

RulemakingComments Resource

From: Treesa Parker <tparker@energysolutions.com>
Sent: Tuesday, November 25, 2014 12:35 PM
To: RulemakingComments Resource
Cc: Dan Shrum; thomas.e.magette@us.pwc.com
Subject: Docket NRC-2009-0279: EnergySolutions LLC Comments
Attachments: 11-25-14 Comments on ANPR, 10 CFR 20, Standards for Protection Against Radiation
Docket NRC -2009-0279.pdf

Please see the attached comments from EnergySolutions LLC, in regards to Docket NRC-2009-0279.

Thank you,

Treesa Parker sent on behalf of Daniel B. Shrum

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November 25, 2014

CD14-0262

Secretary
US Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

Subject: Comments on Advanced Notice of Proposed Rulemaking, 10 CFR 20,
Standards for Protection Against Radiation

Reference: Docket ID NRC-2009-0279

Dear Ms. Vietti-Cook:

EnergySolutions hereby provides comments in response to the Advanced Notice of Proposed Rulemaking (ANPR) for 10 CFR 20, Standards for Protection Against Radiation. Our comments on the draft regulatory basis are summarized below and described in more detail in the attachment.

EnergySolutions is in general agreement with the Nuclear Energy Institute's (NEI) view that some of the contemplated changes involve substantial costs that would burden the industry without substantive benefit to health and safety. We also are in general agreement with certain views expressed by the Society of Nuclear Medicine and the American College of Nuclear Medicine that proposed changes in dose limits have not been clearly shown by science to improve health and safety.

However, EnergySolutions does believe that some aspects of a revised radiation protection standard have merit, such as the proposed revisions to bring NRC regulations in line with the latest radiation protection science and to assure greater consistency across NRC regulations. We support changes that provide clear benefit to worker safety and public health, such as lower limits for the declared pregnant worker and fetus/embryos. We also encourage revisions to the regulations that support consistent reporting of occupational exposures across all segments of the regulated community.

Conversely, we do not agree with proposed changes described in the ANPR that are not indicated by sound science, such as the significantly reduced dose limits to the lens of the eye (LOE). We agree with the view of established authorities that there is a need to further study the radiation effects on the LOE. The considerable cost and burden to the regulated community associated with these changes cannot be justified given the

questionable benefits to worker safety that are assumed to be afforded by more restrictive dose limits. We also oppose adding prescriptive ALARA requirements to Part 20. The existing radiation control programs already in place effectively reduce occupational exposures well below the required dose limits.

Our review in support of this effort noted over 35 separate sections in Title 10 of the *Code of Federal Regulations* that reference dose levels, quantity and concentration limits, and definitions that may be affected by a revision of Part 20 methodology. While it is challenging for the regulated community to operate under regulations based on inconsistent standards or calculation methods, sweeping conforming changes would be an enormous task that would come at high cost to the industry with little to no benefit to worker and public safety. We propose that the Commission consider conforming changes that do provide some clear benefit and are consistent with current science.

One conforming change that the NRC should include in any Part 20 rulemaking is to the low-level radioactive waste classification tables in 10 CFR 61.55. Considering that the classification tables are directly dependent upon the same ICRP methodology that is driving the updates to Part 20, any updates to Part 20 should be completed in parallel with updates to 10 CFR 61, *Licensing Standards for Land Disposal of Radioactive Waste*. It would be most efficient for the NRC to update those portions of Part 61 that are affected by the new methodology as part of a rulemaking focused on radiation protection.

We appreciate the opportunity to provide comments, which are detailed in the attachment. Questions may be directed to me at (801) 649-2109 or dshrum@energysolutions.com.

Sincerely,



Daniel B. Shrum
Senior Vice President
Regulatory Affairs

EnergySolutions' Comments on Advanced Notice of Proposed Rulemaking for Radiation Protection

EnergySolutions appreciates the opportunity to provide comments on potential changes to the radiation protection regulations in 10 CFR 20. As requested in the ANPR, we are providing our comments to each of the six issues NRC has identified. In addition, we have provided answers to several of the specific questions in the FR notice.

