HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

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U.S. Nuclear Regulatory Commission
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Subject: Comments in Response to Advance Notice of Proposed Rulemaking for Potential Changes to 10 CFR Part 20, Standards for Protection Against Radiation

The Health Physics Society[1] (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments in response to the Advance Notice of Proposed Rulemaking (ANPR) published July 25, 2014 relating to potential changes to 10 CFR 20.

Where the HPS has a formal position, it is noted; where it does not, we have provided information that the NRC may want to consider. We will continue to follow the rulemaking as it evolves.

The HPS appreciates this opportunity to provide comments. If you have any questions regarding these comments, please feel free to contact me at 714-456-5607 or bhamrick@uci.edu.

Sincerely,

Barbara L. Hamrick

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c: Brett Burk, HPS Executive Director
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[1] The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

***Issue 1*: Update 10 Code of Federal Regulations, Part 20 (10 CFR 20), to Align With International Commission on Radiological Protection (ICRP) Publication 103 Methodology and Terminology**

Issue: Should the Nuclear Regulatory Commission (NRC) revise 10 CFR 20 to more closely align with the ICRP Publication 103 (2007) methodology and terminology for dose assessment?

Response: In January 1992, the Health Physics Society (HPS) issued a position statement, "Compatibility in Radiation Safety Regulations," which was most recently reaffirmed in July 2007. This statement recommends that "radiation safety standards . . . be consistent with the recommendations of the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and scientific consensus standards."[1] From that perspective, HPS supports revision of 10 CFR 20 to more closely align with the ICRP Publication 103 methodology and terminology. However, this realignment may result in little, if any, improvement in worker or public safety. Therefore, HPS recommends that the NRC work closely with licensees throughout the process to minimize the resource burden that implementation will cause.

Q1–1: What are the implications of changing the NRC's regulations to specify ''total effective dose'' in place of the current term ''total effective dose equivalent"?

- To the extent possible, please provide specific implementation and operational cost information on the impacts of this change relative to licensee procedures, training, recordkeeping, and reporting. This information is necessary for the NRC to determine whether the imposition of such requirements on NRC licensees is justified.

Response: HPS supports the use of "total effective dose" or "effective dose" to align with ICRP Publication 103; however, the costs could be significant. The nuclear power industry has indicated that costs could exceed $500,000 per facility to make the necessary documentation and software changes and to provide training to the workforce. HPS did not independently assess the potential costs or validate the foregoing estimate.

Other organizations, such as dosimetry vendors, academic medical centers, research reactors, and even small material licensees would also bear additional costs related to procedure and software revisions and to training.

[1] Health Physics Society. Compatibility in radiation safety regulations. Health Physics Society position PS004-1; reaffirmed July 2007. Available at: http://hps.org/documents/compatibility_ps004-1.pdf. Accessed 9 March 2015.

Q1–2: 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: The NRC may want to consider allowing three to five years for implementation.

Discussion: Previous revisions to NRC regulations to coincide more closely with ICRP recommendations represented significant changes in the way radiation doses were calculated as well as changes to the dose limits. In this case, the proposed change is to terminology and methodology for calculating doses but not to the dose limits (with the exception of dose to the lens of the eye). Given the fact that this proposed change refers primarily to methodology and terminology and not the dose limits themselves, the period of time over which it would be reasonable to implement the changes could be quite short; on the other hand, since the changes to terminology and methodology are not expected to result in any significant safety savings, the time to implementation is not critical from a worker or public safety perspective.

Given the potential costs and the low safety significance of the proposed changes, it may be appropriate to provide a moderate period (perhaps three to five years) to allow licensees to make a phased transition over time.

Q1–3: How should the calculations of effluent concentration, currently in the 10 CFR 20 radiation protection regulations, be modified to reflect advances in modeling that are now available?

- In particular, the NRC is interested in preliminary views on the age- and gender-averaged approach.

Response: The existing calculational approaches have been demonstrated to be conservative and protective of the public and the environment. From a practical standpoint, the inclusion of gender- and age-specific concentrations will generally result in default to the use of the most conservative number, since a licensee cannot control the population that may be exposed. As suggested in the advance notice of proposed rulemaking (ANPR), consideration of a gender- and age-weighted standard person may be the most appropriate approach.

