



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

November 30, 2020

Maxwell Amurao, Ph.D., MBA
Radiation Safety Officer
Washington University in St. Louis
660 S Euclid Avenue
Campus Box 8053
St. Louis, MO 63110-1093

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY COMMISSION (NRC) REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* (CFR) SECTION 35.610(e), FOR WASHINGTON UNIVERSITY IN ST. LOUIS, NRC LICENSE NOS. 24-00167-11

Dear Dr. Amurao:

By letter dated October 16, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20301A418), call on October 15, 2020 (ML20324A706), and as supplemented in a RAI response dated November 13, 2020 (ML20321A072), Washington University in St. Louis (the licensee) submitted to the U.S. Nuclear Regulatory Commission (NRC) Region III Office a request for an exemption from the Title 10 of the *Code of Federal Regulations* (CFR) Section [35.610\(e\)](#) requirements, regarding annual training and drills in the use of emergency procedures for remote afterloader units and gamma stereotactic radiosurgery units for NRC Materials License Nos. 24-00167-11. The NRC's ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In its request, the licensee stated that due to the COVID-19 public health emergency (PHE), they may be unable to fully complete training and emergency drills required by 10 CFR [35.610\(e\)](#) while adhering to social-distancing requirements. In the subsequent letter dated November 13, 2020 (Accession No. ML20321A072), the licensee stated that they have transitioned to drilling staff in small groups and training remains in progress. As of November 13, 2020, the licensee has completed 94% of required remote afterloader emergency procedure training and 74% of gamma stereotactic radiosurgery emergency procedure training. While the licensee anticipates completing all training prior to the regulatory deadline, it is requesting this exemption to ensure that no interruptions to patient care result due to training limitations created by the PHE.

The exemption provision in 10 CFR [35.19](#) states:

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that 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 NRC staff reviewed the request in accordance with 10 CFR [35.19](#) and finds that the criteria contained therein are met. The regulation from which the licensee is requesting a temporary exemption is 10 CFR [35.610\(e\)](#), to not provide annual training and drills in the use of emergency procedures for remote afterloader units and gamma stereotactic radiosurgery unit to operators, authorized medical physicists, and authorized users.

The regulation in 10 CFR [35.19](#) authorizes the granting of exemptions specific 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.

In its review, the NRC determined the relatively short delay of annual training and drilling does not constitute a significant increase in risk to public health and safety. The NRC staff notes that the licensee is continuing to take steps to ensure the majority of operators, authorized medical physicists, and authorized users receive their training in a timely manner. Additionally, the licensee must continue to ensure that operators, authorized medical physicists, and authorized users complete initial training in drills of emergency procedures in accordance with 10 CFR [35.610\(e\)](#).

The NRC staff notes that, absent the proposed exemption, additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee's employees, contractors, patients, or members of the general public to the COVID-19 virus. Additionally, the NRC staff notes that interruptions to patient care could result if the licensee were to complete all required training and drills prior to the annual requirement date. 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.

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

From December 31, 2020 until March 31, 2020 the licensee is exempted from the requirement in 10 CFR [35.610\(e\)](#) 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 this annual instruction during the emergency caused by the COVID-19 pandemic.

An environmental assessment for this action is not required, since this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (CFR) Section 51.22(c)(25)(vi)(H). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from NRC's ADAMS.

M. Amurao

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If you have any questions, please contact Laura Cender, at (630) 829-9712, or by email at laura.cender@nrc.gov.

Sincerely,

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

License No. 24-00167-11
Docket No. 030-02271
Mail Control No. 623490

cc: Cassandra Frazier

Letter to Maxwell Amurao from Robert Orlikowski dated November 30, 2020.

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ADAMS Accession Number: ML20332A161

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