



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

May 15, 2020

MEMORANDUM TO: David Alley, Chief
Medical Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

FROM: Lymari Sepulveda, Mechanical Engineer
Materials Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

A handwritten signature in blue ink, appearing to read "Lymari Sepulveda".

SUBJECT: SUMMARY OF APRIL 23, 2020, PUBLIC SEMINAR TO DISCUSS
TEMPORARY REGULATORY RELIEF PATHWAYS FOR TITLE 10 OF
THE *CODE OF FEDERAL REGULATIONS* PART 30 AND 34 THE
U.S. NUCLEAR REGULATORY COMMISSION RADIOACTIVE
MATERIALS LICENSEES DURING THE COVID-19 PUBLIC HEALTH
EMERGENCY

Meeting Identifier: 20200419

Date of Meeting: Thursday, April 23, 2020; 1:00 p.m. EDT

Location: Webinar with Moderated Bridge Line

Type of Meeting: Category 3

Purpose of the Meeting: The purpose of this seminar was to discuss the ability of licensees to request exemptions from certain regulations contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30 and 34 during the COVID-19 public health emergency (PHE). Additionally, the U.S. Nuclear Regulatory Commission (NRC) staff requested input concerning the regulations from which types of exemptions may be required during the ongoing public health emergency.

General Details: 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 the Coronavirus disease (COVID-19). The NRC recognizes that during the current COVID-19 PHE, licensees may experience challenges in meeting certain regulatory requirements. On

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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](#).

On April 23, 2020, the NRC's Materials Safety and Tribal Liaison Branch held a public meeting to expand upon the information contained in the April 7 regulatory relief letter. The meeting was conducted remotely through use of webinar and an operator-moderated bridge line. There were approximately 248 participants in the meeting. The public meeting notice was issued on April 20, 2020 (ADAMS Accession No. [ML20114E062](#)). The meeting notice provided webinar registration and bridge line instructions for attendees.

The meeting began at 1:00 p.m. EDT with a 25-minute presentation by NRC staff on regulatory relief pathways and the process by which Part 30 & 34 material licensees can request temporary regulatory exemptions (See Staff's Presentation ADAMS Accession No. [ML20114E015](#)). During the presentation, the staff indicated that on April 17, 2020, the NRC issued exemption templates for specific types of requirements under 10 CFR Part 30 and 34. The staff provided examples of recent actions related to license conditions including area surveys, source inventories, routine door lock checks, etc. One exemption that has been approved for 10 CFR Part 34 is relief for a radiographer certifying agency for radiography certifications that are set to expire from March 31 – September 30, 2020.

Following the staff's presentation, the meeting was opened to receive public questions and comments. Nine participants asked questions and/or provided comments. During the meeting, the NRC received multiple comments and questions regarding Part 37 licensees. The NRC stated that if an exemption of Part 37 is required licensee should reach out to the Regional representative to discuss the need for the request. The public meeting for 10 CFR Part 37 exemptions was subsequently held May 5, 2020.

Comments and questions received during the meeting can be found in the Enclosure.

Next Steps: Part 30 & 34 licensees should continue to make requests through their respective regional offices. The NRC will continue to review these requests as quickly as practicable.

Enclosure:
As stated

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DATE: May 15, 2020

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**ADAMS Accession Nos.: PKG ML20136A218; Meeting Summary ML20136A167
NRC Slide Presentation ML20114E015; Meeting Notice ML20114E062**

***via email**

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Public Seminar to Discuss Temporary Regulatory Relief Pathways for 10 CFR Part 30 and 34 NRC Radioactive Materials Licensees during the Covid-19 Public Health Emergency

Summary of Comments and Questions Received

No.	Comments/Questions	NRC Response
1.	Why would someone need an exemption if a device is in storage?	Leak testing of devices in storage is not generally required for devices regulated under Part 34 (see 10 CFR 34.27(c)(3)). Devices regulated under other parts and specific license conditions for devices regulated under Part 34 may require testing. Licensees should verify and comply with the requirements of their license or request an exemption.
2.	Will the NRC recognize exemptions issued by an Agreement State to an Agreement State licensee working under reciprocity in NRC jurisdiction, if the exemption affects items reviewed during reciprocity inspections?	The answer to this question is currently under review by the NRC. When an answer becomes available it will be posted at: https://www.nrc.gov/about-nrc/covid-19/materials/med-indust-academic.html
3.	Can exemptions be granted retroactively for scheduled items such as survey frequency?	Exemptions are not retroactive; however, enforcement discretions could be exercised, if warranted.
4.	Compliance with 10 CFR 20.1101 annual inspections will be difficult, as they are usually performed in person. Currently, this commenter indicated that to meet the due date, the annual review of the radiation protection program content and implementation is being performed remotely from a corporate office.	NRC does not specify how the annual review is performed by licensees. It may be possible for licensees to successfully perform annual reviews remotely.
5.	Should the guidance being provided during this meeting be considered applicable to a 10 CFR Part 70 license that is also a Type A broad scope licensee.	The number of exemption requests coming from broad scope licensees that possess source and special nuclear material is expected to be small and the guidance provided for 10 CFR Part 30 may be applied to broad scope licensees who also possess source and special nuclear material.
6.	How would a request for exemption from a 6-month inventory ensure security of sealed sources housed at a remote facility if they cannot be inventoried because of travel restrictions.	Current exemption templates provide relief for only 90 days and that was considered acceptable given the current conditions.

