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October 31, 2011

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Washington, DC 20555-0001

Attn: **Rulemakings and Adjudications Staff**

Subject: **CORAR Comments on New ICRP Recommendations on the Annual Dose Limit to the Lens of Eye.**
Docket ID NRC-2009-0279

Reference: **Federal Register Vol.76, No 168, August 30, 2011, Pages 53847-53851. New International Commission on Radiological Protection Recommendations on the Annual Dose Limits to the Lens of the Eye.**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)[1]. CORAR manufacturers' and distributors' operations involve occupational exposure to the lens of the eye which can be critically limiting for certain operations and dosimetry procedures in compliance with current regulatory requirements.

CORAR has reviewed the comments on this subject submitted by the Health Physics Society, referenced below, and fully agrees with them. We too think that the new scientific data on radiation effects on the lens of the eye needs to be carefully examined before considering any changes that affect dose limits.

1. CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

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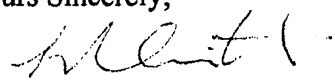
A major concern is that the ICRP recommended LED limit of 20 mSv (2 rem) is the same as the ICRP recommended TED limit in ICRP 103 although the comparative risks of LED are about an order of magnitude lower than TED. This is similar to the current ICRP recommended small area skin dose limit, which is also unnecessarily restrictive when compared to the TED limit.

CORAR recommends that the NRC should wait until the ICRP has thoroughly examined the basis for their recommendations and plan to coordinate any changes to LED limits together with any other changes that are needed in radiation protection standards.

CORAR perceives that a reduction in the LED limit could adversely impact licensee operations and be difficult to demonstrate compliance. We think that such a change will need detailed stakeholder input to develop compliance guidance to ensure that licensed operations remain viable. In anticipation of this need, the attached comments are focused on the practical consequences of reduced LED limits. We also anticipate that there would be a need to investigate new technologies to advance the control of radiation exposure to meet such a challenge. CORAR would probably need to complete a survey of occupational LED distribution in our industry similar to those submitted earlier this year to the NRC on prenatal dose and TED.

CORAR appreciates the opportunity to submit comments, is keen to participate in these developments and would be glad to provide clarification or additional information.

Yours Sincerely,



Leonard R. Smith, CHP
Co-chair CORAR Committee on Manufacturing Quality and Safety.

Reference: Health Physics Society comments to the NRC on Recommendations on the Annual Dose Limit to the Lens of the Eye. October 13, 2011. Docket ID NRC-2009-0279.

Enclosure: CORAR Comments to the NRC on New ICRP Recommendations on the Annual Occupational Dose Limit to the Lens of the Eye.

October 31, 2011

CORAR COMMENTS TO THE NRC ON NEW ICRP RECOMMENDATIONS ON THE ANNUAL OCCUPATIONAL DOSE LIMIT TO THE LENS OF THE EYE

Page 5, Section IV, Issues and Options. Third Paragraph.
"... REIS data for the past 5 years (2006-2010) and found ... upwards of 1,000 cases where a 20 mSv (2 rem) per year eye dose level was exceeded."

Are these 1,000 cases in 5 years, i.e. 0.1 % of reports, or 1,000 cases per year, i.e. 0.5 % of reports?

Page 7, Question 1
"To what extent has dose to the lens of the eye been an issue in the implementation of your radiation protection program."

Licensed material operations on major manufacturer and distributor sites are planned, facilities designed and procedures developed to cost-effectively optimize radiation protection. Radiation protection programs are typically integrated and the level of protection graded, as necessary, to ensure that occupational exposure is ALARA overall. The primary objective is to provide adequate protection to the most radiation sensitive organs and tissues in the body. This is most easily achieved if less sensitive tissues, such as the lens of the eye and extremities are allowed to receive higher levels of exposure.

In operations where the radiation is penetrating, the external radiation field is fairly uniform and where radiation exposure is adequately controlled without shielding, the lens of the eye receives a similar dose as the deep dose to the "whole body". Under the current regulations the deep dose to the whole body is the critical dose and is usually monitored by a single dosimeter worn on the torso. Under these conditions the dosimeter may indicate a higher dose at 3 mm depth than at 1 cm depth when the incident radiation includes a low energy gamma component, and the dosimeter may be relocated closer to the eyes. These exposure conditions typically result in annual doses that are well below the current dose limits.

