MEDICAL

LICENSE FILE NO: 20-00742-18
20-00742-19

ATTACHED

DOCKET No. (s) 030-04022 / 030-32109

/ / Appendix A / / Appendix B / / Appendix C

INSPECTION REPORT NO. 90-001

LICENSEE CONTACT: Rosemary Kennedy RSO

Name: Beth Israel Hospital

TELEPHONE NO.: 617-735-2510

Address: 330 Brookline Avenue
Boston Mass 02215

LICENSE NO: 20-00742-18 PRIORITY: 1 Program Code: 02110

20-00742-19 PRIORITY: 3 Program Code: 3510

PRIORITY: Program Code:

INSPECTION DATE (s): 7/30/90 7/31/90

TYPE OF INSPECTION: / / SPECIAL / / ANNOUNCED

/✓/ ROUTINE /✓/ UNANNOUNCED

/ / DAYSHIFT / / OTHER

SUMMARY OF FINDINGS AND ACTION

/✓/ NO NONCOMPLIANCE, CLEAR 591 ISSUED

/ / ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B

/ / NO NONCOMPLIANCE, LETTER

/ / NONCOMPLIANCE, 591 ISSUED

/ / NONCOMPLIANCE, APPENDIX A

/ / SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE APPENDIX C

/ / CHANGE PROGRAM CODE

/ / CHANGE PRIORITY TO:

/ / NEXT INSPECTION DATE: 7/93

PERSONS CONTACTED

- Rosemary Kennedy RSO
- Mac ... VP for Clinical Research
- ... Smith, Rad Tech
- ... Berkowitz, Asst RSO
- ... NMT Chief
- ... Permit Holder

Lisa Fox RSO for Research at ... (Research East Bldg / Emanuel Science Bldg)

Gaetano Barletta Med Physicist Brigham

... Med Physicist Brigham

Dr. Singer Researcher

* Present at Exit

INSPECTOR: [signature]

APPROVED: Mary ... [signature] 8/6/90

REGION I Form 198-C
(June '88)

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PDR FOIA
STOLL92-58 PDR

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1. ORGANIZATION

a. Organizational structure meets license requirements. (✓) Yes ( ) No [L/C]
Remarks. VP for Clinical Research
Chairman - RSC
Dept of Radiology
RSO
Harvard Consultants (Nucl. Research)
Asst RSO New England Deaconess Hosp (Brachytherapy)
Tech

b. Use supervised by authorized individuals. (✓) Yes ( ) No [35.22(b)(2)]
Remarks. as approved by Radiation Safety Committee -
26 permits issued
3 active permits

c. Radiation Safety Committee meets at quarterly intervals.
(✓) Yes ( ) No more frequently 2 month intervals
6/89 9/89 11/89, 1/90, 3/90, 5/90, 7/90 minutes not yet prepared

(1) Membership in accordance with 35.22(a)(1)] (✓) Yes ( ) No
Remarks. 28 members - RSC and Radioactive Drug Research Committee combined

(2) Record of Committee meetings. (X) Yes ( ) No [35.22(a)(4)]
Remarks.

(3) Consultants. (✓) Yes ( ) No formal contract in preparation previously "gentlemen" agreement
Remarks. Harvard provides film badge, survey, environmental monitoring services, disposal services also
New England Deaconess provides services for brachytherapy procedures (inventories, pt surveys)

e. Licensee uses the services of a visiting authorized user.
( ) Yes (X) No [35.27(a)]

(1) Licensee has a copy of visiting authorized user license.
N/A ( ) Yes ( ) No [35.27(a)(2)]

(2) License has records (maintained for 2 years) of visiting authorized users
N/A last visit. ( ) Yes ( ) No [35.37(c)]

f. License utilizes mobile nuclear medicine services.
( ) Yes (X) No [35.29]

g. Licensee delegates RSO sufficient authority, organizational freedom, and management prerogative. (X) Yes ( ) No
RSO has authority to suspend, revoke permits, resources appear ample for equipment purchase - new computer system recently purchased to facilitate records

h. Appropriate review by Committee in accordance with 35.22(b).
(✓) Yes ( ) No

2. INSPECTION HISTORY

Violations or deviations noted during last inspection conducted on 5/23-24/85
( ) Yes (✓) No.

Response letter dated N/A
(See Appendix B for details)

3. SCOPE OF PROGRAM

Briefly list medical procedures and their frequency.

