




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

January 4, 2019

SECRETARY

MEMORANDUM TO: Margaret M. Doane
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary 

SUBJECT: STAFF REQUIREMENTS – SECY-18-0112 – PETITION FOR
RULEMAKING AND RULEMAKING PLAN ON INDIVIDUAL
MONITORING DEVICES FOR INDUSTRIAL RADIOGRAPHIC
PERSONNEL (PRM-34-7; NRC-2016-0182)

The Commission has approved closure of the Petition for Rulemaking (PRM-34-7) docket by accepting the petition in part (to allow the use of digital output personnel dosimeters in industrial radiographic, irradiator, and well logging operations) and denying the petition in part (the petitioners' request regarding the use of dual-function electronic alarming dosimeters) and the publication of the related *Federal Register* notice, subject to the edits provided in the enclosure.

The Commission has approved staff's recommendation to initiate and publish under the signature of the Executive Director for Operations a direct final rule to amend 10 CFR Parts 34, 36, and 39.

Enclosure:
As stated.

cc: Chairman Svinicki
Commissioner Baran
Commissioner Burns
Commissioner Caputo
Commissioner Wright
OGC
CFO
OCA
OPA
ODs, RAs, ACRS, ASLBP (via E-Mail)
PDR

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 34, 36, and 39

[Docket No. PRM-34-7; NRC-2016-0182]

Individual Monitoring Devices for Industrial Radiographic Personnel

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; partial consideration in the rulemaking process.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will consider in its rulemaking process one issue raised in a petition for rulemaking (PRM), PRM-34-7, submitted by the American Society for Nondestructive Testing (ASNT) and the Nondestructive Testing Management Association (NDTMA), and is denying one aspect of PRM-34-7. The petitioners request that the NRC amend its regulations to authorize the use of “improved” individual monitoring devices for industrial radiographic personnel.

DATES: The docket for the petition for rulemaking, PRM-34-7, is closed on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID NRC-2016-0182 when contacting the NRC about the availability of information for this petition. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Public comments and supporting materials related to this petition can be found at <http://www.regulations.gov> by searching on the petition Docket ID NRC-2016-0182 or the future rulemaking Docket ID NRC-20XX-XXXX. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **The NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Document collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-Based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section.

- **The NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Edward M. Lohr, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0253; e-mail: Edward.Lohr@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. The Petition

The NRC received and docketed a petition for rulemaking (ADAMS Accession No. ML16228A045) dated July 14, 2016, filed by Dr. Arny Bereson of ASNT and Mr. Walt Cofer of NDTMA.¹ On November 9, 2016 (81 FR 78732), the NRC published a notice of docketing and requested public comment on the petition.

The NRC identified two issues in the petition, as follows:

Issue 1: The petitioners request that the NRC amend its regulations to authorize the use of digital output personnel dosimeters to satisfy the requirements in § 34.47(a) in Title 10 of the *Code of Federal Regulations* (10 CFR).

Issue 2: The petitioners request that the NRC amend its regulations to authorize the use of dual-function electronic alarming dosimeters (EADs) to satisfy the requirements in § 34.47(a).

The petitioners interchangeably use 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, and clarifies that digital output personnel dosimetry is a specific type of personnel dosimetry used to demonstrate compliance with the occupational dose limits in § 20.1201. The petitioners use 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

¹ The November 2016 *Federal Register* notice incorrectly identified each petitioner’s organization. ~~The correct associations are Dr. Arny Bereson, ASNT, and Mr. Walt Cofer, NDTMA.~~

under § 34.47(a). This document uses the term “EADs” to describe these dual-function devices.

