



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 5, 2020

All Holders of, and applicants seeking,
U.S. Nuclear Regulatory Commission (NRC)
Licenses Authorizing Medical Use
Under 10 CFR Part 35 and
NRC Master Materials Licensees

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION PLANNED ACTIONS RELATED TO CERTAIN REQUIREMENTS FOR TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* PARTS 19, 20, 30, AND 35 DURING THE CORONAVIRUS DISEASE 2019 PUBLIC HEALTH EMERGENCY

As you know, on January 31, 2020, the U.S. Department of Health and Human Services declared a public health emergency (PHE) for the United States to aid the nation's healthcare community in responding to the Coronavirus Disease 2019 (COVID-19). On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization. The U.S. Nuclear Regulatory Commission (NRC) is aware that during this COVID-19 PHE, each licensee may experience regulatory challenges for which they may seek relief. By letter dated April 7, 2020 (Agencywide Documents Access and Management System Accession No. ML20094G166), *U.S. Nuclear Regulatory Commission Methods for Providing Regulatory Relief During the Coronavirus Disease 2019 Public Health Emergency*, the Director of the Office of Nuclear Material Safety and Safeguards outlined potential regulatory options for licensees (including byproduct material, uranium recovery, decommissioning (both materials and reactors), fuel facilities, and spent fuel storage facilities) to seek regulatory relief that may be necessary during the COVID-19 PHE. One of the options described in the April 7 letter is specific exemptions.

In all of our actions, the NRC staff continues its commitment to following the NRC's Principles of Good Regulation (independence, openness, efficiency, clarity, and reliability) while performing our mission. In keeping with these principles, this letter provides information regarding licensee requests for temporary exemptions from certain Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 19, 20, 30, and 35 requirements during the COVID-19 PHE, and the process that the NRC plans to use when reviewing such requests. The NRC plans to issue separate information regarding licensee requests for 10 CFR Part 37 temporary exemptions.

Under the NRC's regulations in 10 CFR 19.31, "Application for Exemptions" and 20.2301, "Application for Exemptions," the NRC may grant exemptions from the requirements of the regulations in parts 19 and 20, respectively, if it determines that the exemptions are authorized by law and would not result in undue hazard to life or property. Under the NRC's regulation in 10 CFR 30.11, "Specific Exemptions," the NRC may grant exemptions from the requirements of the regulations in parts 30, 31 through 36, and 39 if the NRC determines that the exemptions are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Consistent with these regulations, this letter contains information that may inform licensee requests for exemptions from certain requirements in 10 CFR Parts 19, 20, 30, and 35. As

described below, the NRC is prepared to review expeditiously temporary exemption requests submitted by individual licensees. The objective of this expedited review process is to facilitate the processing of licensee requests for temporary exemption from certain regulatory requirements to ensure that the requirements do not unduly limit licensee flexibility in using personnel resources in a manner that most effectively manages the impacts of the COVID-19 PHE to maintain the safe and secure operation of licensed activities. Additionally, these temporary exemptions would, if granted, facilitate the licensee's implementation of its radiation safety program in a manner that does not conflict with practices recommended by the Centers for Disease Control and Prevention to limit the spread of the coronavirus.¹

When a licensee expects that it will not be able to comply with one or more of the requirements authorized by its materials license, the licensee should, as soon as practicable, notify the NRC in writing that it is requesting a temporary exemption from the specific subsection(s) of the regulations. To aid the NRC in its expedited review, any such request should, at a minimum, include the following information:

- a statement that the licensee expects that it will no longer be able to comply with the requirements of the specific subsection(s) of 10 CFR Part 19, 20, 30, and 35;
- the site-specific reason that the COVID-19 PHE prevents the licensee from being able to meet the specific regulatory requirement from which it is seeking an exemption; and
- the specific regulatory provision from which the licensee is seeking an exemption.

Provision of all the requested information will facilitate the NRC's expedited review of licensee exemption requests.

