CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo Drive
Moraga, CA 94556-1551
(925) 283-1850
Fax: (925) 283-1850
E-mail: corar@silcon.com

Henry H. Kramer, Ph.D., FACNP
Executive Director

9/27/2010
75 FR 59160

(16)

January 28, 2011

RECEIVED
2011 FEB -4 PM 4:07
RULES AND DIRECTIVES BRANCH

Cindy K. Blady, Chief,
Rules, Announcements and Directives Branch,
Office of Administration,
Mail Stop 5B01M,
U. S. Nuclear Regulatory Commission,
Washington, DC 20555-0001

Subject: **CORAR Comments to NRC on Potential Changes to Radiation Protection Regulations Considering ICRP 103 Recommendations.**

Reference: **Federal Register Vol.75, No 186, September 27, 2010, Pages 59160-59167. Radiation Protection Regulations and Guidance; Public Meetings and Request for Comments.**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)[1]. CORAR submitted comments on this topic on March 29, 2010 and is now providing additional comments in response to the new questions that the NRC has raised. Many of the comments provided last March address similar questions and options in this more recent request and we advise NRC to revisit our previous comments accordingly.

CORAR recognizes that all NRC regulatory limits are adequately protective and do not need to be changed to provide more protection. Several CORAR members maintain manufacturing and distribution facilities in numerous countries and provide products and services to customers worldwide. Because of the increasingly global nature of our operations we need to develop our radiation protection programs in line with international standards and comply with national and international regulations. This is necessary to facilitate the exchange of staff and products, minimize redundant compliance training and simplify regulatory compliance. CORAR consequently supports the harmonization of federal regulations with international regulations and recommendations. In particular CORAR supports the NRC adoption of ICRP 103 Recommendations, wherever and whenever this is practical.

SUNSI Review Complete
Template = ADM-013

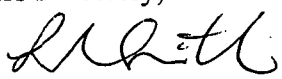
E-RIDS = ADM-03
Add = K. Morgan Butler
(Kmb1)

CORAR recognizes that the development of national and international recommendations and regulations is an uneven process with some sections being updated sooner than others. We are also aware that practices and conditions vary between industries and in different countries and it can be difficult to establish a standard to suit all. Considering these difficulties, CORAR recommends that the NRC continue to align regulations with ICRP recommendations but also provide flexibility for operations that are necessarily different from those in other countries. CORAR is aware that licensees must also comply with other US. laws that are different from those in other countries. In particular we must accommodate a pregnant radiation worker's autonomy and right to choose whether to declare her pregnancy and submit to more restrictive dose limits.

CORAR is also aware that the ICRP has not yet been able to adequately review recent developments in extremity and skin dosimetry. We recommend that NRC continues to promulgate the better extremity dose limit standard based on NCRP recommendations until ICRP has adequately reviewed these new findings.

CORAR appreciates the opportunity to comment on this important subject and would be glad to provide clarification or additional information.

Yours Sincerely,



Leonard R. Smith, CHP
Co-chair CORAR Committee on Manufacturing Quality and Safety.

1. CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

CORAR COMMENTS TO NRC ON POTENTIAL CHANGES TO RADIATION PROTECTION REGULATIONS CONSIDERING ICRP 103 RECOMMENDATIONS

Issue No. 1: Effective Dose and Numerical Values

1. **Issue 1.1. Clarifying Effective Dose Methodology and Assessing Implication for Licensee Compliance with Dose Limits and Changes to Terminology**

   CORAR recommends Option 1.1b to change the current regulation to align with the ICRP 103 recommendation expressing dose as Total Effective Dose (TED).
   CORAR prefers this option because TED is used now in most developed countries and in most scientific publications. It is important that the change to TED is made simultaneously by the NRC and all Agreement and Non-Agreement States. This implies a three year period to implement the change because some States will likely take that long.