Q1–4: Should the public dose limit of 0.5 mSv continue to be the basis for the effluent concentration limits for the radionuclides in 10 CFR 20, Appendix B, Table 2, Columns 1 and 2? Should it be reduced or otherwise modified?

Response: HPS recommends maintaining the public dose limit of 0.5 mSv. There is substantial and convincing scientific evidence for health risks following high-dose exposures. However, below 50–100 mSv (which includes occupational and

environmental exposures), risks of health effects are either too small to be observed or are nonexistent.[2]

Furthermore, there is no indication that the current effluent limits result in any actual individual doses to the public in excess of 1 mSv. Reductions in dose limits may result in an increase in risk in other areas and should be evaluated within the context of all risks and benefits. For example, a cyclotron producing radionuclides for diagnosis and treatment of cancer or other diseases, if unable to meet more restrictive effluent limits in other ways, may need to decrease production to meet reduced effluent limits, decreasing the number of patients who can receive the benefit of these radionuclides and potentially raising the cost of imaging and therapeutic procedures. Thus, reduced effluent limits could result in a reduction in dose to a *theoretical* individual, while denying access of potentially lifesaving radionuclides to *actual* patients. Changing the effluent limit is also likely to have a significant financial impact, with an undetectable increase in public safety.

***Issue 2*: Occupational Dose Limit for the Lens of the Eye**

Response: HPS recommends that NRC perform further evaluation before making any decisions regarding a reduction to the dose limit for the lens of the eye.

Q2–1: 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: HPS suggests that NRC may wish to consider conducting an in-depth analysis of the current state of the scientific data on this subject. The most recent publications on cataract risk following occupational exposure continue to support a lower risk threshold; however, the recommended dose limit remains open to further discussion.

Discussion: Present dose limits are based on decades-old observations of accidentally exposed individuals or radiation-therapy patients with short follow-up periods and relatively small numbers of subjects with exposures below 2 Gy.[3] The ability to quantify early, radiation-associated lens changes was limited by methodological approaches which failed to take into account the fact that at lower doses lens changes take years to progress to true visual disability.

Within the past decade, newer findings (including a diverse range of individuals and settings such as occupational, therapeutic, and accidental exposures) strongly suggest

[2] Health Physics Society. Radiation risk in perspective. Health Physics Society Position Statement PS010-2; revised July 2010. Available at: http://hps.org/documents/risk_ps010-2.pdf. Accessed 9 March 2015.

[3] Kleiman NJ. Radiation cataract. Ann ICRP 41(3–4), 80–97; 2012. DOI:10.1016/j.icrp.2012.06.018.

that radiation-associated visual disability may occur at significantly lower doses and that given sufficient latency, chronic, prolonged exposures and acute exposures result in similar cataract outcomes.[4] These epidemiological and clinical findings are further supported by a variety of experimental data, including animal studies, which indicate genotoxic damage leading to aberrant cell division and differentiation as the likely initiating insult.[5]

Most recently, detailed dilated slit-lamp examinations of the lenses of physicians who routinely perform fluoroscopically guided procedures demonstrated an almost twofold increase in prevalence of radiation associated lens changes relative to nonirradiated controls.[6] It should be noted, however, that while lower dose limits appear prudent and supported by a variety of epidemiological, biological, and clinical data, additional dosimetry would be useful to establish a clear threshold, if any, and a more reliable dose-effect relationship.

Q2–2: How should the impact of a radiation-induced cataract be viewed in comparison with other potential radiation effects?

Response: HPS wishes to bring the following information to the attention of NRC:

- Cataract surgery is generally viewed as an ophthalmological procedure with relatively low morbidity and mortality but with considerable overall economic costs; e.g., consuming greater than 40% of overall U.S. ocular disease expenditures (approximately $5.1 billion) in 1999.[7] Nevertheless, available data suggest mortality following cataract surgery is on the order of 0.1%[8,9] and that morbidity, defined both from an ophthalmological as well as medical standpoint, is considerably higher.
- Of equal import, prior to a documented clinical need for cataract surgery, there may be accompanying progressive decreases in visual acuity, contrast sensitivity, and visual function that may negatively impact worker performance.[10] There is anecdotal

[4] Shore RE, Neriishi J, Nakashima E. Epidemiological studies of cataract risk at low to moderate radiation doses: (not) seeing is believing. Rad Res 174(6):889894; 2010. DOI:10.1667/RR1884.1.