However, certain manufacturing and distribution operations, involving curie quantities of gamma and/or high energy beta emitting radionuclides, generate non-uniform radiation fields and/or radiation fields that must be shielded to provide adequate protection. In some manufacturing facilities operations in a "hot cell" can cause the lens of the eye to receive 50 % to 100 % more dose than the torso. This is because the hot-cells in these facilities are usually designed to provide more shielding to protect the radiosensitive torso using lead walls, than to the lens of the eye using leaded glass windows. The necessary lead wall shielding thickness is typically 15-25 cms and roughly double this thickness is needed for the windows. Refraction of visible light passing through these thick glass windows distorts the image of the operations in the cell that are being viewed. Consequently there is a competing need to minimize the window thickness to enhance control. Also, the operator's face is usually closer to the window than their torso is to the cell wall. This too can cause the lens of the eye to receive slightly more dose than the whole body.

However, in our industry radiation workers typically spend less than half their time in radiation areas at hot cell work stations and the cells are usually conservatively sized to provide adequate shielding for the maximum quantities of radioactive materials that they seldom contain. Hence, the dose from operations in hot cells is usually easy to control well below current regulatory limits.

The most critical lens of eye and whole body dose occurs in manufacturing and distribution operations involving:

1. The transfer of radioactive materials between shielded enclosures.

2. Processing, dispensing and radwaste operations at partially shielded work stations that are designed to provide for a higher level of dexterity and control than can be achieved in a hot cell.

3. Maintenance and decontamination of radionuclide production cyclotrons, hot cells and radiochemical processing equipment.

These operations may involve exposure to high and/or low energy gamma and/or high energy beta radiation. Radiation fields are typically non-uniform and can be extremely intense close to their source. To comply with current regulatory dose limits, partially shielded operations are usually designed to provide more protection against deep dose to the torso. The lens of the eye typically receives more dose than the torso in these operations due to both less shielding and exposure to different quality radiation. The lens of the eye may be exposed to lower energy gamma and bremsstrahlung radiation than the torso and also be exposed to beta radiation while the torso receives none. Also the absorbed dose is higher at 3 mm depth than at 1 cm depth for these different quality radiations. Although rare, the difference in exposure can cause the lens of the eye to receive more than three times the deep dose to the torso.

For radiation workers who are tracking above the licensee's administrative dose limits it is often necessary to locate the dosimeter close to the eyes or to wear two dosimeters, one near the eyes and one at the highest deep dose region on the torso.

The most effective passive dosimeter currently used by manufacturers and distributors is the Optically Stimulated Luminescent Dosimeter (OSLD). However, it is sometimes difficult to establish the correct algorithm for estimating the dose at 3 mm using an OSLD when the eye is exposed to mixed radiation including high energy betas. Consequently, our industry experiences a few cases a year where the lens of eye dose is overestimated by a factor of 3 to 10 or more. Unless corrected, these overestimated doses to the lens of the eye become the most critical and limiting value. Attempts to correct these overestimates are usually labor intensive, require high expertise in dosimetry and require the use of multiple dose measuring devices and complex documentation. This challenging situation exists with the current regulatory limits.

Page 7, Question 1
" ... and would a change in the limits cause operational and administrative impacts?"

If the dose limit for the lens of the eye were reduced to 20 mSv (2 rem) averaged over defined periods of 5 years, with no single year exceeding 50 mSv (5 rem), we would anticipate significant impacts on manufacturing and distribution operations and administration. For many operations, particularly those involving the highest individual annual doses, the dose to the lens of the eye would become the critical and limiting dose. We would anticipate more individuals to exceed reduced administrative constraints and also more to exceed administrative limits (which are typically set at 60-80 % of the regulatory limits). This would be technically challenging because the most critical dose to a radiation worker would become the dose to the lens of the eye, which is more difficult to measure than deep dose to the whole body. Consequently radiation protection staff would be more challenged and also operation mangers, Radiation Safety Committees and ALARA review teams would be challenged to reduce worker dose.