ISSUE 1 – UPDATE TO ALIGN WITH ICRP 103 METHODOLOGY AND TERMINOLOGY

If NRC updates Part 20 then certain conforming changes should be made to other affected regulations within Title 10. EnergySolutions generally agrees with changes to regulations that reflect updated methodology and terminology and show a clear benefit to health and safety. The NRC has a responsibility to efficiently and reliably implement regulations. If the primary driver of a revision to Part 20 is to incorporate the latest ICRP methodologies, then it stands to reason that other regulations dependent upon the same ICRP methodology should also be revised. In past rulemakings, for example revisions to the license termination regulations, the NRC adopted changes that created inconsistencies in its regulations which led to unintended consequences for licensees. Radiation protection standards are fundamental to the work of the NRC and it is important that their rules consistently reflect agreed upon standards. In light of this, it would be beneficial to the NRC and regulated community for the Commission to update the waste classification tables in 10 CFR 61, *Licensing Standards for Land Disposal of Radioactive Waste*, as part of its rulemaking to update 10 CFR 20. The data in the low-level radioactive waste classification tables in 10 CFR 61.55 is directly dependent upon the same ICRP methodology that is driving the updates to Part 20.

NRC should coordinate with other Federal agencies to ensure that the Federal Government adopts consistent radiation health standards. EnergySolutions believes that it is important to ensure consistency among radiation protection regulations promulgated by all federal agencies. When regulatory agencies (federal and state) adopt regulations based on different standards, it not only leads to confusion among stakeholders but contributes to errors in assuring compliance with regulations, increases costs, and adds unnecessary burdens to the regulated community. Any changes to Part 20 should be coordinated with other federal agencies so that there is alignment among radiation protection standards across all agencies. Varying dose limits between the NRC (2 Rem) and DOE (5 Rem) would be an example of an inconsistency that is unacceptable.

It is acceptable to use the latest methods now available (based on ICRP 60), and change to ICRP 103 when available. EnergySolutions agrees with using the methods of ICRP 103 as they relate to the use of the new weighting factors for tissue and radiation, as well as the use of age and gender averaged groups to calculate dose. Similarly, we agree that the revised definition of “reference person” and the use of “effective dose” versus “TEDE” will improve the regulations by providing consistent terminology and aligning the regulation with the calculation methodology.

EnergySolutions understands that NRC staff has analyses that estimate the impact of the updated methodology on calculated public dose using the methods of the DOE standard, which are based on ICRP 60 methods and dose conversion factors. However, the staff does not have complete data sets on how the new methods would affect the calculation of public dose because not all of the dose conversion factors (DCFs) are available. EnergySolutions suggests the NRC write the technical basis document using language that allows adoption of the most recent dose conversion factors. This would allow the staff to upgrade to the latest methods completely when the complete set of DCFs become available without the need for further rulemaking.

While EnergySolutions generally endorses upgrading to certain changes in ICRP 103 as described above, EnergySolutions believes it unnecessary to adopt other parts of ICRP 103 including those in Section 8 that support dose calculations to reference animal and plant organisms. More specifically, it is not necessary to implement additional standards for environmental protection since the ICRP maintains that the standards used to protect the general public also ensure that other species are not placed at risk. The current regulatory framework is sufficient to protect both public health and safety and the environment.

Answers to FR Questions

Q1-1 – There would be relatively minor impacts of change from TEDE to “total effective dose.” The benefits of having the same terminology in the governing regulations would be to minimize confusion. The change will come at some additional but minor cost to the regulated community to provide training and change procedures to reflect the new terminology.

Q1-2 – NRC should allow the regulated community 3 years to implement the changes by sequencing the training program revisions with the industry-approved accredited training program cycles, thereby reducing costs and maximizing efficiencies.

