



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

October 27, 2020

EA-20-051

Ms. Darlena Chadwick, Vice President
Patient Care
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF \$7,500 CIVIL PENALTY, NRC INSPECTION REPORT 030-14522/2019-001

Dear Ms. Chadwick:

This letter refers to the inspection conducted May 28-30, 2019, at your facility in Honolulu, Hawaii, with continued in-office review through February 19, 2020. The inspection was conducted in response to a medical event that occurred on May 8, 2019. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, regulations, and the conditions of your license. A final exit briefing was conducted telephonically with you and staff representatives on June 25, 2020. The details regarding the Severity Level IV violation associated with the medical event and three unrelated NRC-identified apparent violations were provided in NRC Inspection Report 030-14522/2019-001, dated June 26, 2020, NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML20178A632.

On August 11, 2020, a predecisional enforcement conference was conducted with you and members of your staff to discuss the three apparent violations, their significance, their root causes, and your corrective actions.

Based on the information developed during the inspection and the information you provided during the conference, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the failure to: (A) monitor occupational exposure of workers from licensed and unlicensed radiation sources, (B) implement certain elements of your radiation protection program sufficiently to ensure compliance with the provisions of Title 10 of the *Code of Federal Regulations* (CFR) Part 20, and (C) provide instruction to individuals who were likely to receive in a year an occupational dose in excess of 100 mrem.

The NRC determined that the violations associated with your personnel occupational radiation exposure monitoring program were attributed to failures on the part of the radiation safety officer and the radiation safety committee to provide adequate oversight of NRC-licensed activities and to take corrective actions to address identified deficiencies. Given the scope and risk-

significance of the NRC-licensed activities at your facility, the oversight functions of the radiation safety officer and radiation safety committee are critically important.

The NRC considers the violations above to be significant because the programmatic deficiencies associated with the personnel occupational exposure radiation monitoring program resulted in the failure to monitor the occupation exposure of nine interventional radiology physicians over the course of several years. The NRC determined that these physicians had a substantial potential to exceed NRC occupational exposure limits because of the deficiencies associated with your personnel occupational exposure radiation monitoring program. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. The NRC Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a Severity Level III problem.

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 NRC Enforcement Policy. The NRC understands that your corrective actions included a revision to your Radiation Safety Plan, a revision to your policies regarding radiation exposure monitoring device (i.e. dosimetry) use, training provided to the interventional radiology physicians regarding dosimeter use, the modification of the contract with the interventional radiology physician group to include provisions regarding dosimeter use, enhanced procedures to address dosimeter use, a commitment to annual, independent audits of your radiation safety program, and a commitment to perform reviews of dosimeter results to verify their proper use. Notwithstanding these completed and planned corrective actions, immediate corrective actions were not taken to restore safety and compliance when your staff first identified the violations in 2016. When assessing *Corrective Action* credit, the NRC evaluates both the promptness and the comprehensiveness of the licensee's corrective actions. Therefore, the NRC determined that *Corrective Action* credit is not warranted.

To emphasize the importance of having an adequate radiation protection program and to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the base amount of \$7,500 for this Severity Level III problem. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection in the future.

The NRC recognizes that many of its licensees have been adversely impacted financially by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, as described in the enclosed Notice, the NRC is extending by 30 days the period of time by which the civil penalty must be paid (i.e., extending the deadline from 30 days to 60 days from the date of this Notice), and the NRC would consider a request for additional time, if appropriate. Please refer to the enclosed Notice for further instructions.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a neutral

mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the Institute on Conflict Resolution at (877) 733-9415; and (2) Ms. Patricia Silva at 817-200-1455 within 10 days of the date of this letter. You may also contact the Institute on Conflict Resolution for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 60-day time period for payment of the civil penalties, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violations; (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 subject inspection report (ADAMS Accession No. ML20178A632) and in the summary of the predecisional enforcement conference (ADAMS Accession No. ML20232D160). 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 and Procedure," a copy of this letter, its enclosure, and your response, if you choose or are required to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its website at http://www.nrc.gov/reading_rm/doc_collections/enforcement/actions/.

D. Chadwick

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If you have any questions concerning this matter, please contact Ms. Patricia Silva of my staff at 817-200-1455.

