

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0279]

**New International Commission on Radiological Protection Recommendations on the
Annual Dose Limit to the Lens of the Eye**

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is continuing its stakeholder outreach of possible changes to the radiation protection standards by seeking public comment on the newly released International Commission on Radiological Protection (ICRP) recommendations for the limitation of annual dose to the lens of the eye. This significant new recommendation has not yet been the subject of any stakeholder or public interactions on any potential changes to the NRC's radiation protection regulations. The NRC has not initiated rulemaking on this subject, and is seeking early input and views on the benefits and impacts of options to be considered before making any decision on whether to consider this issue for future rulemaking. Stakeholders and the public are encouraged to submit comments concerning potential impacts, burdens, benefits, and concerns on the issues discussed in this notice.

DATES: Submit comments by **[INSERT DATE 60 DAYS FROM DATE OF PUBLICATION]**.

Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID **NRC-2009-0279** in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. Members of the public are invited and encouraged to submit comments by any of the following methods:

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for documents filed under Docket ID **NRC-2009-0279**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Telephone: 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, telephone: 301-415-3781, e-mail: Solomon.Sahle@nrc.gov, or Dr. Donald Cool, telephone: 301-415-6347, e-mail: Donald.Cool@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site <http://www.regulations.gov>. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this notice using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the

public can gain entry into ADAMS, which provides text and image files of the 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 e-mail to pdr.resource@nrc.gov.

- **Federal rulemaking Web site:** Public comments and supporting materials related to this proposed rule can be found at <http://www.regulations.gov> by searching on Docket ID **NRC-2009-0279**.

II. Background

Regulations issued by the NRC are found in Chapter I of Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR). Chapter I is divided into Parts 1 through 199, and contains requirements that are binding for all individuals and entities that possess, use, or store nuclear materials or operate nuclear facilities under the NRC's jurisdiction. Of these, the regulations that are most relevant to the subject of this notice are contained in 10 CFR Part 20, "Standards for Protection against Radiation." Through the existing compatibility criteria, the NRC Agreement States have certain requirements that are essentially identical to those contained in 10 CFR Part 20 for their licensees. Additional requirements, specific to particular uses or classes of facilities, are found in other portions of the NRC's regulations. For example, 10 CFR Part 35, "Medical Use of Byproduct Material," contains requirements related to the medical use of radioactive material, and 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," contains additional requirements for power reactors. Other portions of the NRC's regulations also may contain radiation protection criteria, and cross references to 10 CFR Part 20.

The ICRP Publication 103 (December 2007) contains the latest in a series of revised ICRP recommendations for radiation protection. On December 18, 2008, the NRC staff provided a Policy Issue Notation Vote Paper (SECY-08-0197; ADAMS Accession No. ML083360582) to the Commission, which presented the regulatory options of moving, or not moving, towards a greater degree of alignment of the NRC regulatory framework with ICRP Publication 103. In a Staff Requirements Memorandum (SRM) dated April 2, 2009 (ADAMS Accession No. ML090920103), the Commission approved the staff's recommendation to begin engaging with stakeholders and interested parties to initiate development of the technical basis for possible revision of the NRC's radiation protection regulations, as appropriate and where scientifically justified, to achieve greater alignment with the recommendations in ICRP Publication 103.

This notice of solicitation of comment represents the third in a series of such requests. Previous notices were published in the *Federal Register* on July 7, 2009 (74 FR 32198), and September 27, 2010 (75 FR 59160). In addition, the NRC staff held a series of facilitated public workshops in October and November 2010, to engage the views of a wide range of stakeholders on the key issues presented by the ICRP recommendations.

On April 21, 2011, the ICRP issued a statement on tissue reactions (see <http://www.icrp.org/docs/ICRP%20Statement%20on%20Tissue%20Reactions.pdf>) stating that it has reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose for radiation-induced cataract formation is now considered by the ICRP to be 0.50 Gy (50 rem). Consequently, for occupational exposure in planned exposure situations, the ICRP is now recommending a limit on equivalent dose for the lens of the eye of 20 mSv (2 rem) per year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv (5 rem). The

ICRP's recommended limits for dose for the lens of the eye are numerically equal to its current recommendation for the limit on effective dose, which is 20 mSv (2 rem) per year, averaged over 5 years, with no single year exceeding 50 mSv (5 rem).

