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

4/20/2010
75 FR 20645
(4)

August 18, 2010

Cindy K. Bladey, Chief,
Rules, Announcements, and Directives Branch (RADB),
Division of Administrative Services,
Office of Administration,
Mail Stop: TWB-05-B01M,
U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001

Subject: CORAR Comments to the NRC on Draft Regulatory Guide DG-4018, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors."

Reference: Federal Register, June 25, 2010, Volume 75, Number 122, Notice of Issuance of Draft Regulatory Guide DG-4018, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors." Pages 36445-36446.

The attached comments are provided on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR[1]). CORAR members and their major material licensee customers have long experience in controlling airborne emissions and participated with the EPA to develop the Constraint Rule and the COMPLY Code. We appreciate the opportunity to comment on this Draft Regulatory Guide and would be glad to provide clarification and further information.

Yours sincerely,

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

Enclosed: CORAR Comments on Draft Regulatory Guide DG-4018, Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors.

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

SUNSI Review Complete
Template = ADM-013

E-RIDS = ADM-03
Cdd = M. Case (MSC)
Y. Chapman (GXC3)
M. Baytsie (mmb1)

CORAR COMMENTS ON DRAFT NRC REGULATORY GUIDE DG-4018, CONSTRAINT ON RELEASES OF AIRBORNE RADIOACTIVE MATERIALS TO THE ENVIRONMENT FOR LICENSEES OTHER THAN POWER REACTORS

Page 3, lines 19-20, section B, Constraints, "The dose limit to members of the public includes doses from all pathways, including direct radiation, liquid effluents and gaseous effluents."

Replace "gaseous" by "airborne" because airborne effluents may include liquid aerosols and solid particulates as well as gaseous materials. Consider specifying the public annual dose limit of 100 mrem (1 mSv) in this sentence or elsewhere in this section to ensure that readers understand the quantity being referred to.

Page 3, section C., REGLATORY POSITION, lines 3-5, "The NRC Staff considers the methods described below acceptable for use by its licensees other than power reactors to determine the exposure resulting from air emissions of radioactive material to the environment."

Replace "exposure" by "dose".

Pages 3-4, section C.1., Applicable Exclusions to the Constraint on Environmental Air Emissions and section C.2., Calculation of Dose to the Member of the Public Likely To Receive the Highest Dose from Air Effluents.

These sections appear to apply to airborne emissions from a licensed facility to an outside public area. However, licensees also need guidance on how to address airborne releases, through open doorways, windows or on roof tops, from a Restricted Area to an Unrestricted Area, occupied by members of the public that may be in an adjacent room or attached building. None of the methods in section C.2. are practical for demonstrating compliance in these situations. The guidance should be clearer in explaining that the 10 mrem (0.1 mSv) constraint rule applies to emissions outside the facility and not to Unrestricted Areas within the licensee's facility.

In section C.2., compliance can be conservatively demonstrated by assuming that all unsealed materials are release in airborne effluent. However, the guidance would be more useful if unsealed materials that are of negligible quantity and/or low fractional release potential are excluded from consideration.

Page 4, section C.2., lines 8-11, "The following methods represent a graded approach, from the method involving the fewest site-specific data and, therefore, the most conservative to the more rigorous methods, with more realistic results, for demonstrating that the constraint has been met. All of these methods are acceptable for demonstrating compliance with 10 CFR 20.1101(d):"

This guidance is not understood by some licensees. It would be helpful to explain whether the NRC expects licensees to implement a graded approach by starting with the most conservative method and using successively more rigorous methods until they find one that demonstrates compliance. Or can a licensee just select any of these methods to demonstrate compliance? We know of an Agreement State inspection action where a licensee was determined to be out of compliance when emission concentrations at the point of release were considered although they had adequately demonstrated compliance using the COMPLY Code indicating annual public dose to be less than 0.1 mrem (0.001 mSv).

Page 5, lines 6-10, section C.2.a., "The concentrations assume a factor of 2 to account for the exposure parameters applicable to age groups other than adults such that the resulting exposure for these groups would be estimated at 100 mrem (1 mSv). The licensee can demonstrate that it meets the constraint if the radionuclide concentration at the point of release is less than 10 percent of the "air" values in Table 2."

The use of a factor of 2 to account for the exposure parameters applicable to age groups other than adults is appropriate for setting the NRC's annual 100 mrem (1 mSv) limit. However, this factor is not applicable to the annual 10 mrem (0.1mSv) constraint. This is because the constraint was based on the EPA requirement to limit individual risk conservatively assuming a 70 year exposure period. (I.e. a total dose of the 700 mrem (7 mSv)). The extra risk incurred during the few years of exposure when not an adult may only increase the total lifetime risk by a factor of less than 1.25 and is consequently insignificant. Hence the10 mrem (0.1 mSv) annual constraint is equivalent to about 20% of the 100 mrem (1 mSv) limit (consistent with USNRC Regulatory Guide 4.20-1996), not 10%.

Section 2a and b should be modified to ensure that the constraint is based on population risk criteria and the following changes made on page 5:

Line 10: substitute "20%" for "10%".
Line 18: substitute "<0.2" for "<0.1".
Line 21: substitute "20%" for "10%".

Page 5, section C.2.b., last paragraph, lines 3-5, "Default values for f are 0.25 for long- and intermediate-term releases greater than 24 hours in duration and 1 for "puff" releases or releases of less than 24 hours."

Manufacturing facilities typically experience multiple low-level short term releases each time they process a radionuclide such as ^{133}Xe, ^{18}F and ^{3}H. When there are 50 to 1000 or more such processes a year the licensee should select f=0.25 for the default value. Extra guidance would be helpful here.

Page 7, section C.3., Report to the U.S. Nuclear Regulatory Commission if a Constraint Has Been Exceeded:

Information in the report should include the method used to estimate the dose to the member of the public.