addressed during each inspection.

APPENDIX B
NUCLEAR MEDICINE INSPECTION FIELD NOTES
Region III

Inspection Report No. 93001 License No. 13-02063-01

Licensee (name and address) Docket No. 030-01603
Methodist Hospital of Indiana, Inc.
1701 North Senate Boulevard
Indianapolis, IN 46206

Licensee Contact: Bob Anger Telephone No: 317-929-3572

Last Amendment No.: 59 Date of Amendment: 9/16/91

Priority: 1

Program Codes:

(x) 02110 - Broad Scope	( ) 02120 - Limited
( ) 02121 - Custom	( ) 02200 - Private Practice - Limited
( ) 02209 - In Vivo	( ) 02201 - Private Practice - Custom
( ) 02210 - Eye Applicator	( ) 02220 - Nuclear Medical Van
( ) 02400 - Veterinary	( ) 02410 - In Vitro
( ) 02500 - Pharmacy	( ) Other -

Date of Last Inspection: 11/19/91

Date of This Inspection: 4/27 & 28/93

Type of Inspection:		
	( ) Announced	(x) Unannounced
	(x) Routine	( ) Special
	( ) Initial	(x) Reinspection

Next Inspection Date: 5/94 (x) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations, Clear 591 or letter issued
(x) Violations, letter issued
(x) Action on Previous Violations

Inspector: James Mullaney Date 5/27/93
(Signature)

Approved: _____ Date _____
(Signature)

1. ORGANIZATION Sam Odle, Senior, V.P.
*Vaughn England, Administrative Director
*Larry Heck, M.D., Chairman of RSC
*Jerry Kight, M.D., Medical Director
*Bob Anger, Radiation Safety Officer
Roger Robinson, Assistant RSO
Mike Loyd, M.A., Medical Physicist
John Kent, M.S., Medical Physicist
Ron Berg, Ph.D., Medical Physicist
*Stan Metzger, Chief Tech, Nuclear Medicine
Pat Gallegher, Ph.D., Pharmacy Chemist

a. Organizational structure meets license requirements [L/C] (x) Y ( ) N

Remarks:

b. Use by authorized individuals [35.22(b)(2)] (x) Y ( ) N

Remarks:

All users are approved by the RSC. No new users approved by the committee since the last inspection.

c. Radiation Safety Committee ( ) N/A

(1)	Membership as specified in [35.22(a)(1)]	(x) Y ( ) N
(2)	Meetings held quarterly [35.22(a)(2)]	(x) Y ( ) N
(3)	Quorums established per [35.22(a)(3)]	(x) Y ( ) N
(4)	Has sufficient authority per [35.23]	(x) Y ( ) N
(5)	Committee reviews conducted per [35.22(b)]	(x) Y ( ) N
(6)	Record of Committee meetings [35.22(a)(4)]	(x) Y ( ) N

Remarks:

Committee appears to function appropriately based upon discussions with RSO, committee members, management and based upon review of actions documented in meeting minutes.

d. Radiation Safety Officer

(1)	Appointed [35.21(a)]	(x) Y ( ) N
(2)	Fulfills duties per [35.21(b)]	(x) Y ( ) N
(3)	Has sufficient authority per [35.23]	(x) Y ( ) N

Remarks:

Bob Anger

e. Visiting Authorized User (x) N/A

(1) Has written permission [35.27(a)(1)] ( ) Y ( ) N
(2) Copy of visitor's license on file [35.27(a)(2)] ( ) Y ( ) N
(3) Performs only those procedures authorized on visitor's license [35.27(a)(3)] ( ) Y ( ) N
(4) Uses material under licensee's license for sixty days per year or less [35.27(b)] ( ) Y ( ) N
(5) Records maintained 3 years after last visit [35.27(c)] ( ) Y ( ) N

Remarks:

f. Mobile Nuclear Medicine Service (x) N/A

(1) Licensee uses mobile nuclear medicine services [35.29] ( ) Y ( ) N
(2) Licensee operates mobile nuclear medicine services [35.29, 35.80] ( ) Y ( ) N

Remarks:

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

a. Last inspection conducted on: 11/19/91

b. Violations or deviations were identified (x) Y ( ) N

c. 591 dated: 11/19/91
d. Violations from Previous Inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status
Housekeeping not trained annually - Corrected & Closed			

e. Any previous violations not corrected ( ) Y (x) N

Explain:

3. SCOPE OF PROGRAM

a. License has multiple authorized locations of use (x) Y ( ) N
b. If so, list location(s) inspected - 1701 facility
( ) N/A
c. List those individuals contacted during inspection:
See page 2 item 1. In addition, multiple technologists, physicians and physicistswere contacted and interviewed during this inspection.
*Indicates presence at exit meeting

d. Briefly describe scope, including types of use involving byproduct material, frequency of use, staff size, etc.:

This large nuclear medicine department currently employs 14 full time technologists and 1 pharmacy chemist who perform approximately 1000 diagnostic studies per month in 5 imaging areas. In addition, the licensee performs approximately 15 hyperthyroid treatments per month averaging 12 millicuries of I-131 liquid, approximately 15 thyroid cancer treatments per year averaging 150 millicurie of I-131 liquid. In addition, the licensee performs approximately 120 HDR treatments, and approximately 6 LDR standard brachytherapy procedures per year. This inspection focused on nuclear medicine, HDR and standard brachytherapy. The limited research program did not receive an extensive review during this inspection. Currently, the licensee conducts research in 4 laboratories. All research performed is performed using microcurie amounts of Ram. The licensee also possesses 2 self shielded irradiators as authorized. A walk thru of these areas showed that posting was adequate and radiation levels around the irradiators were well below 2 mR/hr at a foot.

