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RS-15-178

June 22, 2015

Secretary
U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555–0001

Subject: Comments Concerning Advance Notice of Proposed Rulemaking 10 CFR 20, *"Radiation Protection"* (79FR43284, dated July 25, 2014, Docket ID NRC–2009–0279)

This letter is being submitted in response to the U.S. Nuclear Regulatory Commission's (NRC's) request for comments concerning the subject Advance Notice of Proposed Rulemaking (ANPR) 10 CFR Part 20, *"Radiation Protection,"* published in the *Federal Register* (i.e., 79FR43284, dated July 25, 2014).

The NRC is issuing this ANPR to solicit input from interested stakeholders on the development of a draft regulatory basis that would support potential changes to the NRC's current Radiation Protection regulations (i.e., 10 CFR 20). The goal of the NRC's effort is to achieve greater alignment between the NRC's Radiation Protection regulations and the recommendations contained in the International Commission on Radiological Protection (ICRP) Publication 103, *"The 2007 Recommendations of the International Commission on Radiological Protection."* As discussed in Section IV, *"Specific Considerations,"* of the subject ANPR, the NRC has identified specific issues and related questions with respect to a possible revision of the NRC's Radiation Protection requirements. Stakeholder comments received, including responses to the specific questions, will be considered by the NRC when it develops the draft regulatory basis.

Exelon Generation Company, LLC (Exelon) appreciates the opportunity to comment on the subject ANPR and offers the attached comments for consideration by the NRC. In addition, Exelon fully supports the comments submitted by the Nuclear Energy Institute (NEI) on behalf of the nuclear power industry related to the subject ANPR.

If you have any questions or require additional information, please do not hesitate to contact Richard Gropp at (610) 765-5557.

Respectfully,

James Barstow
Director, Licensing and Regulatory Affairs
Exelon Generation Company, LLC

Attachment

bcc: Director, Licensing and Regulatory Affairs, Midwest
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ATTACHMENT

Advance Notice of Proposed Rulemaking 10 CFR 20 - Radiation Protection
Federal Register 79FR43284, dated July 25, 2014
Docket ID NRC-2009-0279

Exelon Generation Company, LLC
Response to Section IV Issues/Questions

ISSUE A

Update 10 CFR Part 20 to Align With ICRP Publication 103 Methodology and Terminology

1.0 Introduction

Should the U.S. Nuclear Regulatory Commission (NRC) revise 10 CFR 20 to more closely align with the International Commission on Radiological Protection (ICRP) Publication 103 (2007) methodology and terminology for dose assessment?

Exelon Generation Company, LLC (Exelon) recommends that the NRC not revise 10 CFR 20[1] to more closely align with the ICRP Publication 103 methodology and terminology. Exelon believes that adoption of the ICRP 103 methodology and terminology into 10 CFR 20 will be a significant, unnecessary resource burden to licensees with little or no improvement to worker or public radiological safety. The reasons for this recommendation are discussed below.

The U.S. nuclear power industry historically has very low internal doses. A number of the changes in ICRP 103 are associated with the models used for calculating internal dose and changes to the tissue weighting factors. These changes will require revision of a number of plants' procedures and updating of computer software used for internal dose evaluations. Based on the historically low internal dose at Exelon's facilities and the nuclear power facilities in general, these changes do not provide a significant improvement in worker safety to warrant the cost to implement these changes. The table below shows the Committed Effective Dose Equivalent (CEDE) reported for U.S. commercial nuclear power licensees from 2009-2012.

Year	Total Facilities Reporting CEDE	Total number of Individuals with CEDE	Total CEDE Reported (mrem)	Average CEDE per monitored individual when CEDE is non zero (mrem)
2009	15	86	852	10
2010	19	78	720	10
2011	13	91	580	7
2012	12	108	1534	15

Source: NUREG-0713, *"Occupational Exposure at Commercial Nuclear Power Reactors and Other Facilities (2009-2012),"* Volumes, 31, 32, 33, 34

[1] 10 CFR Part 20, *"Standards for Protection Against Radiation."*

ICRP 103 has updated both tissue and radiation weighting factors which will result in some changes to calculated values of Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs). In addition, NRC Issue Paper 1[2] contains a discussion about ALI and DAC values for a number of different age groups. None of these changes are available at this time as the new ALI and DAC values are still being determined. The impacts from these new values could be significant and again, the benefits (if any) to worker and public radiological safety is not clear.

Exelon believes that the introduction of the term "TED," in lieu of Total Effective Dose Equivalent (TEDE), would be an undue burden on licensees with no improvement to worker or public radiological safety. The term TEDE is an NRC term, created to assist in implementing changes to 10 CFR 20 in the early 1990s. This term is understood by workers and is in common use throughout the nuclear industry. Changing to the ICRP term, "TED" with the associated training burdens, procedure changes, and computer software impacts is not justified by any accompanying increase in worker or public radiological safety.

In summary, Exelon believes the adoption of the ICRP Publication 103 methodology and terminology into 10 CFR 20 will be significant and impose an unnecessary resource burden to Exelon and other licensees with little or no improvement to worker or public radiological safety.

2.0 Response to Specific Questions for Public Comment

2.1 A-1: *What are the implications of changing the NRC's regulations to specify "total effective dose" in place of the current term "total dose effective dose equivalent?" Please provide specific implementation and operational cost information on the impacts of this change relative to licensee procedures, training, recordkeeping and reporting.*

Response

Changing the term to "TED" from TEDE will impact many areas within Radiation Protection programs. For instance, training programs will require modification to change the terminology. Numerous Radiation Protection procedures, Emergency Plans and implementing procedures, and licensing basis documents such as Updated Final Safety Analysis Reports (UFSARs), will require changes to update the terminology to TED. In addition, costly computer software changes will also be required.

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[2] NRC ADAMS Accession Number ML14084A342, http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html, p.8.

The following are cost estimates on a per facility basis:

- Training modification costs (including lesson plan preparation and approval, computer-based training content changes and approvals of both) - $20,000.
- General Employee Training (GET) delivery and attendance costs - $200,000.
- Technical training for Radiation Protection staff costs (includes lesson preparation, approval, delivery and student attendance) - $40,000.
- Procedure costs (includes revision, approval and distribution for approximately 50 procedures) - $400,000
- Plant UFSAR/Emergency Plan costs revisions and approvals - $5,000 (provided extensive 10 CFR 50.54(q) and 10 CFR 50.59 evaluations are not required).
- Software modification costs (including coding changes, testing and implementation - $50,000.

The total cost for simply changing TEDE to TED could approach $800,000 per facility to implement.

2.2 A-2: ***If the NRC adopts the dose assessment terminology and methodology of ICRP Publication 103 (2007) in a future rulemaking, what time period should the NRC consider providing for implementation of the ICRP Publication 103 (2007) methodology and terminology?***

Response

Exelon believes that it will require a minimum of three to five years to prepare for implementation after publication of all new ALIs and DACs and associated use strategies (e.g., Regulatory Guides, etc.). This does not include the resources that would be necessary to implement the other five changes being considered by NRC in this ANPR. In addition, other regulatory harmonization changes (e.g., 10 CFR 50, Appendix I[3], 40 CFR 190,[4] etc.) would add to the total time required for implementation. If changes are made to these regulations, coordination by the NRC and U.S. Environmental Protection Agency (EPA) will be critical to reduce the cost and burden associated with multiple program and procedure changes by licensees.

[3] 10 CFR 50 Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low as is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents."

[4] 40 CFR 190, "Environmental Standards for Uranium Fuel Cycle Facilities."

2.3 A-3: *How should the calculations of effluent concentration, currently in the 10 CFR Part 20 radiation protection regulations, be modified to reflect advances in modeling that are now available, including the age and gender averaged approach?*

Response

Exelon believes that it is not necessary to revise the effluent concentration standards in 10 CFR 20. 10 CFR 50, Appendix I and the methods described in NRC Regulatory Guides 1.109[5] and Regulatory Guide 4.16[6] currently protect and adequately consider different age segments by requiring use of radionuclide and age-specific dose factors. This is confirmed by NRC in NUREG/CR-2907:

> *"...the highest total body dose from all facilities was less than 0.4 mrem, highest organ dose from all facilities was less than 0.9 mrem. None of the doses from liquid or gaseous effluents exceeded 1 mrem."* [7]
>
> *"...Doses to the public due to effluents from NPPs are less than 0.1% (one-tenth of one percent) of what the average person receives each year from all sources of radiation."* [8]

In addition, prior to revising the definition of the "reference person," Exelon recommends that the NRC further analyze and evaluate exposure data generated by the U.S. Department of Energy[9] (DOE) which currently uses additional age-specific subgroups by their fractional representation in the U.S. population. This evaluation could determine if this change in methodology will provide a substantial reduction in public radiation exposure.

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[5] NRC Regulatory Guide 1.109, "Calculations of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10CFR Part 50, Appendix I."

[6] NRC Regulatory Guide 4.16, "Monitoring and Reporting Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Cycle Facilities."

[7] Nuclear Regulatory Commission, NUREG/CR-2907, "Radioactive Effluents Report," Vol. 15 (2009), p.3-54.

[8] Ibid., pp.2-6.

[9] U.S. Department of Energy Technical Standard DOE-STD-1196-2011, "Derived Concentration Standard" (April 2011).

Should the NRC determine that 10 CFR 20 changes in this area are required to provide a stronger regulatory framework for licensees not regulated by 10 CFR 50[10] and 10 CFR 70[11], a provision should be added to 10 CFR 20, exempting 10 CFR 50 and 10 CFR 70 licensees from additional compliance responsibilities associated with 10 CFR 20 effluent concentration changes.

2.4 A-4: *Should the public dose limit of 0.5 mSv (50mrem) continue to be the basis for the effluent concentration limits for radionuclides in 10 CFR Part 20, Appendix B, Table 2, Columns 1 and 2? Should it be reduced or otherwise modified?*

Response

Exelon believes that the existing public dose limits should remain in place. There are multiple layers of existing NRC and U.S. EPA regulatory framework relevant to effluent releases. Limits on dose to the public are regulated by the NRC in 10 CFR 50, Appendix I and the U.S. EPA in 40 CFR 190.

