74FR32198
7/07/09
(15)

PUBLIC SUBMISSION

As of: April 02, 2010
Received: March 31, 2010
Status: Pending_Post
Tracking No. 80acdb13
Comments Due: March 31, 2010
Submission Type: Web

Docket: NRC-2009-0279
Potential Changes to Radiation Protection Regulations; Solicitation of Public Comment

Comment On: NRC-2009-0279-0001
Solicitation for Public Comment on Potential Changes to the Agency's Radiation Protection Regulations

Document: NRC-2009-0279-DRAFT-0011
Comment on FR Doc # E9-15950

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General Comment

please see attached comments

Attachments

NRC-2009-0279-DRAFT-0011.1: Comment on FR Doc # E9-15950

SUNSI Review Complete
Template = ADM-013

E-RIDS = ADM-03
Add: D. Cool (dac)

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March 29, 2010

Dr. Kimyata Morgan Butler
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Washington, DC 20555-0001

RE: [NRC-2009-0279]
Solicitation for Public Comment on Potential Changes to the Agency's Radiation Protection Regulations. Federal Register Vol. 74, No. 128, July 7, 2009

These comments concerning the possible changes to the NRC's radiation protection regulations are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

CORAR agrees with the Commission's position that the NRC's current regulatory framework provides adequate protection of health and safety of workers, the public and the environment. At the same time we recognize that regulatory compliance is the minimum performance expectation with regard to radiological health and safety. Operations within our industry reflect best practices including recommendations of organizations such as the ICRP. CORAR constituents include companies with operations outside the US where, unlike the US, ICRP recommendations are readily adopted. These recommendations and standards may be viewed as the "standard of care" for our industry and for this and other reasons we have essentially adopted self-imposed limits and constraints into our policies, programs and procedures while NRC and other agencies in the US have been relatively slow to integrate ICRP recommendations from previous reports. It is in the best interest of all parties for NRC to begin the process of adopting the recommendations of ICRP.

As part of this process, we agree with NRC that outreach and stakeholder input will be an important key to the successful development and implementation of any rulemakings. A one-size-fits-all approach to adopting the recommendations will likely not be possible and some flexibility will be needed to enable the entire regulated community to comply with ICRP recommendations that are adopted into the regulations. In addition to the following comments, CORAR would like to take advantage of any opportunities to be additionally engaged as a key stakeholder in future workshops, forums and other meeting to discuss in more detail proposed options and the relevant issues involving revision of radiation protection regulations.

Implementation

In SECY-08-0197, NRC has proposed the following three principal options for revising their regulatory protection framework:

Option 1 – No Action

This option assumes that, as NRC contends, the current regulations provide adequate protection of public health and safety. That may be the case. However, CORAR believes that there is a need for US radiation protection regulations to be more closely aligned with ICRP recommendations as well as regulations within the international community.

Option 2 – Update 10 CFR Part 50 and Appendix I

This option would align 10 CFR 50 and Appendix I with 10 CFR 20. Since these regulations have limited if any applicability to CORAR constituents, we defer to the nuclear power industry and other relevant stakeholders for their input on this option.

Option 3 – Align the radiation protection regulatory framework with ICRP 103.

This option would move the framework of 10 CFR 20 toward closer alignment with ICRP 103 and, ultimately, most of the radiation protection regulations globally.

Recommendation

CORAR prefers Option 3 to align the radiation protection regulatory framework with ICRP 103.

NRC should undergo a process of revising its regulations that will result in greater alignment with international recommendations as well as global radiation protection regulations. We commend NRC for starting this process with a solicitation of input on potential options and issues and a willingness to engage stakeholders throughout any rulemaking. This input needs to be included in an impact/benefits assessment. The process should be undertaken with execution of clearly defined deliverables and timelines. However, we agree with NRC that it would be inappropriate to complete any rulemaking before the necessary dose conversion factors are available from ICRP. NRC should include in the rulemaking a provision to adopt new dose conversion factors but delay implementation until the new values are published by ICRP.