Q1-3 – The use of age and gender averaged models for dose calculation is acceptable since the projected doses are more accurate. It is recognized that individual isotope release concentrations will increase for some isotopes, and decrease for others. This is acceptable as long as effluent concentration limits are increased correspondingly for those isotopes shown to still meet the 100 mrem public dose limit. The NRC staff should also allow licensees to use site-specific data when it can be shown to be more representative of the site area demographics than national census data.

Q1-4 – NRC should not continue to use the public dose limit of 50 mrem as the basis for the effluent concentration limits for the radionuclides in 10 CFR Part 20. The Appendix B effluent limits can be based on the public dose limit of 100 mrem since improved modeling will allow more accurate projection of offsite impacts thus eliminating the need for added conservatism.

ISSUE 2 – OCCUPATIONAL DOSE LIMITS FOR LENS OF EYE

The dose limits for the lens of the eye (LOE) should remain unchanged. The dose limits in 20.1201(a)(2)(i) should remain unchanged pending development of a clear scientific basis that indicates a reduction is warranted. While *EnergySolutions* fully endorses radiation protection standards that prevent deterministic effects, we also support the view that there is insufficient scientific evidence warranting a reduced dose limit, and that cataracts should not be considered at the same risk level as other radiation induced effects. Furthermore, the lower eye dose limit would present significant implementation difficulties related to radiation protection practices.

It is not appropriate to lower the dose limit without further evidence showing a clear scientific basis to reduce the LOE dose. Despite efforts made by the international community to reduce the LOE dose limit, there continues to be disagreement among recognized experts as to the impact of reduced limits.^{1,2,3} Specifically, the Society of Nuclear Medicine (SNM) found no evidence that adults permitted a maximum of 15 rem to the lens of the eye annually have any significantly measurable increase in incidence of cataracts. The SNM questioned the validity of previous studies that suggested a higher incidence of cataracts as a relationship of dose, and provided suggestions for improved approaches to the assessment of this relationship.

¹ Society of Nuclear Medicine (SNM) Letter to NRC, October 28, 2011

² SNM and American College of Nuclear Medicine Letter to NRC, February 24, 2010

³ Health Physics Society Letter to NRC, October 13, 2011

EnergySolutions endorses the recommendations made by the Health Physics Society (HPS) that oppose lower lens dose limits. This is due to the uncertainty in the ICRP's basis for selecting the lower limit, operational difficulties in assessing and achieving lower doses, a need for further study to validate the dose effects (if any) from fractionated doses, and a lack of understanding in how to differentiate dose effects from lens opacities versus cataracts.

Answers to FR Questions

Q2-1 – No. EnergySolutions does not believe that adoption of the ICRP Publication 118 (2012) recommendations regarding the dose limits to the lens of the eye is appropriate based on currently available scientific information. NRC should seek additional studies to evaluate data regarding the effects of acute versus fractionated, protracted occupational exposures on the lens of the eye, and the mechanisms by which radiation exposure might cause cataracts and opacities. Absent data that provides a more definitive linkage between occupational exposures and its effects, it is not justified to reduce the regulatory dose limits from 15 to 2 rem as described in ICRP 118.

Q2-2 – The occurrence of cataracts is less of a concern than other radiation induced effects because they can be surgically corrected. Given the uncertainties between threshold doses necessary to cause opacities rather than cataracts, NRC should carefully evaluate the available data before considering any changes to the annual LOE dose limits.

Q2-3 – Under the present LOE dose limit (15 Rem), the existing radiation protection practices which are protective for the whole body limits are also sufficiently protective to the eye dose limit. However, should the LOE dose limit be reduced to 2 rem per ICRP 118, it is unclear how this can be accomplished without considerable cost and burden to the regulated community related to changes in programs, procedures, practices, personal protective equipment (PPE) and shielding. Further, there is considerable uncertainty on how eye lens dosimetry and dose assessment could be accomplished to assure compliance with the reduced limits. The dose reduction techniques that are effective in some portions of the regulated community (e.g., pull-down shields or leaded protective glasses used in interventional radiology) would not be viable techniques in other industries.