[5] Bouffler S, Ainsbury E, Gilvin P, Harrison J. Radiation-induced cataracts: the Health Protection Agency's response to the ICRP statement on tissue reactions and recommendation on the dose limit for the eye lens. J Radiol Prot 32:479–488; 2012. DOI:10.1088/0952-4746/32/4/479.

[6] Vano E, Kleiman N, Duran A, Romano-Miller M, Rehani M. Radiation-associated lens opacities in catheterization personnel: results of a survey and direct assessments. J Vasc Interven Radiol 24:197–202; 2013. DOI:10.1016/jvir.2012.10.1016.

[7] Smithen LM, Brown GC, Brown MM. Dollars and sight: the economics of ophthalmology. Curr Opin Ophthalmol 15(3):173–180; 2004.

[8] Badrinath SS, Bhaskaran S, Sundararaj I, Rao BS, Mukesh BN. Mortality and morbidity associated with ophthalmic surgery. Ophthalmic Surg Lasers 26(6):535–541; 1995.

[9] Greenberg PB, Liu J, Wu W-C, Jiang L, Tseng VL, Scott IU, Friedmann PD. Predictors of mortality within 90 days of cataract surgery. Ophthalmol 2010 117(10):1894–1899. DOI:10.1016/j.ophtha.2010.02.009

[10] Lundström M, Goh PP, Henry Y, Salowi MA, Barry P, Manning S, Rosen P, Stenevi U. The changing pattern of cataract surgery indications: a 5-year study of 2 cataract surgery databases. Ophthalmology 122(1):31–38; 2015. DOI:10.1016/j.ophtha.2014.07.047.

evidence that the decrement in contrast sensitivity associated with posterior subcapsular cataract[11], the type most closely associated with radiation exposure, is a more important factor in worker performance than frank changes in visual acuity. For example, interventional physicians report difficulty in seeing fluoroscopic images well before documented acuity changes on eye exams.

- An additional consideration regarding lens exposure is that the high radiosensitivity of the lens, coupled with the ability to noninvasively quantify radiation-associated lens changes over time in an individual, may prove useful in quantifying individual radiation exposures and responses as well as in providing a biological dosimeter regarding radiation exposure to other tissues and structures above the neck.

Q2–3: What mechanisms could be applied to keep the cumulative exposure to the lens of the eye below the threshold of 0.50 Gy?

Response: Personal protective equipment such as lead-glass eyewear with side shields, lead-glass face shields, and/or adjustable lead-glass shields, when properly used, can provide the necessary protection to reduce exposure to the eye below this dose. See Q2–5 below.

Q2–4: What methods should be allowed for measurement or assessment of the dose to the lens of the eye?

Response: ***HPS offers the following recommendation from NRCP 168[12] for consideration.*** "Recommendation 25: Monitoring of equivalent dose to the lens of the eye should be performed with a personal dosimeter placed either at the collar level outside any radiation protective garment or near the eyes."

Nevertheless, it should be noted that even small deviations in dosimeter placement can significantly change the estimated dose to the lenses of the eyes. A substantial amount of guidance should be developed to direct licensees as to appropriate measurement and calculational techniques, acknowledging that in the real world the measured dose to the lenses of the eyes will be an approximation within a much larger range of possible actual doses.

Q2–5: What methods should be allowed for recording dose to the lens of the eye when the eyes are protected?

[11] Stifter E, Sacu S, Thaler A, Weghaupt H. Contrast acuity in cataracts of different morphology and association to self-reported visual function. Invest Ophthalmol Vis Sci 47(12):5412–5422; 2006.

[12] National Council on Radiation Protection and Measurements. Radiation dose management for fluoroscopically guided interventional medical procedures. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report 168; p 142; 2011.

Response: HPS recommends NRC consider adopting regulations that allow for a reduction in the dose recorded on the dosimeter of record based on the additional protection provided (e.g., lead glass eyewear). This corrected dose would be the dose of record for the lenses of the eyes.