Should the NRC determine that 10 CFR 20 changes in this area are necessary to provide a stronger regulatory framework for licensees not regulated by 10 CFR 50 and 70, a provision should be added to 10 CFR 20, exempting 10 CFR 50 and 10 CFR 70 licensees from additional compliance responsibilities associated with 10 CFR 20 effluent concentration changes.

[10] 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

[11] 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

ISSUE B

Occupational Dose Limit for the Lens of the Eye

1.0 Introduction

Should the NRC revise 10 CFR 20 to more closely align with the ICRP Publication 103 (2007) by reducing the annual occupational dose limit to the lens of the eye from 150 mSv (15 rem) to 50 mSv (5 rem)?

Exelon recommends that the NRC not revise 10 CFR 20 to reduce the annual occupational dose limit to the lens of the eye from 150 mSv (15 Rem) to 50 mSv (5 Rem). The implications and consequences of this decision have not been fully considered by the NRC. These include the economic impact, lack of current regulatory and industry consensus standards, development of significant programmatic changes, extensive training, and the additional costly protective equipment and/or dosimetric devices to demonstrate regulatory compliance and protection of workers. Most importantly, the scientific data supporting the proposed change is weak and radiation-induced cataracts are not well understood.

A Cataract is a medical condition "*...used to describe any detectable change in the normally transparent lens of the eye....*"[12] In addition, "*...Cataracts affect over 24.4 million Americans age 40 and older, or about one in every six people in this age range.*"[13]

The lens consists mostly of fiber cells and contains no blood supply, and dividing cells are limited to the pre-equatorial region of the epithelium. The lens is a self-renewal tissue, as cell division occurs throughout the life cycle of the individual, but is unique in that there exists no mechanism for cell removal upon cell death or injury. Instead of being removed from the lens tissue, these cells migrate toward the posterior pole. Injured and dead cells lack the translucent nature of healthy cells, and thus their opacity induces a cataract. Cataracts can be repaired through a well-documented and frequently performed surgical procedure.

As stated in ICRP 118, "*...there is no direct mechanistic evidence that a single damaged cell can give rise to a cataract, which would be the hallmark of a stochastic effect.*"[14] In order to

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[12] Hall, Eric J. and Amato Giacca. *Radiobiology for the Radiologist*. Philadelphia: Lippincott Williams and Wilkins. 2006 Textbook. p 181.

[13] Prevent Blindness America: *Vision Problems in the U.S.*, prevent blindness.org, http://www.visionproblemsus.org/cataract/cataract-definition.html

[14] International Commission on Radiological Protection, ICRP publication 118, "ICRP statement on tissue reactions and early and late effects of radiation in normal tissues and organs--threshold doses for tissue reactions in a radiation protection context" (2012). p.297.

understand why comparing cataracts to other potential radiation effects, such as cancer, is unjustified, the effects of radiation at the molecular level must be understood. Radiation becomes detrimental to cells through the following process: radiation interacts and causes a single or double break in DNA strand(s), the broken DNA causes radiation-induced chromosomal aberrations in various forms, the mutated DNA continues to replicate at an exponential rate, and an abnormal colony is formed. Cancer is an abnormal growth of cells. Since there is no indication that cataractogenesis stems from the same process described above, cataracts should therefore not be compared to nor classified in the same manner as cancer.

In October 2011, the Health Physics Society (HPS) responded to the NRC Docket ID NRC-2009-0279. The position taken by the HPS was that the *"current dose limits are adequately protective for workers"*[15] with the basis that the available scientific data was not sufficient to justify the policy changes suggested for lower lens of eye dose limits.

The HPS noted that clarity should be provided between the opacity threshold and that of cataracts. The 0.5 Gy threshold identified by scientific studies is for acute exposures and does not accurately represent occupational, fractionated exposure. Since occupational exposures are rarely acute doses except in accident scenarios, the acute threshold value for cataract induction should not be the basis for the regulatory threshold. For these reasons, it was the recommendation of the HPS that additional data be obtained to increase the understanding of cataract development in occupational workers. Suggestions for study populations included retired occupational radiation workers and interventional radiologists so that a reasonable latency period could be observed.

As an industry and a scientific community, Exelon strongly contends that the dose limit to the lens of the eye should not be changed. Exelon concurs with the recommendations and conclusions of the ICRP regarding this issue, both scientifically and from a regulatory perspective:

> *"A view that the literature is not consistent and the results are tenuous. This type of change has huge cost implications and the risk to the eyes may be considered small."*[16]
>
> *"The work of the key international organizations on this topic (ICRP, IAEA) seem to be hurried, with an inadequate period for consultation."*[17]
>
> *"The economic and social considerations should be taken into account when introducing the limits into the relevant regulations of each country."*[18]

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[15] Kathryn Pryor, "Recommendations on the Annual Dose Limit to the Lens of the Eye," letter to NRC, 13 Oct. 2011.

[16] J. Broughten, M.C. Cantone, M. Ginjaune, B. Shah, *"Report of Task Group on the implications of the implementation of the ICRP recommendations for a revised dose limit to the lens of the eye."* (2013) p. 863.

[17] Ibid., p. 863.

[18] Ibid., p. 865.

2.0 Response to Specific Questions for Public Comment

2.1 B-1: *Is closer alignment with or adoption of the ICRP Publication 118 (2012) recommendations regarding the dose limits to the lens of the eye appropriate given the scientific information now available?*

Response

Given the current scientific information available, acceptance of the recommendations in ICRP Publication 118 is not appropriate for the lens of eye dose. While there are a few studies that have been published that suggest cataracts are induced by acute or fractionated exposures at this level, these limited studies do not provide a sound scientific basis for a change to regulations. It must be noted that several of these limited studies have one or more uncertainties in key variables, such as actual individual doses received. Facts should be tested and repeated, and results should be reproducible. In consideration of the implications that this change would have on regulation, the science to support this change must have a greater certainty than has been presented. The following examples and data are presented to demonstrate that the information contained in ICRP Publication 118 is insufficient to justify the reduction of the lens of eye dose.

Table 2.1
A Summary of the Studies of Exposure and Opacities of Cataracts Contained In Annex A of ICRP 118.

Author and Date	Population	Threshold Dose (95% CI)	Technique for Assessment	Comments
Worgul et al. (2007)	Chernobyl Clean-up Workers (n=8607)	Stage 1 posterior cortical opacity, 0.34 Gy (0.18–0.51); Stage 1 PSC opacity, 0.35 Gy (0.19–0.66)	Ophthalmoscopic and slit-lamp assessment. Ophthalmologists were trained for standardized assessment, but opacity rates varied by examiner.	Individual doses were mainly estimated from "official doses" with adjustments based on a limited comparative set of Electron Paramagnetic Resonance dose estimates, and not actual dosimeter readings, so individual dose uncertainties were substantial.
Kleiman et al. (2009)	Interventional Cardiologists (n=78)	–	Slit-lamp examination after pupil dilation.	Doses not known. Doctors were older than nurses/technicians. Study suggests that protracted radiation exposures may lead to opacities, but age needs to be ruled out.
Chodick et al. (2008)	Radiologic Technologists (n=35,705)	Found marginally significant difference between workers in highest (mean = 60 mGy) and lowest (mean = 5 mGy) dose categories	Mail surveys of cataracts and numerous potential risk factors.	Based on self-reported cataracts and cataract surgeries. *Probably appreciable dose uncertainties*, especially for those employed before approximately 1955 when there was limited film-badge information.
Neriishi et al. (2007)	Atomic Bomb Survivors (n=3761)	*Best estimate*: 0.1 Gy (<0–0.8)	Ophthalmoscopic examination to determine indication of cataract surgery.	Anatomical location of the cataracts was not characterised. This was the first substantial evidence that radiation doses of <1 Gy are related to clinically significant cataracts. No dependence of threshold dose on stage or site of the cataract.

Worgul [19] is one of the key research studies for fractionated exposure to occupational workers that reasons the reduction of the dose limit to 0.50 Gy (50 rad). It should be

[19] Worgul, B.V., Kundiyev, Y.I., Sergiyenko, N.M., et al., 2007. Cataracts among Chernobyl clean-up workers: implications regarding permissible eye exposures. Radiat. Res. 167, pp.233–243.

noted that the percentage of individuals identified as having Posterior Subcapsular (PSC) cataract formation was only 8% (five of 59 individuals studied) in the Worgul study. When compared to other published ophthalmic studies that were not targeted towards radiation exposure, PSC opacities were observed in 6% of the sampled population where the sample population was 4926 persons.[20]

There are several studies that have uncertainty of the actual doses received by the study participants. These dose estimations should be considered, as several of the studies that indicate that the threshold is "lower than expected" fall into this category. It is mentioned that corrections were made in several incidences for these variables. In several of the major studies, including Chernobyl clean-up workers[21], a threshold value was not determined. These variables are not presented in the summary tables in the body of ICRP Publication 118. Annex A of ICRP Publication 118 has additional details on each of the key studies and have been included above in Table 2.1, *"A Summary of the Studies of Exposure and Opacities of Cataracts Contained In Annex A of ICRP 118."*

Due to the lack of strong scientific evidence of radiation-induced cataracts, the regulatory limits should not be altered to align with ICRP Publication 118. There are wider implications to be considered from this change and without a strong, irrefutable basis, the NRC should not proceed until the data supports the change.

2.2 B-2: *How should the impact of a radiation-induced cataract be viewed in comparison with other potential radiation effects?*

Response

ICRP 118 states that *"there is no direct evidence that a single damaged progenitor ...cell can produce a cataract."*[22] The ICRP's acknowledgement of the current lack of evidence for a single damaged progenitor thus does not align with the formation, and therefore, the risk basis for radiation-induced effects. With the additional knowledge that the lens tissue is a self-renewal tissue, the biological basis for the risk level that is being identified with these proposed new limits is unfounded.

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[20] Klein B.E., R. Klein, K.L. Linton. Ophthalmology. 1992 Apr; 99(4):pp.546-52. Congdon.