2. **Question 1.1-1:"...are there any potential impacts on the ability to comply with the options for dose limits (DDE vs. TED)?"**

   Some licensees will incur costs in making a change to TED. However, we are not aware of any significant impacts on the ability for material licensees to comply with these options.

3. **Question 1.1-2:"What are the anticipated impacts on records and reports?"**

   Material licensees will need to update dose record systems to use the new TED terminology instead of TEDE. This should not be difficult to implement especially if the NRC issues a revised Form 5.

4. **Issue 1.2. Numerical Values and Weighting Factors**

   CORAR recommends Option 1.2b to change the current regulation to align with ICRP 103 recommendations to use new numerical values, models, radionuclide decay data and weighting factors.

5. **Question 1.2-1, "...impacts of the timing (2014) of making changes to the current numerical values and weighting factors."**

   CORAR anticipates that the changes will be small for most material licensees and the timing not critical. However, the changes would have an impact on internal dose determinations for radiation protection purposes when planning the administration of radiopharmaceuticals to patients. The change could be simplified and the impact lessened if TED and the new numerical values and weighting factors were adopted at the same time in or after 2014. We do not think it necessary for the NRC to promulgate new data for a limited set of radionuclides before 2014. Also, change management would be simplified if regulatory guidance material was available well before the implementation date for regulatory changes.

6. **Question 1.2-2:"Should NRC use the values developed by the EPA which will be based on a US population, instead of the ICRP values which are based on a more diverse world population?"**

   CORAR recommends using the ICRP values. The differences between large populations with significant exposure to radiation are likely to be small. It would, therefore, be expedient to use one set of values worldwide that have the highest level of acceptance. Also, the most affected populations are licensee employees and members of the public that visit or live close to the licensee. There is likely to be more differences between these local populations than between general populations. This is not a concern because licensees typically set administrative constraints that are below regulatory limits and could be required to do so as a license condition if necessary.

Issue No. 2: Occupational Dose Limits

1. CORAR recommends Option 2.a. with a modification to promote a constraint on annual TED exceeding 2 rem (20 mSv). Comments on Issue No. 4 discuss ways to implement an occupational dose constraint.

   Several major manufacturing licensees also have sites in countries where the occupational dose limit is 2 rem/y (20 mSv/y). These licensees would prefer to adopt a 2 rem/y (20 mSv/y) limit to facilitate international commerce and exchange of radiation workers. However, there are practices in the US. that could have difficulty in maintaining individual doses below 2 rem/y (20mSv/y) and may currently only be able to do this by using a larger number of less skilled radiation workers with an unavoidable increase in collective dose. The increase in collective dose is due to the extra radiation workers being less skilled, taking longer to complete high dose rate operations, being less able to avoid high dose rate radiation fields, more rework and more workers receiving unproductive dose from entering and leaving and setting up and closing down operations in the radiation area. Also, when you reduce a radiation workers time doing work in the radiation area they become less practiced and less skilled.

   CORAR recognizes that most material licensees in the US. maintain annual occupational TEDE below 2 rem (20 mSv). There are, however, certain practices where higher doses are prevalent due to high medical patient load or individuals handling greater quantities of licensed materials. To transition towards Option 2.b, the current ICRP 103 recommendation of "10 rem (100 mSv) over 5 years, with a maximum of 5 rem (50 mSv) in any one year," the NRC could maintain the 5 rem (50 mSv) annual limit and establish a constraint (as defined in ICRP 103) of 2 rem (20 mSv) per year. Licensees could be required to review, justify and/or reduce annual doses exceeding the constraint. This would be compatible with current regulatory ALARA requirements and should promote continuous adjustments to dose control, while avoiding unproductive administrative burdens, to a time when the 5 rem (50 mSv) would be redundant and a 2 rem (50 mSv) limit practical.

