

February 28, 2008

IA-08-001

Ms. Shannon A. Russell
[HOME ADDRESS DELETED
UNDER 10 CFR 2.390(A)]

SUBJECT: NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2007-018

Dear Ms. Russell:

This is in reference to an investigation conducted by the Nuclear Regulatory Commission's (NRC) Office of Investigations (OI) involving the administration of iodine-131 to a patient without a signed written directive. The purpose of the investigation was to determine whether your actions were deliberate. The investigation found that you deliberately caused Ball Memorial Hospital to be in violation of the NRC regulation 10 CFR 35.40. This regulation requires, in part, that a written directive must be dated and signed by an authorized user prior to administration of iodine-131 in quantities of greater than 30 microcuries. Specifically, on April 30, 2007, you administered a dose of iodine-131 in a quantity greater than 30 microcuries and you did not have a signed written directive authorizing you to administer this dose. A summary of the OI report is attached to the enclosed letter to Ball Memorial Hospital.

Based on our review of the investigation report, an apparent violation of the NRC's regulation prohibiting deliberate misconduct, 10 CFR 30.10 has been identified. This regulation prohibits an employee or contractor of a licensee from deliberately engaging in misconduct that causes a licensee to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission. A copy of this portion of the regulation is enclosed.

This apparent violation is being considered for escalated enforcement in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

Before the NRC makes its enforcement decision, we are providing you the opportunity to:

- (1) request a pre-decisional enforcement conference (PEC) to discuss the apparent violation,
- (2) request Alternative Dispute Resolution (ADR) to resolve this issue, or
- (3) respond in writing to the apparent violation within 30 days of the date of this letter.

These venues provide you an opportunity to explain why the NRC should be confident that, while engaged in NRC-licensed activities, you will abide by the NRC's regulations.

If you request to attend a PEC, it will be closed to public observation, and will be transcribed. This conference would be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In addition, you may have an attorney or personal representative attend the conference, but it should be understood that the NRC will address its questions to you.

Instead of a PEC, you may request Alternative Dispute Resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and you) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Additional information concerning the NRC's ADR can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: (1) assisting the parties in determining ADR potential for their case, (2) advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, (3) explaining the extent of confidentiality, and (4) providing other logistic assistance as necessary. Please contact ICR at 607-255-1124 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Alternatively, you may choose to respond in writing. If so, your written response should be submitted to the NRC within 30 days of the date of this letter and clearly marked as a "Response to Apparent Violations, IA-08-001." Your written response should be addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. At the same time, a copy should be sent to the Regional Administrator at NRC Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4351. The written response should include: (1) The reason for your actions which caused the apparent violations, or if you don't agree, then the reasons why you don't agree; and (2) The actions that you have taken, or will take, to ensure this will not happen again, including the date when these actions will be completed. Your response should be notarized. NRC will consider the thoroughness of your corrective actions in determining whether further action by the NRC is necessary. The NRC has prepared an Information Notice, IN 96 28, "Suggested Guidance Relating To Development And Implementation Of Corrective Action," which may be helpful. An excerpt from this Information Notice was included with the enclosed letter to Ball Memorial Hospital.

Please be advised that the number and characterization of the apparent violations described above may change as a result of further NRC review. If the NRC concludes that you engaged in deliberate misconduct, the possible sanctions available to the NRC include issuing to you a Notice of Violation, a civil monetary penalty,¹ or an order. If the NRC issues an order to you, the order may prohibit your future involvement in NRC-licensed activities. You will be advised by separate correspondence of the results of our deliberations in this matter. If you decide not to attend a conference, invoke ADR, or provide a written response within the time specified, the

¹ Although the NRC can issue a civil penalty to an individual, a civil penalty is not normally imposed on unlicensed individuals.

NRC will proceed with its enforcement decision, unless the NRC has granted you an extension of time.

Please contact Mr. John Madera at (630) 829-9834 within 10 days of the date of this letter to notify the NRC of your decision to respond in writing or to participate in a PEC or in ADR.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html> (the Public Electronic Reading Room). However, the NRC will delay making available a copy of this letter until an enforcement decision has been made. At that time, in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, with your home address removed, will be made available to the Public, provided enforcement action was taken.

This letter will be maintained by the Office of Enforcement (OE) in a NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html> by selecting the first entry and then selecting the system of record.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-01586
License No. 13-00951-03

Enclosures:

1. Letter to Ball Memorial Hospital w/encls.
2. Excerpt from Title 10 of the Code of Federal Regulations, §30.10

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BY EXPRESS DELIVERY

NRC DISTRIBUTION WITH ENCLOSURE 1 ONLY:

See next page

* See previous concurrence

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Letter to S. Russell from Steven A. Reynolds dated February 28, 2008

SUBJECT: NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2007-018

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TITLE 10--ENERGY

CHAPTER I--NUCLEAR REGULATORY COMMISSION

PART 30 – RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF
BYPRODUCT MATERIAL

Sec. 30.10 Deliberate misconduct.

(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

[63 FR 1896, Jan. 13, 1998]