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## STATUS OF NCRP SCIENTIFIC COMMITTEE 1-23 COMMENTARY ON GUIDANCE ON RADIATION DOSE LIMITS FOR THE LENS OF THE EYE

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### Abstract

Previous National Council on Radiation Protection and Measurements (NCRP) publications have addressed the issues of risk and dose limitation in radiation protection and included guidance on specific organs and the lens of the eye (NCRP 1987, 1989, 1993a, 1993b, 1995a, 1995b, 2000b, 2001b, 2010a, 2010b, 2013). NCRP decided to prepare an updated commentary intended to enhance the previous recommendations provided in these earlier reports. NCRP Scientific Committee 1-23 (SC 1-23) (NCRP 2015) is charged with preparing a commentary that will evaluate recent studies on the radiation dose response for the development of cataracts, and also consider the type and severity of the cataracts as well as the dose rate; provide guidance on whether existing dose limits to the lens of the eye should be changed in the United States; and suggest research needs regarding radiation effects on and dose limits to the lens of the eye. A status of the ongoing work of SC 1-23 was presented at the NCRP 2015 Annual Meeting, “Changing Regulations and Radiation Guidance: What Dose the Future Hold?” The following represents a synopsis of a few main points in the current draft commentary. It is likely that several

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#### Conflicts of interest:

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changes will be forthcoming as SC 1-23 responds to subject matter expert review and develops a final document, expected later in 2015.

### Keywords

National Council on Radiation Protection and Measurements; radiation-induced cataract; radiation-dose limit for human lenticular opacification

The major radiation damage response of the clear crystalline lens of the eye is the loss of lens clarity resulting in clouding or opacification, known as a cataract, that in an extreme case (usually after high doses >5 Gy in a single exposure) can cause blindness. However, exposure to low doses of radiation can lead to minor opacifications many years later. This is dependent on the type of radiation, how the exposure was delivered, genetic susceptibilities of the individual exposed, and where the cataract forms relative to the visual axis (Blakely et al. 2010; Blakely 2012). The International Commission on Radiological Protection has recently recommended a significant reduction in dose limits to the lens of the eye, based on an evaluation of the epidemiological evidence of cataracts in radiation-exposed human populations (ICRP 2012). Consideration of these recommendations for lower dose limits, and the cost-benefit consequences associated with adopting them, is taking place worldwide in several countries including the United States (UNSCEAR 2008, 2011, 2013a, 2013b; Ainsbury et al. 2009; IAEA 2011, 2012, 2013; Pryor 2011; Bouffler et al. 2012; Broughton et al. 2013; CNSC 2013; EPRI 2013). An NCRP commentary was requested by the U.S. Nuclear Regulatory Commission to evaluate clinical and experimental evidence for the risk of radiation-induced cataracts, to consider cataract types and dose and dose-rate dependence of cataract formation, to provide guidance on whether existing dose limits to the eye should be changed in the United States, and to identify whether any research gaps exist in our understanding of radiation effects on the lens of the eye.

The visual examination of human cataracts, their categorization by type and their severity based on scoring have undergone a major evolution in the last few decades. Furthermore, the accuracy and relevance of dosimetry methods have also improved markedly in recent years. Ophthalmologic instrumentation has improved from hand-held microscopes and subjective scoring, to capturing digital images, and using more objective methods to score cataracts. Since cataracts are also associated with normal aging of the eye, and cataracts can arise due to numerous diseases or exposure to toxins other than radiation, it is important to obtain frequent eye examinations and maintain medical records to document and assess the baseline level of lens clarity. However, most of the epidemiological evidence for radiation-induced cataracts has not been obtained with these new quantitative tools. As a result, many epidemiological studies of radiation-associated cataracts are lacking high-quality, baseline data on lens clarity in individuals who later develop cataracts, and recently identified technical deficiencies in cataract-scoring methods have contributed uncertainties to some of the most significant data acquired (EPRI 2014).

In recent years, the field of lens biology has expanded with new molecular and cellular characteristics revealing underlying mechanisms responsible for the differentiation of the lens epithelial cells into lens fiber cells, and how radiation damage can hinder this process in

a dose-dependent manner, perhaps linked to the latency of cataract appearance. Radiation cataracts have been considered the epitome of a deterministic effect or “tissue reaction” that appears only after a dose threshold has been exceeded. However, the latest understanding of the threshold dose for cataract formation is that the dose for an effect appears to be lower than we thought previously. Much of the mechanistic evidence can be interpreted in support of a stochastic mechanism. The choice of a biological model for investigating a statistically-relevant, experimental, radiation-induced cataract has been heavily influenced by rodent studies, driven by cost issues, especially at low radiation doses; however, the lifespan of rodents is significantly shorter than that of humans. In addition, other differences between rodents and humans exist including anatomical and physiological characteristics that influence a number of species-dependent lens outcomes; hence it is not clear how to extrapolate rodent cataract risk data to humans. Recent evidence supporting the role of stem cells in the lens may offer future biological modifications to moderate radiation responses. The important comparison of the risk of cataracts and loss of visual acuity that can be partially overcome by successful lens replacement surgery, with the risk of radiation-induced cancer with its more serious consequences and more invasive treatments has implications for the risk-benefit analysis of radiation-induced detriment to the lens, and any decisions to consider reducing the dose limit.

Current epidemiological studies of the effects of radiation on the lens of the eye indicate an association between exposure to ionizing radiation and initiation or development of posterior subcapsular cataract, mixed and/or cortical cataracts in humans for various exposure situations, perhaps even at lower doses than previously considered. However, most of the very limited data either have large uncertainties or are currently under question due to recently identified technical shortcomings. Due to these limitations, it is not yet possible to quantitatively estimate a specific threshold value for either acute or chronic lens exposures. Therefore, there may not be sufficient justification to make a change in the current NCRP recommendation (NCRP 1993b) (i.e., an occupational equivalent dose limit to the lens of the eye of 150 mSv y<sup>-1</sup>).

There is justification to wait for future radiation dose-dependent cataract data from the atomic-bomb survivor study (RERF 2013a, 2013b, 2014a, 2014b). There is also a need for epidemiology utilizing more objective scoring methods, as well as basic research on underlying mechanisms of cataractogenesis. A baseline measure of individual age-dependent opacities prior to radiation exposure is also missing. Having information on these issues for a population exposed to a range of relatively low-dose exposures and followed for a significant time after exposure (e.g., radiation workers) would greatly contribute to reducing the uncertainty of whether a dose threshold exists. Concurrently, there is also a need to develop lens-specific dosimetry or methods to accurately assess doses to the lens of the eye.

There is an urgent need for NCRP to develop a comprehensive evaluation of the overall effects of radiation on the lens of the eye [e.g., similar to NCRP Report No. 159 on the risk to the thyroid from ionizing radiation (NCRP 2008)]. Such a comprehensive evaluation should include a further reassessment of the lens of the eye dose limit values. As previously recommended by NCRP in Report No. 168 (NCRP 2010b), until current dose-limit values

are reassessed, it is prudent to regard eye exposures in much the same way as whole-body exposures (i.e., ensure exposures are consistent with the “as low as reasonably achievable” principles). This includes careful justification and optimization in all exposure situations including radiation doses to the lens of the eye.

The Committee emphasizes that there is an ongoing opportunity for dose-sparing optimization and the need for more education and more accurate assessment for individuals that have the potential of exceeding the current occupational dose limit to the lens of the eye.

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