

LICENSE NO: \_\_\_\_\_

DOCKET NO. (s) 030-20020

PAGE \_\_\_\_\_ OF \_\_\_\_\_

030-19201

ATTACHED

- ☐ Appendix A  
☐ Appendix B  
☐ Appendix C  
☐ Memo

INSPECTION REPORT NO. 87-01

DANA FARBER CANCER INSTITUTE

44 BUNNEY STREET

BOSTON, MASSACHUSETTS 02115

LICENSEE CONTACT: Dr Treves, Chairman of RSC

Telephone No: (617) 732-3487

LICENSE NO: 20-19761-02

CATEGORY 31

PRIORITY: 2

20-19761-01

CATEGORY 5

PRIORITY: 3

CATEGORY \_\_\_\_\_

PRIORITY: \_\_\_\_\_

INSPECTION DATE (s): 11/20/82

TYPE OF INSPECTION:

- ☐ SPECIAL ☐ ANNOUNCED  
☐ ROUTINE ☒ UNANNOUNCED  
☐ DAYSHIFT  
☐ OTHER

SUMMARY OF FINDINGS AND ACTION

- ☐ NO NONCOMPLIANCE, CLEAR 591 ISSUED  
☐ NO NONCOMPLIANCE, LETTER  
☒ NONCOMPLIANCE, APPENDIX A

- ☐ ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B  
☐ NONCOMPLIANCE, 591 ISSUED  
☐ SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS  
SEE BASIS IN APPENDIX C

☐ CHANGE CATEGORY TO: \_\_\_\_\_

☐ CHANGE PRIORITY TO: \_\_\_\_\_

☒ NEXT INSPECTION DATE: \_\_\_\_\_

PERSONS CONTACTED

William A. Corbett Jr

Ronald K Ameling

S. Treves, M.D

Mark Gatta

Mark Bigoness

Associate Director for Research Administration

Radiation Safety Officer

Chairman - Radiation Safety Committee

H.P Tech

H.P Tech

INSPECTOR: [Signature]

APPROVED: [Signature]

9301110166 920520  
PDR FOIA  
STOLL 92-58 PDR

D/101

INSPECTION PLAN AND REPORT NUMBER \_\_\_\_\_ Page \_\_\_\_\_ of \_\_\_\_\_

Plan Approved: \_\_\_\_\_ Date: \_\_\_\_\_

Licensee: \_\_\_\_\_ License No. \_\_\_\_\_

Inspection Items	Scheduled for Inspection	Post Inspection Status	Module No.
Management Meeting - Entrance and Exit Interviews (Required)			30703B
Program Requirements, MC 2860 (Required)			78710B
Followup on Noncompliance and Deviations			92702B
Independent Inspection Effort (Required)			92706B
Transportation			86740B

INSPECTION REPORT NUMBER \_\_\_\_\_

Page \_\_\_\_\_ of \_\_\_\_\_

787106 - Medical

AREAS INSPECTED AND FINDINGS

Licensee: Dana Farber Cancer Inst License No: 20-19761-02 Amendment No: \_\_\_\_\_  
20-19761-01

INSPECTION ITEMS	CRITERIA	FINDING
1. <u>Organization</u>	Lic Cond _____	<u>C</u>
Structure of organization as described in requirements?		<i>RSD splits time between Dana Farber &amp; Childrens Hospital</i>
Scope of Program? Patient load?		<i>Nuc Med program - no brachy therapy or I-131 therapy</i>
NOTES & REMARKS:		<i>~ 300 authorized users; 250 laboratories</i>
2. <u>Licensee Internal Audits</u>	Lic Cond _____	<u>C</u>
Scope and frequency of audits as required?		
Conducted by appropriate persons?		
Records maintained?		
Reviewed by management?		
Deficiencies identified and corrected?		
NOTES & REMARKS:		
3. <u>Training and Qualification of Personnel</u>	Lic Cond _____	<u>C</u>
Training & retraining conducted as required?		
Written & oral exams conducted?		
Examination results reviewed by management?		
Instructions to workers per 19.12?	19.12	
Authorized users? On license? Available in emergency?	Lic Cond _____	
NOTES & REMARKS:		
4. <u>Radiation Protection Procedures</u>	Lic Cond _____	<u>C</u>
Procedures available and implemented?		
Identify radiopharmaceutical and dose(s)?		
Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?		
Close out Surveys on Patients receiving temporary implants?	35.14 (b)(5)(v)	
Emergency procedures for spills, etc?		
Personnel understand procedures?		
NOTES & REMARKS:		

## AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
<u>5. Use of Materials</u>		
Procurement and use as required? Authorized form & route of administration?	35.14(b)	<u>C</u>
Special tests (moly breakthrough, leak tests, etc) required?	35.14(b)(4)	
Inventory of brachytherapy sources?	35.14(b)(5)	
Dose calibration checks performed?		
Posting & labeling as required?	20.203	
NOTES & REMARKS:		
<u>6. Storage of Materials</u>		
Material secured in both restricted and unrestricted areas? Adequately?	20.207	<u>NC</u>
NOTES & REMARKS: <i>On May 28, 1987, inspector observed a janitor enter the hot lab and remove a container of non-radioactive waste. The hot lab was unlocked and unattended by the Nuc Med personnel. The janitor did not speak fluent English.</i>		
<u>7. Facilities</u>		
As described in lic cond or application?	Lic Cond _____	<u>C</u>
Any changes made? Adequacy?		
NOTES & REMARKS:		
<u>8. Instruments</u>		
Survey meters & instruments adequate for program?	Lic Cond _____	<u>C</u>
Instruments & meters operable? Calibrated?		
Calibration adequate?		
NOTES & REMARKS:		

## AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEMS	CRITERIA	FINDING
9. <u>Receipt and Transfer of Material</u>		<u>C</u>
Written procedures for pickup, receiving, opening packages?	20.205	
Survey of packages when received?	20.205(c)(1)	
Records of survey of packages?	20.401(b)	
Transfer of materials proper? Transfer records maintained?	30.41, 30.51	
Authorized containers used? Shipping papers & package labels proper for packages on hand?	71.5	
NOTES & REMARKS:		

10. <u>Personnel Protection - External</u>		<u>C</u>
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate?	20.201	
Records of monitoring, surveys?	20.401	
Levels in unrestricted areas within limits? (Particularly around nuclear med. hot lab rooms of brachytherapy patients)	20.1, 20.105	
NOTES & REMARKS:		

<u>11. Personnel Protection - Internal</u>		<u>NC</u>
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131)	20.103	<i>Several researchers performed iodinations involving millicuries of I-125, and had not <del>been</del> had their thyroids counted</i>
Exposures to minors?	20.104	
Posting of airborne radioactivity areas?	20.203(d)	
Survey, monitoring bioassay adequate for airborne radioactivity, surface contamination?	20.201	
Records maintained?	20.401	
Procedures for use of Xe-133 followed?		
NOTES & REMARKS:		



## AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
12. <u>Effluent Controls, Waste Disposal</u>		<u>C</u>
Release of effluents controlled? (particularly Xe-133, radioiodine where used)	20.106, 20.33	
Waste disposals controlled?	20.301, 20.303, 20.304, 20.305	
Procedures, records maintained?	20.401, Lic Cond _____	
Surveys made? Adequate?	20.401	
NOTES & REMARKS:		
13. <u>Notifications and Reports</u>		<u>C</u>
To individuals?	19.13	
Overexposures, excessive levels & concentrations, incidents?	20.403, 20.405	
Personnel exposures and monitoring, termination reports?	20.407, 20.408	
Theft or loss of licensed material?	20.402	
Misadministrations?	35.41-35.45	
NOTES & REMARKS:		
14. <u>Posting of Notices</u>		<u>C</u>
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	
NRC-3 posted?	19.11(c)	
NOTES & REMARKS:		
15. <u>Other License Conditions</u>		_____

