

ISSUES RELATED TO IMPLEMENTATION OF

10CFR 20.1201 (a) (2) (ii) and (c)

EXECUTIVE SUMMARY

The radionuclides and radiopharmaceutical manufacturing and distributing industry is taking all necessary actions to assure that extremity exposure to ionizing radiation is controlled and the health and safety of workers is being adequately protected. Industry is developing improved methods for demonstrating regulatory compliance to NRC and Agreement State inspectors. Inconsistent and overly prescriptive interpretations by NRC staff of regulatory requirements for monitoring and recording extremity doses may lead to unintended consequences, such as increased overall dose to workers and unnecessary regulatory burden on licensees, without a substantive benefit to protection of worker health and safety. Adoption of non-prescriptive, practical performance-based guidance will help improve flexibility and efficiency in licensee implementation of NRC requirements and thereby reduce unintended consequences.

BACKGROUND TO ISSUES CONCERNING EXTREMITY MONITORING

In the Nuclear Regulatory Commission (NRC) and Agreement State regulatory framework, licensees have been subject to an annual 50 rem shallow dose limit to the skin of the extremities for more than a decade. When extremity exposure is fairly uniform it is straightforward to establish practical dosimeter placements to provide a representative dose measurement to demonstrate regulatory compliance. However, there are routine repetitive operations or abnormal conditions where extremity exposures are not uniform. In recent years there has been increased interest by regulators and licensees in the need to characterize and control non-uniform extremity exposure. This includes a need for practical methods to account for any differences between the maximum extremity dose and the dose recorded by conventional extremity dosimeters. In non-uniform exposure conditions licensees are challenged to demonstrate compliance with a regulatory limit applicable to the highest exposed contiguous small area of skin basal layer cells. Until April 5, 2002 the NRC annual limit was 50 rem to the highest exposed contiguous 1 cm² of skin of the extremities.

Another dose control issue of interest to manufacturing licensees is skin exposure from small area skin contamination. Skin contamination in manufacturing most commonly occurs to the hands, wrists and forearms. In the 1990s the National Council on Radiation Protection and Measurements (NCRP) was aware of CORAR's concern that regulatory limit on small area skin contamination was much more restrictive than and therefore incompatible with other dose limits in current use. On April 5, 2002 the NRC published a "Revision of the Skin Dose Limit" establishing annual limit to be 50 rem shallow dose to the highest exposed contiguous 10 cm² of skin. This revised skin dose limit fully resolved CORAR's concern.

CORAR also recognized that the NRC's April 5, 2002 rule, where the 50 rem per 10 cm² limit was applicable to all forms of extremity exposure, was a useful simplification of the regulation. However, this new rule has caused licensees, who have operations with potential external exposure to extremities, to re-evaluate their dosimetry practices.

On January 16, 2003 the NRC held a public meeting with CORAR members and other interested stakeholders to discuss extremity dosimetry issues. At this meeting CORAR committed to review these issues and provide the NRC with the results of this review. Attached is a list of the issues that appeared to be of greatest importance. CORAR hopes that the NRC's consideration of these issues will help to develop useful guidance to licensees and facilitate regulatory inspections.

SPECIFIC ISSUES CONCERNING EXTREMITY MONITORING

1. ISSUE: There is a need for a reasonable and practical approach for licensees to demonstrate compliance with 10CFR20.1201 (a)(2)(ii) and (c). in routine, well controlled operations.

DISCUSSION: Regulatory agencies should acknowledge that there is an adequate basis for establishing practical guidance on dosimeter placement in routine well-controlled operations. In establishing practical guidance, the inherent conservatism in the dose limit (in the routine situation) should be recognized. The fact that current dosimeter placement practices have provided sufficient feedback on dose control to ensure protection should also be considered.

