervised individuals instructed in radiation safety principles appropriate to their use of byproduct material [35.25(a)(1)] ( ) Y ( ) N

B. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] ( ) Y ( ) N
List individual(s) found to be inadequately trained:

3. **DESCRIPTION OF EVENT**

A. Event classified as misadministration [35.2] ( ) Y ( ) N
If yes, which paragraph(s) under 35.2 best describes the event:_____

B. Describe sequence of events leading to misadministration:

C. If not a misadministration, describe the event:

D. Number of patients or others exposed/overexposed:_____

E. Time period:_____

F. Occupational workers exposed ( ) Y ( ) N
If yes, describe:

G. Licensee evaluation and actions

1. Calculated prescribed and actual doses ( ) Y ( ) N
Prescribed:_____ Actual:_____
2. Evaluated effect on patient ( ) Y ( ) N
3. Corrective actions taken to prevent recurrence ( ) Y ( ) N
4. If licensee did not evaluate or take action, reason provided:

4. EVALUATION OF THE EVENT

A. Cause of event

1. Human error ( ) Y ( ) N
2. Patient intervention ( ) Y ( ) N
3. Mechanical error ( ) Y ( ) N

a. Manufacturer/vendor:_____
b. Serial number:_____
c. Model number:_____

Remarks:

4. Computer software error ( ) Y ( ) N

a. Manufacturer/vendor:_____
b. Version:_____
c. Serial number:_____
d. Model number:_____

Remarks:

5. Failure to follow QMP ( ) Y ( ) N

a. Authorized user [35.32(a)] ( ) Y ( ) N
b. Supervised individual [35.32(a)(2)] ( ) Y ( ) N

Describe:

B. Root cause(s) and contributing factor(s) that led to this incident:

1. Identified by licensee:

2. Evaluated by inspector (See IP 87103):

5. NOTIFICATIONS

A. NRC's Operations Center within next calendar day after discovery [35.33(a)(1)] ( ) Y ( ) N
Report Number and date:_____

B. Referring physician and ( ) Y ( ) N
Patient within 24 hours after discovery [35.33(a)(3)] ( ) Y ( ) N
(Referring physician may inform the licensee either that he will inform the patient; or that, based on medical judgement, telling the patient would be harmful)

C. If patient was notified, patient also notified in writing within 15 days after discovery [35.33(a)(4)] ( ) Y ( ) N
If not within 15 days, date notified:_____

What information was provided in the report:

D. If patient was not notified, the licensee notified the responsible relative or guardian ( ) Y ( ) N
If no, licensee documented justification for decision ( ) Y ( ) N

Remarks:

E. Record of misadministration(s) retained [35.33(b)] ( ) Y ( ) N

The record must contain:
- Names of all individuals involved
- Patient's Social Security number/identification number
- All documents and correspondence associated with event
- A brief description of event including why it occurred, effect on the patient, improvements needed to prevent recurrence, actions taken to prevent recurrence.

Remarks:

F. Licensee identified misadministrations that were not subsequently reported [35.3(a)] ( ) Y ( ) N
If yes, briefly describe the reasons for not reporting:

G. Inspector identified misadministrations that the licensee failed to identify [35.2, 35.33] ( ) Y ( ) N

H. Licensee submitted written report to NRC within 15 days after discovery [35.33(a)(2)] ( ) Y ( ) N

Remarks:

6. CONSULTANTS

A. At the time of inspection, NRC medical or scientific consultant is reviewing this case (See MD 8.10) ( ) Y ( ) N

Name of consultant(s):

B. If not, case has been referred to a NRC consultant ( ) Y ( ) N

Name of consultant(s):

7. Time spent completing this module:_____hours

NOTE: These field notes are intended to supplement the Nuclear Medicine Field notes and the Quality Management (QM) Program Fieldnotes. All sets of field notes must be completed in accordance with current inspection guidance provided by NMSS.