The supporting information reviewed by the ICRP was provided for public consultation in December 2010 (<http://www.icrp.org/docs/Tissue%20Reactions%20Report%20Draft%20for%20Consultation.pdf>). This draft report will be revised in light of the comments received by the ICRP during the public consultation period, and is expected to become a final ICRP report towards the end of 2011.

The international radiation protection community is currently examining the issue of revising the dose limits for the lens of the eye. In particular, the International Atomic Energy Agency has specifically considered and is now incorporating, the new limits into the revision of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources.

Protection of the eye against the effects of ionizing radiation is designed primarily to prevent the formation of cataracts. The sensitive part of the eye for this health effect is the lens, and radiation dose to the eye is defined as the lens dose equivalent (LDE) at a tissue depth of 0.3 cm (10 CFR 20.1003). Cataract formation falls under the class of radiation effects referred to as deterministic (or tissue reactions in current ICRP terminology). At doses above the threshold, the severity of cataract formation increases with dose, but the radiation-induced incidence below the threshold dose is believed to be essentially zero. Currently, 10 CFR Part 20 limits annual occupational exposures to the lens of the eye to 150 mSv (15 rem) per year (10 CFR 20.1201).

The NRC is supplementing its standard rulemaking process by conducting enhanced public participatory activities before the initiation of any formal rulemaking process, to solicit early and active public input on major issues associated with radiation protection regulations.

As a first step, the NRC has prepared an issues paper that describes issues and alternatives related to limits for the lens of the eye. The intent of this paper is to foster discussion about these issues and alternatives before a rulemaking to set standards would begin. The content of the issues paper is contained in Section IV of this document. The NRC will also utilize its rulemaking Web site to make the issues paper available to the public and to solicit public comments.

III. Request for Written and Electronic Comments

The NRC is soliciting comments on the items presented in the issues paper in Section IV of this notice. Comments may be submitted either in writing or electronically as indicated in the **ADDRESSES** section of this document.

In addition to inviting public comments on the issues presented in Section IV, the NRC is soliciting specific comments related to: 1) quantitative and qualitative information on the costs and benefits resulting from consideration of the factors described in the issues paper; 2) operational data on radiation exposures and administrative control methods that might result in increased or reduced exposures when implementing the associated change in a dose limit; 3) whether the presented factors are appropriate; and 4) whether other factors should be identified and considered, including providing quantitative and qualitative information for these factors. The Commission believes that the stakeholders' comments will help to quantify the potential impact of these changes and will assist the NRC, as it continues to consider alternatives for the radiation protection framework.

The NRC does not plan to provide specific responses to the comments received during this solicitation. Based on the comments received, the NRC staff will prepare policy issues for Commission consideration on whether to proceed with the development of a proposed rule or

take other regulatory action. If the Commission decides to proceed further with a proposed rulemaking, any proposed rule will be published in the *Federal Register* for public review and comment.

IV. Issues Paper on the Dose Limit to the Lens of the Eye

INTRODUCTION:

On April 21, 2011, the ICRP issued a statement on tissue reactions, indicating that it has now reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose for radiation-induced cataract formation is now considered to be 0.5 Gy (50 rem). Consequently, for occupational exposure in planned exposure situations, the ICRP is now recommending a limit on equivalent dose for the lens of the eye of 20 mSv (2 rem) per year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv (5 rem).

ISSUES AND OPTIONS:

To understand the magnitude of the doses incurred by the lens of the eye in the various industries regulated by the NRC, the NRC staff initially queried the Radiation Exposure Information and Reporting System (REIRS) database for occupational dose records over the past 16 years (1994-2010). Under 10 CFR 20.2206, seven NRC-licensed industry groups must report occupational radiation exposure data. These licensed industries are commercial nuclear power reactors; industrial radiographers; fuel processors (including uranium enrichment facilities), fabricators, and reprocessors; manufacturers and distributors of byproduct material; independent spent fuel storage installations; facilities for land disposal of low-level waste; and

geological repositories for high-level waste. Currently, there are no NRC-licensed facilities for land disposal of low-level waste or geological repositories for high-level waste. Therefore, these licensee categories do not submit occupational radiation exposure reports to the REIRS database. Other categories of NRC licensees (e.g., medical licensees) are not currently required to submit reports of occupational exposure. While Agreement State licensees are not required to provide reports to the NRC, some licensees within the industrial radiography and nuclear pharmacy categories have voluntarily submitted occupational radiation exposure reports to the REIRS database.

