

November 10, 2010

EA-10-171
EA-10-203

Robert Falaguerra
Vice President, Facilities
St. Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report Nos. 03001246/2010001;
2010002

Dear Mr. Falaguerra:

This refers to the U.S. Nuclear Regulatory Commission (NRC) inspections conducted between June 28 and July 2, 2010, at the St. Francis Hospital and Medical Center (St. Francis) in Hartford, Connecticut. The inspections consisted of an examination of your licensed activities as they relate to radiation safety and security and to compliance with the NRC's requirements and the conditions of your NRC license. In addition to the on-site reviews, the inspections also involved in-office review of additional information St. Francis provided the NRC in correspondence dated July 7, 13, and 26, 2010, and September 10 and 16, 2010. This information, in part, related to the corrective actions implemented in response to the apparent violations identified during the inspection.

The results of the safety inspection were discussed with you and other members of your organization by telephone during an exit meeting on August 20, 2010, and were transmitted to you in a letter dated August 23, 2010, which enclosed the applicable inspection report (public). The results of the security inspection were discussed with Kathleen Luczyk (Chief Operating Officer for Collaborative Laboratory Services) and other members of your organization by telephone during an exit meeting on September 16, 2010, and were transmitted to you in a letter dated September 22, 2010, which enclosed the applicable inspection report (non-public).

The NRC's August 23 and September 22, 2010, letters stated that, based on the results of the inspections, the NRC identified three apparent safety violations, and one or more apparent security-related violations. The number of security-related violations is sensitive information, and is not included in this letter, but is provided in a non-public enclosure.

Enclosures 2 and 3 transmitted herewith contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 and 3, this transmittal document and Enclosure 1 are decontrolled.

R. Falaguerra

2

In a telephone conversation on October 6, 2010, Mr. Marc Ferdas of my staff informed you that the NRC was considering escalated enforcement for several of the apparent violations identified during the inspections, and that we had sufficient information regarding the apparent violations and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference (PEC) or a written response from you. You indicated that a PEC would not be necessary, and that St. Francis did not plan to submit a written response. Therefore, based on the information developed during the inspections and the information that St. Francis provided in its communications noted above, the NRC has determined that violations of NRC requirements occurred.

The violations associated with the safety inspection are cited in the enclosed Notice of Violation (Notice, Enclosure 1). The circumstances surrounding the violations are described in detail in the inspection report issued on August 23, 2010. The most significant violation involved the failure by St. Francis, on more than one occasion, to ensure that an authorized medical physicist (AMP) was physically present during the initiation and continuation of patient treatments involving the high dose rate remote afterloader (HDR). During the inspection, the NRC observed a patient undergoing HDR treatment and noted that when the treatment was initiated, the assigned AMP was not present at the console. The inspector informed the authorized user (AU) that the AMP is required to be present at the initiation of an HDR treatment per NRC requirements. The AMP, who had been in another area of the radiation oncology department, was immediately called to the HDR unit for the continuation of the treatment.

During subsequent interviews, the AMP informed the inspector that, due to a misinterpretation of the regulation, St. Francis believed that the dosimetrist, who is trained in the operation of and emergency response for the HDR unit, could be present in place of the AMP. The AMP further stated that the St. Francis dosimetrist had, in fact, been present at patient treatments, in lieu of the AMP, periodically since 2006. Although the NRC concluded that there were no health and safety consequences to the patients or the public, not having an AMP present during HDR brachytherapy treatments could affect patient safety if an emergency medical intervention would have been necessary during the procedures. Therefore, in accordance with the NRC Enforcement Policy, the NRC has categorized this violation at Severity Level (SL) III. Two additional violations, also documented in the Notice, have been categorized in accordance with the NRC Enforcement Policy as SL IV. The circumstances surrounding these violations are documented in detail in the above-referenced inspection report.

The violation(s) associated with the security inspection is(are) cited in the enclosed, non-public Notice of Violation (Notice, Enclosure 2) and the surrounding circumstances are described in detail in the subject inspection report issued on September 22, 2010. The NRC has characterized the violation(s) at Severity Level (SL) III. The basis for the significance determination, discussion of why the violation(s) is(are) of concern to the NRC, and a description of the corrective actions taken by St. Francis are provided in the non-public Enclosure 3 (Final Determination of Significance and Description of Corrective Action).

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC has concluded that credit is warranted for your corrective actions taken to address the safety and security violations. Corrective action taken to address the safety violation involved revising the St. Francis HDR operating procedure to clearly state that an AMP must be physically present

R. Falaguerra

3

during all HDR treatments and requiring each St. Francis AMP to review the procedure change. A description of the corrective actions taken by St. Francis for the security-related violation(s) is provided in the non-publicly available Enclosure 3.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these SL III violations constitutes escalated enforcement action that may subject you to increased inspection effort in the future.

The NRC has concluded that information regarding the reason for the violations, the corrective action taken to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and its enclosures, in the communications provided to the NRC in correspondence dated July 7, 13, and 26, 2010, and September 10 and 16, 2010, and in Inspection Report Nos. 03001246/2010001 and 03001246/2010002. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosure 1, and your response to the safety violations, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Because Enclosures 2 and 3 involve security-related information, they are withheld from public disclosure. Security-related information is also discussed in Regulatory Issue Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information," which is available on the NRC Web site at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005>. If you choose to respond to the security violation(s), your response will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

R. Falaguerra

4

If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. Otherwise, mark your entire response "Security-Related - Withhold under 10 CFR 2.390."

