

Individual Monitoring Devices Rulemaking  
Docket ID NRC-2019-0031; RIN 3150-AK29

Working Group Charter

**PURPOSE**

The purpose of the Individual Monitoring Devices rulemaking working group (WG) is to draft a direct final rule package that would allow the use of digital output personnel dosimeters in industrial radiographic, irradiator, and well logging operations by revising Part 34 of Title 10 of the *Code of Federal Regulations* (10 CFR), "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." In developing the rulemaking package, the working group will ensure that all options to accomplishing the outcome of the rulemaking, including non-rulemaking options, have been considered. This charter describes the WG composition, roles and responsibilities, activities, and schedule for drafting the rulemaking package.

**BACKGROUND**

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to develop quality rules consistent with all applicable laws and regulations and to promote efficient rulemaking. A rulemaking request generally arises in one of four ways: (1) staff-developed regulatory issue; (2) 2.802 petition for rulemaking; (3) Executive Director for Operations (EDO) or Commission directive; or (4) Congressional mandate or Executive Order. This proposed rulemaking is a result of a 2.802 petition.

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. 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.

On July 14, 2016, petitioners submitted a petition for rulemaking (PRM) to allow the use of modern dosimetry in industrial radiographic operations (docketed as PRM-34-7). Specifically, the petitioners requested that the NRC amend its regulations to authorize the use of digital output personnel dosimeters to satisfy the requirements in 10 CFR 34.47(a).<sup>1</sup> The NRC recognized that the same issue was also applicable to Parts 36 and 39 and expanded the scope to include these Parts.

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<sup>1</sup> 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.

On January 4, 2019, in the staff requirements memorandum to SECY-18-0112, "Petition for Rulemaking and Rulemaking Plan on Individual Monitoring Devices for Industrial Radiographic Personnel" (ML19004A449), the Commission approved staff's recommendation to initiate and publish a direct final rule to amend 10 CFR Parts 34, 36, and 39 to allow the use of digital output personnel dosimeters in industrial radiographic, irradiator, and well logging operations. As part of the working group's evaluation, the group will evaluate various options for permitting the use of digital output dosimetry. If regulatory basis development, including public comment, leads to a conclusion that rulemaking should not be pursued, communication to the Commission will be required.

A direct final rule is a regulatory document that is used for non-controversial regulatory amendments. The direct final rule process allows an agency to issue a rule without having to go through the review process twice (i.e., at the proposed and final rule stages), while at the same time offering the public the opportunity to comment. As such, the time and associated schedule to issue a direct final rule are shorter than a standard rule.

**MEMBERSHIP**

The WG is sponsored by the Office of Nuclear Materials Safety and Safeguards (NMSS) Division of Rulemaking (DRM) and Division of Materials Safety, Security, State, and Tribal Programs (MSST). Management sponsors for this activity are June Cai, Branch Chief, NMSS/DRM and Hipolito Gonzalez, Branch Chief, NMSS/MSST.

On January 16, 2019, the NMSS issued NMSS Procedure SA-801A, "Agreement State Participation in Rulemaking Working Groups" (ML18263A239). SA-801A details the procedure for NRC and Agreement State interactions during the entire rulemaking process and complements other NRC directives and guidance for rulemaking activities. In accordance with SA-801A, this is an NRC/OAS WG as described under MD 5.3 and co-chaired by an NRC staff member and a representative from the Organization of Agreement States, Inc. (OAS), and. The membership and roles are depicted in the following table:

Organization	Working Group Members
NRC/NMSS/MSST	Anthony McMurtray, Regulatory Basis Project Manager and Technical Support
OAS	TBD
NRC/NMSS/DRM	Ed Lohr, Rulemaking Project Manager
NRC/NMSS/MSST	Richard Struckmeyer, Technical Support
NRC/Office of Research	Terry Brock, Technical Support
NRC/Region I	Jim Cassata, Regional Support
NRC/OGC	Sheldon Clark, Legal
NRC/NMSS/DRM	Doris Duran-Hernandez, Rulemaking Support

The WG may seek additional expertise on an as-needed basis.