10 CFR Parts 19, 20, 30, and 35 Requirements for Which NRC May Consider Expedited Requests for Temporary Exemption

The NRC staff has received several requests from medical use licensees for regulatory relief due to the COVID-19 PHE. On April 22, 2020, the NRC staff held a public meeting to hear from medical licensees about the types of exemptions they think they might need during the PHE. Additionally, on April 30, 2020, the Advisory Committee on the Medical Use of Isotopes (ACMUI) held a public meeting to discuss the ACMUI COVID-19 Subcommittee report, "Proposal for NRC Regulatory Relief Options during COVID-19 Pandemic." The attached table contains a list of regulatory requirements, the exemption from which may be suitable for expedited review.

How to Submit Requests

Licensees should make every effort to submit timely exemption requests in accordance with 10 CFR 19.5, "Communications," 20.1007, "Communications," or 30.6, "Communications," as applicable. To ensure the timely receipt and review of these exemption requests, licensees that plan to request an expedited review should contact their facility's NRC project manager or Regional office for assistance before submitting the request. An email to the facility's NRC

¹ The recommended Centers for Disease Control and Prevention practices can be found at the following website: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html> (last visited April 29, 2020).

project manager or Regional Office from a senior level licensing manager² with decision-making authority with a copy to the NRC Document Control Desk is an acceptable format for the written exemption request. In addition, exemption requests may be submitted online. To submit requests for exemptions, see the nuclear materials relief request form at <https://www.nrc.gov/about-nrc/covid-19/materials/>.

Review Process

The NRC will consider these requests on a case-by-case basis and, if the requirements for an exemption are met, will provide a written decision. If sufficient time is not available for the NRC to provide a prior written decision for the exemption, then the NRC may provide a verbal decision that will be followed promptly by a written evaluation documenting the approval or a letter documenting the denial of the request.

Duration of Exemption

Most exemptions that the NRC has approved so far under this expedited process are in effect for a period of 30, 90, or 120 days. Licensees must come back into compliance with the Parts 19, 20, 30, and 35 regulations by the deadline specified in the exemption or receive approval for an additional exemption period from the NRC. As with the initial approval, subsequent approvals would be granted in writing or verbally, depending on the timing of the licensee's request.

Alternative Approaches

This letter does not preclude requests for exemptions that take a different approach or present different rationales or proposed end dates. The NRC cannot guarantee expedited consideration of such requests.

Further Questions

If you have any further questions about this matter, please contact Lisa Dimmick (Lisa.Dimmick@nrc.gov) of my staff for assistance.

Paperwork Reduction Act

This letter contains information regarding implementing the voluntary information collections related to requesting exemptions from requirements contained in 10 CFR Parts 19, 20, 30 and 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget under control numbers 3150-0044, -0014, -0017, -0010, respectively. Send comments regarding these information collections to the Information Services Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, Office of Management and Budget, Washington, DC 20503.

² Region I-issued materials licenses, James Trapp, RI/Division of Nuclear Materials Safety (DNMS), James.Trapp@nrc.gov; Region III-issued materials licenses, David Pelton, RIII/DNMS, David.Pelton@nrc.gov; Region IV-issued materials licenses, Mary Muessle, RIV/DNMS, Mary.Muessle@nrc.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Sincerely,

Kevin Williams, Deputy Director
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Medical Use Licensee Temporary Exemptions

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION PLANNED ACTIONS RELATED
TO CERTAIN REQUIREMENTS FOR TITLE 10 OF THE *CODE OF FEDERAL
REGULATIONS* PARTS 19, 20, 30, AND 35 DURING THE CORONAVIRUS
DISEASE 2019 PUBLIC HEALTH EMERGENCY

DATED: MAY 5, 2020

DISTRIBUTION:

Public
MLayton, NMSS
KWilliams, NMSS
CEinberg, NMSS
LDimmick, NMSS

ADAMS Accession Number: ML20126G385 - Package

***via email**

OFFICE	NMSS/MSST	NMSS/MSST	OGC	NMSS/MSST
NAME	LDimmick	CEinberg	EHouseman	KWilliams
DATE	5/5/2020	5/5/2020	5/5/2020	5/5/2020

OFFICIAL RECORD COPY