7.	Is the NRC aware if licensees are able to support routine in-person inspections? If so, what conditions would be necessary?	Access restrictions associated with the COVID-19 public health emergency (PHE) have prevented licensees from gaining full site access to licensed facilities. These restrictions have also impacted NRC's inspections of these facilities. The NRC has delayed some in-person inspections due to covid-19. The NRC will consider remote inspections on a case-by-case basis.
8.	If our location has continued operations, but we have not used the nuclear sources since the shelter in-place orders, will that count as suspended operations?	When reviewing an exemption request, one of the factors the NRC may consider is whether the licensee has suspended its use of licensed material. Generally, a licensee that has placed its licensed nuclear material in safe storage and therefore is not using the material has suspended its use of licensed material, even if the licensee has not suspended other operations.
9.	Based on a previous comment regarding remote inspections being done in some Agreement States, is the NRC already performing remote inspections for materials licensees?	Some remote inspections have been performed by the NRC for a very limited number of activities associated with independent spent fuel storage installations in Region I. In addition, some inspection items, such as record reviews, can be performed remotely. The NRC staff reiterated that remote inspections are being considered.
10.	Will the NRC require licensees to submit supplemental documentation related to mitigation of potential hazards with exemption requests.	When an exemption is requested, licensees should describe any compensatory measures they are taking to ensure the safety and security of licensed materials subject to the exemption. If the NRC determines that licensed material can remain safe and secure, then an exemption may be granted.
11.	We are following the guidance provided for Part 35 licensees. The guidance being discussed at this meeting is for 10 CFR Parts 30 and 34. Are there any plans to look at other Parts of 10 CFR for exemptions?	This was a considered during the development of the exemption information for 10 CFR Parts 30 and 34 but based on the limited quantity of NRC licensees with NRC licenses for 10 CFR Parts 36 and 39 activities, the NRC decided that the guidance provided for 10 CFR Parts 30 and 34 could be used to inform its evaluation of any 10 CFR Parts 36 or 39 requests on a case-by-case basis.
12.	Currently, the broad scope license in-person audit review has been suspended at a certain university licensee since the university is closed except for essential research. All other activities are currently suspended until further notice. Is this acceptable to suspend this audit review? And	The NRC does not specify how an annual program review must be performed. Licensees could attempt to conduct their reviews remotely based on emails or discussions with cognizant personnel. Note that this is an annual program review. Therefore, some programs will have performed routine audits during the year and that will help provide an understanding of the status of the program. This will help to evaluate the safety of the material program. If a licensee determines

	The biggest regulatory challenge that licensees have is meeting the annual audit of their radiation protection program.	that key program elements cannot be performed, they should request relief through an exemption.
13.	Some licensees will face challenges meeting 10 CFR Part 34.43(e) and have possible issues with conducting performance observations during industrial radiographic operations. This can be a challenge in remote areas and due to travel restrictions. Is this requirement subject to relief through an exemption?	This is one of the regulations listed in the NRC template for 10 CFR Part 34 exemptions.
14.	I want to thank the NRC staff for emphasizing that once access restrictions are lifted, NRC inspections will be primarily focused on ensuring the safety and security of licensed materials and not minor administrative violations.	No response was needed
15.	I want to thank the NRC staff for their presentation. The design and outline of the requirements for our program during COVID-19 outbreak has been helpful.	No response was needed
16.	I want to thank the NRC for its efforts working with licensees. I thought that the 90-day extensions were reasonable for the items discussed and appreciate being able to request further extensions, if needed. Our facility will have an overall research ramp-up plan. Regarding inspections, it is likely that we will not initially be using unsealed radioactive material and if this material is used, its use will be limited. In-person NRC inspections will have to meet State and facility requirements for social distancing and the use of face masks. We will likely be staggering workers' schedules as well.	No response was needed

17.	A challenge that we may face in the future has to deal with the price of oil. We may be forced to shut down operations and that would complicate the 10 CFR Part 37 weekly inspections.	This issue should be addressed during the future public meeting for 10 CFR Part 37 exemptions.
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