Annually, the NRC receives approximately 200,000 occupational radiation exposure reports to the REIRS database (NUREG-0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities" (ADAMS Accession No. ML110820543). The reports are generally submitted electronically as an NRC Form 5 record of occupational exposure for a monitoring period. The form includes fields to report deep dose equivalent (DDE), lens dose equivalent (LDE), committed effective dose equivalent (CEDE), total effective dose equivalent (TEDE), and shallow dose equivalent (SDE). For the purpose of this overview, the staff assumes that the reported DDE and LDE are taken from the same measurement, and that there is relatively infrequent direct measurement of LDE within the 200,000 records submitted annually.

In terms of the new ICRP recommendations for the lens of the eye, the staff focused on REIRS data for the past 5 years (2006-2010) and found that current practices have resulted in upwards of 1,000 cases where a 20 mSv (2 rem) per year eye dose level was exceeded. None of these situations exceeded the current annual limit for the lens of the eye of 150 mSv (15 rem). The initial examination of REIRS data did not determine whether the same individual exceeded a 2 rem per year average over the 5-year period. The REIRS database did not contain a record where the deep dose equivalent exceeded a value of 50 mSv (5 rem) in a

single year.

It can be concluded, based on this preliminary analysis, that current radiation protection practices would result in a considerable number of instances where dose to the lens of the eye exceeds 20 mSv (2 rem) per year. It should be noted that the reported TEDE and LDE values, above 20 mSv (2 rem) per year, are not necessarily associated with the same individuals each year. To obtain data on accumulated DDE for individuals, the NRC staff initially analyzed data for the past 16 years and found that no individual in any of the NRC-licensed industries reporting to REIRS, including individuals in those categories as reported by Agreement State licensees, has exceeded a cumulative exposure of 0.5 Sv (50 rem) during this period (1994 – 2010).

The information available to the NRC staff indicates that the majority of NRC-regulated workers are usually exposed to fairly uniform radiation fields. In this exposure environment, and without the use of shielding for portions of the body, the equivalent dose to the lens of the eye is typically similar to the TEDE. Therefore, measures to minimize radiation exposure, in general, will also result in a reduction in dose to the lens of the eye. Likewise, in many instances, an annual whole body dose that exceeds an annual level of 20 mSv (2 rem) would likely mean that the lens dose would also exceed 20 mSv (2 rem).

There are other types of licensed uses for which reporting of dose is not currently a requirement. For example, the NRC staff has been made aware of possible eye dose issues associated with licensees using depleted uranium in the fabrication of shielding, counterweights, etc. Further, some types of exposure, such as to machine-produced radiations (e.g., x-rays), are not the subject of NRC jurisdiction, and thus exposures in these categories are not reported to the NRC. However, the occupational dose to individuals exposed to both NRC-licensed radioactive materials, as well as non-NRC-licensed sources (e.g., x-rays), is regulated to the 10 CFR Part 20 dose limits. Exposures to the lens of the eye may be particularly important in

some of these fields, and others, such as medical interventional radiology and cardiology, which are subject to regulation by the States, but are not necessarily under NRC jurisdiction.

In situations where there may be a non-uniform radiation field, or where shielding reduces the exposure to significant portions of the body, the dose to the lens of the eye might be greater than the TEDE. In such circumstances, specific additional protection measures might be necessary to reduce exposure to the lens of the eye. The NRC staff understands that the use of leaded safety glasses has proven effective in significantly reducing dose to the lens of the eye from soft x-rays, and use of such glasses with side shields is effective in situations where there is significant scatter of low energy radiation, such as in interventional radiology and cardiology, where shielding is already provided for the torso to reduce the effective dose. The use of leaded safety glasses might not be effective for use by industrial radiographers, where the greater energies of the radiation make it difficult or impractical to provide significant shielding to the lens of the eye.

