



POLICY ISSUE **(Notation Vote)**

November 8, 2018

SECY-18-0112

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: PETITION FOR RULEMAKING AND RULEMAKING PLAN ON
INDIVIDUAL MONITORING DEVICES FOR INDUSTRIAL
RADIOGRAPHIC PERSONNEL (PRM-34-7; NRC-2016-0182)

PURPOSE:

The purpose of this paper is to request Commission approval to grant in part and deny in part a petition for rulemaking (PRM) submitted by Dr. Amy Bereson of the American Society for Nondestructive Testing (ASNT) and Mr. Walt Cofer of the Nondestructive Testing Management Association (NDTMA). For the portion of the petition that would be accepted into the rulemaking process, the staff would proceed with a rulemaking to allow the use of digital output personnel dosimetry in industrial radiographic operations, irradiator operations, and well logging operations. Amendments would be needed to Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," of Title 10 of the *Code of Federal Regulations* (10 CFR); 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"; and 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging."

SUMMARY:

The U.S. Nuclear Regulatory Commission (NRC) received a PRM under 10 CFR 2.802, "Petition for rulemaking – requirements for filing," from ASNT and NDTMA (the petitioners) on

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301-415-0253

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July 14, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16228A045). In accordance with 10 CFR 2.803, "Petition for rulemaking – NRC action," the staff docketed the petition as PRM-34-7 and reviewed the petition pursuant to 10 CFR 2.803(h)(1). The staff recommends granting the petitioners' request to amend 10 CFR Part 34 to allow the use of digital output personnel dosimetry and denying the petitioners' request to amend 10 CFR Part 34 to allow the use of dual-function electronic alarming dosimeters (EADs). The basis for the denial is that, subsequent to the receipt of the petition, staff issued a generic communication that clarified that dual function electronic alarming dosimeters are acceptable to meet the applicable requirements in 10 CFR 34, which obviated the need for rulemaking.

BACKGROUND:

In staff requirements memorandum (SRM) for SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016 (ADAMS Accession No. ML16034A441), the Commission approved institution of a requirement that the staff submit, for Commission approval through a SECY paper, any recommendation to grant a PRM and develop a proposed rule for public comment. Specifically, the Commission approved implementation of a slightly modified version of the streamlined rulemaking plan. Accordingly, the staff requests approval to initiate a rulemaking that would consider one issue presented in the PRM described in the discussion section below.

The NRC's regulations related to the safe use of sealed sources of byproduct material in industrial radiography are codified in 10 CFR Part 34. Since the promulgation of 10 CFR Part 34, several technological advances in dosimetry for personnel monitoring during radiographic operations have been made. For example, digital output personnel dosimeters, which can provide instantaneous dose readings through the use of internet-enabled computers, smartphones, and tablets, have been developed. Also, EADs, which combine the functions of a direct reading dosimeter and an alarming ratemeter into one dual-function device, have established a track record for reliability in the nuclear industry over the past several years.

Section 34.47(a) requires radiographic personnel to wear, at all times during radiographic operations, (1) a direct reading dosimeter, (2) an operating alarm ratemeter, and (3) a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each of the devices serves a redundant, "defense-in-depth" safety function. For example, the direct reading dosimeter backs up the personnel dosimeter, and the operating alarm ratemeter backs up the hand held radiation survey meter that is separately required by 10 CFR 34.49(a). Thus, if one device fails, another device provides reasonable assurance of protection against radiation overexposures at industrial radiographic work sites, as well as a device to determine an individual's radiation dose.

On July 14, 2016, the petitioners submitted a request that the NRC "amend sections of 10 CFR Parts 20 and 34 and to change the guidance in NUREG-1556, Vol. 2 [Program-Specific Guidance about Industrial Radiography Licenses]" to allow the use of modern dosimetry in industrial radiographic operations. Specifically, the petitioners requested that the NRC amend

10 CFR Parts 20 and 34 and associated guidance, as appropriate, to authorize the use of digital output personnel dosimeters and dual-function EADs to satisfy the requirements in 10 CFR 34.47(a).¹

A notice of docketing and request for comment was published in the *Federal Register* (FR) on November 9, 2016 (81 FR 78732), and the comment period ended on January 23, 2017. The NRC requested comments from the public on the petition and three specific technical areas to gain further understanding of the scope and basis for the issues raised by the petitioners.

