UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

September 3, 2013

EA-13-126

Wesley P. Lo, Chief Executive Officer
Maui Memorial Medical Center
221 Mahalani Street
Wailuku, Hawaii 96793

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT NO. 03003561/2013-001

Dear Mr. Lo:

This letter refers to the special inspection conducted on February 28, 2013, at your facility located in Wailuku, Hawaii, with continued in-office review through July 5, 2013. The inspection was conducted in response to a condition in which three written directives were signed by a physician who was not authorized for use of 10 CFR 35.300 material, and therefore, not authorized to sign written directives. Your staff had identified all three instances. A preliminary exit was conducted on February 28, 2013, during the onsite portion of the inspection. By letter dated June 6, 2013 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13163A475), you provided corrective actions that you have taken or plan to take. The results of the inspection were discussed with Mr. Philip Manly, Radiation Safety Officer; Les Chun, M.D., Chief of Clinical and Medical Affairs; and Ms. Donna McCall, Regional Imaging Director, during a telephonic exit briefing conducted on July 5, 2013, by Mr. Michael Vasquez, Chief, Nuclear Materials Safety Branch-A.

During the telephonic exit briefing, Mr. Vasquez informed your staff that the NRC was considering escalated enforcement for a violation involving the failure to ensure that written directives are signed by an authorized user. Mr. Vasquez also informed your staff that we had sufficient information regarding the violation and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from you. Ms. McCall stated that Maui Memorial Medical Center did not believe that a predecisional enforcement conference or written response was needed.

Based on the results of this inspection and the information you provided in your June 6 letter, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Enclosure 1) and the circumstances surrounding it are described in the enclosed NRC inspection report (Enclosure 2). The violation involved the failure to ensure that written directives were signed by an authorized user in accordance with 10 CFR 35.40(a). The written directives were required because each administration involved more than 30 microcuries of iodine-131 (I-131) sodium iodide. The physician who signed the written directives thought that because he was an authorized user for diagnostic administrations under 10 CFR 35.100 and 10 CFR 35.200, he (the physician) was authorized to sign written

directives for diagnostic administrations of greater than 30 microcuries of I-131 sodium iodide. Your staff informed the inspector that the physician had received training appropriate for the use of 10 CFR 35.300 material and had been authorized to sign written directives in or around 1999. However, the physician did not have the documentation to show this, and the physician had not received related continuing education since that time. The physician's 1999 training in the use of written directives exceeds the 7-year limit for recentness of training in 10 CFR 35.59. Therefore, the NRC concluded that the physician did not meet the requirements to be an authorized user of I-131 sodium iodide greater than 30 microcuries and to sign written directives.

An unauthorized individual conducting licensed activities is of significant concern to the NRC. The training requirements contained in 10 CFR Part 35 are designed to provide reasonable assurance that licensed materials are used appropriately and to provide for the safety of patients, the public, and licensee staff. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Because your facility has not been the subject of escalated enforcement actions within 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. As described in your June 6, 2013, letter, your corrective actions include retraining the physician and nuclear medicine staff about the qualifications necessary to sign written directives, training on authorized user requirements with the physician and nuclear medicine staff, requiring the nuclear medicine staff to check that the physician is authorized to sign a written directive before the administration of 10 CFR 35.300 material, and discussing the issue with the radiation safety committee on January 14, 2013.

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 this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the enclosed inspection report and in your letter dated June 6, 2013. 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, its enclosures, and your response, should you provide one, 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. If you provide a response, 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.

If you have any questions concerning this matter, please contact Mr. Vasquez at (817) 200-1130.

Sincerely,

/RA/

Steven A. Reynolds
Acting Regional Administrator

Docket No. 030-03561
License No. 53-13519-01

Enclosures:
1. Notice of Violation
2. NRC Inspection
   Report 03003561/2013-001

cc/w enclosures:
Jeffrey M. Eckerd, Supervisor
Radiation Section
Hawaii Department of Health
Indoor & Radiological Health Branch
591 Ala Moana Boulevard, Rm 133
Honolulu, HI 96813

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.

