



THE QUEEN'S MEDICAL CENTER

1301 Punchbowl Street ▪ Honolulu, Hawaii 96813 ▪ Phone (808) 538-9011 ▪ FAX: (808) 547-4646

July 20, 2020

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Reply to a Notice of Violation; EA-20-051

Licensee's name: The Queen's Medical Center (license 53-16533-02)

To whom it may concern,

This letter is written to document our receipt and our reply to the notice of violation; EA-20-051.

Description of the violation:

10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

1. The reason for the violation;
 - a. The administered dose of Y-90 microspheres was less than the prescribed dose due to failure of the micro-catheter. The occlusion of the catheter could not be overcome.
 - b. The checklist was based upon the manufacturer's checklist. We added more detail to fit our current practice but we did not add recommendations for troubleshooting as described in their package insert.
2. The corrective steps that have been taken and the results achieved;
 - a. All staff were retrained in the correct procedure for administration set-up and in the details of the administration procedure.
 - b. The TheraSphere policy and checklist was updated to better define roles and responsibilities and troubleshooting suggestions.
 - c. Since this incident, no deviations exceeding +/- 20% of the prescribed dose have occurred.
3. The corrective steps that will be taken;
 - a. We do not believe that any additional corrective steps are either warranted or required.
4. The date when full compliance will be (was) achieved.
 - a. June 26, 2019

Sincerely,

Dale Schippers, RSO, DABR

CC:

Ms. Mary Muessle, Director, Division of Nuclear Materials Safety,
Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011;
and emailed to R4Enforcement@nrc.gov