Sincerely,

/RA/

Scott A. Morris
Regional Administrator

Docket No. 030-14522
License No. 53-16533-02

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
Jeffrey Eckerd, Manager
State of Hawaii Radiation Control Program

NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY \$7,500 NRC
INSPECTION REPORT 030-14522/2019-001 - DATED OCTOBER 27, 2020

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Cvr Ltr & All Encl: ADAMS ACCESSION NUMBER: **ML20301A667**

SUNSI Review: PAJ ADAMS: Non-Publicly Available Non-Sensitive Keyword: By:
 Yes No Publicly Available Sensitive

OFFICE	ES:ACES	C:MLIB	TL:ACES	RC	OE	NMSS
NAME	PJayroe	PSilva	JGroom	DCylkowski	JPeralta	RSun
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	9/9/2020	9/15/20	9/9/2020	9/10/20	10/19/20	9/23/20
OFFICE	OGC	D:DNMS	RA			
NAME	LBaer	MMuessle	SMorris			
SIGNATURE	/NLO/ E	/RA/ E	/RA/ E			
DATE	10/16/20	10/22/20	10/27/20			

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

The Queen's Medical Center
Honolulu, Hawaii

Docket No.: 030-14522
License No.: 53-16533-02
EA-20-051

During an NRC inspection conducted on May 28-30, 2019, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The violations and associated civil penalty are set forth below:

- A. 10 CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from January 2011 to May 28, 2019, the licensee failed to monitor individuals' occupational exposure to radiation sources under the control of the licensee and require the use of individual monitoring devices. Specifically, nine interventional radiologist physicians whose occupational exposure exceeded 10 percent of the limits in 10 CFR 20.1201(a) were not monitored over the course of several years.

- B. 10 CFR 20.1101(a) requires, in part, that each licensee implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

The Queen's Medical Center Radiation Safety Plan, dated April 2017, provides information regarding the licensee's radiation safety program implementation. The Radiation Safety Plan states, in part, that the radiation safety committee shall ensure that licensed material is used in compliance with NRC regulations and establish investigational levels for occupational radiation exposures. It further provides, in part, that the radiation safety committee shall: (1) review quarterly the radiation safety officer's summary report of occupational radiation exposure records, giving attention to excessive exposures; (2) review at least annually the radiation safety officer's summary report of the radiation safety program to determine that activities are being conducted safely and in accordance with the regulations; and (3) recommend remedial action to correct any deficiencies identified in the radiation safety program.

The Queen's Medical Center Policy RSO-14-101-B, "Radiation Safety Guidelines Regarding Personnel Monitoring," dated April 2014, states, in part, that the radiation safety officer will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

Contrary to the above, from April 2014 to May 28, 2019, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed

Enclosure

activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Specifically, the licensee's radiation safety committee failed to: (1) adequately review the radiation safety officer's quarterly summary report of occupational exposure records with regards to compliance with dosimeter usage; (2) adequately review at least annually the radiation safety officer's summary report of the radiation safety program to determine that activities were being conducted safely and in accordance with the regulations; and (3) recommend remedial action to correct deficiencies identified in the radiation safety officer's summary report of the radiation safety program with regards to compliance with dosimeter usage. Additionally, policy RSO-14-101-B and the Radiation Safety Plan failed to include provisions regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures.

- C. 10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, from January 2011 to May 28, 2019, the licensee failed to provide instruction to individuals who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide adequate instructions regarding the proper use of dosimeters to nine interventional radiologist physicians who were likely to receive in a year an occupational dose in excess of 100 mrem.

This is a Severity Level III Problem (NRC Enforcement Policy Section 6.7.c) Civil Penalty - \$7,500 (EA-20-051)

The NRC has concluded that information regarding: (1) the reason for the violations; (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 subject inspection report (ADAMS Accession No. ML20178A632) and in the summary of the predecisional enforcement conference (ADAMS Accession No. ML20232D160).

However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-20-051," and send it to U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511.

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.

You may pay the civil penalty proposed above in accordance with NUREG/BR-0254, "Payment Methods," (NRC's Agencywide Documents Access and Management System (ADAMS) Accession ML19163A244), and by submitting to the Director, Office of Enforcement,

U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. However, in recognition of the financial impact to licensees by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19), the NRC is extending the period of time by which the civil penalty must be paid from 30 days to 60 days from the date of this Notice. Should you fail to pay the civil penalty within 60 days of the date of this Notice, the NRC may issue an order imposing the civil penalty.

Should you elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation; EA-20-051" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty. Separately, you may request an additional extension of time to pay the civil penalty as a result of impacts to the licensee from COVID-19. Such an extension request must be in writing and should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 50 days from the date of this Notice (i.e., at least 10 days before the initial 60-day deadline to pay the civil penalty).

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, and the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and emailed to R4Enforcement@nrc.gov.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's 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 or proprietary 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 that such material is withheld from public disclosure, you must specifically identify the

portions of your response that you seek to have withheld and provide in detail the bases for your claim (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 are required to post this Notice within 2 working days of receipt.

Dated this 27th day of October 2020