II. Public Comments on the Petition

The notice of docketing of PRM-34-7 invited interested persons to submit comments, and the comment period closed on January 23, 2017. The NRC received 13 comment submissions on the PRM.²

In the notice of docketing, the NRC requested public comment and supporting rationale in three specific areas: 1) how the use of dual-function EADs could achieve the current safety purpose of using independent devices; 2) whether changes similar to those proposed in the petition should be applied to other radiation protection regulatory requirements, such as those in 10 CFR Part 36, “Licenses and Radiation Safety Requirements for Irradiators,” and 10 CFR Part 39, “Licenses and Radiation Safety Requirements for Well Logging”; and 3) what experiences or challenges users have encountered in the use of digital output personnel dosimeters. Not all commenters submitted comments on all three specific areas of interest. None of the commenters referenced publicly-available technical, scientific, or other data or information to support their positions.

Public comments were received from industry, government and non-government organizations, and members of the public. The name of the submitter, the submitter’s affiliation (if any), and the ADAMS accession number for each unique comment submission are provided in the following table.

² One commenter retracted his original comment and submitted a replacement comment.

Comment #	ADAMS Accession number	Commenter	Affiliation
1	ML16326A439	Sander Perle	Private Citizen
2	ML17039A670	Cody A. Bayn	Private Citizen
3	ML16349A645	Anonymous	Anonymous
4	ML16356A574	Brian Companik	Private Citizen
5	ML16356A658	Kyle Ledbetter	International Radiography Inspection Service Non- Destructive Testing
6	ML16356A663	Anonymous	Anonymous
7	ML17017A339	Rick Ruhge	Private Citizen
8	ML17018A431	Nima Askeboussi	Nuclear Energy Institute
9	ML17024A384	Steve Matthews	State of Washington
10	ML17024A400	David Tebo	TEAM Industrial Services, Inc.
11	ML17024A415	John Merrill	Consumers Energy
12	ML17024A440	Mark Salasky	Landauer, Inc.
13	ML17024A447	James A. Brink	American College of Radiology

The NRC binned the public comments into three groups based on the areas of interest highlighted in the notice. The NRC reviewed and considered the comments in its decision to accept or deny the issues raised by the petitioners. The following discussion provides a summary of each area of interest addressed in the public comments and the NRC's response to those comments.

NRC's Responses to Comments on PRM-34-7

Area 1: Could the use of dual-function EADs achieve the current safety purpose of using independent devices?

Comment: The new technology is more reliable, more accurate, and less likely to give false readings than the devices currently allowed under § 34.47(a). The new technology offers more safety options for the worker, such as vibrating, audible, and visual alarm capabilities. (Commenters 1, 2, 4, 5, and 7 through 11)

NRC Response: The NRC agrees with the comment. In a memorandum dated

April 4, 2017 (ADAMS Accession No. ML17095A319), the NRC concluded that dual-function EADs were reliable and had a proven track record at nuclear power plants. Furthermore, 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 dual-function EADs (also referred to as combination dosimetry devices in the RIS) may be used to satisfy the requirements in § 34.47(a).

Comment: Defense-in-depth safety that is provided by the use of single-function devices will be lost if dual-function EAD devices are allowed to be used to meet the requirements in § 34.47(a). (Commenters 3 and 6)

NRC Response: The NRC disagrees with the comment. Dual-function EADs that combine the functions of an alarm ratemeter and a direct reading dosimeter do not compromise defense-in-depth (backup) provided by the single devices. The survey meter required under § 34.49(a) provides redundancy (backup) for the function of the operating alarm ratemeter. An individual's personnel dosimeter, required by § 34.47(a), provides redundancy (backup) for the function of the direct reading dosimeter.

Comment: Having all the dosimetry concentrated in a single device will present an all-or-nothing scenario to industrial radiographers who forget the device. It is extremely likely that the temptation will be there for a company or individual to use his or her multimeter as a survey meter of sorts. By doing so, he or she negates the value of the dosimetry, which will no longer correspond to the exposures experienced by his or her body. In the event of an exposure event, the individual's dosimetry will thus likely report a higher value than actually experienced. (Commenter 6)

NRC Response: The NRC interprets this comment to mean that combining all

the functions of the devices required by § 34.47(a) (the alarm ratemeter, the direct reading dosimeter, and the personnel dosimeter) would compromise the defense-in-depth safety provided by three single devices. The NRC determined that the comment was out of scope as the petitioner's request was specifically for the use of dual-function EADs and not for a single device that combined all the functions required by § 34.47(a). Although this comment is beyond the scope of PRM-34-7, the NRC may consider this subject in a future rulemaking that will potentially propose performance-based standards for 10 CFR Part 34 ("Industrial Radiographic Operations and Training" rulemaking, Docket ID NRC-2017-0022).

