



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 1, 2020

Ms. Danielle Sheen
Executive Director, Environment, Health & Safety
The Regents of The University of Michigan
1239 Kipke Drive
Ann Arbor, MI 48109-1010

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY
COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS*
(10 CFR) 35.610(d)(2)

Dear Ms. Sheen:

By letter dated May 13, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20134J117), The Regents of The University of Michigan, the licensee, requested an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) 35.610(d)(2) for NRC License No. 21-00215-04.

In its request, the licensee stated that, due to the COVID-19 public health emergency (PHE), it has made several changes in operations by following social distancing guidelines and institutional protocols to limit staff. These operational changes have led to challenges in providing annual operational and safety instructions to individuals who operate the licensee's high dose rate afterloader (HDR) unit, as required by 10 CFR 35.610(d)(2). As a result, the licensee requests regulatory relief in the form of a 90-day extension to provide these annual instructions.

The exemption provision in 10 CFR 30.11(a) states:

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the request in accordance with 10 CFR 30.11(a) and finds that the criteria contained therein are met. The regulation from which the licensee is requesting exemption is Title 10 of the *Code of Federal Regulations* (10 CFR) 35.610(d)(2). The regulation, in part, requires the licensee to provide operational and safety instructions initially and at least annually to all individuals who operate the HDR at the facility, as appropriate to the individual's assigned duties.

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions to Part 35. The NRC staff has determined that the granting of the requested exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

The regulation from which the licensee is requesting an exemption is the portion of 10 CFR 35.610(d)(2) that requires licensees provide operational and safety instructions at least annually to individuals who operate the HDR unit at the facility. The purpose of this exemption would be to allow the licensee to delay this annual instruction during the emergency caused by the COVID-19 PHE.

The NRC staff notes that, absent the requested exemption, additional staff would be required to come into the medical facilities and provide in-person instruction, increasing the possibility of exposing employees, contractors, patients, or members of the public to the COVID-19 virus. The NRC staff has also determined that the 90-day delay of annual instruction does not constitute a significant increase in risk to public health and safety. The licensee must continue to provide initial radiation safety instruction to individuals who operate the unit at the facility and must also continue to provide instruction in accordance with 10 CFR 35.610(d)(1). Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.

The licensee requested relief from the requirements described above during this PHE for a period no more than 90 days.

Based on the above findings, the NRC grants the following exemption for the specified period:

- Until September 8, 2020, the licensee is temporarily exempt from 10 CFR 35.610(d)(2) that the licensee must provide operational and safety instructions at least annually to individuals who operate the unit at the facility. The purpose of this exemption would be to allow the licensee to delay these annual instructions during the emergency caused by the COVID-19 pandemic.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(E). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC website at <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact Robert Gattone at robert.gattone@nrc.gov or 630-829-9823.

Sincerely,

Robert Orlikowski, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

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

Letter to Danielle Sheen from Robert Orlikowski dated June 1, 2020.

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