We agree with NRC staff that there are some current provisions in 10 CFR 20 that do not warrant changes. At the same time there are aspects of ICRP 103 not covered by the options and issues covered in SECY-08-0197. CORAR questions whether NRC will consider these within the scope of any rulemaking and in the process of engaging stakeholders. A list of issues not mentioned by NRC includes, but is not limited to, the following:

- Scope of regulation and radiation protection control (also covered in ICRP 104)
- Optimization and justification (formerly ALARA)
- Regulatory exclusion and exemption
- Restriction of dose in emergency and existing exposure situations
- Restriction of occupational exposure of lens of the eye, skin, and extremities
- Restriction of dose from natural sources beyond the control of licensees
- Designation of areas
- Security of sources
- Safety culture
- Mutual trust and reporting
- Patient release criteria
- Definition of applicable terms

The expectation is that consideration to revise NRC's radiation protection regulations could include many of these issues but will likely not result in adoption of them all to the extent recommended by ICRP. NRC also needs to consider the implications of potential differences between revised NRC radiation protection regulations and the regulations of other radiation protection agencies where NRC does not have jurisdiction and where jurisdiction may overlap. Other implications to consider include the need to allow adequate time for both the

NRC and licensees to incorporate the changes into regulatory guidance, licenses, programs, policies and procedures.

Technical Options and Issues

A. TEDE versus TED

In Enclosure 2 of SECY-08-0197, NRC is considering changing the terminology in 10 CFR 20 from TEDE to TED.

Recommendation

CORAR recommends that NRC replace the term total effective dose equivalent (TEDE) in its regulations with the term total effective dose (TED).

In December 2007, NRC amended 10 CFR 20.1003 to clarify the definition of total effective dose equivalent (TEDE) to mean the sum of the effective dose equivalent (EDE) and the committed effective dose equivalent (CEDE). At the same time, NRC stated its policy to accept the deep dose equivalent (DDE) as the TEDE for dose received by exposure to external sources. When dosimeters are used for this purpose, the DDE must be used in place of TEDE, provided the DDE is measured at the part of the whole body receiving the highest exposure.

At the time of this rule change it was recognized that the DDE is not always proportional to risk and the use of mixed quantities (DDE and EDE) to determine TEDE is not consistent with NCRP and ICRP. ICRP 103 defines TED as the sum of the personal dose equivalent (determined by dosimeter measurement) for external exposure, and the committed effective dose (CED) from internal exposure. According to this definition, adoption of the term TED will resolve the issue of mixed quantities. It might also be worthwhile for NRC to consider adopting the term personal dose equivalent (PDE) in the place of DDE for additional consistency with ICRP 103.

The ongoing allowance by NRC for the use of DDE instead of TEDE addresses the need for a practical yet conservative means of determining the TEDE for external exposures, and ICRP 103 states that the use of a dosimeter is a sufficiently precise means of determining the personal dose equivalent. However, this comes with the conditions that the whole body is uniformly exposed and the exposure results in relatively low dose. This is problematic in situations such as in interventional radiology, repair and maintenance of particle accelerators (where NRC does not have jurisdiction), and other situations where relatively high dose rates may be encountered and resulting exposure is not uniform.

A rule change should take into the account the need to afford licensees the opportunity to engage on any potential issues and adequate time to make any significant radiation protection program changes.

B. Dose Limits

1. Public Dose Limits

In Enclosure 2 of SECY-08-0197, NRC states that it has not identified changes to the public exposure dose limits as an issue but recognizes that interested parties and stakeholders may wish to make this a point of discussion.

Recommendation

CORAR recommends that, consistent with ICRP 103, NRC maintain the limit of 1 mSv per year to individual members of the public from planned exposures due to licensed operations established in 10 CFR 20.1301.

