ISSUE PAPER 2

OCCUPATIONAL DOSE LIMIT FOR THE LENS OF THE EYE

I. Introduction

In Staff Requirements Memorandum (SRM) SECY-12-0064, "Recommendations for Policy and Technical Direction To Revise Radiation Protection Regulations and Guidance," dated December 17, 2012, [1] the Commission directed the U.S. Nuclear Regulatory Commission (NRC) staff to continue discussions with stakeholders about the occupational dose limits for the lens of the eye.

II. Objective

Determine whether the dose limits for the lens of the eye should be reduced and develop regulatory requirements accordingly.

III. Background

The International Commission of Radiological Protection (ICRP) Publication 26, "Recommendations of the International Commission of Radiological Protection," issued in 1977, provides an occupational dose limit of 300 millisieverts (mSv) (30 rem) per year for the lens of the eye. ICRP Publication 26 (1977) provides little discussion on the basis for setting dose limits and no justification of the risk associated with these limits. During the 1980s, epidemiological studies showed that the risks from radiation exposure were higher than those anticipated when the ICRP Publication 26 (1977) recommendations were published. As a result, ICRP reevaluated the dose limit recommendations in its 1977 publication.

---

1 SRM-SECY-12-0064 is available on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/commission/srm/2012/.

The ICRP Publication 60, “1990 Recommendations of the International Commission on Radiological Protection,” issued in 1991, recommends an occupational dose limit of 150 mSv (15 rem) per year for the lens of the eye, which was 50 percent of the previously recommended limit of 300 mSv (30 rem) per year in ICRP Publication 26 (1977). In its 1991 amendments to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection against Radiation,” the NRC adopted the ICRP Publication 60 (1991) recommendations in 10 CFR 20.1201(a)(2)(i). In addition, the 1991 amendments added a definition of lens dose equivalent (LDE), which is the external exposure of the lens of the eye at a tissue depth of 0.3 centimeter (cm) (300 milligrams per square centimeter (cm^2)). (See the definition for LDE in 10 CFR 20.1003, “Definitions.”)

As the ICRP continued to reexamine its radiation protection principles, it noted that (1) the eye is one of the most sensitive organs of the body, (2) the protection of the eye against the effects of ionizing radiation is designed primarily to prevent the formation of cataracts, and (3) the most sensitive part of the eye for cataract formation is the lens. Cataract formation falls under the class of radiation effects referred to as “deterministic” (or “tissue reactions,” as it is referred to in ICRP Publication 103, “The 2007 Recommendations of the International Commission on Radiological Protection,” issued in 2007). At doses above a certain threshold, the severity of cataract formation increases with dose; however, the radiation-induced incidence of cataract formation below the threshold dose is believed to be essentially zero.

In a statement on tissue reactions issued on April 21, 2011, the ICRP indicated that a review of recent epidemiological evidence suggests that there are some tissue reaction effects, particularly those with very late manifestation, in which threshold doses are, or might be, lower than previously considered. For the lens of the eye, the ICRP now considers the threshold in absorbed dose for radiation-induced cataract formation to be 0.5 gray (50 radiation absorbed dose (rad)). The ICRP based its April 21, 2011, statement on draft report, “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," which was published on January 20, 2011, for public review and comment. The draft report reviewed the early and late effects of radiation in 36 normal tissues and organs in regard to radiation protection. It also updated estimates of threshold doses for tissue injury in all organ systems and for morbidity and mortality following acute, fractionated, or chronic exposure.

The ICRP revised the January 20, 2011, draft report based on the comments received, and issued +ICRP Publication 118, "ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs—Threshold Doses for Tissue Reactions in a Radiation Protection Context," dated August 28, 2012. ICRP Publication 118 (2012) formalized the new ICRP recommendations relative to the dose limits for the lens of the eye. For occupational exposure in planned exposure situations, the ICRP recommended that the limit on equivalent dose for the lens of the eye be reduced to 20 mSv (2 rem) per year, averaged over 5 consecutive years (i.e., 100 mSv (10 rem) in 5 years), with no single year exceeding 50 mSv (5 rem). The current NRC limit for the lens of the eye is 150 mSv (15 rem) per year, as established in 10 CFR 20.1201(a)(2)(i).

The ICRP based its recommendation to reduce the annual dose limit for the lens of the eye on a review of recent epidemiological studies of radiation-induced cataracts; these studies suggest that the threshold dose for causation of cataracts is lower than previously considered. The ICRP noted that earlier studies generally had short followup periods, failed to take into account the longer latency period for lower eye dose exposures, had relatively few subjects with lower exposures, and were not designed to detect early lens changes. More recent studies in populations exposed to far lower doses of radiation, including individuals undergoing diagnostic or therapeutic procedures, astronauts, atomic bomb survivors, Chernobyl accident victims/cleanup workers, and interventional radiologists/cardiologists, revealed dose-related lens opacities at significantly lower doses.