INSPECTION REPORT NUMBER \_\_\_\_\_

Page \_\_\_\_\_ of \_\_\_\_\_

787108 -- Medical

AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

---

INSPECTION ITEMS	CRITERIA	FINDING
------------------	----------	---------

---

16. Confirmatory Measurements \_\_\_\_\_

NRC Instrument: \_\_\_\_\_ Calibration Due Date: \_\_\_\_\_

---

17. Independent Inspection Effort \_\_\_\_\_

---

18. Incidents and Events \_\_\_\_\_

Any incidents of misadministrations,  
contamination, etc., not otherwise  
covered by reports?

35.41 -35.45  
20.402, 20.403, 20.405

---

INSPECTION REPORT NUMBER 87-01

Page \_\_\_\_\_ of \_\_\_\_\_

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: Dan Farber

License No: 20-19761-C2-  
20-19761-01

Reference	Basis for noncompliance
Report item <u>6</u> 10 CFR <u>20.207</u> Lic Cond _____ Type n/c <u>IV</u>	Failure to maintain hot lab locked when not under constant control and surveillance
Report item <u>11</u> 10 CFR _____ Lic Cond <u>25</u> Type n/c <u>IV</u>	Failure to perform thyroid counts on certain individuals who performed iodinations involving <sup>131</sup> I or more of I-125
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 _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	



INSPECTION REPORT NUMBER 87-01

Page      of     

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: Dana Farber Cancer Institute

License No: 20-1974-02

Identification and summary of action taken			Status
Report No: <u>85-01</u>	Type n/c: <u>IV</u>	Describe: <u>Failure of the RSC to hold four meetings each year</u>	<input type="checkbox"/> OPEN <input checked="" type="checkbox"/> CLOSED
Action taken: <u>Radiation Safety Committee met as required</u>			
Report No: <u>85-01</u>	Type n/c: <u>IV</u>	Describe: <u>Failure to check air flow in the room storage &amp; preparation area semi-annually with an anemometer</u>	<input type="checkbox"/> OPEN <input checked="" type="checkbox"/> CLOSED
Action taken: <u>Licensee had checked air flow with anemometer at required frequency</u>			
Report No: <u>85-01</u>	Type n/c: <u>IV</u>	Describe: <u>Failure to perform quarterly linearity and drift accuracy test at required frequencies</u>	<input type="checkbox"/> OPEN <input checked="" type="checkbox"/> CLOSED
Action taken: <u>Licensee was performing linearity tests quarterly and accuracy test annually</u>			
Report No: <u>85-01</u>	Type n/c: <u>IV</u>	Describe: <u>Failure to perform surveys in Nuc Med Dept at required frequency</u>	<input type="checkbox"/> OPEN <input checked="" type="checkbox"/> CLOSED
Action taken: <u>Nuc Med Dept was surveyed at the required frequency. Records of these surveys were recorded</u>			
Report No: <u>85-01</u>	Type n/c: <u>IV</u>	Describe: <u>Failure to make proper evaluation for missing extremity badges</u>	<input type="checkbox"/> OPEN <input checked="" type="checkbox"/> CLOSED
Action taken: <u>Licensee has implemented procedure to evaluate exposure/doses when dosimeters, whole body, or extremity are lost</u>			
Report No: <u>85-01</u>	Type n/c: <u>IV</u>	Describe: <u>    </u>	<input type="checkbox"/> OPEN <input checked="" type="checkbox"/> CLOSED
Action taken: <u>Physical inventories have been performed at the time of leak test and are therefore documented</u>			

(July 82)

INSPECTION REPORT NUMBER \_\_\_\_\_

Page \_\_\_\_\_ of \_\_\_\_\_

APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_

- 
- ☐ Uncorrected/repeated noncompliance
  - ☐ Unusual occurrence, conditions, etc
  - ☐ Basis for change of Category or Priority

