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

December 15, 2020

MEMORANDUM TO: Christian Einberg, Chief
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Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

FROM: Sarah L. Lopas, Project Manager
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SUBJECT: SUMMARY OF NOVEMBER 17, 2020, U.S. NUCLEAR REGULATORY COMMISSION PUBLIC MEETING ON REGULATORY RELIEF FOR MEDICAL AND OTHER MATERIALS LICENSEES DURING THE COVID-19 PUBLIC HEALTH EMERGENCY

Meeting Identifier: 20201295

Date of Meeting: Tuesday, November 17, 2020; 1:00 p.m. EST

Location: Webinar

Type of Meeting: Category 3

Purpose of the Meeting: To summarize the status of existing Coronavirus disease (COVID-19) regulatory relief available to U.S. Nuclear Regulatory Commission (NRC) medical, industrial, and academic materials licensees, and to obtain feedback from licensees and stakeholders on their use of the available regulatory relief and any additional relief that may be needed during the ongoing COVID-19 public health emergency (PHE).

Background Information: On January 31, 2020, the U.S. Department of Health and Human Services declared a PHE for the United States to aid the nation's healthcare community in responding to COVID-19. On April 7, 2020, the NRC issued a letter to its byproduct material, uranium recovery, decommissioning, fuel cycle, and spent fuel storage licensees that outlined options to seek regulatory relief that may be necessary during the COVID-19 PHE. This letter is available in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. ML20094G166. In April and early May 2020, the NRC then held a series of information meetings on PHE-related temporary regulatory relief for licensees under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," Part 35, "Medical Use of Byproduct Material," and Part 37, "Physical Protection of Category 1 and 2 Quantities of

Radioactive Material." Summaries of these initial meetings are available in ADAMS at Accession No. ML20135G471 for 10 CFR Part 35 licensees, Accession No. ML20136A218 for 10 CFR Parts 30 and 34 licensees, and Accession No. ML20134H965 for 10 CFR Part 37 licensees. Following the initial meetings, in May 2020 the NRC issued letters to these licensees outlining the available temporary regulatory relief and process for applying for this relief. These letters are available in ADAMS at Accession Nos. ML20126G386 and ML20233B145 for medical licensees, Accession No. ML20133K127 for 10 CFR Parts 30 and 34 licensees, and Accession No. ML20134H934 for 10 CFR Part 37 licensees. The NRC also issued Enforcement Guidance Memorandum (EGM) 20-002 and its attachments in spring 2020, which discuss different areas of enforcement discretion that can be applied by NRC inspectors during the PHE if licensees meet certain criteria (Accession Nos. ML20083K794, ML20136A085, and ML20143A066).

General Details: The NRC recognizes that as the PHE continues into 2021 and worsens in many parts of the country, medical and other materials licensees may continue to experience challenges in meeting certain regulatory requirements. The NRC staff held a public meeting on November 17, 2020 to discuss medical and other materials licensees' ongoing need for temporary regulatory relief related to the PHE. The NRC published the official public meeting notice on November 2, 2020, providing the agenda and webinar registration instructions for attendees (Accession No. ML20307A666).

The meeting was conducted remotely via webinar and began at 1:00 p.m. EDT with a 20-minute presentation by NRC staff on existing regulatory relief pathways, examples of temporary exemptions that have been approved to date, and NRC consideration of additional regulatory relief (e.g., an enforcement guidance memorandum for licensees that have continued, or are restarting, operations). The NRC staff also noted that Agreement States are handling their COVID-19 responses individually, and Agreement State licensees should contact their State regulatory agency regarding potential relief pathways. The staff's slide presentation is available in ADAMS at Accession No. ML20310A440.

Following the staff's presentation, the meeting was then opened to receive public comments and questions. Approximately 174 people participated in the meeting. A list of NRC meeting participants is enclosed. The meeting concluded at 2:05 p.m. EST. The staff has summarized the comments and questions below.

Summary of Questions and Comments Received:

Specific Exemption Circumstances

One participant asked whether an exemption is needed for sealed source leakage and inventory requirements when a facility is closed due to the PHE. NRC staff responded that an exemption request should be submitted, but to first check with the NRC project manager, because in some circumstances, a sealed source that is not being used can be classified as "in storage" and a leak test can be performed when the facility reopens and before the device is first used again.

Another commenter asked about a temporary exemption for physical presence requirements for gamma knife treatments, noting that the gamma knife console area is a small space that doesn't allow for physical distancing. The NRC staff advised that the licensee would need to submit an exemption request with additional details regarding any telemedicine considerations.