Nuclear Med - 5500 per year - ~ 25 diagnostic procedures/day
I-131 [illegible] per month
7 techs + Chief tech
Brachy therapy [illegible] primarily gyn. Cs-137 implants
Pathology P-32 S-35 for Cell Proliferation Assay Cloning studies
Research [illegible] I-125 C-14 H-3 37 [illegible] permits

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. (X) Yes ( ) No ( ) N/A
[illegible] audits by RP staff

b. Investigations or inspections conducted. (✓) Yes ( ) No
[35.21(a) and (b)(2)]
Remarks. Random inspections of labs by RP office
Harvard group does weekly & monthly survey

c. Records maintained. (✓) Yes ( ) No [35.21(b)(2)(xi)]
Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. License referenced training program.

(1) Training program implemented. (X) Yes ( ) No
Remarks. Permit holders required to complete Harvard course; tests given
Nuc Med techs trained by Chief N Med Tech and RP office
Housekeeping trained by RPO - training session observed on 7/31/90; translation in 3 languages: English, Spanish, French

(2) Retraining program implemented. (✓) Yes ( ) No
Remarks. Annually

Instruction to workers in accordance with 10 CFR 19.12.
( ) Yes ( ) No
Remarks.

*c. Describe the QA program to mitigate therapeutic misadministrations.
N/A - None

(1) Have secondary checks of the dose calculations been done?

( ) Yes ( ) No

(2) Do the second party checks of the dose calculations provide assurance that the final treatment plan will provide the dose prescribed on the patient chart? ( ) Yes ( ) No

(3) Do technologists consult with the doctor if the prescription or other orders are unclear? ( ) Yes ( ) No
Remarks.

d. Followup on therapy or serious diagnostic misadministrations

(1) 10 CFR 35.43 properly implemented? ( ) Yes ( ) No

(2) Was proper medical care given for the patient pursuant to the NRC medical consultant recommendations? ( ) Yes ( ) No

(3) Were appropriate actions implemented to prevent recurrence?
( ) Yes ( ) No

(4) Were the technologist and dosimetrist made aware of these actions?
( ) Yes (No)

(5) Do the licensee's QA/QC procedures address these actions to prevent recurrence? ( ) Yes ( ) No
Remarks.

N/A
action indicated

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Radiation Safety program changes reviewed. (Exception to changes without license amendment may be found in 35.13 and 35.606.)
( ) Yes ( ) No

*Inspect when QA rule becomes final.

6. (cont'd)

b. Records of changes in procedures reviewed. ( ) Yes ( ) No [35.21(c)]
Remarks.

c. Radioactive materials used in accordance with current procedures.
( ) Yes ( ) No [35.21(b)(2)]
Remarks.

(1) Describe individuals understanding of current procedures.

(2) Examples of key procedures:
(a) ordering and accepting packages of RAM
(b) general rules for safe use of RAM
(c) emergency procedures
(d) survey procedures
(e) handling of volatile RAM (e.g., Xe-133, I-131)
(f) precautions for use of RAM (sealed and unsealed) for therapy
(g) emergency procedures posted?
(h) do licensee personnel understand emergency procedures?
(i) safety procedures for patient therapy in accordance with 35.315 and 35.415

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. ( ) Yes ( ) No
Remarks.

b. Isotope, chemical form, quantity and use as authorized.
( ) Yes ( ) No [L/C]
Remarks.

c. Syringes containing radioactive material properly labeled and shielded unless contraindicated. ( ) Yes ( ) No [35.60(a)(b)(c)]

d. Vials containing radioactive material properly labeled and shielded.
( ) Yes ( ) No [35.61(a)(b)]

...ntory No. _____

...ont'd

e. Tests required by regulations.

(1) molybdenum-99 breakthrough. ( ) Yes ( ) No [35.204(b)]
(2) performed as required. ( ) Yes ( ) No [35.204(a)]
(3) records maintained. ( ) Yes ( ) No [35.204(c)]
Remarks.

(4) Leak tests. ( ) Yes ( ) No

(5) Leak tests performed as required. ( ) Yes ( ) No [35.59(b)]
Dates and Remarks.

f. Inventory of sealed sources.