Discussion: This approach would be consistent with that described in NRC Regulatory Issue Summary 2002-06: Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-rays (16 April 2002), which provides methods to adjust a worker's total effective dose equivalent based on the number and placement of dosimeters worn in conjunction with protective leaded clothing. In addition, it may be appropriate to assign different protection factors for different types of equipment designed to protect the lenses of the eyes, much like the protective factors used to modify internal exposure when a respirator is used (see 10 CFR 20, Appendix A).

Appropriate standards or guidance should describe acceptable types of protective eyewear and dose reduction factor(s). For example, it has been demonstrated that when the source is in front of the operator of x-ray equipment, the lead equivalence of the protective eyewear is important. When the source is to the side of the operator, the presence of side shields had a significant impact on protection.[13]

Q2–6: 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 to 50 mSv?

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

Response: It is likely that such a reduction would require the increased use of protective eyewear and/or shields in a medical setting. Prescription eyewear containing lead glass and side shields generally cost in excess of $300 per individual and would need to be replaced every 12 to 24 months as the individual refraction prescription changes with age. A single additional in-room shield generally costs in excess of $5,000. The dollar figures are approximate and have not been validated.

A review of existing procedures for reporting the assigned dose to lenses of the eyes should be undertaken to assess the size of the population that may be affected by a reduction in dose limits.

The Landauer Corporation responded to a request from HPS by supplying 68,749 monthly dosimeter readings for 2014 from the population of occupational workers that

[13] Sturchio GM, Newcomb RD, Molella R, Varkey P, Hagen PT, Schueler BA. Protective eyewear selection for interventional fluoroscopy. Health Phys 104(2S):S11–S16; 2013.

wear two badges (generally, one at the collar and one near the waist under a leaded garment). The request was for all readings that had a deep dose equivalent of at least 0.01 mSv.

These data provide an informal basis for several preliminary insights into the question regarding the impacts of a dose limit reduction. Several assumptions were made in this analysis:

- Each reported dose is representative of a typical monthly exposure.
- No worker was wearing eye protection.
- The reported doses were multiplied by 12 to estimate the annual exposure for each worker.

Further it was assumed that in terms of the actually exposed worker population (i.e., a reading of at least 0.01 mSv on the monitor):

- 12% of the workers would exceed the proposed 50 mSv limit.
- 0.26% would exceed the current 150 mSv limit.
- 75 mSv is the 99^{th} cumulative percentage (99^{th} percentile).

While most dosimeter system designs incorporate a mechanism to measure the lens dose at the tissue thickness of interest (3 mm), American National Standards Institute (ANSI) N13.11 and the National Voluntary Laboratory Accreditation Program (NVLAP) protocols based upon the consensus standard currently emphasize the shallow and deep tissue depths. While it may be argued that these depths span the dose point of interest for the lens of the eye, the profession may deem it necessary to modify these key aspects of personnel dosimetry accreditation to better support a more restrictive limit on dose to the lens of the eye.

Since the question often arises as to how other countries are able to comply with reduced limits, it is worth pointing out that a review of the literature from the last two years on this topic showed:

- No discussion or reference to regulatory guidance about how one should assign a protection factor for protective eyewear.
- The dose can vary dramatically across the face of a medical worker based on the angle of the worker's head with respect to the patient when using fluoroscopy.
- There are no commercially available dosimeters designed specifically to assess eye dose.
- There is no universal standard for assessing eye dose beyond simply reporting the dose from a collar badge or from thermoluminescent dosimetry chips placed beneath the eyewear without modification.
- Recommendations to reduce dose include using overhead shielding, lead glass eyewear, and side shields, but there is no universal standard for assigning a protective factor for the use of these devices.

Without specific standards governing the positioning of the dosimeter and the appropriate algorithm to modify dosimeter dose based on positioning of the dosimeter versus the source, or by the use of protective equipment, it is not possible to evaluate the true compliance rate in countries with the reduced dose limit.

Issue 3: Dose Limit for Embryo/Fetus of a Declared Pregnant Occupational Worker

Response: There does not appear to be adequate justification to reduce this limit at this time.