e. Radiation safety program changes pursuant to [35.31] ( ) Y ( ) N (x) N/A

f. Records of changes maintained [35.31(b)] ( ) Y ( ) N ( ) N/A

Remarks:

4. INTERNAL AUDITS OR INSPECTIONS

a. Audits or inspections are conducted (x) Y ( ) N ( ) N/A

(1) Audits conducted by: Bob Anger, RSO
(2) Frequency: Quarterly

b. Audits are required by license condition (x) Y ( ) N

c. Records maintained (x) Y ( ) N

Remarks:

Audits performed are general health physics reviews that include surveys and wipe test for contamination. Last quarterly audit was performed on January 15, 1993.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] (x) Y ( ) N

Remarks:

b. Training program required [L/C] (x) Y ( ) N ( ) N/A

(1) Training program implemented (x) Y ( ) N
(2) Retraining program required (x) Y ( ) N
(3) Retraining program implemented (x) Y ( ) N
(4) Records maintained (x) Y ( ) N

Remarks:

Training includes topics suitable for persons who need to frequent restricted areas and are provided training initially and at least once a year. Technologist receive ongoing training in topic areas needed to keep current with procedures and license requirements.

c. Supervision of individuals by authorized user in accordance with [35.25] (x) Y ( ) N

Remarks:

6. FACILITIES AND EQUIPMENT

a. Facilities as described in license application (x) Y ( ) N

Remarks:

b. Areas for storage and use of RAM

(1) Adequate method used to prevent an unauthorized individual from entering restricted area (x) Y ( ) N
(2) RAM is secured to prevent unauthorized removal from an unrestricted area [20.207] (x) Y ( ) N

Remarks:

All deliveries of RAM are made to the hot lab in the nuclear medicine department where the material is secured during off duty hours.

c. Dose calibrator

(1) Licensee possesses and uses dose calibrator(s) per [35.50(a)] (x) Y ( ) N ( ) N/A
(2) Constancy checked per [35.50(b)(1)] (x) Y ( ) N
(3) Linearity tested per [35.50(b)(3)] (x) Y ( ) N
(4) Accuracy tested per [35.50(b)(2)] (x) Y ( ) N
(5) Geometry dependence tested per [35.50(b)(4) (x) Y ( ) N ( ) N/A
(6) Readings mathematically corrected if linearity error is greater than 10% [35.50(d)] ( ) Y ( ) N (x) N/A

(7) Records maintained [35.50(e)] (x) Y ( ) N
(8) RSO signs linearity, accuracy and geometry dependence tests [35.50(e)] (x) Y ( ) N

Remarks:

d. Survey instruments

(1) Appropriate operable survey instruments possessed per [35.120,220,320,420] or available per [35.520] (x) Y ( ) N ( ) N/A
(2) Calibration performed as required in [35.51] (x) Y ( ) N
(3) Records maintained [35.51(d)] (x) Y ( ) N
(4) Proper operation checked with check source per [35.51(c)] (x) Y ( ) N

Remarks:

The licensee possesses a variety of survey instruments that appear adequate for all the licensee's programs. Each department has an adequate number of instruments available.

e. Syringes containing RAM properly labeled and shielded unless contraindicated per [35.60] (x) Y ( ) N
f. Vials containing RAM properly labeled and shielded per [35.61] (x) Y ( ) N

Remarks:

7. RADIOLOGICAL PROTECTION PROCEDURES

a. Radioactive materials used in accordance with current procedures [L/C] (x) Y ( ) N

Remarks:

b. Individuals' understanding of current procedures is adequate in:

(1) general rules for safe use of RAM (x) Y ( ) N
(2) in emergency procedures (x) Y ( ) N

Remarks:

Laboratory rules are posted as well as emergency procedures in case of Xe-133 release. Individuals interviewed appeared to be knowledgeable in these procedures.

8. MATERIALS

a.	Licensee uses unit doses	( ) Y (x) N
b.	Licensee uses generators	(x) Y ( ) N
c.	Licensee possesses sealed sources or brachytherapy sources per [35.59]	(x) Y ( ) N
d.	Isotope, chemical form, quantity and use as authorized [L/C, 31.11, 35.100,200,300,400,500]	(x) Y ( ) N

Remarks:

The licensee uses three generators a week in which two are new generators. Old generators are held for decay.

e. Molybdenum-99 breakthrough ( ) N/A

(1)	Test performed per [35.204(b)]	(x) Y ( ) N
(2)	Records maintained per [35.204(c)]	(x) Y ( ) N

Remarks:

f. Leak tests and Inventory

(1)	Leak tests performed on sealed sources and brachytherapy sources per [35.59(b)]	(x) Y ( ) N
(2)	Inventory of sealed sources and brachytherapy sources per [35.59(g)]	(x) Y ( ) N
(3)	Leak tests records in microcuries	(x) Y ( ) N
(4)	Leak test/inventory records signed by RSO	(x) Y ( ) N
(5)	Records maintained of leak tests and inventories for 5 years	(x) Y ( ) N