Q2-4 – As with dose reduction techniques, there would also be considerable challenges and uncertainties in performing dose assessments to assure compliance with reduced eye dose limits. The industry would have to develop new radiation protection practices to differentiate between whole body and eye dose, involving the complicated placement and use of multiple dosimeters in techniques that are not in common practice today.

Q2-5 – During the public presentation⁴ of this ANPR topic, NRC staff stated the industry could apply protection factors for the eye similar to the approach taken in respiratory protection when respirators are used. However, EnergySolutions is not aware of protection factors for the lens dose approved by national standards nor do its radiological protection procedures provide for such protection factors. It is unclear how protection factors could be applied or justified without an industry-recognized approved standard.

Q2-6 – A reduction in annual LOE dose limit from 15 to 2 rem cannot be accomplished without considerable burden to the regulated community. A reduction of the LOE dose limit to 2 rem would result in a *de facto* whole body limit of 2 rem since the industry would have to drive the whole body dose to the LOE limit because of uncertainties in LOE dosimetry and dose reduction methods. This could only be accomplished at considerable cost to the regulated community including changes to programs, procedures, practices, PPE, shielding, and dose assessment. We do not believe these impacts are justified given the questionable benefits to worker health and safety afforded by more restrictive dose limits.

ISSUE 3 – DOSE LIMIT FOR EMBRYO/FETUS OF DECLARED PREGNANT OCCUPATIONAL WORKER

It is acceptable to reduce the dose limit to 100 mrem for the remainder of the pregnancy with no retrospective assessment, as specified in *Position Paper Option 2*. The existing regulatory requirements in 20.1208(a), 20.1208(b) and 20.1208(d) are sufficiently protective of the health and safety of the worker and fetus for the low doses involved. Further, for most licensees in the regulated community, the current normal practice is to assign a declared pregnant worker to a position with essentially no occupational exposure for the duration of the pregnancy. Most licensees in the regulated community could accommodate a reduction in the 20.1208(a) dose limits to 100 mrem to make the embryo/fetus dose limit consistent with a member of the public. The reduced dose limits would result in additional costs at each plant site related to training and program changes, but we believe these costs to be minimal.

Should the occupational exposure limit become 100 mrem, the reduced limit should be applied for the remainder of the pregnancy without a retrospective assessment. Given that the most sensitive time for the developing fetus is early in the gestation period and occupational exposure would be very limited for the remainder of the pregnancy, an

⁴ NRC Webinar on October 2, 2014

additional retrospective assessment is not warranted. ICRP applied additional controls to the declared pregnant worker to attain a level of protection to the fetus similar to that provided to a member of the public as a matter of radiation protection policy.

Answers to FR Questions

Q3-1 – The existing policy is to control doses of a declared pregnant worker by reassigning the worker to a job with essentially no dose for the remainder of the pregnancy. Thus, there would be minimal impact from the reduced dose limits. It should be noted that an unintended consequence of the reduced limits might be that workers would under report pregnancies to maintain job and or/pay status.

Q3-2 – There are no significant benefits to applying the reduced dose limits over the entire gestation period. As stated above, a retrospective assessment is not warranted in light of existing practices and since there is already minimal risk to the safety of the worker and the fetus at these very low doses. The ICRP judged that the cancer risk from a prenatal exposure was similar to that from irradiation in early childhood. The reduced dose limit would present an insignificant change in differential risk to the safety of the worker and fetus.

Q3-3 – In light of the existing practices to minimize the dose to a declared pregnant worker, there would be essentially minimal implementation impacts on recordkeeping and operational costs since the proposed change in dose limit is already covered by existing policy. There would be costs associated with reduced limits related to procedure changes and training. However, we believe these costs to be minimal.

Q3-4 – We are aware of at least one technological issue that would make lower limits difficult to implement. As described in the ANPR (Position Paper 3 Section IV), the generally accepted minimum detectable exposure (10 mrem) for most dosimetry systems would make monitoring to assure compliance challenging and very costly.

