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Subject: Advisory Statement on the Proposed Changes to 10 CFR Part 20, issued on July 25, 2014

The Texas Radiation Advisory Board's (TRAB's) members are expert advisors on issues relating to radiation and radioactive materials. The TRAB provides recommendations regarding radiation issues to the appropriate agencies, legislature and the governor. As such, the TRAB is addressing the topic of radiation safety regulatory changes proposed by the U.S. Nuclear Regulatory Commission in 10 CFR Part 20, *Standards for the Protection Against Radiation*, which were published in the July 25, 2014 issue of the *Federal Register*.

***B. Occupational Dose Limit for the Lens of the Eye*:** 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).

The TRAB opposes going forward with the proposed decrease of the annual occupational dose to the lens of the eye, from the current NRC regulatory standard of 150 mSv (15 rem) to the proposed annual dose limit of 50 mSv (5rem). The TRAB does not endorse this change for the following reasons:

1. The medical literature does not unequivocally establish a statistically significantly-increased risk (over age-related degenerative changes) of provider impairment or other morbidity due to cataracts or other lens opacifications. Moreover, with the temporal latency between exposure and lens changes, the TRAB does not feel that it is unequivocally established that visual issues will occur during the practitioner's career.

2. There is no universally agreed upon standard for measuring or estimating dose delivery to the eye in general or in particular to the lens of the eye. Variables that may affect this calculation include badge placement, use of protective shields, and correction factors for those shields. Without a precise definition of a monitoring program, the impact of the change on the current workforce cannot be precisely ascertained. Also, of specific concern, it cannot be established that this will not affect a significant portion of the medical provider workforce.

3. With a significantly lowered exposure limit, this regulation has the potential to negatively affect a substantial number of providers' (physicians, technicians, nurses and others) productivity. As providers approach or exceed limits, the regulatory change and other regulatory frameworks would necessitate removing those individuals from the exposure environment and from direct patient care. Even a single provider removed from the patient care environment adversely affects patient care without a clear benefit to the provider, as discussed under point 1 above.

4. The ability of the healthcare system to lower lens exposure is not well-defined and is not described in these proposed regulatory changes. A cost-benefit and/or risk-based approach to decreasing exposure would be very appropriate. For example, certain highly-limited specialists may not be able to adopt high-level-protective shielding, which reduces eye exposure by two-thirds, because they are engaged in very sensitive procedures where higher lens exposure may be justifiably required.

The TRAB remains very interested in this issue. However, with the very significant gaps in the body of scientific evidence, as described above, the TRAB cannot support the potentially over-burdensome impact of the 66-percent reduction in the lens dose, upon the healthcare environment. The TRAB will continue to study this issue, and will support the development of a body of literature and a regulatory framework appropriate for the medical environment.

C. Dose Limit for Embryo/Fetus of a Declared Pregnant Occupational Worker.
Reducing the dose limit to the embryo/fetus of a declared pregnant woman, from 5 mSv (500 mrem) to 1 mSv (100 mrem) for the entire pregnancy.

The ICRP 103 publication recommends the changing of several dose limits for radiation protection. The NRC has asked for public input into whether or not they should adopt the new dose limits. In the case of the dose limit to the embryo/fetus, the recommendation is to reduce the limit from 5 mSv (500 mrem) to 1 mSv (100 mrem) during the gestation period. The TRAB does not endorse this change to adopt the new standard based on the following:

1. There is no evidence that this change would increase the protection of the embryo/fetus of declared pregnant workers.

   As stated in NCRP 174, *"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 (20 rad) (dose to the embryo or fetus) at the most vulnerable stage of pregnancy;"* and *"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)."*

   Even within ICRP 103, it states, "...that risks of malformation after in-utero exposure to doses well below 100 mGy (10 rad) are not expected." (Page 57)

   In either of these cases, the current limit of 5mSv (500 mrem) during the gestational period is well below these respective doses.

Several studies were conducted, after the NRC changed the dose limit in 1994 to 5 mSv (500 mrem), that showed that there were no increases in abnormalities to embryos exposed to less than 5 mSv (500 mrem).

2. Many institutions and facilities already have administrative limits for declared pregnant workers that are below the current 5 mSv (500 mrem) limit. Thus, implementing the new lower limit may not provide additional protection for the embryo/fetus.