## ACTIVITIES AND SCHEDULE

The goal is for the WG to complete a draft direct final rule package for submission to NRC and OAS management for review by November 22, 2019. A more detailed schedule is being developed. Major milestones are:

WG kick off meeting	03/19/2019
Publish draft regulatory basis	06/03/2019
Publish final regulatory basis	09/05/2019
Publish proposed rule and direct final rule	03/27/2020
Publish conformation <i>Federal Register</i> notice	05/26/2020

## LEVEL OF EFFORT

To support the schedule and activities listed, 80 hours of effort is expected:

1. During regulatory basis development, the level of effort would be 7 weeks @ 6 hours per week. The WG meetings would be scheduled during March and April 2019, as 2 meetings per week for 2 hours each with 1 hour of preparation time. (42 hours total)
2. During proposed rule and direct final rule development, the level of effort would be 9 weeks @ 2 hours per week. The WG meetings would be scheduled during September and October 2019, as 1 meeting per week for 1 hour with 1 hour of preparation time. (18 hours total)
3. During WG products reviews, the level of effort would be 9 weeks @ 2 hours per week in April and October 2019. (18 hours, total)
4. Briefings with interested managers will be held every two weeks during the development of the regulatory basis, with the frequency to be adjusted as needed after the regulatory basis stage.

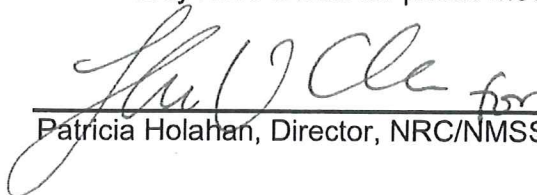
The NRC WG members should charge time associated with the activities identified in this charter to CAC 001129 - NB-NMU-RULEMAKING-FINAL RULEMEETINGS and EPID U-2019-RU5-0000; 01/04/2019 - Individual Monitoring Devices for Parts 34, 36, and 39.

It is anticipated that all meetings will be teleconference supported. Maximum use will be made of available electronic communication options to facilitate interaction within the WG and among its members. Examples of these options include conference calls, e-mail, the NRC BOX Enterprise and File Synchronization System (EFSS, a cloud-based service that provides a secure mechanism for sharing files with external collaborators), and GoToMeeting.


## WORKING GROUP MEMBERS ROLES AND RESPONSIBILITIES

The responsibilities of the Agreement State representative to the Individual Monitoring Devices WG are specified in Section IV.I of SA-801. Responsibilities of WG members from other NRC offices depend on their areas of programmatic responsibility and expertise. The following points reflect the duties and responsibilities listed in NMSS Policy and Procedures 6-10, Revision 3 (September 2018), "NMSS Procedures for Preparation and Review of Rulemaking Packages." In general, WG members are responsible for:

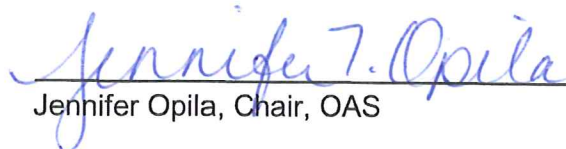
1. Working with the project manager (PM) to: assess the tasks needed to prepare the rule package, including the rule documents; review and comment on drafts; address comments; assist in estimating any information collection burden; assist in the development of cost estimates; assist in preparing briefing materials; and facilitate concurrence on the rule package.
2. Keeping their Branch and Division managers apprised of the rulemaking action, obtaining comments and input on policy decisions from their branch and division managers, and notifying their Branch Chiefs of potential problems or policy issues.
3. Ensuring that their management's opinion is understood and presented to the WG.
4. Keeping all regions apprised of the rulemaking actions, soliciting and addressing regional comments.
5. Attending WG meetings and coming prepared to participate.
6. Providing timely input.
7. Providing correct technical information or legal advice.
8. Informing the PM of conflicting priorities, previously unanticipated problems, and other potential sources of delay.
9. Preparing associated licensing, inspection, and enforcement guidance as appropriate (if the same WG is used for the guidance) and developing milestones so that draft guidance will be available at the beginning of the public comment period on the proposed rule and final guidance will be available upon publication of the final rule, as the Commission expects for consideration of Cumulative Effects of Regulation issues. Note that publication does not need to be on the same day the rule is published, but the guidance should be available within a short time thereafter. Exceptions should be rare and will require Commission approval. The programmatic division has the lead for preparing guidance documents and coordinating with affected organizations. Often the members of the WG for the rule will also participate on the WG for the guidance.
10. Keeping their management on the Steering Committee (if the rulemaking has one) informed.
11. Facilitating the rulemaking concurrence process by keeping their management informed of significant issues of concern and helping to develop an appropriate resolution of those issues. Ideally, a WG member should have kept his or her management apprised enough that the reviewing manager identifies no new issues during the concurrence process.
12. Supporting any briefings or public meetings.
13. Preparing and presenting material related to the guidance or other areas for which they may have a lead for public meetings.

  
 Patricia Holahan, Director, NRC/NMSS/DRM

4/11/19  
 Date

  
 Andrea Kock, Director, NRC/NMSS/MSST

4/10/19  
 Date

  
 Jennifer Opila, Chair, OAS

5/7/19  
 Date