DISCUSSION:

The NRC staff considered the petitioners' request for each type of dosimeter separately based on information provided by the petitioners, public comments on the notice of docketing, operational experience, and literature searches performed by the staff. The staff recommends considering the petitioners' request regarding digital output personnel dosimetry in the rulemaking process. The "Digital Output Personnel Dosimetry" section below, therefore, provides the staff's rationale (in the "Description and Scope" section), as well as the information required to be included in rulemaking plans presented to the Commission to request initiation of a rulemaking. The staff also recommends denying the petitioners' request regarding EADs and provides information to support the denial in the "Dual-Function EADs" section below.

Digital Output Personnel Dosimetry: Partial Acceptance of Petitioners' Request

Title

Individual Monitoring Devices for Industrial Radiographic Personnel

Estimated Schedule

Initiate regulatory basis phase – Immediately after issuance of SRM.

Complete draft regulatory basis – 4 months after issuance of SRM.

Complete final regulatory basis – 8 months after issuance of SRM.

Publish proposed and direct final rule (DFR) – 18 months after issuance of SRM.

Preliminary Priority

Using the common prioritization of rulemaking (CPR) methodology, the staff estimates that this rulemaking would be a medium priority rule. This rulemaking is estimated to score 23 points (medium priority) because: a) it would be a moderate contributor toward the NRC Strategic Plan safety goal and it would implement several of the Plan's safety strategies; b) it would be a moderate contributor to implementing the Principles of Good Regulation; and c) it would ensure that regulations are applied consistently, are practical, and accommodate technology changes

¹ The petitioners interchangeably used the terms "improved individual monitoring devices," "electronic personnel monitoring dosimeters," "electronic dosimeters," and "digital personnel dosimeters" to describe "improved" personnel dosimetry. This document uses the term "digital output personnel dosimetry" in place of these terms, meaning a specific type of personnel dosimetry used to demonstrate compliance with the occupational dose limits in 10 CFR 20.1201. The petitioners used the terms "dual-function alarm ratemeter/electronic dosimeter" and "dual-function electronic dosimeter/alarm ratemeter" to describe devices that combine the functions of the alarm ratemeter and direct reading dosimeter required under 10 CFR 34.47(a). This document uses the term "EADs" to describe these dual-function devices.

in a timely manner. This estimate is consistent with the priority assigned to rulemakings that do not raise an immediate safety, environmental, or security concern.

Description and Scope

Digital output personnel dosimeters do not meet the requirements for personnel dosimetry in 10 CFR Parts 34, 36, and 39. In all cases, these regulations require licensees to use personnel dosimetry that is processed by NVLAP accredited facilities. The term "processing," as used in the NRC's regulations related to personnel dosimetry, means:

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. Processing is necessary with film or thermoluminescent (TLD) dosimetry to obtain the dose information. With film or TLD dosimetry, the quality of the processing is dependent on the competence of the processor, and not on the dosimeter design. Quality is built into the design of dosimeters that do not require processing.

For film or TLD dosimetry, the devices passively detect radiation and require processing by qualified technicians on separate equipment to obtain data for computation to determine dosage. For digital output personnel dosimeters, however, the data is extracted from the detector and then digitally transferred from the dosimeter for computation. As such, dose information is not obtained by processing the device in a manner that meets the definition of "processing" referenced above. Hence, the design of the digital output personnel dosimeter, rather than the training and qualifications of the processing technician, ensures accurate dose information from the dosimeter after exposure to radiation. This digital output personnel dosimeter technology was not available when the requirements in 10 CFR Parts 34, 36, and 39 were written.

