

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM 20-002 - DISPOSITIONING VIOLATIONS OF NRC REQUIREMENTS UNDER 10 CFR PARTS 30-36, AND 39, RESULTING FROM IMPACTS OF THE COVID-19 PUBLIC HEALTH EMERGENCY (PHE), WHERE THE LICENSEE SUSPENDED THE USE OF LICENSED MATERIAL AND PLACED MATERIAL IN SAFE STORAGE (ATTACHMENT 2)

Purpose:

The purpose of this attachment is to provide guidance to U.S. Nuclear Regulatory Commission (NRC) inspection staff for the disposition of violations of NRC requirements under Title 10 of the *Code of Federal Regulations* (CFR) Parts 30-36 and 39 that occurred because of the COVID-19 public health emergency (COVID-19 PHE).¹ Specifically, discretion may be granted for certain noncompliances by a licensee that chooses to suspend use of licensed material² and has placed and maintained all licensed radiological material in safe storage in accordance with applicable requirements during the COVID-19 PHE.

Background:

NRC licensees are expected to comply with all applicable NRC requirements; however, the NRC acknowledges the possibility that the COVID-19 PHE might impact a licensee's ability to maintain compliance with all requirements. The NRC has received inquiries from materials licensees and industry groups regarding both potential and actual impacts of the COVID-19 PHE and their ability to remain in compliance with NRC regulations and license conditions.

The NRC anticipates that licensees will implement social distancing practices, which may result in their suspension of the use of licensed material for the purpose of conforming with: the President's Coronavirus Guidelines for America; the Centers for Disease Control and Prevention Interim Guidance for Businesses and Employers; and the Occupational Safety and Health Administration 3990-03, "Guidance on Preparing Workplaces for COVID-19"; as well as additional applicable guidance, recommendations, or restrictions imposed at the Federal, State, and local levels.

Discussion:

Licensees may choose to suspend use of licensed material in response to State and local COVID-19 orders or federal guidelines. The impact of social distancing, stay-at-home orders, or illnesses due to COVID-19 could result in licensees not having sufficient staff to continue their use of licensed material. Some regulatory requirements can only be met when an individual is onsite and in an at-work status. Given these circumstances, licensees may be challenged to comply with certain regulatory requirements and/or license conditions. Examples of these

¹ The provisions of this EGM are to be applied to noncompliances that occurred since the Secretary of the United States Department of Health and Human Services declared the COVID-19 PHE on January 31, 2020, and not more than 1 year from the issuance date of this EGM.

² For the purpose of this EGM, "suspend use of licensed material" means the licensee has placed or maintained all existing radiological material in safe storage in accordance with applicable requirements; suspended use of licensed materials; no licensed material is accessed for use or disposal; and no additional material is obtained.

requirements include: equipment testing, checks, or calibration; equipment maintenance or exchange; program reviews; retraining/recertification; dosimetry exchange; monitoring/sampling and surveys; and the submission of reports to the NRC. Table 1 lists specific regulations for which the NRC may choose to exercise enforcement discretion in accordance with this EGM. The regulations are sorted by topic, and each grouping includes a basis for discretion as well as guidance for restoring compliance when a licensee resumes the use of licensed material.

Should a licensee suspend its use of licensed material and place licensed radiological material in safe storage in accordance with the regulations, the NRC will continue to have reasonable assurance of adequate protection of public health and safety and the common defense and security if certain other required activities are postponed for a specified brief period of time and are completed in a timely manner upon the resumption of use of licensed material. Accordingly, the NRC believes it is appropriate, under certain conditions, and for a specified brief period of time, to exercise enforcement discretion for certain violations by licensees that have suspended use of licensed material and placed the material in safe storage in accordance with NRC regulations. Once a licensee decides to resume the use of licensed material, it must also restore compliance in accordance with the timelines in Table 1.