Page 7, Question 1,
"What other types of impacts would you foresee?"

Manufacturers and distributors would need to restrict some radiation worker's time in the radiation area and use additional workers to complete tasks involving radiation exposure. In the longer term there would be a need to reduce exposure by modifying facilities, equipment and procedures. Changes in dosimetry, facilities, equipment and procedures would all require retraining the radiation workers and radiation protection staff. There is likely to be a need to identify operations where more sophisticated and accurate dosimetry and/or radiation monitoring is required using multiple and various types of dosimeters and radiation monitors.

Page 7, Question 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?"

We anticipate that some operations could be modified to reduce eye dose. For certain quality radiation, workers may be able to reduce lens of eye dose by shielding with thick lensed safety glasses, goggles or with face shields. However, this is also likely to reduce visibility, control and ergonomic viability which may diminish the intended dose reduction to the lens of the eye and increase extremity and whole body dose.
The most likely short term accommodation would be to share the dose amongst more radiation workers. Operations incurring the greatest exposure are currently carried out by the most highly skilled and specialized radiation workers. Using other less skilled workers to complete tasks in the radiation area will significantly increase collective dose. This is a concern if the collective lens of the eye dose is increased but an even greater concern is that we would also expect the collective whole body dose to increase significantly.
In the longer term it would be necessary to modify facilities to use more automation and/or shielding. In radiochemical manufacturing, individuals may have several work stations dedicated to them. Partially shielded work stations typically cost over $100,000 to build and hot-cells cost $250,000-$500,000 each. Modification of these work stations are typically so expensive or ineffective it is normally easier to decommission them and build new ones. Renewing such work stations is normally only practical as part of the ongoing business cycle of facility and equipment renewal every 10 or more years.

Page 7, Question 3.
"What might be the anticipated impacts of a rule change on recordkeeping and reporting?"

The immediate impact on record keeping would be the need to carefully document radiation measurements of critical operations to update the radiation exposure characterization of each operation and to obtain a more accurate dose estimate. There would also be a need to track more radiation workers exceeding reduced administrative constraints. This necessarily involves reports to and reviews by the RSO, radiation protection staff, operations managers and RSC members.
If radiation workers have already accumulated significant dose to the lens of the eye such that now or in the future they may exceed an acceptable lifetime limit such as 500 mSv (50 rem) it will be likely that licensees would be required to determine and record lifetime cumulated dose.

Page 7, Question 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."

The main difference would be the need to more intensely monitor lens of eye dose. This would probably increase the work load of radiation protection experts. As mentioned above, another difficulty is that of properly calibrating OSLDs to accurately measure mixed radiation. It is generally more difficult to optimize the location and orientation of dosimeters near the eye than those on the torso. These issues will become significantly more challenging if the lens of the eye dose limit is reduced. There should, however, still be sufficient sensitivity in existing dosimeters.

Page 7, Question 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?"

CORAR is concerned that in situations where TEDE and dose equivalent to the lens of the eye are similar there will likely be more uncertainty in determining the lens of the eye dose. This may require establishing more complex dosimetry procedures for the lens of the eye and/or establishing reduced administrative constraints.

Another concern is that the comparative risks associated with TEDE are higher than for the lens of the eye dose. This implies, of course, that the recommended lens of eye dose limit is unnecessarily restrictive.

Page 7, Question 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?"

One alternative would be to establish a lifetime cumulative lens of the eye dose equivalent record for each individual who received dose to the lens of the eye above a specified administrative annual limit. Dosimeter vendors are experienced in providing services to track lifetime dose.

Page 7, Question 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?"

