

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[Docket No. PRM-20-25]

Sander C. Perle, ICN Worldwide Dosimetry Service, Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt of a petition for rulemaking, dated March 19, 2003, which was filed with the Commission by Sander C. Perle, Technical Director of ICN Worldwide Dosimetry Service. The petition was docketed by the NRC on March 26, 2003, and has been assigned Docket No. PRM-20-25. The petitioner requests that the NRC amend its regulations to require that any dosimeter, without exception, that is used to report dose of record and demonstrate compliance with the dose limits specified in the Commission's regulations be processed and evaluated by a dosimetry processor holding accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. The petitioner also requests that the definition of *Individual monitoring devices (individual monitoring equipment)* be revised to include "electronic dosimeters, optically stimulated dosimeters" as examples of certain devices.

DATE: Submit comments by (insert date 75 days after publication in the Federal Register).

Comments received after this date will be considered if it is practical to do so, but the

Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include "PRM-20-25" in the subject line of your comments. Comments submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at <http://ruleforum.llnl.gov>. Address questions about our rulemaking web site to Carol Gallagher (301) 415-5905; email cag@nrc.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this petition may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there

are problems in accessing the documents located in ADAMS, contact the NRC's PDR Reference staff at 1-800-397-4209, 301-415-4737 or by email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Telephone: 301-415-7163 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

The Petitioner

The petitioner is the Technical Director of ICN Worldwide Dosimetry Service. According to the petitioner, ICN Worldwide Dosimetry Service processes approximately 5 million dosimeters annually (film, TLD and CR39).

The Petitioner's Request

The petitioner requests that the NRC amend its regulations in 10 CFR Part 20 to require that all dosimeters used to determine the radiation dose of record and demonstrate compliance with the dose limits specified in the Commission's regulations be processed and evaluated by a dosimetry processor holding receive personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. The petitioner also requests that the definition of *Individual monitoring devices (individual monitoring equipment)* be revised to include "electronic dosimeters" and "optically stimulated dosimeters" as examples of certain devices for the assessment of dose equivalent or to comply with § 20.1202.

Justification for the Petition

The petitioner states that the current wording of § 20.1501(c) precludes the testing and accreditation requirements for an electronic dosimeter (currently excludes “processed” dosimeters). The petitioner states that today’s electronic dosimeters use multiple microprocessors that include many complex user input parameters that ultimately affect the final dose and/or dose rate reported. The dose determined from an electronic dosimeter is a “processed” dose. The electronic dosimeter requires that the licensee program the dosimeter to respond to various spectra, based on the calibration and other licensee set parameters. According to the petitioner, the NRC’s position is that because the current § 20.1501(c) doesn’t appear to include the definition of an electronic dosimeter, nothing prohibits a licensee from using an electronic dosimeter as a dose of record. He states that the NRC’s philosophy is that the NRC onsite inspector can assess the validity of the electronic dosimeter quality assurance program. The petitioner believes that the NVLAP onsite assessor is the most appropriate individual to assess a facility’s quality assurance program, and to determine if the electronic dosimeter is capable of measuring and reporting accurate and precise dose results for workers in a specific radiation work environment, as they do for all other NVLAP accredited whole body dosimeters.

The petitioner states that the current wording of § 20.1501(c) precludes the testing and accreditation requirements for an extremity dosimeter (finger or wrist dosimeter). He states that because § 20.1201, *Occupational dose limits for adults*, specifies a dose limit, the annual limits to the extremities, which are a shallow dose equivalent of 50 rems (0.5 Sv) to the skin or to an extremity, it would seem logical that the dosimeter used to make this dose determination should be accredited through the same process as a whole body dosimeter. The petitioner states that NVLAP has accredited extremity dosimeters per Standard ANSI N13.32-1995, Performance

Testing of Extremity Dosimeters for the past 8 years. The petitioner believes that there is no reason to continue excluding extremity dosimeters from requiring accreditation.

The petitioner notes that the NRC participated in an Electronic Dosimetry Workshop on October 14 -16, 1998 (Journal of Research of the National Institute of Standards and Technology, Volume 103, No. 4, July-August 1998). The petitioner states that the "Conference Report" (documenting that workshop) concludes that electronic dosimeters need to be measured by the same standard as the passive dosimeters currently in use and defines the electronic dosimeter as a processed dosimeter.