- ☐ Unresolved items
- ☐ Inspector's comments

11/01/87

PAGE 1

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

DOCKET NUMBER: 88-00020

REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	CLOSING OPTION	REFER
1 87-001	OPEN	05/29/87	/ /	MILLER&TRIPP	VIOL	
ITEM: 100F20.207 FAILURE TO SECURE LICENSED MATERIAL IN THE NUCLEAR MEDICINE HOT LAB						
2 87-001	OPEN	05/29/87	/ /	MILLER&TRIPP	VIOL	
ITEM: FAILURE OF RESEARCHERS TO HAVE THYROID MONITORED AFTER PERFORMING IODINATIONS						

Docket Nos. 030-20020  
030-19201

20 NOV 1987

License Nos. 20-19761-02 ✓  
20-19761-01

Dana Farber Cancer Institute  
ATTN: William M. Corbett, Jr.  
Associate Director for  
Research Administration  
44 Binney Street  
Boston, Massachusetts 02115

Gentlemen:

Subject: Routine Inspection No. 87-001

On May 28 and 29, 1987, Mr. Lester Tripp and Mr. John Miller of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC licenses. 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. In addition, our inspection examined the activities covered in your letter dated July 25, 1985. The findings of the inspection were discussed with you and Dr. Treves and Mr. Amoling of your staff at the conclusion of the inspection.

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.

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.

Item A described in the attached Notice of Violation involving the storage and control of licensed material is classified as a Severity Level IV violation. As indicated in Supplement IV of the NRC Enforcement Policy, significant violations of this type are normally classified as Severity Level III. However, after careful consideration of the factors involved in this specific instance, it is felt this incident posed a minimal health and safety problem. We have exercised our judgment under the NRC Enforcement Policy and have classified this violation as Severity Level IV. Similar violations of this type in the future may result in additional enforcement action.

RETURN ORIGINAL TO  
REGION I

IE:07

OFFICIAL RECORD COPY

8711230300-XA  
2pp.

D/102

Your cooperation with us is appreciated.

Sincerely,

Original Signature  
John R. White

John R. White, Chief  
Nuclear Materials Safety Section C  
Division of Radiation Safety  
and Safeguards

Enclosure: Appendix A, Notice of Violation

cc:

Public Document Room (PDR)

Nuclear Safety Information Center (NSIC)

✓ Commonwealth of Massachusetts

✓ Ronald Amoling, Radiation Safety Officer

bcc:

Region 1 Docket Room (w/concurrences)

✓ Management Assistant, DRMA

RI:DRSS  
J. Miller  
10/1/87

*J. Miller*  
10/1/87

RI:DRSS  
J. White  
10/1/87

*J. White*  
10/1/87



APPENDIX A

NOTICE OF VIOLATION

Dana Farber Cancer Institute  
Boston, Massachusetts 02115

Docket No. 030-20020  
License No. 20-19761-02

As a result of the inspection conducted on May 28 and 29, 1987, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on May 28, 1987, the Nuclear Medicine Laboratory, which contained millicurie quantities of licensed material, was unlocked when it was not under constant surveillance and immediate control.

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

- B. Condition 25 of License No. 20-19761-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated January 17, 1984.

Item h on page 17 of the Radiation Safety Manual enclosed with the above application requires that each person who performs an iodination involving 1000 microcuries or more must have a thyroid scan performed within one month of each iodination.

Contrary to the above, as of May 29, 1987, researchers had performed iodinations involving 1000 microcuries or more of iodine-125 and had not had their thyroids scanned within one month of each iodination.

