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General Comment

See attached file(s)

Attachments

10 CFR 20 ANPR Comments

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Secretary
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Washington, DC 20555-0001
ATN: Rulemaking and Adjudications Staff

RE: Docket ID NRC-2009-0279

Please find attached the comments of the Vermont Department of Health Radiological and Toxicological Sciences Program as related to the issuance of an Advanced Notice of Proposed Rulemaking on July 25, 2014 in the Federal Register. The ANPR focused on possible revisions to 10 CFR 20. We understand the comment period for the ANPR was extended through June 22, 2015.

Sincerely,

William E. Irwin, Sc.D., CHP
Radiological and Toxicological Sciences Program Chief

Summary

The Vermont Department of Health Radiological and Toxicological Sciences Program (VDH) appreciates the opportunity to comment on the Nuclear Regulatory Commission's advance notice of proposed rulemaking regarding potential changes to radiation protection regulations. Our comments on each of the issues follows.

Issue #1 - Update 10 CFR Part 20 to Align With ICRP Publication 103 Methodology and Terminology

Response: The VDH supports closer alignment with ICRP Publication 103 methodology and terminology.

Q1-1: What are the implications of changing the NRC's regulations to specify "total effective dose" in place of the current term "total effect 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: Vermont is revising its regulations as we plan to apply to become an NRC Agreement State. We are writing all our documents to use SI units in an effort to make the reading of the regulations easier without parenthetical traditional units. As such there will be no significant implication. We will likely spend less time writing documents because we will not have to include parenthetical traditional units. Our registrants and future licensees may have some costs to transition to SI units, but that it hard to estimate.

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 terminology? What would be an appropriate implementation time frame and approach to transition of terminology?

Response: The VDH should be allowed three years to change its regulations after NRC regulatory changes. We hope it will not take that long given the timing of our current regulation revisions, but we do not know the final extent of NRC revisions. Some of our registrants and future licensees may need more time, but a maximum of five years is recommended.

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 preliminarily views on the age and gender average approach.

***Response*:** The VDH recommends the use of the age and gender averaged approach to provide a more realistic representation of a member of the public for purposes of demonstrating compliance with the effluent dose limitations that are currently incorporated in 10 CFR 20 regulations.

Q1-4: Should the public dose limit of 0.5 mSv (50 mrem) continue to be the basis for the effluent concentration limits for the radionuclides in 10 CFR Part 20, appendix B, Table 2, Columns 1 and 2? Should it be reduced or otherwise modified?

***Response*:** Since the public dose limit is not changing, there should be no need to change the dose basis for the effluent concentration limits. Using 0.5 mSv is a conservative approach that seems appropriate given the unknowns of public exposures.

Issue #2 – Occupational Dose Limit for the Lens of the Eye

Response: The VDH supports the closer alignment with the ICRP as proposed by the NRC change to an annual dose limit to the lens of the eye of 50 mSv.

Q2-1: Is closer alignment with or adoption of the ICRP Publication 118 (2012) recommendation regarding the dose to the lens of the eye appropriate given the scientific information now available?

Response: The VDH believes the scientific literature has provided sufficient evidence that reducing the lens of the eye dose limit is justified.

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

Response: The prevention of disease and the possible harm to a person's well-being due to serious lost visual acuity are considered adequate justification.

Q2-3: What mechanisms could be applied to keep the accumulated exposure to the lens of the eye below the threshold of 0.50 Gy (50 rad)?

Response: The VDH considers leaded eye glasses and leaded shield screens would be sufficient personal protection. Focusing radiation worker attention on an accurate record of accumulated lens dose may also promote better worker awareness of the concern while promoting licensee actions to manage work to 0.5 Gy through administrative control levels.

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

Response: It is anticipated that existing methods of dose assessment for the lens of the eye should be sufficient.

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

Response: It is anticipated that existing methods for does assessment accounting for shielding or other protections in place should be sufficient.