   Continuous long term dose reduction is potentially still feasible in the radiochemical manufacturing industry due to continuous modernization of facilities and the implementation of more sophisticated process control, monitoring equipment and personnel dosimetry procedures. However, it can take up to 30 years before a facility can be replaced by a more efficient one and an ongoing concern is that US. businesses are continuously reducing staffing to meet increasing international competition.

2. **Question 2-1,"Are there any significant anticipated impacts in assessing and retaining dose histories for each individual in order to comply with a multi-year average?"**

   This should not be a problem for most licensees because most licensee employees will have doses each year that are less than the 2 rem (20 mSv) average annual limit. Hence, dose histories will only be necessary for those few individuals who may have exceeded the average annual limit in one or more years.

3. **Question 2-2, "Are there any anticipated implementation impacts if the dose limit is decreased?"**

   In the radiopharmaceutical and radiochemical industry about 1% to 2% of radiation workers currently exceed 2 rem/y (20 mSv/y) dose. The highest exposed individuals are typically highly skilled specialists who may receive these doses over a 20 year, or longer, period. Typically individuals who receive higher planned doses are highly trained to control their radiation exposure. They could be required to limit their time in the radiation field and their function completed by less trained and less skilled individuals with a consequent increase in collective dose. In practice, licensees usually must constrain doses to well below the current limit in accordance with internal ALARA policies and to ensure that the regulatory limit is not inadvertently exceeded. Depending on the controls in place, it is usually necessary to set administrative dose constraints at 60% to 80% of the corresponding dose limit or dose constraint mandated by a regulation or a license condition. This needs to be considered when setting a lower limit.
   There is increasing evidence that some engineered controls and personal protection provisions to minimize occupational dose inadvertently cause increase risk from non-radiological hazards. For example, working in a glove box or with lead shielded equipment or wearing a respirator increase the risk of ergonomic injuries, fatigue and accidents due to reduced dexterity. Consequently, licensees need to consider all hazards when optimizing facility and operational safety. In industry this is typically addressed in hazard review processes pror to authorizing new or modified facilities, equipment or procedures by review teams that include the responsible manager, experienced operator and appropriate radiation protection and industrial safety specialists. However, most regulations are designed to address a particular hazard without adequate consideration of other potential hazards in the work place. This is one of several reasons why the licensee is often in a better position to determine whether a radiation dose constraint is beneficial to a practice.

4. **Question 2.3. NRC seeks information about the dose distributions for industrial and medical licensees.**

   NRC should already have available annual dose data for licensees under NRC jurisdiction (NUREG-0713). CORAR can provide data on licensees in the radiopharmaceutical and radiochemical industry, including those who are regulated by Agreement States, provided that it can be collected without disclosing specific data for individual CORAR entities. In this effort, we would consult with NRC to determine the appropriate format for providing the required information with the necessary detail. It is likely that the data will be similar to that already reported for radiopharmaceutical industry licensees in NUREG-0713.

5. **Question 2.4, "For the medical industry, are there any potential impacts on patient care?"**

   CORAR understands it may not be currently practical for the medical industry to be subject to a reduction in the dose limit. This difficulty is compounded by the fact that many of the challenges faced by the healthcare community result from x-ray applications that are currently not regulated by the NRC. We defer to members of that community to speak in more specific terms regarding the impact. CORAR's recommendation, above, takes into account the practical need to allow for the transition to a lower dose limit, while using a constraint to promote continual dose reduction.

   CORAR also continues to support the extremity occupational dose limit of 50 rem (500 mSv) averaged over the maximum exposed contiguous 10 cm^2 based on NCRP recommendations. This is necessary to enable efficient handling of fluoroscopy patients and radiochemical manufacturing maintenance while minimizing TED and optimizing radiation protection.