[21] Worgul, B.V., Kundiyev, Y.I., Sergiyenko, N.M., et al., 2007. Cataracts among Chernobyl clean-up workers: implications regarding permissible eye exposures. Radiat. Res. 167, pp. 233–243.

[22] ICRP 118, p. 302.

The ICRP viewpoint outlined in Publication 103 is "*to manage and control exposures to ionizing radiation so that deterministic effects [tissue reactions] are prevented.*"[23] These tissue reactions of the eye do not present the same risk level to an occupational worker as do other potential radiation effects. Limiting the effective dose to the whole body is more important than limiting the effective dose equivalent to one tissue, the eye, as the probability of cancer should be weighed as a more serious detriment to the occupational work than cataracts.

If adopted, this would be the first change that is due to a possible tissue reaction. The justification for the proposed change is due to a lower than previously expected dose threshold. Damage to the lens of the eye is being defined by a threshold value, characteristic of non-stochastic effect, yet is being used as a stochastic effect in that the probability of incidence increases with dose. A regulatory limit for occupational dose should have a definitive basis. However, the lack of clarity in the definition of risk, as it is known to the radiation protection profession and in regards to the lens of the eye, demonstrates that the opacities and cataracts presented in the reports and studies described above have not been fully compared to other radiation risks.

2.3 B-3: *What mechanisms could be applied to keep the cumulative exposure to the lens of the eye below the threshold of 0.50 Gy (50 rad)?*

Response

In order to optimize protection for the occupational worker, engineering controls, administrative controls, and personal protective equipment are mechanisms that should be applied to ensure that the cumulative exposure to the lens of the eye is less than the proposed threshold of 0.50 Gy (50 rad). Unfortunately, there is limited technology that has been developed and distributed commercially for lens of eye monitoring. If this proposed regulatory change is implemented, these three mechanisms identified by the IAEA[24] will increase the program likelihood of successful monitoring of cumulative personnel exposure.

Engineering controls are the first barrier to protecting the occupational worker. IAEA recommends that the "*optimization of protection with due account being taken of the exposure of the lens of eye should be considered first and foremost at the design stage of*

[23] ICRP 103, p. 41.

[24] IAEA TECDOC No. 1731: "Implications for Occupational Radiation Protection of the New Dose Limit for the Lens of the Eye" (2013).

equipment and installations."[25] In many cases for existing equipment and shielding, this was not an initial consideration. The whole body dose is the region of the body that was intended to be protected. Facilities and equipment will have to be retro-fitted for the installation of engineering controls for the lens of eye, where appropriate.

Administrative controls would need to be established and enforced as the secondary barrier to ensure the cumulative exposure to the lens of the eye remains below the threshold of 0.50 Gy (50 rad). Reevaluation of the current procedures and programs would be necessary to ensure that the controls are sufficient to monitor the lens of eye dose. Any changes to protective clothing should be part of the administrative control analysis performed to support the lens of eye dose change.

Changes to personal protective equipment would also be required to ensure the cumulative exposure to the lens of the eye remains below the 0.50 Gy (50 rad) threshold.[26] The IAEA recommended acrylic glasses for beta radiation fields and lead for predominately penetrating radiation fields.[27] Caution could be taken; however, in several incidences with usage of eyewear to minimize lens of eye dose. In high beta fields, bremsstrahlung may be generated. Field directionality relative to the worker's eye should also be considered in instances where workers have changing job locations and tasks, such as at a nuclear energy facility, where all access directions (2π) are possible. Protective eyewear should also be practical and comfortable for the worker.

If personal protective equipment is to be relied on as a method to protect the worker, similar considerations given to laser safety glasses should be applied. Glasses should provide shielding superiorly, inferiorly, and laterally from the lens for changing radiation field directions to provide sufficient protection from the source. The Electric Power Research Institute's (EPRI's) 2013 study[28] of radiation protection programs at nuclear power plants indicated a majority of U.S. nuclear facilities used safety glasses or face shields for eye protection. It was noted that this eyewear is being used for industrial safety purposes only. Although the intention of these glasses was not initially for radiation protection shielding, they could be used for both radiological and industrial safety. Attenuation factors should be developed for glasses, similar to the way in which

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[25] Ibid., p. 10.

[26] Ibid., p. 10.

[27] Ibid., p. 10.

[28] Electric Power Research Institute, Report Number 3002000486 "Lens of the Eye Dose Limit Changes: Current Status of the Potential Regulatory Changes and Possible Effects on Radiation Protection Programs at Nuclear Power Plants" (2013).

optical density factors have been developed for laser eye protection. This would allow taking credit for industrial safety glasses as a protection factor, as long as they provide shielding from all directions. Precautions for this methodology include a change in the radiation characterization. If a nuclear facility has a predominantly gamma radiation field but accident conditions arise, it must be understood by emergency personnel and responders that this radiation field change may have different dose monitoring requirements.

Active (i.e., direct-reading) dosimeters for the lens of the eye are non-existent at this time. Development of ALARA technologies, such as those that are currently available for whole body gamma dose and dose rate monitoring, would bolster Radiation Protection programs so as to more accurately monitor dose throughout the annual monitoring year. Frequent dosimetry change-outs on a monthly or quarterly basis would enhance the monitoring capabilities; however, this becomes burdensome on Health Physics programs due to the cost and time requirements to perform this exchange.

2.4 **B-4: *What methods should be allowed for measurement or assessment of the dose to the lens of the eye?***

Response

IAEA identified three categories of workers whose lens of the eye dose should be considered: 1) workers exposed to a uniform whole-body field; 2) workers exposed to a non-uniform field where the lens of eye would receive the greatest exposure; and 3) workers who may be exposed to low energy beta or photons.[29] For the first group of workers, those exposed to a uniform whole-body field, a significant difference in the deep dose equivalent and the lens dose equivalent is often not present if the radiation type and energy is sufficient to penetrate to the $H_p(10)$ depth. Note that at nuclear power facilities, the high gamma energies from activation products, such as cobalt-60, explain why the deep dose is nearly equivalent to the lens of eye dose. EPRI published a study in 2013 of Radiation Protection programs at nuclear power plants.[30] Researchers polled a number of nuclear power plants, where the first category of workers (uniform whole body field) would be prevalent. The difference noted between the average lens of eye dose versus the average deep dose equivalent was 0.59% in 2010 and 2.9% in 2011. A majority (35 out of 37) of these facilities determine the lens of eye dose through a dosimetry algorithm. The administrative dose limit, in conjunction with the dose threshold for restricted radiation worker duties, set by facilities (generally 60-80% of the total facility administrative dose), provides that the use of an algorithm is sufficient to

[29] IAEA TECDOC No. 1731, p. 6.

[30] EPRI Report Number 3002000486.

ensure that the annual dose to the lens of the eye will not be exceeded if the energy characterization of the facility is not significantly different between the $H_p(3)$ and $H_p(10)$ depths.

It is equally acceptable to use an algorithm to determine the lens of eye dose in non-uniform fields; however, direct monitoring should be used when appropriate. The non-uniform field should be well characterized through the determination of dose gradient, radiation decay type and energy, and the penetration ability at the deep versus lens tissue depths. This data can then be used to perform a dosimetry evaluation for relocation and/or the need for direct lens of eye monitoring. If the radiation field is above the worker and $H_p(3)$ is comparable to $H_p(10)$, the normal whole-body dosimeter should be placed on the head so a more accurate assessment of the dose to the lens of eye can be made. The distance between the head and chest of the worker may be enough to underestimate the lens of eye dose if the chest (normal) location is used. If the whole body dosimeter is shielded by a lead/tungsten vest or the lens tissue depth varies significantly from the deep tissue depth, then direct monitoring is more appropriate than the use of the normal whole body dosimetry with an applied algorithm so as to prevent lens of eye dose underestimation.

It should be noted that if the regulations are changed, then major revisions and applicability determination of Regulatory Guide 8.40[31] will be required. Regulatory Guide 8.40 defines Effective Dose Equivalent for External (EDEX) as the sum of the Deep Dose Equivalent (DDE) and Committed Effective Dose Equivalent (CEDE). There is currently no direction in Regulatory Guide 8.40 for the Lens of Eye Dose Equivalent (LEDE). If the lens of eye dose is the limiting dose to occupational workers, a clear explanation must be provided on how to use the $H_p(3)$ depth in a method that was created for the risk at $H_p(10)$. Regulatory Guide 8.40 specifies that the "*assigned DDE must be for the part of the body receiving the highest radiation exposure*"[32] and is not location specific like the lens of eye dose. If the source term relative to the body is significantly inferior to the lens, the dose to the lower organs and the associated risk may not be monitored adequately without robust guidance.

2.5 B-5: *What methods should be allowed for recording dose to the lens of the eye when the eyes are protected?*

[31] NRC Regulatory Guide 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure."

[32] Ibid., p. 1.

Response

If the eyes are protected, the method for recording the dose to the lens of eye depends on whether or not the eyes are being directly or indirectly monitored. If the eyes are being directly monitored, the recorded dose should be determined from the lens dosimeter. As there is limited availability of direct dosimetry that measures at the lens of eye depth, an algorithm must be applied to the indirect dosimeter results if the eyes are considered protected.

Regardless of indirect or direct monitoring, the methods of dosimetry are not well-established for the lens of eye and could result in difficulty when demonstrating regulatory compliance. It is recommended that a standard criterion for testing be established for the method of recording and verifying dosimetry results for the lens of eye. While deep and shallow dose testing criteria have been well established through documents like ANSI/HPS N13.11-2009[33], there is no clear direction in this area for lens of eye monitoring. A single document enables consistency across Radiation Protection programs, which increases the validity of the program's monitoring capabilities. The specific considerations of this document should include dependency of the radiation field through well-defined test categories, phantom construction, irradiation levels, assignment of personal dose equivalent values, and the administrative procedures that are to govern these criteria.

