



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

June 26, 2020

Matthew Daut, Sr. Manager EHS
Siemens Medical Solutions USA, Inc.
221 Gregson Drive
Cary, NC 27511

SUBJECT: TEMPORARY EXEMPTION FROM TITLE 10 CODE OF FEDERAL
REGULATIONS 30.34(c) AND PART OF LICENSE CONDITION 17 OF NRC
LICENSE 32-35165-01, SIEMENS MEDICAL SOLUTIONS USA, INC., MAIL
CONTROL NO. 621121

Dear Mr. Daut:

By letter dated May 18, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20160A024), Siemens Medical Solutions USA, Inc. (Siemens), the licensee, requested an exemption from the portion of License Condition 17.A. of NRC License No. 32-35165-01 that requires the licensee to enforce the commitment stated in its license application to exchange personnel extremity dosimeters issued to certain employees on a quarterly basis.

In its request, the licensee stated that their vendor, Mirion Technologies, is experiencing a shortage of extremity dosimeters. According to correspondence between Siemens and Mirion, this shortage is due to the COVID-19 public health emergency (PHE) (ML20177A243). Siemens requests that the dosimeters it originally intended to be used from April 2020 through June 2020, a period of three months, be used through September 2020, resulting in a three-month extension. The licensee's historic exposure records indicate that its workers' exposures are consistently within regulatory limits. If an event occurs that results in a potential over-exposure of ionizing radiation to its workers, the licensee's extremity dosimeters can be expeditiously processed. The quarterly exchange of extremity dosimeters is required by License Condition 17.A., which enforces the commitment stated in the licensee's application to exchange extremity dosimeters on a quarterly basis.

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 license condition from which the licensee requested exemption was imposed upon the licensee by the U.S. Nuclear Regulatory Commission (NRC) per 10 CFR 30.34(e). The regulation in 10 CFR 30.34(c) requires that the licensee confine its use of the byproduct material to the locations and purposes authorized in the license. Therefore, exemptions to the

requirement in 10 CFR 30.34(c) to comply with the terms of a license may be granted pursuant to 10 CFR 30.11.

The NRC staff reviewed the request in accordance with 10 CFR 30.11(a) and finds that the criteria contained therein are met. The requirement from which the licensee is requesting exemption is:

The portion of License Condition 17.A. that requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in the application dated August 6, 2014 (ML14230A072), specifically the statement that for personnel who work on radiation generating equipment or work with radiation sources, extremity rings will be exchanged quarterly in accordance with the following wear periods: January 1 – March 31, April 1 – June 30, July 1 – September 30, October 1 – December 31.

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions specific to Part 30. 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 also determined that the three-month duration of this exemption is relatively brief compared to the required dosimetry exchange interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety. The NRC also notes that, absent the requested exemption, the licensee's medical clientele may not be able to provide needed medical care. Therefore, the NRC staff finds that the requested 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:

The licensee is exempt from the quarterly extremity dosimeter exchange required by License Condition 17.A. for the wear period of April 2020 through June 2020. The licensee shall perform its next exchange of extremity dosimeters on or before September 30, 2020. The licensee shall resume its quarterly exchange of extremity dosimeters for the wear period of October 2020 through December 2020, as required by License Condition 17.A.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(C). 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 Web site at <https://www.nrc.gov/reading-rm/adams.html>.

M. Daut

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If you have questions, please contact Michael Reichard at Michael.Reichard@nrc.gov or 610-337-6945.

Sincerely,

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 32-35165-01
Docket No. 030-38762
Mail Control No. 621121

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35165-01, SIEMENS MEDICAL SOLUTIONS USA, INC., MAIL CONTROL NO. 621121,
DATED JUNE 26, 2020

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SUNSI Review Complete: Michael Reichard

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