Comment: It is possible for a "single advanced electronic device" to fulfill both operational needs of timely dose evaluations and integrated dose reporting, improving dosimetry monitoring of the individual and management of the entire radiological program. (Commenter 12)

NRC Response: Although the technology may be available now or in the immediate future to have a single electronic device that meets all the requirements in § 34.47(a), current regulations do not have a performance standard for this type of device. Although this comment is beyond the scope of PRM-34-7, the NRC may consider this subject in a future rulemaking that will potentially propose performance-based standards for 10 CFR Part 34 ("Industrial Radiographic Operations and Training" rulemaking, Docket ID NRC-2017-0022).

Comment: Electronic transfer of dosimeter data utilizing the internet and wireless communication will improve data integrity and compliance compared to hand recording and data transfer. Advanced digital electronic devices can include additional features to determine irradiation conditions (e.g., geometry and motion) and compliance (e.g., was

the dosimeter worn?). These additional features should be considered in any evaluation concerning the modification of any regulations or guidelines. (Commenter 12)

NRC Response: The NRC agrees with the comment that additional features built into electronic devices for use as personnel dosimeters may have safety and operational benefits. Although this comment is beyond the scope of PRM-34-7, the NRC may consider this subject in a future rulemaking that will potentially propose performance-based standards for 10 CFR Part 34 (“Industrial Radiographic Operations and Training” rulemaking, Docket ID NRC-2017-0022).

Comment: How will the proposed combination device be calibrated for correct response to radiation? An alarming ratemeter already has calibration requirements under 10 CFR Part 34, but what of the dosimetry functions? Users of film badges never had to worry about this because they were sent out for processing. (Commenter 6)

NRC Response: The NRC interprets this comment to mean the commenter was concerned that dual-function EADs will have different calibration requirements than devices currently required under § 34.47(a). The NRC disagrees with the comment. The direct reading dosimeter part of the dual-function EAD is still considered a “secondary” dosimeter; that is, it is not intended to be used for directly determining an individual’s dose of record. The worker is still required to use a “primary” personnel dosimeter such as a film badge, thermoluminescent device, optically stimulated luminescence device, or other approved personnel dosimeter for the dose of record. Therefore, any calibration procedures previously used for the direct reading dosimeters, such as those used for a personal ionization chamber, would continue to apply for the direct reading dosimeter part of the dual-function EAD.

Comment: How long can a multimeter be trusted to function within the required ranges? (Commenter 6)

NRC Response: The NRC interprets this comment to mean the commenter was concerned that dual-function EADs (multimeters) will not stay in calibrated ranges for the period between calibrations. The NRC disagrees with the comment. In a memorandum dated April 4, 2017 (ADAMS Accession No. ML17095A319), the NRC concluded that dual-function EADs were reliable and had a proven track record at nuclear power plants. All aspects of the use of dual-function EADs, including calibration, were reviewed and no issues were identified.

Area 2: Should changes similar to those proposed in the petition be applied to other radiation protection regulatory requirements, such as those in 10 CFR Parts 36 and 39?

Comment: While the PRM focuses on 10 CFR Part 34, emerging monitoring technologies can be adopted by other licensees that will also benefit from revised rule language and related guidance. Therefore, in principle, we support the PRM and recommend that the NRC revise rule language and related guidance to allow a more performance-based approach that recognizes the use of emerging personnel monitoring technology to demonstrate regulatory compliance. (Commenter 8)

NRC Response: The NRC agrees with the comment. Amending the requirements for personnel dosimetry at 10 CFR Parts 36 and 39 would provide other licensees the same benefit of access to modern dosimetry as requested for ~~p~~Part 34 by the petitioners. When appropriate, NRC develops regulations and guidance that are performance-based.