NRC Inspections During the COVID-19 Public Health Emergency

A number of questions were asked about NRC inspections during the PHE, including whether they would be conducted virtually or on-site, and if they were to be conducted on-site, would those inspections be announced? One commenter noted that their facility was not allowing visitors during the PHE, and another commenter added that only essential personnel were currently allowed on-site. The NRC staff responded that currently, all inspections are announced so that licensees have time to prepare and NRC staff can accommodate any COVID-19 related safety protocols that are required by the licensees. The NRC staff responded that inspections may be conducted in a hybrid-type manner, with a visit to the site but review of the program done remotely through teleconference interviews and requests for electronic documents. The staff noted that inspections are conducted remotely where appropriate and possible, and they involve video conference techniques. The NRC is continuing to assess optimal approaches for use of remote inspection techniques to support consistent implementation across the agency.

A representative of the Agreement States asked whether the NRC was following-up remote inspections with in-person inspections. The NRC staff replied that if an inspection is conducted remotely, the NRC may decrease the time interval between the next inspection (effectively moving up that next inspection) so that the staff can follow-up in-person at that time.

A few commenters asked how the NRC was protecting the safety of licensees during inspections, including whether NRC inspection staff would comply with licensee protocols for COVID-19 precautions, including on-site COVID-19 testing. The staff replied that NRC inspectors are taking measures such as using personal protective equipment and maintaining social distancing, and that NRC inspectors would seek to cooperate fully with any safety measures required by NRC licensees, including compliance with a licensee's COVID-19 testing protocol.

Virtual Training for Physician Authorized Users

There was a question about exemptions for hands-on training requirements for authorized users, and whether the NRC was considering requests for virtual training. A follow-up question, related to virtual training, asked whether physicians earning American Board of Nuclear Medicine certificates during the PHE would still be "specialty board eligible" for authorized user status. The NRC staff noted that an exemption from a regulation related to training via the board certification pathway will need to be submitted by the medical specialty board, detailing the circumstances and the specifics of the virtual training, and how the proposed training would continue to satisfy the NRC's training and work experience requirements for authorized users. The staff noted that there is no change to the NRC's recognition of American Board of Nuclear Medicine certificates issued during the PHE.

Exemption Request Process

One commenter asked whether there was a deadline to submit exemption requests. Another commenter asked about how long it took for the NRC to review exemption requests. The NRC staff responded that licensees should submit exemption requests as soon as the need is identified, ideally requesting the exemption with sufficient time for NRC review before a violation occurs. The staff noted that the NRC's exemption request review process has typically been taking between two and four weeks.

NRC Mailing Lists

A number of commenters asked how to be added to materials licensee mailing lists. The NRC has a Medical List Server for automatic e-mail notifications of medical-related generic communications, *Federal Register* notices, and topics that may be of interest to the medical community. To subscribe to the NRC's Medical List Server, send an e-mail to Medical-GC.Resource@nrc.gov with the word "subscribe" in the subject line. Other materials licensees should contact Lymari.Sepulveda@nrc.gov to be added to the 10 CFR Parts 30 and 34 licensee distribution list, and Paul.Goldberg@nrc.gov for the 10 CFR Part 37 licensee distribution list.

Next Steps: The NRC staff will continue to evaluate the need for additional PHE-related regulatory relief, including additional requirements that may be suitable for expedited review of temporary exemption, and the need for additional enforcement discretion for licensees that have continued or are restarting operations. Visit the NRC's website, "COVID-19 Regulatory Activities for Nuclear Materials – Medical, Industrial & Academic Uses of Nuclear Materials and Agreement States," for updated information: https://www.nrc.gov/about-nrc/covid-19/materials/med-indust-academic.html.

ENCLOSURE:
NRC Meeting Participants

U.S. NUCLEAR REGULATORY COMMISSION MEETING TO DISCUSS TEMPORARY REGULATORY RELIEF FOR MEDICAL AND OTHER MATERIAL LICENSEES DURING THE ONGOING COVID-19 PUBLIC HEALTH EMERGENCY

November 17, 2020

NRC Meeting Participants

Name	NRC Affiliation
David Alley	Chief, Material Safety and Tribal Liaison Branch (MSTB), Office of Nuclear Material Safety and Safeguards, Division of Materials Safety, Security, State, and Tribal Programs (NMSS/MSST)
Maryann Ayoade	NMSS/MSST, Medical Safety and Events Assessment Branch (MSEB)
Michelle Burgess	NMSS/MSST/MSEB
Lisa Dimmick	Medical Team Leader, NMSS/MSST/MSEB
Chris Einberg	Chief, NMSS/MSST/MSEB
Paul Goldberg	NMSS/MSST, Source Management and Protection Branch (SMPB)
Tomas Herrera	NMSS/MSST/MSTB
Ian Irvin	Office of the General Counsel
Kellee Jamerson	NMSS/MSST/MSEB
Sarah Lopas	NMSS/MSST/MSEB
Tim Mossman	Chief, NMSS/MSST/SMPB
Juan Peralta	Chief, Office of Enforcement, Enforcement Branch
Randy Ragland	Region I, Division of Nuclear Material Safety, Commercial, Industrial, R&D, and Academic Branch
George Smith	NMSS/MSST/SMPB
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Katie Wagner	NMSS/MSST/MSTB
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