



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

May 15, 2020

Mr. Evan T. Western, CHP
Manager, Health Physics
Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY COMMISSION
REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* 20.2206(c)

Dear Mr. Western:

By letters dated April 30, 2020, and May 5, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession Nos. ML20125A008 and ML20126G395, respectively), Cardinal Health, the licensee, requested a temporary exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2206(c) for NRC License Nos. 34-29200-01MD and 34-31473-02MD.

In its request, the licensee stated that due to the COVID 19 public health emergency (PHE) the licensee has made several changes in business operations. These operational changes have led to challenges in compiling all individual dosimetry data for Form NRC 5 and in the validation of the data. Therefore, the licensee will not meet the reporting date requirement in 10 CFR 20.2206(c). As a result, the licensee requests regulatory relief in the form of a 45-day extension to the date set forth in 10 CFR 20.2206(c) to file and submit the required information.

The exemption provision in 10 CFR 20.2301 states:

The Commission may, upon application by a licensee or upon its own initiative, grant an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

The NRC staff reviewed the request in accordance with 10 CFR 20.2301 and finds that the criteria contained therein are met. On April 30, the NRC provided the licensee with a verbal approval of the exemption request. This approval was made after the licensee provided the information the NRC staff needed to review the request, the NRC staff determined that it understood the licensee's request, the NRC staff found that the requested exemption satisfied the criteria in 10 CFR 20.2301, and the NRC determined that sufficient time was not available for the NRC to provide a prior written decision for the exemption. This letter contains the written safety evaluation documenting the approval of the request. The regulation from which the licensee is requesting exemption is 10 CFR 20.2206(c). This regulation requires the licensee to file the annual individual radiation monitoring report covering the preceding year as required by 10 CFR 20.2206(b), on or before April 30 of each year and submit the report to the REIRS Project Manager.

The regulation in 10 CFR 20.2301 authorizes granting of exemptions specific to Part 20. 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 NRC staff has determined that the 45-day extension provided by this exemption is relatively short compared to the annual reporting period. The NRC notes that the licensee will continue to monitor the internal and external occupational dose for its workers in accordance with 10 CFR 20.1502 during the period of the exemption request. In addition, the licensee will immediately, or within 24 hours, report to the NRC any radiation over exposures as specified in 10 CFR 20.2202. The licensee will also provide a 30 days report to the NRC for the over exposures specified in 10 CFR 20.2203 and, in accordance with 10 CFR 20.2205, a report to each individual who exceeded the dose limits specified in 10 CFR 20.2203 and 20.2204. Therefore, the exemption does not constitute a significant increase in risk to public health and safety. The NRC staff finds that the requested exemption would not result in undue hazard to life or property. The NRC also notes that, absent the requested exemption, the licensee may be required to take actions that may be contrary to guidance on preventing the spread of the virus that causes COVID-19.

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

The licensee is temporarily exempt from the NRC regulation requirement stated in 10 CFR 20.2206(c). The licensee shall perform the required filing and submit the annual individual radiation monitoring reports in accordance with 10 CFR 20.2206(c) no later than June 15, 2020.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(B). 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 Frank Tran at frank.tran@nrc.gov or 630-829-9623.

Sincerely,

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

License Nos. 34-29200-01MD
and 34-31473-02MD
Docket Nos. 030-36973 and 030-38569

Letter to Evan Western from Robert Orlikowski dated May 15, 2020.

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* 20.2206(c)

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