If use of industrial safety glasses is to be credited for shielding, testing must be performed to determine the shielding or protection factor (i.e., similar to protection factors currently used for respiratory protection) of the eyewear. If the whole body dosimetry is to be kept by facilities and applied to the lens of eye dose, the use of a correction factor should be determined (through scientific study) and applied to more accurately report the lens of eye dose. Note that should additional eye protection be required, licensees must ensure that this eyewear is appropriate for use in varying working conditions without resulting in additional external dose to workers or cause vision-related issues from use of this eyewear.

2.6 **B-6:** ***What are the potential operational impacts of lowering the annual occupational dose to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)? Would a reduction in the occupational dose limit for the lens of the eye require changes in programs, procedures, practices (e.g., increased use of***

[33] American National Standard N13.11-2009, "Personnel Dosimetry Performance - Criteria for Testing."

protective eyewear), or in-room shielding? Please describe these changes, including any potential implementation and operational costs.

Response

Radiation Protection programs would require revision if this reduction is imposed by the NRC. This includes procedure revisions and training for all radiation workers to make them aware of the new limit. As part of the training, clear communications would have to be established for all knowledge and experience levels of radiation workers.

Physical modifications may be required to install additional shielding to meet the new criteria (i.e., engineering controls). The cost of physical modifications to facilities includes the cost of material, installation labor, and salary to health physicists who would perform these shielding design changes. If additional personal protective equipment is to be purchased for the protection of workers, the equipment purchase and the personnel time required to implement the necessary program administrative controls should also be considered in the programmatic costs as a result of this change.

Computer software changes would be required and distributed throughout various industries. Extensive lead time would be necessary for software vendors to perform these changes, including verification and validation to ensure quality assurance of the programs prior to release of new versions to work sites.

2.7 B-7: ***What are the potential impacts on State regulatory programs of a reduction in the occupational limit to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)?***

Response

As described in B-6 (2.6) above, it is expected that the same impacts would apply to State regulatory programs.

ISSUE C

Dose Limit for Embryo/Fetus of a Declared Pregnant Occupational Worker

1.1 Introduction

Should the NRC revise 10 CFR 20 to more closely align with the ICRP Publication 103 (2007) by reducing the dose limit for the embryo/fetus of a declared pregnant occupational worker from 5 mSv (500 mrem) for the entire pregnancy to 1 mSv (100 mrem) from the declaration of pregnancy and for the remainder of the pregnancy?

Exelon does not recommend that the NRC change the dose limit for the embryo/fetus of a declared occupational worker. A reduction in occupational dose limit for the embryo/fetus of a declared pregnant occupational worker from the current 5 mSV (500 mrem) dose limit for the entire pregnancy to the proposed 1 mSv (100 mrem) from the declaration of pregnancy and for the remainder of the pregnancy will not provide a declared pregnant worker an appreciable reduction in risk for the embryo/fetus as confirmed by recently published scientific data. This conclusion is based on the following published scientific information:

1. Tissue Effects: Based on the scientific excerpts listed below, Exelon believes that the current limit for a declared pregnant worker of 5 mSv (500 mrem) provides protection against genetic effects, embryonic and fetal death, major and minor congenital malformations, growth retardation, mental retardation, decreased Intelligence Quotient (IQ), neurobehavioral effects, and convulsive disorders.

   According to National Council on Radiation Protection (NCRP) 174:

   > *"While there are limited epidemiologic studies of ionizing radiation exposures in human pregnancies from which to determine the no-adverse-effect level for developing opmental and reproductive effects, there are extensive animal studies that support a conclusion that the no-adverse-effect level from acute exposure for birth defects, growth retardation, pregnancy loss, and other tissue reactions (deterministic effects) is ~ 0.2 Gy* (~20 rad) *(dose to the embryo or fetus) at the most vulnerable stage of pregnancy... The experimental animal data also indicate that tissue reactions for protracted and fractionated irradiation are diminished compared to the effects of acute irradiation...."*[34]
   >
   > *"There is no convincing direct evidence of germline mutation manifest as heritable disease in the offspring of humans that is attributable to preconception exposure to*

[34] National Council on Radiation Protection and Measurements, "NCRP Report 174, Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance", May 2013, p. 230.

ionizing radiation, yet preconception exposure clearly induces mutations in microbes and somatic cells of rodents and humans, and in offspring of irradiated male mice..."[35]

"Based on animal studies, absorbed doses to the embryo > 0.2 Gy (> 20 rad) *increase the incidence of embryonic loss during the preimplantation and presomite developmental stage, but in general the surviving embryos do not have an increased incidence of malformations (reflecting an all-or-none phenomenon)... Increased risks to the embryo or fetus have not been observed for mental retardation, birth defects, growth retardation, neurobehavioral effects, impaired school performance, convulsive disorders, or embryonic or fetal death below a dose of 0.1 Gy* (10 rad) *(weighted uterine dose)... "*[36]

"Mental retardation (IQ<70) can be produced by ionizing radiation exposure during the 8th to 15th week postconception (10th to 17th week of gestation) with an incidence of 40% Gy^{-1} (weighted uterine dose), and during the 16th to 25th week postconception (18th to 27th week of gestation) with an incidence of 15% Gy^{-1} (weighted uterine dose). No increase in mental retardation has been observed at fetal doses in the diagnostic imaging range (< 0.1 Gy) (< 10 rad)...." [37]

2. Cancer (stochastic effect): According to NCRP 174, there appear to be some increases in Excess Relative Risk (ERR) for leukemia that have been associated with medical x-ray exposures of the abdomen and for solid cancers among the adult atomic bomb survivors who were either exposed in uterine or as a child less than 15 years of age; however, the data appears to be inconclusive when estimating radiation-related dose response.

   Concerning the association between in utero exposure and cancer in the offspring:

   "Data from case-control studies (including two large studies that relied on medical records for exposure determination) support a statistical association between childhood leukemia in offspring and the mother's exposure to diagnostic x-rays during pregnancy. The excess relative risk (ERR) of childhood leukemia based on a meta-analysis of 32 case-control studies is estimated as 1.3 (95% CI = 1.2 to 1.5). Investigators have debated whether the statistical associations are causal as well as the magnitude of the leukemogenic risk per unit fetal dose."[38]

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[35] Ibid., pp.230-231.

[36] Ibid., p. 231.

[37] Ibid., p.231.

[38] Ibid., p.231.

"Meta-analysis of cohort studies (concerning exposure of mothers to diagnostic x-rays during pregnancy) have found small, but not statistically-significant increases of total cancer, but confidence intervals (CI) were compatible with a composite increase similar to that of the case-control studies of 30% or a composite estimate compatible with no increase in risk. Overall, the cohort studies are characterized by limited numbers of total childhood cancer and the subset of childhood leukemia cases, and with insufficient statistical power and substantial uncertainties, thus limiting the ability to draw firm conclusions." [39]

"Among atomic-bomb survivors in utero at the time of the bombings, there was no statistically-significant evidence of a dose-related increase in cancer mortality among persons younger than 15 y of age at follow-up. This study did not provide detailed radiation-related childhood cancer incidence data between 1945 and 1957." [40]

"The Japanese Atomic-Bomb Survivor Study is the only study to evaluate and compare adult leukemia and cancer risks following in utero exposure to those following early childhood exposure. There have been too few leukemia deaths (and data lacking on leukemia incidence during 1945 to 1957) to estimate radiation-related dose response. To date, the study reveals statistically-significant radiation-dose related increases in solid cancer risks [ERRs per gray (weighted uterine dose)] at the same attained age of 50 y in both groups. ERRs for cancer per gray (weighted uterine dose) following in utero exposure are lower than those exposed in early childhood. Excess absolute rates (EAR) per 10,000 person years per gray in the study revealed a substantially lower increase with attained age among those exposed in utero than the marked increase with attained age among those exposed in early childhood."[41]

Although an increase in cancer risk appears to have been observed for diagnostic x-rays of the abdomen (acute exposure); there appears to be no observable increase in risk for occupationally exposed pregnant workers (chronic exposure) or the data appears to be inconclusive.

3. Occupational Exposures – Nuclear Industry: According to NCRP 174, *"A few case-control studies investigating risks of cancer in young persons living in proximity to nuclear plants have observed increased incidence of leukemia and non-Hodgkin's lymphoma, particularly in relation to the Sellafield Nuclear Fuel Reprocessing Plant, the Dounreay Nuclear Energy*

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[39] Ibid., pp.231-232.

[40] Ibid., p.232.

[41] Ibid., p.232.

Plant, and the Aldermaston and Burgfield Nuclear Weapons Producing Plants in the United Kingdom (Gardner et al., 1990; Urquhart et al., 1991). To evaluate reasons for the sustained excesses of childhood leukemia and lymphoma that were observed in the village of Seascale near Sellafield, Gardner et al. (1990) conducted a case-control study and reported an association between leukemia and lymphoma in young persons and paternal preconception exposure. To further evaluate the potential relationship between leukemia in persons under 25 y of age and parental occupational exposure to ionizing radiation, the Nuclear Industry Family Study was undertaken which examined cancer risks in 39,557 children of male workers and 8,883 children of female workers. The offspring ranged from less than one month to 58 y of age. The median length of follow-up was ~23 y for both groups. Of the 111 children that developed a malignancy before 25 y of age (28 diagnosed with leukemia), standardized incidence ratios were not increased for offspring of mothers (or fathers) and there was no leukemia in children of women who were monitored for external sources of ionizing radiation (Roman et al., 1999). Relatively few children in this very large study had mothers whose work in the nuclear industry required monitoring and thus even this very large study could not contribute dose-response information about occupational radiation exposures during pregnancy and risk of childhood leukemia."[42]

4. Occupational Exposures – Medical Radiation Workers: According to NCRP 174, "*Cancers diagnosed prior to 20 y of age were examined among 105,950 offspring born during 1921 to 1984 to members of the U.S. radiological technologists' cohort (Johnson et al., 2008a). There were 145 childhood hematopoietic and lymphoproliferative malignancies (111 diagnosed in offspring of female radiologic technologists, 34 in offspring of male radiologic technologists) and 149 childhood solid tumors (115 diagnosed in offspring of female radiologic technologists, 34 in offspring of male radiologic technologists). The mean estimated in utero doses in the offspring of both male and female radiologic technologists declined about four – to sixfold from the 1930s through the 1970s and 1980s. Among female radiologic technologists, there was no statistically-significant increase in risk or dose response for leukemia, lymphoma, all solid tumors combined, or childhood cancer in their offspring overall in relation to in utero radiation exposure (in utero dose ranged from 0 to 13 mGy (0 to 1300 mrad). Based on 48 cases of lymphoma in offspring of female radiologic technologists, risks ranged from two- to threefold, elevated in all dose categories, but there was no statistically-significant linear trend. Overall, there was no convincing evidence of an increased risk of childhood cancer in the offspring of radiologic technologists in relation to the estimated maternal in utero doses."*[43]

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[42] Ibid., p.132.