Discussion: A reduction in occupational dose limit for the embryo/fetus of a declared pregnant occupational worker from the current 5 mSv dose limit for the entire pregnancy to the proposed 1 mSv 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.

NRC is faced with striking a reasonable balance between the dose limits and the mother's contributions as a radiation worker. Based on the excerpts provided below, it appears that the current limit for a declared pregnant worker of 5 mSv is protective 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 NCRP Report 174:

> *While there are limited epidemiologic studies of ionizing radiation exposures in human pregnancies from which to determine the no-adverse-effect level for developmental and reproductive effects, there are extensive mammalian 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 (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 . . .* [14]
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> *There is no convincing direct evidence of germ line mutation manifest as heritable disease in the offspring of humans that is attributable to preconception exposure to ionizing radiation, yet preconception exposure*

[14] National Council on Radiation Protection and Measurements. Preconception and prenatal radiation exposure: health effects and protective guidance. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report 174, p. 230; 2013.

> *clearly induces mutations in microbes and somatic cells of rodents and humans, and in offspring of irradiated male mice . . .* [15]
>
> *Based on animal studies, absorbed doses to the embryo > 0.2 Gy 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).*[16]
>
> *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 (weighted uterine dose) . . .* [17]
>
> *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) . . .* [18]

According to NCRP Report 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 exposed in utero; however, the data appear 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*.[19]

[15] Ibid., pp. 230–231.
[16] Ibid., p. 231.
[17] Ibid., p. 231.
[18] Ibid., p. 231.
[19] 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.[20]

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.[21]

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.[22]

Q3–1: Are there any significant anticipated impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman, including operational impacts? What are the potential implementation and operational costs?

Response: Depending on the timing of the declaration and the accumulated worker exposure, the limit of 1 mSv postdeclaration may be unduly limiting and it may be necessary or prudent to restrict the declared pregnant worker from any radiological work for the remainder of the pregnancy. However, it may also be less restrictive than the

[20] Ibid., pp. 231–232.
[21] Ibid., p. 232.
[22] Ibid., p. 232.

current regulations depending on when the pregnancy is declared. Furthermore, a reduction in dose limit may also give the perception that the current dose limit of 5 mSv is not protective.

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 at nuclear utilities who are paid only for hours worked and for whom nonradiological work is usually not available.

Changes in the monitoring program may be necessary (i.e., different dosimetry, different restrictions on work, etc.), and meeting a new lower limit of detection (LLD) may prove challenging, if administrative limits are also revised downward.

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 radionuclide uptake and transfer of the radionuclides across the placenta.

Q3–2: 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 if applied over the entire gestation period may be unduly limiting as the margin between dose received and the regulatory limit is significantly reduced. In many cases, it is likely that a declared pregnant worker would be restricted from any further radiological work in order to avoid exceeding an administrative limit, set to give early warning of a potential exceedance of a regulatory limit.

If the limit of 1 mSv applies postdeclaration, it may still be necessary to restrict the declared pregnant worker's activities; however, that will depend upon the timing of the declaration, which is up to the worker. In general, this would likely result in fewer restrictions than if the 1 mSv limit were applied over the entire gestation period, and comports with the ICRP position that no retrospective dose calculation be performed relative to the predeclaration gestation period.

Note: If NRC decides to apply the limit over the entire gestation period, the NRC may want to consider also including a requirement similar to that currently found in 10 CFR 20.1208(d),[23] such that licensees are deemed to be in compliance with the regulations

[23] Dose Equivalent to an Embryo/Fetus, 10 C.F.R. Sect. 20.1208 (2011).

when the retrospective assessment determines that the 1 mSv limit was exceeded prior to declaration.

Q3–3: Are there any anticipated implementation impacts on recordkeeping if the dose limit to the embryo/fetus is lowered to 1 mSv? What are the potential implementation and operational costs?

Response: In general, there are costs associated with any regulatory change, including the costs of recordkeeping which will generally require revised forms, revised software, and training.

Q3–4: Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP Publication 103 (2007) recommendation difficult in certain circumstances?