If a licensee has more than one license, the licensee may suspend use of licensed material under one license and continue use of licensed material under another license; however, note that for the discretion described in this EGM to be granted, the material storage areas must not be co-located. For example, a hospital with two licenses may be granted discretion if licensed activities are suspended by the organization using materials under the first license (e.g., its research department), as long as the designated safe storage area for the materials under that license is not accessed by personnel conducting activities under the second license (e.g., diagnostic department).

A licensee may also submit an exemption request if relief is needed for a regulation that is not listed in Table 1, or if it needs relief from the timelines listed in Table 1 to restore compliance. For a noncompliance that meets Conditions A – E of this EGM (below), a licensee does not need an exemption in order for the NRC to exercise discretion.

Actions:

Basis for Granting Enforcement Discretion:

In accordance with the NRC Enforcement Policy, Section 3.5, “Violations Involving Special Circumstances,” the NRC may exercise enforcement discretion and not cite licensees for violations of NRC requirements when application of the normal process is not appropriate given the circumstances. Given the special circumstances of the COVID-19 PHE and the impacts that licensees may encounter, in particular challenges to staffing levels due to illnesses or due to compliance with state and local social distancing orders, licensees may suspend use of licensed material and, as a result, be challenged to comply with all regulatory requirements or license conditions.

The NRC believes it is appropriate to exercise enforcement discretion for violations by affected licensees under certain conditions, and for a specified brief period of time, provided NRC continues to have reasonable assurance of adequate protection of public health and safety and the common defense and security. Table 1 provides a list of requirements, with corresponding bases, that may be considered for enforcement discretion.

For a materials licensee that has suspended use of licensed material and placed all of its licensed radiological material in safe storage in accordance with applicable requirements (e.g., 10 CFR 20.1801, 30.34(i), 34.23, 34.35(c), and 39.31(b)), the NRC has reasonable assurance of adequate protection of public health and safety and the common defense and security if the licensee continues to comply with storage requirements and upon the resumption of use of licensed material restores compliance in a timely manner as stipulated in Table 1.

If an inspector identifies a noncompliance with specific requirements in 10 CFR Parts 30-36, and 39 (Table 1) and the licensee has maintained the material in safe storage and meets the conditions of this EGM, enforcement discretion may be granted. The inspector shall consult with the appropriate branch chief prior to granting discretion.

Note that this EGM does not provide guidance with respect to enforcement discretion for any violation associated with the requirements of 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

Conditions:

Enforcement discretion is reasonable if the licensee meets the following five conditions:

- A. The licensee's noncompliance occurred after the declaration of the COVID-19 PHE.
- B. The identified noncompliance is listed in Table 1.
- C. The licensee suspended use of licensed material during the COVID-19 PHE.
- D. The licensee maintained radioactive materials in safe storage in accordance with applicable requirements (e.g., 10 CFR 20.1801, 30.34(i), 34.23, 34.35(c), and 39.31(b)).
- E. The licensee restored compliance in accordance with Table 1 upon the resumption of use of licensed material (but in any event no later than 1 year from the issuance of this EGM).

Enforcement Discretion:

Enforcement discretion may be exercised for a noncompliance if conditions A – E described above are met. Violations associated with this enforcement discretion do not require discussion at an enforcement panel; however, they do require assignment of an enforcement action (EA) tracking number and shall be documented in an inspection report. When exercising enforcement discretion in accordance with this EGM, the cover letter to the inspection report that discusses the violation should include the following or similar language:

"A violation of [insert specific regulation or license condition] was identified. Because the violation occurred as a result of the COVID-19 PHE described in Enforcement Guidance Memorandum 2020-002 (EGM-20-002) and because the licensee was implementing the conditions specified in EGM 2020-002, Attachment 2, the NRC is exercising enforcement discretion in accordance with Section 3.5, "Violations Involving Special Circumstances," of the NRC Enforcement Policy and is not issuing an enforcement action for this violation."

Long-Term Actions:

The NRC recognizes that impacts on a licensee could continue after the official termination of the PHE. Consequently, the provisions of this EGM may be applied after termination of the PHE to allow, on a case-by-case basis (not to exceed 1 year from the issuance date of the EGM), appropriate consideration of specific circumstances that arise during the inspection cycle following the PHE recovery.