Remarks:

No major problems were noted; however, the inspector did notice that the Inventory record includes leak test data whether leak tests on sealed sources were performed or not. When ~~a leak test~~ is performed ~~and the results are negative~~, the RSO signs and dates the inventory form that indicates that a leak test was performed. Since inventories of sealed sources are performed quarterly and leak tests are performed every six months, to avoid confusion, the licensee agreed to delete leak test information from the inventory record during periods when leak test are not performed.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Describe how packages are received and by whom: ( ) N/A

Packages are brought directly to the nuclear medicine laboratory by the carrier and received by nuclear medicine personnel. During off duty hours the material is secured in the hot lab by security.

b.	Opening procedures established and followed [20.205(d)]	(x) Y ( ) N
c.	Incoming packages wiped per [20.205(b)]	(x) Y ( ) N
d.	Incoming packages surveyed per [20.205(c)]	(x) Y ( ) N
e.	Transfer(s) performed per [30.41]	(x) Y ( ) N
f.	Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51]	(x) Y ( ) N

Remarks:

10. AREA SURVEYS ( ) N/A

a.	Ambient exposure rate surveys conducted per [35.70(a),(b),(c)]	(x) Y ( ) N
b.	Contamination surveys conducted per [35.70(e),(f)]	(x) Y ( ) N
c.	Trigger levels established [35.70(d), (g)]	(x) Y ( ) N
d.	Exposure rate survey records in mR/hr	(x) Y ( ) N
e.	Contamination survey records in dpm/100 sq cm	(x) Y ( ) N
f.	Records maintained per [35.70(h)]	(x) Y ( ) N

Remarks:

11. RADIOPHARMACEUTICAL THERAPY ( ) N/A

a.	Licensee provides safety instruction [35.310] and implements safety precautions [35.315] or equivalents [L/C]	(x) Y ( ) N
b.	Patient room contamination surveys per [35.315]	(x) Y ( ) N
c.	Release of patients containing radiopharmaceuticals meets [35.75]	(x) Y ( ) N
d.	Thyroid burden measured on individuals involved in dose administrations [35.315(a)(8)]	(x) Y ( ) N
e.	Records maintained	(x) Y ( ) N

Remarks:

See item No. 23 for QMP deviations.

12. BRACHYTHERAPY ( ) N/A

a.	Licensee provides safety instruction [35.410] and implements safety precautions [35.415] or equivalent [L/C]	(x) Y ( ) N
b.	Patient surveys performed per [35.406]	(x) Y ( ) N
c.	Release of patients containing permanent implants meets [35.75]	(x) Y ( ) N
d.	Release of patients treated with temporary implants meets [35.404]	(x) Y ( ) N

e. Brachytherapy sources inventoried per [35.406] (x) Y ( ) N
f. Brachytherapy source storage area surveyed quarterly and record signed by RSO [35.59(h)] (x) Y ( ) N
g. Records maintained (x) Y ( ) N

Remarks:

See item No. 23 for QMP deviations. The inspector observed an HDR treatment and confirmed the licensee has taken action to comply with the requirements of Bulletin 93-01. For example, an authorized user and 2 physicist were present during treatment and the licensee did perform a patient survey when the source was removed after treatment.

13. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD supplier: Landauer Frequency: Monthly
b. Supplier is NVLAP - approved (x) Y ( ) N
c. Reports reviewed by: RSO Frequency: Monthly
d. NRC inspector reviewed personnel monitoring records for period from January 1991 to March 1993

e. NRC forms or equivalent

(1) NRC-4: ( ) Y (x) N Complete: ( ) Y ( ) N ( ) N/A
(2) NRC-5: (x) Y ( ) N Complete: (x) Y ( ) N ( ) N/A [20.401(a)]

f. List maximum exposures (millirem):
The maximum annual total whole body exposure noted was in nuclear medicine with a reading of 610 mRem and the maximum annual total extremity exposure noted was in nuclear medicine with a reading of 7580 mRem.

g. Licensee has implemented an ALARA program [35.20] (x) Y ( ) N

Remarks:

14. PERSONNEL RADIATION PROTECTION - INTERNAL ( ) N/A

a. Potential for exposure of individuals to airborne RAM exists (x) Y ( ) N
b. Monitoring for airborne radioactivity conducted [20.201(b) to meet 20.103, 35.90, and 35.205] (x) Y ( ) N
c. Records maintained [20.401, 35.205(d), and L/C] (x) Y ( ) N
d. Bioassay program implemented as described in correspondence with NRC (x) Y ( ) N
e. Radioactive gases

(1) Clearance time and safety procedures are posted [35.205(d)] (x) Y ( ) N
(2) Reusable collection systems checked monthly (x) Y ( ) N
(3) Ventilation rates checked each six months for negative pressure [35.205(e)] (x) Y ( ) N

Remarks:

The inspector reviewed bioassay results for the inspection period and noted no levels greater than the MDA of 0.00678 µci. The licensee uses a Canberra Series 35 uptake probe for bioassays. The inspector had the licensee run an efficiency test on the probe and the licensee was able to demonstrate that the MDA was accurate.

15. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. RAM in effluents to unrestricted areas ( ) Y ( ) N
b. Release in accordance with regulatory limits [20.106(a)] ( ) Y ( ) N

Remarks:

Not reviewed.

c. Describe waste disposal method(s) - solid and liquid:

Solid was is held for decay. Long lived Ram is shipped for burial; however, no shipments were made during the inspection period.

d. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below: N/A

(1) Adequate control of waste in storage is maintained ( ) Y ( ) N
(2) Package is labeled and package integrity is adequately maintained ( ) Y ( ) N
(3) Adequate records of surveys and material accountability are maintained ( ) Y ( ) N

e. Disposal of waste in accordance with regulatory requirements [20.301] Not Reviewed (x) Y ( ) N
f. Decay-in-storage waste disposed per [35.92] (x) Y ( ) N
g. Records maintained [20.401(b) and 35.92(b)] (x) Y ( ) N

Remarks:

16. NOTIFICATION AND REPORTS

a.	Licensee in compliance with [19.13] (reports to individuals)	( ) Y ( ) N (x) N/A
b.	Licensee in compliance with [20.402] (theft or loss)	( ) Y ( ) N (x) None
c.	Licensee in compliance with [20.403] (incidents)	( ) Y ( ) N (x) None
d.	Licensee in compliance with [20.405] (overexposures)	( ) Y ( ) N (x) None

Remarks:

17. MISADMINISTRATIONS

a.	Misadministrations have occurred	( ) Y (x) N
	(1) Diagnostic	( ) Y ( ) N
	(2) Therapeutic	( ) Y ( ) N
b.	Licensee in compliance with reporting therapeutic misadministrations [35.33(a),(b)]	( ) Y ( ) N
c.	Licensee in compliance with reporting diagnostic misadministrations, if required [35.33(c)]	( ) Y ( ) N
d.	Appropriate action taken to prevent recurrence	( ) Y ( ) N
e.	Records maintained [35.33(d)]	( ) Y ( ) N

Remarks:

18. POSTING AND LABELING

a.	NRC-3 "Notice to Workers" posted	(x) Y ( ) N
b.	Parts 19, 20, and 21 and license 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 [20.203]	(x) Y ( ) N

Remarks:

19. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

a. Licensee makes shipments of RAM (x) Y ( ) N
b. If so, describe shipment content and method:

Not inspected since no Ram shipments were made during the inspection period

c. Licensee is aware of 10 CFR 61 requirements ( ) Y ( ) N ( ) N/A

d. Licensee classifies and characterizes waste ( ) Y ( ) N ( ) N/A

e. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N ( ) N/A

(2) Package type used:

(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N ( ) N/A

(4) For special form sources, performance test record on file [173.476(a)] ( ) Y ( ) N ( ) N/A

(5) Packages properly labeled [172.403, 173.441] ( ) Y ( ) N ( ) N/A

(6) Packages properly marked [173.200] ( ) Y ( ) N ( ) N/A

(7) Proper shipping papers prepared and used [172.200-204] ( ) Y ( ) N ( ) N/A

Remarks:

f. Licensee makes return shipments of radiopharmacy doses ( ) Y ( ) N (x) N/A

(1) If YES, licensee assumes responsibility of all shipper requirements ( ) Y ( ) N

(2) If NO, describe arrangements made between licensee and radiopharmacy as to performance of shipper responsibilities:

20. RECORD KEEPING 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)] ( ) Y ( ) N

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

Remarks:

Inspector reviewed 30.35(g) requirements with the RSO.

21. INDEPENDENT MEASUREMENTS

a. Survey instrument used: Xetex 305B and Ludlum 14C with pancake probe
b. NRC Serial No.: 009003 and 034265
c. Last date of calibration: 11/19/92 and 1/31/93
d. Inspector's measurements were compared to licensee's (x) Y ( ) N
e. Describe the type and results of measurements:

General radiation surveys in unrestricted areas indicated radiation levels were well below 2 mR/hr and surveys in restricted areas varied depending on the location of Ram. Occupied areas in restricted boundaries were no greater than 0.2mR/hr in the areas checked. Side by side measurements using the licensee instruments and NRC instruments showed good agreement.

22. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee (x) Y ( ) N
b. Licensee took appropriate action in response to Bulletins, INs, etc. (x) Y ( ) N

Remarks:

23. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

The following issues were identified concerning the licensee's QMP:

1. The licensee's QMP dated January 22, 1992, requires in the Quality Management Plan Audit Section that the QMP will be audited annually by the Radiation Safety Officer. The review will include a representative sample of appropriate radiopharmaceutical and brachytherapy patient administrations. In actuality, a quarterly review is performed by the RSO of all radiopharmaceutical therapy and administrations of greater than 30 μCi NaI-131 performed during that quarter. This frequency exceeds the requirements of the QMP for radiopharmaceutical use. A monthly audit is performed on all HDR and standard brachytherapy cases performed during that month by the radiation physics staff which is again exceeds the requirements of the QMP. However, the HDR and standard brachytherapy QMP was not audited by the RSO as required. The inspector learned that the physics staff performs the audits and submits the results to the RSO for review. The physics staff audit did not appear to be as comprehensive as the RSO's audit of the radiopharmaceutical program. The NRC inspector addressed this observation during the exit meeting with licensee management and was well received by the licensee management. However, since this deficiency is associated with a portion of the licensee's QMP [redacted], no

enforcement action will be taken by the RIII staff at this time. GJ.

