DOSE LIMIT CHANGES TO THE LENS OF THE EYE

DOSE LIMIT CHANGES TO THE LENS OF THE EYE & ITS REGULATORY IMPLICATIONS

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Lay Abstract

The International Commission on Radiological Protection ("ICRP"), the independent governing body responsible for radiation protection, since the early 1950s has been issuing recommendations that are widely used as radiological protection standards by regulatory agencies worldwide, primarily UN member states. Since its inception in 1928, the ICRP has served as the basis for radiation protection and value based judgements in protecting both human and non-human biota. In 2011, the commission published (ICRP Pub. 118) its review of epidemiological studies and decided to recommend a change to the previously established eye dose limit.

Based on the review of the literature and the research conducted within the academic, veterinary, nuclear and medical industry, there is general consensus in Canada and among IAEA members states that the dose limit for the lens of the eye should be reduced from the original proposed limit, but not to the recommendations suggested by ICRP 118.

Abstract

The commission on radiological protection through publication 118 decided to recommend a change to the eye dose limit in 2011. ICRP recommendations made in publications, especially 'publication 60' and its subsequent update 'publication 103' has served as standards for regulatory authorities worldwide in limiting ionizing radiation exposure both to workers and members of the public. For example in Canada, the Canadian Nuclear Safety Commission (CNSC) generally directly adopts recommendations from ICRP. The previous dose limit for the lens of the eye was 150 mSv $year^{-1}$, based on Publication 60 and 103. Regulatory agencies worldwide have been using this value and subsequently nuclear facilities, hospitals and universities have designed their radiation protection program based on this dose limit for several decades. The new revised eye dose limit now being equivalent to the whole body dose limit will pose significant challenges for sectors where the eye exposure was not characterized as the limit was previously five times over the whole body exposure.

A two-step approach was used in conducting this study, firstly a through literature search was conducted on the effects of ionizing radiation to the eye, its radiobiology, fundamentals in established both dose limits was analyzed. Secondly, the authors spent time researching institutions that use ionizing radiation and interviewed engineers, medical physicists, radiation safety officers and regulators from a wide array of fields and industries. Based on the ICRP publications, the review of the literature and the interviews conducted with the

nuclear industry, there is consensus in Canada and among IAEA member states that the dose limit for the lens of the eye should be reduced from the original proposed limit of 150 mSv per year. However not to the recommendations suggested by ICRP 118, but, to a standard reasonable and an achievable limit that is 50 mSv per year.

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There are so many people to thank during my journey, for which I feel so privileged, I have been be surrounded by such wonderful people, without whom this would be impossible. I would to thank Dr. Fiona McNeill, Dr. David Chettle and Dr. Kevin Diamond for all their support throughout my career and my graduate studies part-time at McMaster University. This would have been impossible without their support, guidance and mentorship.

Dr. Douglas B. Chambers without who I would not have been successful in the field of Medical Physics & Radiation Sciences. I would like to thank Doug & ARCADIS Canada for allowing me to start my thesis part time, COG (Candu Owners Group) for selecting our team and allowing us to review literature on the Lens of the Eye and for accepting and publishing the team's report on the lens of the eye. The Canadian Nuclear Safety Commission for their one on one sessions with me and their events held at the CRPA. I would also like to thank John Chase from Ontario Power Generation (Nuclear) for the data he has provided and the expertise provided on this subject matter. I would also like to acknowledge Jovica Atanackovic for his expertise and input on measuring radiation fields around nuclear power plants. I would also like to thank Dr. Tom Farrell (Medical Physicist) from Jurvanski Cancer Centre for his support over the years and insight into this subject matter as well. I would also like to thank Dr. Ernest Osei, Chief Medical Physicist Grand River Hospital for his insight on the policy changes and experiments of Grand River Hospital.

Last but not the least I would like to thank Fiona Ahlang for all the help she has provided, for all the paperwork, course changes, administration and moral support she has provided me with for so many years. I am truly grateful and feel blessed having such great people around me.

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List of Acronyms and Symbols

AAO	American Association of Ophthalmology
ABS	Atomic Bomb Survivors
ATB	At the Time of Bombings
BC	British Columbia
BDES	Beaver Dam Eye Study
BMES	Blue Mountains Eye Study
BSS	Basic Safety Standards
CI	Confidence Interval
CNSC	Canadian Nuclear Safety Commission
COG	CANDU Owners Group
CT	Computed Tomography
DS86	Dosimetry System 1986
DS02	Dosimetry System 2002
EAR	Excess Absolute Risk
ED_1	Estimated Dose for 1% incidence
FLD	Focal Lens Defect
ENEA	Italian National Agency for New Technologies
ERR	Excess Relative Risk
Gy	Gray
GZ	Germinative Zone
H_p (10)	Dose Equivalent at 10 mm depth
HR	Hazard Ratio
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiological Units and Measurements
IRPA	International Radiation Protection Association
kerma	Kinetic Energy Released per Unit Mass
kVp	Peak kilo Voltage
LET	Linear Energy Transfer
LOCS	Lens Opacities Classification System
LOCS II	Lens Opacities Classification System, version II
LOCS III	Lens Opacities Classification System, version III
MCP-N	(lithium fluoride: Magnesium , Copper ,Phosphate) based TLD
MCNPX	Monte Carlo Code N-Particle Extended
MeV	megaelectron Volt
mGy	milliGray
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NEW	Nuclear Energy Worker

NSRD	Nuclear Substances and Radiation Devices
OR	Odds Ratio
ORAMED	Optimization of Radiation Protection for Medical Staff
PEI	Prince Edward Island
PENELOPE	Penetration and Energy Loss of Positrons and Electrons
PMMA	Polymethyl Methacrylate
PSC	Posterior SubCapsular
RBE	Relative Biological Effectiveness
ROS	Reactive Oxygen Species
RP	Radiation Protection
RPP	Radiation Protection Program
RR	Relative Risk
SEE	Salisbury Eye Evaluation
SSK	German Commission On Radiological Protection
Sv	Sievert
TCD	Taiwan Cumulative Dose Exposure Assessment System
TLD	Thermoluminescence Dosimeter
UK NRPB	United Kingdom National Radiological Protection Board
UK SRP	United Kingdom Society for Radiological Protection
US	United States
UV	Ultraviolet
VIP	Visual Impairment Project

Declaration of Academic Achievement

Ryan Das led the primary study, literature review, data collection, analysis and interpretations of the information collected herein, including all the interviews, round table discussions, site visitations and industry specific data collection.

Would like to acknowledge the Supervisory committee i.e. Dr. Douglas B. Chambers (Arcadis Canada), Dr. David Chettle (McMaster University), Dr. Kevin Diamond (McMaster University) and Dr. Michael Farquharson (Chair, Examining Committee, McMaster University) for their guidance, help and support.

Preface:

During the course of the research conducted, a significant amount of the material presented has been used in the publication of COG (Candu Owners Group Inc.) Report 13-3001-I 'Radiobiology and Regulations for Eye Dose in CANDU Facilities' published in November 2014. All data, graphs and material presented herein is with permission.

The work presented here was started in conjunction with ARCADIS Canada, McMaster University and originally funded by the COG R&D Health, Safety and Environment Program Work Package No. 30119. Reference to the COG Report is provided in section 13 of this publication.

1.0 INTRODUCTION

1.1 BACKGROUND

Since its inception in 1928, the International Commission on Radiological Protection (ICRP) has issued and published over 139 reports that have served as the basis for radiation protection and value based judgements in protecting both human and non-human biota. The recommendations of the ICRP are widely used as radiological protection standards by regulatory agencies worldwide, in particular, UN member states.

ICRP recommendations are made in their publications, 'publication 60' and its subsequent update 'publication 103' have served as standards for regulatory authorities worldwide in limiting ionizing radiation exposure both to workers and members of the public. For example in Canada, the Canadian Nuclear Safety Commission (CNSC) directly adopts recommendations from ICRP and enforces acts and regulations (enacted by Parliament of Canada, through the Minister of Natural Resources), which all Nuclear Substance and Radiation Devices (NSRD) licensees are required to follow. This includes nuclear power facilities, hospitals, cancer centers, Universities, University Hospitals, Veterinarians, etc. Other countries in the commonwealth such as Australia directly adopts ICRP recommendations and apply regulatory standards to its licensees based on the reports and recommendations published by the commission; the United States normally operates similarly but has its own independent body i.e. NCRP (National Council on Radiological Protection) which generally adopts ICRP publications after their own internal review process.

Dosimetric quantities such as radiation weighting factor, tissue-weighting factor, etc; are all adopted and based on ICRP recommendations made in their publications. Ultimately, the dose is determined from the intake or inhalation based on recommended dose coefficients established by the ICRP and the limits are set accordingly. The dose limits by which the regulatory frameworks are designed and radiation exposure is characterizeare also based on ICRP publications that have assessed the intakes of radionuclides from bioassay measurements. The dose metric is E(t), the committed effective dose, which is derived from absorbed dose, based on factors recommended by the ICRP.

In 2011, the commission published 'ICRP *Pub.* 118', which provides its review of epidemiological studies of radiation effects and the effects of ionizing radiation on the lens of the eye. The ICRP committee through its recommendations in publication 118, decided to change the eye dose limit for the first time since 1990. The previous dose limit for the lens of the eye was 150 mSv per annum as described in both *Publication 103* (2007) and *Publication 60* (1990). Regulatory agencies worldwide have been using this value for a long time and subsequently nuclear facilities, hospitals, universities and other institutional facilities with sources of ionizing radiation have designed their Radiation Protection (RP) program based on this dose limit, as this dose limit has been in use since the 1990s.

The new dose limit recommended by the ICRP has been reduced and is now equivalent to the effective dose limit of 20 mSv year^{-1}, and 100 mSv in a defined 5-year period. This is a substantial reduction from the previously recommended dose limit of 150 mSv year^{-1}. Since the previous dose limit was significantly higher than the whole body dose limit, the nuclear and health care facilities including academic institutions worldwide did not directly measure the *eye dose* of a worker, whether they were classified as Nuclear Energy Workers (NEWs) or not. This was under the notion that the human eye at a target depth of 3mm received only a fraction of the whole body dose and since the limit was significantly higher, direct measurement was not compulsory. The new revised eye dose limit now being equivalent to the whole body dose limit completely changes the scenario and creates significant challenges for all industries as the limit was previously five times over the whole body exposure, creating a new urgent need for characterizing dose to the lens of the eye in all sectors.

1.2 APPROACH

A two-step approach was used in conducting this study. Firstly a thorough literature search was conducted on the effects of ionizing radiation to the eye, its radiobiology, epidemiological studies of dose to the eye and evolution of dose limits. A wide range of studies both supporting and contradicting the new ICRP recommendations were examined and in addition, knowledgeable and experienced engineers, medical physicists, radiation safety officers and regulators from a wide variety of fields and industries were interviewed.

It may be pertinent to note that in Canada, medical workers such as radiologists and international radiologists (i.e. use of X-rays) are currently regulated provincially in Canada by agencies such as Minister of Labour in Ontario. Whereas, use of nuclear power, radionuclides used in treatment of cancer and use of radioactive sources in devices is regulated federally in Canada, by the Canadian Nuclear Safety Commission. To deal with changing dose limits and to harmonize standards for radiation protection across industries both federally and provincially the Federal Provincial Territorial Radiation Protection Committee (FPTRPC) was recently established.

The reviewed publications and scenarios include a wide variety of studies and exposure scenarios, including exposure from accidents and nuclear incidents, exposures to interventional radiologists, atomic bomb survivors and workers involved in Chernobyl. Over one hundred publications were shortlisted and data from over 25 publications reviewed from an epidemiological standpoint.

Interviews were conducted with representatives of the largest groups, which are the Nuclear Power Operators, Hospitals and Educational Institutions. In anticipation of the regulatory changes, the dosimetery group in the Canadian Power Sector have already spent significant amount of resources and time investigating how to determine and or finding methods in characterizing dose to the lens of the eye. Something, which was not conducted previously as the whole body dose, was only a fraction of dose to the lens of the eye. The new limit has created significant technical challenges and workloads for both industry, government and the private sector as a whole. Through conferences with the two of the largest reactor operators in Ontario, Canada, it was discovered that the two groups have decided to work together in finding solutions in characterizing dose to lens of the eye and identifying the most impacted groups of workers by creating a system to determine what workers need monitoring versus workers that can be exempted. In conduction of the research, it was discovered that over ten thousand dosimeters had to be evaluated by the nuclear industry in Ontario alone to create a pool to study what segments need monitoring and further investigation.

2.0 Radiation and The Lens Of The Eye

The primary endpoint and tissue effect in concern from exposure to radiation and the lens of the eye is cataracts. The word cataract is associated with any detectable change in the lens of the eye that is normally translucent. When light passes through eyes that have Cataracts, the light is deflected or refracted causing problems in vision. Cataract is also referred to as clouding of the eye lens. There are many forms and stages of cataracts, although generally treatable, can untreated progress to blindness. Over twenty million people are blind due to cataracts and it is the leading cause of blindness in the world (Song et al. 2018). Other symptoms include but are not limited to blurry vision, halo generation, loss of night vision, increased sensitivity, etc.

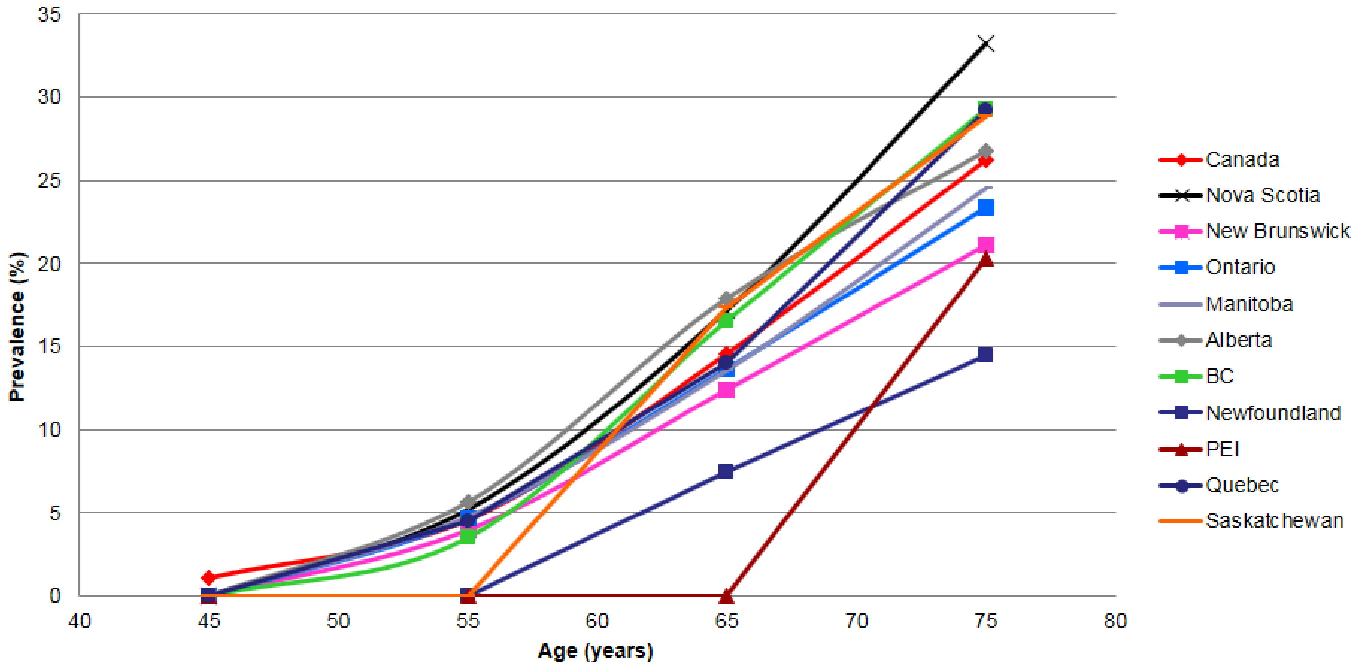
Similar to Cancer, the cause of cataracts is multifactorial. There are many causes of cataracts, the primary being age. However, unlike Cancer and other radiation-induced endpoints, it is age dependent and are generally treatable through surgery. The proteins in the eye denature with age which leads to cataracts and as a result the risk of developing cataracts starts at the age of 40 and doubles by the time someone is 80 years old.

There is epidemiological evidence from Chernobyl studies that high acute exposure to radiation can induce and/or accelerate the onset of cataracts. However, the mechanisms of how radiation creates cataracts are yet to be fully understood especially if there is any clear ‘threshold dose’ for cataract development. It may not be directly equitable to the ‘Linear

No Threshold theory' or directly equated to other radiation-induced endpoints such as ACR (acute radiation syndrome) as age plays a crucial and a significant role in the onset of cataracts.

2.1 Role of Age in Cataract Development

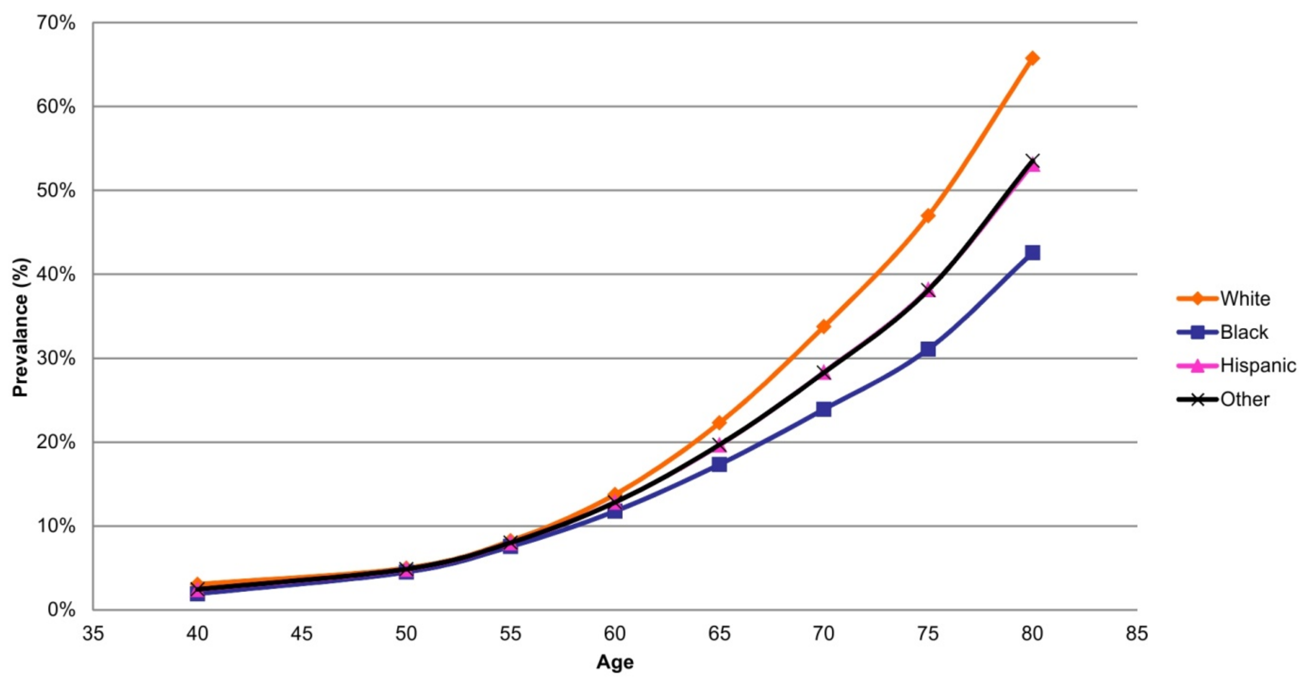
The lens of the eye is considered as the most radiosensitive tissue in the human body. The onset of cataracts has been estimated to be induced at low acute doses of less than 2 Gy of low-LET ionizing radiation and less than 5 Gy for prolonged radiation exposure. Even though there has been quite a lot of work done in this segment the exact mechanisms of cataractogenesis due to radiation is still not fully understood, especially at low doses and in determining a threshold. Previously, cataracts had been classified as a deterministic effect with a threshold of approximately 2 Gy. According to the review conducted it is evident that recent literature on mechanistic and human studies concerning the induction of cataracts by ionizing radiation indicate a threshold for cataract development that is much less than what was previously assumed. Radiation cataractogenesis with an adjustment for age is much closer to a linear no-threshold theory. Current estimates by the International Commission on Radiological Protection suggests a threshold dose of 0.5 Gy.



