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

June 2, 2020

Ms. Sheila Shaffer, M.S.
Radiation Safety Officer
Beaumont Health System
3601 W. 13 Mile Rd.
Royal Oak, MI 48073

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* 35.60(b), 35.61(a), 35.67(b)(2), 35.67(g), AND 35.310(a)

Dear Ms. Shaffer:

By email dated May 04, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20126G243), Beaumont Health System, the licensee, requested an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) 35.60(b), 35.61(a), 35.67(b)(2), 35.67(g), and 35.310(a).

In its request, Beaumont Health System stated that due to restricted access of areas of the hospital, and staff shortage due to redeployment, layoffs, or work from home status caused by the COVID-19 pandemic, these regulations cannot be safely met without increasing the possibility of exposing licensee's employees, contractors, patients, or members of the general public to the COVID-19 virus. Beaumont Health System request temporary exemption from the following requirements: 10 CFR 35.60(b), 35.61(a), 35.67(b)(2), 35.67(g), and 35.310(a).

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 regulations from which Beaumont Health System is requesting exemption are:

The requirement in 10 CFR 35.60(b) that the licensee calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions.

The requirement in 10 CFR 35.61(a) that the licensee calibrate survey instruments used to show compliance with 10 CFR Parts 20 and 35 annually.

The requirement in 10 CFR 35.67(b)(2) that the licensee test sealed sources and brachytherapy sources for leakage at intervals not to exceed 6 months at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

The requirement in 10 CFR 35.67(g) that the licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession.

The portion of 10 CFR 35.310(a) that requires licensees to provide radiation safety instruction at least annually to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75.

The regulation in 10 CFR 30.11(a) authorizes 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.

The extension of calibration time does not constitute a significant increase to the risk of failure of these instruments or to public health and safety. 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 regulation in 10 CFR 35.61(a) requires licensees to calibrate survey instruments used to show compliance with 10 CFR Parts 20 and 35 before first use, annually, and following repair. This exemption would only be from the requirement to perform annual calibrations, not to the requirement to perform calibrations before first use and following repair. The extension provided by this exemption is relatively short compared to the one-year time period between calibration of survey instruments. This relatively short extension does not constitute a significant increase in risk to public health and safety. 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 extension provided by exemption to 10 CFR 35.67(b)(2) is relatively short. In addition, licensees must still perform leak tests if the sources exhibit signs that the source might be leaking, such as increased dose rates of the patient following procedures, which would indicate significant leakage. Therefore, this exemption does not constitute a significant increase in risk to public health and safety. 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 extension provided by the exemption to 10 CFR 35.67(g) is relatively short. In addition, licensees must still maintain control of all sealed sources and brachytherapy sources per 10 CFR 20.1801 and 20.1802. Therefore, this exemption does not constitute a significant increase in risk to public health and safety. 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 extension provided by the exemption to 10 CFR 35.310(a) is a relatively short period 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 staff caring for patients or human research subjects who cannot be released. 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:

For instrumentation that, in accordance with the requirement in 10 CFR 35.60(b), is due to be calibrated between the date of this letter and 90 days after issuance, Beaumont Health System is temporarily exempt from the calibration time interval required by 10 CFR 35.60(b). The licensee may instead extend the required time interval for calibration of the instrumentation by the requested extension, up to 90 days. If the instrumentation exhibits signs that it might be malfunctioning, the licensee must suspend use of the instrumentation until it can be calibrated. This exemption does not apply to any instrumentation for which nationally recognized standards or manufacturer's instructions require calibration more frequently than once per month. In addition, this extension must not be combined with extensions in calibrations intervals recommended by nationally recognized standards due to the COVID-19 emergency. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to calibrate instrumentation as soon as is safely possible. Beaumont Health System requested to extend the required time interval for calibration during the emergency caused by the COVID-19 pandemic.

For instrumentation that, in accordance with the requirement in 10 CFR 35.61(a), is due to be calibrated between the date of this letter and 90 days after issuance, Beaumont Health System is temporarily exempt from the calibration time interval required by 10 CFR 35.61(a) and may instead extend the required time interval for calibration of the instrumentation by the requested extension, up to 90 days. If the instrumentation exhibits signs that it might be malfunctioning, the licensee must suspend use of the instrumentation until it can be calibrated. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to calibrate instrumentation as soon as is safely possible. Beaumont Health System requested to extend the time interval for calibration during the emergency caused by the COVID-19 pandemic.

For sealed sources or brachytherapy sources that, in accordance with the requirement in 10 CFR 35.67(b)(2), are due to be leak tested between the date of this letter and up to 90 days after issuance, Beaumont Health System is temporarily exempt from the requirements of 10 CFR 35.67(b)(2) and may instead extend the required time interval for leak testing of the sources by the requested extension, up to 90 days. If the source exhibits signs that it might be malfunctioning, the licensee must suspend use of the source until it can be leak tested. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to leak test sources as soon as is safely possible. Beaumont Health System requested to extend the leak test interval required by paragraph (b)(2) of this section for brachytherapy and/or sealed sources during the emergency caused by the COVID-19 pandemic.

For semi-annual physical inventory, in accordance with the requirement in 10 CFR 35.67(g), that is due to be made between the date of this letter and up to 90 days after issuance, Beaumont Health System is temporarily exempt from the requirements of 10 CFR 35.67(g) and may instead extend the required time interval for semi-annual physical inventory of the sealed sources or brachytherapy sources by the requested extension, up to 90 days. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to perform their semi-annual physical inventory as soon as is safely possible. Beaumont Health System requested to extend the semi-annual physical inventory interval required by paragraph g of this section for brachytherapy and/or sealed sources during the emergency caused by the COVID-19 pandemic.

From the date of issuance of this letter until 90 days after issuance**,** the licensee is temporarily exempted from the requirement in 10 CFR 35.310(a) that the licensee must provide annual instruction to personnel caring for patients or human research subjects who cannot be released

under 10 CFR 35.75. The purpose of this exemption would be to allow Beaumont Health System to delay this annual instruction 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)(C)-(E) and (F). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be 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 website at https://www.nrc.gov/reading-rm/adams.html.

In accordance with the letter dated April 7, 2020, (ML20094G166) addressed to all U.S. Nuclear Regulatory Commission Licensees Authorized to Possess Byproduct, Source and Special Nuclear Material to Include Nuclear Materials Users, Uranium Recovery, Decommissioning (Both Reactors and Materials), Fuel Cycle, and Spent Fuel Storage Facilities with The Exclusion of Operating Power Reactors and Research Test Reactors, should additional time beyond the expiration of the exemption of amendment be needed to restore compliance due to the COVID-19 PHE condition, the NRC would consider an extension to the exemption or amendment based on a subsequent request that updates all the information in the initial request.

If you have questions, please contact Erin Kennedy at erin.kennedy@nrc.gov or 630-829-9876.

Sincerely,

Robert J. Orlikowski

Digitally signed by Robert J. Orlikowski
Date: 2020.06.02 11:25:59 -05'00'

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

cc: Katherine Tapp
Lisa Dimmick

Letter to Sheila Shaffer from Robert Orlikowski dated June 2, 2020.

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