UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

September 11, 2018

NRC REGULATORY ISSUE SUMMARY 2018-04
NOTICE OF ISSUANCE OF ENFORCEMENT GUIDANCE MEMORANDUM—INTERIM GUIDANCE FOR DISPOSITIONING APPARENT VIOLATIONS OF 10 CFR PARTS 34, 36, AND 39 REQUIREMENTS RESULTING FROM THE USE OF DIRECT ION STORAGE DOSIMETRY DURING LICENSED ACTIVITIES

ADDRESSEES

All holders of and applicants for a possession and use of byproduct material license under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations."

All holders of and applicants for a specific byproduct material license under 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," and 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging."

INTENT

The intent of this regulatory issue summary (RIS) is to inform the addressees that on May 11, 2018, the U.S. Nuclear Regulatory Commission (NRC) issued Enforcement Guidance Memorandum (EGM) 18-001, "Interim Guidance for Dispositioning Apparent Violations of 10 CFR Parts 34, 36, And 39 Requirements Resulting from the Use of Direct Ion Storage Dosimetry During Licensed Activities," concerning the dispositioning of inspection findings related to use of direct ion storage (DIS) dosimetry during NRC-licensed activities under the following regulations:

- 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging"

The RIS does not require any specific action or written response and is being provided for information purposes only.

BACKGROUND INFORMATION

On October 24, 2000, the Commission issued a direct final rule (Volume 65 of the *Federal Register* (FR), page 63750 (65 FR 63750)) permitting the use of alternative technologies for personnel dosimeters used to determine the radiation dose (i.e., personnel dose of record) for licensees subject to 10 CFR Parts 34, 36, or 39. The stated purpose of the rule was "to allow licensees to use any type of personnel dosimeter that requires processing to determine the

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radiation dose, provided that the processor of the dosimeter is accredited to process this type of dosimeter under the National Voluntary Laboratory Accreditation Program (NVLAP), operated by the National Institute of Standards and Technology (NIST)." Specifically, the rulemaking identified Optically Stimulated Luminescent Dosimeters as an example of these new technologies. The rulemaking acknowledged that "new dosimeter technologies and other processing techniques are likely to appear in the near future." Thus, the rulemaking eliminated specific requirements to use film badges and thermoluminescent dosimeters in 10 CFR 34.47, 10 CFR 36.55, and 10 CFR 39.65, all titled "Personnel monitoring," in order "to allow the use of dosimeters that require alternative processing techniques."

The phrase "processed," as it appears in these requirements, has been defined as "a process, separate from, and independent of, the design of the dosimeter that is required to extract dose information from the dosimeter after exposure to radiation" (70 FR 2579). As such, licensees subject to 10 CFR Parts 34, 36, or 39 have usually handled the processing and evaluation of dosimetry by physically sending the dosimeter to an accredited NVLAP processor in order to extract the information stored in the dosimeter to establish the dose of record. However, the current wording of the combined requirements addressing dosimetry in these parts of the CFR has resulted in questions about applicability for certain new dosimetry technologies.

The DIS dosimetry technology available does not require that the device worn by the radiation worker be physically sent from the licensee's facility to a NVLAP-accredited processor to extract dose information. Rather, the technology includes the on-board capability to extract dose information from the DIS, which is then transmitted using vendor-supplied software from the user's computer to the vendor (for the dosimetry system currently available) for evaluation and dose computation.

SUMMARY OF ISSUE

The regulations in 10 CFR 34.47(a), 10 CFR 36.55(a), and 10 CFR 39.65(a) require that an accredited NVLAP processor must process and evaluate personnel dosimeters. However, the available DIS dosimetry technology does not require that the devices be physically sent to an NVLAP-accredited processor in order to extract dose information. The subject EGM sets criteria that, if followed, would allow licensees to use DIS dosimetry without the NRC pursuing enforcement.