The data were acquired; from, Beaver Dam Eye Study and USA; BMES: Blue Mountains Eye Study & the German Commission on Radiological Protection 2009, SSK1 2009, COG Report 2014..

Figure 2. 1 Prevalence of Cataracts as a Function of Age

Similar data are available for other populations, as illustrated in Figures 2.1 and 2.2 for Canadian and US males, respectively. The large province-to-province variation shown in Figure 2.1 is interesting and shows the large variation of cataract prevalence by province and age. Whether this variation is simply due to province-to-province differences in reporting or other factors is not known. The above graphs illustrate the age dependent onset on cataractogenesis in Canada and province-to-province variability that may be due to different provincial definitions of a cataract. Overall, despite province-to-province variation, all provincial data show the importance of age and the typical quite late onset of cataract prevalence. These data suggest that geographical location (at least within the country/Canada) does not play an important role and the onset cataractogenesis and factors such as background terrestrial radiation do not appear to play a major role in development of cataracts.



The data were acquired; from, Beaver Dam Eye Study and USA; BMES: Blue Mountains Eye Study & the German Commission on Radiological Protection 2009, SSK1 2009.

Figure 2. 2 Cataract Prevalence in US Males (Hereditary Effects)

Similarly, Figure 2.2 shows quite large variation in the prevalence of cataracts with age and race, which suggests that genetics plays an important role in the prevalence of cataracts especially after 60 years of age. All of the data that is in both males and females plotted in

Figure 2.3 and Figure 2.4 suggests that incidence of cataracts is quite rare below age 45 in both male and females which is very different from stochastic or deterministic effect, especially cancer.

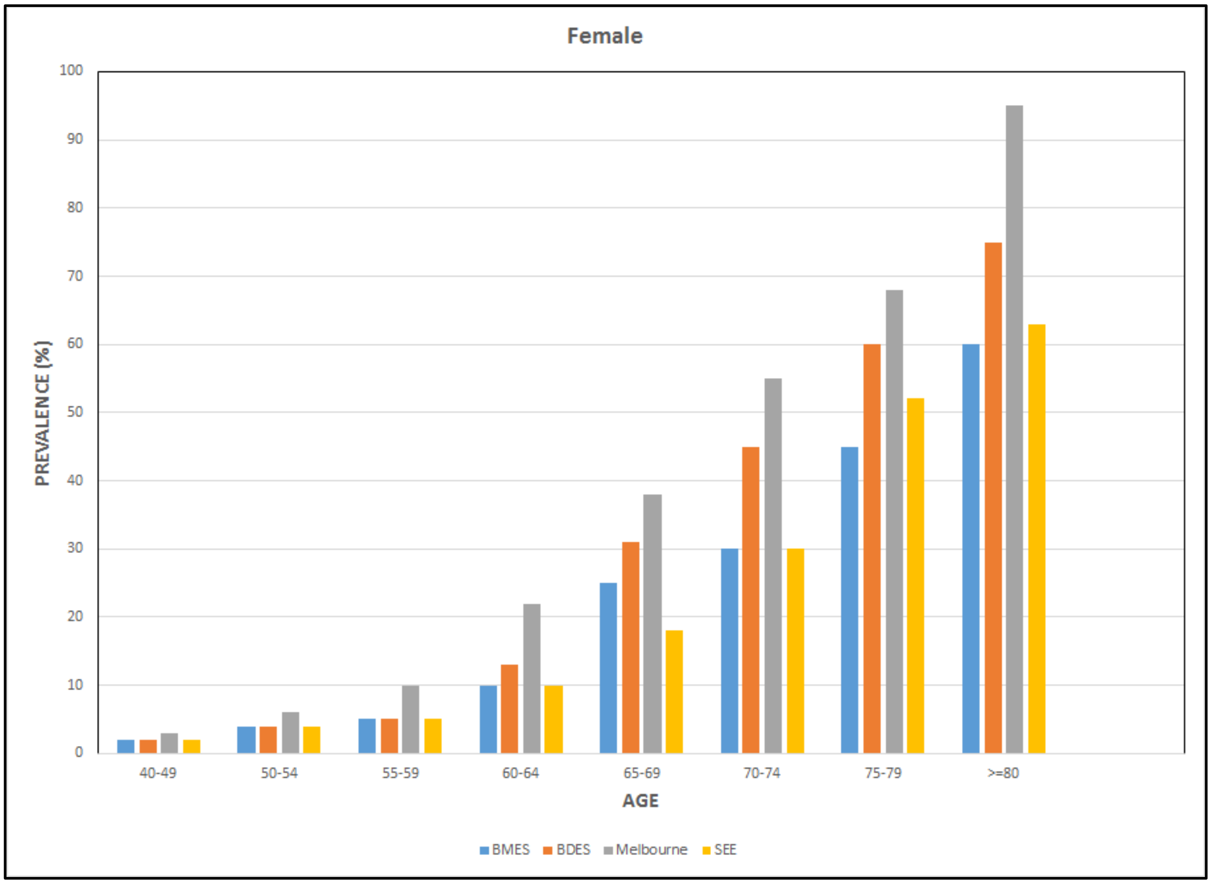
Stipulations and depictions in Figure 2.2 show that unlike other radiation induced stochastic effects, cataracts is not only age dependent but that it is also multifactorial, as genetics plays an important role amongst other factors. It can be illustrated from the graph above that factors such as a person's ethnicity can also influence the onset of cataracts after a certain age. From the plot above the variation between races or ethnicities become quite significant after 60 Years old.

Another important point to note is that the prevalence of cataracts and the onset of the endpoint is quite marginal below the age of 45 years old, which is quite different compared to all the other radiation-induced endpoints. Thus, methodologies used in establishing dose coefficients or dose limits for the lens of the eye have to be treated a little bit differently compared to other endpoints such has hair loss, erythema or acute radiation syndrome as ethnicity. Even when compared to most stochastic effects induced by acute or protracted radiation, age plays a critical role in cataractogenesis, and especially after 45 years old (Figures 2.3 and 2.4). It is evident from plots made in Figure 2.3 and Figure 2.4 below that the onset of cataracts is the same in both the sexes, age being the primary factor (after 45 years), and progression being similar in both the sexes. Unlike other stochastic effects, which normally follow a LNT (Liner no threshold) theory.

The change in dose limits for the lens of the eye was first proposed by the Internal Commission on Radiological Protection in 2011, and as a result certain countries have automatically implemented it into their regulation. The first recommendation change was made in ICRP publication number 118. According to *ICRP Publication 118*, Cataract is the leading cause of blindness in the world. More than a hundred and nineteen (119) million are visually impaired and approximately twenty-five (25) million go blind because of it each year. (ICRP 118). Early lens changes also referred to as opacities are associated with cortical and posterior sub-capsular regions of the eye (Martin 2011). With time these opacities potentially lead to partial or complete lens opacification of the PSN (posterior sub-capsular) or cortical regions of the eye (Kleiman 2012). The rate at which these changes progress is strongly dependent on dose (inversely proportional to delivered dose), where age acts as a modulating factor (Kleiman 2012). Other environmental cofactors associated with PSC (posterior sub-capsular) cataract are ocular inflammation and cortical steroid usage. Smoking and ultraviolet exposure on the other hand are more strongly associated with nuclear and cortical cataracts (Kleiman 2012). The word cataract is used to describe any detectable change in the normally transparent lens of the eye. When light passes through a lens with cataracts it is diffused and or scattered. The effect of cataracts may vary from tiny flecks in the *lens (cloudiness)* to complete opacification and blindness. Hence sometimes these terms are used interchangeably. It is evident from ICRP's publication 2012 that world-wide, cataracts is the leading cause of blindness and over a hundred (100) million people are affected globally. Cataracts are usually linked with old age and less commonly, with trauma, chronic ocular infection and abnormal metabolic disorder. Other factors include, smoking and Ultraviolet (UV) exposure which is strongly associated with nuclear and cortical cataracts (Kleiman 2012).

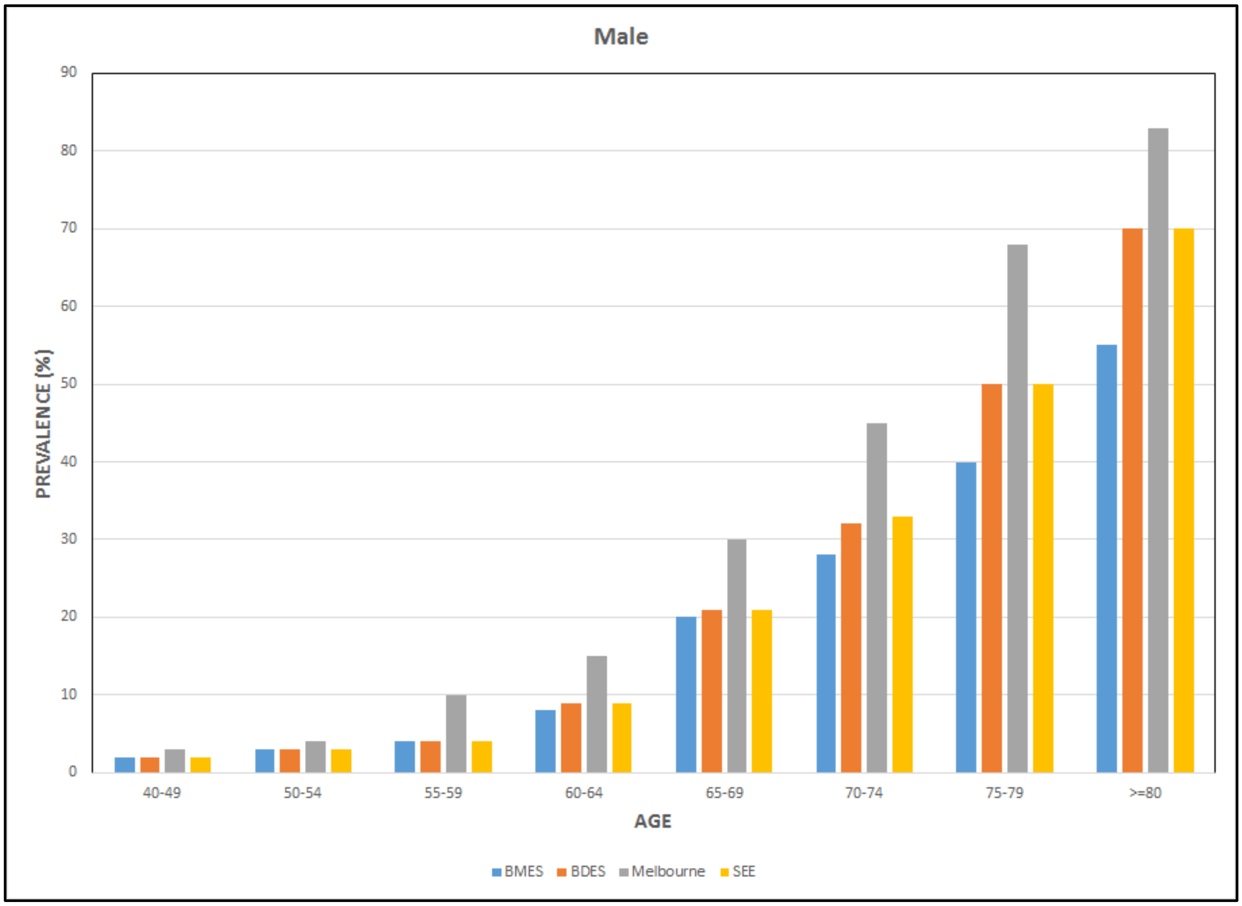
Most cataracts progress after the age of 45 as illustrated in Figure 2.1 to 2.3, but with recent advancements in medicine, most cataracts are treated relatively easily by surgery (Rehani *et al.* 2011). Although the development of cataracts is multi-factorial, it is important to note that the biggest factor is *aging*. As shown in Figure 2.4, at the age of 55, few individuals have cataracts; however, after this age the incidence rises sharply, and by age 65 – 69, some level of vision impairment occurs in 20 - 40% of individuals. (SSK[1] 2009).

[1] German Commission on Radiological Protection



The data were acquired by SSK from BDES: Beaver Dam Eye Study, USA; BMES: Blue Mountains Eye Study, Sydney, AUS; Melbourne VIP: Melbourne Visual Impairment Project, AUS; SEE Project: Salisbury Eye Evaluation Project, USA).

Figure 2. 3 Prevalence of Cataracts as a Function of Age -Female



The data were acquired by SSK from BDES: Beaver Dam Eye Study, USA; BMES: Blue Mountains Eye Study, Sydney, AUS; Melbourne VIP: Melbourne Visual Impairment Project, AUS; SEE Project: Salisbury Eye Evaluation Project, USA)

Figure 2. 4 Prevalence of Cataracts as a Function of Age -Male

The data extrapolated above were acquired by SSK from BDES: Beaver Dam Eye Study, USA; BMES: Blue Mountains Eye Study, Sydney, AUS; Melbourne VIP: Melbourne Visual Impairment Project, AUS; SEE Project: Salisbury Eye Evaluation Project, USA). Graph acquired from (SSK[1] 2009).

It is evident from the illustrations above that the most critical factor in lens opacity development and cataracts is age. Furthermore, below the age of forty-five (45) cataract is incidence is almost negligible as evident from plots in Figure 2.1, 2.3 and 2.4.

3.0 ICRP'S NEW RECOMMENDATION

ICRP publication 118 published in 2011/12 has significantly reduced the eye dose limit for the lens of the eye causing a rippling effect across the regulatory landscape worldwide. The sudden change and reduction directly influences regulated agencies, nuclear operators, research facilities, emergency workers and health care facilities globally as ICRP standards are used as best practice in all fields of ionizing radiation.

Exposure of the eye to ionizing radiation is associated with the development of cataracts. Studies of patients treated with x- or γ-rays have provided some insight into how radiation cataractogenesis works, based on the dose that reaches the lens of the eye.

In ICRP's general recommendations 'publication 103' in 2007, the ICRP concluded that its previous recommendations for protection of the lens of the eye, namely 150 mSv/yr (as equivalent dose), continued to provide *"an appropriate level of protection"*. However, ICRP (2007) also noted that new data on the radiosensitivity of the eye and associated visual impairment was expected and that a new ICRP Task Group would be established to review data.

The radiosensitivity of the lens of the eye has been recognized for many years and this has been considered by the International Commission on Radiological Protection (ICRP) in its system of protection since its inception as illustrated below:

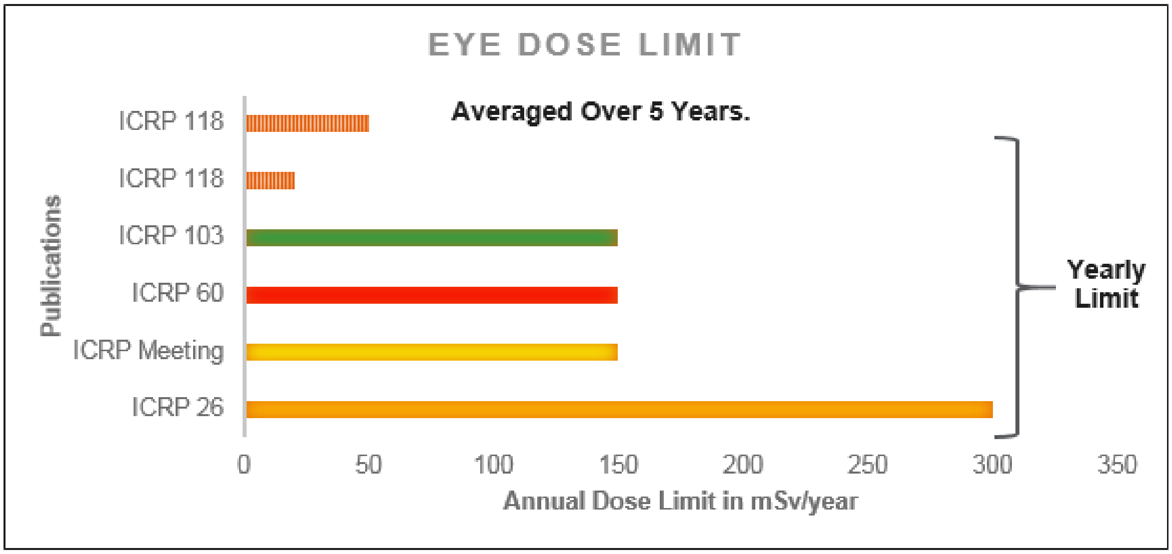


Figure 3. 1 Evolution of ICRP Dose Limit for The Lens of The Eye

In April 2011, the ICRP issued a statement on tissue reaction (2012), with a threshold absorbed 0.5 Gy for cataract to the lens of the eye, and new recommended dose limits of 20 mSv/y averaged over defined periods of 5 years, with no single year to exceed 50 mSv. The time frame for this question was extremely short and the statement was issued without much opportunity for comment.

In 2012, the ICRP issued Publication 118, which included the April 2011 statement as Part 1 and “Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold

Doses for Tissue Reactions in a Radiation Protection Context" as Part 2. It is to be noted that although Part 2 contains a detailed consideration of the threshold dose value, there is no discussion on the rationale for the recommended dose limits.

The International Atomic Energy Agency (IAEA) in their Basic Safety Standards (BSS) (IAEA 2011) adopted the ICRP lens of the eye dose limits of 20 mSv/yr averaged over 5 years with no single year to exceed 50 mSv. In Canada in August 2013, the Canadian Nuclear Safety Commission which is the federal regulatory body for radiation protection issued & proposed new radiation protection regulations which endorsed the recommendations of ICRP 103 and the IAEA's revised BSS and proposed to ensure that the CNSC's "requirements are in line with internationally accepted norms". Based on subsequent presentations and group discussions taken place as a part of this research, it is evident that the Canadian Nuclear Safety Commission is intending on moving towards the direction of the ICRP dose limit that is equivalent to the whole body dose limit.

The United Kingdom Society for Radiological Protection (UK SRP) has raised concerns with the new ICRP limits and the process used to derive the new limits as early as 2012 and 2013. Earlier publications such as that of Martin (2011) and Englefield (2011); have also identified issues with the strength of the science and the lack of time to review the proposed recommendation prior to it being included in the IAEA BSS. Moreover, there are still questions whether both ICRP and IAEA considered the issue of practical implementation of the new recommendations, as there are gaps in understanding the onset of cataractogenesis and approved commercial eye dosimeters do not exist, even today, over seven years after their original publication in 2011. Based on the interviews conducted as part of this thesis there are concerns that the new limit could restrict work on future emergency works, their abilities and could restrict the number of procedures in certain health care settings such as the number of procedures an interventional cardiologist performs in a month.

In view of the potential implications of the new ICRP recommendations for the protection of the lens of the eye, the CANDU Owners Group (COG) commissioned studies to investigate the implications of the proposed change for operation of nuclear power plants, as described in the preface; this study among them.

3.1. Evolution of ICRP Dose Limit for Lens of the Eye.

The International Commission on Radiological Protection (ICRP 26) published in 1977, was the first documentation to evaluate the effect radiation has on the lens of the eye. Understanding the exact mechanism for radiation cataract genesis or radio cataractogenesis is difficult and it was only in 1977 ICRP in publication 26 the commission evaluated the effect of radiation on the lens of the eye. The first evaluation made by *ICRP Publication 26* suggested that an occupational lifetime equivalent dose with both high and low-LET of 15 Sv would not produce any adverse effects to the lens of the eye and that 15 Sv accumulated over a working lifetime would not produce opacities that would interfere with vision. Based on available human information (at that time) the commission recommended the first eye dose limit to be set at 300 mSv.