REMOTE AFTERLOADING DEVICE FIELD NOTES

REGION I

Inspection Report No. 95-001

License No. 06-00819-03

Licensee (name and address):

Docket No. 030-01247

Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 065-04

Licensee Contact for Afterloaders: Mike Bohan - RSO

Telephone No. 203-785-2750

Program Code(s):

(X) 02230 High-, Medium-, and Pulsed-Dose Rate Remote Afterloaders

( ) 02231 Mobile High-, Medium-, and Pulsed-Dose Rate Remote Afterloaders

( ) Low-Dose Rate Afterloader

A17

I. PROGRAM ADMINISTRATIO.

A. Radiation Safety Committee (RSC)

1. RSC approved use of afterloader and reviews use at RSC meetings (35.22) (X) Y ( ) N ( ) NA

2. RSC reviews use of afterloaders in annual program audit (35.22, 20.1101) (X) Y ( ) N ( ) NA

3. RSC has implemented corrective actions (LC) ( ) Y ( ) N (X) NA

B. Authorized Users

1. Device used under supervision of an authorized user (LC) (X) Y ( ) N

2. Names of Users: Ken Roberts, M.D.
Barry Kavinsky, M.D.
Yung Song, M.D.
Jonathan Fanning, M.D.

C. Scope of Program

1. Multiple places of use ( ) Y (X) N

If yes, list locations:

_____

_____

_____

_____

Are all locations listed on license? (LC) ( ) Y ( ) N (X) NA

2. Were onsite inspections performed at each location? ( ) Y ( ) N (X) NA

If no, explain

3. Describe scop of the program (staff size, num r of procedures performed, etc.) 3 tech, 3 physicists, RSO, 4 authorized users,
About 100-250 fractions performed each year.
Licensee has Gamma Med 12i on site, but it has no source. Inspector observed removal of old source from the Gamma Med IIi 8/1/95, the cleaning of the HDR by a Med rep on 8/2/95 and the loading of the new source 8/2/95. Also observed the following survey & confirmed measurements.

D. Training

1. Facility individuals received initial and periodic training

   a. 10 CFR 19.12 training (19.12) (X) Y ( ) N

   b. Proper use of device (LC) (X) Y ( ) N

2. Individual(s) providing training are listed in license application (LC) ( ) Y ( ) N

   Name of individual(s):

   Mike Robson

   Jennifer Orrato

   Mary Stein

   Vendor will train on Gamma Med 12i at installation

3. Periodic retraining (interval ≤12 months) is provided to device operators (LC) (X) Y ( ) N

4. Operators, physicians, and medical physicists have been given emergency training including dry run (LC) (X) Y ( ) N

5. Briefly describe training/retraining program
   Original training done by Med. Now done by RSO annually

E. Reports and Notifications

1. Any misadministrations ( ) Y (X) N

2. If yes, were they reported (35.33) NA ( ) Y ( ) N

3. Any failures/problems of device ( ) Y (X) N

4. If yes, were they reported under 10 CFR Part 21 ( ) Y ( ) N (X) NA

F. Quality Managemen. lan (QMP)

1. License has developed QMP (35.32) (X) Y ( ) N

2. Licensee has implemented QMP (35.32) (X) Y ( ) N

3. Licensee staff has received training on QMP (35.25(a)(1)) (X) Y ( ) N

Remarks:

II. FACILITIES AND EQUIPMENT

A. Facilities

1. Physical Plant

a. General Requirements

(1) Device, sources, and keys are stored against unauthorized use and removal (20.207, 20.1801) (X) Y ( ) N

(2) Devices used in authorized locations (X) Y ( ) N

(3) Unauthorized individual prevented from entering use area (LC) (X) Y ( ) N

(4) Devices and places of use or storage properly posted (20.203, 20.1902, 20.1905) (X) Y ( ) N

(5) Only one radiation device can be placed in operation at a time within one treatment room (LC) (X) Y ( ) N

b. High-, Medium-, and Pulsed-Dose Rate Remote Afterloaders (X) Y ( ) N ( ) NA

(1) Use is limited to locations approved in License (LC) (X) Y ( ) N

(2) Dedicated treatment rooms are equipped with continuous viewing and intercom systems (LC) (X) Y ( ) N

(3) Viewing and intercom systems are checked at the beginning of each day of use (LC) (X) Y ( ) N

(4) Back-up system is available to observe patient's during treatment (LC) (X) Y ( ) N

If no, are treatments suspended NA ( ) Y ( ) N

(5) Electrical interlock systems are installed at each entry (LC) (X) Y ( ) N

(6) Interlock is operational (X) Y ( ) N

(7) Once activated door interlock must be reset (LC) (X) Y ( ) N

(8) Interlock operation tested daily (LC) (X) Y ( ) N

(9) Records of interlock operation are maintained for three years (X) Y ( ) N

c. Low-Dose Rate Remote Afterloaders ( ) Y ( ) N (X) NA

(1) Devices are used in locations within a single building approved on license (LC) ( ) Y ( ) N