Comment: While PRM-34-7 was submitted for NRC consideration with industrial radiography stakeholders in mind, the American College of Radiology believes the spirit

of the PRM should be adopted and explicitly applied to medical radiation workers (i.e., via the pertinent subparts of 10 CFR Part 20) to protect the continued use of advanced technology dosimeters within the medical community, including medical applications of radiation not directly under the NRC's oversight. (Commenter 13)

NRC Response: The NRC interprets this comment to mean that the commenter did not want any changes made to the regulations that will hinder the current use of digital output personnel dosimetry by 10 CFR Part 35 licensees. The NRC agrees with the comment. In authorizing the use of digital output personnel dosimeters to satisfy the requirements in § 34.47(a) (i.e., accepting Issue 1), the NRC intends to expand the availability of digital output personnel dosimeters to licensees licensed under 10 CFR Parts 34, 36, and 39 and not hinder the current use of the dosimetry by other licensees.

Comment: If the NRC were to deny PRM-34-7, it will set a detrimental precedent for State programs that will likely sweep across the broader stakeholder spectrum, thereby disallowing continued use of advanced technology dosimeters in these other occupational domains. (Commenter 13)

NRC Response: The NRC agrees with the comment. Under the Agreement State Program, the requirements in § 34.47 are categorized as a compatibility level C. This means that the essential objectives of a program element are adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed by the Agreement States need not be the same as the NRC's, provided the essential objectives are met. Because the essential objectives are met for personnel dosimetry (i.e., personnel dosimetry is used to determine an individual's dose of record), several Agreement States have allowed the use of digital output personnel dosimeters to meet the monitoring requirements for industrial radiography and other areas. In accepting Issue 1, the NRC intends to expand the availability of digital output personnel

dosimeters to licensees licensed under 10 CFR Parts 34, 36, and 39 and not impede the current use of the dosimetry by Agreement State licensees, including reciprocity activities in NRC jurisdictions.

Currently, several Agreement States allow the use of digital output personnel dosimeters to meet the monitoring requirements for industrial radiography and other areas. Agreement State regulations for individual monitoring of occupational dose do not have to be identical to NRC regulations, but need to meet the NRC's health and safety objectives. For the most efficient regulation of activities conducted in different jurisdictions under reciprocity, personnel dosimetry standards should be similar for both NRC and Agreement State licensees.

Area 3: What experiences or challenges have users encountered in the use of digital output personnel dosimeters?

Comment: During incidents and emergency situations, current monitoring badges must be returned to the processor for emergency evaluation. This requires that the individual be suspended from operations until the results of the processing are received, resulting in potential lost wages. Projects may also be put on hold awaiting results, resulting in down time, lost revenue, and additional cost and time to complete projects. With the new digital dosimeters, readings can be immediately downloaded (even at the jobsite), allowing the radiographer to potentially return to work and saving time and cost. Required reports to the appropriate agency are also provided within a much quicker time frame (sometimes as soon as the next day), allowing for the issue to be resolved in a much shorter timeframe than with the current technology.

(Commenters 1, 2, 7, and 10)

NRC Response: The NRC acknowledges that digital output personnel dosimeters may provide enhanced capabilities that allow for expedited dosage

determinations. Digital output personnel dosimeters do not have to be sent offsite for evaluation, making the determination of a potential dose for an individual more timely.