Eight years later *ICRP Publication 41* published *in* 1984, reviewed the effect of radiation on eyes and the lens of the eyes and suggested a new threshold for the lens of the eye. The commission reviewed non-stochastic effects of ionizing radiation and reviewed the health and biological effects of ionizing radiation, with particular emphasis on dose limits and radioprotection. The commission and its committee of publication 41 reviewed multiple endpoints (among them being the lens of the eye) reviewed multiple publications and summarized data from *Merriam et al. 1972* , *Ruben and Casarett, 1972* and UNSCEAR 1982. Based on estimates of threshold dose for patients exposed to conventionally fractionated therapeutic low-LET radiation such as gamma rays, it was found that there was an effect in 25-50% of Patients at a dose of 12 Gy and in 1-5% oF the patients it was as low as 5 Gy. As a result it was suggested that an acute exposure of 5 Sv could cause cataracts and vision impairment, resulting in the reduction of the annual limit from 300mSv to 150 mSv or 15 rem.

In 1991 the commission intended to publish a report to guide regulatory agencies worldwide at the regional, national and international level in making appropriate radiological protection decisions. The commission set out the recommendations in the report and its subsequent annexes to guide industry specialists in policymaking. Chapters in the report also deal with the commission's main recommendations and discusses the practical implementation of the recommendations (summarized in the report). This report published as ICRP 60 '1990 Recommendations of the ICRP' reviewed multiple endpoints along with the lens of the eye. ICRP discussed that the lens of the eye are among the most radiosensitive tissues, and that the onset of cataracts of vison impairment needed a separate dose limit because it does not contribute to the whole body effective dose. The commission decided to continue the recommendation of ICRP publication 41 and recommended the equivalent dose limit for the lens of the eye to remain at 150 mSv. In March of 2007 the commission revised the recommendations and replaced the commission 1991 publication to update detriment and tissue weighting factors based on new available scientific data and new information on the biophysics of radiation exposure. The primary objective of the report remained the same i.e. justification, optimization and the application of dose limits. The publication did start discussions on personal dosimeters for the lens of the eye but kept the dose limit the same. hence, both major publications used in the regulatory landscape i.e. *ICRP Publication 60* and *103* evaluating the occupational eye dose limit in 1991 and 2007 continued to keep the dose limit and threshold the same without any modification to the 150 mSv dose limit.

Over three decades the dose limit for the lens of the eye had been kept at 150 mSv based on the data provided in *Merriam et al. 1972* , *Ruben and Casarett, 1972* and UNSCEAR 1982. The estimated threshold dose for patients exposed to conventionally fractionated therapeutic low-LET radiation was 12 Gy (in 25-50% of Patients) and 5 Gy (1-5%). The 5 Gy threshold estimate resulted in the original reduction of the annual limit from 300mSv to 150 mSv or 15 rem. It wasn't until 2012 that the International Commission on Radiological Protection decided on reducing the threshold by ten times to 0.5 Gy, resulting in the recommended change of dose limit equal to the annual dose limit which is 20 mSv. As evident prior to ICRP Publication 118 (2012) the accepted threshold for cataract formation was significantly greater than the suggested absorbed dose of 0.5 Gy. The basis of the recommendations for the protection of the eye in ICRP Publication 118 (2012) seems extreme, as the 1% criterion for the threshold dose seems inappropriate and unjustified especially for readily treatable cataracts.

4.0 Epidemiology

The vast majority of data on both stochastic and deterministic effect we have for all endpoints is from the atomic bomb survivors from both Nagasaki and Hiroshima. Albeit an unfortunate and a tragic event, it has been the basis for the majority of epidemiological and radiobiology studies done for ionizing radiation protection. Data from the atomic bomb survivors have been used by the International Commission on Radiological Protection and Regulatory Agencies worldwide in setting regulatory standards and regulations for occupational exposure worldwide including the Canadian Nuclear Safety Commission (erstwhile Atomic Energy Board of Canada, AECB).

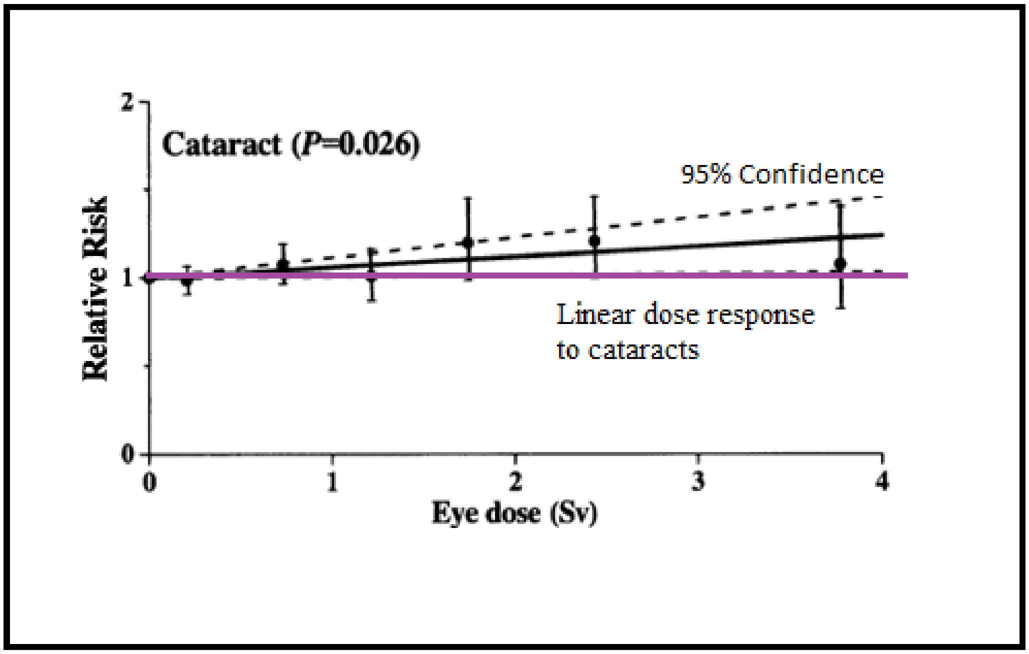
Five different studies discussed in this report have focused on bomb survivors from Hiroshima and Nagasaki. The type of radiation exposed to were Gamma and Neutrons, for which all the authors have used a Relative Biological Effectiveness (RBE) of 10 for neutrons. Minamoto (2004), Nakashima (2006), Yamada (2004) looked at opacities developments where as Neriishi (2007) and Neriishi (2012) looked for cataracts extraction surgery. It is important to note that exposure to the atomic bomb survivors was for acutely exposed individuals only.

One of the most extensive studies performed on the atomic bomb survivors were by Yamada and Nakashima published studies in 2004. The studies performed by Yamada reviewed non-cancerous disease incidences in bomb survivors, between the periods 1958 and 1998. The number of people i.e. atomic bomb survivors examined or studied were people who visited clinics at least twice and included a total number of 10, 332 atomic bomb survivors. What was interesting to note is that from this cohort approximately sixty percent (60%) of the population were younger than 20 years old and approximately two percent of the exposed population that visited the clinic at the time of bombings were over forty years old.

A dosimetry system was established prior to calculating or estimating the dose for the study group or cohort. A joint U.S., Japan research program known as Radiation Effects Research Foundation (RERF) developed a dosimetry system to study radiation effects on Atomic Bomb Survivors in 1986 (Kerr, 1988). The system used was known in short as DS86, and was used to estimate both absorbed dose and tissue kerma in air to survivors who were exposed during the bombings. An integrated system was developed and installed in the RERF's mainframe computer using gamma and neutron radiation fields at four different heights from both cities (Hiroshima & Nagasaki). Using the DS86 model, the mean dose obtained for the cohort was approximately 0.57Gy.

There was no threshold dose estimation performed by Yamada, however it was noted that among the population that visited the clinics at least twice, there was an increase in risk to survivors who were 20 years or younger at the time of bombing when compared to the same population that were 40 years and above. With these data at hand, it can be summarized that there is a positive linear dose-response when comparing effect on the lens of the eye and exposure to radiation.

Figure 4.1 represents the 95% Confidence Interval (shown by the dotted line) and the linear dose response to cataracts indicated by the solid line. According to the study the RR (relative risk) at 1 Sievert (Sv) is 1.6 (95% Confidence Interval), taking into considerations such as smoking, age, geographical data, etc. While there is some positive association, the confidence intervals on the dose response overlap the horizontal line at a relative risk (RR) of 1 which is the baseline risk, thus showing very little evidence of an above baseline risk of cataracts.

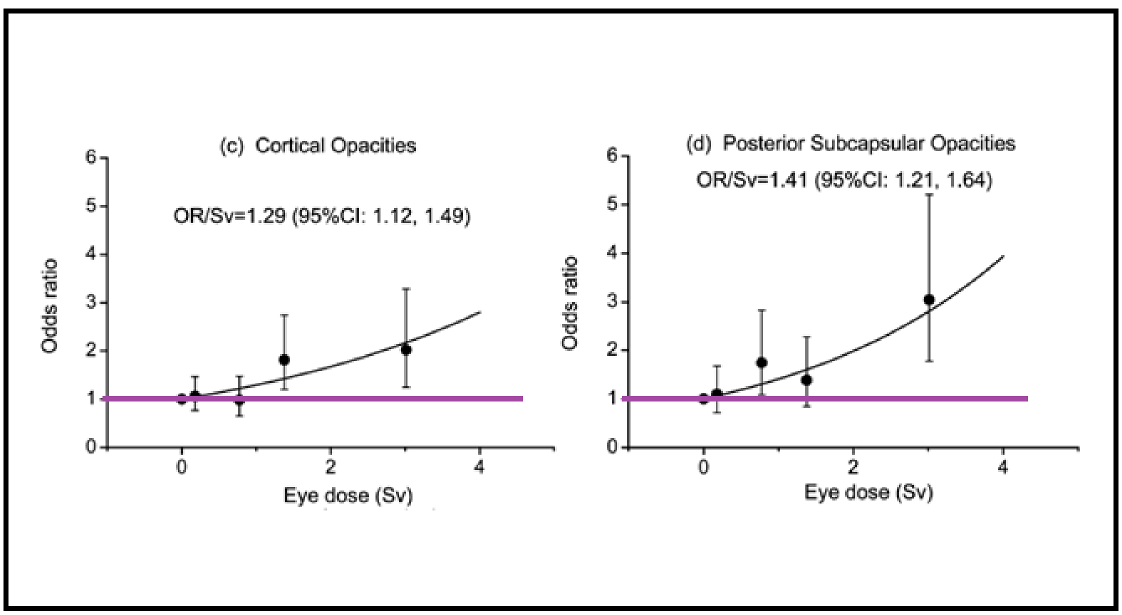


(Graph extrapolated from Yamada *et al.* 2004.)

Figure 4. 1 Relative Risk for Cataracts as a Function of Dose (Yamada *et al.* 2004)

Fifty-seven (57) years after the atomic bombs were dropped over eight hundred atomic bomb survivors were re-evaluated by Manimoto (2004) to study the relationship between radiation dose and changes to the lens of the eye. The cohort group consisting of the survivors similar to Yamada et al. 2004 studies included a younger age group with the age ranging from 0.8 to 37.9 years of age at the time of bombing. Manimoto (2004) used digital photography and a slit-lamp examination system to study the eyes and classify the cataracts, referred to as the Lens Opacities Classification System, version II (LOCSII). Similar to the model Yamada used, Manimoto (2004) also used the DS86 model to estimate dose to the exposed population or ASB.

The dose to the cohort ranged from <0.005 to 2 Sv and the the Odds ratios were divided between two types of opacities i.e. Cortical Opacities (at the periphery of the eye) and Posterior Subcapsular Opacities (beneath the lens capsule). Correcting for multiple factors such as smoking, geographical location and age, the odds ratio was 1.29 for cortical opacities and 1.41 for sub-capsular opacities. Minamoto et al. 2004 concluded that there was an increase in both types of lens opacities, but the examinations were done blindly without prior knowledge of whether or not the patient had actually been exposed. Figure 4.2 represents the 95% Confidence Interval (shown by the black line) and the purple solid horizontal line shows the baseline risk for the group for the two types of opacities. For Cortical Opacities, there are statistically significant points only after 1.3 Sv



(Graph extrapolated from Minamoto *et al.* 2004.)

Figure 4. 2 Odds Ratios for Prevalence of Cortical and Posterior Sub-Capsular Opacities as a Function of Eye Dose.

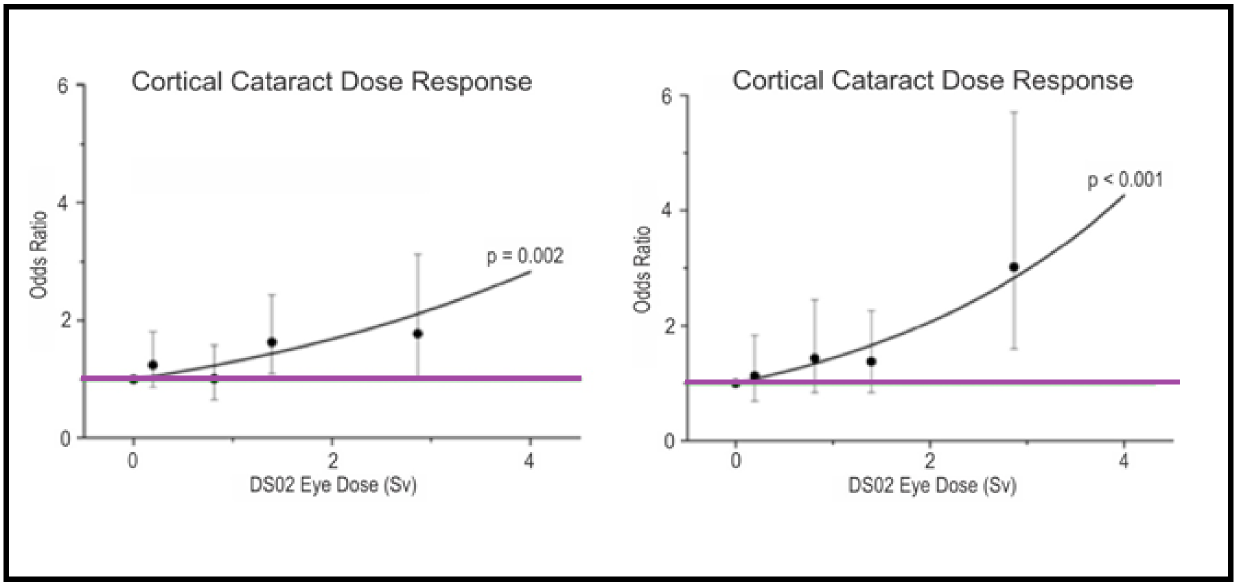
and for Posterior Subcapsular Opacities only aft 3 Sv, thus, indicating that the excess is not significant statistically for doses > 1 Gy[2]. Indicating a lack of a threshold dose at 0.5Gy, as suggested by ICRP 118.

Another study cohort conducted was by Nakashima et al. in 2006 carried out a re-analysis of the digital images taken during the studies that were conducted by Manimoto in 2004. Unlike Manimoto who had multiple physicians, Nakashima's study utilized a single physician or an examiner, thus reducing and minimizing variations in the interpretations of the photographs and or images. The cohort studied by Nakashima et al. 2006 included a smaller group as the examiners decided to ignore atomic bomb survivors (ABS) that were in-uetro during exposure. The total number of people examined was just over seven hundred (700). There was also an update made regards to the dose model used by the previous two publications. Nakashima and group used DS02 i.e. Dosimetry System 2002 instead of DS 86. Like the DS 86 model, the DS02 was also developed by the U.S., Japan research program, Radiation Effects Research Foundation (RERF) and were both based on similar models with just improvements in computation powers. The dose to the cohort that was re-examined ranged from 0 to 4.940 Sv. The mean radiation dose for the previous study was < 0.5 Sv and the re-examination led to a mean dose of 0.522Sv. The opacity grading mechanism was the same as Manimoto (2004) that is the Lens Opacities Classification System, version II (LOCSII).

[2] Greys and Sievert have been used interchangeable, to stay consistent with the reporting of the actual studies. Based on whether the study reported equivalent dose or absorbed dose.

There was no dose response for atomic bomb survivors for the cohort that was exposed in utero. The odds ratio per Sv was 1.30 for cortical cataracts and 1.44 for posterior sub-capsular opacities. The re-examination illustrated in Figure 4.3 below indicated that the study that Nakashima et al. 2006 conducted was statistically more significant in relating dose effects and opacities in both cortical and posterior sub-capsular regions. The data have been used to indicate that as the dose increases, the risk of developing cataracts also increases. The threshold that was calculated was 0.7 Sv and 0.6 Sv for posterior sub-capsular opacities and cortical cataracts respectively. The odds ratio per Sv for for cortical opacities was 1.30 (95% CI of 1.10-1.53) and PSC opacities was 1.44 at 10 years ATB (95% CI of 1.19-1.73).

The publications also concluded that the thresholds are also comparable to zero threshold dose indicating that cataract formation may be a stochastic effect and not a deterministic effect. Figure 4.3 below illustrates the dose response relationship for cortical and posterior subcapsular cataracts of the study that was re-examined by Nakashima and his colleagues based on the cohort that was studied by Manimoto (2004). The horizontal line as per Figure 4.3 below also indicates no excess risk.

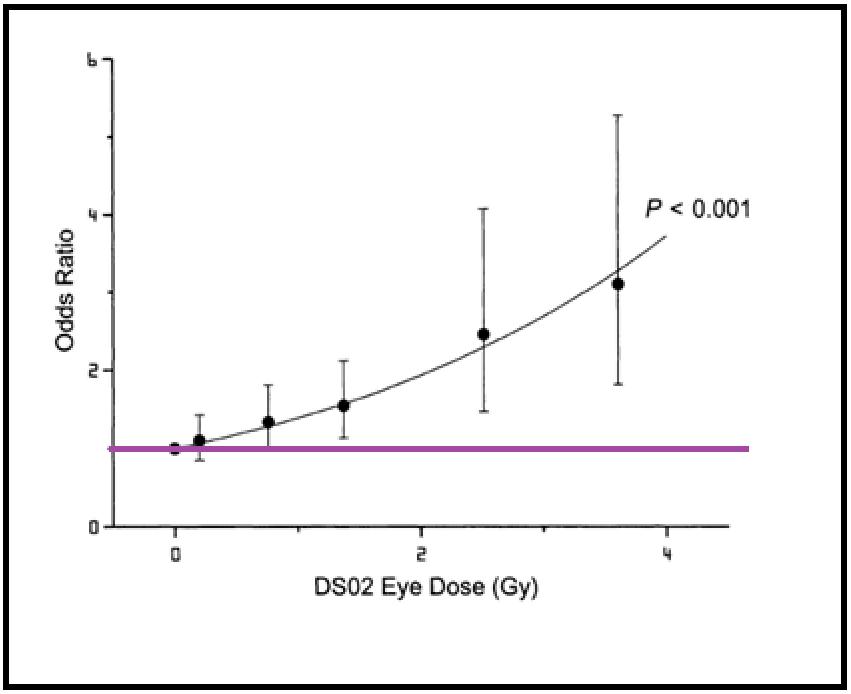


(Graph interpolated from Nakashima, et al. 2006.)

Figure 4. 3 Odds Ratios for Prevalence of Cortical and Posterior Sub-Capsular Opacities as a Function of Eye Dose.

The study by Neriishi (2007) explored the relationship between radiation exposure and clinically significant cataracts (surgical removal of cataracts). This study is unique and reliable because no slit-lamp microscopy was required and so there was no uncertainty in the level of cataracts. Fifty- five (55) years after the bombing ophthalmoscopic examinations performed between 2000 and 2002 and out of 3761 subjects in the study, 476 cases with postoperative cataracts were found to have gone under cataract removal surgery. While it's a good representation of severe cataracts, not all the individuals would have gone through the surgery because of old age or sickness of unwillingness. Neriishi estimated that 61% of the individuals with severe cataracts underwent cataract extraction surgery. The result obtained from the report, showed an increase in the cataract surgery with increasing dose no matter what the age at the time of bombing.