(2) Portable shields are available for use (LC) ( ) Y ( ) N

(3) Licensee has capability to monitor patient during treatment (LC) ( ) Y ( ) N

Remarks:

B. Equipment

1. Radiation Detection Equipment

a. Permanent radiation monitor - All remote afterloaders but low-dose rate

(1) Monitor is installed in dedicated treatment room (LC) (X) Y ( ) N ( ) NA

Make: Privalert Model: 10

(2) Monitor has/does the following (LC)

- Visible notice when source is exposed or partially exposed (X) Y ( ) N
- Visible to someone entering room (X) Y ( ) N

Has separate backup power supply separate from power supply to afterloader (X) Y ( ) N

(3) Monitor operation is checked daily before use (LC) (X) Y ( ) N

(4) Records of monitor checks are maintained for three years (X) Y ( ) N

b. Portable Survey Instruments - All remote afterloaders

(1) Meters required by 10 CFR 35.420 (X) Y ( ) N

(2) Meter range is adequate (LC) (X) Y ( ) N

(3) Meters are calibrated before (LC) first use, annually and following repair (35.51) (X) Y ( ) N

(4) Meter checked with dedicated (LC) check source daily before use (X) Y ( ) N

(5) List meter model and range

Keithley 36150 0-300 R/hr

Ludlum 3 0-300 mR/hr

2. Afterloader

a. Operation

(1) Afterloaders authorized by license are used (LC) (X) Y ( ) N

(2) Afterloader and storage devices (LC) are properly labelled (X) Y ( ) N

(3) Back-up battery (source retraction) is tested monthly for operation (LC) (X) Y ( ) N

(4) Source position indicators are (LC) checked periodically (X) Y ( ) N

b. Maintenance

(1) Only authorized individuals perform maintenance, repair and inspection (LC) (X) Y ( ) N

Name of organization/individual:

Manufacturer

(2) Records of maintenance, inspection and service maintained for duration of device use (LC) (X) Y ( ) N

(3) Afterloaders inspected annually (LC) (X) Y ( ) N

Date of last inspection: 8/17/95, 3/29/95, 12/9/94

Manufacturer's schedule for service is followed (LC) ( ) Y ( ) N

Frequency: daily and annually

Date of last service: 12/9/94, 8/2/95

c. Calibration

(1) Only qualified or authorized individuals perform calibrations (LC) (X) Y ( ) N

(2) Device calibration measurements are performed following installation of new source and before patient treatment and monthly thereafter (LC) (X) Y ( ) N

Date of last source replacement: 8/2/95, 3/29/95

Date of last monthly calibration: 8/2/95, 11.1 Ci

(3) Radioactive Sources

- Approved sources are used/possessed (LC) (X) Y ( ) N
- Source homogeneity is confirmed (LC) (X) Y ( ) N
- Source inventory are performed quarterly (LC) (X) Y ( ) N
- Leak tests are performed semi-annually (LC) (X) Y ( ) N

  Date of last test: 6/22/95

- Source installation and replacement by authorized individuals only (LC) (X) Y ( ) N

Name of organization/individual:

Mike Bohan, Yale-N.H.H.

(4) Calibration/Dosimetry System

(a) Dosimetry system calibrated by NIST or AAPM lab., every two years (LC) (X) Y ( ) N

Name of calibration lab: K&S Associates

Last date of calibration: 8/26/92

Remarks:

III. OPERATIONS

A. Operating Procedures - All Devices

1. Procedures are posted (LC) (X) Y ( ) N
2. Procedures are identical or more restrictive than those submitted with license (LC) (X) Y ( ) N
3. Procedures are approved by RSC (LC) (X) Y ( ) N
4. Radiation survey of device and patient is performed to ensure source is returned to shielded position (35.404(a), LC) (X) Y ( ) N
5. Records of radiation surveys maintained for three years (35.404(b), LC) (X) Y ( ) N

B. High-, Medium-, and Pulsed-Dose Rate Remote Afterloaders (X) Y ( ) N ( )NA

1. At least one individual trained in safe use and emergency procedures is physically present while device in use (LC) (X) Y ( ) N
2. Authorized user and either medical physicist or RSO is physically present while device in use (LC) now (X) Y ( ) N
3. Only patient is in treatment room during device use (LC) (X) Y ( ) N

