



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

EGM 20-003

July 15, 2020

MEMORANDUM TO: David C. Lew, Regional Administrator, Region I
Laura A. Dudes, Regional Administrator, Region II
John B. Giessner, Regional Administrator, Region III
Scott A. Morris, Regional Administrator, Region IV
Ho Nieh, Director, Office of Nuclear Reactor Regulation
John W. Lubinski, Director, Office of Nuclear Material Safety
and Safeguards
Brian E. Holian, Director, Office of Nuclear Security and Incident
Response

FROM: George A. Wilson, Director
Office of Enforcement

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM - INTERIM
GUIDANCE FOR DISPOSITIONING VIOLATIONS OF LICENSED
MATERIAL POSSESSION AND USE LIMITS

Purpose:

The purpose of this enforcement guidance memorandum (EGM) is to provide enforcement guidance to regional and program offices on dispositioning violations involving terms and conditions of licenses granted by the Nuclear Regulatory Commission (NRC) in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.34, "Terms and Conditions of Licenses," specifically, violations associated with licensed possession and use of byproduct material.

Background:

10 CFR 30.34(c) requires, in part, that each licensee under Parts 30 through 36 and 39 confine its possession and use of the byproduct material to the location and purposes authorized in the license. The licensing process is a basic component of the NRC's regulatory structure to ensure safe use of byproduct material. Possession of byproduct material without a license, or not in accordance with a license, denies the NRC the opportunity to perform the necessary oversight to ensure the material's safe use, and calls into question whether the licensee understands its license and has sufficient controls in place to ensure that it operates within its limits.

Under the current NRC Enforcement Policy, a violation of 10 CFR 30.34(c) for a "failure to seek required NRC approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance," (e.g., an increase in the quantity or type of radioactive material being processed or used that has radiological significance) is an example categorized as a severity level (SL) III violation. Although there is not a specific SL IV example in the current Enforcement Policy, some violations of 10 CFR 30.34(c) for possession of

CONTACT: Leelavathi Sreenivas, OE/EB
(301) 287-9249

unauthorized material with little to no radiological or programmatic significance have been categorized as SL IV.

Basis for Discretion:

If a particular noncompliance poses little to no adverse impact on radiological or programmatic activities, it is appropriate to disposition the noncompliance as an SLIV violation. An example of a situation with little to no adverse impact on radiological or programmatic activities would be characterized by all of the following factors:

- The license authorized the possession and use of that isotope, type, and form of material.
 - This demonstrates that the NRC was aware the entity possessed material, NRC had an opportunity to inspect the licensee, and NRC had verified through inspection the licensee's ability to control and use that type of material.
- No significant increase in the quantity of material, such that no additional procedure or programmatic changes are (or would have been) required for possession of additional material.
 - If no substantive license condition amendments are necessary and an administrative amendment is sufficient to document the increase in the quantity of material, then the procedures, processes, personnel training, and license conditions provide reasonable assurance that the licensee could safely control and use the additional quantity.
- The failure was not willful, was isolated, and was not repeated from previous inspections
 - This provides confidence that the licensee's program has sufficient controls in place to ensure that operations are conducted within the specified limits on the license; this occurrence was isolated and was not a failure or inadequacy in the licensee's program).
- All other significant safety/security requirements have been met.
 - If no additional escalated violations were identified, it provides confidence that the licensee's program is otherwise adequate such that the additional material was properly controlled and used.

Action:

If an inspector identifies a potential noncompliance with 10 CFR 30.34(c) requirements that appears to meet the conditions below for disposition as an SL IV violation, the inspector shall notify the applicable branch chief before the exit meeting with the licensee. All of the potential non-compliances that are being considered for disposition as an SL IV violation shall be assigned an enforcement action number (EA #) to document the exercise of enforcement discretion.

(Note: The citation should be against 10 CFR 30.34(c) and specify the license condition (e.g., 10 CFR 30.34(c) requires a licensee to comply with the conditions in their license. Contrary to the above, the licensee failed to comply with its license. Specifically, the licensee failed to comply with the limits specified in License Condition ##. The licensee possessed 10mCi of isotope X, and the license condition limited possession to 5mCi of isotope X.))

The Regional Office shall evaluate each potential noncompliance and make one of the two following determinations:

- A. In cases where “A licensee fails to seek required NRC approval before implementing an increase in the quantity of regulated material that results in little to no adverse impact on radiological or programmatic activities,” the Region may use discretion in accordance with this EGM and characterize the violation as an SL IV violation.

An example of a situation with little to no adverse impact on radiological or programmatic activities would be characterized by all of the following:

1. The license authorized the possession and use of that isotope, type, and form of material.
2. No significant increase in the quantity of material, such that no additional procedure or programmatic changes are (or would have been) required for possession of additional material.
3. The failure was not willful, was isolated, and was not repeated from previous inspections.
4. All other significant safety/security requirements have been met.

If the case meets the example above, thereby demonstrating that there is little to no adverse impact on radiological or programmatic activities, then the Region may process the case without a Headquarters panel.

If the case does not meet the example above, but the Region has determined that the noncompliance poses little to no adverse impact on radiological or programmatic activities, then the Region should bring it to a Headquarters panel (modified or full) for alignment on the severity level.

In accordance with the Enforcement Policy, this SL IV violation will normally escalate to SL III due to willfulness.

In preparing Notices of Violation, in cases where the violation is to be assessed as SL IV, the subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION," as described in Section 3 of the Enforcement Policy.

The following, or similar, language should be included in the text of the inspection record or report discussing the inspection finding when exercising enforcement discretion in accordance with this EGM:

“A violation of 10 CFR 30.34(c) was identified during this inspection and is described in the attached Notice of Violation. In accordance with the Enforcement Policy, this violation would normally be categorized at Severity Level III and considered for escalated enforcement action. However, in accordance with NRC Enforcement Guidance Memorandum (EGM) 20-003, issued July 15, 2020, the NRC is exercising enforcement discretion to categorize this violation as a Severity Level IV violation.”

- B. Process the case in accordance with the current Enforcement Policy to evaluate and disposition the noncompliance.

Expiration:

This EGM will remain in effect until the next revision of the Enforcement Policy. At that time, the staff will propose a change to the Enforcement Policy to update the SL III example and to create an SL IV example to reflect this graded approach.

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM - INTERIM GUIDANCE FOR
DISPOSITIONING VIOLATIONS OF LICENSED MATERIAL POSSESSION LIMITS
DATE: 07/15/2020

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DATE	5/6/2020		6/4/2020	6/9/2020	5/6/2020
OFFICE	RII/RA	RIII/RA	RIV/RA	OGC	OE/OD
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