At the date corresponding to 90 days after the date of this RIS, licensees using DIS dosimetry will be expected to have documented agreements in place to meet the conditions identified in EGM 18-001, Action 1.b. and records identified in EGM 18-001, Action 1.d. Before that date, if a review by NRC staff of new or existing open inspection items shows that a licensee does not have a documented agreement meeting the criteria in EGM 18-001, Action 1.b., then the involved NRC staff should review records of the licensee's performance with respect to promptly identifying and addressing replacement, calibration or recalibration, or other concerns related to the use of DIS dosimetry. During this preliminary time period, the licensee's records may not meet the criteria of EGM 18-001, Action 1.d.; however, based on its review of the existing records, the NRC staff may still conclude that the licensee's performance is adequate. If, based on its review of applicable records, the NRC staff identifies an inadequate demonstration of the licensee's performance, then this EGM does not apply, and enforcement will be considered.

If a licensee meets the conditions described in the EGM, the NRC will not pursue enforcement action; otherwise, the staff will follow the normal enforcement process and will assess the

severity level for failure to meet the applicable 10 CFR requirements accordingly. Similarly, if the DIS dosimeter is found to be out of calibration, or its use exceeds the NVLAP processor's recommendations for replacement, calibration, or recalibration, then the staff will consider citing a violation of applicable requirements in the same manner as for any dosimeter identified in these conditions.

BACKFITTING AND ISSUE FINALITY DISCUSSION

This RIS informs the addressees of the issuance of EGM 18-001. 10 CFR parts 34, 36, and 36 do not contain backfitting or issue finality provisions. Therefore, a backfit analysis is not required.

FEDERAL REGISTER NOTIFICATION

The NRC did not publish a notice of opportunity for public comment on this RIS in the *Federal Register* because this RIS is informational and announces the issuance of EGM 18-001.

CONGRESSIONAL REVIEW ACT

The NRC has determined that this action is not subject to the Congressional Review Act (5 U.S.C. 801–886) and, therefore, is not subject to the Act.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). Existing requirements were approved by the Office of Management and Budget under approval numbers 3150-0007, 3150-0158 and 3150-0130.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/ (Sabrina D. Atack for)

Daniel S. Collins, Director
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Note: NRC generic communications may be found on the NRC public Web site, https://www.nrc.gov/reading-rm/doc-collections/gen-comm/, under NRC Library/Document Collections.

Enclosure:
EGM 18-001

NRC REGULATORY ISSUE SUMMARY 2018-04, "NOTICE OF ISSUANCE OF ENFORCEMENT GUIDANCE MEMORANDUM—INTERIM GUIDANCE FOR DISPOSITIONING APPARENT VIOLATIONS OF REQUIREMENTS FOR 10 CFR PART 34, 36, AND 39 ACTIVITIES RESULTING FROM THE USE OF DIRECT ION STORAGE DOSIMETRY DURING LICENSED ACTIVITIES" DATE: September 11, 2018

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

May 11, 2018

EGM-18-001

MEMORANDUM TO: David C. Lew, Acting Regional Administrator, Region I
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FROM: Anne T. Boland, Director */RA/*
Office of Enforcement

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM—INTERIM GUIDANCE FOR DISPOSITIONING APPARENT VIOLATIONS OF 10 CFR PARTS 34, 36, AND 39 REQUIREMENTS RESULTING FROM THE USE OF DIRECT ION STORAGE DOSIMETRY DURING LICENSED ACTIVITIES

PURPOSE:

This enforcement guidance memorandum (EGM) provides guidance for dispositioning potential violations of U.S. Nuclear Regulatory Commission (NRC) requirements for personnel dosimetry during NRC-licensed activities under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations"; 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"; and 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging." For licensees subject to these requirements who use direct ion storage (DIS) dosimetry for personnel monitoring (i.e., dosimetry used for the dose of record), the NRC will not pursue enforcement action for some potential violations of NRC requirements associated with the use of these dosimeters, provided the conditions detailed in the Action section are met. These conditions include the following:

(1) The dosimetry system is designed for remote data evaluation, where the data is digitally transferred to an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor for evaluation.

(2) An NVLAP-accredited processor provides the dosimeters and determines the dose of record.

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Enclosure

(3) The licensee and NVLAP-accredited processor implement the necessary quality controls to ensure that the DIS dosimeter is calibrated at the appropriate intervals and replaced when circumstances warrant.

The scope of this EGM is limited to the DIS dosimetry systems meeting these three criteria, as further detailed in the Discussion and Action sections. Presently, only one DIS dosimetry system designed for remote data evaluation (the patented Instadose™ system) is available for licensees that are subject to 10 CFR Parts 34, 36, and 39; however, other similar systems are emerging.