[43] Ibid., p.133

5. Summary for Fetal Exposure and Subsequent Cancer Risk: NCRP 174 also reports, *"There was little evidence from epidemiologic studies of increased risks of childhood leukemia, other childhood cancers or adult cancers in offspring of mothers or fathers who were nuclear workers or medical radiation workers. These findings, however, were based on relatively few studies."*[44]

Dose Response Relationships for Stochastic Effects:

Although the Linear Non-Threshold (LNT) model is still being used to estimate risk, there is still much uncertainty in the shape of the dose-response curve below 0.1 Gy (10 rad).

According to NCRP 174, *"From the viewpoint of protecting individuals and populations exposed to ionizing radiation by establishing a practical radiation protection system, use of the linear-non-threshold hypothesis is a cautious and functional approach. From the viewpoint of quantitative risk assessment at the lower levels of organ or whole-body dose (e.g., < 0.1 Gy [<10 rad]) experienced by most individuals and populations from the prevalent ionizing radiation sources, use of a linear- non-threshold dose-response relationship is more uncertain. Based on the evaluation of health effects presented in this [NCRP 174], this uncertainty in quantitative risk assessment is particularly the case at these lower doses for stochastic effects on the gamete, embryo, fetus, and nursing infant."*[45]

NCRP 174 also reports, *"Radiation-induced carcinogenesis is assumed to be a stochastic effect with no threshold dose, so that theoretically there is a risk at low doses. The increased risk of cancer following high doses of ionizing radiation to adult populations has been demonstrated in the atomic-bomb survivors and in many other populations receiving high doses. However, the magnitude of the risk of cancer from embryonic and fetal exposures following diagnostic radiological procedures remains controversial. The arguments center around interpreting the same observed data, with some emphasizing the strong statistical associations seen in many case-control studies of prenatal x ray (Wakeford, 2008) and others questioning the causal nature of the association because of possible interview bias as well as the absence of a statistically-significant increase in risk in cohort investigations (Boice and Miller, 1999). Recent publications and analyses of the Japanese atomic-bomb survivor data indicate that the risk is lower for the irradiated embryo and fetus than for the irradiated child (Preston et al., 2008)."*[46]

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[44] Ibid., p.148.

[45] Ibid., pp.31-32.

[46] Ibid., pp.65-66.

2.0 Response to Specific Questions for Public Comment

2.1 C-1: *Are there any significant anticipated impacts associated with reducing the dose limit to the embryo/fetus of a declared woman, including operational impacts? What are the potential implementation and operational costs?*

Response

Based on the current scientific knowledge, a limit of 1 mSv (100 mrem) post-declaration could be unduly limiting or less restrictive than the current regulatory limit of 5 mSv (500 mrem); depending on when the woman declares her pregnancy and the amount of accumulated occupational radiation exposure received prior to declaration. For example:

1. A woman declares her pregnancy within the first two months of conception. Her pre-declaration dose is 0 mSv (0 mrem). She is allowed to receive 1 mSv (100 mrem) over the remaining 7 months. Assuming an administrative threshold control level of 0.8 mSv (80 mrem), the declared pregnant worker would be allowed approximately 0.11 mSv (11 mrem) per month for the next 7 months. This monthly threshold control level would essentially restrict her from any more occupational exposure for the rest of her pregnancy.

2. A woman declares her pregnancy within the first two months of conception. Her pre-declaration dose is 6 mSv (600 mrem). Per the current NRC regulations she would be allowed an additional 0.5 mSv (50 mrem) of exposure. Per ICRP 103, she would be allowed an additional 1 mSv (100 mrem) of exposure.

An unintended consequence of lowering the dose limit over the entire gestation period and possibly even for the time since declaration could be that fewer workers will be willing to declare a pregnancy to avoid potential loss of income. This could be particularly true for "supplemental" outage workers in nuclear power plants who are paid only for "hours worked" and for whom non-radiological work is usually not available. In effect, for these workers the embryo-fetus could potentially receive more dose under the newly proposed limit vs. the current limit.

Changes in exposure monitoring programs may be necessary (i.e., different dosimetry, different restrictions on work, etc.), and meeting the required Lower Limit of Detection (LLD) (outside of the laboratory) with existing personnel dosimetry may provide challenges to licensees if the limit is lowered to 1 mSv (100 mrem).

It should also be recognized that the lowering of the prenatal dose limit could place difficult restraints on licensees for monitoring of internal exposures that may already be at the sensitivity or detection levels for bioassay measurements for many radionuclides. Calculation of prenatal radiation doses from internally deposited radionuclides already has many associated difficulties, including the lack of quantitative information about prenatal radionuclides and transfer of the radionuclides across the placenta.

2.2 C-2: *Are there any benefits or impacts associated with applying the reduced dose limit over the entire gestation period, or only to the period after declaration?*

Response

The impact of a dose limit of 1 mSv (100 mrem) if applied over the entire gestation period would become unduly limiting and the margin between dose received and the regulatory limit is significantly reduced. The worker would most likely be restricted from any further radiological work in order to avoid exceeding a regulatory limit. Furthermore, the worker may decide not to declare the pregnancy (possibly due to economic considerations) and would therefore, not be afforded the protections that are set forth upon declaration.

As discussed in response to Question C-1, based on the current scientific knowledge, a limit of 1 mSv (100 mrem) post-declaration could be unduly limiting or less restrictive than the current regulatory limit of 5 mSv (500 mrem); depending on when the woman declares her pregnancy and the amount of accumulated occupational radiation exposure received prior to declaration. Please refer to the example contained in Question C-1 above.

However, should the NRC align their regulations with ICRP Publication 103, a 1 mSv (100 mrem) dose limit applied after declaration, then no retrospective calculation (as currently required by NRC regulations) would be necessary, reducing licensee resources expended for this assessment.

Note: If the NRC decides to apply the limit over the entire gestation, the same regulatory requirement that currently exists in 10 CFR 20.1208(d)[47] would need to be added to ensure licensees are deemed in compliance with the regulations when the retrospective assessment determines that the 1 mSv (100 mrem) was already exceeded prior to declaration.

[47] 10 CFR Part 20.1208, "*Dose equivalent to an embryo/fetus*".

2.3 C-3: *Are there any anticipated implementation impacts on recordkeeping if the dose limit to the embryo/fetus is lowered to 1 mSv (100 mrem)? What are the potential implementation and operational costs?*

Response

If the NRC decides to align their regulations with ICRP Publication 103 (i.e., 1 mSv (100 mrem) post declaration) then no retrospective calculation would be necessary, reducing licensee resources expended for this assessment. The following are the potential implementation and operational costs expected should the NRC align their regulations to ICRP 103:

- General Employee Training will require revision, incorporating the new limits and guidance. This may require two (2) revisions based on the timing for the limitation of the proposed regulation and any revisions that will be required to Regulatory Guide 8.13[48]. The estimated costs for this would be approximately $5000 per revision per facility.

- Conduct employee training. We anticipate that this could be accomplished during annual general employee training, taking approximately 15 minutes per employee. Total costs for implementation are dependent on number of employees at a facility, but is anticipated to be at a minimum of $50,000 per facility.

- Procedures will require revision to incorporate the revised guidance. Typically, two (2) procedures will require revision or approximately $12,000 per facility to revise and implement the revised procedures.

- The revision will likely result in increased monitoring and reading of dosimetric devices. While the actual costs of reading these devices are minimal, there will be the associated administrative burden to process the information into personnel dosimetry records. The cost associated with this is approximately $1000 per declared pregnant worker.

The approximate cost for implementing this change will approach $80,000 per facility.

[48] NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure".

2.4 C-4: *Are there technological implementation issues, such as limits of detection, which could make adoption of the ICRP Publication 103 (2007) recommendation difficult in certain circumstances?*

Response

Meeting the required LLD (outside of the laboratory) for both internal and external dose monitoring may provide challenges to licensees if the limit is lowered to 1 mSv (100 mrem). Internal monitoring methods must have adequate sensitivities and accuracy to meet the program objectives and demonstrate compliance with the applicable limits. If the dose limit is lowered, it will be more difficult to estimate internal exposures for a number of reasons. Embryo/fetus dose cannot be directly measured but must be based on estimates of worker intakes derived from bioassay sampling. There may be circumstances where monitoring techniques do not have the sensitivity to accurately detect the embryo/fetus dose at the 1 mSv (100 mrem) level which could place licensees in a regulatory non-compliance situation.

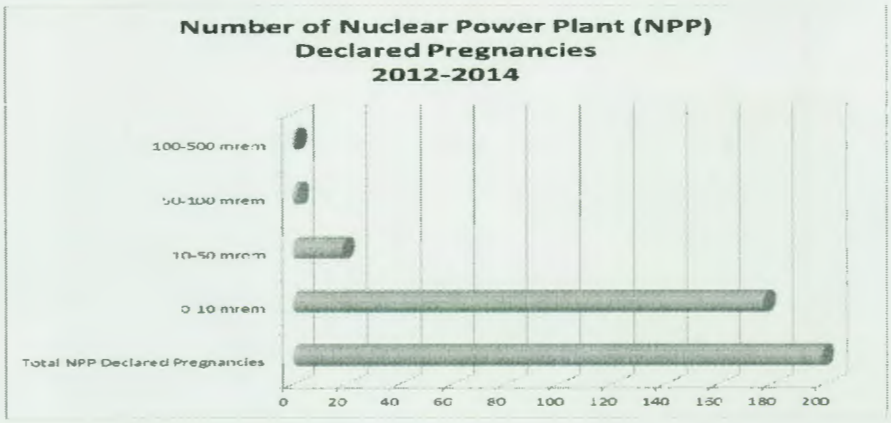
External monitoring methods with the current dosimetry for personnel must also demonstrate compliance with applicable limits. If the dose limit is lowered it will be more difficult to meet the LLD for the Thermoluminescent Dosimeter (TLD) or Optically Stimulated Luminescence Dosimeter (OSLD) when trying to ensure a uniform monthly exposure and keep the total dose after declaration well below the regulatory limit. Again, this would essentially restrict the declared pregnant worker from any further occupational radiological exposure.