Response: Meeting the required LLD for both internal and external dose monitoring may provide challenges to licensees if the limit is lowered to 1 mSv. Methods to assess internal exposure must have adequate sensitivities and accuracy to meet the program objectives and demonstrate compliance with the applicable limits and also with the licensee's administrative limits. If the dose limit is lowered, it will be more difficult to estimate internal exposures for a number of reasons. Embryo/fetus doses cannot be directly measured but must be based on estimates of worker intakes. There may be circumstances where monitoring techniques do not have the sensitivity to detect the embryo/ fetus dose at the 1 mSv level which would place licensees in a regulatory noncompliance situation.

External monitoring methods with current personal dosimetry must also demonstrate compliance with applicable limits. If the dose limit is lowered it will be more difficult to meet the LLD for the dosimeter when trying to ensure a uniform monthly exposure and keep the total dose after declaration well below the regulatory limit. For example, access control would need to be denied at a value less than 1 mSv (i.e., at the administrative dose threshold) and the remaining dose would have to be divided up over each month leading to monthly averages of < 0.1 mSv. Although individual dosimeters are capable of recording doses in this range, it leaves a very small margin for uncertainty.

Issue 4: Individual Protection—ALARA Planning

Response: In lieu of additional as low as reasonably achievable (ALARA) requirements, the NRC may wish to consider enhanced guidance that reinforces the need for and methods to achieve an active and effective ALARA program.

Discussion: Given the often highly subjective nature of the ALARA philosophy, it does not lend itself easily to prescriptive regulation. Concepts such as ALARA are often difficult to enforce because of their inherent (and intentional) flexibility.

ALARA planning is already an integral part of the day-today operations of a successful radiation safety program. Guidance already counsels that administrative control levels (ACLs) should be set by the local radiation safety committee. ACLs are set based on the anticipated workload and the most common exposure pathway or operation. These ACLs require professional judgment that is based on training and experience in the environment in which these ACLs are set (e.g., medical facility versus laboratory research facility versus nuclear power plant), thus the need for the flexibility inherent in the concept.

HPS has a position paper on occupational doses and ALARA:

> *HPS believes the implementation of radiation safety standards and regulations has been responsible and adequate in providing for a safe industry, taking into account changes in occupational work practices over the last 50 years. This position is based on consideration of the following:*
>
> 1. *From the beginning of the widespread use of radiation and radioactivity in the United States, specific responsibilities have existed for those individuals and agencies charged with regulating the safe use of these materials.*
> 2. *Since the mid-1950s, radiation safety standards have included provisions for incorporating the philosophy of as low as reasonably achievable (ALARA) in radiation safety work practices.*
> 3. *The application of ALARA is founded in the professional judgment of radiation safety managers and personnel and is not, therefore, able to be used as a measure of whether or not a particular radiation safety program is adequate in comparison with other programs.*
> 4. *The citation of a deficiency, regulatory violation, or area for improvement does not necessarily provide an indication of an unsafe condition or an unsafe facility.*
> 5. *Implicit within regulations is the expectation that employers recognize unsafe conditions and cease operations that have been determined to be unsafe.*[24]

Q4–1: What are the potential implications of adding specific ALARA planning and implementation requirements to the 10 CFR 20 regulations?

Response: As noted, above, the ALARA concept does not easily lend itself to prescriptive regulation. It may be more practical to develop further guidance rather than

[24] Health Physics Society. Occupational radiation safety standards and regulations are sound. Health Physics Society Position Statement PS013-1; revised July 2012. Available at: http://hps.org/documents/occupationaldose_ps013-1.pdf. Accessed 9 March 2015.

attempt to codify planning and implementation for the very wide variety of licensees subject to the regulations.

- What changes to licensee radiation protection programs could be anticipated?

Response: As with any new regulation, there would be changes to procedures, computer-based records and planning documents, and training, and there likely would be additional delays from the beginning of a new process or procedure to performance, owing to the additional planning, review, or oversight included in new ALARA requirements. .

- What would be the potential implementation and operational costs?

Response: There are always costs associated with new regulation and the activities noted in response to the question above. These will be different for each licensee, depending upon the size and scope of their program and how well developed their current ALARA program is.

Q4–2: What regulatory language should be used for an additional ALARA planning requirement and what is the rationale for this language?