3. The implementation of the new 1 mSv (100 mrem) limit may cause pregnant workers to either delay or eliminate their notification of pregnancy due to a fear that the reduced dose limit may restrict their work or project activities.

4. The increase in paperwork and effort put forth by the licensees may put an undue burden, with little benefit to the worker or risk reduction to the embryo/fetus.

5. Finally, and perhaps most importantly, this would also give a distinct impression that the old limit of 5 mSv (500 mrem) during gestation was an unsafe limit for declared pregnant workers, while there has been no evidence suggesting that the current limit is unsafe.

D. Individual Protection - ALARA Planning: In this regard, the NRC would require each licensee, as a part of its radiation protection program, to establish mechanisms to examine cumulative occupational doses, and to implement control measures limiting additional doses if an occupational worker approaches his or her cumulative dose criterion. This would add specific ALARA planning and implementation requirements to the 10 CFR Part 20 regulations.

The current as low as is reasonably achievable (ALARA) regulations are adequate for ensuring that working with radiation is as safe as possible. Given the subjective nature of the ALARA philosophy, the TRAB is not convinced that regulatory expansions in this area would be effective. ALARA planning is an integral part of the day-to-day operations of a successful radiation safety program. Current regulations already mandate that ALARA be practiced and alert and investigational processes are required for the licensees. ALARA alert or investigational levels are set based on the anticipated work load and the most common exposure pathway for an individual facility's operations. These levels require professional judgment based on the experience in the environment in which the specific work is being performed (e.g., medical facilities, research laboratories, radiographic services, etc.).

This opposition to the proposed regulatory expansion 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 radioactive materials.

2. Since the mid-1950s, radiation safety standards have included provisions for incorporating the philosophy of ALARA in radiation safety work practices.

3. The application of ALARA is based on the judgment of radiation safety managers and radiation workers, and may not be useful when comparing various radiation safety 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.

Also, regarding the establishment of Administrative Control Levels (ACLs), a single dose cannot be set as a "one-size-fits-all" prescription. The TRAB believes that regulatory mandated ALARA alert and/or investigational levels would be counterproductive. The decision on setting the value of alert and investigation levels must be left to those licensees who understand the specific working conditions best, who are the local radiation protection personnel. If regulatory-mandated ACLs are set for the purpose of taking action to reduce future doses, these ACLs would effectively be dose limits, i.e., dose levels not to be exceeded. This should never be the intent or impact of the ALARA regulations.

F. Reporting of Occupational Exposures: The NRC does not require Agreement States to adopt the 10 CFR 20.2206 provisions. Although an Agreement State can choose not to require their licensees to submit annual reports of occupational radiation dose information to either itself or the NRC, some Agreement State licensees voluntarily report occupational dose information to the REIRS database. Should Agreement States be required to adopt regulations that are compatible with the requirements in 10 CFR 20.2206?

In general, there are no benefits of reporting occupational exposure to the NRC or to an Agreement State, since normal doses received are well below the threshold for any measurable effects. Also, such exposures are effectively monitored during routine inspections. The collection of this information places an unnecessary burden on the states' licensees and regulators.

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)?

Collection of the data must provide a significant public health and safety benefit. For example, the information should be part of a long-term study including follow-up over the worker's lifetime. Additionally, the dose that the workers receive must be high enough that a measurable effect is observable and quantifiable.

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?

The case of a worker who works at more than one facility and exceeds the dose limit without it being detected by the licensees is likely to be a very rare occurrence. It is also extremely unlikely that any dose will ever exceed twice the limit in this situation. Thus, an over-exposure of this type will not lead to detectable biological effects. The costs and labor in collecting occupational exposures to possibly discover the few rare cases of minimal over-exposure is not justifiable.

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

No, see the TRAB's responses to the other questions related to this issue.

Q6–4: 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?

No, the number of existing reporting categories should be reduced.

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

The database used in the Texas program could not be modified for this purpose, so a separate custom database would have to be developed, or Texas would need access to an NRC database. The later choice is preferred with the licensees directly entering their data, so that the state is not involved, as in similar fashion to the NSTS database. Texas has more than 6,000 radiographers performing work in the state; so with that group alone, Texas does not have the resources to support that amount of data entry and could certainly not support an expanded program.

Respectfully Submitted,

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