C. Low-Dose Rate Remo. Afterloaders ( ) Y ( ) N (X) NA

1. Device operator trained in emergency procedures is physically present or available by telephone during treatment (LC) ( ) Y ( ) N

2. Medical physicist or RSO and authorized user available for prompt assistance in emergency (LC) ( ) Y ( ) N

3. Written operating procedures are provided to nurses prior to device use (LC) ( ) Y ( ) N

Remarks:

III. EMERGENCY ACTIONS

A. Procedures are posted in conspicuous location (LC) (X) Y ( ) N

B. Individuals will carry radiation monitor if room monitor is non-functional (LC) (X) Y ( ) N

C. Licensee has responded to emergencies ( ) Y (X) N

If yes, were authorized user and medical physicist or RSO notified ( ) Y ( ) N

If yes, was NRC notified (LC) ( ) Y ( ) N

D. Emergency source recovery equipment available (LC) (X) Y ( ) N

Remarks:

IV. RADIATION PROTECTION

A. Radiation Levels in unrestricted areas are within limits (20.105, 20.1301) (X) Y ( ) N

B. Radiation levels in unrestricted areas are monitored after source exchange/replacement or unit relocation (LC) (X) Y ( ) N

Date of last source exchange: 8/9/95

Date of radiation survey: 8/2/95

C. Personnel monitoring is provided to appropriate individuals (LC, 20.202, 20.1502) (X) Y ( ) N

Remarks: Badges & alarming dosimeter-

V. WASTE DISPOSAL

Sources transferred to authorized individuals (20.301, 20.2001) (X) Y ( ) N ( ) NA

Name of organization: RTS

Remarks:

VI. CONFIRMATORY MEASUREMENTS

Detail location and results of confirmatory measurements

0.5 mR, 5.1 mR in milk, 1.1 mR in use of HDR Transfer

area: 0.3 mR at door, 0.2 mR by film reader, 0.2 mR in radiation room.

INSPECTION REPORT NO. 95-001 LICENSE NO. 06-00819-03

LICENSEE Yale-New Haven Hospital DOCKET NO. 030-01844,

PRIORITY : 1,3 PRIMARY PROGRAM CODE: 2110,

DATE OF LAST INSPECTION: 9/20-22/94, 9/27-30/93

Inspection Manual Chapter 2800 requires that the inspection interval shall be extended under certain circumstances and that it may be reduced under other circumstances. This form is to be filled out by the inspector and signed by the supervisor at the end of every inspection.

The criteria that must be considered to extend the inspection interval are (1) the current and preceding inspections meet criteria for documentation on an NRC Form 591 and no more than two Severity Level IV violations per inspection occur; and (2) the licensee has not had a significant program change since the preceding inspection.

Some of the criteria that may be considered to reduce the inspection interval are (1) a Severity Level I, II, or II violation on the most recent inspection, or; (2) issuance of an Order or escalated enforcement on the most recent inspection, or; (3) if a "management paragraph" appears, in the cover letter transmitting the NOV on the most recent inspection, or; (4) an event requiring a reactive inspection, or (5) repetitive violations.

Based on evaluation of the licensee's performance (Inspection No. XXX and Inspection No. XXX (previous inspection)) against the above criteria, the next inspection should be:

[X] No change in inspection frequency, next inspection should be on 9/96

[ ] Increase inspection interval, next inspection should be on __ __
Priority 1 normally 1, increase up to 2 years
Priority 2 normally 2, increase up to 3 years
Priority 3 normally 3, increase up to 5 years
Priority 5 normally 5, increase up to 7 years

[ ] Decrease inspection interval, next inspection should be on __ __
(Inspection interval may be reduced by any length)

INSPECTOR: Richard W. McKinley DATE: 8/7/95

APPROVED: Thomas F. Johnson DATE: 8/23/95

A14

Yale-New Haven Hospital
1826
20 York Street, New Haven, CT 06504

January 30, 1995

Docket No.: 030-1244 Report No.: 94-002 License No.: 06-00819-03

John R. McGrath, Acting Chief
Medical Inspection Section, DRSS
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Response to Notice of Violation dated 12/14/94

Dear Mr. McGrath:

In response to the Notice of Violation dated 12/14/94, Yale-New Haven Hospital hereby informs the Commission that the next of kin of the patient in question has now been notified of the misadministration and has received a copy of the original report written in connection with the misadministration. We will therefore consider this matter closed.