Response: Given the wide variety of licensees that would be impacted by new regulation in this area and given the subjectivity and flexibility inherent (and intentional) in the ALARA philosophy, NRC may want to consider language that is broad and performance based rather than prescriptive.

Q4–3: 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 licenses?

Response: A full evaluation of the three methodologies prescribed was not undertaken; however, it appears that an approach similar to that discussed in NRC Regulatory Issue Summary 2002-06: Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-rays (16 April 2002), which allows for multiple methods to assess dose (i.e., endorsement of multiple methodologies), would work equally well here.

Q4–4: 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: As previously noted, ACLs are generally set based on the anticipated workload and the most common exposure pathway or operation. Setting ACLs requires professional judgment that is based on training and experience in the environment in which these levels are set (e.g., medical facility versus laboratory research facility versus industrial radiography operations). This may include different levels set for different work groups. For example, while an ACL of 5 mSv per calendar quarter may be appropriate for triggering a review of practices for a physician who routinely uses fluoroscopy, the same level would be less effective (i.e., too high) to conservatively identify practices leading to dose for a researcher who uses relatively small quantities of ^{32}P in vitro. Therefore, it is reasonable to suggest that a licensee, such as an institution whose operations include both medical and laboratory uses of radioactive materials, might consider setting different ACLs. The appropriate number (and value) of ACLs is site specific. Also, because these levels are set for the purpose of taking action to reduce future doses, it is important to keep in mind they are not, in and of themselves, dose limits.

Q4-5: How do the different methodologies previously discussed impact the ability of licensees to best address radiation protection within their programs?

No response.

Q4-6: Other than the methodologies discussed in the preceding section, are there other ways to evaluate occupational lifetime cumulative exposures that should be considered?

No response.

Q4–7: 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?

Response: It appears this is already implicitly required by 10 CFR 20.1201(f), which states, "The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person."

- Are there any dosimetry vendors that provide concurrent dose records?

Response: This question should be addressed specifically to the dosimetry vendors.

- 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: From a regulatory standpoint, it is not clear that placing a regulatory requirement upon an individual (rather than a licensee) would be practical or readily enforceable. This question should be posed to the Agreement States.

Q4–8: Should the Agreement States be allowed to use more restrictive or prescriptive requirements if the NRC decides to use a performance-based approach?

Response: HPS supports uniform dose standards across the country, regardless of Agreement State status.[25]

***Issue 5*: Metrication—Units of Radiation Exposure and Dose**

Issue: How and in which order should units (International System [SI] and traditional) of radiation exposure and dose be expressed and reported to the NRC?

Response: HPS supports the use of SI units and has fully transitioned to SI units for all its scientific pursuits.

Discussion: HPS has a position statement which speaks directly to the topic of the use of SI units for expressing radiation exposure and dose.

> *It is the position of the Health Physics Society (HPS) that the International System of Units (SI) should be used exclusively when expressing radiological quantities. The continued use of traditional, yet outdated, units to express radiological quantities in the United States can have significant repercussions with regard to effective response to radiation emergencies. It will also have negative impacts on educating and conditioning future generations in the United States who are not well versed in the current scientific and internationally adopted radiological units.*
>
> *The continued use of traditional units:*
> - *Hinders the exchange and interpretation of information even among radiation safety professionals, especially during a radiation emergency;*
> - *Provides an unnecessary barrier to public communication, and*

[25] Health Physics Society. Compatibility in radiation safety regulations. Health Physics Society Position Statement PS004-1; reaffirmed July 2007. Available at:http://hps.org/documents/compatibility_ps004-1.pdf. Accessed 9 March 2015.

- *Educates and conditions yet another generation of radiation protection practitioners who are not well versed in the current scientific and internationally adopted radiological units.*

Nearly all countries in the world, many with well-established nuclear industries, have effected this transition successfully, without compromising health and safety, and have demonstrated that complete conversion to current international units is certainly practical and doable.

The HPS believes the exclusive use of SI units to express radiological quantities is the responsible practice to promote—a practice that is long overdue in the United States.[26]

Q5–1: Will promulgation of amendments to the 10 CFR 20 regulations with dose limits and other measurements shown in dual units, with the SI units shown first, followed by the traditional units in parentheses, cause an undue burden or hardship upon any licensee or class of licensees?