The doses to the bomb survivors were calculated using the Dosimetry System 2002 (DS02). The dose threshold analysis indicated a threshold of 0.1 Gy (with 95% CI of 0-0.8) after correcting for age, gender, diabetes, and other potential confounders. The lower limit of 0 Gy implies that a threshold doesn't exist, and that radiation cataractogenesis might be a stochastic effect. The upper limit suggests that if there exists a threshold then their data are consistent with threshold below 0.8 Gy. The results have led to a linear, but not of linear-quadratic dose response. (see image below) The odds ratio (OR) at 1 Gy was 1.39, with a 95% Confidence Interval of 1.24 to 1.55. The average age of cataract surgery was 72.9 years. It is believed that the lens is most sensitive at younger ages. Noting that the youngest subject in the study was 55, and the average age of surgery was 72.9 years and that only 61% of the individuals with cataracts have gone through cataract extraction surgery, the dose threshold could be even lower in the future.



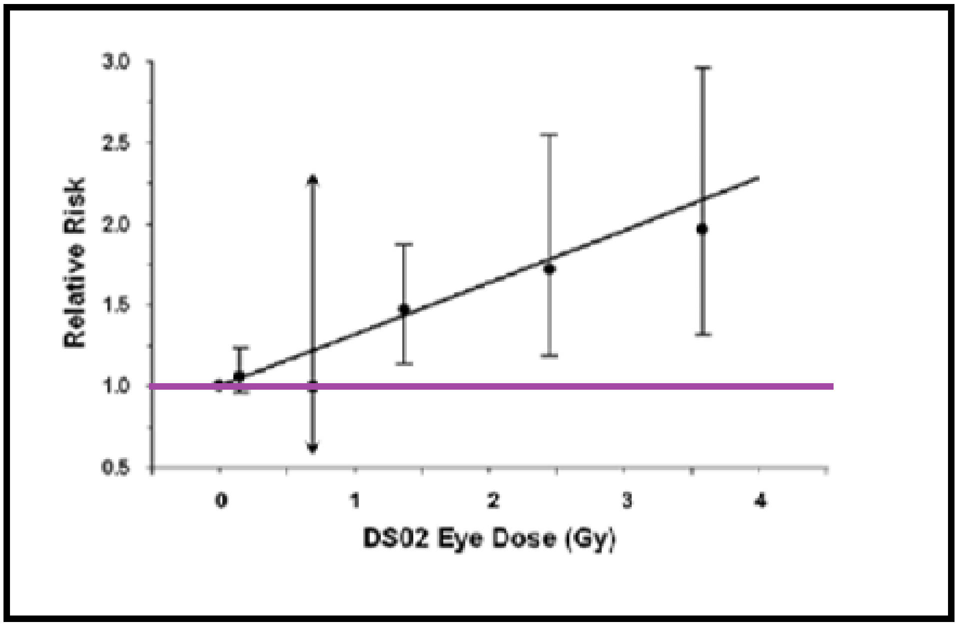
(Graph interpolated from Neriishi *et al.* 2007)

Figure 4. 4 Odds Ratio for Cataracts as a Function of Dose (Neriishi *et al.* 2007)

The final and the most recent study that focused on atomic bomb survivors were performed by Neriishi (2012). The purpose of the study was also to determine the relationship between radiation dose and cataract surgery incidents, similar to the study done by Neriishi in 2007, but in this publication the study period was between the years 1986 and 2005 compared to the previous publication where the study period was between 2000 and 2002. A total of 6066 people visited Radiation Effects Research Foundation Clinic at least twice between 1986 and 2005. The mean age at exposure was 20.4 years (range was 0–54 years) and the mean age at which cataract extraction was performed was 74.4 years (range was 49–95 years).

Neriishi found 16 risk factors for lens opacities using a literature search, which included education: marital status, history of smoking, body mass index, systolic and diastolic blood pressure, platelet count, lactic acid dehydrogenase level, uric acid level, g-glutamyltransferase level, history of diabetes mellitus, hypercholesterolemia, hypertension, angina pectoris, myocardial infarction, and corticosteroid medication use. After adjustment for all factors simultaneously almost no effect on radiation risk was observed. The mean dose to the cohort was 0.50 Gy(range 0.0–5.14 Gy), which was estimated using DS02. A dose threshold analysis was performed using two different models, both of which provided similar estimates of 0.50 Gy (95% CI: 0.10-0.95) for the Excess Relative Risk (ERR)[3] model and 0.45 Gy (95% CI: 0.10-1.05 Gy) for the Excess Absolute Risk (EAR)[4] model. The dose response was again nearly linear (see image below) however Neriishi concluded that there individuals exposed at younger ages are more at risk to developing cataracts. The reason for this is unclear.

[3] ERR is ratio used by epidemiologists to describe the increase in risk proportionally over absolute risk without exposure.
[4] EAR is ratio used by epidemiologist to describe the additional risks over absolute risk



(Graph interpolated from Neriishi *et al.* 2012)

Figure 4. 5 Risk for Cataracts as a Function of Dose (Neriishi et al. 2012)

Chernobyl Accident:

Chernobyl accident liquidators were individuals who were part of a group that were cleaning up radioactive debris from the Chernobyl nuclear accident. The study on liquidators done by Worgul (2007) shows that there is increased risk of developing lens opacities which can lead to vision impairing cataracts in the future, even when the individuals are exposed to protracted low-dose exposures. The results obtained in this study were similar to the resulted obtained in the atomic bomb survivor studies. The exposure in both studies was acute and both the studies have suggested that dose fractionating does not lead to reduced risk of developing cataracts.

Worgul examined the lens of the eye using slit-lamp biomicroscopy and used Merriam-Focht scoring system on 8607 liquidators. The study was done 12 and 14 years after the accident and the mead age of the cohort was 44.9 years at first examination (12 years after exposure) and 47 years at the second examination (14 years after exposure). Since the mean age was only 47 years the prevalence of age related cataracts was low and so any signed of cataracts would be due to the radiation exposure. The dose to each individual was calculated using the individual personal dosimeters, analytical dose reconstruction methods, and ‘group Dosimetry’ method, where a single dosimeter was used to estimate the dose to a group of individuals. The mean dose to the group was between 0.1 Gy and 0.199 Gy and so the dose to lens were mostly on the lower side (<0.4 Gy in 94% of the cohort and <0.7 Gy in 98% of the cohort). At the first examination (12 years after the accident) Worgul observed that 20% of the cohort had developed Stage 1 Cataracts and at the second examination (2 years after the first examination) 5% of the cohort that did not have stage 1-5 cataracts at the first examination, had developed stage 1 cataracts.

Worgul determined the odds ratios at 1 Gy for developing stage 1 posterior subcapsular or cortical cataracts was 1.49 (95% CI 1.08–2.06). The threshold Stage of developing cataracts of stage 1–5 was 0.50 (0.17–0.65). The analysis also included cofounding variables which included age, sex, smoking, diabetes mellitus, histories of corticosteroid and phenothiazine use, occupational exposures to hazardous chemicals, ionizing radiation (other than Chernobyl), and infrared and ultraviolet (UV) radiation. Worgul suggested that the relationship between lens opacities and dose is linear, with weak evidence of upward curvature. This study has already showed an increased risk for lens changes at low-dose exposures, but taking into account the young age of the cohort, future studies of liquidators would provide a very good relationship between vision impairing cataracts and dose.

4.2 Epidemiological Studies Conducted after ICRP Dose Change

Cataract was one of the earliest pathologies associated with radiation and it had been long thought that cataracts can only be induced after high dose exposure to the lens of the eye. This result was based on results of studies done on early cyclotron workers, who received a high dose from neutron exposure and studies done on Japanese A-bomb survivors who received doses over 2-3 Gy. (Shore 2010). The lens of the eye is one of the most radiosensitive part in the body and the International Commission on Radiological Protection (ICRP) had previously suggested that cataract caused by radiation exposure is a deterministic effect and the threshold for detectable opacities was 0.5-2.0 Gy for acute exposure and 5 Gy for chronic exposure. Previously ICRP and National Council on Radiation Protection and Measurements (NCRP) have reported a threshold of 2-10 Sv for acute exposure and 8 Sv for chronic exposure (ICRP 103, NCRP 105). These regulations were based on studies that had too few subjects with doses below few Grays, didn’t take into account the long latency period with low doses, these studies generally had a short follow up period, and were not designed to detect any early lens changes. (Kleiman 2012). Table 4.1 shows the results of threshold estimates from some of the older studies. The results show that as the cohort size of the subjects and follow up period increases better estimates can be obtained. Although ICRP Publication 41 states that threshold for development of minor opacities is 0.5-2.0 Gy, they had set the annual limit at 0.15 Sv/yr. Therefore if an individual received 150 mSv to the eye for 4 years, they would have passed the threshold for minor opacities. ICRP publication 41 states "dose-equivalent limit (0.15 Sv) each year for 50 years would not cause a vision-impairing cataract, although it might give rise to opacities that could be detected ophthalmologically in some exposed individuals". From this statement it can be assumed that the ICRP did not consider that minor opacities could, with given enough time, develop into visually-impairing cataracts, which the ICRP wants to prevent from occurring.

Table 4. 1 Changes in estimated threshold as the years progressed. (Data taken from (Kleiman 2012)

Source	Best threshold estimate	Subjects	Years post exposure
Anecdotal, pre-1950	5-15 Gy	<100	N/A
Cogan and Dreisler (1953)	6 Gy	40	7
Merriam and Fochet (1957)	2-5 Gy	276	Av = 8
Otake and Schull (1982)	1.2 Gy	2125	18-19

The recent studies had an advantage compared over the older studies because they had better techniques for identifying and quantifying the early lens associated with radiation exposure. (Martin 2011) More recent studies have shown that early stages of cataracts can develop many years following exposure to low levels. Numerous recent studies have taken into account the inverse relationship of cataract development time to exposure and have shown that the threshold for radiation cataract is much lower, while some studies also suggest that radiation cataract could be a stochastic effect. (ICRP 118) After reviewing recent studies ICRP has set the threshold to absorbed dose of 0.5 Gy, without any indication that fractionation of dose is less harmful then dose delivered actually, and also reduced annual equivalent dose limit to the lens from 150 mSv to 20 mSv averaged over 5 years (ICRP 118). According to ICRP 118 the main objective of radiation protection is to "prevent acute radiation effects, and to limit the risks of late effects to an acceptable level".

5.0 Dosimetry

The major concern for eye lens exposure is in the medical field of the physicians, nurses and support staffs of interventional cardiology, radiology and fluoroscopy. (Bouffler et al. 2012, Damet 2011, Gualdrini 2011) Some other fields of concern also include nuclear decommissioning and weapons productions. (Bouffler et al. 2012) For radiation protection purposes it is important to determine the dose to individuals as accurately as possible, because this would allow for the accurate determination of radiation effects and the dose response relationships can be accurately examined. For the assessment of accurate dose the ICRP and ICRU have developed a system for radiation protection purposes. (Wernli C. 2004).

System of Radiation Protection:

The system is composed of basic physics quantities, protection quantities and operation quantities. (Wernli C. 2004) Basic physical quantities are quantities for which the units are obtained directly through standards at national standers laboratories, measurable (ex.

Fluence, absorbed dose, kerma) and are the basis for protection and operational quantities. (Wernli C. 2004, Dietze G.) These are point quantities, meaning they are defined at all points in the field. (Dietze G.) Protection quantities allows for a quantitative assessment of the extent of exposure from internal and external exposure, which are based on absorbed dose averaged over a tissue or organ of interest. (Wernli C. 2004) It takes into account the different sensitivity of humans to different types of radiation and the sensitivity of tissues to different kinds of radiation (effective dose). (Wernli C. 2004) In radiation protection the effective dose to a tissue or organ from an external source is not possible to measure, and so in this case operation quantity are used to approximate of the effective dose using a personal dosimeter. (Jun I. T. 2013, Szumska A. et al. 2011, Wernli C. 2004)

Operational Quantities:

Since protection quantities are not measurable, operational quantities are used to provide estimate of dose from external exposure only. They used area monitoring and individual monitoring. Incident radiation is categorized as either penetrating radiation or as low-penetrating radiation depending on the ratio of skin dose to effective dose. If the ratio is greater than ten for a broad radiation beam normally incident, then the radiation is considered low-penetrating radiation and for ratios less than 10 the radiation is considered penetrating. (Wernli 2004)

Dose Equivalent and Quality Factor:

The quantity used for dose estimation at a point of interest is Dose equivalent (*H*) which is defined as

$$H = D * Q,$$

where D is the absorbed dose at the point of interest inside the tissue of interest and Q is the quality factor of the radiation contributing to the dose. (Dietze G. et al. 2005) The quality factor at the point of interest is a function of the type of radiation and the energy of the radiation at the point of interest. (Dietze G. et al. 2005) The quality factor at the point of interest is defined in ICRP Publication 60 as:

$$Q = \frac{1}{D}\int_{L=0}^{\infty} \mathrm{Q}(L) D_L \, dL$$

where D_L is the distribution of *D* in *L* for the radiation contributing to absorbed dose at the point of interest and Q(L) is a dose quality function defined as

$$\mathrm{Q}(L) = \begin{cases} 1 & for \quad L < 10\ keV/\mu m \\ 0.32L - 2.2 & for \quad 10 \leq L \leq 100\ keV/\mu m \\ 300/\sqrt{L} & for \quad L > 100\ keV/\mu m \end{cases}$$

where L is the Linear Energy Transfer of the radiation in water.

There are different types of operational quantities: one is used for area monitoring used for setting control area and the second used for individual monitoring is personal dose equivalent. (Wernli C. 2004, Dietze G. et al. 2005) The reason behind defining different operational quantities is to correct for the different fields seen by both dosimeters. A measurement done by area monitors is done in free air compared to measurement done by individual monitor is done using dosimeters worn on the individual. The measurement done by both monitors will show different results, because the fields seen by the individual monitor is greatly affected by the absorption and backscatter in the body, whereas this situation does not arise in free air measurements. (Dietze G. et al. 2005).

Monitoring Specific Operational Quantities:

H_p(10) is the term used to describe dose at a depth (body) of 10mm and is a term that used in personal dose measurement and dosimeter applications. H_p (10) is used to describe the equivalent dose in the radiation field According to ICRU (1993), the primary application of H_p (10) is for monitoring highly penetrating or deep dose, i.e. neutrons and photons. While the depth dose H_p (10) is sufficient for photons, for charged particle according to ICRU publication in 1998, H_p (0.07) is also used, to refer to dose that is less penetrating for example: when measuring for skin dose. 0.07 refers to a depth of only 0.07 mm. Both H_p (10) and H_p (0.07) are commonly used methodologies in dosimetry and are evident in majority of dose reports and most thermoluminescent dosimeters can easily measure both quantities and can determine both whole body dose and skin dose using these methodologies.

For measuring dose to the lens of the eye, both these parameters cannot be used, since it's a special scenario. The term defined by ICRU for measuring dose to the lens of the eye is H_p (3). The dose is measured at a depth of 3mm for the lens of the eye. However, there are currently very few instruments for measuring accurate dose to the lens of the eye. There are no approved dosimeters at the moment that can practically and effectively measure H_p (3). It poses a challenge to both the regulators and the industries that would like to implement or test out their radiation exposure to the lens of the eye. The Canadian Nuclear Safety Commission is yet to approve a dosimeter equipped with H_p (3) for measuring radiation dose to the lens of the eye.

Different operational quantities have been defined by ICRU for the measurement of different monitoring purposes:

$$\begin{Bmatrix} H_p(10): Personal\ Dose\ Equivalent \\ H^*(10): Ambient\ Dose\ Equivalent \end{Bmatrix}$$

Used for monitoring strong penetrating radiation (ex. photons with energies of greater than 14 keV and neutrons) and also used for control of effective dose.

$$\begin{Bmatrix} H_p(0.07): Personal\ Dose\ Equivalent \\ H'(0.07, \Omega): Directional\ Dose\ Equivalent \end{Bmatrix}$$

Used for monitoring week penetrating radiation (ex. β-particles and α-particles) and also used for control of dose to the extremities and skin dose.

$$\begin{Bmatrix} H_p(3): Personal\ Dose\ Equivalent \\ H'(3,\Omega): Directional\ Dose\ Equivalent \end{Bmatrix}$$

Used for monitoring personal and directional dose to the lens of the eye, because the most radiosensitive part of the eye (lens) is at a depth of 3 mm.

Dosimeter for Dose measurement in Operational Quantity $H_p(3)$:

Until ICRP lowered the threshold for cataract development from radiation exposure to the lens of the eye and also reduced the annual eye dose limit from 150 mSv to 20 mSv. Previously the dose to the lens had been monitored but only based on specific industries and with limited accuracy as under uniform whole body exposure it would be difficult to exceed the eye dose limit without exceeding the whole body dose limit. Therefore, in the past, there were no special dosimeters that monitor the eye dose (Dietze G. et al. 2005). Now that the ICRP 118 has lowered the dose limit it is possible for the eye dose limit to be exceeded especially for staff working in interventional procedures and so a dosimeter that can accurately measure the eye dose is required.

Previous Practices:

Until recently there were no dosimeters that can measured the dose to the eye, because there were no eye lens calibration phantoms and reliable conversion coefficients did not exist. (Bilski P et al. 2011) For this reason eye dose measurements were hardly done in the past and even if they were done, they were not accurate because the operation quantity $H_p(0.07)$ and $H_p(10)$ were used to approximate the eye dose. (Bouffler et al. 2012). For dosimeters calibrated in terms of $H_p(0.07)$ the dose to the lens of the eye can be over estimated by a factor of up to 550, for beta fields of energy of 1MeV while $H_p(10)$ can underestimate the dose to the lens of the eye. (Bouffler et al. 2012, Bilski P et al. 2011, Geber T. et al. 2011)

An important requirement for the operational quantity is that the dosimeters should be able to be calibrated under reference conditions and therefore calibration phantoms that represent the human body have been developed (ex. pillar phantoms for dosimeters worn on wrist or ankle, rod phantoms for dosimeters worn on fingers, and a slab phantom for dosimeters worn on the waist) to take into account the back scatter from the body. (Wernli C. 2004)

ORAMED:

The ORAMED (Optimization of Radiation protection for MEDical staff) project has studied the dose received by staff in interventional radiology using wide range of simulations and measurements. (Gualdrini 2011) The results will be used to come up with guidelines to reduce the dose to the staff. (Gualdrini 2011) One of their goals was to develop an operating dosimeter that responds in terms of $H_p(3)$ and for that a new calibration phantom was also made. (Gualdrini 2011)

5.1 Issues Surrounding Hp (10) and Hp (0.07)

Overestimation issues exists in doses determined for Hp (0.07) and there is an accuracy problem. Based on models designed by nuclear operators fluence modelling is needed as Gamma and Beta radiation needs to be distinguished. According to nuclear operators there is an issue in measuring doses primarily at low energies (below 1 MeV). In areas surrounding nuclear reactors, according to the investigations conducted so far, the Fluence approximation is 95% Gamma and 5% Beta. Current dosimetry is uncertain and potentially leads to misclassification primarily for beta radiation as Hp(10) undermines the actual dose to the lens at 10 mm and Hp(0.07) is inadequate as the correct depth for the lens of the eye is 3mm or Hp(3).

5.2 Need for Dosimeters

There are currently three licensed dosimetry providers in Canada, LANDAUER, Mirion Technologies and NDS (National Dosimetry Provider) by Health Canada. The three providers currently provide dosimeters for the entire country. However, majority of their dosimeters only have either Hp (0.07) or Hp (10) filters that currently measures skin dose and/or Hp(10) that measures deep dose, which are both not suitable for measuring dose to the lens of the eye. There is a significant gap in that the Canadian Nuclear Safety Commission is yet to approve a dosimeter or a service that can measure eye dose accurately. The proper depth or filter needed for measuring eye dose is 3mm or Hp (3). In interviews conducted with the dosimetry service providers it has been discovered that the biggest issue is accuracy and capturing dose to both eyes independently. Another important factor is proper positioning, ergonomics and aesthetics.