ISSUE 4 – INDIVIDUAL PROTECTION-ALARA PLANNING

NRC should not change Part 20 to include prescriptive ALARA rules.

EnergySolutions endorses the alternate approach to use administrative control levels (ACLs). The current regulations in 20.1101(a) and (d) provide sufficient protection for workers to keep occupational exposures well below the NRC limits. EnergySolutions opposes prescriptive ALARA rules because such constraints could become the dose limit requirement. For those exceptional cases where worker exposures chronically approach the regulatory limits, the NRC could use specific license conditions.

Should NRC change 20.1101, EnergySolutions endorses the second methodology considered by NRC (ANPR 43295) based on NRCP Report 116, which recommends an occupational dose limit of 5 rem per year with an administrative control level (ACL) set at a cumulative exposure of 1 rem times the individual's age in years.

Adding ALARA planning requirements to Part 20 is not needed for the regulated community because licensees already have ALARA programs. The ALARA programs in place under the existing regulations are well established and effective to track exposures and to establish action levels well below the regulatory limits and to establish mitigating measures should exposures approach the limits. The commercial nuclear power and broader regulated industry⁵ has done a good job under the existing regulations to reduce worker occupational exposures. The reductions have taken years to develop requiring advances in design and engineering controls to achieve lower doses. For NRC to mandate additional reductions without the concurrent advances in design and engineering controls could have unwanted consequences, such as unsafe work practices from induced pressures or decreases in medical treatment with the attendant impact on public health. Prescriptive rules could have severe financial impact for some of the regulated community and result in significant costs related to the needed changes in operational programs.

Answers to FR Questions

Q4-1 – The principal objection is that prescriptive ALARA planning and implementation requirements could in effect impose new (lower) dose limits. The ALARA concept balances the benefits of reducing dose below specified regulatory limits with operational considerations. This balance would be lost if required ALARA implementation requirements resulted in *de facto* limits.

Q4-2 – Part 20 should not be revised to include additional ALARA planning requirements.

Q4-3 – EnergySolutions believes that a single methodology is appropriate even for different classes of workers. The practice at our facilities is to use administrative control limits (ACLs) for all workers to assure occupation exposures remain below the dose limits and are ALARA. When a worker's exposure approaches the ACL, further exposure is prohibited without upper management review and approval. Thus, we endorse Option 2 on the use of administrative control levels (ACLs). It is common

⁵ Council of Radionuclide and Radiopharmaceuticals Letter dated August 19, 2011

practice in the regulated community to use ACLs at 50% of the ALI values. EnergySolutions uses 2.5 rem as the annual TEDE administrative limit.

Q4-4 – There should not be different ACLs for different work groups because it would make record keeping and dose tracking too complicated.

Q4-7 – EnergySolutions believes there are potential impacts with amending 20.2104 to account for concurrent employment. Specifically, it is unclear what the impacts would be on dosimetry vendors to provide records, or even whether vendors can respond to increased requirements to report doses from concurrent employment on a regular basis. Radiation workers should continue to be required to report dose from concurrent employment based on readily available sources (pocket dosimeters, self-reading dosimeters), and this information should continue to be used to track exposures against reduced ACLs as the best approach to avoid exceeding the regulatory limits. We believe worker self-reporting to be the most reliable and cost effective approach.

Q4-8 – Agreement States should not be allowed to use more restrictive or prescriptive requirements. There should be only one standard for radiation protection, including the application of the ALARA principle. There is no scientific basis for concluding that radiation protection standards should vary from state-to-state. Not only is such variability unjustified from a human health and safety perspective, it undermines public confidence in the ability of the regulatory system to establish and enforce protective radiation standards. The Agreement State compatibility category for 10 CFR 20.1101 should be A. State program elements should be essentially identical to those of the NRC and they should be required to demonstrate compatibility.