NRC should streamline its regulatory restriction of public dose, defined by NRC as the "dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee," and align with ICRP recommendations by doing the following:

- Retain the current limit of 1 mSv per year in 10 CFR 20.1301
- Adopt the ICRP concept of "representative person" for the purpose of radiological protection
- Establish a system of dose-based constraints at appropriate levels for individual sources of planned exposure from individual under licensee control (i.e. sources of external radiation, and airborne and liquid discharges) without an obligation to report exceedances as long as the dose from all sources does not exceed the 1 mSv annual limit and the licensee takes actions in accordance with license conditions specified for public dose constraints.
- Consider the current annual constraint of 0.1 mSv due to airborne emissions in 10 CFR 20.1101 as one of the dose-based constraints for individual sources.
- Eliminate the limit of 0.02 mSv in any one hour in 10 CFR 20.1301(a)(2) or make this a constraint at this or other more appropriate level without obligation to report exceedances as long as the 1 mSv annual limit is not exceeded and the licensee takes actions in accordance with license conditions specified for public dose constraints.

2. Dose Limit to an Embryo/Fetus of a Declared Pregnant Woman

Current regulations in 10 CFR 20.1208 establish a dose limit of 5 mSv to the embryo/fetus of a declared pregnant worker for the duration of gestation with 0.5 mSv additional dose allowed if the dose to the embryo/fetus has already exceeded 5 mSv at the time of declaration. In Enclosure 2 of SECY-08-0197, NRC has offered the following three options:

Option 1 - Retain the current dose limit in 10 CFR 20.1208.

This option seems to be supported by NRC's own stated position that the current regulatory framework already provides adequate protection of workers, the public and the environment. There also is a lack of consensus among the scientific community as well as convincing evidence regarding potential long term risk to the embryo/fetus from levels of ionizing radiation dose permitted by regulation.

However, maintaining the current limit presents a challenge to CORAR companies with global operations where locations outside the US are subject to regulations consistent with the limit recommended by ICRP. While it is likely that licensees within the radiopharmaceutical industry already have internal constraints and other self-imposed dose restrictions below the current NRC limit, there are other situations in the medical and other communities that could be significantly impacted. There is also a need to take into account the legal rights afforded to women that allows them to take responsibility for making informed career/health decisions.

Option 2 - Establish a new limit of 1 mSv applicable from the declaration of pregnancy for the remainder of the gestation period.

This option is consistent with the recommendations of ICRP 103 as well as most regulations outside the US. It could ultimately provide the same level of radiological protection to the embryo/fetus of pregnant woman that is afforded to the general public while simplifying record keeping requirements to demonstrate compliance. Most licensees in the radiopharmaceutical industry already have established self-imposed constraints that are at or below this limit. However, there could be an impact on some licensees where there are a disproportionate number of women in the employee population, and particularly in other industries such as those involving healthcare and where there may be difficulty assessing dose from exposure of the pregnant worker to unsealed radioiodine.

Option 3 - Establish a new limit of 0.5 mSv applicable from the declaration of pregnancy for the remainder of the gestation period.

NRC has proposed this option noting that "the embryo/fetus is several more times more sensitive to radiation exposure than members of the public and should be afforded additional protection." It is unclear what the basis is for NRC to make this statement. While also recommending that additional measures be made to reduce exposures to the embryo/fetus, ICRP takes the position that optimization of protection for members of the public should be sufficient to afford an adequate level of protection to the embryo/fetus of pregnant workers.

Further reduction of the dose limit as proposed in Option 3 may reduce dose to the embryo/fetus but this is unwarranted if protection to the level afforded the public is adequate and lowering the limit has adverse impact. Subjecting workers to a lower limit could render a radiation worker unable to perform work assignments, in some cases jeopardizing employment, and may prompt a decision on the part of the worker not to declare pregnancy thereby subjecting the embryo/fetus to exposure to the occupational limit.

Recommendation

CORAR prefers Option 2. NRC should adopt the ICRP 103 recommendation of 1 mSv TED from the time of declaration.

CORAR makes this recommendation with recognition of the fact that that there would be challenges to implementing this embryo/fetal dose limit for a number of licensees and encourages NRC to solicit stakeholders for any input on this option as part of any rulemaking process. The NRC should consider whether implementation of this dose limit may have the unintended consequences of unnecessarily restricting women's career opportunities or causing pregnant radiation workers to delay declaration of pregnancies.

3. **Occupational Dose Limits**

Option 1 – Retain present 50 mSv (5 rem) annual occupational dose limit.