(1) Inventory of Group VI sources. ( ) Yes ( ) No [35.59(g)]
Dates:

(2) Inventory of calibration sources. ( ) Yes ( ) No [35.59(g)]
Dates:

g. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. ( ) Yes ( ) No [20.207]

Remarks.

(3) Area wipe tested? ( ) Yes ( ) No
Remarks.

h. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. ( ) Yes ( ) No
[35.120, 220, 320, 420]
Remarks.

Illustrated by Hazard, records maintained

Medical License No. _____

7. (cont'd)

b) Capability of radiation survey instruments is adequate for program.
( ) Yes ( ) No
Remarks.

(3) Calibration of survey instruments required. (✓) Yes ( ) No

(a) Performed as required. (✓) Yes ( ) No [35.50]
Dates and Remarks.

(4) Records of calibration maintained for 2 years. [35.50(e)]
( ) Yes ( ) No

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom?

(a) Where stored? Security? [L/C]

(b) Survey of incoming packages. ( ) Yes ( ) No [20.205(b)(1)]
Remarks.

(1) Record of survey. (✓) Yes ( ) No [20.401(b)]
Remarks.

(c) Procedure for opening packages. ( ) Yes ( ) No [20.205(d)]
Remarks.

(d) Returned licensed material transferred in accordance with 10 CFR 30.41.
(✓) Yes ( ) No
Remarks.

8. cont'd

(e) Records of receipt and transfer maintained. ( ) Yes ( ) No
[30.51]
Remarks.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier Landauer Frequency Monthly

b. Reports reviewed by RSO? Yes Others Harshaw?
Frequency monthly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period _____
to _____

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes ( ) No Complete: ( ) Yes ( ) No
Necessary ( ) Yes ( ) No

(2) NRC-5: ( ) Yes ( ) No Complete: ( ) Yes ( ) No
[20.401(a)]
Remarks.

e. Maximum quarterly whole-body exposure. _____

f. Maximum quarterly extremity exposure. _____

g. Licensee has implemented an ALARA program. ( ) Yes ( ) No
[35.50] [see Procedure No. 83822, "Radiation Protection]
Remarks.

h. Radiation survey of unrestricted areas. (✓) Yes ( ) No
(20.201(b) to show compliance with 20.105(b)) [35.315(a)(4)];
[35.415(a)(4)]
Remarks.

Survey of unrestricted areas adjacent to brachytherapy room.
Conducted at time of inspection
3 mR/hr at door

9. (cont'd)

(1) Record of surveys maintained. ( ) Yes ( ) No
[20.401(b) to show compliance with 20.105(b)]
Remarks.

i. Radiation survey of storage and use areas:

(1) Quarterly survey brachytherapy source storage. (✓) Yes ( ) No
[35.59(h)]

(2) Temporary implant patient release survey. (✓) Yes ( ) No
[35.404(a)]

(3) Radiopharmaceutical and permanent implant patient release survey.
( ) Yes ( ) No [35.75]

(4) Radiopharmaceutical therapy room contamination survey.
( ) Yes ( ) No [35.315(a)(5) and (7)]

(5) Patient survey upon implant. ( ) Yes ( ) No [35.406(c)]

(6) Radiopharmaceutical storage and laboratory use areas.
( ) Yes ( ) No [35.70]
Remarks.

j. Record of survey maintained. ( ) Yes ( ) No [35.70(h)]
Remarks.

k. Inventory of brachytherapy sources after use. ( ) Yes ( ) No
[35.406]
Remarks.

l. Records maintained. (✓) Yes ( ) No [35.59(g)]; [35.406]

m. Dose calibrator calibration and checks performed as follows:
Constancy (✓) Yes ( ) No Accuracy (✓) Yes ( ) No
Linearity (✓) Yes ( ) No Geometric dependence (✓) Yes ( ) No
[35.50]

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists.
( ) Yes ( ) No
Remarks.

b. Monitoring for airborne radioactivity conducted. (.) Yes ( ) No
[20.201(b) to show compliance with all sections of 20.103 and 35.90]
Remarks.

(1) Records of monitoring maintained. ( ) Yes ( ) No
[20.401(b) or L/C]
Remarks.

c. Bioassay program implemented as described in correspondence with NRC.
( ) Yes ( ) No [35.315(a)(8)]

d. Control of airborne radioactivity in accordance with 35.205.
( ) Yes ( ) No

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. ( ) Yes ( ) No

b. Release in accordance with regulatory limits. ( ) Yes ( ) No
[20.106(a)]
Remarks.

c. State solid waste disposal method.

d. State liquid waste disposal method.