As a matter of clarification, 10 CFR Part 20, "Standards for Protection against Radiation," addresses DIS dosimetry used by licensees to which the dosimetry requirements in 10 CFR Parts 34, 36, and 39 do not apply. Therefore, this enforcement guidance does not apply to licensees who do not need to meet the requirements in 10 CFR Parts 34, 36, and 39.

BACKGROUND:

On October 24, 2000, the Commission issued a direct final rule in the *Federal Register* (65 FR 63750) permitting the use of alternative technologies for personnel dosimeters used to determine the radiation dose (i.e., personnel dose of record) for licensees subject to 10 CFR Parts 34, 36, or 39. The stated purpose of the rule was the following:

> …to allow licensees to use any type of personnel dosimeter that requires processing to determine the radiation dose, provided that the processor of the dosimeter is accredited to process this type of dosimeter under the National Voluntary Laboratory Accreditation Program (NVLAP), operated by the National Institute of Standards and Technology.

The rulemaking acknowledged that "new dosimeter technologies and other processing techniques are likely to appear in the near future." Thus, the rulemaking eliminated specific requirements to use film badges and thermoluminescent dosimeters in the "Personnel Monitoring" regulations in 10 CFR 34.47, 10 CFR 36.55, and 10 CFR 39.65 "to allow the use of dosimeters that require alternative processing techniques."

The phrase "processed and evaluated", as it appears in these requirements, has been specified as "a process, separate from, and independent of, the design of the dosimeter that is required to extract dose information from the dosimeter after exposure to radiation" (70 FR 2579). Thus, licensees subject to 10 CFR Parts 34, 36, or 39 have usually handled the processing and evaluation of dosimetry by physically sending the dosimeter to an accredited NVLAP processor to extract the information stored in the dosimeter to establish the dose of record. However, the current wording of the combined requirements addressing dosimetry in these 10 CFR parts has raised questions about their applicability to certain new dosimetry technologies.

The available DIS dosimetry technology does not require that the device worn by the radiation worker be replaced and physically sent from the licensee's facility to an NVLAP-accredited processor. Rather, the data are extracted from the DIS dosimeter using vendor-supplied software and transmitted in electronic form from the DIS dosimeter to the NVLAP-accredited processor (also the vendor for the dosimetry system currently available) for evaluation.

DISCUSSION:

To clarify the current regulations, the NRC staff is considering revising the requirements in 10 CFR Parts 34, 36, and 39 to make the use of personnel dosimetry technology neutral. Related to this effort is the July 14, 2016, petition from the Nondestructive Testing Management Association and the American Society for Nondestructive Testing to the NRC to amend 10 CFR Part 34 and authorize use of improved individual monitoring devices for industrial radiographic personnel—specifically, electronic personnel monitoring dosimeters and dual-function alarming ratemeters or electronic dosimeters. This wording can be interpreted to include DIS dosimetry designed for remote data evaluation. Further, the NRC is evaluating this petition under Petition for Rulemaking (PRM)-34-7, "Individual Monitoring Devices for Industrial Radiographic Personnel."

To meet current NRC requirements in 10 CFR 34.47(a) and (a)(3), 10 CFR 36.55(a), and 10 CFR 39.65(a), an accredited NVLAP processor must process and evaluate personnel dosimeters. NVLAP accreditation of a processor provides reasonable assurance that the measurement quality objectives for accuracy, precision, and reliability are met (including calibration to a national standard, a source traceable to the National Institute of Standards and Technology). Specifically, NVLAP accredits a processor to provide dosimetry within a defined scope of accreditation that is specific to a dosimetry system and to specific radiation fields (beta, gamma, neutron, mixed fields) and ranges of energies. Notably, NVLAP accreditation is specifically limited to the processor and does not accredit a dosimetry system or equipment.

DIS dosimetry designed for remote data evaluation does not require that the dosimeter be physically returned to the NVLAP-accredited processor's facility to extract the data from the dosimeter. Rather, the raw data generated by the dosimeter from exposure to radiation are extracted using an NVLAP-accredited processor's software on the licensee's computer that directly interfaces with the dosimeter via a docking station or similar interface. These raw data are then digitally transferred from the licensee's computer to the NVLAP-accredited processor's computer server where algorithms are used to convert the data to dose information that ultimately becomes an evaluated and reported dose reading sent to the licensee. This DIS dosimetry is immediately available for reuse and does not need to be replaced after each extraction of the data for determining dose. In addition to providing the software, the NVLAP-accredited processor ensures that quality checks for the dosimeters, software, and the process, including related data evaluation for dose reporting, are all consistent with its NVLAP accreditation. Specifically, licensees do not independently process such dosimeters or access the dosimeter data.