Response: The burden will vary greatly with the size and scope of the license. Many institutions across the country already use dual units (either traditional first, followed by SI, or vice versa). As stated in the position statement quoted above, "The HPS believes the exclusive use of SI units to express radiological quantities is the responsible practice to promote."

Q5–2. Should 10 CFR 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.

Response: See response to previous questions regarding the use of SI units.

Q5–3. Should the NRC amend the appendices for 10 CFR 20 to show values in SI units only, in traditional units only, or in both sets of units?

Response: As stated above, HPS believes the use of SI units to express radiological quantities is the responsible practice to promote. It would not be unreasonable, however, to allow for a transition period for this change to occur, wherein dual units are used for a limited amount of time.

[26] Health Physics Society. Exclusive use of SI units to express radiological quantities. Health Physics Society Position Statement PS025-0; February 2012. Available at:http://hps.org/documents/SIunits_ps025-0.pdf. Accessed 9 March 2015.

- If both SI and traditional units are provided, which set of units should be considered as the regulatory standard?

Response: As discussed above, HPS supports the exclusive use of SI units. If non-SI units are provided, the SI units should be considered 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 why or why not.

Response: NRC may want to consider publishing an appendix to the regulations that provides the necessary information and definitions.

Issue 6: Reporting of Occupational Exposure

Response: In general, there is value in the collection of exposure data, both for tracking occupational dose (particularly of individuals with more than one employer) and also to identify dose trends in various occupational settings. Nevertheless, nationwide tracking may be complicated by state statutes regarding privacy or other concerns. In particular, in medical settings, few if any individuals receive doses from byproduct materials that come close to the annual limits specified by NRC regulations. Doses that approach statutory limits usually result from exposure to scattered x rays from fluoroscopically guided procedures, which are not regulated by NRC. It is unclear whether an NRC regulation requiring nationwide reporting could reach this very important source of exposure.

Q6–1: 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: HPS encourages NRC to first identify reasons for expanding reporting requirements, which may then guide decisions as to what additional reporting would have value.

Q6–2: 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: As noted above, in general there is value in the collection of exposure data, both for tracking occupational dose (particularly of individuals with more than one employer) and also to identify dose trends in various occupational settings; however, there are a number of operational issues that need to be considered.

1. Authority to collect certain relevant data: As discussed above, it is not clear that NRC regulation could reach exposures resulting solely from machine-produced radiation or diffuse naturally occurring radioactive material, which are two very important sources of occupational exposure.
2. Use of data: Cooperation in this effort would likely be enhanced if NRC clearly states the goals and objectives of collection of these data.
3. Cost: Anecdotal information indicates that a single nuclear power plant may spend as much as $50,000 per year to report worker dose data to the Radiation Exposure Information and Reporting System. Cooperation would likely be enhanced if NRC could ensure the dose reporting system is simple and reasonably inexpensive to use.
4. Identification of workers: Many licensees are moving away from tracking individuals using social security numbers to protect organizations from identify theft issues. NRC may want to consider other means by which to track individual dose (e.g., licensee-specific and unique identifiers).

Q6–3: Should Agreement States be required to adopt regulations that are compatible with the requirements in 10 CFR 20.2206?

Response: HPS favors compatibility in regulation.[27]

Q6–4: Should the NRC consider a gradual expansion of the 10 CFR 20.2206 licensee reporting categories in a stepwise fashion (e.g., staggered compliance dates for different categories of licensees)? What are the advantages or disadvantages for this option?

Response: It is likely different categories of licensees will have differing opinions in this regard. Individual licensees are likely in the best position to enumerate advantages and disadvantages for their particular facility.

Q6–5: What are the potential implementation and operational costs associated with expanding the occupational exposure reporting requirements?

Response: As previously noted, with any new regulation, there would be costs associated with changes to procedures, computer-based records, and training, at a minimum. These will be different for each licensee, depending upon the size and scope of the program.

[27] Health Physics Society. Compatibility in radiation safety regulations. Health Physics Society Position Statement PS004-1; reaffirmed July 2007. Available at:http://hps.org/documents/compatibility_ps004-1.pdf. Accessed 9 March 2015.