Manufacturer and distributor licensees in the U.S. that have substantive international operations, including sites in foreign countries, would prefer dose limits to be uniform in all countries. However, if the radiation exposure conditions are necessarily significantly different in the U.S. from other countries there is recognition of the need for U.S. regulations to accommodate this difference. The advantage of uniform international regulations includes:

1. Flexibility in transferring radiation workers between sites in different countries.

2. Simplification of radiation protection training.

3. Improved understanding of regulations.

4. Better credibility of regulatory agencies by the public and the radiation workers.

However, the primary objective should still be to control and minimize occupational stochastic exposure to ALARA and ensure that threshold doses for tissue reactions are not exceeded. Consequently, it would be considered counterproductive if reduced lens of the eye dose limit resulted inadvertently in increased collective TEDE in the U.S..

Page 7, Question 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?"

Licensees may need to record the dose history of a foreign worker, who has been transferred to the U.S., to protect against potential litigious liability.

Pages 7-8, Question 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?"

CORAR is not aware of any at this time.

Page 8, Question 10.
"How are licensees monitoring to demonstrate compliance with the existing dose limits for the lens of the eye?"

Manufacturing and distribution licensees evaluate proposed, new and ongoing operations to determine if LED is significantly different from TEDE. If LED is greater than TEDE the radiation worker is usually required to locate their reference dosimeter close to the eye. If LED is much greater than TEDE the radiation worker is usually required to wear 2 dosimeters, one on the torso and the other near the eye.

Additional Issues

CORAR has significant concerns about the ICRP considerations that we are currently aware of, as follows:

1. In ICRP Draft Report for Consultation on "Early and Late Effects of Radiation in Normal Tissues and Organs: Threshold Doses for Tissue Reactions and Other Non-cancer Effects of Radiation in a Radiation Protection Context" it appears that the evidence for late effects is still being evaluated, implying that it might be premature to change dose limits.

2. CORAR understands that the threshold dose for cataract formation that is being considered is 500 mSv (50 rem). However, it appears that there is only a greater than 1% chance of radiation-induced cataracts after a very long latency period of 50 years after accumulating 500 mSv (50 rem) from acute exposures. If this is correct, then there is only a need to control normal occupational exposure of the lens of the eye during the early part of a radiation worker's career. For example, if a worker's life expectancy is 80 years and the latency period is 50 years, LED only needs to be controlled up to age 30 years. If such an individual starts radiation work at 25 years age, LED only needs to be limited to 500 mSv (50 rem) in 30-25= 5 years, i.e. 10 rem/year which is not that much different from the current annual limit of 150 mSv (15 rem).This implies that it might be better to establish a lifetime accumulative limit for the lens of the eye up to age 30 years, and keep the 150 mSv (15 rem) annual limit for all radiation workers. This should be the recommended dose limitation standard at least until there is better evidence of the late effects.

3. The ICRP is using a 1% risk of radiogenic cataract formation late in life. However, very late in life the impairment of visual capability is commonly caused by cataracts or other reasons. This implies that radiogenic cataracts do not necessarily affect the quality of life. Alternatively, considering the advances in medical technology for treating cataracts, there may be very little loss in quality of life. It appears inappropriate to increase the risk of cancer and cardiac and cerebral malfunction due to increasing TEDE just to avoid getting cataracts very late in life which are mostly curable. Clearly these practical radiation protection relationships need to be fully researched before changes to the LED limit is recommended.

4. CORAR recognizes that these ICRP recommendations are intended to prevent unacceptable visual impairments. It appears that the recommended LED limit to protect all radiation workers is impractical to implement. This approach may be more appropriate if applicable only to acute radiation exposures which should be both relatively rare and easy to identify. However, most radiation workers cumulate LED by fractionated and protracted exposure. The new scientific findings suggest that such exposures can cause opacities. The ICRP should consider alternative methods to protect these individuals from subsequent impairment of vision. To do this, the ICRP should investigate the potential for the early detection of opacities and the efficacy of medical intervention and/or subsequent restrictions on exposure to prevent future impairment of vision. Those radiation workers that do not have opacities could continue their radiation work subject to a higher LED limit, such as the current limit. This approach could provide a more practical control of LED for most radiation workers while also fully protecting those individuals who are most sensitive.

Rulemaking Comments

From: NRCREP Resource
Sent: Tuesday, November 22, 2011 2:12 PM
To: Rulemaking Comments
Subject: Lens of the Eye comment...EOM
Attachments: smith comment.pdf