In operations where hands are exposed to gamma, x-rays and/or bremsstrahlung from radiation sources that are shielded and/or deliver dose well below regulatory limits, there is a need for the licensee to be able to routinely use a single dosimeter on each hand to measure extremity dose. The justifications for this practical dosimetry method are:

a) The radiation fields around well shielded photon sources are not strongly divergent. A single dosimeter placement can be selected that adequately measures the average dose to the hand. The average dose is not significantly different from the maximum dose to any part of the hand.

b) The ICRP recommends that it is not necessary for the measurement to be highly accurate to demonstrate compliance with regulatory requirements when the dose delivered to the hand is an order of magnitude lower than the regulatory limit.

PROPOSED RESOLUTION: CORAR should obtain agreement from regulatory agencies on practices which deliver uniform or practically uniform doses to the hands and practices which deliver doses that are well below regulatory limits. CORAR should also obtain agreement that certain badge placements are acceptable for measuring hand dose and assigning this measured dose to the workers records. An example of a suitable badge placement would be one finger ring dosimeter worn on each hand at the base of a finger orientated towards the anticipated radiation source when the practice involves uniform exposure and/or doses that are well below regulatory limits.

2. **ISSUE:** Some regulatory inspectors require that radiation workers routinely wear one or more dosimeters on finger tips or other specified locations in order to directly measure the maximum dose when extremities are potentially exposed to non-uniform and changing radiation fields. Licensees are concerned that routine use of multiple dosimeters can be ergonomically unsafe and increase radiation exposure.
- DISCUSSION:** Dosimeters that can be worn on finger tips or other specified locations on the hand are costly, not widely available nor highly developed. They are often difficult to fix on the hand and commonly lost or damaged when in use. Some dosimeters are ergonomically unsafe because they restrict blood supply to the finger or make it difficult to bend the finger. They commonly cause a loss of dexterity which can lead to accidents or slow down operations causing an increase in dose to the hands and/or lens of eye and/or shallow and/or deep dose to the whole body. While careful planning, selection and experience can reduce these impediments it is common experience that they can't be eliminated. Consequently, the routine use of multiple dosimeters should be anticipated to have undesirable side effects which include incomplete extremity dosimetry and increase dose to the extremity or to more radiosensitive parts of the body.
- PROPOSED RESOLUTION:** It is recognized that the judicious location of multiple dosimeters can characterize the non-uniform exposure pattern in some practices. However, regulators should not require that these be used routinely. Instead licensees should have the option of using multiple dosimeters periodically to characterize and confirm exposure patterns. Licensees should be allowed to use these multiple dosimeter measurements to compare with the results from routine standard dosimeter placements to assess the need for and provide the basis for adjustments to dose records.

3. **ISSUE:** Regulatory inspectors sometimes expect every exposure configuration to be elaborately characterized. While this may be prudent practice for frequently performed operations accumulating significant dose, licensees are concerned that they are expected to characterize infrequent operations that contribute only a small fraction of the total dose.
- DISCUSSION:** Regulatory inspectors commonly justify this approach by the need to conservatively determine the dose to the maximally exposed part of the extremity. However, there is considerable conservatism already incorporated in the extremity dose limit, especially in routine situations, to allow some flexibility in determining the total dose.
- PROPOSED RESOLUTION:** CORAR should propose how licensees should characterize dose patterns. The proposal should consider the frequency of an operation, the dose accumulated and the fraction of the total dose accumulated to a worker from all operations.

4. ISSUE Regulatory inspectors and licensees sometimes do not agree on how to average a non-uniform extremity dose over the maximally exposed 10 cm²

DISCUSSION: Some licensees have recognized and characterized non-uniform exposure conditions and determined methods appropriate to the conditions to monitor the exposure and use the (these) measurement(s) to estimate the dose to the maximally exposed 10 cm². Examples include:

a) When one side of a finger facing an external high energy beta source is exposed, the maximally exposed 10 cm² area extends roughly the entire length of the finger. Hence the average dose to the maximally exposed 10 cm² is well represented by the average of the doses measured by a finger tip dosimeter and a ring badge at the base of the finger, both orientated towards the exposure source.

b) In an operation involving external exposure of the finger tip to high energy gamma source the maximally exposed 10 cm² is the entire upper joint of the finger. One dosimeter located in the middle of the joint should give a good representative measurement.