6.0 Radiobiology

The specific mechanism by which radiation damages the lens is not known, but there are a few hypotheses (Shore *et al.* 2010). In general, radiation damage occurs in the epithelial cells located at the anterior of the lens (Figure 6.1). The terminally differentiated lens fibre cells located at the anterior migrate to the posterior side of the lens. These lens fibre cells have a high protein content, which makes transparency and refractivity possible (Bouffler *et al.* 2012).

The lens itself consists largely of fibre cells with the ocular lens enclosed in a capsule. Dividing cells differentiate into lens fibres and congregate at the equator. Sufficient exposure to ionizing radiations (such as x- or γ-rays, charged particles, or neutrons) can cause a cataract (Hall & Giaccia 2012).

An important consideration for dosimetry is that the lens of the eye is approximately three millimeters inside the eye and has three differentiable structures: the capsule, the lens epithelium, and the lens fibres. The lens capsule is the outermost layer, followed by the lens epithelium and lens fibres. The bulk of the interior part of the lens is comprised of lens fibres. The cells of the lens epithelium are only found on the anterior side of the lens.

Lens growth, from early in embryogenesis, is entirely determined by proliferation of a small band, approximately 60 cells wide, in an area of the anterior epithelium near the lens equator termed the germinative zone (GZ). Cells in the GZ following terminal cell division migrate towards the equator and queue up in precise registers called ‘meridional rows’ and begin to differentiate into mature lens fibre cells (Chandani 2013, Hall & Giaccia 2012).

Since the lens of the eye has no blood supply (avascular), there is no mechanism to remove dead cells from the eye. However, cell division in the lens continues for life (eventually tripling in size); there is no loss of cells over the lifetime in the lens (even if the cells are damaged). Therefore, when dividing cells are injured by radiation (or other causes), the resulting abnormal fibres are not removed from the lens and this constitutes the beginning of a cataract (Chandani, 2013, Hall & Giaccia, 2012).

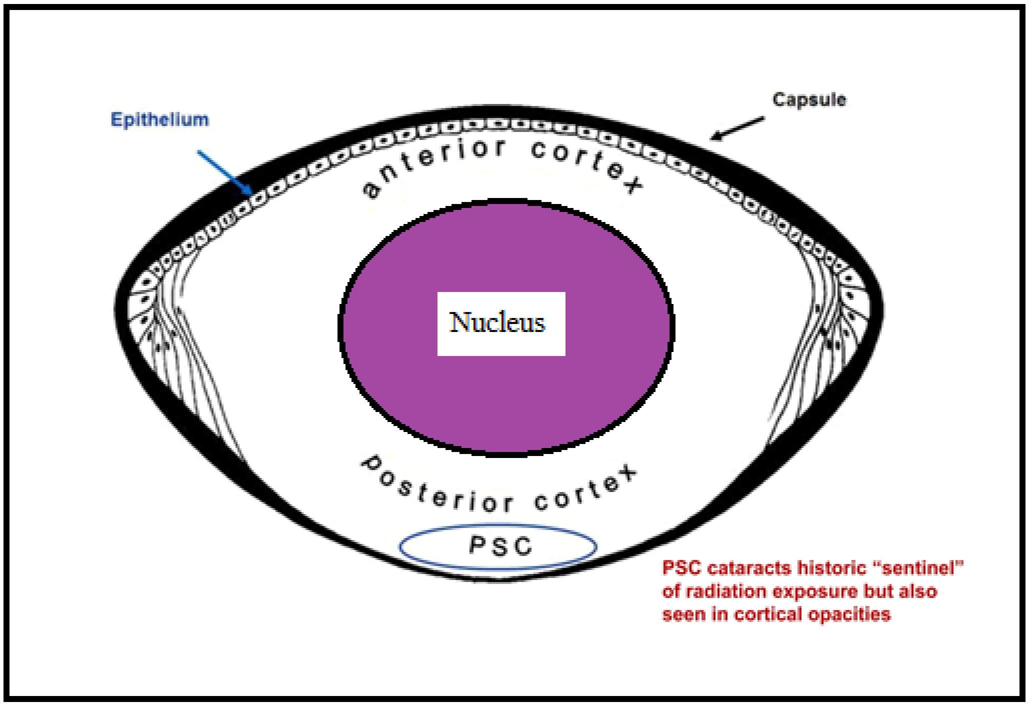


Figure 6. 1 Schematic of Lens of the Eye (Adapted From IAEA)

It is believed that gamma radiation exposure to these proteins can induce changes to the lens crystalline structure, which can cause cataracts. These protein changes are similar to protein changes observed in age-related cataracts, which suggests that accumulating radiation exposure might be acting as a premature aging factor in the lens of the eye (Bouffler *et al.* 2012). The transparency of the lens is dependent on the regular arrangement of the lens fibre cells and the cytoplasm. Disorganization of the cells or cytoplasm causes light to scatter and cataracts to develop (Brown 2001).

According to Kleiman (2012), the cellular and molecular pathways for cataracts that occur due to radiation exposure are similar to the carcinogenic response due to radiation exposure in other tissues of the body. Therefore, if this hypothesis is correct, it is possible that cataracts arise from damaged or misrepaired DNA.

DNA damage in the epithelial cells due to radiation can occur via direct photochemical action or oxidative mechanisms. Due to the low metabolic activity levels in the lens of the eye, one might not expect the lens to be a site where oxidative stress plays a major role, but because of the constant exposure of the lens to light (which includes UV and radiation), it is one of the most oxidatively-stressed tissues in the body (Williams 2008).

Various papers have discussed the mechanisms and effect of oxidative stress on lens proteins (e.g., Berthoud and Beyer 2009, Williams 2008, Shore *et al.* 2010). The source of this stress is the presence of free radicals or reactive oxygen species (ROS) as illustrated in Figure 6.2, including superoxide anion ($\cdot O_2^-$), and hydroxyl free radicals ($\cdot OH$), and H_2O_2. The lens has several mechanisms to maintain its redox state and to protect components of the eye (e.g., proteins, lipids, DNA, etc.) from oxidative stress. These mechanisms include: enzymatic pathways, high concentration of ascorbate, and reduced glutathione.

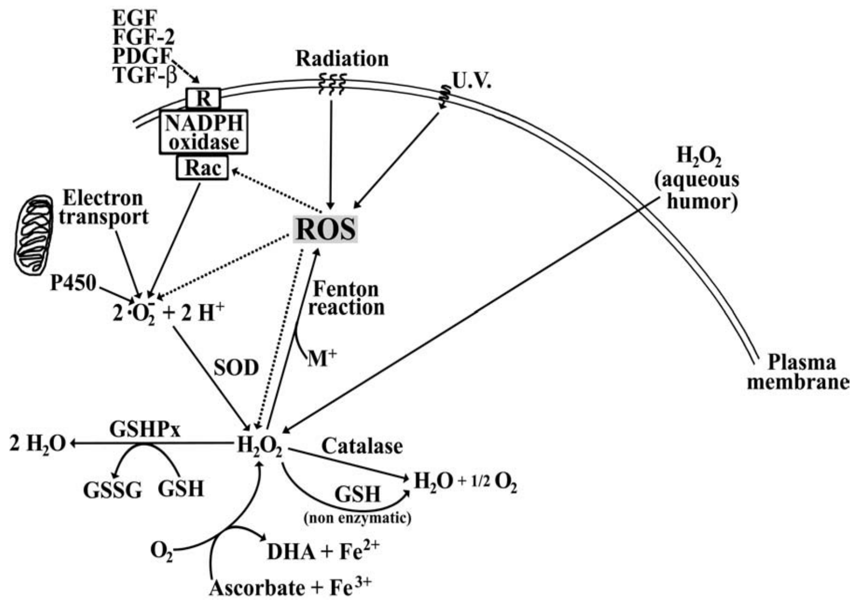


Figure 6. 2 Different Pathways of ROS generation in the lens of the eye (after Berthoud and Beyer 2009)

In proteins, oxidative stress can lead to oxidization of thiol groups on the lens crystalline structure to disulfide bridges, which leads to protein aggregation, resulting in loss of transparency (Berthoud and Beyer 2009, Williams 2008). Oxidative stress also causes damage to the DNA and apoptosis in the epithelial cells. Since epithelial cells differentiate into fibre cells throughout the individual's life, what may lead to development of opacities in the lens (Shore *et al.* 2010). Cells with damaged DNA produce abnormal protein, which does not behave in the same way as the proteins formed by normal cells. Due to the abnormal nature of the crystalline proteins they do not fold in the correct formation, leading to deregulated morphology of the lens (Shore *et al.* 2010). In summary, oxidative stress may affect lens proteins, lipids, and DNA, leading to changes in intracellular communication, mutations in DNA, and changes in the protein structures and functions.

Kleiman (2012) has suggested two mechanisms of damage to the lens from ionizing radiation:

1) Radiation causing damage to the central zone cells which then results in insufficient metabolic regulation of the underlying cortical fibre cells by the epithelial cells.
2) Radiation causing damage or mutations to the DNA of cells in the GZ. The cells of these damaged DNA cells divide, which produce an increasing population of abnormal lens fibre cells, leading to deregulated morphology of the lens (Kleiman 2012, Shore *et al.* 2010).

Kleiman (2012) suggested that the second mechanism is more important since animal studies have observed that radiation cataracts do not occur if cell division in the lens is inhibited in the GZ of the anterior region, or if the dividing cells are shielded from radiation exposure.

The ICRP (2012) acknowledges that the exact mechanism for radiation damage to the lens is not known, but postulated two mechanisms (somewhat different than Kleinman (2012)), by which radiation can cause cataracts:

1. Radiation causes damage to a single epithelial cell of the lens fibre cells, which would result in a microscopic opacity that is not visually impairing. These minor

opacities then accumulate or coagulate together causing a larger defect in the lens and eventually could result in visually impairing cataracts.

2. Radiation causes damage to a single lens epithelial cell which divides and differentiates, leading to a group of defective lens fibre cells from one damaged cell.

Various studies suggest that the genetic makeup of each individual plays a key role in cataract development due to radiation exposure. Jacob *et al.* (2011) concluded that the animals with mutant genes had greater sensitivity to radiation. Another study (Ainsbury *et al.* 2009) found that when mice heterozygous for Rad9[5] and Atm[6] genes and exposed to 0.5 Gy of x-rays in one eye, that PSC opacities were observed to develop earliest in mice that were double heterozygous ($Atm^{+/-}/Rad9^{+/}$), followed by mice that were single heterozygous, while wild type mice took the longest to develop opacities. A similar trend was observed in the unirradiated eye (Ainsbury *et al.* 2009).

Bouffler *et al.* (2012) indicated that cell proliferation plays an important role in cataract development and also that radiation cataractogenesis has a similar mechanism to tumorgenesis. Ainsbury *et.al* (2009), reported that heterozygosity of the Atm and Rad9 genes led to increased sensitivity to radiation. Figure 6.3 (adapted from Brown 2001)

[5] RAD9 plays multiple roles in regulating process that influence genomic stability and DNA repair, etc.
[6] Atm also plays a crucial role in maintaining genetic integrity.

shows the many different possible mechanisms possible for cataract formation from radiation.

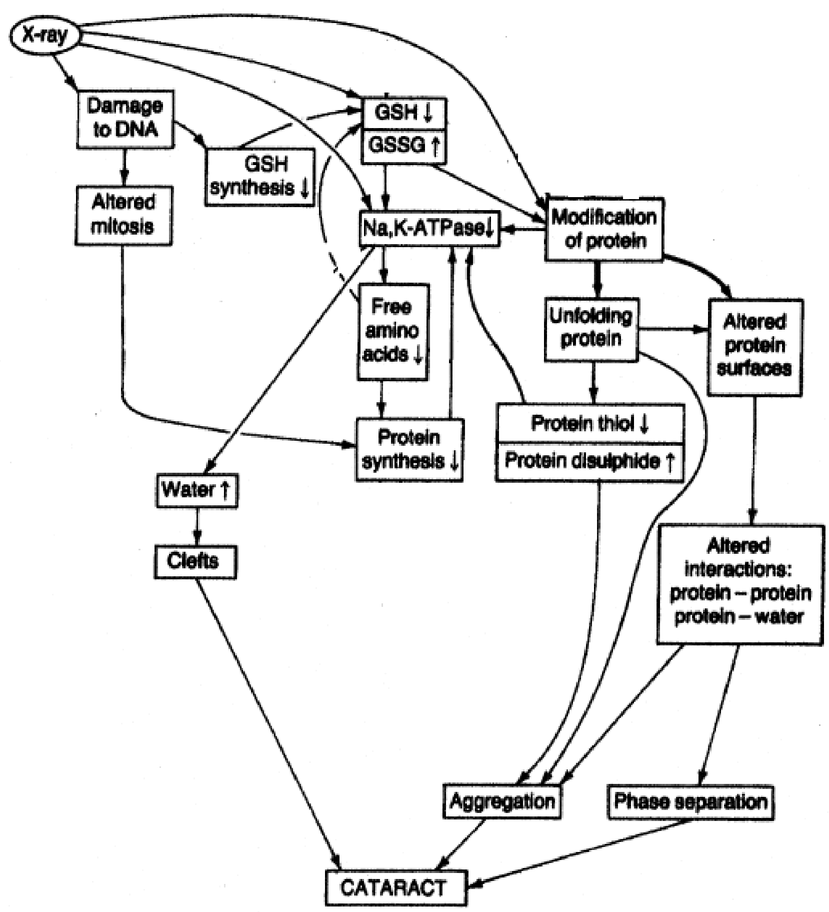


Figure 6. 3 Different Possible Mechanisms for Radiation Cataractogenesis (after Brown 2001)

The latency period and the severity of cataract development is largely dependent on the age at exposure, type of radiation, dose, dose-rate, fractionation of dose, division and migration rates of the epithelial cells, and the number of genomically damaged cells (Ainsbury *et al.* 2009).

6.1 Evaluation of ICRP's Recommendations for Lens of the Eye

Both the National Council on Radiation Protection and Measurements (NCRP) and the ICRP have previously categorized a radiation induced cataract as a "deterministic effect." The ICRP and NCRP have reported threshold doses of 2-10 Sv for acute exposure and 8 Sv for chronic exposure for visually impairing cataracts (ICRP 2007, NCRP 1989), although ICRP (2007) indicates that the eye may be more radiosensitive than previously thought. ICRP (2012) discusses more recent studies with larger populations and longer follow-up than were previously available. ICRP (2012) now refers to "deterministic effects" as "tissue effects" since some radiation effects previously referred to as "deterministic" may take years to develop.

Cataracts was one of the earliest pathologies associated with radiation and it had been long thought that cataracts can only be induced after high dose exposure to the lens of the eye. This result was based on results of studies done on early cyclotron workers who received a high dose from neutron exposure, and studies done on Japanese A-bomb survivors who received doses over 2-3 Grays (Gy) (Shore *et al.* 2010).

A summary of some of the threshold dose values reported in some older studies is provided in Table 6.1 (derived from data in Kleiman (2012) and Ainsbury *et al*, (2009)). This shows how the threshold dose estimate has changed over time as the size of the study and follow-up period increases.

Table 6. 1 Changes in Estimated Threshold as the Years Progressed

Source	Best threshold estimate	Subjects	Years post exposure
Anecdotal, pre-1950	5-15 Gy	<100	N/A
Cogan and Dreisler (1953)	6 Gy	40	7
Merriam and Fochet (1957)	2-5 Gy	276	Av = 8
Otake and Schull (1982)	1.2 Gy	2125	18-19
UK National Radiological Protection Board (NRPB) (1996)[7]	1.3 Gy	-	-
German Radiation Protection Board (SSK) (2007)[8]	2 Gy	-	-

[7] Based on work from Merriam and colleagues in the 1950s (Ainsbury *et al.* 2009).
[8] Mentioned that the estimated threshold is overestimated (Ainsbury *et al.* 2009).

Changes in estimated threshold as the years progressed. (Data taken from Kleiman 2012 and Ainsbury *et al.* 2009).

ICRP (1984) indicated that the threshold dose for the development of minor opacities was 0.5 - 2.0 Gy and suggested an annual limit of 0.15 Sv/yr for radiation protection. ICRP (1984) stated that "*the aim of radiation protection should be to prevent detrimental non-stochastic effects*" and "*… to limit the probability of stochastic effects to levels deemed to be acceptable*". ICRP (1984) goes on to state that a "*dose-equivalent limit (0.15 Sv) each year for 50 years would not cause a vision-impairing cataract, although it might give rise to opacities that could be detected ophthalmologically in some exposed individuals*." From this statement it can be assumed that at the time minor opacities were "acceptable" in some sense.

ICRP (2007) did not change its recommendation for the threshold or the annual dose limit to the lens of the eye from the previous publications (ICRP 60 and ICRP 41). However, as previously noted, ICRP (2007) stated that "*recent studies have suggested that the lens of the eye may be more radiosensitive than previously considered*" and that "*new data on the radiosensitivity of the eye with regards to visual impairment are expected*".

Some deterministic effects are now referred to as tissue reactions, because of the increasing observations that some effects from radiation exposure will not be manifested at the time of exposure, but may take years to develop (ICRP 2012). The manifestation of injury to the tissue exposed by radiation differs depending on the "cellular composition, proliferation rate, and mechanisms of response to radiation" (ICRP 2012). Tissue reactions are further divided into two types of reactions: early tissue reactions and late tissue reactions. Early tissue reactions occur within hours to weeks after irradiation, whereas late tissue effects take months to years to develop. Late tissue reactions are further considered as '*generic*' (occur as a result of injury directly in the target tissue) or '*consequential*' (occur as a result of severe early reactions) (ICRP 2012). It has been known for a long time that eye lens exposure to several Grays of ionizing radiation can lead to development of cataracts. These cataracts developed over a short time and so long follow-up periods were not required. More recent studies have studied individuals for a long time (which takes into account the inverse relationship of cataract formation time and dose) who were exposed to low doses and have found an increased risk of cataracts.

Most studies have tried to identify the confounding factors; the most common ones are age, smoking, and gender, but Shore et al. (2010), suggest that in general there is little evidence that confounding factors have been a serious problem in the studies. Bouffler et al. (2012) also agreed that confounding factors have very little effect on radiation induced cataracts, because of the great diversity of people for which radiation induced cataract information is available (e.g., Chernobyl workers and interventional practitioners from Europe, occupational workers from North America, bomb survivors and residents of contaminated buildings from Asia).

ICRP118, basis for selecting a 1% threshold for cataracts nor the reasoning for setting the new annual limit at 20 mSv is fully clear. Prior to ICRP Publication 118 (2012), the threshold was 8 Sv for visually impairing cataracts for chronic exposure and so if a worker had worked for 50 years receiving 150 mSv annually, the cumulative lifetime dose would be 7.5 Sv. Now after the reduced limit is in place, if a worker works for 50 years receiving 20 mSv each year their cumulative lifetime dose would be 1 Sv. A dose of 1 Sv is twice the threshold defined by the ICRP and so in order to keep the cumulative dose below 0.5 Sv the annual dose limit should have been set below 10 mSv. Bouffler et al. (2012) make a similar argument, but then in their conclusion it was stated that 20 msv annual dose limit is appropriate, because it is the same as the annual effective dose limit (not really since dose to eye is in units of dose equivalent and if a detriment weighting factor were applied, the effective dose arising from an eye dose of 20 mSv dose equivalent would be much smaller, perhaps by a factor of 100). Since many occupational exposures are uniform, doses received by the eye and the whole body will be the same, which would provide sufficient protection against cataracts (Bouffler et al. 2012). Given the very small detriment arising from 1% incidence of minor cataracts, one can question the appropriateness of the new dose limit for the eye.

