

Docket Nos. 030-19201
030-20020

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

Dana-Farber Cancer Institute
ATTN: Steven J. Alford, M.S.
Radiation Safety Officer
44 Binney Street
Boston, Massachusetts 02115

Dear Mr. Alford:

Subject: Routine Inspection No. 030-19201 and 030-20020/93-001

This letter refers to your January 5, 1994 correspondence, in response to our December 22, 1993 letter.

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.

No reply to this letter is required. Thank you for your cooperation.

Sincerely,

Original Signed By:
Jenny M. Johansen

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

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

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RETURN ORIGINAL TO
REGION I

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bcc:
Region I Docket Room (w/concurrences)



DRSS:RI
Dwyer/gc

2/4/94

DRSS:RI
Johansen

2/8/94 

030-20020
030-19201



DANA-FARBER
CANCER INSTITUTE

44 Binney Street, Boston, MA 02115

THE JIMMY FUND

January 5, 1994

Docket Nos. 030-20020
030-19201

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

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Subject: Reply to a Notice of Violation

Dear Sirs:

On behalf of Dana-Farber Cancer Institute, I am writing this letter to respond to the Notice of Violation issued as a result of an inspection on December 1, 1993, in which a 1-millicurie package of Sulfur-35 was unattended in a hallway outside of a laboratory in our Mayer Building.

Dana-Farber never actually lost control of the radioactivity and even though the package posed minimal health or safety problem hazard, we can assure you we took full responsibility for its retrieval. Additionally, since we responded promptly with preventive measures without intervention from the NRC, we accept this citation with some reluctance. However, since we do appreciate that the violation was classified as Severity Level IV instead of Severity Level III, we do not choose to dispute it.

Therefore, we present the following measures taken to help prevent further violations for unsecured radioactive materials:

1. The laboratory specifically responsible for the unsecured package was immediately reprimanded by the Radiation Safety Office with 2 safety citations, to remain on the laboratory's safety record for a period of one year. In addition, the laboratory faced further scrutiny from the Radiation Safety Committee with our in-house policy for enforcing radiation safety violations.
2. A notice was sent to all permit holders on November 5, 1993 sternly expressing that unsecured radioactive materials will not be tolerated. A copy of this memo is provided as Attachment I.
3. All permit holders and their staff were informed on December 14, 1993 about the results

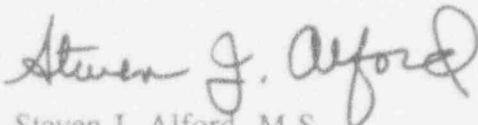
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of the NRC Inspection, and were told once more about unsecured radioactive materials. A copy of this memo is provided as Attachment II.

4. The Radiation Safety Committee voted that effective January 1, 1994, a stricter policy for enforcing radiation safety violations would go into effect, making unsecured radioactive materials a major safety violation. DFCI staff were informed about this policy change on December 14, 1993. The newly revised DFCI Radiation Safety Violation Policy is included as Attachment III.

With these corrective actions taken, I can assure you that Dana-Farber Cancer Institute is continually striving for full regulatory compliance, and we thank you for your assistance with this matter.

Sincerely,



Steven J. Alford, M.S.
Radiation Safety Officer

Attachments I, II, and III

cc: Regional Administrator, NRC Region I
Bernard Janicki, Ph.D.
William Corbett
Elizabeth Gross
S.T. Treves, M.D.
William Kaplan, M.D.
Frances Keech

Attachment I

DANA-FARBER CANCER INSTITUTE
RADIATION SAFETY OFFICE
JIMMY FUND 133
(617) 632-3005

TO: All DFCI Permit Holders

FROM: Steven Alford

SA

DATE: November 5, 1993

SUBJECT: Security of Radioactive Materials

The Radiation Safety Office has stressed the importance of ensuring radioactive materials are secured against unauthorized removal. It is because of a recent incident that you must remind your staff again about its importance.