PROPOSED RESOLUTION: CORAR should propose practical methods to measure and/or estimate the average dose to the maximally exposed 10 cm² from defined non-uniform exposure conditions.

5. **ISSUE:** Method to estimate extremity doses using multiple dosimeters and calculations often require intensive supervision of workers and the considerable involvement of experienced health physicists. Most licensees cannot provide this level of resources for the routine use of these methods.
- DISCUSSION:** Radiation workers in certain industries and operations must necessarily be highly qualified and trained to carry out complex functions. Adding complex dosimetry procedures that also make tasks more difficult can lead to higher dose and increase risk. There is a need to establish routine extremity dosimetry practices to demonstrate compliance that are easy to implement and maintain and that are easy to train workers to implement.
- PROPOSED RESOLUTION:** CORAR should propose routine extremity dosimetry methods found to be easy to implement for operations widely practiced by licensees.

6. **ISSUE:** Licensees have been receiving different advice from regulatory inspectors on when adjustments to measured doses, to account for non-uniform exposure, should be assigned to dose records.
- DISCUSSION:** This issue is of particular concern when non-uniform extremity exposures approach the regulatory limit. Licensees commonly assign a finger ring badge to measure extremity exposure. They may also conduct a study were multiple badges are used and compared with the badge and the maximally exposed 10 cm² estimated. Some inspectors advise that these studies should be used to adjust all routine measurements and assign the adjusted dose to the worker dose records. Others recommend that licensees record adjusted doses, but continue to assign the routinely measured dose to the dose records.
- PROPOSED RESOLUTION:** CORAR should propose when to assign routinely measured dose to a workers records and when to adjust these routine measurements and assign the adjusted dose.

7. **ISSUE:** Licensees recognize that although commonly used dosimetry methods are adequate for many operations there can be circumstances when extremity exposure must be individually evaluated. Licensees, therefore, need the flexibility to use non-routine dosimetry methods when appropriate.
- DISCUSSION:** When there is a reasonable expectation that exposure conditions are significantly different from existing operations, situations that warrant individual evaluation include:
- a) New operation.
 - b) Change in existing operation.
 - c) Deviation from normal operation.
 - d) New individual in operation with different skills or training.
 - e) Ergonomic variance.
- PROPOSED RESOLUTION:** CORAR should request regulators to recognize that licensees need the flexibility to use modified dosimetry methods for individual exposure conditions that are different from normal practices.

8. ISSUE CORAR with NRC has focused on demonstration of compliance with extremity dose limits in nuclear pharmacy operations. However, there is a need for regulators and licensees to reach comprehensive agreement for all operations involving extremity exposure.

DISCUSSION: In the NRC workshop on January 16, 2003 and in associated discussion with CORAR members, the primary focus has been on nuclear pharmacy operations with mostly low energy gamma and x-ray emitting radionuclides. There is a need to consider manufacturing and R&D uses with radionuclides that emit gamma and high energy beta radiation.

PROPOSED RESOLUTION: CORAR should present to the NRC characteristics of operations with potential for significant extremity exposure to ensure that guidance on practical methods to demonstrate compliance are comprehensive.

9. ISSUE

It is difficult to characterize practices where extremities are externally exposed in operations where the operator technique varies or an operator carries out numerous different tasks with multiple radionuclides emitting different types of radiation with different energies.

DISCUSSION:

The difficulty in monitoring is further complicated by different operations requiring different placement and orientation of extremity dosimeters. The regulatory approach of moving the dosimeter to the maximally exposed location for each part of an operation and using the most conservative applicable calculation factors can lead to a significant over-estimation of the dose.

PROPOSED RESOLUTION:

CORAR should recommend how to interpret dosimeter measurements in these mixed exposure conditions and what calculations are acceptable to adjust the measured doses.

RECOMMENDATION

CORAR and NRC should conduct a workshop to develop input to guidance on monitoring and recording of extremity doses.