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Enclosures:
1. Notice of Violation
2. NRC Inspection
   Report 03003561/2013-001

cc/w enclosures:
State of Hawaii Radiation Control
Program Director

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ADAMS	☐ No	■ Yes	■SUNSI Review Complete	Reviewer Initials: LMH
☐ Publicly Available		■Non-publicly Available	■Sensitive	☐ Non-sensitive
Category: A.3		**KEYWORD**: **MD 3.4 Non-Public A.3**		

RIV:NMSB-A	NMSBA:BC	ACES:ES	ACES:BC
LMHanson	GMVasquez	MCMaier	HJGepford
/RA/	***/RA/***	***/RA/*** **E**	***/RA/***
07/29/2013	08/05/2013	08/09 /2013	08/12/2013

D:DNMS	RC	DRA	RA
AVegel	KFuller	TBergman	SAReynolds
/RA/	***/RA/***	***/Ra/***	***/RA/***
08/12/2013	08/13/2013	8/20/13	9/3/13

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Leela.Sreenivas@nrc.gov;
Kerstun.Day@nrc.gov;
Lauren.Casey@nrc.gov;
Michele.Burgess@nrc.gov;
Robert.Sun@nrc.gov;

Hard copy:
RIV Materials Docket File

NOTICE OF VIOLATION

Maui Memorial Medical Center
Wailuku, Hawaii

Docket No. 030-03561
License No. 53-13519-01
EA-13-126

During an NRC inspection conducted from February 28 through July 5, 2013, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.40(a) states, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries).
>
> Condition 12.A. of NRC Materials License No. 53-13519-01 states, in part, that licensed material is only authorized for use by, or under the supervision of, individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
>
> Condition 12.B. of NRC Materials License No. 53-13519-01 lists the authorized users, and the material and medical uses for which they are authorized, including specific physicians authorized for medical use under 10 CFR 35.300.
>
> Contrary to the above, on October 31 and November 21, 2012, the licensee failed to ensure that a written directive was dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries). Specifically, on three occasions, the license allowed a physician to sign a written directive for the administration of 5-millicurie diagnostic dosages of I-131 sodium iodide, and the physician was not listed as an authorized user for the material and medical uses under 10 CFR 35.300, on NRC Materials License No. 53-13519-01.

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

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 No. 03003561/2013001, and in your letter dated June 6, 2013 (ADAMS Accession No. ML13163A475). 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-13-126," 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 IV, 1600 East Lamar Boulevard, Arlington, TX 76011-4511, 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, United States 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 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. Therefore, 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.

Dated this 3rd day of September 2013

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-03561
License:	53-13519-01
Report:	03003561/2013001
EA:	EA-13-126
Licensee:	Maui Memorial Medical Center
Facility:	Main Office
Location:	Wailuku, Hawaii
Inspection Dates:	February 28, 2013, through July 5, 2013
Inspector:	Latischa Hanson, Health Physicist Nuclear Materials Safety Branch A
Approved By:	G. Michael Vasquez, Chief Nuclear Materials Safety Branch A Division of Nuclear Materials Safety Region IV
Attachment:	Supplemental Inspection Information

Enclosure 2

EXECUTIVE SUMMARY

Maui Memorial Medical Center
NRC Inspection Report 03003561/2013001

This was a special, unannounced inspection of licensed activities to review the circumstances involving a physician who signed three written directives when he was not authorized under the license to sign written directives. Each of the written directives involved an administration of 5 millicuries (mCi) of iodine-131 (I-131) sodium iodide. The inspection was limited to a review of the licensee's radiopharmaceutical administration records requiring a written directive in the nuclear medicine department for Calendar Year 2012.