Issue No. 3: Doses to Special Populations

1. **Issue 3.1, Dose Limits for Embryo/Fetus of a Declared Pregnant Worker**

   CORAR recommends NRC Option 3.b. Change the current regulation to align with ICRP 103 limit of 100 mrem (1 mSv) after the declaration of pregnancy. Several CORAR members need this change to align with operations on sites in other countries. However, we are aware that exposure conditions and laws in the US. are different to other countries which may make it difficult to implement this change. The ICRP has tended to avoid accommodating fluctuating legal and ethical considerations in individual countries. The ICRP treats the protection of an embryo/fetus as a member of the public whereas in the US. the pregnant radiation worker has this responsibility.

2. **Question 3-1, "Are there any significant anticipated impacts associated with reducing the limit to the embryo/fetus of a declared pregnant woman, including operational impacts?"**

   One concern on reducing the dose limit is that it could have an adverse impact on a declared pregnant worker's earnings and/or career. Some pregnant workers may decide to not declare their pregnancy to keep their employment and consequently subject their embryo/fetus to unmonitored dose.

3. **Question 3-2, "Are there any anticipated implementation impacts on record keeping?"**

   CORAR is not aware of any such impacts resulting from a change in the dose limit as long as it is possible to coordinate the start of occupational monitoring with the time the employee declaration is made.

4. **Question 3-3, "Is there a reduction in assessment and record keeping if the ICRP recommendation is considered for adoption?"**

   CORAR is not aware of any such impacts resulting from a change in the dose limit.

5. **Question 3-4, "Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP recommendation difficult in certain circumstances?"**

   There would be a need for NRC to determine and communicate the methodology accepted for determining dose to the embryo/fetus from intake of radionuclides and/or indirectly from intake by the declared pregnant worker. This would need to be based on ICRP updated metabolic dose models which will not be available for several years. Even at the current 500 mrem limit it is impractical for a declared pregnant radiation worker to continue working with certain commonly used unsealed radiochemicals. Of particular concern are potentially volatile radiochemicals. Handling radioiodine is usually prohibited during the third trimester when the fetus thyroid gland is developing.

6. **Question 3-5, "Is there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for this data? Is this data available to share with the NRC?"**

   CORAR is not aware of any actual data that is available from its members.

7. **Issue 3.2, Dose Limits for Members of the Public**

   CORAR recommends NRC Option 3.2-a where NRC would maintain the limit of 100 mrem (1 mSv) per year to individual members of the public, while retaining the provision in 20.1301(d) to require prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 500 mrem (5 mSv), excluding sensitive populations.

8. **Question 3.2-1, "Are there any significant anticipated impacts associated with limiting the applicability of alternative public dose limits?"**
   Question 3.2-2, "Are these impacts the same for the options of a rule change, or for changes to guidance?"
   Question 3.2-3, "Is there data available about the actual use of alternative dose criteria? Is this data available to share with the NRC?"

   CORAR continues to support the need for caregivers, including the family members, of a nuclear medicine patient to receive up to 500 mrem (5 mSv) per year. The need to minimize exposure should continue to be explained in guidance documents and information provided by the licensed nuclear medicine provider to the patient and their caregivers. There may be situations where the benefit to a patient or other person, resulting from a dose to a member of a sensitive population greater than 100 mrem (1 mSv) but less than 500 mrem (5 mSv), outweighs the risk to the member of the sensitive population. Appropriate dose reference levels and additional guidance could be established, for example, in the case of resulting exposure to sensitive populations from medical practices. CORAR defers to specific input from members of the medical community.

Issue No. 4: Incorporation of Dose Constraints

1. CORAR recommends Option 4.c. In addition to requiring the establishment and use of constraints, require that the licensee use a numeric value that does not exceed some specified value. One such value for occupational exposure could be the 2 rem (20 mSv) per year level. However, a specific value should not be prescribed by NRC but should be determined by licensees as part of a dose management system already defined as part of a radiation protection program integrated into the license, reviewed and approved by NRC.

   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, if appropriate, 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. **Question 4-1, "Are there any significant anticipated benefits and impacts associated with the use of constraints in a licensee's radiation protection program?"**

With regard to a constraint on occupational dose, 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 part of a system of 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 instead serves to promote periodic licensee action to review practices and conditions and ensure that radiation protection is optimized.