This option is supported by NRC's own stated position that the current regulatory framework already provides adequate protection of workers, the public and the environment. There also is a lack of a consensus among the scientific community as well as convincing evidence regarding potential long term risk from levels of ionizing radiation dose permitted by regulation.

At the same time, this option would not address the need to bring U.S. radiation protection regulations in line with ICRP recommendations and the international community, a long-term outcome desired by companies with global operations. The current limit is also higher than the internal constraints or limits typically established by the radiopharmaceutical industry as part of their ALARA programs incorporated into materials licenses. There would be little value added to the process of optimization recommended by ICRP for CORAR constituents who have adopted a constraint or other annual occupational dose restriction closer to 20 mSv, which may be perceived as the "standard of care" for the industry and already consistent with ICRP recommendations.

Option 2 – Change the annual occupational dose limit to 100 mSv (10 rem) over any 5 year period not to exceed 50 mSv (5 rem) in any year.

This option would align NRC regulations with the recommendations of ICRP 103 on occupational exposure and would essentially limit occupational exposure to a level that would typically be achievable by the radiopharmaceutical industry while providing flexibility in implementation and compliance not afforded by Option 3. While CORAR constituents would likely be able to comply with the limit proposed in Option 2, adoption would result in the burden of having to reconfigure systems of

occupational dose measurement, assessment and recordkeeping to enable licensees to determine and demonstrate compliance and would impact, without benefit, the design basis of new and existing facilities and operations.

Option 3 – Lower the annual occupational dose limit to 20 mSv (2 rem).

Option 3, while simpler in approach than Option 2 in the effort to establish essentially the same regulatory limit, the impact would likely be more significant on licensees (e.g. interventional radiology, transient nuclear power workers, industrial radiography) outside the CORAR community. Implementation of a 20 mSv per year limit would be impractical and likely counterproductive to the goal of optimization which, according to ICRP 103, should be "a forward-looking iterative process aimed at preventing or reducing future exposures...taking into account both technical and socio-economic developments." In practice, operations that are currently challenged to meet this limit may be inclined to add new or inexperienced workers resulting in an increase in collective dose as well as additional costs and other administrative and operational burdens.

Recommendation

CORAR prefers an enhanced version of Option 1. We recommend the option of a constraint of 20 mSv per year (or 100 mSv over 5 years) for planned exposures (as defined in ICRP 103) with an absolute limit of 50 mSv in any year. This approach is consistent with ICRP's recommendation to control planned occupational exposures below a source-related constraint and with the use of a prescribed dose limit. With regard to the objective of incorporating ICRP's recommendations into NRC's radiation protection regulations, this option will achieve the following:

- Move NRC regulations toward alignment with ICRP recommendations.
- Retain the occupational dose limit in 10 CFR 20.1201 that already provides adequate occupational protection.
- Employ a regulatory scheme that provides a constraint as a desired bound for optimization.
- Allow the needed flexibility to accommodate, at least in the short-term, all affected licensees.

Implementation of this modified option will require that the constraint should not be considered a regulatory limit but rather a desired bound for the optimization process.

At this time CORAR also recommends that NRC not adopt the ICRP recommendation to limit effective dose to the skin against stochastic effects based on an average dose over 1 cm^2 of skin regardless of the area exposed. Consistent with NCRP, NRC should maintain its requirement in 10 CFR 20.1201(c) that the assigned shallow-dose equivalent must be the dose averaged over the contiguous $10cm^2$ of skin receiving the highest exposure.

C. Incorporation of Constraints

1. Occupational Exposure

In Enclosure 2 of SECY-08-0197, NRC discusses the issue and options for consideration of the ICRP concept of constraints and reference levels as part of a process to optimize radiation protection.

Recommendation

As stated in our comments concerning options for restricting radiation dose, **CORAR recommends the use of a constraint of 20 mSv per year (or 100 mSv over 5 years) for planned exposures along with NRC Option 1 for restriction of occupational exposure.**

Implementation of a constraint needs to take into account the ICRP position that national authorities should have the freedom to authorize dose constraints that are appropriate for particular circumstances. This could be done by a process defined in regulation that provides for an appropriate value to be established as part of an ALARA program incorporated into the license along with a protocol for investigating and correcting situations when the constraint is breached. Most materials licensees already have similar provisions established in accordance with 10 CFR 20.1101 and NUREG-1556.