Nonetheless, we continue to request clarification regarding the Commission's interpretation of existing regulations which from our reading do not explicitly require next of kin to be notified in cases in which it has been deemed harmful to inform a patient of a misadministration. We first requested such clarification in our last response, dated October 26, 1994, a copy of which I enclose herewith. Moreover, in that letter we explicitly agreed to the notification if indeed the NRC insisted, but merely requested your clarification prior to notification. For that reason, we object to the issuance of a Notice of Violation in this case.

Although we have now proceeded with the notification in this case, we would still appreciate some written clarification with regard to this issue.

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1/1

Thank you for you assistance.

Sincerely,

Stuart G. Warner
Assistant Counsel

Norman G. Roth
Vice President, Administration

cc: Ravinder Nath, Ph.D.
Robert Lange, Ph.D.
Joseph Chambers, M.D.
Michael Bohan, RSO

encl.

Yale-New Haven Hospital
1826
20 York Street, New Haven, CT 06504

October 26, 1994

John R. McGrath, Acting Chief
Medical Inspection Section
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
476 Allendale Road
King of Prussia, PA 19406

Re: Notification Requirements for Therapeutic Misadministration

Dear Mr. McGrath:

Your letter of September 27, 1994 has been referred to this office for response. Your letter does not mention our letter of July 1, 1993, in which we indicated that it was deemed by the referring physician that notification would be harmful to the patient, and therefore, the patient was not notified. As stated in that letter, in this case the misadministration was deemed to have had no health implications for the patient. A copy of our response, together with a letter written by the referring physician are enclosed for your reference purposes.

When this letter was initially prepared I had written that Dr. Chambers, the referring physician in this case remained of the opinion that to notify the patient would be harmful. I had written that in fact, she was quite elderly and her condition had deteriorated significantly since that time, making his feelings even stronger on this point. Since my initial draft, the patient has died of multiple medical problems unrelated to her cancer, primarily her heart disease. We remain of the opinion that our action in not notifying the patient is an acceptable one pursuant to Part 35.33(a)(3) of the Regulations and indeed there is no mention of any notification of kin as a requirement under the regulations.

In the event that you find it necessary, Dr. Chambers may agree to notify the patient's son of the misadministration. Please let us know whether this is deemed necessary by the NRC and cite any relevant regulatory provisions.

9501160047 2pp.

Should you have any questions, please do not hesitate to contact me at 203-785-2291.

Very truly yours,

Stuart G. Warner

Stuart G. Warner
Assistant Counsel

cc: Norman G. Roth, V.P. Administration
Joseph Chambers, M.D.
Ravinder Nath, Ph.D.
Michael Bohan

encl.

DEC 14 1994

Norman G. Roth, Vice President
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Dear Mr. Roth:

SUBJECT: Notification Requirements of a Therapeutic Misadministration

This refers to the therapeutic misadministration that occurred at your facility on July 5, 1991, and that was subsequently discovered by you on January 30, 1992. This also refers to the letter dated October 26, 1994, from your Assistant Counsel in response to our letter dated September 27, 1994. You submitted a written report of this misadministration to the NRC Region I on February 13, 1992, that also stated that based on medical judgement, the patient was not notified of this misadministration.

The NRC considers that if the referring physician personally informs a licensee that based on medical judgement, notifying the patient would be harmful, the licensee is required to inform the patient's responsible relative or guardian, even if the patient is a competent adult. Additionally, as to the requirement to provide a written report of a misadministration to the patient, regardless of whether the licensee or the referring physician notified the patient, the licensee is still responsible for providing the written report to the patient. The NRC Information Notice IN 93-36 dated May 7, 1993, reminded the licensees of the notification and reporting requirements.

Based on the review by the NRC of the documents related to the above misadministration, it appears that you have not fully complied with all NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes the violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy).

You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A. Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response.

OFFICIAL RECORD COPY - S:\PENDING\YALE-NH2.NOV - 12/14/94 A19

RETURN ORIGINAL TO REGION I

IE:07

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room. The response requested by this letter is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:

John R. McGrath, Acting Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Report No. 030-01244/94-002
Docket No. 030-01244
License No. 06-00819-03

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut

bcc:
Region I Docket Room (w/concurrences)
D. Holody, RI
J. Glenn, NMSS

OFFICE	RI/DRSS	RI/DRSS	/		
NAME	SLodhi	JMcGrath			
DATE	12/01/94	12/ /94	12/ /94	12/ /94	12/ /94

