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Arkansas Department of Health

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Governor Mike Beebe
Paul K. Halverson, DrPH, FACHE, Director and State Health Officer

October 30, 2011

Josephine M. Piccone, Ph.D., Director
U.S. Nuclear Regulatory Commission
Division of Intergovernmental Liaison
and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs
11545 Rockville Pike
Rockville, Maryland 20852

Re: OPPORTUNITY TO COMMENT ON THE NEW INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION RECOMMENDATION TO THE LENS OF THE EYE (FSME-11-084)

Dear Dr. Piccone:

The Arkansas Department of Health (Department), Radioactive Materials Program, has reviewed the Request for Public Comment relating to the New International Commission on Radiological Protection (ICRP) recommendations on the reduction of the annual dose limit to the lens of the eye, published in the *Federal Register*, Vol. 76, No. 168, August 30, 2011. **Docket ID NRC-2009-0279.**

The Department has reviewed the recommendation and provides the following general comments and specific responses to questions contained in the *Federal Register* notice:

- Based on the operating experience gained in implementing the Arkansas Agreement State Program, the proposed reduction in the lens of the eye dose limit does not seem to be justified for radioactive material licensees.

- The adoption of the proposed lens of the eye dose limit will equally apply to registrants of the Arkansas X-Ray Program, including interventional medicine personnel, whose dose to the lens of the eye from x-rays has become a concern. However, it is understood from input received by the Department that adoption of the proposed annual limit is not realistic for certain interventional medicine disciplines, and the proposed dose limit could be exceeded early in a given year by individuals in a busy practice.

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- Imposition of reduced dose limits may result in certain individuals not consistently wearing lens of eye dosimeters during procedures to avoid recording exposure resulting in an unmonitored dose. While this is not a specific reason for not adopting a lower annual dose, it is reported that it could well be a detrimental result of imposing a reduced limit.

The following response is provided to questions presented in the *Federal Register* notice on pages 53850 and 53851:

1. To what extent has dose to lens of eye been an issue in implementation of radiation protection program, and would change in limits cause operational and administrative impacts? What other types of impacts would you foresee?

Response

The dose to the lens of the eye has not been an issue in the Arkansas Agreement State Program for radioactive material. There have been no reported events by Arkansas licensees in which the current annual dose equivalent limit has been exceeded.

However, elevated doses to the lens of the eye resulting from the use of x-rays in interventional procedures have been identified in Arkansas X-ray Program. There has been one individual who exceeded the current annual dose equivalent limit for the lens of the eye (15 rems).

Future impacts on the Arkansas Radiation Control Program, both Radioactive Materials (RAM) and X-Ray Programs would be as follows:

Administrative

The Rules and Regulations for Control of Sources of Ionizing Radiation would have to be revised to incorporate the changes in the dose limits in accordance with the Arkansas Administrative Procedures Act. The typical length of time for this process, including public hearings, is about two years for final enactment and implementation of revised regulations.

Licensees would be required to submit radioactive material license amendment requests for incorporating the revised program for the lens of the eye dose monitoring into the radioactive material license.

Operational

Radiation Control (RAM and X-ray programs) staff personnel training on the implementation of the revised regulations and the Department's inspection and enforcement policies and practices in each of the Radiation Control programs.

Licensees and registrants would be required to revise radiation safety operating procedures to incorporate revised limits along with the new/revised methods for dose monitoring and reporting and to also train personnel in the operating procedures and methods.

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?

Response

Licensees and registrants would be required to implement radiation safety programs consistent with the potential lens of eye exposure at their facility to help insure the dose to the lens of the eye is ALARA. Adoption and implementation of more restrictive ALARA administrative limits would be expected.

The revised radiation safety programs provided by radioactive material licensees would be reviewed by the Department and incorporated into the license.

3. What might be the anticipated impacts of a rule change on recordkeeping and reporting?

Response

Because of the significant lowering of the annual lens of the eye dose limit, licensees and registrants will be required to place additional emphasis on monitoring and reviewing the periodic dosimetry reports from dosimeter service vendors. Individual counseling on dose reduction and the implementation of additional radiological controls for individuals approaching or who have exceeded the established administrative limits would be required and these actions would be reviewed during compliance inspections.

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.

Response

Specific guidance on the placement of dosimeters to more accurately measure the dose to the lens of the eye is needed and is necessary (via regulatory guidance).

Also, it is understood in certain circumstances that the consistent actual wearing of lens of the eye dosimeters by individuals during procedures (primarily in the use of X-rays) is a concern and may become even more so with the adoption of a reduced annual limit.

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?

Response

The Department does not support revising the lens of the eye annual dose limit and does not support revising the TEDE limits. Neither does the Department support the possibility of two dose limits for the lens of the eye (2 rem per year, averaged over 5 years, with no single year exceeding 5 rem for radioactive materials, and 15 rem for X-ray).

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 the employee?

Response

Licensees and registrants must adopt and implement ALARA administrative limits and implement an aggressive review program to ensure the dose to the lens of the eye is ALARA for all potentially exposed individuals. Specific radiological controls for individuals who are approaching or who have exceeded the established administrative limits must be implemented to insure an individual's dose is ALARA and remains below the regulatory limit.

Licensees and registrants must continually emphasize the need to maintain doses ALARA and the resultant consequences (both medically and professionally) if regulatory limits are exceeded.

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 the alignment of NRC regulatory requirements and guidance with international standards?

Response

The Department believes that U.S. regulatory requirements should be consistent with those adopted internationally whenever a demonstrated need to do so is presented. However, the demonstrated need (for example, radiation dose limit reduction) must strongly consider the U.S. business community radiological work practices and the radiation dose history of the U.S. work force of radiation users. Certainly, concern exists for radiation doses that are reportedly being incurred by interventional medicine personnel using X-rays; however, these individuals are not (and appropriately so) the subject of the current NRC rulemaking.

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?

Response

The Department believes that licensees should monitor and report radiation doses as required by their current Radioactive Material License.

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?

Response

Not at this time.

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

Response

Licensees are reviewing and monitoring the dosimetry results as provided by their current dosimetry service vendor.

The NRC should most definitely continue with the current lens of the eye annual dose limit and no rulemaking on the reduction of the annual dose limit should be proposed at this time.

Thank you for the opportunity to comment.

Sincerely,

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FROM: Bernie Bevill, Section Chief **PAGE 1 OF** 7
Radiation Control Section

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Proposed Lens of Eye Dose A

T Bevill