The root cause of this apparent deficiency was the RSO's misunderstanding of the QMP audit requirement. He thought that reviewing the results of the audit performed by the physics staff was adequate. The inspector reviewed the specific requirements of the licensee's QMP and the RSO agreed that he should have performed at least one audit in 1992 of the HDR and Brachytherapy QM program.

2. The licensee's QMP requires for any administration of NaI-131 or NaI-125 greater than 30 μCi that prior to administration, an authorized user must sign and date a written directive. The licensee's QMP defines a written directive as an order in writing showing the dose for a specific patient which is signed and dated by an authorized user prior to the administration of a radiopharmaceutical. The inspector reviewed the results of the RSO's audits performed on radiopharmaceutical use to date. The audit showed that on three occasions, the licensee failed to make a written directive prior to the administration of a 5 millicurie of NaI-131 work-up cancer treatment thyroid uptake study. These three recordable events were discovered by the RSO during the October 26, 1992 audit and are maintained in the licensee's file as recordable events. Of 87 cases involving the administration of >30μCi of NaI-131 during the period from January 27, 1992, through October 26, 1992, three non-therapeutic cases did not have written directives. It appears, however, that the administrations were given as intended by the authorized user. These findings and the resulting additional training of supervised and non-supervised individuals were discussed at the November 3, 1992, Radioisotope Committee meeting. The Committee recommended a follow-up report be given at the next meeting to determine the effectiveness of actions taken.

The root cause of this licensee identified apparent violation was the lack of attention to detail by the authorized user and technologist during busy periods in the department. All three events were identical cases, i.e. work-up therapeutic uptake doses in which the licensee routinely administers 5 millicuries of NaI-131. The licensee performed 29 work-up cases during the review period. Corrective action was accomplished by retraining the authorized users and the nuclear medicine technologist. According to the RSO, this type of recordable event has not recurred since the October 26, 1992 audit. This was verified by the NRC inspector's random review of QMP records to date. Although there is safety significance associated with this violation, to the implementation of QMP, these work-up procedures were performed under standing orders and all adults received the same quantity of NaI-131, 5 millicuries. The absence of written directives for non-routine therapeutic procedures would have carried greater safety significance. This finding is subject to enforcement action since it is specifically required by 10 CFR Part 35.

3. The following additional problems were noted in the licensee's audit concerning written directives made prior to administration of >30 μCi of NaI-131 for the period between January 27, 1992, and October 26, 1992. Of 87 administrations of >30 μCi of NaI-131, written directives for 13 of the cases were not dated by the authorized user; 1 did not have a signature or date and 2 did not have signatures on the written directives.

   The root cause of this licensee identified apparent violation is the lack of attention to detail when performing these cases during busy periods in the nuclear medicine department. The RSO stated that he continues to instruct authorized users to complete the directive prior to administration. The inspector stressed the importance of this requirement at the closeout meeting with licensee management who assured that this violation would not recur in the future. This finding is subject to enforcement action since it is specifically required by 10 CFR Part 35. This violation is of minimal safety significance.

4. The licensee's HDR QMP requires that after treatment completion, the radiation oncologist or physicist review, date and sign the printed record of treatment delivery produced by the Nucletron computer. This record shall be placed in the patient's radiation therapy chart. The significance of the signature and date is to assure the auditor that the staff properly reviewed the treatment data to assure that treatment was in accordance with the written directive. The inspector reviewed 4 patient charts for compliance with this requirement and found that the authorized user and/or physicist had failed to sign and date the computer generated treatment record on 3 occasions. The licensee assured the inspector that the computer generated record is reviewed after treatment as required. Again the apparent root cause of this violation is the lack of attention to detail during busy periods in the oncology department. This observation was discussed with licensee management who acknowledged the finding and agreed to take corrective action to comply with it's QMP. However, since this is a deficiency associated with a portion of the licensee's internal QMP [redacted], no enforcement action will be taken by the RIII staff at this time.

24. LIST OF VIOLATIONS NOT RELATED TO QMP

1. 10 CFR 35.404(b) requires the licensee to retain a record showing surveys which are performed on patients immediately after removing the last temporary implant source from the patient. The inspectors review of 6 HDR patient files showed that 4 patient surveys were not documented as required. The licensee again assured the inspector that patients are always surveyed after the HDR source is removed. The inspectors review of other HDR and standard brachytherapy charts revealed the patient survey was

documented. In addition to the final patient survey, the licensee does utilize a prime alert radiation detector which monitors the source on/off condition. According to the licensee, no problems have been noted with the detector. The NRC inspector tested the monitor and it appeared to be functioning properly. In addition, the door interlock functioned properly as well.

The apparent root cause of the violation appears to be a lack of space provided for the signature on some forms used by the physics staff. Other forms did have a space identified as the signature block for the person performing the surveys to sign.

2. 10 CFR 35.406 requires the licensee to make a record of brachytherapy source use and is required to document certain specific information such as when sources are removed from storage for patient use, the patients room number needs to be recorded and upon return to storage, the activity returned, the patient's name and the total activity in the safe needs to be recorded. The inspectors review of the brachytherapy source use log showed that on multiple occasions, the above information was not documented.

The apparent root cause of the violation appears again to be caused by a lack of a standardize form which indicates what information needs to be documented. The licensee agreed to standardize the use log to indicate all the information required by Part 35.

