



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

January 29, 2020

Ms. Danielle Sheen, Director
Environmental Health and Safety
The Regents of the University of Michigan
1239 Kipke Drive
Ann Arbor, MI 48109-1010

SUBJECT: REISSUED – NRC SPECIAL INSPECTION REPORT NO. 03001988/2019003
(DNMS) – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

Dear Ms. Sheen:

On July 5, 2019, the U.S. Nuclear Regulatory Commission (NRC) issued NRC Special Inspection Report (No. 03001988/2019003 (ML19189A162)), which contained a Notice of Violation for two violations of Regulatory Requirements: 1) Title 10 of the *Code of Federal Regulations* (CFR) Section 35.63(d), and 2) 10 CFR 35.6(b)(2). Following the November 8, 2019, exit meeting for a routine inspection at your facility, you and your staff provided additional information regarding the NRC-identified characterization of those two violations. As a result, the NRC has re-evaluated those issues, and in light of the information provided, re-characterized the violations as licensee-identified Non-cited Violations in accordance with the NRC Enforcement Policy. The NRC is therefore reissuing the report in its entirety to reflect the updated results and to eliminate the previously enclosed Notice of Violation section, as it is no longer applicable.

From May 13, 2019 to June 17, 2019, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an in-office review regarding information provided by your staff pertinent to your radiation protection program. As a result, Mr. Gattone was made aware of two violations of NRC requirements. On June 17, 2019, Mr. Robert Gattone of my staff informed your radiation safety officer about the results of the in-office review.

Based on the results of the in-office review, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the licensee's: (1) administration of a dosage to a human research subject that differed from the prescribed dosage by more than 20 percent, contrary to 10 CFR 35.63(d); and (2) failure to obtain "informed consent," as defined and described in the Federal Policy, from the human research subject, contrary to 10 CFR 35.6(b)(2). These non-repetitive, licensee-identified, and corrected violations are being treated as Noncited Violations, consistent with Section 2.3.2.b of the Enforcement Policy.

The inspector determined that the root cause of the violations was human error (i.e., the research study team was less familiar with a consent document). Your staff implemented corrective actions to prevent similar violations on March 11, 2019. Specifically, the Principal Investigator provided the study team with training and a checklist to prevent similar violations. In addition, a separate source document was implemented to verify that human research subjects do not get scans until they are qualified and have completed informed consent.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein 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 IR 03001988/2019003 (DNMS)" 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 III, within 30 days of the date of this letter. 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and any response you provide will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Gattone if you have any questions regarding this inspection. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA/

Robert Ruiz, Acting Branch Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01988
License No. 21-00215-04

cc: State of Michigan
Mark Driscoll, RSO

Letter to Danielle Sheen from Robert Ruiz dated January 29, 2020.

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DATE	1/29/2020		01/29/2020					

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