Program Overview

Maui Memorial Medical Center is a hospital authorized by NRC Materials License 53-13519-01 to perform activities under 10 CFR 35.100, 200, 300, and 400, which includes administration of radiopharmaceuticals requiring a written directive. (Section 1)

Violation

On two occasions on October 31, 2012, and on one occasion on November 21, 2012, Maui Memorial Medical Center failed to ensure that written directives were dated and signed by an authorized user before the administration of I-131 sodium iodide in a quantity greater than 1.11 megabecquerels (MBq) (30 microcuries(uCi)). (Section 2)

Corrective Actions

The licensee's corrective actions included:

1) Initiated a hospital incident report to the address the occurrences;

2) Informed the physician that he was not authorized to sign a written directive, including a written directive for iodine-131 in quantities greater than 30 uCi;

3) Reviewed authorized user requirements with the physician and the nuclear medicine staff and reviewed with the staff who was authorized under the license to sign which written directives;

4) Audited the nuclear medicine department (focusing on written directives in 2012);

5) Held an in-services meeting on January 9, 2013, specifically addressing NRC generic reportable events and the processes to be followed when handling written directives for any therapeutic dose under 10 CFR 35.300;

6) Developed check lists for procedures, which included a verification that the physician signing the written directive is authorized on the license to sign it; and

7) Discussed the issue with the Radiation Safety Committee on January 14, 2013. (Section 3)

Report Details

1 Program Overview (87131)

1.1 Inspection Scope

Maui Memorial Medical Center (licensee) is a hospital authorized by NRC Materials License No. 53-13519-01 to perform activities under 10 CFR 35.100, 200, 300, and 400, which includes administration of radiopharmaceuticals requiring a written directive and manual brachytherapy.

During the NRC's last routine on-site inspection conducted on June 21, 2011, the NRC issued a clear inspection report and closed a March 2008 inspection Non-Cited Violation for the licensee's failure to document radiation surveys of disposal of licensed materials during the 4th quarter 2007.

2 Radiopharmaceuticals Requiring a Written Directive

2.1 Inspection Scope

The inspector reviewed records associated with written directives for calendar year 2012, the licensee's 2012 annual radiation audit of the nuclear medicine department, dated January 12, 2013, the licensee's radiation safety committee minutes, dated January 12, 2013, and the licensee's Annual Radiation In-Service training conducted January 9, 2013. The inspectors interviewed selected individuals of the nuclear medicine staff and management.

2.2 Observations and Findings

10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)).

Condition 12.A. of NRC Materials License No. 53-13519-01 states, in part, that licensed material is only authorized for use by, or under the supervision of, individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14. Condition 12.B. of the license lists the authorized users, and the material and medical uses for which they are authorized, including specific physicians authorized for medical use under 10 CFR 35.300.

During the February 28, 2013, on-site inspection, the inspector found that the licensee had identified three instances in Calendar Year 2012 where written directives were signed by a physician who was not listed on the NRC license as an authorized user for 10 CFR 35.300 medical uses. Through independent review of all written directives signed in Calendar Year 2012, the inspector confirmed there were no more instances. The physician who signed the written directives, was not listed on the license for 10 CFR 35.300 medical uses, but was listed on the license for medical use under 10 CFR 35.100 and 35.200. A review of the annual audit record dated January 1, 2013, documented the finding identified by the radiation safety officer (RSO) of the three

written directives that were signed by an unauthorized user. The radiation safety committee meeting minutes, dated January 14, 2013, documented its review of the annual program audit.

On February 8, 2013, the licensee's health physics consultant documented in a letter to the NRC, that the RSO was notified of a potential medical event involving administration of I-131. After reviewing the circumstances, the RSO determined that no medical event had occurred. A hospital incident report was initiated and the RSO conducted an investigation. The hospital's health physics consultant reported that before the written directive was prepared for the first procedure (administered on October 31, 2012); the nuclear medicine technologist asked the physician if he was authorized to sign the written directive. The physician indicated that since it was for a diagnostic procedure, he was authorized to sign the written directive.