Requirements in 10 CFR 34.47(a)(3) and 10 CFR 39.65(a) identify that processing and replacement is to be completed every three months. As discussed below, in order to meet the conditions of this EGM, the three-month interval will continued to be applied for data extraction and dose evaluation for DIS dosimetry that is designed for remote evaluation. This frequency for evaluating the dose of record continues to provide the same level of assurance as is currently provided in these sections of the CFR.

Therefore, until issuance of a revised rulemaking that addresses DIS dosimetry designed for remote data evaluation or a determination by the NRC that rulemaking will not be pursued, the NRC staff will not pursue enforcement action when licensees use DIS dosimetry designed for remote data evaluation to meet the requirements of 10 CFR 34.47(a) and (a)(3), 10 CFR 36.55(a), or 10 CFR 39.65(a), provided that the following conditions are met:

- The dosimetry is being provided and dose data evaluated and reported for the dose of record by an NVLAP-accredited processor that is accredited to provide the specific dosimetry processing service appropriate to the licensee's operations and specific for the expected radiation fields and ranges of energies expected in the licensed operation with the subject dosimeter.

- The licensee and NVLAP processor have a documented agreement specifying arrangements to identify and address the following areas for the DIS dosimeters designed for remote data evaluation that are used to measure a radiation worker's dose of record: (1) replacement of dosimeters (e.g., resulting from end-of-life deterioration of the dosimeter or quality assurance concerns) and (2) calibration checks or recalibration of each dosimeter performed at a frequency identified by the NVLAP-accredited processor.

- The licensee uses the NVLAP-accredited processor's software to extract the data from the dosimeter and transmits it to the processor at a minimum frequency of every 3 months and documents the results to comply with applicable requirements in 10 CFR 34.83(c), 10 CFR 36.81(e), or 10 CFR 39.65(c).

- The licensee maintains complete records to demonstrate that it has implemented the arrangements identified above.

ACTIONS:

If an inspector finds that a licensee is using the DIS dosimetry described in the Discussion section of this EGM to provide personnel dosimetry (i.e., dose of record) under 10 CFR 34.47, 10 CFR 36.55 ("Personnel Monitoring"), or 10 CFR 39.65, the inspector should take the following actions:

(1) Verify the following before conducting the exit meeting with the licensee:

a. The licensee is able to show documentation (e.g., in the form of a contract, purchase order, or other document) demonstrating that the subject DIS dosimetry is being provided and the dose data evaluated and reported as the dose of record by an NVLAP-accredited processor. This processor must be accredited to provide the specific dosimetry processing service for the expected radiation fields and ranges of energies expected during the licensed operation with the subject dosimeter.

b. The licensee has a documented agreement established with its NVLAP-accredited processor. The agreement specifies arrangements that clarify how the licensee will identify, in a timely manner, the need for promptly providing the DIS dosimeter to the processor and by what means the dosimeter will be provided when replacement or calibration is indicated or for other reasons identified by either the processor or licensee. The agreement should address the following areas for the DIS dosimeters that are used to measure a radiation worker's dose of record: (1) replacement of dosimeters (e.g., because of end-of-life deterioration of the dosimeter, damage, or quality assurance concerns) and (2) calibration checks or recalibration of each dosimeter performed at a frequency identified by the NVLAP-accredited processor. These time periods

should not exceed any manufacturer-specified replacement and calibration or recalibration criteria and time periods. If the licensee fails to establish and implement this agreement, then the provision of this EGM to defer to the agreement is voided until the licensee implements adequate corrections. Further, the NRC may pursue enforcement and examine apparent violations of 10 CFR 34.47(a) and (a)(3), 10 CFR 36.55(a), or 10 CFR 39.65(a). When a DIS dosimeter in use has not been replaced or calibrated as arranged in the agreement, a failure to meet the requirement to have that category of dosimeter in use will be examined for enforcement (i.e., apparent violations of 10 CFR 34.47(a) and (a)(3), 10 CFR 36.55(a), or 10 CFR 39.65(a)).

c. The licensee uses the NVLAP-accredited processor's software to extract the data from the dosimeter and transmits it to the processor at a frequency of every 3 months or sooner and documents the results to comply with applicable requirements in 10 CFR 34.83(c), 10 CFR 36.81(e), or 10 CFR 39.65(c).

d. The licensee maintains complete records to demonstrate that it has implemented the arrangements in item b above.