11. (cont'd)

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). ( ) Yes ( ) No [35.92(a)]
Remarks.

(1) Records of disposal. ( ) Yes ( ) No [35.92(b)]
Remarks.

f. Survey of waste prior to disposal. ( ) Yes ( ) No
[20.201(b) to show compliance with 20.301 - 35.92(a)(2)]
Remarks.

(1) Records of survey maintained. ( ) Yes ( ) No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals).
( ) Yes ( ) No [19.13]
Remarks.

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
( ) Yes ( ) No [20.405(a)]
Remarks.

c. Licensee in compliance with 10 CFR 20.403 (incidents).
( ) Yes ( ) No [20.403]
Remarks.

12. (cont'd)

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).
( ) Yes ( ) No [20.402(a) or (b)]
Remarks.

e. Licensee in compliance with reporting therapeutic misadministrations and taking corrective action. ( ) Yes ( ) No [35.33(a)(b)(d)]
Remarks.

f. License in compliance with reporting diagnostic misadministrations and taking corrective action as needed under conditions set forth in 10 CFR 35.33(c).
( ) Yes ( ) No
Remarks.

13. POSTING OF NOTICES

Notices to workers posted. ( ) Yes ( ) No [19.11(a), (b), or (c)]
Remarks.

14. CONFIRMATORY MEASUREMENTS

a. Measurements made by inspector. ( ) Yes ( ) No

b. Survey instrument and probe _____
NRC Serial No. _____

c. Describe type and results of measurements and compare with licensee's measurements.

15. INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. ( ) Yes ( ) No

b. Survey instrument _____
NRC Serial No. _____

c. Describe type and results of measurements.

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203.
( ) Yes ( ) No [20.203]
Remarks.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. ( ) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. ( ) Yes ( ) No
Remarks:

18. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.
List: N/I

b. Bulletins and Information Notices received by licensee. ( ) Yes ( ) No
Remarks.
N/I

c. Licensee took appropriate action in response to Bulletins and Information Notices. ( ) Yes ( ) No
Remarks.
N/I

19. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

	Yes	Violation?
a. License makes shipments of RAM? If "Yes", complete the following items.	( )	( )

b. Such shipments consisted of:
( ) radwaste
( ) sources/products
( ) other _____

19. (cont'd)

c. For radwaste, shipments are:
( ) by licensee, using common carrier
(x) through Radwaste Broker
name of Broker Radiac (1443)
Hazard prefer by Solid waste

d. Licensee is aware of 10 CFR 61:

Radwaste requirements for generators?	(y)	( )
Licensee has classified and characterized its radwaste? (20.311(d))	(y)	( )

e. For shipments:

Licensee uses authorized packages? [(173.415-16)]	(y)	( )
Package type used. _____		
For DOT-7A, licensee has performance test records on file? [173.415(a))]	( )	( )
For special form sources, licensee has performance tests records on file for each source design? [(173.47(a))]	( )	( )
Packages are properly labeled? [172.403)] [173.441)]	( )	( )
Packages are properly marked? [172.200)]	( )	( )
Proper shipping papers are prepared for each shipment? [172.203(d))]	( )	( )

Remarks.

f. Does licensee make return shipments of radiopharmacy doses? ( ) ( )
(If Yes, does licensee assume responsibility for all shipper requirements?) (If No, what arrangements/understanding have been made between licensee and radiopharmacy as to performance of shipper responsibilities?)
(Describe)
Remarks.

20. ITEMS OF NONCOMPLIANCE

Clear

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

INSPECTION REPORT NUMBER ____________

APPE..DIX A - DOCUMENTATION OF NONCOMPL.ANCE

LICENSEE: ____________ License No. ____________

Reference	Basis for noncomp'iance
Report item ______	
10 CFR ______	~~5X59~~
Lic Cond ______	
Type n/c ______	
Report item ______	
10 CFR ______	
Lic Cond ______	
Type n/c ______	
Report item ______	
10 CFR ______	
Lic Cond ______	
Type /c ______	
Report item ______	
10 CFR ______	
Lic Cond ______	
Type n/c ______	
Report item ______	
10 CFR ______	
Lic Cond ______	
Type n/c ______	
Report item ______	
10 CFR ______	
Lic Cond ______	
Type n/c ______	