NMSS Enforcement Point of Contact:

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ADAMS: EGM-02-002 Memo: ML20083K794

ADAMS: EGM-20-002 Attachment 2 Memo: ML20136A085 * Via Email

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EGM 20-002, Attachment 2

Table 1 – Requirements that may be Considered for Enforcement Discretion

#	Item (Topic)	Description ³	Basis for Discretion	Regulations (If Applicable)	Deadline for Restoring Compliance
1	Reports to NRC	Reports to NRC due in timeframes of 30 days or longer.	Reports that are due to NRC on a timeframe of greater than 30 days are reports of lower significance items, or are follow-up reports of higher significance items where an initial report has already been submitted to the NRC. Accordingly, if the licensee maintained internal reports or other sufficient information to complete these reports and submits these reports within 30 days of resuming the use of the licensed material, it would still maintain reasonable assurance of adequate protection of public health and safety and the common defense and security.	30.34(c) ⁴ 30.50(c)(2) 31.5(c)(5) 31.5(c)(8) 31.5(c)(14) 32.52 32.56(a)	Within 30 days of resuming use of licensed material

³ This column is applicable for noncompliances with a regulation, Order, or license condition.

⁴ The regulation in 30.34(c) applies when the requirement described in the "Description" column is contained in a license condition.

#	Item (Topic)	Description ³	Basis for Discretion	Regulations (If Applicable)	Deadline for Restoring Compliance
2	Leak Testing	<p>Routine leak testing of sealed sources and testing for depleted uranium contamination.</p> <p>Note 1: This does not include leak tests if the sources exhibit signs that the source might be leaking.</p> <p>Note 2: The leak testing requirement for a sealed source and device (SSD) ranges from 6 months to 3 years.</p>	<p>Because the licensee has suspended use of licensed material, that eliminates the movement of and exposure to sources, decreasing both the potential for and safety consequences of potential leaks.</p> <p>Postponing leak tests does not pose a safety concern, as long as any leak tests that were due during the discretion period are completed prior to use. Therefore, this exercise of discretion would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security.</p>	<p>30.34(c) 31.5(c)(2) 34.27(c)(1) 34.27(e) 35.67(b)(2) 36.59(a) 39.35(c)</p>	<p>Prior to resuming use of licensed material</p>

#	Item (Topic)	Description ³	Basis for Discretion	Regulations (If Applicable)	Deadline for Restoring Compliance
3	Equipment Testing/ Calibration	<p>Routine equipment testing, checks, or calibration required monthly or less frequently (such survey instrument calibrations that are unable to be performed due to vendor closures).</p> <p>Note: This does not include testing, checks, or calibrations required daily, per use, or after repairs.</p>	<p>Where a licensee has put all licensed material in safe storage and is not accessing that material, the potential for contamination is eliminated. Because there is no potential for contamination, and therefore no need to detect and measure contamination, the licensee does not need to use equipment while its use of licensed material is suspended. Therefore, postponing testing and calibration of this equipment does not pose a safety concern, as long as any testing and calibration that was due during the discretion period is completed prior to resuming use of licensed material. With respect to the requirement to test and calibrate HDR and GSR units, postponing testing and calibration of these units does not pose a safety concern, as long as any testing and calibration that was due during the discretion period is completed prior to resuming use of the licensed material.</p> <p>This exercise of discretion would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed material and is not using these instruments.</p>	<p>30.34(c) 34.25(b)(1) 35.60(b) 35.61(a) 35.630(a) 35.633(a)(3) 35.633(a)(4) 35.635(a)(3) 39.33(c)(1)</p>	<p>Prior to resuming use of licensed material</p>