This approach would be consistent with the current NRC 10 CFR 20 definition of constraint which is, "a value above which specified licensee actions are required." Consistent with ICRP recommendations, there should not be a regulatory obligation for a licensee to formally report constraint exceedances. However, NRC would have the opportunity to determine during inspections whether the licensee met its obligation to take the actions specified in the license.

2. Public Exposure

In Enclosure 2 of SECY-08-0197, NRC considers the need for establishing the ICRP concept of constraints for members of the public.

In 10 CFR 20.1301, NRC has a limit of 1 mSv per year on to individual members of the public from licensed operations. In 10 CFR 20.1101, NRC also has a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters. The constraint is established by licensees other than those subject to 10 CFR 50.34(a), such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee must report the exceedance as provided in 10 CFR 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

Recommendation

CORAR recommends that NRC implement the use of dose constraints for individual sources of public dose due to planned exposures in addition to the annual dose limit of 1 mSv.

This approach would be consistent with the current NRC 10 CFR 20 definition of constraint which is, "a value above which specified licensee actions are required." Public dose constraints should be established as upper bounds on the annual doses that the public could receive from planned operation of any controlled source. Consistent with ICRP recommendations, there should not be a regulatory obligation for a licensee to formally report constraint exceedances as is currently the case for airborne emissions under 10 CFR 20.2203. However, NRC should have the opportunity to determine during inspections whether the licensee met its obligation to take the actions specified in the license.

CORAR recognizes that there would be challenges to the practicality of implementing public dose constraints and encourages NRC to solicit stakeholders for any input on this option as part of any rulemaking process. Constraints on public dose from multiple sources should be better established as a license condition to accommodate the unusual demographic proximity conditions that justify the need for constraints.

D. Changes to Weighting Factors and Numeric Values

1. Numeric Values of Weighting Factors

NRC believes that it is appropriate to update the weighting factors for tissues and types of radiation specified in 10 CFR 20 with the values in ICRP 103, and to engage stakeholders and other interested parties on possible issues and implications.

Recommendation

CORAR recommends that the ICRP radiation and tissue weighting factors should be incorporated into 10 CFR 20. A table of new factors should be provided in a section of the regulations pertaining to determination of effective dose, rather than in the definition of "weighting factor" in 10 CFR 20.1003. It makes sense to adopt the values that are used globally to determine the overall radiation detriment due to stochastic effects from the individual contribution(s) of individual tissue dose. A rule change should be implemented only after NRC has afforded stakeholders the opportunity to engage on any potential issues and without the obligation for licensees to re-compute past or existing dose determinations using any new values.

2. **Numeric Values of Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) in 10 CFR Part 20, Appendix B.**

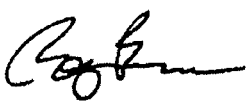
NRC believes that it is appropriate to amend the regulations to reflect revised ICRP values for ALI and DAC when the updated values are available. ICRP has indicated that these are in development but will not be available before 2014.

CORAR recommends that Appendix B of 10 CFR 20 be amended to reflect updated values of Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) when made available by ICRP. NRC should include the rulemaking a provision to adopt new dose conversion factors but delay implementation until the new values are published by ICRP. A rule change should be implemented taking into the account the need to:

- Afford stakeholders the opportunity to engage on any potential issues.
- Afford licensees adequate time to make any significant radiation protection program changes (e.g. bioassay procedures, dose calculations, air sampling analysis, etc).
- Avoid the obligation for licensees to re-compute past or existing dose determinations using any new values.
- Consider that adopting ICRP stochastic ALIs could be problematic if NRC retained the 50 mSv annual dose limit.

CORAR appreciates the opportunity to express comments in response to this solicitation of comments on potential changes to NRC's radiation protection regulations. Please contact us if there should be any questions or if any additional information is needed concerning these comments.

Sincerely,



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