(2) Notify the Branch Chief of the cognizant inspecting organization before conducting the exit meeting with the licensee.

(3) Document the use of DIS dosimetry in the inspection report and include the following or similar language:

> The inspector reviewed the licensee's compliance with personnel dosimetry requirements under 10 CFR 34.47 (36.55) or (39.65) and determined that the licensee is using direct ion storage (DIS) dosimetry designed for remote data evaluation to meet these requirements. The inspector reviewed the conditions described in EGM-18-001 and found that (1) the DIS dosimeters are being provided and dose data evaluated and reported for the dose of record by an NVLAP-accredited processor, (2) the licensee and NVLAP processor have implemented specified quality controls to ensure that the dosimeter is calibrated and/or replaced appropriately, and (3) the licensee has maintained the necessary documentation and records to demonstrate that the criteria of EGM-18-001 are being implemented.

A standard transmittal letter for an inspection report may be used as identified by the standard procedure for each region, rather than a template enforcement letter that transmits the inspection report. A tracking number ("EA number") in the Enforcement Action Tracking System should be obtained and used with the inspection report and any transmittal letter to track the use of this EGM. Further, the inspection report and letter should be profiled in the Agencywide Documents Access and Management System (ADAMS) with the EA number identified as the case reference number.

(4) This guidance may be used to address applicable unresolved items remaining open from previous inspections, where the licensee can demonstrate that it meets the criteria in Item 1 above, this EGM should be applied.

The NRC plans to notify licensees subject to this EGM (e.g., through a Regulatory Issue Summary) to inform them of the criteria identified in this memo. At the date corresponding to 90 days after the date of the NRC notification (unless a different date is specified in the notification), licensees will be expected to have their documented agreements in place to meet the criteria in Action 1.b. and the records identified in Action 1.d. Before that date, if review of new or existing open inspection items finds that a licensee does not have a documented agreement meeting the criteria in Action 1.b., then inspectors should consider reviewing evidence and records of the licensee's performance based on Action 1.b. to promptly identify and address replacement, calibration or recalibration, or other concerns raised about a dosimeter. For this review during this preliminary time period, the licensee records may not meet the full criteria of Action 1.d. but should be found to be adequate to demonstrate performance. If this NRC review identifies an inadequate demonstration of the licensee's performance, then this EGM does not apply, and enforcement should be considered.

If a licensee meets the conditions described above in Action 1 or 4, the NRC will not pursue enforcement action; otherwise, the staff will follow the normal enforcement process and will assess the severity level for failure to meet the applicable 10 CFR requirements. Similarly, if the DIS dosimeter is found to be out of calibration, or its use exceeds the NVLAP processor's recommendations for replacement, calibration, or recalibration, then the staff should consider citing a violation of applicable requirements in the same manner as for any dosimeter identified in these conditions.

EXPIRATION OF THIS EGM:

The NRC is reviewing a currently docketed petition for rulemaking (PRM-34-7, "Individual Monitoring Devices for Industrial Radiographic Personnel"). If rulemaking is implemented, the staff intends to address the use of dosimetry designed for remote data evaluation to record personnel dose, along with other dosimetry systems identified in the petition. This EGM will expire (1) upon issuance of a revised rule that addresses the same subject DIS dosimetry system that is designed for remote data evaluation and digitally transferred data for evaluation or (2) upon the NRC's determination that it will not pursue rulemaking.

cc: V. McCree, EDO
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SECY

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM—INTERIM GUIDANCE FOR DISPOSITIONING APPARENT VIOLATIONS OF 10 CFR PARTS 34, 36, AND 39 REQUIREMENTS RESULTING FROM THE USE OF REMOTELY PROCESSED DOSIMETRY DURING LICENSED ACTIVITIES DATE: 05/11/018

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