Early one evening, a DFCI researcher received a package containing 1 mCi of ^{35}S , and instead of bringing it directly to his bench, he temporarily placed it in the hallway outside the lab door. After finishing his day's work, he left for the evening, completely forgetting about the package. Shortly thereafter, the housekeeping staff collected all the empty boxes and trash left in the hall, including the unmarked ^{35}S package. Several hours later, the researcher, remembering his mistake, returned to the lab to correct the problem. Unfortunately it was too late, and the package had already been thrown in the dumpster.

His response was the correct response: to immediately call DFCI Security at 2-3131 to report the missing package. It was only by digging through more than 4000 pounds of our hospital garbage at the BFI Waste Transfer Station that we were able to reclaim the radioactivity. As a result, the laboratory was only cited for two safety violations: unsecured radioactive materials, and radioactive materials in the regular trash. Had the package not been located, the Radioisotope Use Permit probably would have been suspended, and even worse, the Institute may have gotten in trouble with the NRC.

It is everyone's responsibility to make sure radioactive materials are secured, locked-up, or attended to by lab personnel at all times, and that all losses or thefts of radioactive materials are reported immediately. Several requirements for this are:

1. Close and lock all lab doors during lunch times, lab meetings and after hours.
2. Do not leave the lab open and unattended for more than 5 minutes at a time.
3. Make sure core refrigerators used for storing radioactivity are kept locked.
4. Never leave radioactivity in the hallways.

This is a very vital issue, and it needs to be made perfectly clear to everyone that we can not afford any mistakes like this. If there are any questions, call me.

Attachment II

DANA-FARBER CANCER INSTITUTE
RADIATION SAFETY OFFICE
JIMMY FUND 133
(617) 632-3005

TO: All Radioisotope Permit Holders and Their Staff

FROM: Steven Alford, RSO

SA

DATE: December 14, 1993

SUBJECT: NRC Inspection and Response to a Violation

The U.S. Nuclear Regulatory Commission inspected the use of radioactive materials here at DFCI on Wednesday, December 1, 1993. As always, the inspector investigated the Nuclear Medicine Department, interviewed researchers, examined records kept in the Radiation Safety Office, and looked at a few other aspects of the Institute's Radiation Safety Program, including both irradiator units in the Redstone Animal Facility and the Blood Component Laboratory.

This year we did not do as favorably with the Inspection as expected. You may recall last year our Inspectors found no violations, and it was the first time in DFCI history we had a clean record. This time, although the Inspector found all records in order, including personal survey forms and isotope inventories for each lab visited, DFCI was cited for **Security of Radioactive Materials**. This violation is for the incident at the beginning of November involving a package containing 1 mCi of ³⁵S left in the hallway outside a lab and was then thrown in the dumpster.

DFCI Researchers were warned on November 5, 1993 and again in the December 1993 issue of the *Health and Safety Newsletter* that we could have faced severe scrutiny from the NRC had the package not been recovered, and also everyone was instructed in those measures they can take to help avoid security violations. At that time, since the ³⁵S package was successfully recovered, nobody predicted we would get the NRC citation. Regardless, DFCI Administration is faced with having to indicate to the NRC the actions taken to prevent similar violations from recurring.

To that end, effective January 1, 1994, the DFCI Radiation Safety Committee has no other alternative but to begin enforcing violations through a stricter Policy. These changes will make DFCI's Policy as equally effective as several other hospitals in the area, and are expected to bring the Institute into better compliance with the NRC, State and local regulations.

- a. The severity level of "unsecured radioactive materials" has been increased from Level II to Level I. This violation will be as severe as radioactivity in the regular trash, unsafe waste packaging, and throwing lead into the radwaste.
- b. All violations in the Level III category have been increased to Level II. There are no more Level III violations.

A major change in the Violation Policy like this can have an impact upon permits which currently have more than one violation on the records. In order for the Radiation Safety Office

to fairly implement this change on January 1, 1994, any Permit which has more than one severity level II violation (the minor violations) on the records shall have the oldest one removed. All other violations, including those for security, will remain on the records at their escalated level until expiration one year from their original issue date.

