



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

October 26, 2020

Michelle White, BA, CNMT
Radiation Safety Officer
Avera McKennan/Nuclear Medicine
1325 S. Cliff Ave
Sioux Falls, SD 57117-5045

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY
COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS*
(10 CFR) 30.34(C)

Dear Ms. White:

By email dated April 27, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20119A005), in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.11(a), Avera McKennan/Nuclear Medicine, holder of a specific license issued in accordance with 10 CFR Part 35, requested an exemption from the requirements listed in condition 13.C. of the NRC license number 40-16571-02. The NRC granted the exemption in a letter dated April 30, 2020 (ADAMS Accession No. ML20121A234). In a subsequent email dated July 30, 2020, the licensee requested another 90-day extension to the exemption granted in April 30, 2020 (ADAMS Accession No. ML20212L520). The NRC granted a second exemption in a letter dated July 30, 2020 (ADAMS Accession No. ML20212L537). Due to the continuation of the COVID-19 public health emergency, the licensee requested in an email dated October 8, 2020 (ADAMS Accession No. ML20282A759) a 1-year extension to the exemption granted in July 30, 2020. Subsequently, in an email dated October 14, 2020 (ADAMS Accession No. ML20288A511), the licensee agreed to a 90-day extension and will submit a license amendment request in the interim to make the requested modification part of the NRC license.

In its request and subsequent information provided, Avera McKennan/Nuclear Medicine stated that due to movement restrictions imposed by a common carrier to its staff as a result of the COVID-19 pandemic, the common carrier will not be able to deliver licensed material to a designated area inside the hospital as required by condition 13.C. of the NRC license. Condition 13.C. 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. The licensee proposed that, if exempted from the delivery requirements of condition 13.C. of the NRC license, it would allow the common carrier to deliver packages containing licensed material to a licensee's management team member at a designated area not inside the hospital. Furthermore, the team member will lock the package containing radioactive material in a designated area and will contact the appropriate radiation safety team member to retrieve the package. In addition, the radiation safety team will instruct the management team on how to complete these steps.

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 conditions from which the licensee requested exemption were 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 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 Avera McKennan/Nuclear Medicine is requesting an exemption is the requirement in condition 13.C. of NRC license number 40-16571-02 that identifies designated restricted areas inside the hospital where common carriers will deliver, and the licensee will receive, licensed material. The licensee requested relief from condition 13.C. to allow a common carrier to deliver packages containing licensed material in an area other than the designated areas inside the hospital during the emergency caused by the COVID-19 pandemic.

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 determined that this exemption is appropriate as the common carrier will require signature and will only leave the material with specific members of the licensee's management team, ensuring adequate control of the radioactive material following delivery. The NRC staff notes that, absent the proposed exemption, additional individuals would need to enter the hospital, which would increase the possibility of exposing licensee's employees, contractors, patients, or members of the general public to the virus that causes COVID-19. Therefore, the NRC staff finds that the proposed exemption, limited to 90 days rather than the 1-year request made by the licensee, 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 the date of issuance of this letter until 90 days after issuance, the licensee is temporarily exempted from the requirement in condition 13.C. of NRC License Number 40-16571-02 that identifies the designated areas inside the hospital where licensed material may be delivered by a common carrier. Licensed material may be delivered in an area not inside the hospital (dock area) provided that:

1. the management team receives and temporarily stores the licensed material in a locked area and/or provides constant surveillance until picked up by the radiation safety staff, in accordance with the licensee's commitments made in condition 13.D.,

2. licensed material is not left unsecured and unattended, in accordance with the licensee's commitments made in condition 13.D., and
3. the management team receives radiation safety training commensurate with its duties, in accordance with the licensee's commitments made in condition 13.D.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(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 Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact Roberto J. Torres at 817-200-1189.

Sincerely,

Heather J. Gepford, Ph.D., CHP, Chief
Materials Licensing & Decommissioning Branch
Division of Nuclear Materials Safety Region IV

Docket: 030-39216
License: 40-16571-02

TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY COMMISSION
 REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* (10 CFR) 30.34(c)
 DATED – OCTOBER 26, 2020

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