Most of the studies described above only observed the beginning stages of cataracts, which do not cause any vision problems. These subjects would have to be followed in the future to assess the risk of developing vision impairing cataracts as a function of dose. Only Neriishi et al. (2007) and Neriishi et al. (2012) studied clinically significant effects of radiation on the lens of the eye, by examining cataract extractions in the bomb survivor cohort. Neriishi et al. (2007) found the threshold for visually impairing cataracts was 0.1 Gy (95% CI <0, 0.8 Gy) and Neriishi et al. (2012) found a threshold of 0.5 Gy (95% CI 0.10, 0.95 Gy).

It may be pertinent to note that ICRP should perhaps first look at developing a tissue-weighting factor for the lens of the eye and attribute in the overall effective whole body dose calculation rather than having a separate dose limit and lowering the dose for the lens of the eye. Thorne (2012) also concluded that "it is illogical to have the same dose limit for the lens of the eye as for the whole body irradiated uniformly". Thorne (2012) believes that if cataracts were to be considered a stochastic effect, then the limit of 20 mSv per year is unduly restrictive. According to Thorne (2012) there are 2 options which are more logical:

- Approach 1: assign the lens of the eye a tissue-weighting factor and then include the lens in the computation of effective dose (Thorne 2012).

- Approach 2: assign a tissue-weighting factor for effective dose calculations along with a special dose limit on equivalent dose, which would make sure no person is exposed to a high amount of radiation (Thorne 2012).

Martin (2011) concludes that there are unsatisfactory data regarding the threshold for cataracts and that the reduced annual limit of 20 msv is not justified. Martin endorses the fact that initial stages of cataracts do not cause any visual impairment and that with time these early stages might develop into visually disabling cataracts, but the evidence of that is insufficient. Martin concluded “given the combination of the lower risk, the more minor condition, the availability of treatment, and the degree of uncertainty, enforcing a dose limit of 20 msv is surely not justified, and a limit of 50 msv would be more in line with the level of risk” (Martin 2011).

7.0 Review of Scenarios & Studies on Lens of the Eye

The studies examined in this report contained: subjects from bomb survivors (Minamoto 2004, Nakashima 2006, Neriishi 2007, Yamada 2004, and Neriishi 2012), patients who underwent radiation therapy(Hall 1999, Wilde and Sjostrand 1997, and Whelan 2010) and diagnostic procedures (Klein et al. 1993 and Hourihan 1999), occupationally exposed (Chodick 2008 and Jacobson 2005), residents of contaminated buildings (Chen 2001 and Hsieh WA 2010) and rivers (Mikryukova 2004), liquidators from Chernobyl accident (Worgul BV 2007), interventional nurses, technicians, and physicians (Ciraj-Bjelac O 2010, Ciraj-Bjelac O 2012, Vano 2010, Mrena 2011, Vano 2013, and Jacob 2012), animal studies (Muranov K o 2009).

Chernobyl Accident Liquidators:

Chernobyl accident liquidators were individuals who were part of a group that were cleaning up radioactive debris from the Chernobyl nuclear accident. The study on liquidators done by Worgul (2007) shows that there is increased risk of developing lens opacities that can lead to vision impairing cataracts in the future, even when the individuals are exposed to protracted low-dose exposures. The results obtained in this study were similar to the resulted obtained in the atomic bomb survivor studies, where the exposure was acute and so both of these results suggest that dose fractionating does not lead to reduced risk of developing cataracts. Worgul examined the lens of the eye using slit-lamp biomicroscopy and used Merriam-Focht scoring system on 8607 liquidators. The study was done 12 and 14 years after the accident and the mean age of the cohort was 44.9 years at first examination (12 years after exposure) and 47 years at the second examination (14 years after exposure). Since the mean age was only 47 years the prevalence of age related cataracts was low and so any sign of cataracts would be due to the radiation exposure. The dose to each individual was calculated using the individual personal dosimeters, analytical dose reconstruction methods, and 'group Dosimetry' method, where a single dosimeter was used to estimate the dose to a group of individuals. The mean dose to the group was between 0.1 Gy and 0.199 Gy and so the dose to lens were mostly on the lower side (<0.4 Gy in 94% of the cohort and <0.7 Gy in 98% of the cohort). At the first examination (12 years after the accident) Worgul observed that 20% of the cohort had developed Stage 1 Cataracts and at the second examination (2 years after the first examination) 5% of the cohort that did not have stage 1-5 cataracts at the first examination, had developed stage 1 cataracts. Worgul determined the odds ratios at 1 Gy for developing stage 1 posterior subcapsular or cortical cataracts was 1.49 (95% CI 1.08–2.06) and the threshold Stage of developing cataracts of stage 1–5 was 0.50 Gy (0.17–0.65).The analysis also included cofounding variables which included age, sex, smoking, diabetes mellitus, histories of corticosteroid and phenothiazine use, occupational exposures to hazardous chemicals, ionizing radiation (other than Chernobyl), and infrared and ultraviolet radiation. With weak evidence of upward curvature, future studies of liquidators are needed to provide a stronger relationship between vision impairing cataracts and dose.

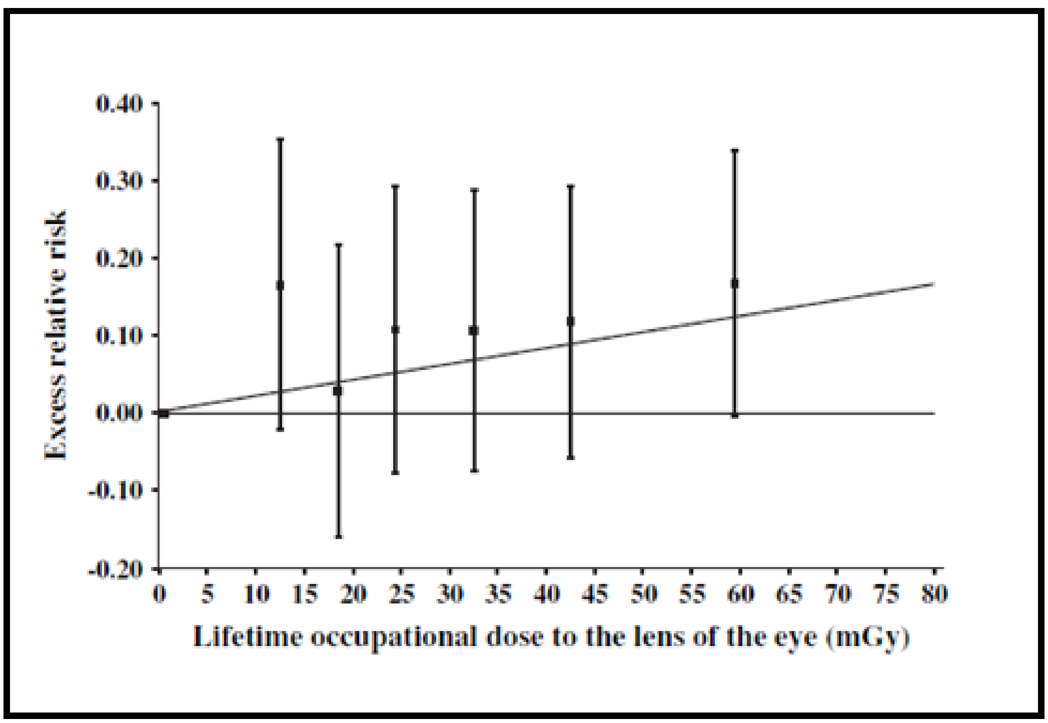
Occupational Exposure:

Occupational studies provided information on dose response to chronic exposure, which would be the most important type of exposures when deciding on occupational dose limits as most exposures in an occupational setting, is chronic. A study done by Jacobson (2005) looked at 97 retired workers, who had been exposed to actinide. The mean age of the study group was 72 years, while the dose to the cohort ranged from 0 to 600 mSv, which was calculated using their personal dosimeter records. The status of for each individual on cataracts was obtained from their respective ophthalmologist. Jacobson found that there was no relation between PSC cataracts and age, but an increase in the OR for PSC cataract incidence of 40.5% /0.1Sv increase in dose was noted. An important result of the study was that 37.5% of the individuals with dose higher than 0.2 Sv had PSC cataracts and 15.1% of the individuals with dose lower than 0.2 Sv had PSC cataracts. A formal dose threshold analysis was not done, but Jacobson suggested that if there exists a threshold then it is low.

A study done by Chodick (2008) was one of the largest studies designed to determine the risk of cataracts development among radiation technologist taking into account their occupational and non-occupational dose. The study included 35,705 radiation technologists, who were 24-44 years at the start of the study and the follow-up was done for on average 19.2 years. The study was conducted using three (3) question, the first was sent out in 1983, the second sent in 1994-1998 and the third sent in 2003-2005. During the study period 2,382 cataracts and 647 cataract extractions were reported by the respondents. Chodick found that three (3) or more x-rays to the head or neck region had a greater risk of developing cataracts compared to those who had none, the hazard ratio of 1.25 (95% CI: 1.06-1.47). The median occupational dose to the lens was estimated to be 0.0281Gy for the entire cohort, which was calculated using individual film-badge measurements and dose records provided by employers.

The Excess Relative Risk per Gy from occupational exposure for cataract was 1.98 (95% CI: 0.69-4.65) after adjusting for sex, age, baseline data on marital status, body mass index, diabetes, smoking, hypercholesterolemia, hypertension, alcohol consumption, arthritis, diagnostic x-rays, and radiotherapy to the head. The odds ratio for individuals exposed to lifetime occupational dose 0.06 Gy compared to 0.005 Gy was 1.18 (95% CI: 0.99-1.40). There was a significant association between radiation exposure and cataracts reported before age of 50 years, which strengthens the evidence that low-dose occupational dose can cause cataracts.

The dose response relationship to excess relative risk showed a linear response (see image below). Figure 7.1 illustrates Dose response relationship for excess relative risk for cataract risk as a function of dose. Figure 7.2 is a plot of severity of the posterior lens change as a function of estimated cumulative dose.



(Graph extrapolated from Chodick *et al.* 2008.)

Figure 7. 1 Excess Relative Risk for Cataract as a Function of Dose (Chodick *et al.* 2008)

Interventional Practices

There has been an exponential increase in the number of interventional procedures over the past few years, which has led to an increased dose to the staff of those who perform these procedures. Studies discussed in this section include nurses, support staff, and physicians from interventional cardiology and radiology.

The physicians would receive the greater dose as they are the closest to the x-ray tube source and they are exposed on average for twice as long compared to other staff. Vano *et al.* (2010) and Ciraj-Bjelac *et al.* (2010) examined the prevalence of lens opacities among 56 interventional cardiologists and 11 nurses and compared the results with age and sex matched controls. Detailed dilated slit lamp examination of posterior lens was performed and the changes were graded using a modified Merriam-Focht technique scoring system.

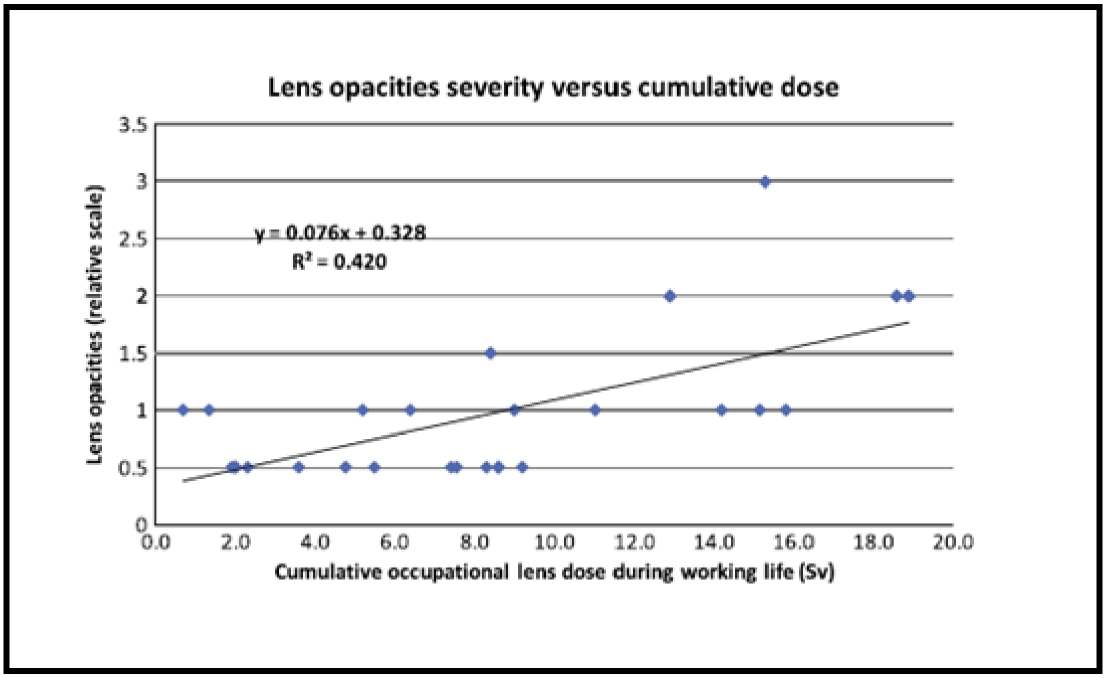
The dose to the individuals was calculated from responses to a questionnaire, combined with data from experimental values of scatter radiation doses measured taking into account any protection used. The mean dose to the interventional cardiologists was 3.7±7.5 (0.02-43) Gy and the mean dose to the nurses was 1.8±3.1 (0.01–8.5) Gy. A total of 34 subjects (46%) were reported to show lenticular changes compared to only 9% of the control group. Although no threshold was calculated, relative risks for the interventional cardiologist was 5.7 (95% CI: 1.5–22) and for the nurses was 5.0 (95% CI: 1.2–21). The results are less significant due to the small study size, but nonetheless, there is a strong relationship between dose and cataracts.

A similar method was used in another study by Ciraj-Bjelac *et al.* (2012), where prevalence of lens opacities among 22 interventional cardiologists and 11 support staff was examined. The mean dose to the interventional cardiologists and the support staff was 1.18±1.7 Sv (range: 0.046–7.3) and 1.88±4.5 Sv (range: 0.026–21). The publication found that 50% of all interventional staff had posterior lens changes and the calculated relative risk was 2.4 (95% CI: 1.2–5.0). In addition, 57% of interventional cardiologists who had a cumulative dose of less than 1 Sv were found with posterior lens changes and 43% of support staff with less than 1 Sv cumulative dose had posterior lens changes, compared to only 20% of the control groups. Again the study size was small, but good evidence of lenticular changes related to radiation dose is observed.

Studies performed by Vano *et al.* (2010) and Vano *et al.* (2013) were done in a similar manner to that of Ciraj-Bjelac *et al.* (2010 and 2012). Vano *et al.* (2010) examined 58 interventional cardiologists, of whom 38% had posterior lens opacities; 58 support staff of whom 21% had lens opacities, and 93 controls of whom only 12% had lens opacities. Individuals with diabetes were excluded, because diabetes is a factor that can lead to cataracts. The mean cumulative dose to the interventional cardiologists was 6.0 ± 6.6 Sv (range: 0.1-27 Sv) and the mean dose to the support staff was 1.5 ± 1.4 Sv (range: 0.2-4.5

Sv). The relative risk of PSC opacities in interventional cardiologists and support staff compared to the control group was 3.2 (95% CI: 1.7-6.1) and 1.7 (95% CI: 0.8-3.7).

The study showed a statistically significant increase in posterior leans opacities in the eyes of interventional cardiology and support staff. Vano *et al.* (2013) examined 54 interventional cardiologists and 69 nurses and technicians. Of these, 50% of the interventional cardiologists had posterior opacities and the estimated mean dose was 8.3±5.4 Sv (range: 0.7–18.9 Sv) compared to the mean dose 3.0 ±2.9 Sv (range: 0.1–9.7 Sv) in interventional cardiologists without opacities. Similarly, 41% of the support staff had posterior opacities and their mean dose was 2.7±2.0 Sv (range: 0.6–6.3 Sv) compared to the mean dose of 1.8±1.9 Sv (range: 0.1–6.8 Sv) in support staff without opacities. Figure 7.2 shows the relationship between lens opacity severities as a function of the cumulative dose (lifetime) to the lens as reported by Vano *et al.* (2013). It is evident from the figure that the relationship between lifetime cumulative eye dose and the severity of posterior lens is weak, especially when considering a R^2 value of just 0.4 as plotted by Vano *et al.* (2013).



(Graph obtained from Vano *et al.* 2013.)

Figure 7. 2 Lens Change as a Function of Dose (Vano *et al.* 2013)

8.0 Industry Experience after ICRP dose changes

To get a better sense of the effect the changes can have and/or have had in the industry, special interviews had to take place with policy makers and radiation protection experts from an array of industries, organization and institutions, as part of research for this paper. During the course of two years, interviews were conducted with staff members from multiple Hospitals, Nuclear Operators, Regulators and Universities. The questionnaire included standard questions for each institution or organization and were conducted in person and each facility was visited to conduct the research and to get a better sense on how and if the change proposed by the commission would have any impact across industries. Figure 8.1 below illustrates some of the key questions asked off radiation physicists, medical physicists and engineers that are involved in the management of radiation safety program and/or divisions that administer and/or use radiation at workplaces. Prior to the proposed change, it was generally accepted that since the lens of the eye dose was five times greater than the whole body dose, safety protocols implemented for protecting workers from the annual dose limit were sufficient. The consensus in the industry had been that that the dose to the eye would be a fraction of the whole body dose and significantly below the 150 mSv dose limit.

The new limit changes the scenario as all the members of the industry have agreed, that the in keeping in line with the ALARA principle, the dose limit poses new restrictions. Especially on how the general radiation program of an institution is run and also poses new challenges as radiation fields now need to be characterized in order to correctly and appropriately attribute dose to the lens of eye.

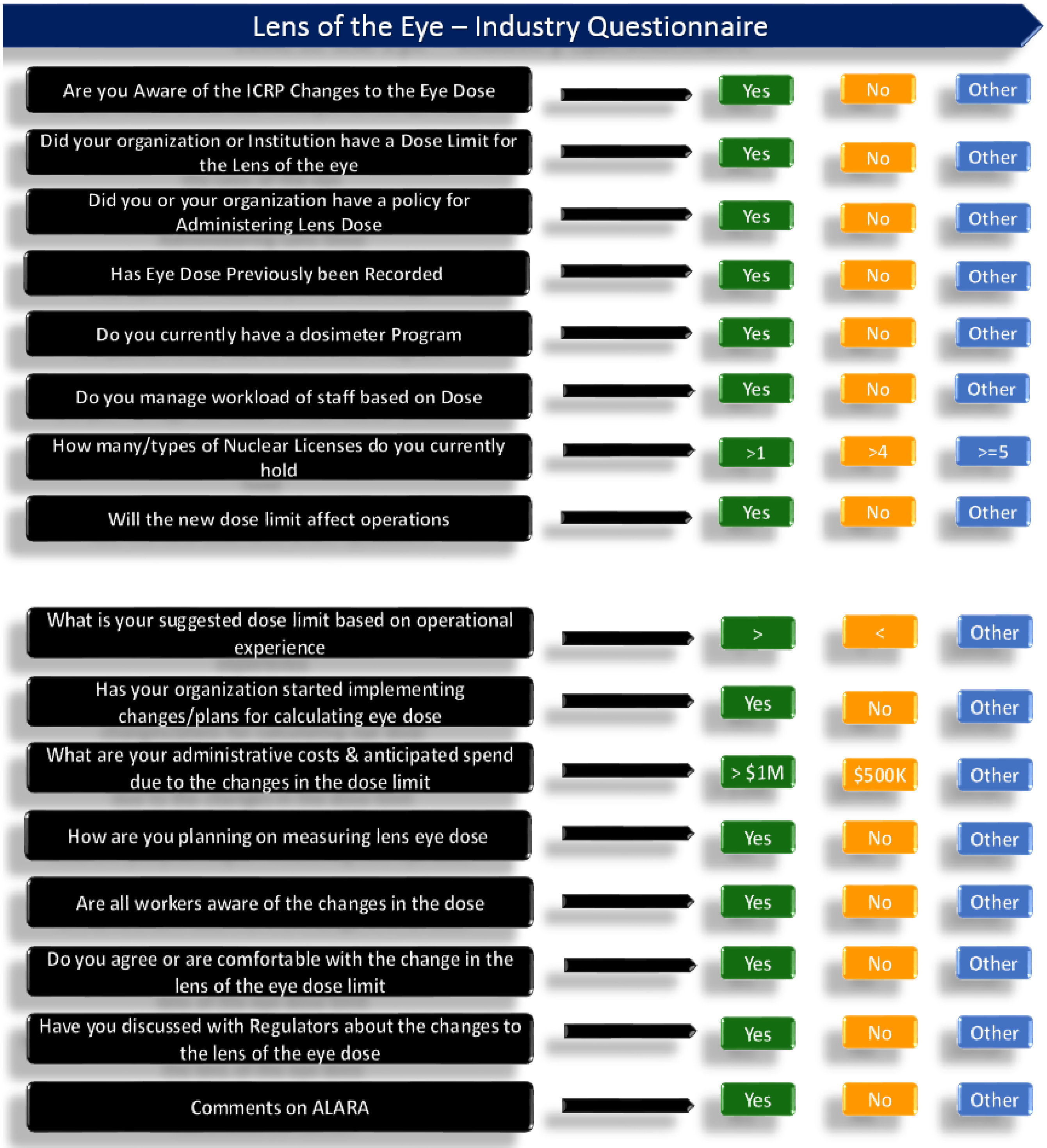


Figure 8. 1 Questionnaire for Industry on Changes to the Lens of the Eye

8.1 Nuclear Power Companies

In interviewing the dosimetry department and nuclear group in Ontario Canada's largest nuclear operating group, the nuclear operators in anticipation of change have already started to implement resources and manpower to categorically study and understand the dose to the lens of the eye. In order to minimize cost and streamline the study of its workers the major nuclear operators have shared their data and are working together in determining and categorizing workers that need monitoring. In an effort to understand the radiation fields, in conjunction with McMaster University, engineers and physicists are developing models and detectors that will help characterize the radiation fields and energy of the work environments in and around the nuclear reactors.