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

Response: The VDH recognizes some financial costs are to be expected, but they should not be prohibitive, and that some procedure and training changes will likely be needed. The VDH also believes guidance on appropriate protection factors is needed for regulators and the regulated community.

Q2-7: What are the potential impacts on State regulatory programs of a reduction in the occupational dose limit to the lens of the eye from the current regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)?

Response: The major state impact will be regulation changes, though the VDH anticipates these will be modest given the timing of our current revisions to regulations. Should the final version of 10 CFR 20 have unanticipated changes, we will have additional regulatory reform and possibly need to make procedure revisions and changes to training of our personnel. Other states may have worse operational impacts as compared to Vermont.

Issue #3-Embryo/Fetus

Response: The VDH does not support the reduction of the embryo/fetal dose to 1 mSv because of the potential that fewer women will declare their pregnancies and therefore the dose to the embryo or fetus may increase. ICRP 103 states that “on the basis of animal data it is judged that there is a true dose threshold of around 100 mGy for the induction of malformations; therefore, for practical purposes, the Commission judges that risks of malformation after in-utero exposure to doses well below 100 mGy are not

expected." Absent evidence to the contrary, it seems inappropriate to reduce the embryo/fetus dose limit.

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: Were the dose limit for a declared pregnant woman, to be revised to 1 mSv for the gestation period, we anticipate there will be modest costs to update regulations, guidance documents and training that refer to the limit. These pale in comparison to the potential problems should fewer women declare their pregnancy because of the dose limit reduction.

Q 3-2: 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: Determination of the date of conception is an inexact science. Currently after declaration, a declared pregnant worker that has already exceeded 5 mSv to the fetus is only allowed another 0.5 mSv for the remainder of the pregnancy. This seems prudent. The value of change does not appear evident.

Q3-3: 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: Increased costs are likely, but they seem trivial if fewer pregnant women declare their pregnancy for fear of economic disadvantage. It is also possible that attribution of lower doses purely to the occupation could be difficult.

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

Response: OSL dosimetry is available that has a minimum sensitivity of 0.01 mSv and other dosimetry has similarly low detection limits. There may be issues with detecting internally deposited radionuclides that contribute to low dose. While neutron doses are detectable to 0.2 mSv on OSL dosimetry in the case of 40 keV neutron energies, the sensitivity falls off as energy rises. In high energy neutron applications, dosimetry sensitivity could be an issue.

Q3-5: Are there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for these data?

The NRC should collect and analyze this data, perhaps from dosimetry vendors, before proposing a reduced dose limit. NCRP 174 “Preconception and Prenatal Exposure Health Effects and Protective Guidance” continues to recommend a dose limit of 0.5 mSv per gestation month. Incorporation of this guidance into the regulations may be appropriate, perhaps in lieu of the terms in 10 CFR 20.1208 (b) - avoiding “substantial variation above a uniform monthly exposure rate.”

Issue #4-Individual Protection – ALARA Planning

Response: The VDH supports the use of the administrative control level (ACL) concept in lieu of prescriptive ALARA regulations. The VDH shares the concern that some worker lifetime cumulative doses may unacceptably increase the risk of adverse health consequences. Various methodologies to constrain lifetime dose are presented in Issue Paper 4. The VDH believes current ALARA planning practices and licensee imposed ACLs should be sufficient to protect the majority of workers from excessive risk from cumulative lifetime dose, but not all. The VDH recommends licensees verify the lifetime cumulative dose for workers to compare them to an ACL based on either the ICRP 103 or NCRP 116 methodology so they can identify those workers for whom ALARA planning will maintain their lifetime cumulative dose within that ACL. This approach will allow licensees flexibility for certain work categories if an ALARA analysis demonstrates that the dose cannot be reasonably reduced to the ACL for those work groups.

Question 4-1: What are the potential implications of adding specific ALARA planning and implementation requirements to the 10CFR part 20 regulations? What changes to programs would be anticipated? What would be the potential implementation and operational costs?