Regarding the application of constraints on public dose, CORAR anticipates that imposing the use of constraints in a licensee's radiation protection program can have both beneficial and adverse consequences. These will depend on the value selected for the constraint and the action to be taken when a constraint is exceeded. It appears to CORAR that the current constraint of 10 mrem (100 μSv) per year for non-reactor licensees' airborne emissions is not useful. This constraint is unnecessary because it is highly unlikely that non-reactor licensees have sufficient inventories of airborne radionuclides to exceed the constraint level. Also, this constraint is treated more like a limit because, when exceeded, reports are required to multiple regulatory agencies and prompt action is required to reduce emissions to below the constraint level. Another difficulty with this constraint is that most licensees are forced to use sophisticated monitoring and calculation methods to demonstrate compliance because the alternative simpler screening methods available can grossly overestimate the impact and are therefore often inadequate for determining compliance. CORAR is not aware of any beneficial constraints imposed on licensees. However, most licensees have established constraints that serve to aid in the administration of their radiation protection programs and promote continuous improvement.

3. **Question 4-2, "Are there any anticipated implementation impacts on inspection, compliance, and reporting anticipated?"**

   Any new constraints, that require material licensees to reduce radiological quantities to below the constraint level, would be regarded as limits that are more restrictive than existing regulatory limits. They would appear unnecessary because the existing regulatory framework already provides adequate protection. However, it might be possible to establish appropriate mandatory constraints that, when exceeded, only require licensees to review their radiation protection program to ensure that it complies with ALARA requirements. Requiring licensees to report conditions exceeding a constraint but complying with regulatory limits or a license condition limit would be an unnecessary regulatory burden.

   One difficulty with mandatory constraints is how to select a value that is appropriate for all licensees. Consequently a better approach might be to mandate the use of a constraint but require each licensee to establish the constraint level that best fits their operations. In the event that a licensee is unable to determine an appropriate constraint the Regulatory agency might impose one as a license condition perhaps using a default value.

4. **Question 4-3, "What relationship should a constraint have to the dose limit, if any?"**

   CORAR previously recommended the use of a constraint of 2 rem (20 mSv) per year (or 10 rem (100 mSv) over 5 years) for planned exposures while retaining an absolute occupational dose limit of 5 rem (50 mSv) per year.

   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, if appropriate, correcting situations when the constraint is exceeded. 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 doses that exceed a constraint. However, NRC would have the opportunity to determine during inspections whether the licensee met its obligation to take the actions specified in the license.

5. **Question 4-4, "Is a requirement to establish and use constraints an appropriate, or inappropriate, insertion of a regulatory requirement?"**

   The requirement to use a constraint is inappropriate if the material licensee is obligated to reduce radiological conditions regardless of whether such action is ALARA.

6. **Question 4-5, "How familiar are you with the use and implementation of constraints or planning values in a radiation protection program?"**

   Constraints and planning values have been commonly used by licensees and/or imposed by regulatory agencies as license conditions for many decades. They can be very useful when set at the appropriate level and updated when conditions and practices change. Their use has resulted in the trend of continual reduction of occupational dose in our industry.

7. **Question 4-6, "Are constraints (planning values) used in your current licensed activities, and if so, can you share some insights on the use of these constraints?"**

   Constraints and planning values are commonly used to control occupational and public doses, radiation and contamination levels, concentration of radionuclides in effluents and situations where there are multiple exposure conditions. They are typically used to simplify administration of radiation control, to encourage employee and supervisor accountability, as buffers to ensure limits are not exceeded and as stretch goals for continuously improving the radiation protection program and reducing exposure and the risk of exposure. They are most effective when they are established for particular conditions and practices and used in conjunction with appropriate deminimis levels. By these means the licensee can focus resources where they are most needed.