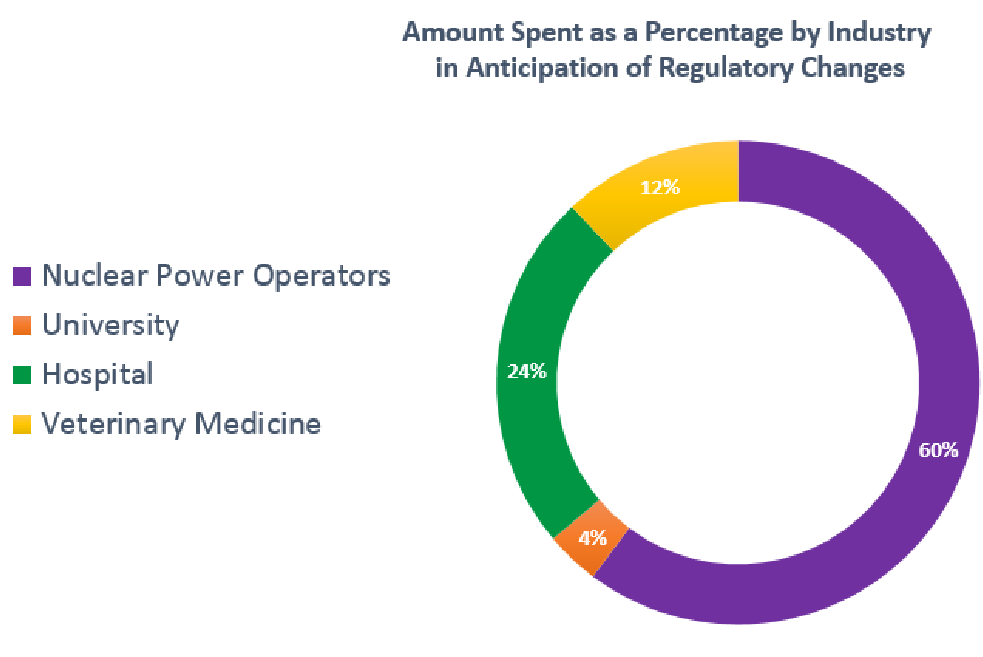


Figure 8. 2 Amount Spent as a Percentage by Industry for Lens of the Eye in Anticipation of New Limit

Based on the interviews conducted, the highest cost implication has so far been incurred by the nuclear power sector, as they constitute the largest number of workers working with radiation and in areas that can potentially expose workers to doses greater than 5mSv. However, what was surprising was the amount of money that the power sector has already spent in trying to characterize and model the radiation fluence, especially at the lower energy levels.

Based on estimates discussed, one power company has already spent in the upwards of a million dollars so far in the project to characterize dose to the lens of the eye in anticipation of the official dose change. The official recommendation and implementation by the regulator, assuming Canadian regulators will follow ICRP guidelines and recommendations (which has generally been the case in the past) has pushed industry to work in advance to try to characterize dose. In conducting interviews across various sectors, what was surprising was the amount of money that each sector has already spent in trying to characterize the dose. Overall the industry as a whole based on data gathered have already spent over 2.7 million dollars, nuclear operators contributing to almost sixty percent of the total spend, followed by the health care industry.

The Primary challenge observed based on the questions and discussions with the dosimetry team at the Nuclear Power Plants is the difficulty in finding an approved Lens dosimetry services provider. Currently there aren’t any dosimeters that can clearly measure the dose to the lens of the eye. As discussed above the challenge is overestimation. There are significant issues in estimating and determining doses using methodologies and films using Hp (0.07) and methodologies for measuring dose to the lens of the eye using Hp (3) has not been fully established.. Based on models established and currently designed by nuclear operators, fluence modelling is necessary.

8.2 Hospitals and Health Care Facilities

As illustrated in Figure 8.3, the biggest group of workers that will be impacted by the change made by the International Council on Radiological Protection to the eye dose limit is the Nuclear Power Sector. There are over ten-thousand workers in the province of Ontario, which are in the dosimetry program run by the nuclear operators. During the course of the research, it was discovered that a majority of the nuclear energy workers would need some sort of monitoring if the Canadian federal government does decide to go the way of ICRP. The National Council Radiological Protection (NCRP), which is an organisation that publishes standards and recommendations for the safe use of ionizing radiation in the United States, has disagreed with the ICRP dose limit and has suggested a dose limit that is more suitable for the industry i.e. an absorbed dose of 50mGy.

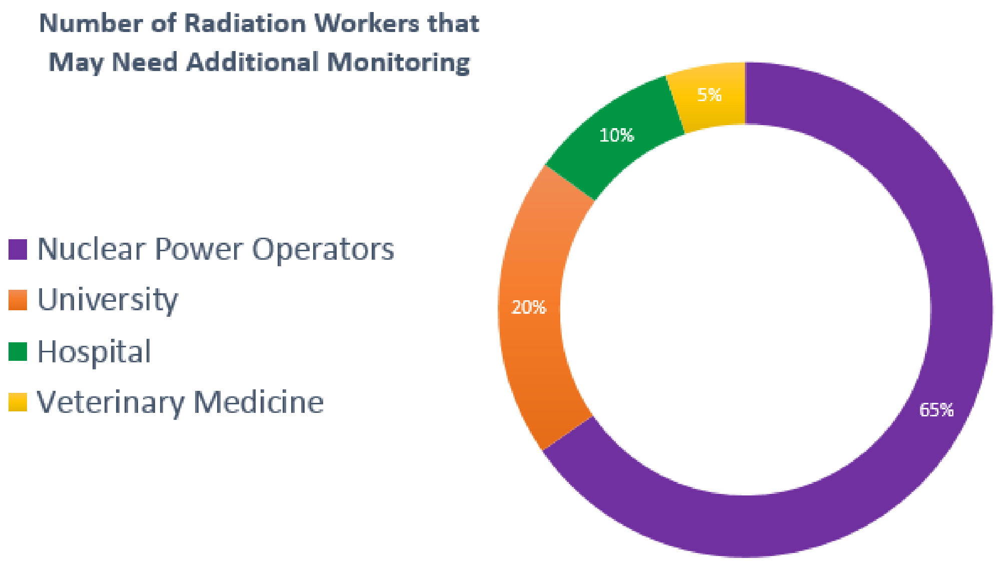


Figure 8. 3 Radiation Workers by Industry (Lens of the Eye)

During the course of this research, several medical physicists and radiation safety officers/managers were interviewed and hospitals were visited to get a better sense if the changes in the limit had any adverse effects to the regulatory landscape of hospitals and human health care facilities.

Surprisingly hospitals and health care facilities too had already spent a significant amount of resources, work force and money, to get a better sense of the potential dose to lens of the eye to their staff members.

Similar to nuclear reactors, some of the larger Cancer Centers had already spent a large amount of money, in trying to conduct experiments and fluence measurements to determine if physicians need additional monitoring or protection. Throughout the course of discussions and interviews, it was determined that cardiologists and interventional radiologists workload will be affected due to their exposure to certain procedures and additional safety management systems may need to be put into place to regulate the workload received by hospital staff. One of the methods discussed, was to evaluate how different types of lead glasses can provide adequate shielding and if interventionists can be protected in this way. Unlike the nuclear power corporations, the hospitals in Ontario currently do not have a unified approach to the study and it was discovered that one group of hospitals was conducting their own experiments with lead glass to get a better understanding and ways of measuring $H_p(3)$ dose. The nuclear operators and the CANDU operators group are spending more time characterizing radiation flux and fluence whereas; the hospitals in the region are focusing their efforts on methodologies in shielding and measurement. The current focus has primarily been on creating models to determine the optimum location for dosimeter to measure accurate eye dose. Nonetheless, it is evident in interacting with both forms of institutions that the dose limit change to the lens of the eye will impact the way both industries will handle dosimetry and management of workloads of workers.

8.3 University and Veterinary Environments

As part of the research and questionnaire process, one the questions that was asked to radiation protection professionals and medical physicists across the board was what the suggested dose limit was for the lens of the eye based on their operational experience keeping the ALARA principle in mind and also industry experience based on best practices for RP protection management. What was surprising was that even the veterinary field have set aside funding on working with its workers to characterize their workloads in their occupational settings to try to reduce the collective effective dose in their departments in anticipation of the regulatory changes to the lens of the eye. They too are working on shielding methods and are currently evaluating lead equivalency materials to try and increase shielding for the lens of the eye for its animal handlers.

Since ICRP publication 118, awareness about the dose limit change to the lens of the eye has significantly increased and scientists across the world have been debating about whether 20 mSv/a is justified and needed, especially considering the endpoint which is multifactorial and nowadays treatable unlike other radiation-induced stochastic effects. The results for the various groups interviewed is represented in Figure 8.4 as follows:

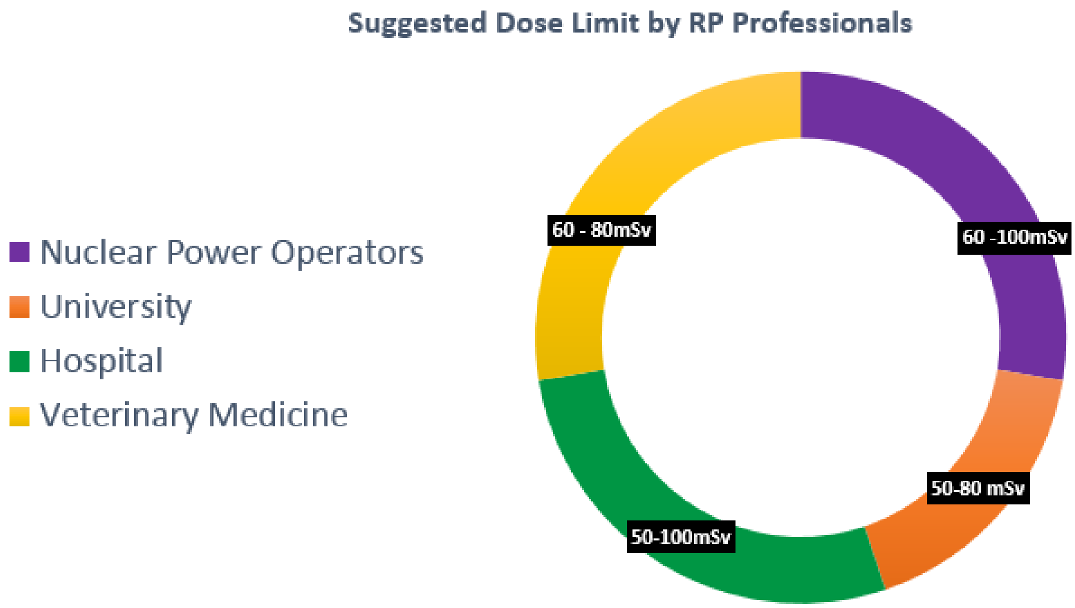


Figure 8. 4 Suggested Eye Dose Limits based on Interviews Conducted

As illustrated in Figure 8.4, almost 90% of faculty and staff interviewed strongly believes that the newly proposed ICRP dose limit for the lens of the eye is too low and that the justification provided for a fivefold reduction is still somewhat unclear in the industry. Having said that almost everyone did agree that keeping the ALARA principle in mind, reducing the dose limit for the lens of the eye is a step in the right direction, but not to 20 mSv per year.

The suggested dose limit as illustrated in Figure 8.4 ranges from 50mSv to all the way to 100mSv per year based upon the industry and type of workers the facility has. Staff;

faculty, policy makers, etc, were interviewed as a part of this study and it seemed everyone was aware of the changes that was taking place concerning the dose limit. The majority of corporations and institutions interviewed had already invested time, money and resources in determining the right approach to either measure dose or to create methodologies that would reduce the overall eye dose in a population or a cohort.

Of the Veterinary Hospitals and Universities communicated with, they were also anticipating changes in their RP program in streamlining the dose to the lens of the eye. For the vast majority of Universities, changes to the lens of the eye is not a big risk, as they primarily work with charged particles and or isotopes with low amounts of radiation. However, having said that, all University RSOs did acknowledge the fact that all internal policies, procedures and overall training of staff and students will change, if CNSC does decide to changes the dose limit for the lens of the eye.

With respect to Veterinary Medicine, not all practices will be affected, Clinics that perform bone scans and work with nuclear medicine would be affected with the change in dose limit due to the way RP policies are set up and the ALARA principle. RSOs responsible for large animal care facilities are already evaluating how they will be able to determine the eye dose in workers working with short-lived gamma emitters, especially for animal handlers and in instances of emergencies.

Table 8.1 below illustrates and categorizes responses from the four sub groups of industries selected to represent the study. As demonstrated, the answers across industries and institutions is quite consistent and ICRP changes will have an affect across the board. What is surprising to note is that the RP community is quite up to date on ICRP publications and regulations worldwide, that there is a lot of collaboration ongoing, and certain groups have decided to work together to characterize the potential eye dose to workers. Moreover, at the same time they are working on innovative techniques to not only measure $H_p(3)$ or attribute dose, but also on shielding the dose to the lens of the eye.

Table 8. 1 Summary of Responses to Queries by Industry

Queries	Nuclear Operators	Universities	Hospitals	Veterinary Medicine
Number of Institutions Investigated	3	12	6	4
ALARA PROGRAM	✓	✓	✓	✓
Previous Eye Monitoring	×	×	×	×
Currently Evaluating RP Program	✓	✓	✓	✓
Current Dosimetry Program	✓	✓	✓	✓
RP Program Modification	✓	×	✓	×
Methods of Measuring Eye Dose	×	×	×	×
Are All Workers Aware Dose Changes	×	×	×	×
Will New Limit Change Operations	✓	×	✓	✓
Are you Waiting for a (approved)dosimeter	✓	✓	✓	✓
Have you currently changed RP Policies	×	×	×	×
Do you intend on Reducing Eye Dose limit	✓	✓	✓	✓

9.0 ALARA Principle and determining Action Levels for Licensees

Overall, based on the interviews conducted and the array of industries and institutes visited i.e. Nuclear Power Operators, Industry, Research, Universities, Hospitals and Veterinary Hospitals, it is evident that the dose limit for the lens of the eye warrants for a reduction from the original limit of 150 mSv per year. However, based on the information gathered, it is not to the level that the ICRP publication has recommended i.e. 20 mSv per year averaged over five years.

Notwithstanding this fact, the biggest problem observed based on industry research and experience is that all licensing facilities have implemented the ALARA principle and all facilities are governed either federally or provincially. As a result, all facilities follow a set of guidelines under the Nuclear Safety Act (NSA) that ensures each licensee operate their facilities with a low dose approach, and keep doses as low as reasonably achievable. Although the whole body dose limit for nuclear energy workers is 20mSv per year, most licensee are expected and do keep annual exposures to their workers to a fraction of that.

The Federal Regulatory Body has a policy under the *Radiation Protection Regulations*, which asks licensees to set 'Action Levels' defined as " a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program, and triggers a requirement for specific action to be taken". Based on the investigations conducted, Action Levels are generally set significantly below dose limits for all licensees and best practise for example by Universities is set at ten percent

(10%) of the annual dose limit. Therefore, if the dose limit for the lens of the eye is set to the ICRP recommended dose limit i.e. 20 mSv per year, it poses a significant regulatory burden on all licensees, especially since most facilities or organisations have multiple NSRD licenses and currently do not have the capability to measure $H_p(3)$ accurately. Moreover, since currently there is no approved Eye dosimetry provider and orientation is a significant factor in attributing dose to the lens of the eye, the low annual dose limit of 20 mSv per year doesn't make much sense in the way the current regulatory framework is set up, especially when it comes to action levels. For example, the nuclear industry has a group of workers that can regularly get doses of upto 10mSv per year.

The significant difference between the whole body dose and the lens of the eye is the endpoint. Unlike stochastic effects such as Cancer, which can also be fatal, the endpoint for exposure to the lens of the eye is cataracts, which is multifactorial and highly treatable. Based on our observations when it comes to cataracts, definition of the endpoint is somewhat blurred between being stochastic vs. deterministic as there is a significant latency period (delay) from exposure to ionizing radiation to the onset of cataracts, which is different than other endpoints for example such as erythema (deterministic) or hereditary effects which follow a Liner No-threshold model.

10.0 Regulator Compliance

The International Radiation Protection Association (IRPA) sent out questionnaires to its forty-eight (48) member states to ask for their views on the revised limit by the International Commotion on Radiological Protection (ICRP), out of which only 12 member states replied.

Industry with the most concern:

The field that will be affected most from the revised limit is the medical sector, particularly interventional cardiology and interventional radiology. In addition some concern could also be seen in diagnostic radiology, and with veterinary X-rays. As noted by Martin (2011) typically the dose to the eye at the present time range from 10-90 µSv per cardiology procedure, without the aid of any eye protection. Therefore, if the interventional cardiologists are restricted at 20 mSv per year then interventional cardiologist would be limited to performing 15-20 procedures each month. IRPA concludes that there will be no implications in the nuclear sector, unless there are frequent situations where there are high beta fields, which could arise in cases after significant accidents.

Dosimetry Implications:

From the responses that IRPA received from its member states, they have concluded that when the exposure is uniform and when exposures and not highly localized, it is sufficient to measure the dose in terms of $H_p(0.07)$ and $H_p(10)$ with passive dosimeters worn on the torso. From those measurements dose to the lens of the eye can be estimated in terms of $H_p(3)$, which can be used to check if the dose received by the individual is in compliance with the limits. For exposures that are not uniform, ex. interventional practices, "double Dosimetry" practice is recommended. Double Dosimetry implies the use of two dosimeters, one under the lead apron and the other above the lead apron, and the dose to the lens of the eye can be estimated from the dosimeter worn above the apron using correction factors. Using the double Dosimetry technique there is a potential for underestimation of the dose and so it is recommended that a dosimeter calibrated in terms of $H_p(3)$ should be worn above the eye level for the best estimation of the lens. Another possible option is to wear a dosimeter calibrated in-terms of $H_p(0.07)$ or $H_p(10)$ can be worn on the collar or the shoulder above the lead apron and then using correction factors can be correct to $H_p(3)$. It is also recommended to wear an active personal dosimeter to real time measurements. The IRPA also asked about the EYE-D™ dosimeter and found that it is not satisfactory from ergonomic point of view.

