November 6, 2006

Douglas Pattullo
Chief Executive Officer
West Branch Regional Medical Center
2463 S. M-30
West Branch, MI 48661

SUBJECT: NRC INSPECTION REPORT 030-17321/06-01(DNMS) AND NOTICE OF VIOLATION - WEST BRANCH REGIONAL MEDICAL CENTER

Dear Mr. Pattullo:

This refers to the special inspection conducted on October 3, 2006, at West Branch Regional Medical Center, West Branch, Michigan, with continued in-office review through October 18, 2006. The inspection was conducted to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event reported to the NRC on September 25, 2006. The in-office review included review of your report, dated October 4, 2006, and a determination that a medical event occurred. A final exit meeting, via telephone, occurred on October 18, 2006, between George Parker of my staff and Stephen Brown of your staff. The enclosed report presents the results of the inspection.

The inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement,** then **Enforcement Policy.**

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation pertains to your staff's failure to insure that a dosage of iodine was administered as prescribed by the authorized user. Specifically, your staff administered a dose of 10 millicuries of iodine-131 to the patient rather than the prescribed dose of 10 microcuries.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and to prevent recurrence is already adequately addressed on the docket in the enclosed report. 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 chose 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, its enclosures, and your response, if you choose to provide one, will be 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.

Sincerely,

/RA/

Kenneth J. Lambert, Acting Chief
Materials Inspection Branch

Docket No. 030-17321
License No. 21-18892-01

Enclosures:
1. Notice of Violation
2. Inspection Report 030-17321/06-01(DNMS)

cc: State of Michigan

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NOTICE OF VIOLATION

West Branch Regional Medical Center
West Branch, Michigan

Docket No.: 030-17321
License No.: 21-18892-01

During an NRC inspection conducted on October 3, 2006, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a) requires that, for any administrations requiring a written directive, licensees develop, implement, and maintain procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

Procedure 3253, "I-131 Thyroid Therapy," developed in accordance with 10 CFR 35.41(a), requires, in part: (1) must obtain a prescription from the ordering physician; (2) must obtain a prescription and written directive completed and signed by the ordering Radiologist; and (3) that after obtaining 1 and 2, order the appropriate dose of iodine-131 (I-131) from Radiopharmacy.

The written directive form, page 2 of Procedure 3253, includes sections on Written Directive, Patient Identification, and Dose Dispensing Record. Reminders at the bottom of the form include, but are not limited to: (1) all administered doses must be within 10 percent of the prescribed dose; and (2) do not proceed with administration if there are any discrepancies.

Contrary to the above, on June 28, 2006, the licensee failed to implement its written procedures to provide high confidence that each administration was in accordance with the written directive when it failed to order the appropriate dose of I-131 in accordance with the written directive and failed to resolve any discrepancies prior to proceeding with the administration. Specifically, the written directive prescribed a dose of 10 microcuries of I-131 and the nuclear medicine technologist order 10 millicuries of I-131. In addition, the discrepancy between the written directive prescribed dose of 10 microcuries and the dose dispensing record prescribed dose of 10 millicuries was not resolved prior to administration.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 030-17321/06-01(DNMS). 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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.

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.

Dated this 6th day of November 2006

U S NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-17321
License No.:	21-18892-01
Report No.:	030-17321/06-01(DNMS)
Licensee:	West Branch Regional Medical Center
Location:	2463 South M 30 West Branch, MI 48661
Date of Inspection:	October 3, 2006
Exit Meetings:	October 3, 2006 (on site) October 18, 2006 (telephonic)
Inspector:	George Parker, Health Physicist
Reviewed by:	Kenneth Lambert, Acting Chief Materials Inspection Branch

Enclosure 2

EXECUTIVE SUMMARY

West Branch Regional Medical Center
West Branch, Michigan
Inspection Report No. 030-17321/06-01(DNMS)

The inspector conducted a special inspection to review the circumstance, root and contributing causes, and proposed corrective actions for a therapeutic radiopharmaceutical medical event which resulted in the patient receiving a dose that differed from the prescribed dose by 20 percent. The authorized user had inadvertently listed the dosage for a diagnostic procedure rather than a therapeutic procedure. The quantity of radionuclide administered to the patient was appropriate for the therapeutic procedure for which treatment was being rendered.

The inspector identified one violation of NRC requirements involving the licensee's failure to ensure each administration is in accordance with the written directive prior to patient treatment. Specifically, the licensee's nuclear medicine technologist failed to reference the written directive form and ordered a quantity of radiopharmaceutical appropriate for the treatment being given based on past experience. The written directive prescribed a dose of 10 microcuries of iodine-131 and the nuclear medicine technologist ordered 10 millicuries of iodine-131, the commonly prescribed dose for therapeutic treatment of Graves disease. In addition the licensee did not resolve discrepancies between the written directive and the dose dispensing record section of the written directive form.

The root cause of the violation was the licensee's failure to appropriately implement its procedure regarding iodine-131 therapy when 10 millicuries of iodine-131 was order rather than the 10 microcuries prescribed on the written directive, and the failure to resolve discrepancies on the written directive form prior to administering 10 millicuries of iodine-131.

To reduce the likelihood of similar events, the licensee initiated several immediate and long term corrective actions to prevent recurrence of a similar event. The corrective actions included: (1) briefing the staff on the importance of following the written directive verbatim. If a question arises, do not proceed with treatment until clarification is received; (2) redesigning the written directive form to specify treatment protocols and question whether the actions required are appropriate.

Report Details

1 Program Scope and Inspection History

NRC License No. 21-18892-01 authorizes West Branch Regional Medical Center to use a variety of byproduct materials for medical purposes, including diagnostic and therapeutic nuclear medicine. The licensee is authorized to conduct licensed activities at the West Branch, Michigan location.