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APPENDIX A

NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, Connecticut

Docket No. 030-01244
License No. 06-00819-03

During an NRC review of documents related to the therapeutic misadministration that occurred on July 5, 1991, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 35.33(a)(3) requires, in part, that the licensee also notify the patient or a responsible relative (or guardian) of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee that, based on medical judgement, telling the patient or the patient's responsible relative would be harmful.
>
> Contrary to the above, on January 30, 1992, the Licensee discovered that a misadministration had occurred at its facility on July 5, 1991, and as of December 1, 1994, the Licensee had not notified the patient's responsible relative (or guardian) of the misadministration and the referring physician had not determined that, based on medical judgement, telling the patient's responsible relative would be harmful to patient's responsible relative (or guardian).
>
> This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Yale-New Haven Hospital, New Haven, CT, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

OFFICIAL RECORD COPY - S:\PENDING\YALE-NH2.NOV - 12/01/94

Yale-New Haven Hospital
20 York Street, New Haven, CT 06504

October 26, 1994

John R. McGrath, Acting Chief
Medical Inspection Section
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
476 Allendale Road
King of Prussia, PA 19406

Re: Notification Requirements for Therapeutic Misadministration

Dear Mr. McGrath:

Your letter of September 27, 1994 has been referred to this office for response. Your letter does not mention our letter of July 1, 1993, in which we indicated that it was deemed by the referring physician that notification would be harmful to the patient, and therefore, the patient was not notified. As stated in that letter, in this case the misadministration was deemed to have had no health implications for the patient. A copy of our response, together with a letter written by the referring physician are enclosed for your reference purposes.

When this letter was initially prepared I had written that Dr. Chambers, the referring physician in this case remained of the opinion that to notify the patient would be harmful. I had written that in fact, she was quite elderly and her condition had deteriorated significantly since that time, making his feelings even stronger on this point. Since my initial draft, the patient has died of multiple medical problems unrelated to her cancer, primarily her heart disease. We remain of the opinion that our action in not notifying the patient is an acceptable one pursuant to Part 35.33(a)(3) of the Regulations and indeed there is no mention of any notification of kin as a requirement under the regulations.

In the event that you find it necessary, Dr. Chambers may agree to notify the patient's son of the misadministration. Please let us know whether this is deemed necessary by the NRC and cite any relevant regulatory provisions.

2nd

Should you have any questions, please do not hesitate to contact me at 203-785-2291.

Very truly yours,

Stuart G. Warner

Stuart G. Warner
Assistant Counsel

cc: Norman G. Roth, V.P. Administration
Joseph Chambers, M.D.
Ravinder Nath, Ph.D.
Michael Bohan

encl.

1826 Yale-New Haven Hospital
20 York Street, New Haven, CT 06504

Radiological Physics - WWW 204

Licensee No.: 06-00817-03 Docket No.: 030-01244

July 1, 1993

Thomas T. Martin, Regional Administrator
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Rd.
King of Prussia, PA 19406

Re: Response to NRC's Patient Notification Inquiry Dated June 3, 1993

Dear Mr. Martin:

We at Yale-New Haven Hospital have reviewed our records regarding the misadministration which occurred on July 5, 1991 and which was discovered during a review of the patient's record on January 30, 1992. The NRC was notified of the misadministration by phone the next day and in a report dated February 13, 1992. In this case, the patient was not notified of the error because the referring physician, using his medical judgement, determined that notification would cause undue anxiety which could be harmful to the patient. In addition, the referring physician concurred with the radiation oncology attending physician that no significant medical consequences could be anticipated from this misadministration.

The referring physician was verbally notified within 24 hours of discovery and received a copy of the misadministration report which was sent to the NRC. The patient was not notified and at the time was a competent adult with no other legal guardian or assigned "responsible relative".

The referring physician was again contacted after receipt of the June 3, 1993, NRC letter requesting further information. The referring physician reviewed the patient's chart but did not discover any notes relating to his decision process at the time of original notification. After reviewing the patient's chart and medical history, he prepared a statement regarding his decision which is attached as Exhibit 1.

Yale-New Haven Hospital believes that based upon NRC guidance available as of January 1992, that we had complied with the requirements of 10 CFR 35(a)(2). In future cases, we will request that the referring physicians document the basis for exceptions to the notification requirements.