Other Implications:

- Could cause changes in methods of current practice
  - Employment issues: If 20 mSv is routinely passed, more interventional staff is required
  - Additional cost of eye examinations
  - Compensation for the additional law suits
- Cost implications:
  - Additional training
  - Additional Dosimetry
  - Additional shielding
  - Possible need to formally classify more workers
  - Possible need for extra staff if current specialists staff reach the dose limit
  - Enhanced medical eye examinations for workers

Numerous countries have shown concern over the rationale for revision of the dose limit and the dose threshold of 0.5 Gy. The criterion used by ICRP for setting a threshold for tissue reactions is the amount of radiation for which clinically significant effects are observed in 1% of exposed group. Whereas according to ICRP publication 103, the detriment adjusted nominal risk coefficient is 4.1% per Sv. Neither tissue reactions nor stochastic effects are less harmful if dose is fractionated and so if a worker working for 50 years receives annual dose of 20 mSv per year, the individual's accumulated dose over 50 years will be 1 Sv and 1 Gy to the whole body and lens of the eye respectively. This would mean that the individual has 4.1% chance of developing a fatal cancer compared to only 2% chance of developing cataracts (given that the dose response curve is linear, which is suggested by Yamada 2004, Neriishi 2012, Chodick 2008, Worgul 2007, Chmelevsk 1998, Otake 1990, and Otake 1991). Given that cataracts can easily be treated by surgical removal and lens replacement, whereas fatal cancer is untreatable in most cases. Cataract surgery has come far from old days when it used to require stay in hospital and a long rehabilitation, but now day's cataract extraction surgery is a quick procedure and benefits can be seen immediately. (Morris 2007) Patients diagnosed with cancer experience "negative psychosocial outcomes and poor quality of life and is identifiable in 30–75% of all cancer patients". (Hulbert-Williams 2011).

Moreover it may be pertinent that ICRP 118(para (i)) notes that "lens replacement is a well established surgical procedure" and Cataract surgery is performed as an outpatient procedure in an operating room, usually lasting less than an hour typically with a sedative and numbing drops to the eye with patients awake. The American Academy of Opthamology (AO 2006) identified that 95% of the patients who underwent cataract surgery were satisfied with their vision after cataract surgery and the other 5% who were not satisfied had other eye problems along with cataracts (AAO 2006), almost half (50%) of which have a pre-existing condition. Compare that to the survival rate for the most common types of cancers (i.e. survival of greater than 10 years) is 46% according to Cancer Research Centre of the UK.

Therefore, it is not clear as to how and why the ICRP has chosen a limit of 20 mSv per year for the lens of the eye, which can take many years to cause any impairment on the vision of the individual and is easily treatable. The risk of a fatal cancer currently in practise at a dose of 0.5 Sv is 2.5% compared to a 1% risk of a cataract at 0.5 Gy that has been chosen by ICRP as a threshold in ICRP 118. If cataracts were to be considered a stochastic effect, the new limit of 20mSv/y seems unduly restrictive.

10.1 TISSUE REACTIONS

Deterministic effects are now referred to as tissue reactions, because of the growing evidence that some effects will not manifest at the time of exposure rather that some of the responses can be modified after exposure and may take years to develop. (ICRP 118) The manifestation of injury to the tissue exposed to radiation differs depending on the "cellular composition, proliferation rate, and mechanisms of response to radiation". (ICRP 118) Tissue reactions are further dived into two: early tissue reactions and late tissue reactions. Early tissue reactions occur within hours or weeks after irradiation, where as late tissue effects take months to years to develop. Late tissue reactions are further divided as 'generic' (occur as a result of injury directly in the target tissue) or 'consequential' (occur as a result of severe early reactions) (ICRP 118).

Tissue reactions are different from stochastic effects as there exists a threshold for tissue reactions. The ICRP defines the threshold dose as ED_1 (also referred to as tolerance dose), which means estimated dose for 1% incidence. The criterion used by ICRP for setting a threshold for tissue reactions is the amount of radiation for which clinically significant effects are observed in 1% of exposed group. ED_1 is not a true threshold because it does not imply that anyone exposed to radiation below the threshold level will not develop biological effects, but it's used as a protection quantity. (ICRP 118) A true threshold is very difficult to determine, and so ED_1 can be determined by looking at the lowest dose in epidemiological study that causes a positive response, which would depend on the model used and the sample size. "ED_1 refers to effects just starting to rise above the baseline levels in un-irradiated, age-matched individuals" (ICRP 118) ED_1 is used for protection purposes only, if levels less than 1% are used then there will be greater amount uncertainties because of the extrapolations of response frequencies to lower doses for which data is not available. (ICRP 118) Levels of above 1% would lead to lower uncertainties, but then ED would be further from the 'true threshold'.

The term tolerance dose is defined as "the maximum amount of radiation that a tissue can withstand without developing clinical signs of injury in more than few percent of individuals" and the criterion is usually taken from <1% (for cases of induced paralysis) up to a few percent (for less severe and treatable injuries.) (ICRP 118) Therefore it is not clear as to why ICRP has used 1% as their criterion when cataract is a readily treatable effect with high success rate.

11.0 Recommendations

All the studies discussed in this paper lead to the conclusion that there is an increased risk of developing opacities after radiation exposure, but most studies do not attempt to calculate a threshold. A study which looked at PSC cataracts in retired workers exposed to actinide found that 20.6% workers had PSC cataracts and 45.6% workers with dose greater than 200mSv had PSC cataracts. (Jacobson 2005) No threshold was determined, but the publication concluded that if there is a threshold then it is low. (Jacobson 2005) Since many studies do not have a large number of participants it might not be possible to derive a threshold. Large size studies involving the bomb survivors provide a threshold of 0.6 Gy cortical cataracts and 0.7 Gy for Posterior Subcapsular opacities (Nakashima 2006), 0.1 Gy (Neriishi 2007) and 0.5 Gy (Neriishi 2012) and study involving Chernobyl liquidators provide a threshold of 0.35 Gy (Worgul 2007).

The results from atomic bomb survivors are for acute exposures and the threshold analysis supports possibility of a zero threshold, where as the results from liquidators are for protracted exposure. (Nakashima 2006, Neriishi 2007, Neriishi 2012, Worgul 2007) Neriishi (2009, unpublished) looked at prevalence of cataract extractions among bomb survivors and a dose threshold analysis estimated a 33% increase in cataract surgery at exposure of 1Gy and a dose threshold analysis found a threshold of 0.4 Gy (95% CI 0-0.8), which provides the strongest evidence to date that visually-impairing cataract formation are in excess at doses below 1 Sv. (Blakely et al. 2010) At only 12 years after mean exposure between 100 and 199 mGy the mean age of liquidators was 45 years and 30% of the liquidators were observed to have precataractous changes. (Worgul 2007) At high exposures lens opacities may develop within few year, but at lower exposures vision impairing cataracts may take many years and so it is known that latency period is inversely proportional to exposure. (Rehaani 2011)

12.0 Summary & Conclusion

Until recently there are no licensed dosimeters that can measure the dose to the eye, because there are no eye lens calibration phantoms and reliable conversion coefficients did not exist. (Bilski P et al. 2011). For this reason eye dose measurements were hardly done in the past and even if they were done, they were not accurate because the operation quantity $H_p(0.07)$ and $H_p(10)$ were used to approximate the eye dose. (Bouffler et al. 2012) Using $H_p(0.07)$ and $H_p(10)$ the doses to the eye can be estimated under uniform upper body phone fields. (Bouffler et al. 2012, Bilski P et al. 2011, Geber T. et al. 2011) For dosimeters calibrated in terms of $H_p(0.07)$ the dose to the lens of the eye can be over estimated by a factor of up to 550, for beta fields of energy of 1MeV while $H_p(10)$ can underestimate the dose to the lens of the eye. (Bouffler et al. 2012, Bilski P et al. 2011, Geber T. et al. 2011). An important requirement for the operational quantity is that the dosimeters should be able to be calibrated under reference conditions. Phantoms should also represent the human body (ex. pillar phantoms for dosimeters worn on wrist or ankle, rod phantoms for dosimeters worn on fingers, and a slab phantom for dosimeters worn on the waist) to take into account the backscatter from the body. (Wernli C. 2004)

Developments in the Field after ICRP Publication:

The ORAMED (Optimization of Radiation protection for MEDical staff) project has studied the dose received by staff in interventional radiology using wide range of simulations and measurements. (Gualdrini 2011) The results will be used to come up with guidelines to reduce the dose to the staff. (Gualdrini 2011) One of their goals was to develop an operating dosimeter that responds in terms of $H_p(3)$ and for that a new calibration phantom was also made. (Gualdrini 2011)

Gualdrini (2011) compares three different phantoms:

Monte Carlo simulations on a 30 × 30 × 15 cm^3 four-element ICRU slab phantom (only one until now for which conversion coefficients were available and the only one recommended by ISO 12794 for calibrating dosimeters in terms of $H_p(3)$) A reduced slab that was initially suggested by ENEA.

Monte Carlo simulation on a 20 cm diameter by 20 cm height cylindrical phantom with 0.5 cm polymethyl methacrylate (PMMA) walls, filled with water, to better represent the human head. The phantom is composed of 4 ICRU tissues with a mass density of 1 $g \cdot cm^{-3}$ and a weight composition of oxygen, carbon, hydrogen and nitrogen.

The analysis was done with simulations done in MXNPC (Monte Carlo code N-Particle eXtended). (Gualdrini 2011) Gualdrini (2011) compared coefficients $H_p(3)/K_a$ for all 3 slabs to the ICRU limiting quantity H_T/K_a for 0° incidence and the ratios between H_T (eye lens)/K_a for lateral irradiation and $H_p(3)$/Ka for the all 3 slabs for 90° incident. The comparison concluded that the for any incidence angle the cylindrical phantom better represents the radiation protection quantity. (Gualdrini 2011). When using or utilizing phantoms, the accuracy can be improved to 90% using test models, however the primary challenge lies in positioning and attributing dose to both the eyes independently, avoiding scatter.

The new dosimeter developed by ORAMED is called EYE-D^{TM}, and is currently commercially available (Bilski P et al. 2011). After performing Monte Carlo simulations they concluded that a MCP-N (LiF:Mg,Cu,P) Thermo Luminescent dosimeter encapsulated with a 3 mm thick polyamide capsule responds best in terms of $H_p(3)$, using the reference conversion coefficients from ENEA report. The reason for choosing LiF based detectors is because of its good dose response (linear up to 1 Sv), sensitivity (detection threshold below 1 μSv), flat energy response and its stable under various conditions. (Bilski P et al. 2011) The detector is sintered pellets of diameter 4.5 mm and 0.9 mm thick composed of 0.2 M% Mg, 1.25 M% Cu and 0.05 M% P (Gualdrini G. et al.

2011, Szumska A. et al. 2011) The dosimeter tested from different beam qualities and the agreement between simulated and measured response were satisfactory. (Gualdrini 2011) The dosimeter can be used for indefinite use and enables cold sterilization. (Bilski P et al. 2011).

The results from both calculations done using Monte Carlo simulations and measurements using phantoms show that the response of the dosimeter is within about 20% for narrow spectra and within 10% for RQR spectra. (Bilski P et al. 2011) The dosimeter was also optimized to achieve a flat photon energy and angular response to the exposure of X-rays. (Szumska A. et al. 2011) The dosimeter was also tested under β-fields. Simulations done using PENELOPE (Penetration and Energy Loss of Positrons and Electrons) Monte Carlo transport code and measurements were done using a β emitting Sr-90/Y-90 source. (Szumska A. et al. 2011) A correction factor of 0.4311 was used to asses a value of $H_p(3)$ from $H_p(0.07)$, given by Behrens (Behrens and Buchholz, 2011). (Szumska A. et al. 2011, Behrens R. 2011) The results showed that an angular dependence to the response of the detector. The dose response was found to be inversely proportional to the angle of incidence. The agreement between measured and simulated for energy and angular response were good. (Szumska A. et al. 2011)

One important issue covered in by Domienik (2013) is where the dosimeter should be worn/positioned. In their study they placed 10 dosimeters across the forehead at the line of the eye brows. The dose was measured using the operational quantity $H_p(0.07)$ using MCP-

N type dosimeters. (Domienik J. 2013) The doses measured at the level of eyebrows depended on the location of dosimeter and a difference of 80% was seen between lowest dose position compared to the highest dose position, because of the attenuation from the head and the increase in distance from left side to the right side of the eye. (Domienik J. 2013) They recommend that the position of the dosimeter should be on the side of the eye, which is closest to the X-ray tube (source). (Domienik J. 2013) Gerber (2011) also concludes that the best position for the eye dosimeter is on the side of the head near the eye, nearest to the X-ray source. If the dosimeter is worn at the collar, the absorbed dose might be underestimated by up to 73%. Geber T. et al. 2011) It is also estimated that if the dosimeter is worn above the eye then the absorbed dose could be under estimated by 45%. (Geber T. et al. 2011).

Licensed Dosimetry:

The biggest challenge for regulators in Canada is that the dosimeters need to be licensed and there are currently only three licensed providers for all Radiation dosimetry. The CNSC regulations states that all employees who have a probability of receiving an effective dose of 5mSv (per year) or greater require licensed dosimeters. However, most licensees provide dosimeters to their employees where there is a reasonable probability of receiving any dose (occupational) or dose greater than 1mSv (Dose limit for the public). In talks with all the dosimetry providers it is evident that neither Health Canada (NDS) nor the CNSC currently have a definitive plan or a provider that they can license or recommend to their license providers. Due to the significant reduction by the ICRP both regulators and the industry are still struggling to find the right method and or approach in determining radiation dose for the lens of the eye and characterizing the DAP and or modeling the flux has been an issue. Individually, certain organizations with large budgets have been able to move ahead and characterize their radiation fields in their work environments, but from interviews conducted it is far and few in between. The regulators worldwide are yet to find a proper standardized method in calculating and determining radiation dose for the lens of the eye are unable to apply it across the board among a wide array of industries. Health Care, Veterinary medicine, Nuclear Power & Emergency workers such as the ones in Fukushima will and currently have a hard time in characterizing the dose in a way that is comparable across the board. Moreover, when RP guidelines such as the ALARA principle are brought in along with the existing framework, it becomes a regulatory and administrative burden for all workers and radiation protection professionals.

The ICRP (2012) has concluded that the eye is more radiosensitive than previously considered, and has recommended a greatly reduced dose limit for radiation protection, namely, a lowering of the annual limit on dose to the eye from 150 mSv (dose equivalent) to 20 mSv (dose equivalent, averaged over 5 years). The CNSC has recently (August 2013) proposed amending its radiation protection regulations to be consistent with the recommendations of the ICRP. As a consequence of the proposed reduction in the limit for dose to the lens of the eye, licensees will need to conduct assessments of eye dose for their workers, and determine which activities and under what conditions, the work activities may pose a risk to the lens of the eye. Based on these assessments, some licensees may be required to specifically determine the dose to the eye using method(s) approved by the CNSC. This change is likely to add some cost and administrative burden. It seems important for operators of nuclear utilities to evaluate the implications of the proposed change to the limit for the dose to the eye.

Conclusion

To get a greater understanding of how the new proposed regulation for the lens of the eye affects the effective management of an organization's radiation safety program; a comprehensive study was conducted. As part of this study and research, a comprehensive process in which all relevant literature were reviewed (including radiobiological literature) and impacted industries such as Nuclear Reactors, Research Facilities, Educational Institutions, Hospitals, etc. were personally visited as part of the research for this paper through a series of round table discussion, seminars and conferences. Staff and nuclear energy workers from Fukushima and the affected areas were also visited and investigated to get a better sense on how dose limits such as this can have an overall impact during an emergency scenario such as that of the Nuclear Disaster after the Tsunami in Japan in March 2011. This new eye dose limit would also be restrictive to emergency workers during a disaster such as that of Fukushima as it would impose a regulatory burden considering the endpoint is significantly different and there are no reliable and accurate eye dosimeter with Hp(3) capablitiles.

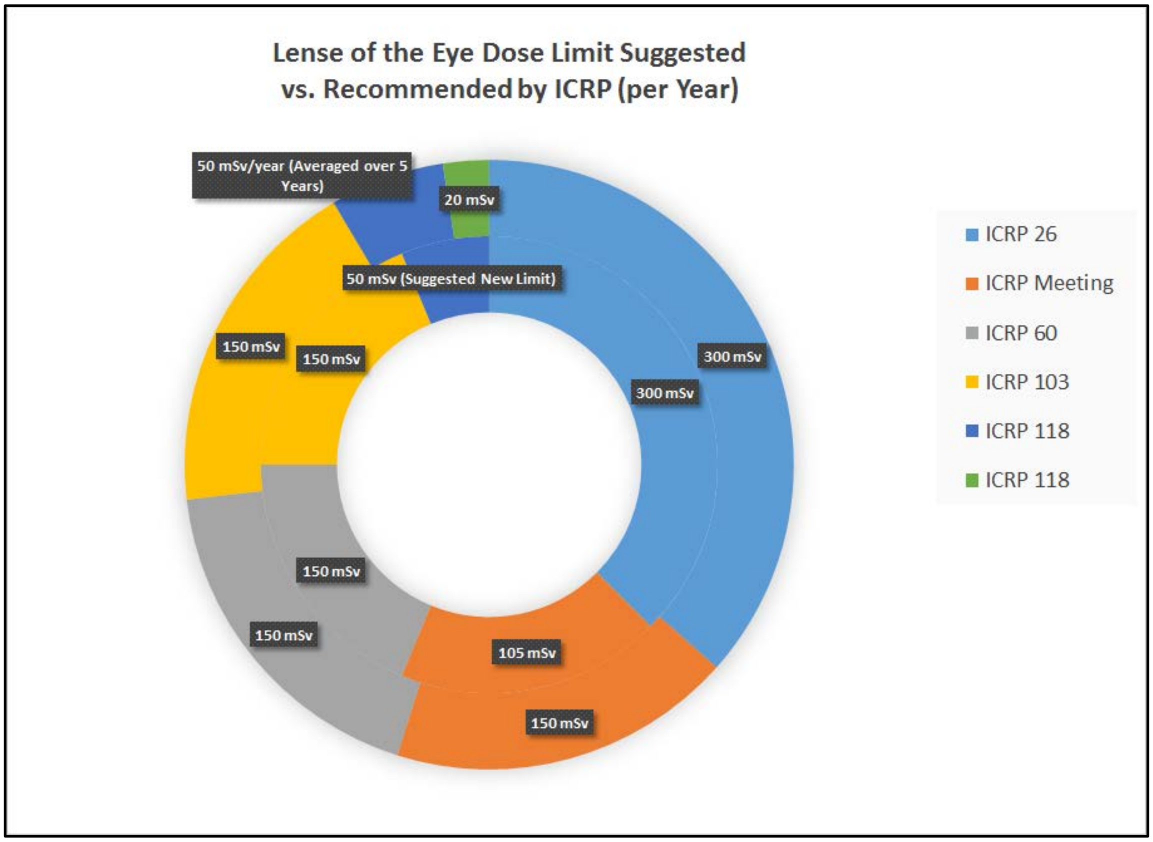


Figure 12. 1 Illustration of the evaluation of the ICRP dose limit for the eye and our suggestion of the corrected new dose limit which is 50 mSv per annum.

Based on the ICRP publications and the review of the literature and the interviews conducted, there is a general consensus in the industry in Canada and among IAEA members states that the dose limit for the lens of the eye should be reduced from the original proposed limit of 150 mSv per year. However not to the recommendations suggested by ICRP 118, which is equivalent to the whole body dose limit, but, to a standard reasonable and an achievable limit that is 50 mSv per year. Perhaps the ICRPs limit should be considered as an ALARA target rather than a strict limit, especially for the IAEA member states.

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