ISSUE 5 – METRICATION – UNITS OF RADIATION EXPOSURE AND DOSE

Part 20.2101 should remain unchanged with quantities on records given in both units, portrayed as traditional (SI). The regulations should not be changed to give preference to metric units at this time. Part 20.2101 should remain unchanged with quantities on records (and calculations) in traditional units as the standard as specified in 20.2101(a), and with quantities in SI units following in parentheses as specified in 20.2101(b) for information purposes. We recognize that this approach is inconsistent with the NRC’s metrication policy; however, there are implementation burdens that are not balanced by the application of this policy to Part 20.

There could be advantages to addressing the inconsistencies within Part 20 and other NRC regulations on the use of SI units. There clearly are costs. We do not see that the

potential advantages outweigh the costs given that there are no health and safety benefits. However, although recommended by the Health Physics Society, the transition to metric units presents significant implementation challenges. Changing Part 20 to use SI for the purposes of calculating and reporting airborne and contamination levels would be difficult to implement operationally. SI units give the perception of large quantities because radiation levels in routine activities are large in the SI units. The use of SI units would impact radiation protection personnel who would be required to perform unit conversions in the field, which would present opportunities for errors that are adverse to safety. *EnergySolutions* recommends an approach whereby records (and calculations) continue to be presented in traditional units and final values can be presented in both units with SI in parentheses for information purposes to allow time to adapt to the new units.

Adopting an approach that aligns Part 20 with Part 37 by listing SI the standard and continuing to include traditional units also presents complications. The cumbersome nature of the Appendix B tables and the complications associated with the potential for rounding to change regulatory standards argue against this approach.

Answers to FR Questions

Q5-1 – A review by the Nuclear Energy Institute (NEI) determined that the cost of conversion to SI units would cost the industry millions of dollars per site without substantive benefit to health and safety.

Q5-2 – No, licensees should not be given discretion in reporting. Allowing licensees the option of choosing one set of units over another undermines the usefulness of the data.

Q5-3 – For the reasons summarized above, we do not advocate nor support changes in the format of the units in Part 20.

ISSUE 6 - REPORTING OF OCCUPATIONAL EXPOSURE

EnergySolutions recommends having one database for the assessment of overall radiation exposure and the effectiveness of radiation protection regulations and programs. There are benefits of having a single database which allows NRC to assess dose and monitor the work that contributes to exposure. These benefits are realized only if the database is complete and accurate to allow a meaningful assessment of collective exposure, exposure trends, and the effectiveness of NRC radiation protection programs. 10 CFR 20.2206(a) identifies the categories of licensees required to submit annual reports of occupational exposure. A reporting ‘gap’ exists because certain NRC licensees are excluded and licensees licensed by Agreement States are not subject to the NRC reporting requirements. The only effective way to close the reporting gap is to address this issue in a comprehensive manner for all categories of licensees regulated by NRC and the Agreement States.

Answers to FR Questions

Q6-1 – EnergySolutions does not see a rationale for exempting any categories of licensees that have workers receiving occupational exposure. The clear benefits of a central database for exposure data are diminished if the database is incomplete because it lacks input from a segment of the regulated community. The reporting criteria should apply equitably and consistently across all segments of the regulated community.

Q6-2 – There is no benefit from reporting annual exposures to address workers who perform concurrent work at multiple facilities relative to controlling exposures that approach the occupation limits as described under Part D Individual Protection, ALARA Planning. The industry is effectively addressing the issue of concurrent employment under the existing programs without a central database.

Q6-3 – Yes, NRC regulations should require sending all reports to the NRC REIRS database. As addressed in the FR notice, the usefulness of the database is compromised by the absence of the data from Agreement State licensees. *EnergySolutions* proposes that the NRC designate the reporting provision of 20.2206 as Category B for Agreement State compatibility purposes.

Q6-5 – The proposed changes to expand the occupational exposure reporting requirements do not affect *EnergySolutions*. All of our licensed activities, whether NRC or Agreement State licensed, required reporting.