Sincerely,

Michael J. Bohan, RSO

Norman G. Roth, Vice President

cc: Joseph Chambers, Ph.D., M.D., Referring Physician
Robert Lange, Ph.D., Chairman, Radiation Safety Committee
Ravinder Nath, Ph.D., Director, Radiological Physics

Attachment

Yale University

School of Medicine
Department of Obstetrics & Gynecology
333 Cedar Street
P.O. Box 3333
New Haven, Connecticut 06510-8063

Campus address:
339 Farnam Memorial Building
333 Cedar Street

July 1, 1993

Dr. Michael Bohan
Radiation Safety Officer
Yale University

RE: July 5, 1992 Gammamed Misadministration

Dear Mr. Bohan:

As per our conversation today with regard to the misadministration of the gammamed device of July 5, 1991, I would like to summarize my thoughts. At the time of being informed of this misadministration in February, 1992, I discussed the case with the patient's radiation oncology attending, Dr. Sean Dowling. To the best of my memory, our decision was not to inform the patient in part because no significant medical consequences could be anticipated from this misadministration. The patient is an elderly woman in her late 70's with multiple medical problems including angina, congestive heart failure, hyperlipidemia and partial paralysis secondary to previous cerebral vascular accident. In addition to these she had a history of hiatal hernia, diverticular disease, cataracts, and peptic ulcer disease. In my medical judgement, I determined that in view of the patient's extensive medical history, age and personality, discussing the issue would cause her undue anxiety and be harmful to her. She has subsequently been followed carefully by me. It was our impression at the time that under the guidelines as presented by the NRC this decision was in keeping with their policies. If you wish me to take other actions with regard to this matter, please let me know.

Sincerely,

Joseph T. Chambers, Ph.D., M.D.
Associate Professor
Gynecologic Oncology

JTC/sc

Yale-New Haven Hospital

20 York Street, New Haven, CT 06504

Michael J. Bohan, Radiation Safety Officer
Radiological Physics - WWW 204
(203) 785-2950

November 3, 1994

Docket No.: 030-01244 Inspection No.: 94-001 License No.: 06-00819-03

John R. McGrath, Acting Chief
Medical Inspection Section, DRSS
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Reply to Notice of Violation, Dated October 18, 1994.

Dear Mr. McGrath:

Yale-New Haven Hospital (YNHH) has reviewed each of the apparent items of non-compliance identified in Appendix A of your letter dated October 18, 1994. The hospital's response to each item is enclosed as Appendix A.

With regard to the reference in your letter regarding labeling radioactive waste packages, we have reviewed the requirements contained within 10 CFR 20.1904 and 10 CFR 20.1905 and have taken necessary steps to ensure full compliance.

If you have any further questions, please feel free to contact the Radiation Safety Officer at the address or phone number above.

Sincerely,

Michael J. Bohan
Radiation Safety Officer/Health Physicist

Norman G. Roth
Vice President, Administration

Robert C. Lange, Ph.D.
Chairman, Radiation Safety Committee

Enclosure: Appendix A - Reply to Notice of Violation

cc: USNRC Public Document Room

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Appendix A

Reply to A Notice Of Violation

Violation A

Restatement of the Violation

A nuclear medicine technologist did not fully complete the Radiopharmaceutical Decay Log as required by the Hospital's "Decay in Stor[illegible]rogram" procedures, dated February 2, 1990. Specifically, the disposal date of a package containing decayed radioactive waste was not recorded.

(1) Reason for the Violation

A review of the "Decay in Storage Program" records was conducted by the Radiation Safety Officer (RSO) to identify the reason for the violation. During the past year, more than 115 decay in storage packages were surveyed and documented prior to release. After review of the records, one package was apparently released without the required survey documentation being entered into the decay in storage log. The entry was apparently neglected by the technologist.

(2) Corrective Steps Taken and Results Achieved

The technologist staff was informed about the missing survey documentation during a staff meeting and about the need to properly account for the disposition of all packages entered into the "Decay in Storage Program".

(3) Corrective Steps Taken to Avoid Further Violations

The Radiation Safety Office will include the "Decay in Storage Program" in it's already established program of monthly and quarterly audits of the Nuclear Medicine Program activities.

(4) Date when Full Compliance Will Be Achieved

The actions mentioned above were implemented immediately after the conclusion of the inspection on September 23, 1994.

Violation B

Restatement of the Violation

The Hospital did not retain records of the ambient dose rate surveys in the areas where brachytherapy sources were stored.

(1) Reason for the Violation

The required records were not being maintained by the Radiation Safety Officer as required by the regulations.