2.5 C-5: *Are there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for these data?*

Response

Data from a recent survey of 36 U.S. Nuclear Power Plants (NPPs) indicates that there were a total of 203 declared pregnant workers over the last three (3) years (2012-2014). The minimum dose during the entire pregnancy was 0 mSv (0 mrem) and the maximum dose was 1.26 mSv (126 mrem). Refer to the following data table and graph.

Total Number of Nuclear Power Plant Declared Pregnant Workers (2012-2014)	0-0.1 mSV (0-10 mrem)	0.1-0.5 mSv (10-50 mrem)	0.5-1 mSv (50-100 mrem)	1-5 mSv (100-500 mrem)
203	180	20	2	1[49]



This data demonstrates that NPPs are adequately applying exposure control to the declared pregnant worker through effective use of ALARA principles.

ISSUE D

Individual Protection - ALARA

1.0 Introduction

Should the NRC revise 10 CFR 20 to add additional requirements and guidance to ensure that cumulative occupational exposures are examined and that progressive restrictions are taken as exposures increase?

Exelon recommends that the NRC not revise 10 CFR 20 to add additional ALARA requirements, as it would be an unnecessary burden on those licensees that have embraced and demonstrated significant dose reduction using the ALARA concept. This is supported in NRC

[49] Note that the 1.26 mSv (126 mrem) maximum was pre-declaration dose; the worker didn't know she was pregnant until she started her next job at another facility. She then declared her pregnancy and received 0 mSv (0 mrem) over the remainder of the pregnancy.

Issue Paper 4, "Individual Protection – ALARA Planning,"[50] where the NRC notes that nuclear power reactor operators have been successful in reducing individual exposures.

NRC regulations currently state that: *"the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."*[51] Clearly the NRC already has authority to enforce these regulations, holding licensees accountable for establishing and implementing effective ALARA programs. If the NRC is concerned that certain classes of licensees are not adequately implementing effective ALARA programs, the Commission should provide adequate guidance on what is expected of those licensees. Regulatory Guides 8.8[52] and 8.10 [53] are examples of such guidance.

NRC Inspection Manual Procedure 88030, "Radiation Protection,"[54] requires inspection of nuclear energy industry licensees' ALARA programs. Appendix B, Section 02.11, specifically provides guidance for ALARA program inspection. Additional inspection guidance is provided in NRC Inspection Procedure 71124, "Radiation Safety – Public and Occupational,"[55] with attachment 71124.02 applying to occupational ALARA planning and controls. For nuclear power reactor operators the Reactor Oversight Process (ROP) adds an additional layer of oversight. Inspection Manual Chapter (IMC) 0308, Appendix C, "Technical Basis for Occupational Radiation Safety Significance Determination Process," describes the ALARA aspect of the NRC's Reactor Oversight Process (ROP).

The 1987 "Federal Radiation Protection Guidance for Occupational Exposure," defines an "administrative control level" as a requirement *"determined by a competent authority of the management of an institution or facility. They are not primary limits, and may therefore be exceeded, upon approval of competent authority or management, as situations dictate."* [56]

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[50] NRC ADAMS Accession Number ML14084A340, http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html, p.6.

[51] 10 CFR 20.1101(b)

[52] NRC Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable".

[53] NRC Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable".

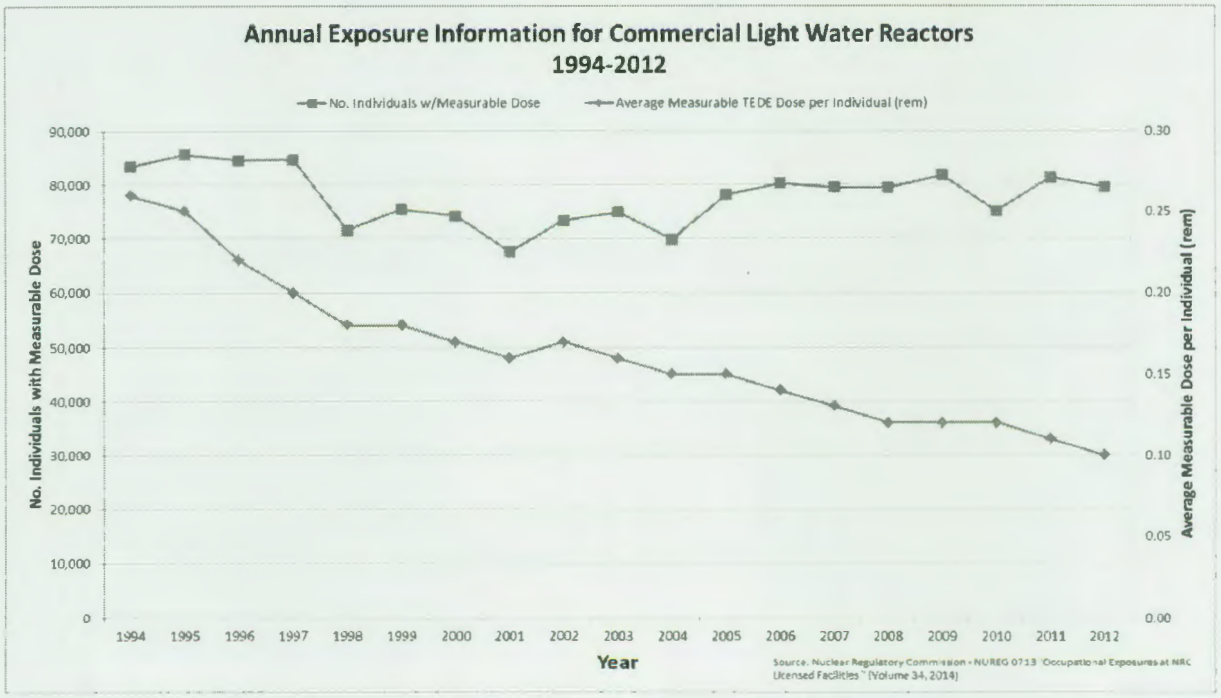
[54] NRC ADAMS Accession Number ML13311A692.

[55] NRC ADAMS Accession Number ML092190586.

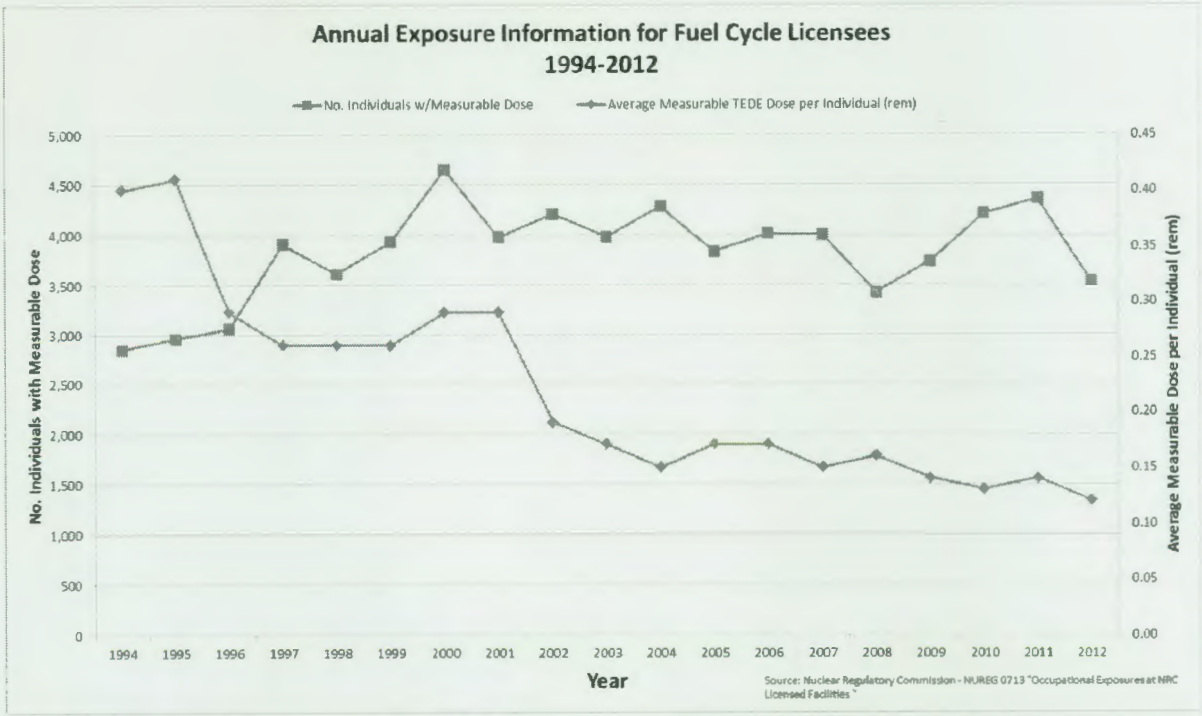
[56] 52 FR 2833; January 27, 1987.

The July 25, 2014, Federal Register ANPR notice sites the above reference in footnote 31. Clearly the use of Administrative Control Levels (ACL) was expected to be a management tool to provide increasing levels of oversight for occupational exposure situations. Nuclear industry licensees have used ACLs, or administrative control thresholds, for many years for numerous applications. For example, many utilities have set an administrative threshold of 20 mSv/year (2 rem/year) to control individual annual dose. To exceed this administrative threshold, specific requirements must be met in order to be granted a "dose extension" by facility management. These requirements include having complete dosimetry records for the current year up to that point, participation in specific ALARA planning activities or briefings, receiving incremental administrative threshold increases to closely monitor dose for the remainder of the year, etc. Furthermore, as NRC regulatory limits are approached, increasing levels of plant management approval is required (e.g., Plant Manager and Vice President) to assure that appropriate ALARA planning and controls are in place to minimize and control further dose for that individual. Therefore, considering that ACLs are intended to be management tools and are already in place at nuclear energy industry facilities, formal ACLs should not be placed into NRC regulations.