Comment: The benefits of advanced technology dosimeters have been apparent in the medical community for nearly a decade. In clinical implementation, advanced technology dosimeters have enabled data-rich and accurate real-time worker dose monitoring, thereby better informing licensees and enhancing the ability to plan and control occupational dose. Advanced technology improves monitoring by enabling date/time of exposure, providing multiple non-destructive readouts of dose (without needing to return the devices to vendors for processing), allowing reassignment to other users, and generating better compliance by the medical professionals who wear them. (Commenter 13)

NRC Response: The NRC acknowledges that digital output personnel dosimeters may provide enhanced capabilities for dosage measurements and has evaluated the technical specifications of these dosimeters in various applications and environments. Digital output personnel dosimeters have been used by NRC medical licensees successfully for a number of years without any reported issues. Additionally, several Agreement States have allowed the use of these dosimeters in medical and other areas, including industrial radiography, for years without any incidents noted by the NRC.

III. Reasons for Consideration

The NRC will consider Issue 1 in the rulemaking process.

Digital output personnel dosimetry does not currently meet the requirements for personnel dosimetry in 10 CFR Parts 34, 36, and 39. The NRC's position has been that

personnel dosimetry used to meet the requirements in these parts must be processed as described in § 20.1501(d). In evaluating the issues raised in this petition, the NRC reviewed the technical specifications of currently available digital output personnel dosimeters to determine whether the use of this personnel dosimetry design would meet the NRC's health and safety objectives. The NRC determined that these dosimeters meet or exceed the environmental requirements (e.g., temperature, humidity) and dose range, and have the quality control necessary for use in industrial radiographic, irradiator, and well logging operations. From a literature search of technical journals, the NRC did not find any articles that highlighted generic performance problems with the use of these dosimeters. Digital output personnel dosimeters have been used successfully by NRC licensees in other operational areas, by several Agreement State licensees in all areas including industrial radiography, and internationally in multiple applications. Based on these findings, the NRC determined that rulemaking should be initiated to allow the use of digital output personnel dosimeters to satisfy the personnel dosimetry requirements in 10 CFR Parts 34, 36, and 39.

IV. Reasons for Denial

The NRC is denying Issue 2 raised by the petitioners.

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 § 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 § 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 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 § 34.47(a).

The NRC determined that RIS 2017-06 provides clarification regarding the ~~assertion made~~issue raised by the petitioners with respect to the use of dual-function EADs and, therefore, rulemaking is not necessary to address this petition request.

V. Conclusion

For the reasons cited in this document, the NRC is denying the petitioners' request to amend the NRC's regulations to authorize the use of dual-function EADs to satisfy the requirements in § 34.47(a) (Issue 2); the NRC finds that rulemaking is not

necessary to address this issue. The RIS 2017-06 provides clarification that dual-function EADs may be used to satisfy the requirements in § 34.47(a).

The NRC will consider in the rulemaking process the petitioners' request to amend the NRC's regulations to authorize the use of digital output personnel dosimeters to satisfy the requirements in § 34.47(a) (Issue 1). As noted in Section III. "Reasons for Consideration," in this document, the NRC determined that these dosimeters meet or exceed the technical specifications for use in radiographic operations. Additionally, digital output personnel dosimeters have been used successfully by NRC licensees in other operational areas, by several Agreement State licensees in all areas including industrial radiography, and internationally in multiple applications.

The review that NRC staff performed regarding the use of digital output dosimeters included the environmental and technical considerations for use by 10 CFR Part 36 and 39 licensees. Based on these findings, the NRC intends to expand the scope of this rulemaking to address requirements for personnel dosimetry in 10 CFR Parts 36 and 39.

The NRC will conduct rulemaking on Issue 1 raised by the petitioners as resources become available.

The NRC tracks the status of all rules and PRMs on its Web site at <https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html>. The public may monitor the docket for the rulemaking to address Issue 1 on the Federal rulemaking Web site, <http://www.regulations.gov>, by searching on Docket ID **NRC-XXXX-XXXX**. In addition, the Federal rulemaking Web site allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (**NRC-XXXX-XXXX**); (2) click the "E-mail Alert" link; and (3) enter an e-mail

address and select the frequency for e-mail receipts (daily, weekly, or monthly).

Publication of this document in the *Federal Register* closes Docket ID NRC-2016-0182 for PRM-34-7.

Dated at Rockville, Maryland, this day of , 2018.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.