#	Item (Topic)	Description ³	Basis for Discretion	Regulations (If Applicable)	Deadline for Restoring Compliance
4	Equipment Maintenance/ Exchange	Routine equipment maintenance or exchange, provided that the licensee has demonstrated no equipment malfunctions. Examples include conduct of annual equipment maintenance outside the normal frequency.	The exercise of discretion for the delay in completing equipment maintenance or exchange would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed materials and the instrument is not in use.	30.34(c) 35.655(a) 39.43(b)	Within 30 days of resuming use of licensed material
5	Physical Inventory	Routine periodic physical inventories of material. Note: Typical frequencies are quarterly, six months, or annual.	The licensee has suspended use of licensed material and is not using the sources or devices, which are in safe storage in accordance with applicable requirements. Therefore, this exercise of discretion would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security.	30.34(c) 34.29(a) 35.67(g) 39.37	Prior to resuming use of licensed material
6	Periodic Program Reviews, Periodic User Performance Audits/ Observations, Annual Safety Reviews, Annual Inspection	Routine periodic program reviews. Routine periodic performance audits, safety reviews, inspections and/or observations of users. Note: With respect to Part 39 licensees, this discretion applies to annual safety reviews and annual inspections as described in 39.13(b)(3) and (d), which are required by license conditions.	The exercise of discretion for not conducting routine oversight activities would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed material.	20.1101(c)) 30.34(c) 34.43(e) 36.51(d) 36.51(e) 36.51(g)	Within 30 days of resuming use of licensed material

#	Item (Topic)	Description ³	Basis for Discretion	Regulations (If Applicable)	Deadline for Restoring Compliance
7	Radiation Safety Committee (RSC) Meetings	<p>Routine periodic RSC meetings.</p> <p>Note1: This does not include RSC meetings in response to an event or incident or from establishing an RSC.</p> <p>Note 2: With respect to Part 35 licensees, this discretion applies to the frequency of meetings of the RSC that is described in 35.24(f), which may be required at a specified frequency by license condition.</p>	The exercise of discretion for not conducting routine oversight activities would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed material.	30.34(c)	Within 30 days of resuming use of licensed material
8	Periodic Retraining/ Recertification	<p>Routine periodic retraining/recertification (such as weapons qualifications, physicals, DOT training, radiation safety or security program training, routine accreditation testing requirements).</p> <p>Note 1: Examples of impacts could be due to travel restrictions, unavailability of staff, social distancing, or the cancellation of vendor training courses.</p> <p>Note 2: This does not include initial training or certifications.</p>	The licensee has suspended use of licensed material and must restore compliance within 30 days of resuming use of licensed material (i.e., provide the required retraining). Therefore, this exercise of discretion would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security.	30.34(c) 34.43(d) 35.310(a) 35.410(a) 35.610(d)(2)	Within 30 days of resuming use of licensed material
9	Dosimetry Exchange	Extension to the dosimetry exchange frequency, provided within manufacturer allowed specifications.	The exercise of discretion for this dosimetry exchange time would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed material and is not using material that requires the tracking of accumulated dose.	30.34(c)	Prior to resuming use of licensed material

#	Item (Topic)	Description ³	Basis for Discretion	Regulations (If Applicable)	Deadline for Restoring Compliance
10	Routine Periodic Monitoring/Sampling	<p>Routine periodic monitoring/sampling.</p> <p>Note 1: This does not include final surveys/release of site.</p> <p>Note 2: This does not include continuous monitoring systems or sampling that is part of any containment system.</p>	The exercise of discretion for this periodic monitoring/sampling would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed material, has placed all licensed material in safe storage, and is not using material that would lead to accumulated dose.	30.34(c)	Prior to resuming use of licensed material
11	Routine Confirmatory Surveys	<p>Routine confirmatory surveys.</p> <p>Note 1: This does not include the final survey required within the period prior to placing the material in storage.</p> <p>Note 2: This does not include surveys tied to continuous monitoring systems.</p>	The exercise of discretion for this survey time would maintain reasonable assurance of adequate protection of public health and safety and the common defense and security, because the licensee suspended use of licensed material and is not using licensed material.	30.34(c)	Prior to resuming use of licensed material