Under current regulations and guidance documents for ALARA, nuclear power plants and fuel cycle facilities have effectively implemented the ALARA principles for many years and have demonstrated significant reduction in worker dose as shown on the graphs below:



[Note: Measurable dose includes any individual with a total effective dose equivalent (TEDE) greater than zero rem, including zero or no detectable dose.]



[Note: Measurable dose includes any individual with a total effective dose equivalent (TEDE) greater than zero rem, including zero or no detectable dose.]

To summarize, if the NRC desires to improve compliance with the current ALARA regulatory requirements, additional guidance should be provided for the class(es) of licensees that require improvement. NRC should not revise existing regulations that are currently being enforced and effective with the nuclear energy industry. Guidance for developing effective ALARA programs should be addressed in industry-specific regulatory guidance, similar to Regulatory Guides 8.8 and 8.10 that apply to the nuclear energy industry.

2.0 Response to Specific Questions for Public Comment

2.1 D-1: *What are the potential implications of adding specific ALARA planning and implementation requirements to the 10 CFR Part 20 regulations? What changes to licensee radiation protection programs could be anticipated? What would be the potential implementation and operational costs?*

Response

Exelon ALARA programs are currently developed and implemented in accordance with existing regulatory requirements and industry best practice guidance such as Regulatory Guides 8.8 and 8.10. If the NRC determines that additional requirements are necessary for other classes of licensees, consideration should be given to developing regulatory guidance specific to those licensees rather than changing existing regulations. In the

event that 10 CFR 20 is changed to require additional specific ALARA methodologies that are different from current industry operating practices, there could be significant costs incurred to revise programs, procedures and computer software as well as retraining of the workforce. Without specific information on what these changes could potentially be, the following is a general cost estimate for each facility:

- ALARA program governance changes - $250,000.
- Training material changes - $15,000.
- Training delivery to radiation workers - $120,000
- Advanced training for ALARA staff & work group ALARA coordinators - $20,000.
- Procedure changes - $80,000.

Total cost, excluding potential computer software changes, is estimated to be approximately $450,000 to $500,000 per facility to modify the ALARA program. If dose and work management software changes are required to implement the changes, the cost could easily exceed $1,000,000 per facility.

2.2 D-2: ***What regulatory language should be used for an additional ALARA planning requirement and what is the rationale for this language?***

Response

Regulatory language should be consistent with current NRC regulations and guidance. This would minimize burden on licensees that currently demonstrate effective ALARA programs by not requiring programmatic changes to align with any new language.

If changes are made to require additional ALARA planning requirements, the language should allow for setting licensee-established administrative dose thresholds below the regulatory limits. Language requiring specific administrative control limits could become a *defacto* regulatory limit and should be avoided. Allowing licensees to use a graded approach for setting administrative thresholds based on their specific operational needs and radiological risk will allow flexibility while providing a means for exercising control over individual and collective dose.

2.3 D-3: ***How does each of the described methodologies for addressing when an individual occupational worker approaches his or her cumulative dose for the year work for***

different classes of licensed uses (e.g., a worker at a nuclear reactor power plant versus an industrial radiographer versus medical personnel)? What are the benefits and impacts of the various approaches to ALARA planning on the various types of licensees?

Response

Any approach that allows a licensee to develop ALARA planning processes that considers their specific operational needs should be acceptable to the NRC. Each licensee has unique exposure situations that must be considered in ALARA planning and in setting administrative dose thresholds. Setting licensee-selected thresholds that require additional management approvals and planning to exceed the threshold is an effective method of addressing individual doses.

NRC regulations currently require: "*procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).*"[57] The NRC should consider providing additional guidance in the form of regulatory guides, or other guidance, to assist licensees in developing stronger ALARA programs specific to each licensee rather than changing the existing regulations.

2.4 D-4: *Should licensees be allowed to establish different ACLs for different groups of occupational workers? If so, what should be the basis for the various groupings?*

Response

Administrative dose thresholds are currently used by most nuclear energy industry licensees to support their ALARA programs and provide a margin to existing regulatory dose limits. However, these licensees do not support the use of 10 CFR 20 to establish a regulatory requirement for ACLs. Such language could result in the ACLs becoming a *defacto* regulatory limit and should be avoided.

Licensees should be allowed to establish different dose control thresholds for worker classes based on the type of work they perform and level of radiological risk for that work. The thresholds should be developed by the specific licensee for internal program use and not prescribed as an industry standard ACL for a worker class.

Unique ALARA controls may be appropriate for different groups of workers depending on their assignments. Workers with limited exposure to radiation may have lower

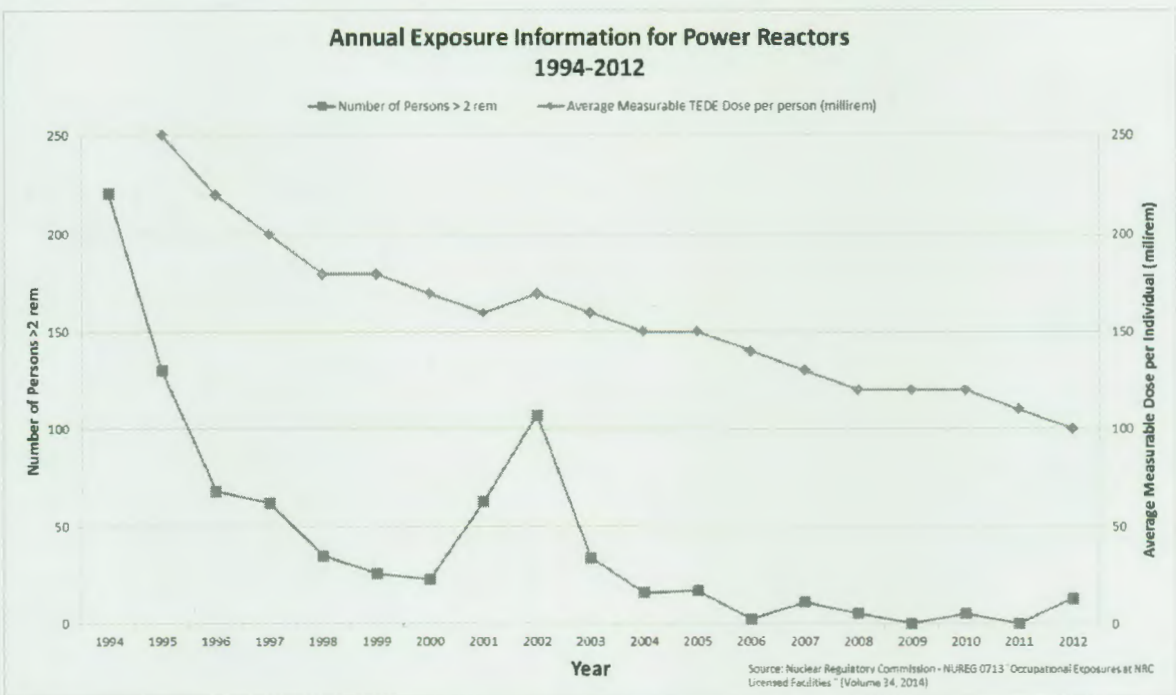
[57] 10 CFR Part 20.1101 (b) "Radiation protection programs".

administrative dose control thresholds than those working in an environment where more dose is expected, and therefore, be given a higher annual threshold. The ability to adjust administrative dose control thresholds based on specific licensee requirements will help to build ALARA programs that are risk-focused and allow financial resources to be applied to higher risk exposure situations.

2.5 D-5: How do the different methodologies previously discussed impact the ability of licensees to best address radiation protection within their programs?

Response

Exelon already has effective processes and programs to manage individual and cumulative exposures; therefore, the methodologies discussed in the Issue Papers are not considered necessary. The following graph shows the results of Nuclear Power Plant (NPP) management and control of worker dose:



[Notes: (1) The data spike in the number of individuals >2 rem in 2002 (107) is primarily due to radiological outage conditions at Quad Cities 1,2. Refer to NUREG-0713, volume 24 (2003), page 4-6 for a description of these events.
(2) Measurable dose includes any individual with a total effective dose equivalent (TEDE) greater than zero rem, including zero or no detectable dose.]

Allowing licensees to develop and set facility-specific administrative dose control thresholds will provide licensees with the ability to design cost-effective programs that are flexible and risk-based.

Finally, not all licensees are required to collect a complete annual exposure history for individuals that work at multiple facilities or for more than one licensee; therefore, determining cumulative exposure will be difficult and a major change for many NRC and Agreement State licensees.

2.6 D-6: *Other than the methodologies discussed in the preceding section, are there other ways to evaluate occupational lifetime cumulative exposures that should be considered?*

Response

In NRC Issue Paper 4[58], there is a discussion about lifetime dose limits and it is noted that in Statements of Consideration for the 1991 final rule the Commission rejected the use of a lifetime dose limit. NRC also states in the same paragraph that *"The NRC staff continues to support this position and does not plan to consider a lifetime limit."*

Collecting lifetime dose was eliminated by the NRC several years ago to reduce regulatory burden (except in the case of a Planned Special Exposure (PSE)). Re-implementation of a requirement to collect lifetime dose suggests that a national dose database would be required to assure all dose to all occupationally-exposed workers is tracked, particularly supplemental/contract workers and medical/other professionals that may work concurrently at more than one location. If workers also receive radiation exposure at facilities outside of the U.S., obtaining their lifetime dose information could be very difficult and time consuming for licensees to satisfactorily and successfully accomplish.