The NRC, in 10 CFR 20.1501(d), requires that dosimeter processing be performed by NVLAP accredited facilities. This requirement ensures that processing equipment is properly calibrated and operated by trained and qualified personnel to obtain consistently accurate dose information (49 FR 1205). With digital output personnel dosimeters, the design of the device ensures consistently accurate dose information. NVLAP does not certify or accredit these types of dosimetry devices, and therefore NVLAP accreditation related to digital output personnel dosimeters is not necessary to achieve the purposes of the requirement in 10 CFR 20.1501(d).

In response to the petition, the NRC staff evaluated the technical specifications of digital output personnel dosimeters and determined that the digital output personnel dosimeters currently available meet or exceed the environmental requirements (e.g., temperature, humidity), dose range, and quality control necessary for use in industrial radiographic operations, as well as irradiator and well logging operations. From a literature search of technical journals, the NRC staff did not find any articles that highlighted generic performance problems with the use of these dosimeters. Moreover, digital output personnel dosimeters have been used successfully by NRC licensees in other operational areas, by some Agreement State licensees in all areas including industrial radiography, and internationally in multiple applications.

Similar to 10 CFR Part 34, the current regulations contained in 10 CFR Parts 36 and 39 do not allow the use of digital output personnel dosimetry. In the notice of docketing for PRM-34-7, the NRC staff requested public comment and supporting rationale on whether changes similar to those proposed in the petition should be applied to other radiation protection regulatory

requirements such as those for irradiator and well logging operations. Based on the public comments and the staff's evaluation of the personnel dosimetry requirements for 10 CFR Parts 36 and 39, the staff recommends that Parts 36 and 39 also be amended to allow the use of digital output personnel dosimeters.

The petitioners provided suggested language changes to 10 CFR 34.47(a). If the Commission approves the petitioners' request to amend the NRC's regulations to allow the use of digital output personnel dosimetry, the staff will consider the suggested language provided by the petitioners.

NRC Staff's Recommendation

The NRC staff recommends that this portion of the petition be accepted into the rulemaking process and that the rulemaking be accomplished by using the DFR approach with the signature authority designated to the Executive Director for Operations (EDO). This recommendation follows the general policy guidance from the Commission as outlined in Management Directive 6.3, "The Rulemaking Process," that the EDO is delegated the authority to issue proposed or final rules that involve a minor change in policy. The DFR approach is appropriate because the proposed changes to the regulations are non-controversial and not expected to result in any significant adverse comments from the public. The public comments received on the NRC's notice of docketing were supportive of amending the regulations to allow the use of digital output personnel dosimeters.

The DFR approach would save the NRC time and resources. A standard rulemaking generally takes 3 years to complete. The DFR process takes approximately 1.5 years to complete, so it could provide the industry access to the modern technology in a relatively short time.

Expanding the scope of the rulemaking to include amending 10 CFR Parts 36 and 39 related to personnel dosimetry would align the requirements for personnel dosimetry in all the parts of 10 CFR. Only 10 CFR Parts 34, 36, and 39 contain requirements related to the processing of personnel dosimetry. These parts would be amended to allow the use of all types of personnel dosimetry for industrial radiography, irradiator, and well logging operations. Public comments received were supportive of this change.

The rulemaking would benefit the NRC and external stakeholders because resources would not be expended for evaluating exemptions to the regulations for the use of digital output personnel dosimeters in industrial radiography. On May 11, 2018, the NRC issued an Enforcement Guidance Memorandum (EGM-18-001) (ADAMS Accession No. ML18068A623) that provides guidance for dispositioning potential violations of NRC requirements for personnel dosimetry during NRC-licensed activities under 10 CFR Parts 34, 36, and 39. For licensees subject to these requirements who use digital output personnel 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 that specified conditions are met. The staff would include similar considerations as it develops the DFR.

Relationship of the Work to the NRC's Strategic Plan

The planned rulemaking supports the NRC's 2018–2022 Strategic Plan (NUREG-1614, Volume 7, "Strategic Plan: Fiscal Years 2018–2022," issued February 12, 2018 (ADAMS Accession No. ML18032A561)) in several areas. Under the Principles of Good Regulation, the

public nature of the rulemaking process supports the openness objective by informing the public and providing them with the opportunity to participate in the regulatory process. Amending the regulations using the DFR process supports the efficiency objective by reducing the cost to the taxpayer for the rulemaking.