REGION I Form 198-C.3
(June '88)

INSPECTION REPORT NUMBER __ 45 661

APPENDIX B - LICENSEE ACTIONS ON PREVIOUS INSPECTION FINDINGS

Licensee: Beth Israel Hosp License No.: 20-00742-78 -13

Identification and summary of action taken		Status
Report No.: _____	Type n/c: _____	Describe: _____
Action taken: 5/89 - Clear		OPEN / CLOSED
Report No.: _____	Type n/c: _____	Describe: _____
Action taken:		OPEN / CLOSED
Report No.: _____	Type n/c: _____	Describe: _____
Action taken:		OPEN / CLOSED
Report No.: _____	Type n/c: _____	Describe: _____
Action taken:		OPEN / CLOSED
Report No.: _____	Type n/c: _____	Describe: _____
Action taken:		OPEN / CLOSED
Report No.: _____	Type n/c: _____	Describe: _____
Action taken:		OPEN / CLOSED

INSPECTION REPORT NUMBER 70-001

APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: [illegible] License No.: 20-00742-18 -19

( ) Uncorrected/repeated noncompliance

( ) Unresolved items

( ) Unusual occurrence, conditions, etc.

( ) Inspector's comments

( ) Basis for change of Category or Priority

Followup of diagnostic misadministrations that occurred on 8/9/90 and 9/29/89. Both involved administration of ~~[illegible]~~ 20 mC. pertechnetate (No Tc-99) instead of 20 mC. of Tc (MDP). Corrective action to change concentration of MDP to be half that of pertechnetate. Corrective action - concentration of MDP reduced by 1/2 verified at inspection.

REGION I FORM 198-C.5
(June '88)

U.S. NUCLEAR REGULATORY COMMISSION
REGION I
OPEN ITEMS TRACKING SYSTEM

DOCKET NUMBER: 30-22193

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1	89-001	CLOSED	05/23/89	05/24/89	L.M.TRIPP	VIOL	89-001
	ITEM: 591/CLEAR						
2	90-001	CLOSED	07/30/90	07/31/90	CAHILL	VIOL	90-001
	ITEM: 591/CLEAR						
3	90-001	CLOSED	07/30/90	07/31/90	CAHILL, M.	VIOL	90-001
	ITEM: 591/CLEAR						

U.S. NUCLEAR REGULATORY COMMISSION
REGION I
OPEN ITEMS TRACKING SYSTEM

DOCKET NUMBER: 30-09062

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1	87-01	CLOSED	01/02/87	01/02/87	WURTZ	VIOL	87-01
	ITEM: CLEAR - 591						
2	85-01	CLOSED	02/01/85	01/02/87	JOHANSEN	VIOL	87-01
	ITEM: APPROPRIATE PROTECTION MEASURES WHEN HANDLING RAM WERE NOT USED. (TONGS AND PLEXIGLASS)						
3	87-199	CLOSED	11/20/87	05/24/89	BETSY ULLRICH	LER	89-001
	ITEM: TWO (2) DIAGNOSTIC MISADMINISTRATIONS						
4	89-146	CLOSED	10/05/89	07/31/90	ULLRICH	LER	90-001
	ITEM: DIAGNOSTIC MISADMINISTRATION						
5	90-034	CLOSED	02/27/90	07/31/90	ULLRICH	LER	90-001
	ITEM: DIAGNOSTIC MISADMINISTRATION						
6	90-001	CLOSED	07/30/90	07/31/90	CAHILL,M.	VIOL	90-001
	ITEM: 591/CLEAR						

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License No. 20-00742-18
Docket No. 030-09062
Control No. 114718

Beth Israel Hospital
ATTN: M. Rosemary Kennedy
Radiation Safety Officer
330 Brookline Avenue
Boston, Massachusetts 02215

Dear Ms. Kennedy:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Your license has been issued in the name of an institution, please ensure that all license amendment or renewal requests are signed by a representative of the institution's management. This will assure that management has concurred with all commitments.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

"SECTION COPY"

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You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Jenny Johansen

Jenny M. Johansen, Chief
Nuclear Materials Safety Section D
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 15
2. Requirements for Materials Licensees
3. Requirements for Medical Licensees
4. NRC Forms 3 and 313