Response: Many licensees already have administrative control levels. The licensees whose workers may approach the annual limit on exposure are driven by current regulations to restrict the exposure of workers. They cannot afford to lose the services of their workers at the end of the year, so they take proactive measures to share high-dose activities among other workers during the entire year or identify means for the individual to accomplish activities with less dose. In addition, the vast majority of licensee workers don’t exceed 10% of annual occupational dose limits, with typically only interventional cardiologists and some radiographers routinely exceeding 20 mSv per year. Still, specific ALARA planning and implementation requirements would unlikely cause these licensees additional impact. For certain licensees where higher doses are more common, the additional costs for planning, training and other dose reduction activities may be worthwhile. Such requirements may require dose triggers as not all licensed work has significant dose implications. The annual dose limits and the ALARA requirements of 10 CFR 20.1101 (b) augmented by an ACL for lifetime cumulative dose may be sufficient.

Question 4-2: What regulatory language should be used for an additional ALARA planning requirement, and what is the rationale for this language?

Response: The language should allow flexibility in how the licensee accomplishes the ALARA goals and objectives in keeping with 10 CFR 20.1101 (b). It should require the licensee to determine the lifetime accumulated dose for its workers so it can plan work to maintain worker doses within an ACL based on an ICRP 103 or NCRP116 formula.

Question 4-3*: 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 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: For a nuclear power plant worker with high exposures that can occur under specific operations, for example working within the steam generator, the best plan could be the most flexible one. The most flexible plan would generally be the ICRP 103 methodology of an average of 20 mSv per year over 5 years with no one year in excess of 50 mSv. The NCRP 116 methodology of age in years times 10 mSv might be better for older workers with low cumulative doses. ALARA planning is already in place at these facilities.

For an industrial radiographer a definitive limit with tight controls may be best given this industry's erratic compliance history, though we prefer the ACL option. Again, the ICRP 103 20 mSv per year average with no one year in excess of 50 mSv may work best because of its flexibility. The NCRP 116 methodology should also work, though caution for workers under 30 years of age is required, as doses under this method may exceed those under the ICRP method. ALARA planning is useful in this class of licensee, though it may require more extensive personnel training.

For medical personnel the ACL option may be most practical since within a given medical facility the expected exposures vary widely with the normal duties of the personnel. ALARA planning incorporating ACLs is a part of almost all medical programs already.

Question 4-4: Should licensees be allowed to establish different ACL's for different groups of individuals? If so, what should be the basis for the various groupings?

Response: Yes, though this could require more administrative effort as compared to having one ACL for all. There may be differences in the specific techniques used for

different groups of individuals as well. Grouping individuals for ALARA planning should be based on similarities in their tasks, work sites, and potential doses.

Question 4-5: How do the different methodologies previously discussed impact the ability of licensees to best address protection within their programs?

Response: The VDH believes that the licensees are best qualified to make this judgement.

Question 4-6: Other than the methodologies discussed in the previous section, are there other ways to evaluate occupational lifetime cumulative exposure that should be considered?

Response: Not that we consider to be more appropriate.

Question 4-7: 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 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*:* The idea of capturing an individual's entire yearly exposure from multiple licensees (if they work for different licensees) is a good one as long as it does not pose an unacceptable burden on the regulated community. 10 CFR 20.1201 (f) requires entire yearly dose tracking of licensees, and requiring it for concurrent dose should be a part of that. Entrusting the tracking of cumulative dose for employees to licensees may be better than expecting it of individual workers. The NRC should ask dosimeter vendors about their ability to provide concurrent dose records.

Question 4-8: 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? [If the NRC issues a proposed rule, this information will be important in establishing an appropriate Agreement State compatibility level for any proposed regulatory requirements]

Response: As to the issue of allowing Agreement States to use more restrictive or prescriptive requirements if the NRC decides to use a performance-based approach, the VDH believes that should be allowed. As to limiting lifetime cumulative dose using the methodologies described in Issue Paper 4, the ICRP 103 20 mSv per year limit and

the NCRP 116 10 mSv times the worker age limits may be the easiest methods to evaluate as regulators. A lifetime ACL of 0.5 or 0.75 Sv may likely require more bookkeeping on the part of licensees in order to demonstrate compliance to regulators. With adequate administration by licensees, these latter two methods could be functional and auditable, however.

