DCS

August 3, 1989

Docket No. 030-01247
License No. 06-01060-01
EA 89-137

Bridgeport Hospital
ATTN: Mr. Christopher Cannon
Vice President
267 Grant Street
Bridgeport, Connecticut 06602

Gentlemen:

Subject: NOTICE OF VIOLATION
(NRC Inspection No. 89-001)

This letter refers to the NRC inspection conducted between March 29-30, 1989 at your facility in Bridgeport, Connecticut of activities authorized by NRC License No. 06-01060-01. The inspection report was sent to you on July 6, 1989. During the inspection, several violations of NRC requirements were identified. On July 14, 1989, an enforcement conference was conducted with you and members of your staff to discuss the violations, their causes, and your corrective actions.

The violations, which are described in the enclosed Notice of Violation, include, (1) failure to notify the NRC of the appointment of a new Radiation Safety Officer; (2) failure to secure the Hot Laboratory when not in use; (3) failure to perform or maintain records of required package receipt radiation level surveys and contamination wipe surveys; (4) failure to perform or maintain records of daily dose calibrator constancy checks; (5) failure to record the results of dose calibrator linearity tests; (6) failure to perform or maintain records of daily area radiation surveys and weekly contamination wipe tests within the Nuclear Medicine department; and (7) failure to properly store radioactive solid waste for a sufficient time prior to disposal.

The NRC recognizes that the prior enforcement history at your facility has been good, as evidenced by the fact that only one minor violation was identified at your facility during the three previous inspections conducted in 1981, 1983 and 1986. However, subsequent to the last inspection, a new Radiation Safety Officer (RSO) was appointed, and since that time, management has not been effective in maintaining the prior good performance, as evidenced by the number of violations identified during this recent inspection.

The violations are of particular concern to the NRC not only because of the large number of violations but also because certain of the violations involve multiple examples. Specifically, there were repeated failures by your staff to perform receipt radiation level and wipe surveys of incoming packages containing radioactive material, as well as numerous failures to perform daily area surveys and weekly contamination surveys in the Nuclear Medicine department. Further, the NRC is also concerned that your system of records, upon which the NRC relies in part to ascertain your compliance with regulatory

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requirements, were either missing or poorly maintained. For example, although no diagnostic misadministrations actually occurred, your prescribed dosage records recorded on the dose calibrator printer were incorrect because the technician did not enter the new prescribed dose for each assay. As a result, the NRC inspector initially believed that diagnostic misadministrations had occurred. The NRC notes that since this inspection, you have committed to maintain appropriate records of each radiopharmaceutical dosage that contain more than 10 microcuries of a radionuclide before use. In addition, further training of the nuclear medicine technologists is appropriate, in that, they were not aware of the NRC's definition of a misadministration as stated in 10 CFR Part 35.2.

These violations, if considered individually, would normally be classified at Severity Level IV or V. However, the violations collectively indicate a recent lack of management oversight of, and attention to, your radiation safety program and demonstrate the need for both management and the Radiation Safety Officer to aggressively monitor and evaluate licensed activities occurring within the Nuclear Medicine department, and in particular, those licensed activities occurring in the "Hot Lab". If adequate attention and oversight of licensed activities had been provided by management, these violations would not have gone undetected until the NRC inspection. Therefore, in accordance with the guidance set forth in Section C.12 of Supplement IV of the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 53 Fed. Reg. 40019 (October 13, 1988) (Enforcement Policy), these violations have been classified in the aggregate at Severity Level III to focus on our underlying concern, namely, a lack of management attention to licensed activities.

Although a civil penalty is normally considered for a Severity Level III violation, I have decided, after consultation with the Director of Enforcement and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, not to issue a civil penalty in this case because: (1) although the violations were identified by the NRC and therefore, provide a basis for 50% escalation of the base civil penalty, this was offset by your prompt and extensive corrective actions (which included establishing formal tracking procedures, as well as a system of audits and assignment of responsibility and accountability to ensure regulatory requirements are adhered to) which provide a basis for 50% mitigation of the penalty; and (2) your past performance, as evidenced by the occurrence of only one minor violation during the last three inspections, is considered good and therefore provides a basis for 100% mitigation of the base civil penalty. Therefore, on balance 100% mitigation is appropriate. The other escalation/mitigation factors were considered and no further adjustment was considered appropriate.

You are required to respond to this letter and the enclosed Notice, and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Furthermore, you should describe the actions taken or planned to improve the oversight of the program by the Radiation Safety Officer. Further, you should confirm your

commitment, made at the enforcement conference, to maintain appropriate records of each radiopharmaceutical dosage that contains more than 10 microcuries of a radionuclide before use. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further action is needed to ensure compliance with regulatory requirements. Furthermore, we emphasize that a license to use byproduct material is a privilege granted by the NRC, and any recurrent violation of the terms of the license may result in more significant enforcement action, such as a civil penalty, or modification, suspension or revocation of the license.

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 its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed 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 No. 96-511.

Sincerely,

Original Signed By
WILLIAM T. RUSSELL

William T. Russell
Regional Administrator

Enclosure: Notice of Violation

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut

bcc w/encl:
Region I Docket Room (w/concurrences)
SECY
Congressional Affairs
H. Thompson, DEDS
J. M. Taylor, DEDR
W. Russell, RI
D. Holody, RI
J. Lieberman, OE
R. Bernero, NMSS
J. Goldberg, OGC
Enforcement Directors, RII-RIII
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F. Ingram, GPA/PA
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B. Hayes, OI
V. Miller, SPA/SP
R. Cunningham, NMSS
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OE:Chron
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E. Ullrich, RI

RI:EO	RI:EO	RI:DRSS	RI:DRSS	RI:DRSS
Christopher/tlm	Holody	Shanbaky	Bettenhausen	Knapp
07/19/89	07/19/89	07/21/89	07/19/89	07/24/89

RI:RC	RI:DRA	RI:RA	OE	DEDO
Gutierrez	Martin	Russell	Lieberman	Thompson
07/ /89	07/ /89	08/3 /89	07/ /89	07/ /89

Rec'd by phone fr OE 8/2/89

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