25. PERFORMANCE EVALUATION FACTORS

Licensee: Methodist Hospital of Indiana, Inc.
Inspector: James R. Mullauer, M.H.S.

Inspection Date: April 27 and 28, 1993

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? (x) Y ( ) N

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

See Item No. 23.1
Regional follow-up on above PEFs citations:

Submit to the NMSS QMP review committee this positive PEF with the recommendation that Region III issue a SLIV Violation and review corrective action during the next routine inspection.

Methodist

ADDENDUM

INTERIM FIELD NOTES

QUALITY MANAGEMENT (QM) PROGRAM

[Note - "Yes" and "No" answers may indicate a "Weakness (W)" or "Substantial Weakness (SW)" based on their significance. If the question is not applicable, indicate "NA"]

1. GENERAL

a. License number(s): 13-02063-01

b. Docket number(s): 030-01603

c. Last inspection date(s): 11/19/91

d. Current inspection date(s): 4/27-28/93

2. MODALITIES

a. Procedures the licensee performs:

(1) Teletherapy	Y	(N)
(2) Gamma Stereotactic Radiosurgery	Y	(N)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	(Y)	N
(4) All Other Brachytherapy	(Y)	N
(5) NaI I-125 or I-131 >30 microCi	(Y)	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	(Y)	N

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3. PROGRAM

a. Licensee has a written QM program, as applicable, that covers all policies/procedures that require a written directive and program review [35.32(a) and (b)(1)] (Y) N (SW)

b. Written QM program and certification (for existing licensee) submitted to NRC [35.32(f)(2)] (Y) N

Date 1/22/92

Remarks:

4. SUPERVISION

a. Supervised individual(s) instructed in the QM program applicable to the modality of use [35.25(a)(1)] (Y) N (SW)

(1) If any individual(s) has not received training, document their name and position. Additionally, briefly describe the reasons as stated by the individual, the RSO, and the supervising authorized user:

Remarks:

QUALITY

MANAGEMENT

PROGRAMS

FILE COPY

Methodist Hospital OF INDIANA, INC.

DEPARTMENT OF RADIOLOGY
1701 North Senate Boulevard
P.O. Box 1367
Indianapolis, IN 46206
Office: (317) 929-3572
Fax: (317) 929-2019

January 22, 1992

Medical Licensing Section
U. S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

In accordance with 10 CFR 35.32, we submit the enclosed Quality Management Program for Methodist Hospital of Indiana, Inc., NRC byproduct materials license number 13-02063-01, and do hereby certify that this program has been implemented effective January 27, 1992.

If you have any questions regarding this information, please let me know.

Sincerely,

Robert T. Anger, Jr.

Robert T. Anger, Jr., M.S., M.P.H.
Radiation Safety Officer

METHODIST HOSPITAL OF INDIANA, INC.
QUALITY MANAGEMENT PLAN POLICIES AND PROCEDURES
GENERAL CONSIDERATIONS

Misadministrations:

A. Definition

1). A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

a) involving the wrong patient or wrong radiopharmaceutical

b) when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries

2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

a) involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration

b) when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage

3). A brachytherapy radiation dose:

a) involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

b) involving a sealed source that is leaking;

c) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

d) when the calculated administered dose differs from the prescribed by more than 20 percent of the prescribed dose;

Misadministration (cont):

A. Definition (cont.)

4). A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

a) involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

b) when the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ

B. Response

1) Misadministrations shall be reported to the Radiation Safety Officer immediately after discovery of the misadministration.

2) The Radiation Safety Officer shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the misadministration.

3) The Authorized User shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the Authorized User either that he will inform the patient or that, based on medical judgement, telling the patient would be harmful. The Authorized User is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the Authorized User shall notify the patient as soon as possible thereafter. Appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, must not be delayed because of any delay in notification.

Misadministration (cont):

B. Response (cont.)

4) The Radiation Safety Officer shall submit a written report to the NRC Region III Office within 15 days after discovery of the misadministration. In addition to identifying the facility, the written report will include:

a) the prescribing physican's name

b) a brief description of the event

c) why the event occurred

d) the effect on the patient

e) what improvements are needed to prevent recurrence

f) whether the patient, or the patient's responsible relative or guardian, was notified, and if not, why not

g) if the patient was notified, what information was provided

The report must <u>not</u> include the patient's name or other information that could lead to identification of the patient.

5) If the patient was notified, the authorized user shall also furnish, within 15 days after the discovery of the administration, a written report to the patient by sending either:

a) a copy of the report that was submitted to the NRC, or

b) a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the Hospital.

Misadministration (cont.):

C. Records

1) The Radiation Safety Officer shall retain a record of each misadministration for five years. The record must contain:

a) the names of all individuals involved, including
   (i) the prescribing physician (authorized user)
   (ii) allied health personnel
   (iii) the patient
   (iv) the patient's referring physician
b) the patient's social security number or [illegible] number if assigned
c) a brief description of the misadministration
d) why it occurred
e) the effect on the patient
f) what improvements are needed to prevent recurrence
g) the actions taken to prevent recurrence

Prescribed dosage:

A. Definition

The quantity of radiopharmaceutical activity as documented:

1). in a written directive; or

2). either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic purposes.