Issue #5-Metrication: Units of Radiation Exposure and Dose

Response: The VDH supports the proposal to use SI units rather than traditional units. The rest of the world has shown it is possible for all licensees to convert to units used by most other industries in the United States. If using both units is allowed, perhaps in a transition to using only SI, it is best to show SI units first, followed by traditional units in parentheses.

Q5-1: 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 parentheses, cause an undue burden or hardship upon any licensee or class of licensees? (If so, please explain and provide examples, including any potential implementation or operational costs.)

Response: While the VDH considers it best to adopt SI units exclusively, it would seem that the transposition of SI units and traditional units from the current orientation would have minimal impact to the Agreement States.

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: The VDH believes it is best to adopt SI units exclusively. Either option of units could be allowed and 10 CFR 20.2101(a) could be amended accordingly for a period of transition to exclusive use of SI units.

Q5-3: Should the NRC amend the appendices for 10 CFR Part 20 to show values in SI units only, in traditional units only, or in both sets of units? If both SI and traditional units are provided, which set of 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: While the VDH considers it best to adopt SI units exclusively, both sets of units could be used during a transition period toward adoption of SI exclusively. In that

interim, for Appendix B tables, consideration should be given to the use of 2 tables rather than putting both units in one table.

Issue #6-Reporting of Occupational Exposure

Response: The VDH is of the opinion that it may be beneficial for additional categories of the regulated community to be included in the 10 CFR 20.2206 dose reporting requirements, including those in agreement states (some of whom are currently voluntarily reporting). However, the expansion should be taken with consideration for the impacts on the regulated community and where the benefits of additional reporting are clear and worth the impacts.

Q6-1: What criteria should the NRC use to identify additional categories of licensees that should be required to submit annual occupational exposure reports in accordance with 10 CFR 20.2206(a)?

Response: The VDH believes that care must be taken when adding other categories of licensees to ensure the value added is worth the resources needed to collect and analyze the dosimetry data. For example, adding medical type licensees as a whole may offer little value since the majority of higher annual doses are received from specific practices like interventional radiology over which 10 CFR 20 has incomplete legal authority. This raises additional concerns if the radiologist uses byproduct material in addition to radiation producing equipment. The radiologist would need to parse out the portion of his or her annual dose received from byproduct material from the dose received from x-ray.

A better approach may be to add certain professions that have historically shown elevated levels of radiation exposure from the use of byproduct material instead of license types as a whole. This will offer more substantive information for determining trends and to evaluate an individual's collective risk of exceeding annual or multiyear limits.

Q6-2: What are the benefits of collecting occupational exposure information in one central database in order 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*:* This offers the benefit of clearly documenting radiation exposures in those licensed individuals who work in more than one facility; especially in the case of those who work across state lines. Consideration should be given to exposures regulated under the Occupational Safety and Health Standards of 29 CFR 1910.1096 as well so the occupational dose of individuals exposed to x-ray sources under OSHA jurisdiction

can be evaluated, too. Research into low dose effects may be aided by such a central database, as well.

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

Response: The VDH believes that the Agreement State regulated community should be treated similarly to the NRC regulated community regarding the 10 CFR 20.2206 reporting requirements.

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)?

Response: The NRC would be the primary data holder so they should adopt a step-wise gradual approach if that works best.

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

***Response*:** Depending on the category of licensee, a large facility with several different smaller divisions that use either byproduct material or x-ray equipment will need to allot additional personnel hours to segregate out the information that is required under 10 CFR 20.2206(a). Also, dosimetry report formatting may need to be altered for workers whose dosimetry data need to be submitted. As noted previously, the value of the data collected must clearly be worth these kinds of costs.