The petitioner presents the following as a summary of the Conference Report:

1. A search for consensus, among recommendations, and was intended to result in the broad acceptance of the electronic dosimeter for dose or record.
2. Ensure that the electronic dosimeter is measured by the same standard as the passive dosimeters currently in use.
3. This focused on defining the electronic dosimeter as a processed dosimeter in order to confirm that it fit the requirements of 10 CFR Part 20 for processed dosimeters.
4. It is clear that a process is used by the electric dosimeter to change from radiation energy deposited in the detector to a dose quantity representing risk to the worker.
5. The user has an important role in routine testing and/or calibration of the electronic dosimeters and this may be the point at which quality control activities (accreditation) should be addressed.

The petitioner believes that requiring NVLAP Accreditation of electronic dosimeters provides an unbiased third-party evaluation and recognition of performance, as well as expert technical guidance to upgrade laboratory performance. NVLAP accreditation signifies that a laboratory has demonstrated that it operates in accordance with NVLAP management and technical requirements pertaining to quality systems; personnel; accommodation and environment; test and calibration methods; equipment; measurement traceability; sampling; handling of test and calibration items; and test and calibration reports. NVLAP accreditation

does not imply any guarantee (certification) of laboratory performance or test/calibration data; it is solely a finding of laboratory competence.

The Petitioner's Suggested Changes

1. The definition for *Individual monitoring devices (individual monitoring equipment)* is revised to read as follows:

§ 20.1003 Definitions.

* * * * *

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent, used by licensees to comply with § 20.1201, such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, electronic dosimeters, optically stimulated dosimeters and person ("label") air sampling devices.

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2. Section 20.1501(c) is revised to read as follows:

§ 20.1501 General.

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(c) All personnel dosimeters used to determine the radiation dose and that are used by licensees to comply with 10 CFR 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license, must be processed and/or evaluated by a dosimetry processor.

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The Petitioner's Conclusions

The petitioner states that when an occupationally exposed worker wears a dosimeter, the worker expects that the dosimeter will measure and report their dose as accurately and precisely as technically feasible. This requires that the dosimeter be capable of performing adequately in the radiation environment that the worker is exposed to. Therefore, a dosimeter must be able to respond adequately in varying radiation environments; i.e., varying gamma, Beta, x-ray and neutron fields of varying dose rates and geometry. The petitioner states that requiring NVLAP accreditation assures the worker, the licensee, management, and the NRC (as well as state regulators) that the dosimeter worn performs as expected. NVLAP accreditation requires both the testing to varying radiation types, energies, dose range and angularity. NVLAP accreditation also provides onsite assessment of the entire Quality System. The petitioner believes that while NVLAP accreditation does not give 100 percent assurance that the licensee is performing to the best of its ability, it does provide a degree of assurance that any serious programmatic deficiencies that exist are documented and NVLAP follow-up is initiated to ensure that these deficiencies are corrected. The most appropriate entity to assess a dosimetry program is an NVLAP technical expert, not an NRC on-site inspector.

The petitioner states that the inspector can assess a dosimetry program, review the NVLAP report, and then take appropriate action to ensure that the licensee does comply with all requirements. Without these suggested amendments, there is no accredited testing performed for either extremity dosimeters or electronic dosimeters. There is no required onsite assessment by NVLAP. The petitioner believes that there is no standard that is required to be met. This does not serve the licensee well, and more importantly, leaves the workers with a dose that has no support from any recognized US or international standard. The petitioner states that the NRC would be better prepared to stand behind a dose that is submitted as dose

of record, and ultimately the dose recorded would stand a better chance of being accepted in the event of litigation. Litigation and valid dosimetry drives the American Nuclear Insurers (ANI) to require any nuclear power plant worker who is expected to exceed 100 mrem in a calendar year, to wear two dosimeters (independent technology) to demonstrate that the dose of record can be substantiated using these varying technologies. The validity of the dose assigned logically requires that whatever dosimeter is used to meet § 20.1201, it must meet recognized standards. The petitioner states that the NRC has stated this in many venues, most notably the Electronic Dosimetry Workshop, documented in the Conference Report, Electronic Dosimetry Workshop, Gaithersburg, MD, October 14-16, 1998, Journal of Research of the National Institute of Standards and Technology, Volume 103, No. 4, July - August 1998. The petitioner believes that it is time for the NRC to implement the necessary changes to § 20.1501(c).

Dated at Rockville, Maryland, this 29th day of April 2003.

For the Nuclear Regulatory Commission.

/RA/

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