Amending the regulations to allow the use of the modern technology of digital output personnel dosimeters supports the NRC's Safety Strategy 1 (Maintain and enhance the NRC's regulatory programs, using information gained from domestic and international operating experience, lessons learned, and advances in science and technology) under the Safety strategic goal (Ensure the safe use of radioactive materials).

Cost and Benefits

The DFR approach would minimize the rulemaking costs associated with this activity. Since the use of digital output personnel dosimetry is voluntary, no increase in burden is imposed on licensees.

The proposed action is estimated to provide the following benefits:

- Make all personnel dosimetry options allowed under 10 CFR 20.1501(d) available to all NRC licensees.
- Eliminate exemption requests for use of digital output personnel dosimetry.
- Provide improved consistency between NRC and Agreement State regulations with regard to the use of digital output personnel dosimetry.
- Save time and resources by using a DFR approach to promulgate the rulemaking.
- Make the modern dosimetry technology available to the industry in a timely manner.

The proposed action is estimated by the NRC staff to cost \$254,000 and to take approximately 1.5 years. This estimate includes the cost for rulemaking for the NRC and Agreement States as well as the cost for the NRC, Agreement States, and industry for implementation.

Cumulative Effects of Regulation

This rulemaking would have a net positive impact on the cumulative effects of regulation for the following reasons:

- All public comments from the notice of docketing of PRM-34-7 in the FR on November 9, 2016 (81 FR 78732) were supportive of the proposed changes.
- The regulation would not add regulatory burden because the use of the digital output personnel dosimetry would be optional for licensees.
- The changes to the regulations would improve consistency between NRC regulations and align with the current practices in several Agreement States.

- The NRC staff currently anticipates that no critical skill sets or other ongoing NRC activities would significantly impact the implementation of the proposed changes.

Agreement State Considerations

The Agreement States would have 3 years to adopt the regulatory changes. Agreement States would be able to adopt the new provisions for the use of digital output personnel dosimetry in industrial radiographic, irradiator, and well logging operations. Many of the Agreement States would not have any changes to make as their regulations already allow the use of digital output personnel dosimeters in these areas. Agreement State licensees that perform radiographic and well logging operations in NRC jurisdictions under reciprocity would be relieved of the burden of having two types of dosimetry for personnel monitoring.

Backfitting and Issue Finality

The proposed revisions to 10 CFR Parts 34, 36, and 39 would not constitute backfitting, as these parts do not have a backfitting provision. Further, the proposed revisions would be a relaxation of current requirements.

Guidance

The following guidance documents would need to be updated, as appropriate, to support the DFR: NUGEG-1556, Volume 2, "Program-Specific Guidance About Industrial Radiography Licenses"; NUREG-1556, Volume 6, "Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses"; and NUREG-1556, Volume 14, "Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses."

Advisory Committee on Reactor Safeguards Review

Because the proposed changes would only affect industrial radiographic, irradiator, and well logging licensees, review of the DFR is outside the scope of the Advisory Committee on Reactor Safeguards charter.

Committee to Review Generic Requirements (CRGR) Review

Review by the Committee to Review Generic Requirements is not necessary because the recommended rulemaking would not constitute backfitting; 10 CFR Parts 34, 36, and 39 do not have a backfitting provision.

Analysis of Legal Matters

The Office of the General Counsel has reviewed this rulemaking plan and has not identified any issues necessitating a separate legal analysis at this time.

Dual-Function Electronic Alarming Dosimeters: Partial Denial of Petitioner's Request

The petitioners asserted that "the Commission has interpreted the language in 10 CFR 34.47 to mean that industrial radiographic personnel are prohibited from using a dual function electronic dosimeter/ratemeters." The petitioners went on to state that "such devices were unavailable when the rule requiring them became effective, but they are now, and there is no rational basis for denying their use."