Enclosed is another copy of the message dated November 5, 1993, as well as a copy of the revised DFCI Radiation Safety Violation Policy. Any questions you have may be directed to either William Corbett, Director for Research Administration at 2-3489 or myself at 2-3005.

enclosures

cc: J. Pettit
B. Janicki
W. Corbett
T. McNamara
W. Kaplan
S.T. Treves
E. Gross

Attachment III

DANA-FARBER CANCER INSTITUTE

RADIATION SAFETY VIOLATION POLICY

The following are some examples of violations found at the Institute, and are broken up into severity levels with Severity Level I violations being major violations, and Severity Level II being minor violations. Associated with each severity level are penalties which are imposed according to the number of repeat violations that occur.

Violations remain on a Permit Holder's record for a period of one year before expiring.

SEVERITY	VIOLATION
LEVEL I	Radioactive materials in non-radioactive trash - radioactive waste in an unlabelled container. Improper radioactive waste disposal of needles, glass pasteur pipettes or other waste which could adversely affect public health. Putting lead into radioactive waste - improper disposal of lead. Unsecured radioactive materials.
LEVEL II	Failing to report for a thyroid scan within 30 days of an iodination with ^{125}I or within 3 days of an iodination with ^{131}I . Evidence of eating, drinking, smoking, or use of cosmetics. Pipetting radioactive materials by mouth. Not wearing proper radiation dosimetry while working with radioactivity. Failing to receive formal radiation protection training - untrained personnel working with radioactive materials. Not wearing protective clothing while working with radioactivity. Failing to register a room for using radioactivity. Unrecorded sink disposal of radioactive materials. Radioactive sink disposal over established limits without RSO approval. Unreported spill of radioactivity. Transferring radioactive materials to another NRC license without RSO approval. Not maintaining an isotope inventory. Not performing personal radiation surveys and documenting results. Unlabelled radioactive materials.

Attachment III (cont'd)

DANA-FARBER CANCER INSTITUTE

POLICY FOR SEVERITY LEVEL I RADIATION SAFETY VIOLATIONS

SEVERITY	OCCURRENCE	ACTIONS
Level I	1st	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Radiation Safety Officer meets with laboratory personnel.3. Permit holder responds in writing to the Radiation Safety Committee* summarizing corrective actions.
	2nd	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Permit holder appears before the Radiation Safety Committee to present corrective actions.
	3rd and subsequent	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Immediate suspension of permit.3. Permit holder and Division/Department/Lab Chief appear before the Radiation Safety Committee to assure that corrective actions have been taken.

Response letters are to be sent within two weeks from the date of the violation letter and/or meeting. Failure to respond to a violation or to follow any part of this policy will result in immediate suspension of the permit.

* Send response letter to : Steve Alford, Radiation Safety Officer
JFB 133

* Send copies of response to: William Kaplan, M.D., Co-Chairperson DFCI Radiation Safety Committee
DFCI Nuclear Medicine

and

S.T. Treves, M.D., Co-Chairperson DFCI Radiation Safety Committee
Children's Hospital, Nuclear Medicine

Attachment III (cont'd)

DANA-FARBER CANCER INSTITUTE

POLICY FOR SEVERITY LEVEL II RADIATION SAFETY VIOLATIONS

SEVERITY	OCCURRENCE	ACTIONS
Level II	1st	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Permit holder must respond in writing to the Radiation Safety Committee * summarizing corrective actions.
	2nd	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Radiation Safety Officer meets with laboratory personnel.3. Permit holder must respond in writing to the Radiation Safety Committee * summarizing corrective actions.
	3rd	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Permit holder appears before the Radiation Safety Committee to present corrective actions.
	4th and subsequent	<ol style="list-style-type: none">1. Violation letter sent to permit holder.2. Immediate suspension of the permit.3. Permit holder and Division/Department/Laboratory Chief appear before the Radiation Safety Committee to assure corrective actions have been taken.

Response letters are to be sent within two weeks from the date of the violation letter and/or meeting. Failure to respond to a violation or to follow any part of this policy will result in immediate suspension of the permit.

* Send response letter to : Steve Alford, Radiation Safety Officer
Jr-B 133

* Send copies of response to: William Kaplan, M.D., Co-Chairperson DFCI Radiation Safety Committee
DFCI Nuclear Medicine

and

S.T. Treves, M.D., Co-Chairperson DFCI Radiation Safety Committee
Children's Hospital, Nuclear Medicine