

December 18 , 2004

MEMORANDUM TO: Luis A. Reyes
Executive Director
for Operations

FROM: Jack R. Strosnider, Director
Office of Nuclear Material Safety
and Safeguards **/RA/**

SUBJECT: DENIAL OF A PETITION FOR RULEMAKING SUBMITTED BY
SANDER C. PERLE, ICN WORLDWIDE DOSIMETRY

Your approval and signature are requested on both the letter to the petitioner and the *Federal Register* notice (Attachments 1 and 2, respectively). The notification for the Commission is provided in Attachment 3.

The Commission received a petition from Sander C. Perle, ICN Worldwide Dosimetry, dated March 19, 2003. This petition was assigned Docket Number PRM-20-25. The petitioner requested that the U.S. Nuclear Regulatory Commission (NRC) amend its regulations to require that:

- (1) 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 specifically referenced electronic dosimeters.
- (2) The definition of "individual monitoring devices" in 10 CFR 20.1003 be revised to mean any device used by licensees to show compliance with 10 CFR 20.1201.
- (3) "Electronic dosimeters and optically stimulated dosimeters" be added as additional examples of individual monitoring devices.

The petition was published in the *Federal Register* on May 5, 2003 (68 FR 23618), for a 75-day comment period. Twelve comment letters were received. Six commenters recommended that NRC deny the petition; three commenters supported the petition, but with substantial changes; and three comments were received from the petitioner, responding to comments that NRC received on the petition.

CONTACT: Torre Taylor, NMSS/IMNS
(301) 415-7900

The NRC staff has reviewed the petition and the public comments, and, for the reasons provided in the attached *Federal Register* notice, recommends that the petition be denied. There is insufficient evidence that the petition, if granted, would solve a regulatory problem or improve health and safety.

The additional requirements would be an increase in burden for licensees, without a commensurate benefit from increased worker health and safety. If the petition is granted as written, the changes would result in requiring NVLAP accreditation of dosimetry processors for essentially all types of dosimeters that might be used in a facility, beyond just the electronic dosimeters the petitioner specifically referenced.

The petition, if granted as written, would remove the current exception for NVLAP accreditation for processors of extremity dosimeters in 10 CFR 20.1501(c). The staff agrees, in principle, that it is a good idea to include extremity dosimetry that requires processing in the requirement for NVLAP accreditation for processors. However, the American National Standards Institute (ANSI) and Health Physics Society (HPS) standard for extremity dosimeters, ANSI/HPS N13.32-1995, "Performance Testing of Extremity Dosimeters," is undergoing a major revision. The petitioner has provided no evidence that there is a current health and safety problem and much of the industry is voluntarily obtaining NVLAP accreditation for processing of extremity dosimetry. Consequently, the staff believes that it is premature to remove this regulatory exception. Therefore, NRC is not taking any regulatory action on this issue.

The decision to deny the petition is consistent with our goals. Three of the Agency's goals, stated in the new Fiscal Year (FY) 2004 - FY 2009 Strategic Plan, that are relevant to this petition are to ensure: (1) protection of public health and safety and the environment; (2) openness in our regulatory process; and (3) that NRC actions are effective, efficient, realistic, and timely.

The Safety Goal, "Ensure protection of public health and safety and the environment," will be met in that the petition is not solving a regulatory problem or improving health and safety. The staff has determined that the current regulations are adequate for protection of health and safety. Electronic dosimeters are not processed as are film or thermoluminescent dosimeters, to obtain the dose information. An accreditation program for electronic dosimetry would not contribute to improved performance or reliability, and would not have any effect on safety.

The Openness Goal, "Ensure openness in our regulatory process," is being met through the petition process, which includes notice of receipt and opportunity for public comment. This petition was published for public comment in the *Federal Register* on May 5, 2003, and NRC received comments from members of the public, including additional comments from the petitioner clarifying comments that NRC received from members of the public. These comments were reviewed and considered during the final review of the petition. The final decision on this petition will be noticed in the *Federal Register* as well.

The Effectiveness Goal, "Ensure that NRC actions are effective, efficient, realistic, and timely," would not be achieved by granting this petition. Requiring NVLAP accreditation for processors of dosimeters that do not require processing would add another layer of regulation that might require verification during licensing of applicants or inspections of licensees, without an added benefit in health and safety. Efficiency and effectiveness would also decrease by spending considerable resources on a rulemaking that would not result in a commensurate benefit in health and safety.

Denying this petition will prevent unnecessary regulatory requirements. This proposed regulatory change would require a backfit. NRC requires backfitting only when it determines that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit, and that the direct and indirect costs of implementation are justified in view of this increased protection. After reviewing the proposed actions, the staff believes that the revisions proposed in the petition would not pass a detailed backfit analysis. There is insufficient evidence that the petition, if granted, would solve a regulatory problem or improve health and safety. The increase in cost to licensees does not warrant granting this petition.

The action does not constitute a significant question of policy, nor does it affect regulations contained in 10 CFR Parts 7, 8, or 9, Subpart C, concerning matters of policy.

In conclusion, after reviewing the petition and the public comments, the staff is recommending that this petition be denied. There is insufficient evidence that the petition solves a regulatory problem or improves health and safety. If the petition were granted, there would be an increase in burden to licensees that is unjustified without a commensurate benefit to health and safety. Therefore, NRC has determined that existing NRC regulations are adequate to provide reasonable assurance that worker health and safety are protected. The appropriate Congressional committees will be informed of the denial of the petition.

Attachments:

1. Letter to Petitioner
2. *Federal Register* Notice of Denial
3. Notice of Petition Denial Signed by EDO

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