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

Pursuant to the provisions of 10 CFR 2.201, Dana Farber Cancer Institute is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including; (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

8711230311-XA  
1 p.  
OFFICIAL RECORD COPY



DANA-FARBER  
CANCER INSTITUTE

44 Binney Street, Boston, MA 02115

WILLIAM M. CORBETT, JR.  
Associate Director  
for Research Administration  
617-732-3487

THE JIMMY FUND

December 14, 1987

Mr. John R. White, Chief  
Nuclear Materials Safety Section C  
Division of Radiation Safety and Safeguards  
Nuclear Regulatory Commission  
Region 1  
631 Park Avenue  
King of Prussia, Pa. 19406

REF: Docket Nos. 030-20020  
030-19201  
License Nos. 20-19761-01  
20-19761-02

Dear Mr. White:

I am responding to your letter of November 20, 1987 regarding Routine Inspection No. 87-001 conducted on May 28 and 29, 1987 at the Dana-Farber Cancer Institute. As a result of that inspection two Severity Level IV violations were identified which require a response as to the corrective action taken regarding the violation.

The first violation concerned a room in the Nuclear Medicine Laboratory which contained millicurie quantities of licensed material which was unlocked when not under constant surveillance and immediate control and therefore open to possible access by unauthorized individuals. In response to this violation the Dana-Farber Cancer Institute subsequent to the inspection, installed a push button combination lock set in the room. This locking device keeps the door to the room locked at all times and limits the access to the room to only those individuals authorized.

The second violation concerned researchers who performed iodinations involving 1000 microcuries or more of iodine-125 but had not reported for the thyroid scans within one month of the iodination. In response to this violation those researchers who were in violation at the time of the inspection were individually notified by the Associate Director for Research Administration that they were in violation of NRC regulations and to report for their thyroid scans immediately or face suspension from further iodination work until the

8804060253 80328  
2F01 11020  
20-17-01-01 PDR 2PP

A Teaching Affiliate of Harvard Medical School

b/103

required scan is done. Those individual reported for thyroid scans.

To prevent further violations of this nature, a general notice was sent to all researchers who perform iodinations reminding them of the thyroid scan requirement. Also, notices have been posted on all iodination hoods as a further reminder. In addition, reminder notices sent to individuals who fail to meet their requirement for as thyroid scan are copied to the Associate Director of Research Administration. The Associate Director upon such notification makes personal contact with each violator stressing the importance of the thyroid scan and an indicating that action will be taken to suspend them from further iodination work unless they report for their scan immediately. This procedure appears to work quite effectively.

In light of the corrective action already taken by Dana-Farber Cancer Institute regarding the violations identified by the inspection of May 28 and 29, 1987, I can now assure you that we are in full compliance.

Sincerely,

*William M. Corbett, Jr.*  
William M. Corbett, Jr.  
Associate Director  
Research Administration

cc: Mr. Ronald Amoling, RSD

28 MAR 1988

Docket Nos. 030-20020  
030-19201

License Nos. 20-19761-02✓  
20-19761-01

Dana Farber Cancer Institute  
ATTN: William M. Corbett, Jr.  
Associate Director  
Research Administration  
44 Binney Street  
Boston, Massachusetts 02115

Gentlemen:

Subject: Combined Inspection Nos. 030-20020/87-01 and 030-19201/87-01

This refers to your letter dated December 14, 1987, in response to our letter dated November 20, 1987.

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,

*Laurence F. Friedman*  
for John R. White Chief  
Nuclear Materials Safety Section C  
Division of Radiation Safety  
and Safeguards

cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Massachusetts

bcc:  
Region I Docket Room (w/concurrences)

OFFICIAL RECORD COPY

DFCI 030-20020 - 0001.0.0  
03/03/88

8804060245 880328  
PDR

RETURN ORIGINAL TO  
REGION I

IE-07

D/104

28 MAR 1988

Dana Farber Cancer Institute

2

RI:DRSS  
JMiller/ca

3/7/88

RI:DRSS  
JWhite

3/16/88

OFFICIAL RECORD COPY

DFCI 030-20020 - 0002.0.0  
03/03/88