In considering possible changes, the NRC staff must consider the implications of the dose limits for the lens of the eye in connection with all of the other issues that have been previously discussed with stakeholders, including the implications of a change to the dose limit for TEDE, and the implications of strengthening or modifying the requirements for optimization analysis using planning values to ensure that exposures are As Low As Is Reasonably Achievable.

As in all regulatory proceedings, the NRC could pursue several possible options. The NRC staff has identified the following three options for initial consideration and assessment in considering a revision to associated regulations and regulatory guidance.

1. No change: Continue with the existing regulatory requirement to limit dose to the lens of the eye to 150 mSv (15 rem) per year.
2. Change the current requirements by adopting the ICRP- recommended dose values.

3. Change the current requirements to adopt a single, reduced dose limit for the lens of the eye. For example, a single limit of 50 mSv (5 rem) or 20 mSv (2 rem).

QUESTIONS:

The NRC staff is seeking stakeholder input on the issues, implications, and options relating to possible changes to the NRC regulatory requirements to reflect the ICRP's recommendations for lowering the dose limit for the lens of the eye. The NRC is soliciting specific comments related to: 1) quantitative and qualitative information on the costs and benefits resulting from consideration of the factors described in this issues paper, 2) operational data on radiation exposures and administrative control methods that might result in increased or reduced exposures in implementing the associated changes in a dose limit; 3) whether the presented factors are appropriate; and 4) whether other factors should be identified and considered, including providing quantitative and qualitative information for these factors. The following questions identify areas in which the NRC staff is seeking specific views and inputs. However, stakeholders are invited to identify and address other areas and implications not specifically mentioned here or in the issues paper.

1. To what extent has dose to the lens of the eye been an issue in the implementation of your radiation protection program, and would a change in the limits cause operational and administrative impacts? What other types of impacts would you foresee?
2. What types of specific administrative and monitoring methods would be available in your use of radiation or radioactive materials to reduce exposures to the lens of the eye, and what would be the costs and operational impacts of implementing such methods?
3. What might be the anticipated impacts of a rule change on recordkeeping and

reporting?

4. Are there technological implementation issues, such as limits of detection as compared to currently used radiation monitoring methods, or availability of dosimetry, that would make adoption of the ICRP recommendations difficult or impractical in certain circumstances? If possible, please provide a typical example of such a circumstance.
5. How does the recommended limit to the lens of the eye influence your views on possible changes to the limits on TEDE, given that these two quantities are expected to be essentially the same for many exposure situations?
6. What alternatives to adoption of the new limits would you suggest in achieving the desired outcome of limiting exposure of the lens of the eye over the working lifetime of an employee?
7. What should be the relationship between the U.S. regulatory requirements and those adopted internationally? What impacts, either positive or negative, would result from an alignment of NRC regulatory requirements and guidance with international standards?
8. Should licensees be required to monitor and report LDE for foreign workers and report the values upon request? Are there other impacts (e.g., operational, administrative, costs, etc.) that should be anticipated if the U.S. regulatory structure were to be different from that being used in other countries?
9. Are there any other NRC regulations and regulatory guidance that might need to be reviewed and revised as a result of ICRP recommendations in reducing the allowable dose to the lens of the eye?

10. How are licensees monitoring to demonstrate compliance with the existing dose limits for the lens of the eye?

Dated at Rockville, Maryland, this 19th day of August 2011.

For the Nuclear Regulatory Commission.

/RA/

Josephine M. Piccone, Director
Division of Intergovernmental Liaison
and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs

10. How are licensees monitoring to demonstrate compliance with the existing dose limits for the lens of the eye?

Dated at Rockville, Maryland, this 19th day of August 2011.

For the Nuclear Regulatory Commission.

/RA/

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and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs

***Concurred via e-mail**

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OFC	RBA/DILR	DILR	ADM	OGC	D:DILR
NAME	SSahle	DCool *	CBladey	BJones NLO w/edits (JBiggins for)	JPiccone
DATE	8/17/11	8/16/11	8/16/11	8/10/11	8/19/11

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