



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

**REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511**

December 21, 2017

EA-17-104

Mr. David Flicek
President/Chief Executive Officer
Avera McKennan
1325 South Cliff Avenue
Sioux Falls, SD 57117-5045

**SUBJECT: NOTICE OF VIOLATION, NRC INSPECTION REPORT 030-11252/2017-001
AND INVESTIGATION REPORT 4-2016-021**

Dear Mr. Flicek:

This letter refers to the investigation conducted by the U.S. Nuclear Regulatory Commission's (NRC's) Office of Investigations at your facilities in Sioux Falls, South Dakota. The purpose of the investigation was to determine if willful violations of NRC and U.S. Department of Transportation requirements occurred at the Avera McKennan Hospital and at North Central Heart. The investigation was initiated on March 22, 2016, and was completed on June 28, 2017. The results of the investigation and details regarding the apparent violations were provided in NRC Inspection Report 030-11252/2017-001, dated November 7, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession ML17278B205).

On December 1, 2017, a predecisional enforcement conference was conducted at the NRC Region IV office with members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions. During the conference, your staff stated that Avera McKennan did not contest the violations and provided additional information about your corrective actions.

Based on the information developed during the investigation and the information that your staff provided during the conference, the NRC has determined that six violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved failures to: (A) properly package shipments of radioactive material that were transported on public highways; (B) describe the hazardous material on shipping papers; (C) mark each package containing hazardous material for shipment; (D) label packages for shipment; (E) secure packages containing radioactive material to prevent shifting during normal transportation conditions; and (F) monitor the external surfaces of labeled packages for radioactive contamination upon receipt.

The NRC considers violations A through D above to be significant violations. Although no actual safety or security consequences were identified, these four violations are significant because Avera McKennan Hospital employees deliberately failed to follow NRC and U.S. Department of Transportation regulations. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$14,000 is considered for a Severity Level III problem. Because your facility is the subject of a willful escalated enforcement action, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has determined that *Identification* credit is warranted because your personnel identified the condition and promptly notified the NRC. The NRC has also determined that *Corrective Action* credit is warranted based on the prompt and comprehensive corrective actions you implemented. During the conference you discussed that the root cause of employees deliberately violating requirements and failing to raise these safety concerns involved a poor safety culture. Your implemented corrective actions to address this cause are documented in Enclosure 2.

Therefore, to encourage prompt identification and comprehensive correction of violations, 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 this Severity Level III problem constitutes an escalated enforcement action that may subject you to increased inspection effort.

You are required to respond to this letter and should follow the instructions specified in the Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room and in 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. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

If you have any questions concerning this matter, please contact Mr. Michael C. Hay of my staff at 817-200-1455.

Sincerely,

/RA/ SAM for

Kriss M. Kennedy
Regional Administrator

Docket No. 030-11252
License No. 40-16571-01

Enclosures:

1. Notice of Violation
2. Corrective Actions

cc w/Enclosure:

T. McCaskell, Administrator
State of South Dakota

NOTICE OF VIOLATION

Avera McKennan
Sioux Falls, South Dakota

Docket No. 030-11252
License No. 40-16571-01
EA-17-104

During an NRC investigation conducted from March 22, 2016, through June 28, 2017, six violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR Parts 171 through 180 appropriate to the mode of transport.

49 CFR 173.410(f) requires, in part, that each package used for the shipment of Class 7 (radioactive) materials must be designed so that the package will be capable of withstanding the effects of any acceleration, vibration or vibration resonance that may arise under normal conditions of transport without any deterioration in the effectiveness of the closing devices on the various receptacles or in the integrity of the package as a whole and without loosening or unintentionally releasing the nuts, bolts, or other securing devices even after repeated use.

Contrary to the above, on multiple occasions between March 2013 and December 2015, licensee employees transported licensed material on public highways and failed to ensure that each package used for the shipment of Class 7 (radioactive) materials was designed so that the package was capable of withstanding the effects of any acceleration, vibration or vibration resonance that may arise under normal conditions of transport without any deterioration in the effectiveness of the closing devices on the various receptacles or in the integrity of the package as a whole and without loosening or unintentionally releasing the nuts, bolts, or other securing devices even after repeated use. Specifically, the licensee transported licensed material (between 50 and 300 millicuries of technetium-99m) in shielded vials inside a plastic bag in a design incapable of withstanding deterioration in the effectiveness of the integrity of the package.

- B. 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR Parts 171 through 180 appropriate to the mode of transport.

49 CFR 172.200(a) requires, in part, that each person who offers a hazardous material for transportation shall describe the hazardous material on the shipping paper in a manner required by Subpart C of 49 CFR Part 172.

Contrary to the above, on multiple occasions between March 2013 and December 2015, licensee employees deliberately transported licensed material, a hazardous material, on public highways and failed to describe the hazardous material on any shipping paper in a manner required by Subpart C of 49 CFR 172. Specifically, the licensee transported the hazardous material (between 50 and 300 millicuries of technetium-99m) from Avera McKennan Hospital to a licensee's off-site authorized facility (North Central Heart) without completing any required shipping papers.