Two of the three written directives were dated October 31, 2012 (two different patients), and the third written directive was dated November 21, 2012. Each administration was a 5-millicurie (mCi) dosage of I-131, which requires a written directive.

The physician who signed the written directives was new to the hospital; he was added to the Maui Memorial Medical Center license on November 21, 2012. He told the RSO that he (the physician) previously had been authorized to sign written directives under 10 CFR 35.300. Since the inspection, the physician has not been able to get documentation of his original training. The facility where he completed his residency in 1999 terminated the residency program, and the program director is working elsewhere. The RSO informed the NRC that the physician had not attended any additional training for use of 10 CFR 35.300 material since his original training. Therefore, the physician's training exceeded the 7-year limit for recentness of training in 10 CFR 35.59, and the NRC concluded that the physician was not qualified to sign the written directive.

10 CFR 35.40(a) requires that a written directive must be signed and dated by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 μCi). The licensee failed to obtain the signature of an authorized user on three written directives for the administration of I-131 sodium iodide, in quantities of about 5 millicuries each, an amount greater than 30 μCi. Two of the three written directives were dated October 31, 2012. The third written directive was dated November 21, 2012. This was identified as a violation of 10 CFR 35.40(a) and License Conditions 12.A and 12.B. of NRC Materials License No. 53-13519-01.

2.3 Conclusions

The inspector identified a violation of 10 CFR 35.40(a) and License Conditions 12.A. and 12.B. of NRC Materials License No. 53-13519-01, involving the licensee's failure to have an individual authorized for the use of 10 CFR 35.300 material sign three written directives. Two of the written directives were dated October 31, 2012 and the third written directive was dated November 21, 2012.

3 Corrective Actions

The licensee's corrective actions are discussed in its letter dated June 6, 2013 (ML13163A475). The licensee's corrective actions included:

1) Initiated a hospital incident report to the address the occurrences;

2) Informed the physician that he was not authorized to sign a written directive for Iodine-131 in quantities greater than 30 uCi;

3) Reviewed authorized user requirements with the physician and the nuclear medicine staff and reviewed with the staff who was authorized under the license to sign which written directives;

4) Audited the nuclear medicine department (focusing on written directives in 2012);

5) Held an in-services meeting on January 9, 2013, specifically addressing NRC generic reportable events and the processes to be followed when handling written directives for any therapeutic dose under 10 CFR 35.300;

6) Developed check lists for procedures, which included a verification that the physician signing the written directive is authorized on the license to sign it; and

7) Discussed the issue with the Radiation Safety Committee on January 14, 2013.

4 Exit Meeting Summary

A preliminary exit meeting was conducted at the conclusion of the reactive inspection with nuclear medicine staff and management. A final telephonic exit briefing was conducted with Mr. Philip Manly, Radiation Safety Officer; Les Chun M.D., Chief of Clinical and Medical Affairs; and Donna McCall, Regional Imaging Director, on July 5, 2013. No proprietary information was identified.

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

+*Philip Manly, Radiation Safety Officer
+Les Chun, MD, Chief of Clinical and Medical Affairs
+*Donna McCall, Regional Director, Imaging Services
+Ronald Frick, Contract Health Physicist

*Individuals present at entrance meeting
+Individuals present for exit meeting

INSPECTION PROCEDURES USED

87131	Nuclear Medicine Programs, Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03561/2013001	VIO	A violation involving the failure to obtain the signature of an authorized user listed on the license for 10 CFR 35.300 medical uses on three written directives for the administration of diagnostic doses of I-131 sodium iodide greater than 30 microcuries.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

VIO	Violation
CFR	Code of Federal Regulations
NRC	U.S. Nuclear Regulatory Commission
RSO	radiation safety officer

Attachment