The last inspection of this licensee was in August of 2004. The inspection resulted in a clear NRC Form 591M being issued to the licensee.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the sequence of events that resulted in the medical event and the licensee's investigation of the event. In addition, the inspector interviewed selected licensee personnel, reviewed patient treatment information, and toured related facilities.

2.2 Observations and Findings

On June 23, 2006, the authorized user completed a written directive for a patient undergoing treatment for Graves disease. The authorized user prescribed a dose of 10 microcuries of iodine-131 for treatment. The normal dosage for such a treatment is 10 millicuries of iodine-131. The technologist noted that the scheduled procedure was a therapeutic treatment for Graves disease and ordered the customary 10 millicurie capsule of iodine without consulting the written directive.

On June 28, 2006, the technologist assayed the iodine capsule (10.65 millicuries) per department protocol prior to administration. Department protocol also requires that the authorized user be present when measuring and administering the dose. The authorized user was present at the assay and signed the dose dispensing section of the written directive indicating a prescribed dose 10.65 millicuries. The assayed dose was subsequently administered to the patient. The authorized user indicated to the inspector that the 10.65 millicurie dose administered to the patient was the intended dose rather than the 10 microcurie dose indicated on the written directive.

The administration of 10.65 millicuries of iodine-131 rather than the prescribed dose of 10 microcuries resulted in a medical event. In accordance with 10 CFR 30.3045, a medical event resulted because the dose delivered to the thyroid differed by more than 50 rem from the dose that would have resulted from the prescribed dose and the administered dose differed by more than 20 percent from the prescribed dose on the written directive.

Title 10 CFR 35.41(a) requires that, for any administrations requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. The written procedures must meet the requirements described in 10 CFR

35.41(b). In accordance with 10 CFR 35.41(b), the licensee's procedure 3253, "I-131 Thyroid Therapy," states in step 1, that one must obtain a prescription from the ordering physician; step 2 states that one must obtain a prescription and written directive completed and signed by the ordering Radiologist; and step 3 states that after obtaining 1 and 2 (prescription and written directive), order the appropriate dose of I-131 from the Radiopharmacy. The licensee's procedure included a written directive form that included sections on written directive, patient identification, and dose dispensing record. The form also contained reminders that included, but not limited to: (1) all administered doses must be within 10 percent of the prescribed dose; and (2) do not proceed with administration if there are any discrepancies.

The written directive for this medical event indicated a prescribed dose of 10 microcuries of sodium iodide-131, while the dose dispensing record indicated a prescribed dose of 10 millicuries and a dose calibrator assay of 10.6 millicuries. The licensee's failure to order the appropriate dose as prescribed in the written directive and to resolve the discrepancies between the written directive and dose dispensing sections of the form prior to proceeding with the administration is a violation of the licensee's procedure and 10 CFR 35.41(b).

On September 25, 2006, a licensee consultant conducting a routine quarterly audit of the nuclear medicine program detected the medical event. The licensee immediately initiated an investigation of the medical event and determined that the root cause and contributing factors included: (1) the technologist did not order the quantity of iodine specified on the written directive nor did he question the unusual dosage as required by department protocol prior to administration; and (2) the authorized user entered the wrong units on the written directive when specifying a treatment for Graves disease.

2.3 Conclusions

A medical event occurred on June 28, 2006, when the licensee delivered a therapeutic radiopharmaceutical dose to a patient that was not prescribed on a written directive. The medical event was caused by the technologist's failure to order the quantity of radiopharmaceutical specified on the written directive and his failure to follow department protocol and question the low dosage. The inspector identified a violation of NRC requirements associated with the implementation of the licensee's written procedures involving I-131 thyroid therapy treatments.

3.0 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's October 4, 2006, written report regarding the medical event, and interviews of selected licensee personnel.

3.2 Observations and Findings

The inspector determined that the licensee initiated several immediate and long term corrective actions to prevent recurrence of a similar event. The corrective actions included: (1) briefing the staff on the importance of following a written directive verbatim

and when encountering an unusual situation to stop treatment until clarification is reached; and (2) changing the written directive to be clearer on the treatment desired and to provide a specific section for revisions to the written directive.

3.3 Conclusions

The inspector determined that the licensee developed appropriate immediate and long term corrective actions to address the violation and to prevent a recurrence.

4 Notification and Reports

4.1 Inspection Scope

The inspector reviewed the licensee's notification to the NRC Operations Center and the associated written report to ensure compliance with reporting requirements.

4.2 Observations and Findings

During the quarterly review of the nuclear medicine program on September 25, 2006, the licensee's consultant identified that a medical event had occurred on June 28, 2006, involving the therapeutic administration of iodine-131 for Graves disease. The NRC Operations Center was notified within 24 hours of the discovery of the event. The licensee provided its written report of the event in a letter dated October 4, 2006. The inspector determined that the written report included the information required by 10 CFR 35.3045 (d).

The licensee notified the patient's referring physician and the patient on September 27, 2006 regarding the medical event. The inspector determined that the notification was made in accordance with the requirement in 10 CFR 35.2045(e).

4.3 Conclusions

The inspector determined that the licensee provided the notifications and written report as required by 10 CFR 35.3045.

5 Exit Meeting

At the conclusion of the onsite inspection, the inspector discussed the findings in this report with licensee management during a preliminary exit meeting. A final telephonic exit meeting was held on October 18, 2006, between Dr. Stephen Brown of West Branch Regional Medical Center and George Parker of the NRC to confirm that a medical event had occurred on June 28, 2006. At the exit meetings, on site and telephonic, the licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

List of Persons Contacted

Douglas Pattullo, Chief Executive Officer
Stephen Brown, M.D., Radiation Safety Officer
Michelle L. Kritzman, Consultant

Attachment