Prescribed dose:

A. Definition

For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Recordable event:

A. Definition

The administration of:

1) a radiopharmaceutical or radiation without a written directive where a written directive is required;

2) a radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

3). a radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

   a) the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and
   b) the difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

4). A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

5). A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

B. Response

1) Recordable events shall be reported to the Radiation Safety Officer as soon as possible after the discovery of the event

2) The Radiation Safety Officer, in conjunction with the authorized user, shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

   a) assembling the relevant facts including the cause;
   b) identifying what, if any, corrective action is required to prevent recurrence

Recordable event (cont.):

C. Records

1) The RSO shall retain a record for three years, in an auditable form, of the relevant facts and what corrective action, if any, was taken.

Written directive:

A. Definition

An order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph 4) below, containing the following information:

1). for any administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131: the dosage;

2). for a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

3) for high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

4) for all other brachytherapy:

a) prior to implantation: the radioisotope, number of sources, and source strengths, and

b) after implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

B. Records

1) Each written directive, and a record of each administered radiation dose or radiopharmaceutical dosage shall be kept, in an auditable form, for three years after the date of administration.

Quality Management Plan Audit:

A. Purpose

The purpose of the Quality Management Audit is to monitor the applicable program area (e.g., radiopharmaceuticals and brachytherapy) to ensure that high quality care is given to the patient and to ensure that the Radiation Safety Guidelines, set by the Radiation Safety Committee in accordance with Nuclear Regulatory Commission regulations and recommendations, are followed for the safety of hospital personnel and patients.

B. Implementation

The Quality Management Audit will be conducted on an annual basis by the Radiation Safety Officer. The review will include a representative sample of appropriate radiopharmaceutical and brachytherapy patient administrations, all recordable events, and all misadministrations since the last review. The number of patient cases to be sampled will be based on the principles of statistical acceptance sampling and will represent each treatment modality performed in the institution, e.g., radiopharmaceutical and brachytherapy.

C. Documentation

Documentation of the annual audit will be provided to and reviewed by the Radiation Safety Committee and will be incorporated into the Committee records. A copy of the audit will be provided to the appropriate staff. The QM program's policies and procedures will be reevaluated by the Radiation Safety Committee after each annual audit to determine whether the program is still effective or to identify actions required to make the program more effective.

D. Content

The annual audit shall evaluate, at a minimum, the following items:

1) timely preparation of written directives

2) proper content of the written directives

3) instruction of supervised individual(s) in the written quality management program and the requirement that the instructions of the authorized user(s) be followed

Quality Management Plan Audit (cont.):

D. Content (cont.)

4) compliance with the written directive, including comparison of final dosage/dose with the prescribed dosage/dose

5) compliance with the requirement to verify the patient's identity by more than one method

6) compliance with the requirement to identify, evaluate, and take appropriate corrective actions for unintended deviations from the written directive

7) compliance with the requirement to respond to each recordable event

8) compliance with the requirement to notify the appropriate individuals and report a misadministration

9) compliance with the requirement to keep appropriate records, including:
   a) annual audits
   b) written directives
   c) radiopharmaceutical dosages and radiation doses
   d) recordable events
   e) misadministrations

METHODIST HOSPITAL OF INDIANA, INC.
QUALITY MANAGEMENT PLAN POLICIES AND PROCEDURES
RADIOPHARMACEUTICAL THERAPIES AND ANY ADMINISTRATION OF NaI IODINE-125 AND IODINE-131 GREATER THAN 30 MICROCURIES

A. Prior to the any therapeutic administration of a radiopharmaceutical or any administration of NaI I-125 or I-131 greater than 30 microcuries, an authorized user must sign and date a written directive.

B. Prior to administration, an authorized user or qualified person under the supervision of an authorized user shall independently confirm the assay of the prepared radiopharmaceutical. Qualified persons are nuclear medicine technologists, nuclear medicine physicist, radiopharmaceutical chemist, associate radiation safety officer, and residents.

C. Prior to administration, the patient's identity must be verified by more than one of the following methods as the individual named in the written directive:

1. the patient shall be asked his/her name
2. the patient's wrist band shall be checked
3. the patient shall be asked to spell his/her name
4. the patient shall be asked to state his/her birth date
5. the patient shall be asked to state his/her address
6. the patient shall be asked to state his/her social security number
7. the patient shall be asked for some identification such as a driver's license

D. Prior to administration, the person administering the dose must confirm that the radiopharmaceutical, dosage, and route of administration are in agreement with the written directive.

E. Prior to administration, the intent of the written directive must be thoroughly understood by the person administering the radiopharmaceutical. If any portion of the written directive is unclear, an authorized user shall be contacted for clarification. If the person preparing the radiopharmaceutical is different from the person administering the radiopharmaceutical, both shall read and understand the written directive.

F. After administration of the radiopharmaceutical, an authorized user or qualified person under the supervision of an authorized user (see above) shall date and sign (or initial) a written record that documents the administered dosage in the patient's chart or other appropriate record.

METHODIST HOSPITAL OF INDIANA, INC.
QUALITY MANAGEMENT PLAN POLICIES AND PROCEDURES
HIGH DOSE RATE (HDR) AFTERLOADER

A. Prior to initiation of therapy, a WRITTEN DIRECTIVE shall be completed, then dated and signed by a radiation oncologist (authorized user). This directive shall include the patient's name, treatment site, radioisotope, and total dose. This will be the patient's prescribed dose.