The International Atomic Energy Agency (IAEA) had essentially completed the process for revising its report entitled, "Basic Safety Standards for Radiation Protection," when the ICRP statement and recommendation became available. Member States of the IAEA were afforded an opportunity to comment on a change to incorporate the new recommendations. Although the IAEA received a number of comments that were similar to the comments raised by stakeholders during the NRC public comment period, the IAEA decided to move forward and incorporate the new recommended limit for the lens of the eye into the final version, which was approved by the IAEA Board of Governors in September 2011 and issued as General Safety Requirements (GSR) Part 3 (Interim) in November 2011. At the time that GSR Part 3 (Interim) was approved by the Commission on Safety Standards, the IAEA Secretariat was asked to develop guidance as early as possible to assist Member States in the observance of this new dose limit for the lens of the eye. As a first step toward the development of such guidance, the IAEA published IAEA Technical Document (TECDOC) No. 1731, "The New Dose Limit for the Lens of the Eye—Implications and Implementation," issued in January 2014. This TECDOC will serve as interim guidance to a number of IAEA safety guides that are currently undergoing revisions involving occupation radiation protection and radiation safety in the medical uses of ionizing radiation. The IAEA expects to publish these safety guides between 2015 and 2016. These safety guides will supersede a number of existing safety guides and safety reports.

IV. Discussion

The ICRP considers the formation of a cataract, occurring at levels greater than the specified threshold value, a "tissue reaction," which was previously called a "deterministic effect." For tissue reactions, the severity of the effect is considered to be proportional to the accumulated dose above the threshold value. This model is in contrast to the model for cancer induction, which is modeled as a "stochastic effect."[2] Evidence of a lower threshold for the induction of the effect therefore suggests a reduction in the limit to avoid accumulated doses that would cause the effect to occur.

The lens of the eye is one of the most radiosensitive of all tissues in the human body. The goal for radiation protection, as published in National Council on Radiation Protection and Measurements Report No. 116, "Limitation of Exposure to Ionizing Radiation," issued 1993, is to *prevent* deterministic events of clinical significance and *limit* stochastic effects to reasonable levels based on societal concerns. The risk of deterministic effects becomes increasingly important for the lens of the eye from doses of more than 0.5 gray (50 rad), regardless of whether the dose is acute or accumulated. There is no indication that protracted delivery of the dose is less damaging than acute exposure. With regard to induction of cataracts by ionizing radiation, the latent period and the severity of the effect are dependent on dose, dose rate, and fractionation. After radiation exposure, changes in the lens of the eye take many years to manifest as visible cataracts. Moreover, not all changes become clinically relevant.

Evidence of lens opacities can be found in more than 96 percent of the population over 60 years of age. A cataract is an irreversible lens disorder commonly caused by certain diseases and by exposure to ultraviolet light or ionizing radiation. Among such causes, cataract formation is most sensitive to ionizing radiation. Radiation-induced cataracts are different from most age-related or other forms of lens opacities because they are generally (but not exclusively) posterior subcapsular in location. The only treatment for a cataract is surgical removal. Medical practitioners recommend lens cataract surgery when severe opacity causes vision impairment in an individual, which greatly inconveniences his or her daily activities.

---

[2] The regulations at 10 CFR 20.1003 defines "stochastic effect" as "health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold."

Although a cataract is an easily curable disease in modern medicine, in developing countries, a cataract is still a severe disease that impairs the daily lives of patients. Initial stages of lens opacification do not usually result in visual disability; however, the severity of these changes may progressively increase with dose and time until vision is impaired and cataract surgery is required.

Dosimetry and shielding are important considerations necessary in reducing the dose limit for the lens of the eye. The dose to the lens of the eye will be very close to the effective dose for relatively uniform exposure fields if the body or the eyes are not significantly shielded, particularly for gamma exposures in which the differences in the dose calculated at 0.007 cm (shallow dose equivalent), 0.3 cm (lens dose equivalent), and 1 cm (deep dose equivalent) are not large. A more substantial difference exists for other types of radiation, such as beta particles, that might need to be taken into account (e.g., resulting in dose to the lens that is higher than the effective dose). A change in the lens dose limit to a value lower than the total effective dose equivalent limit would mean that the lens of the eye was the most restrictive requirement. However, for many situations, such as industrial radiography or most reactor exposures, a separate measurement of lens dose would not likely be necessary. Dosimetry processors today use algorithms to estimate lens dose based on the measured deep dose equivalent and shallow dose equivalent.

There are some situations where shielding comes into play. For example, for cases in which two dosimeters are used to measure effective dose and shielding is provided for the torso of the body, the dose to the lens of the eye will be the same as the deep dose equivalent measured above the shielding; however, it will be greater than the effective dose that would be calculated for the individual. This case is particularly true for interventional radiology and cardiology in which the routine use of leaded aprons results in the effective dose being much lower than the reading of a badge worn outside the apron. In this case, the lens dose would be an issue unless the individual uses leaded glasses with side shields. Eye protection with side shields is important in reducing potential side exposure and exposure from backscatter when an individual is spending time in a particular orientation (e.g., when an individual is standing at a 45 degree angle to the radiation source versus 90 degrees).

V. Proposal

The NRC believes that it is appropriate, and scientifically justified, to explore in greater detail the impacts of a reduction in the dose limit for the lens of the eye to 50 mSv (5 rem). The NRC also believes that further discussion on how the prevention of cataracts (which can be corrected by a well-established surgical procedure) compares to efforts to reduce the probability of cancer (a disease posing a far greater health risk) is necessary. The approaches under consideration include aligning closer with the ICRP recommendations, adopting the ICRP recommendations, or retaining the current dose limit. Any new requirements will have implications for measurements of occupational exposures and the need to better estimate the dose to the lens of the eye.

The NRC staff believes that additional input from the public, the regulated community, and other stakeholders is necessary to understand the implications of potential options on this issue.