Sincerely,

/RA/ Original Signed by David C. Lew for

William M. Dean
Regional Administrator

Docket No. 03001246
License No. 06-00854-03

Enclosures:

1. Notice of Violation for Safety Issues
2. Notice of Violation for Security Issue(s) **(Contains Security-Related Information)**
3. Final Determination of Significance and Description of Corrective Action **(Contains Security-Related Information)**

cc w/encl:
Kathleen Luczyk, Chief Operating Officer, Collaborative Laboratory Services
Gregory Heisel, Radiation Safety Officer
State of Connecticut

R. Falaguerra

If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. Otherwise, mark your entire response "Security-Related - Withhold under 10 CFR 2.390."

Sincerely,

/RA/ Original Signed by David C. Lew for

William M. Dean
Regional Administrator

Docket No. 03001246
License No. 06-00854-03

Enclosures:

1. Notice of Violation for Safety Issues
2. Notice of Violation for Security Issue(s) **(Contains Security-Related Information)**
3. Final Determination of Significance and Description of Corrective Action **(Contains Security-Related Information)**

cc w/encl:

Kathleen Luczyk, Chief Operating Officer, Collaborative Laboratory Services
Gregory Heisel, Radiation Safety Officer
State of Connecticut

SUNSI Review Complete: MMM

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\EA-10-171 St Francis NOV Ills Formated.docx
After declaring this document "An Official Agency Record" it will be released to the Public. ADAMS Accession No.: ML103140671
To receive a copy of this document, indicate in the box: "C"= Copy without attachment/enclosure "E"=Copy with attachment/enclosure "N"=No copy

OFFICE	RI/ORA	RI/DNMS	RI/DNMS	RI/ORA	RI/ORA
NAME	MMcLaughlin/MMM*	M Ferdas/ MSF*	J Kinneman/ JDK*	K Farrar/ KLF*	D Holody/ DJH*
DATE	10/12/10	10/25/10	10/25/10	10/27/10	10/27/10
OFFICE	HQ/OE*	RI/ORA			
NAME	LSreevinas via email	W Dean/DCL for			
DATE	11/08/10	11/10/2010			

OFFICIAL RECORD COPY

*HQ to perform a quick review. ** see previous concurrence page

R. Falaguerra

5

DISTRIBUTION w/encl:

ADAMS (PARS)

SECY

CA

OEMAIL

OEWEB

W Borchardt, EDO

M Weber, DEDMRT

R Zimmerman, OE

A Campbell, OE

N Hilton, OE

N Riddick, OE

N Hasan, OE

L Sreenivas, OE

C Miller, FSME

C Carpenter, FSME

R Lewis, FSME

J Luehman, FSME

M Burgess, FSME

G Villamar, FSME

D White, FSME

Enforcement Coordinators

RII, RIII, RIV (C Evans; S Orth; W. Jones)

C Scott, OGC

E Hayden, OPA

H Bell, OIG

C McCrary, OI

M Williams, OCFO

S Titherington-Buda, OCFO

J Kinneman, DNMS, RI

P Henderson, DNMS, RI

M Ferdas, DNMS, RI

T Weidner, DNMS, RI

D Screnci, PAO-RI / N Sheehan, PAO-RI

D Janda, SAO-RI

K Farrar, RI

D Holody, RI

A DeFrancisco, RI

M McLaughlin, RI

C O'Daniell, RI

S Villar, RI

R1DNMSMailResource

Region I OE Files (with concurrences)

~~OFFICIAL USE ONLY—SECURITY-RELATED INFORMATION~~
ENCLOSURE 1

NOTICE OF VIOLATION FOR SAFETY VIOLATIONS

St. Francis Hospital and Medical Center
Hartford, Connecticut

Docket No. 030-01246
License No. 06-00854-03
EA-10-171

Based on an NRC inspection on June 28 and June 30 through July 1, 2010, as well as an in-office review of information provided by St. Francis Hospital Medical Center (St. Francis) on July 7 and 26, 2010, for which a telephonic exit meeting was held on August 20, 2010, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.615(f)(2) states, in part, that for high dose-rate (HDR) remote afterloader units, the licensee shall require an authorized medical physicist to be physically present during continuation of all patient treatments involving the unit.

Contrary to the above, on July 1, 2010, and on an indeterminate number of occasions prior to that date, a St. Francis authorized medical physicist was not physically present during initiation and continuation of patient treatments involving the HDR unit.

This is a Severity Level III violation (Enforcement Policy Section 6.3).

- B. 10 CFR 35.610(a)(1) states, in part, that a licensee shall secure the HDR unit, the console, the console keys, and the treatment room when the HDR is not in use or is unattended.

Contrary to the above, on July 1, 2010, St. Francis did not secure the HDR console keys when the HDR unit was not in use or was unattended. Specifically, following the completion of a spot check procedure, St. Francis personnel did not remove the HDR console keys prior to leaving the console area.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

- C. 10 CFR 20.1906(b)(1) states, in part, that each licensee shall monitor the external surfaces of a labeled package for radioactive contamination.

Contrary to the above, prior to July 1, 2010, St. Francis did not monitor the external surfaces of labeled packages, received in the Positron Emission Tomography suite, for radioactive contamination.

This is a Severity Level IV violation (Enforcement Policy Section 6.7).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03001246/2010001, in the communication provided by St. Francis on July 7 and 26, 2010, and in the letter transmitting this Notice of Violation (Notice). Therefore, no response to this Notice is required. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response

as a "Reply to a Notice of Violation, EA-10-171," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 10th day of November 2010.