B. Treatment plans prepared by physicists or dosimetrists to fulfill the written directive shall be reviewed, signed, and dated by a radiation oncologist (authorized user) prior to treatment delivery. In addition, a physicist who did not do the treatment plan shall check the plan qualitatively for conformance to the prescribed dose, reasonable time values, point dose location accuracy, data entry accuracy, and source type and strength. This will be done by a dosimetrist if a second physicist is not available. Treatment plans shall be based on film localization of inactive source dwell position markers unless a template is employed or film views are not sufficiently informative of source location. If the radiation oncologist (authorized user) determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of the treatment.

C. Prior to treatment, the patient's name shall be verified by two or more of the following methods:

1. Patient shall be asked his/her name
2. Patient's wrist band shall be checked
3. Patient shall be asked to spell his/her name
4. Patient shall be asked to state his/her birthdate
5. Patient shal be asked to state his/her address
6. Patient shall be asked to state his/her social security number
7. Patient shall be checked for match with photo in chart
8. Patient shall be asked for I.D. such as a driver's license

D. After the machine operator (radiation therapist) enters the treatment parameters into the Nucletron console computer, but prior to treatment, the physicist or dosimetrist and the radiation oncologist (authorized user) shall separately check the data entered in order to verify that the specific details of the administration are in accordance with the written directive and the plan of treatment.

E. The intent of the written directive must be thoroughly understood by the physicist(s), dosimetrist(s), and radiation therapist(s) developing and executing the treatment plan. Any question regarding the written directive and/or plan of treatment must be clarified by a radiation oncologist (authorized user) prior to treatment.

F. After treatment completion, a radiation oncologist (authorized user) or physicist shall review, date, and sign (or initial) the printed record of treatment delivery produced by the Nucletron computer. This record shall be placed in the patient's radiation therapy chart.

G. Each treatment or dose calculating computer program that is to be used for brachytherapy HDR calculations shall undergo an acceptance testing procedure. This procedure shall be developed and performed by a medical physicist certified in Therapeutic Radiological Physics by the American Board of Radiology (or equivalent qualifications). A record of the testing procedure and results shall be maintained.

METHODIST HOSPITAL OF INDIANA, INC.
QUALITY MANAGEMENT PLAN POLICIES AND PROCEDURES
OTHER BRACHYTHERAPY

A. A WRITTEN DIRECTIVE shall be completed for each patient satisfying the following criteria:

1. Prior to administration, the written directive shall be completed stating the treatment site, patient's name, radioisotope, number of sources, and source strength. This written directive shall be signed and dated by a radiation oncologist (authorized user)

2. After implantation, but prior to completion of the procedure, the written directive shall be appended by the radiation oncologist (authorized user) to include the radioisotope, total source strength, total time sources are to be implanted and the total dose to be delivered. For temporary implants, the source loading sequence will be recorded. For permanent implants, the total number of sources actually implanted will be recorded. This written directive update shall be signed and dated by the radiation oncologist (authorized user).

B. Treatment plans prepared by physicists or dosimetrists to fulfill the written directive may be completed after implantation but shall be completed prior to expected completion on the implant. For permanent implants, the treatment plan shall be completed within one week of the time the sources were implanted. For both temporary and permanent implants, plane film or CT localization will be performed of source and applicator locations employing inactive source markers whenever possible. If a template is employed resulting in a fixed predictable source arrangement, this expected source arrangement may be employed for calculations when the applicator opacity or the number of sources precludes accurate source identification on radiographs. The treatment plan shall be reviewed, signed and dated by the radiation oncologist (authorized user). In addition, a physicist who did not do the treatment plan will check the plan (prior to the planned completion of the implant, if temporary, or within one week for a permanent implant) for match to the written directive, total time of implant, point dose location accuracy, source type, source strength, source loading sequence, and source position. This check will be performed by a dosimetrist if a second physicist is not available.

C. Prior to treatment, the patient's identity shall be verified by two or more of the following methods:

1. Patient shall be asked his/her name
2. Patient's wrist band shall be checked
3. Patient shall be asked to spell his/her name
4. Patient shall be asked to state his/her birthdate
5. Patient shal be asked to state his/her address
6. Patient shall be asked to state his/her social security number
7. Patient shall be checked for match with photo in chart
8. Patient shall be asked for I.D. such as a driver's license

D. Prior to implantation of the sources, the physicist preparing the sources must confirm that the radioisotope, number of sources, source arrangement, and source strengths are in agreement with the written directive and the plan of treatment.

E. Prior to implantation, the intent of the written directive must be understood by the physicist preparing the sources. Any questions regarding the written directive must be clarified with the radiation oncologist (authorized user).

F. For temporary implants, after treatment completion, a radiation oncologist (authorized user), physicist or dosimetrist shall document the total dose and treatment time. The radiation oncologist (authorized user) must sign and date this summary which will be placed in the patient's radiation therapy chart.

G. Each treatment or dose calculating computer program that is to be used for brachytherapy calculations shall undergo an acceptance testing procedure. This procedure shall be developed and performed by a medical physicist certified in Therapeutic Radiological Physics by the American Board of Radiology (or equivalent qualifications). A record of the testing procedure and results shall be maintained.

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2/4/92

To the NRC —
Please note that ⊙ originally mailed
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mailroom apparently did not put
sufficient postage on. To cover
the return receipt service.
Thank you,