Currently, 10 CFR 20.2104(a)(2) only requires that NRC licensees attempt to collect cumulative dose information, except in the case of a PSE. If collecting lifetime dose data becomes a requirement, 10 CFR 20 must also be revised, along with NRC Regulatory Guide 8.7,[59] to provide instructions for collecting the information and reporting on NRC Form 4.

Given the difficulties and burden of collecting lifetime dose information, the most efficient means of managing lifetime dose would be to require effective ALARA programs along with effective regulatory guidance to assist licensees in developing strong ALARA programs. Furthermore, NRC inspection procedures should be aligned

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[58] NRC ADAMS Accession Number 14084A340, http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html, p.11.

[59] NRC Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

with the regulatory guidance to instruct inspectors on examining individual annual doses that exceed the licensee's administrative dose thresholds. The guidance documents should be developed to include strategies for managing individual dose and limiting dose well below the regulatory limits. The guidance should also include recommendations for managing dose for individuals working at more than one facility or multiple licensees.

2.7 D-7: ***What are the potential impacts to licensees, contractors, and dosimetry vendors of amending 10 CFR 20.2104 to require a licensee to account for exposure from an occupational worker's concurrent employment with another licensee? Are there any dosimetry vendors that provide concurrent dose records? Should the NRC consider provisions that would require individual occupational workers to provide their occupational dose information in addition to requiring such information from licensees?***

Response

Exelon currently requests year-to-date dose reports from individuals or from previous licensees for contractors and other transit workers; therefore, there would be minimal impact in most cases. Individuals working at nuclear energy facilities understand the importance of providing up-to-date dose records and how the lack of current records could limit their ability to work in these facilities (i.e., most licensees will not allow an individual to exceed their company or plant's administrative dose threshold without up-to-date record dose data).

Since dosimetry may be provided by several companies/vendors during the year for individuals that work at several facilities, it is probable that no single provider would possess the individual's total annual dose history. If dosimetry providers are required to provide dose information to licensees from other licensees, a licensee would be required to make such a request. In addition, this request would be subject to individual consent to release. In order to provide a nationwide means of collecting worker dose information, a national database should be established by the NRC for all radiation exposure similar to the nuclear power industry's Nuclear Energy Institute's (NEI's) Personnel Access Data System (PADS). Even if this database were to be developed, obtaining dose information for workers receiving dose outside of the U.S. may continue to be difficult to obtain.

For concurrent employment situations, ensuring real-time updates of dose information would provide an additional burden to licensees as workers could move between multiple facilities on a day-to-day basis. At best, dose estimates could be entered into a

database (if available), but dose of record can only be made available when primary dosimetry is processed.

2.8 **D-8:** ***Should the Agreement States be allowed to use more restrictive or prescriptive requirements if the NRC decides to use a performance-based approach? What are the benefits and impacts of the various methodologies discussed in the preceding section on Agreement State regulatory programs and Agreement State licensees?***

Response

Exelon believes that Federal and State requirements should be the same.

ISSUE E

Metrication – Units of Radiation Exposure and Dose

1.0 Introduction

How and in which order should units (SI and traditional) of radiation exposure and dose be expressed and reported to the NRC?

Exelon recommends that the NRC express radiation exposure and dose in either order, provided that they allow licensees to continue to use traditional units for the performance of facility-required regulatory functions and report to the NRC using traditional units. It is recognized that some professional organizations, such as the Health Physics Society,[60] support exclusive use of SI units for measuring and reporting radiation exposure and dose. However, Exelon recognizes several potentially negative unintended consequences that could result from such a change that are not considered by these professional organizations. These include the significant potential for human error that could lead to negative impacts on worker protection and protection to members of the public.

2.0 Response to Specific Questions for Public Comment

2.1 E-1: ***Will promulgation of amendments to the 10 CFR Part 20 regulations with dose limits and other measurements shown in dual units, with the SI units shown first, followed by the traditional units in parenthesis, cause an undue burden or hardship upon any licensees or class of licensees? If so, please explain and provide examples, including any potential implementation or operational costs.***

Response

Providing both traditional and SI units (in either order) within 10 CFR 20 is not expected to cause an undue burden or hardship upon nuclear energy industry licensees, provided that this practice continues to allow licensees to use traditional units for the performance of facility-required regulatory functions.

2.2 E-2: ***Should 10 CFR Part 20.2101 (a) be revised to allow licensees the option of providing records in SI units or in traditional units? Should licensees be allowed to provide reports in the units used in licensee records? Should licensees be required to record and report in both sets of units? Please provide reasons why or why not.***

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[60] Health Physics Society Position Statement, PS025-0, "Exclusive Use of SI Units To Express Radiological Quantities." (2012).

Response

While Exelon supports regulation that expresses radiation and exposure in both traditional and SI units, Exelon believes that regulations should allow licensees the option to continue to use and record doses in traditional units at nuclear energy facilities. Exelon also recommends that licensee records should be reported to NRC and radiation workers in traditional units. Reporting in dual sets of units would cause an undue burden upon nuclear energy industry licensees with little cost-benefit and provide no additional improvement of radiological protection to workers, the public or the environment.

Transition to the SI unit structure would require significant cost and effort for licensees to address, including:

- significant revision of existing radiation protection program procedures;
- re-training of nuclear workers and radiation protection personnel to the new units;
- conversion of radiation protection instrumentation, including some that would constitute modification of installed plant equipment; and
- conversion of existing records and reporting computer software platforms to support the use of SI units.

Exelon has decades of experience working under the traditional units and comprehends the quantity of these units. Even with significant costly worker training efforts, Exelon believes that full transition to SI units would result in a significant potential for worker error in converting between units and conceptual misunderstanding in the difference between the units. For example:

- A millirem is not the same as a millisievert;
- nuclear workers are trained that 1 millirem is a small quantity - 1/1000 of a rem; however,
- 1 millisievert is a significantly larger quantity of radiation and is equal to 100 millirem.

According to Eichholz et al., "*...it is generally assumed that even a conscientious and well-trained person may unconsciously revert to earlier training concepts under the effects of fatigue, nervous strain, pressure or frequent disturbances...*"[61] Exelon believes that this change would lead to nuclear worker confusion and errors in unit conversion, but most importantly, in worker comprehension of the radiological risk, having the potential to negatively impact nuclear worker protection and protection to members of the public, especially during radiological emergency situations.

Transition to SI units would also require changes to Emergency Preparedness (EP) regulations and implementation. This includes NRC and Federal Emergency Management Agency (FEMA) emergency planning regulations and guidance documents, and off-site response agency (e.g., State and county) emergency plans. Re-training on the use of SI units for public officials involved in nuclear emergency preparedness and licensee emergency response personnel would also be required.

Not transitioning EP plans concurrent with facility radiation protection programs would lead to inconsistency in unit usage among emergency responders, radiation protection professionals, and the public. As a consequence, potentially significant errors in protection of workers and the public could occur.

It is expected that there will be substantial monetary and resource costs on the part of nuclear energy licensees and public officials to transition to SI units with limited benefits. Most importantly, such a transition could adversely affect radiological protection to nuclear workers and to members of the public.

2.3 E-3: *Should the NRC amend the appendices for 10 CFR Part 20 to show values in SI units only, in traditional units only or both sets of units? If both SI and traditional units are provided, which sets of units should be considered as the regulatory standard? If only one set of units is specified, what would be the most effective means to provide the other set of units (e.g., in a separate guidance publication)? Please provide reasons for why or why not.*

Response

While Exelon supports regulation that includes both traditional and SI units, we believe that such language should allow licensees the option to continue to use traditional units and to provide reports in those units.

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[61] NUREG/CR-1419, ORNL/NUREG-68, "Cost-Benefit Effects of Conversion to SI Units In Health Physics," (1980) p.28.

As such, a revision to 10 CFR 20 and any supporting appendices should provide values either in traditional units, or in both units. It is recognized that providing both units may necessarily add complexity to the tables; however, reorganization of the appendices to separate the three tables should be sufficient to allow the use of both sets of units while maintaining readability.

ISSUE F

Reporting of Occupational Exposure

1.0 Introduction

How should the NRC improve reporting of occupational exposure by NRC and Agreement State licensees, including those who do not currently submit reports?

Exelon believes that the NRC should not revise current regulations requiring additional licensees, including Agreement State licensees, to report occupational exposure per 10 CFR 20.2206 without first performing a thorough cost benefit analysis for each potential licensee class. This analysis should assess if the value of collecting dose information exceeds the resources necessary to establish a process or platform to collect data and licensee resources to manage data collection for regulatory compliance.

2.0 Response to Specific Questions for Public Comment

2.1 F-1: *What criteria should the NRC use to identify additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR 20.2206(a)?*

Response

Exelon believes that the NRC should establish criteria for any licensee with regulated sources of exposure that could reasonably result in an excess of 10% of the dose limit, which is currently 50 mSv (5 rem).

2.2 F-2: *What are the benefits of collecting occupational exposure information in one central database to assess the total annual occupational exposure of those individuals who work at more than one licensed facility or contractor facility during the calendar year and receive occupational exposures at these facilities?*

Response

Exelon believes that several benefits are gained by utilizing one central database to collect and analyze occupational exposure, including the ability: 1) to capture all dose from licensees; 2) to trend dose based on licensee type and ability to analyze for adverse trends; 3) for regulators to assess data prior to development of radiation protection regulation revisions and potential occupational radiation exposure incidents;

and 4) of regulators to more accurately respond to public information requests for such exposure information.

2.3 **F-3:** ***Should Agreement States be required to adopt regulations that are compatible with the requirements in 10CFR 20.2206?***

Response

Exelon currently complies with 10CFR20.2206(s) and offers no comments related to this question.

2.4 **F-4:** ***Should the NRC consider a gradual expansion of the 10 CFR 20.2206 licensee reporting categories in a step-wise fashion (e.g., staggered compliance dates for different categories of licensees)? What are the advantages or disadvantages for this option?***

Response

Exelon currently complies with 10CFR20.2206(s) and offers no comments related to this question.

2.5 **F-5:** ***What are the potential implementation and operational costs associated with expanding the occupational exposure reporting requirements?***

Response

Exelon currently complies with 10CFR20.2206(s) and offers no comments related to this question.