- C. 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR Parts 171 through 180 appropriate to the mode of transport.

49 CFR 172.300(a) requires, in part, that each person who offers a hazardous material for transportation shall mark each package, freight container, and transport vehicle containing hazardous material in the manner required by Subpart D of 49 CFR Part 172.

Contrary to the above, on multiple occasions between March 2013 and December 2015, licensee employees failed to mark each package, freight container, and transport vehicle containing hazardous material in the manner required by Subpart D of 49 CFR 172. Specifically, the licensee failed to mark packages of licensed material (between 50 and 300 millicuries of technetium-99m) that was transported from Avera McKennan Hospital to the licensee's off-site authorized facility (North Central Heart).

- D. 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR Parts 171 through 180 appropriate to the mode of transport.

49 CFR 172.400(a) requires, in part, that each person who offers for transportation or transports a hazardous material shall label the package or containment device with labels specified for the material in the 49 CFR 172.101 table and Subpart E of 49 CFR Part 172.

49 CFR 172.403(c) requires, in part, that each Class 7 (radioactive) materials package with a Transportation Index of 0, and a maximum radiation level at any point on the external surface of less than 0.005mSv/h (0.5mrem/h) be labelled WHITE-I.

Contrary to the above, on multiple occasions between March 2013 and December 2015, licensee employees failed to label Class 7 (radioactive) materials packages with a Transportation Index of 0, and a maximum radiation level at any point on the external surface of less than 0.005mSv/h (0.5mrem/h) as WHITE-I. Specifically, the licensee failed to label packages of licensed material (between 50 and 300 millicuries of technetium-99m) that were transported from Avera McKennan Hospital to the licensee's off-site authorized facility (North Central Heart).

This is a Severity Level III problem (NRC Enforcement Policy, Section 6.8.c).

- E. 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR Parts 171 through 180 appropriate to the mode of transport.

49 CFR 173.448(a) requires, in part, that each shipment of Class 7 (radioactive) materials must be secured to prevent shifting during normal transportation conditions.

Contrary to the above, on multiple occasions between March 2013 and December 2015, licensee employees transported licensed material and failed to secure these shipments to prevent shifting during normal transportation conditions. Specifically, the licensee employees transported licensed material (between 50 and 300 millicuries of technetium-99m) on public highways from Avera McKennan Hospital to the licensee's off-site authorized facility (North Central Heart) and failed to secure these shipments to prevent shifting during normal transportation conditions.

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

- F. 10 CFR 20.1906(b)(1) requires, in part, that each licensee shall monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4.

Contrary to the above, on multiple occasions between March 2013 and December 2015, licensee employees failed to monitor the external surfaces of a labeled package for radioactive contamination and the package did not contain radioactive material in the form of a gas or in special form. Specifically, bulk doses of between 50 and 300 millicuries of technetium-99m were distributed from Avera McKennan Hospital and received at the licensee's off-site authorized facility (North Central Heart), and external monitoring surveys were not performed upon receipt at North Central Heart.

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

Pursuant to the provisions of 10 CFR 2.201, Avera McKennan is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, TX 76011-4511, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-17-104" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved.

Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management 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, then 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 material, 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).

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

Dated this 21st day of December 2017

Corrective Actions

To address the root cause you provided detailed information on implementation of the following corrective actions during the predecisional enforcement conference:

- Disciplinary actions were administered for supervisors involved in the deliberate misconduct,
- The radiation safety officer and nuclear medicine department manager established the philosophy of safety culture in the workplace involving routine discussions with employees on its importance,
- A compliance coordinator position was created to ensure all regulatory requirements are being met, to establish and execute a department quality assurance program, and assist in training activities for the employees,
- Training was conducted for all technicians covering:
 - Ethical behavior
 - Regulatory requirements
 - Radioactive material transportation requirements involving packaging, labeling, blocking and bracing, and shipping papers (practical exercises were developed and administered to ensure all staff could properly transport material)
- Established a “Respectful Work Environment Policy” and each employee signed an agreement form stating they endorse the policy,
- Established a “stop work” policy for those activities that employees feel might be inappropriate if conducted,
- Established a “Variance Log” that tracks deficiencies or concerns identified by employees as they conduct their daily activities that is monitored to identify performance trends and potential training needs,
- Implemented mandatory monthly staff meetings with an agenda consisting of discussing regulatory issues, compliance with requirements, expectations and responsibilities, and training on various topics such as proper use of equipment,
- Implemented semi-annual one-on-one meetings between the radiation safety officer, the nuclear medicine department manager, and each staff member conducted separately to facilitate concerns being discussed freely by employees,
- Increased radiation safety audits of technologists conducted by the compliance coordinator, and
- Updated the Nuclear Medicine Radiation Safety Policies.

NOTICE OF VIOLATION, NRC INSPECTION REPORT 030-11252/2017-001 AND INVESTIGATION REPORT 4-2016-021 – DATED December 21, 2017.

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