Since the promulgation of 10 CFR Part 34, there have been several technological advances in dosimetry for personnel monitoring during industrial radiographic operations. On September 19, 2017, the NRC issued Regulatory Issue Summary (RIS) 2017-06, "NRC Policy on Use of Combination Dosimetry Devices during Industrial Radiographic Operations" (ADAMS Accession No. ML16137A077), clarifying that licensees may use dual-function EADs (also referred to as combination dosimetry devices in the RIS) for meeting the direct reading dosimeter and the alarm ratemeter device requirements specified in 10 CFR 34.47(a). The RIS explained that dual-function EADs have been used routinely and reliably for over 25 years as a secondary dosimeter in the operating environment of nuclear power reactors with no subsequent degradation in personnel safety. This determination was based on the NRC staff not finding any evidence of generic performance problems with EADs in an industrial setting in a review of the recent literature and NRC documents, or in discussions with NRC, military, and industry health physicists with EAD experience. Further, the NRC staff did not identify any adverse trends that would preclude using EADs as a dual-function device in industrial radiography operations to meet the requirements in 10 CFR 34.47(a). The many years of operational experience in the reactor arena have demonstrated that EADs are effective for monitoring dose and dose rate, as well as for providing visual/audible alarms for preset thresholds. Therefore, the NRC staff determined, as stated in the RIS, that licensees may use dual-function EADs for meeting the direct reading dosimeter and the alarm ratemeter device requirements specified in 10 CFR 34.47(a).

In evaluating the petition, the NRC staff determined that RIS 2017-06 provides clarification regarding the assertion made by the petitioners with respect to the use of dual-function EADs and, therefore, rulemaking is not necessary to address this portion of the petition. Therefore, the NRC staff recommends denying the petitioners' request to amend the NRC's regulations to allow the use of EADs.

COMMITMENT:

If the Commission approves initiation of the rulemaking, the staff will include the rule in its CPR, as well as in the public rulemaking tracking and reporting system. The staff will publish a DFR on the schedule described above.

RECOMMENDATION:

The staff recommends that the Commission:

1. Approve closure of the PRM docket by accepting the PRM in part (to allow the use of digital output personnel dosimeters in industrial radiographic, irradiator, and well logging operations) and denying the PRM in part (the petitioners' request regarding the use of EADs).
2. Approve the staff's initiation and publication (for signature by the EDO) of a DFR to amend 10 CFR Parts 34, 36, and 39.
3. Approve the draft notice regarding PRM acceptance and denial (Enclosure 1) for publication in the FR.

4. Note:

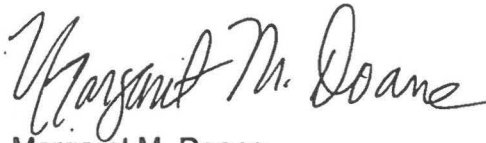
- a. The appropriate Congressional committees will be informed;
- b. a letter is enclosed for the Secretary's signature (Enclosure 2) informing the petitioners of the Commission's decision on the petition; and
- c. the Office of Public Affairs does not plan to issue a press release.

RESOURCES:

If the staff recommendation is approved by the Commission, resources would be required in fiscal year (FY) 2019 and FY 2020 to complete the rulemaking activities. Currently, there are no resources budgeted for this rulemaking in the FY 2019 Congressional Budget Justification. If rulemaking is authorized by the Commission, resources for FY 2019 will be reallocated within the Nuclear Materials Users business line. Resources for FY 2020 will be addressed in accordance with the planning, budgeting, and performance management process. A more detailed breakdown of estimated resources for current and future years is provided in Enclosure 3 entitled, "Resource Estimates."

COORDINATION:

The Office of the General Counsel has no legal objection to this action. The Office of the Chief Financial Officer has reviewed this paper and has no concerns with the estimated resources in Enclosure 3.



Margaret M. Doane
Executive Director
for Operations

Enclosures:

1. Draft *Federal Register* notice
2. Letter to the Petitioners
3. Resource Estimates (not publicly available)

PETITION FOR RULEMAKING AND RULEMAKING PLAN ON INDIVIDUAL MONITORING
 DEVICES FOR INDUSTRIAL RADIOGRAPHIC PERSONNEL (PRM-34-7; NRC-2016-0182)
 DATED NOVEMBER 8, 2018

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