(2) Corrective Steps Taken and Results Achieved

Survey record forms which meet the regulatory requirements were created for each brachytherapy source storage room. A survey of each room will be conducted and documented during quarterly inventories of the brachytherapy sources.

(3) Corrective Steps Taken to Avoid Further Violations

A summary survey record form including all brachytherapy source storage areas will be attached to the quarterly inventory records to ensure it is documented on a quarterly basis.

(4) Date when Full Compliance Will Be Achieved

Full compliance will be achieved during the next quarterly inventory scheduled for December 29, 1994.

Violation C

Restatement of the Violation

The records of removable contamination in the nuclear medicine area were not being maintained in units of disintegrations per minute per 100 square centimeters (dpm/100 cm^2).

(1) Reason for the Violation

The RSO had calibrated nuclear medicine's MultiChannel Analyser (MCA) based wipe test counter for dpm/100 cm^2 , however, technical difficultiues with the system's printer delayed implementation of procedural changes to use the system software and printing mechanisms to document the results in the required units.

(2) Corrective Steps Taken and Results Achieved

The problem with the printer was corrected and the system was recalibrated by the RSO to express wipe survey results in dpm/100 cm^2.

(3) Corrective Steps Taken to Avoid Further Violations

The technologists who perform the surveys were instructed to use the MCA system's printer feature to document wipe test results in dpm/100 cm^2.

(4) Date when Full Compliance Will Be Achieved

Full compliance was achieved on Setember 26, 1994.

November 25, 1994

Norman G. Roth, Vice President
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

SUBJECT: Routine Inspection NO. 030-01244/94-001

Dear Mr. Roth:

This refers to your letter dated November 3, 1994, in response to our letter dated October 18, 1994.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

[illegible]

John R. McGrath, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Docket No. 030-01244
License No. 06-00819-03

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut

bcc:
Region I Docket Room (w/concurrences)

RI:DRSS	RI:DRSS
Lodhi	McGrath
11/23/94	11/27/94

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RETURN ORIGINAL TO REGION I

IE:07

100062

030-01244-03

October 18, 1994

Mr. Norman G. Roth
Vice President
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Dear Mr. Roth:

Subject: Routine Safety Inspection No. 030-01244/94-001

From September 20 to September 23, 1994, Dr. Sattar Lodhi of this office conducted a routine safety inspection at the above address of activities authorized by the NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and members of your staff, at the conclusion of the inspection.

From the discussions between your staff members and Dr. Lodhi during the exit meeting on September 23, 1994, it is our understanding that you will take necessary steps to ensure that all the packages containing radioactive waste are properly labeled to comply with regulatory requirements. Please inform this office immediately if our understanding differs from yours.

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

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

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RETURN ORIGINAL TO
REGION I

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In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:

John R. McGrath, Acting Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Docket No. 030-01244
License No. 06-00819-03

Enclosure:
Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut

bcc:
Region I Docket Room (w/concurrences)
D. Holody, RI

RI:DRSS
Lodhi
10/05/94

RI:DRSS
McGrath
10/17/94

OFFICIAL RECORD COPY - S:\PENDING\YALE.INS - 10/04/94

APPENDIX A

NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, Connecticut 06054

Docket No. 030-01244
License No. 06-00819-03

During an NRC inspection conducted From September 20 to September 23, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written radiation safety procedures established by the licensee.

The written radiation safety procedures entitled "Decay in Storage Program", dated February 2, 1990, require, in part, that the Radiopharmaceutical Decay Log be fully completed and the disposal date be recorded.

Contrary to the above, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, did not fully complete the Radiopharmaceutical Decay Log. Specifically, the disposal date of a package containing decayed radioactive waste was not recorded.

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

B. 10 CFR 35.59(i) requires, in part, that a licensee in possession of a sealed source or brachytherapy source retain for three years a record of each quarterly ambient dose rate survey conducted in all areas where such sources are stored. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

Contrary to the above, as of September 23, 1994, the licensee did not retain records of the ambient dose rate surveys in the areas where the licensee's brachytherapy sources were stored.

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

C. 10 CFR 35.70(h) requires, in part, that the records of removable contamination surveys be kept in disintegrations per minute per 100 square centimeter.

Contrary to the above, the records of removable contamination surveys of

the nuclear medicine areas were maintained in counts per minute.

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

Pursuant to the provisions of 10 CFR 2.201, Yale-New Haven Hospital, New Haven, CT, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.