



Council on Radionuclides and Radiopharmaceuticals, Inc.

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Executive Director

July 6, 2000

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1 May 00
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David L. Myer, Chief
Rules and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop: T6D59
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Reference: NUREG-1600, General Statement of Policy and Procedure for NRC Enforcement Actions
Washington, D.C. May 1, 2000

These comments on the above referenced policy and procedure statement are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)*. CORAR submitted comments on this subject on June 29, 1998, but has additional comments on the final guide that we hope the NRC will address in future updates of this guide or by an Information Notice.

Generally CORAR finds NUREG-1600 to be a useful document to licensees. In particular, the listing of examples of violations and their severity level can help licensees prioritize the allocation of resources to maintain regulatory compliance. However, CORAR is concerned that examples of violations of 10 CFR 30.50 notification requirements were not included in NUREG-1600.

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

Template: ADM-013

E-RIDS = ADM-03
Add: Renee Pedersen
(RMP)

Material licensees have had difficulty in interpreting 10 CFR 30.50. When these regulations were published in the federal register on Aug. 16, 1991 the NRC provided useful examples of reportable events in a preface to the regulation. However, most licensees are not aware of this preface and have difficulty in interpreting the regulation. Furthermore, Agreement States are required to implement 10 CFR 30.50 and CORAR is aware that Agreement State agencies also have difficulty in interpreting this regulation.

Because of these difficulties CORAR recommends that the NRC should consider including examples of violations of 10 CFR 30.50 notification requirements in future updates to NUREG-1600. Meanwhile it would be beneficial to material licensees if such information were communicated by an Information Notice or similar method.

CORAR hopes these comments are useful to the NRC and would be glad to provide clarification or further information if needed.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'L. R. Smith', written in a cursive style.

Leonard R. Smith
Chairperson CORAR Committee on Regulatory
and Legislative Issues

REC 7/5/00

4:45 pm
65FR# 3615
Jan 24, 2000
⑧

From: Vicki Bier
To: N. P. Kadambi
Date: Wednesday, July 5, 2000
Subject: Public comment on guidelines for performance-based activities

Please consider this a public comment on the January 24, 2000, Federal Register notice.

1) I share the concern raised by other reviewers about whether the NRC would be dependent on licensees' own reports regarding performance, and am glad that the NRC is thinking about this issue. I suspect that some performance measures may be more difficult for the NRC to independently verify than others will. If some performance measures cannot be easily verified, then perhaps the agency should consider the use of incentives to reward honest disclosure (and/or penalize dishonest disclosure) by licensees. I would imagine that sanctions for penalizing dishonest reporting already exist, but may need to be revisited with the adoption of the new guidelines.

2) With regard to inspection and enforcement considerations, it is important that such considerations be addressed during the formulation of regulatory changes (rather than afterwards). I agree with the proposal that reduced NRC scrutiny or other possible incentives could be used as rewards for performance above some threshold. Careful thought is needed, however, in determining the exact nature of such reduced scrutiny. For example, if reduced scrutiny is used as an incentive for good performance, the agency must ensure that it still has adequate means of detecting possible future departures from good performance.

3) The fact that licensees would have flexibility in meeting the established performance criteria under a performance-based approach is a desirable feature of the proposed approach. As pointed out by Scholz (1984, "Cooperation, Deterrence, and the Ecology of Regulatory Enforcement," Law and Society Review, Volume 18, pp. 179-224), such flexibility may be another possible incentive or reward for performance above a specified threshold. In other words, the agency may want to consider being more prescriptive when performance drops below the threshold. This would allow licensees with a history of good performance to adopt lower-cost ways of meeting the intent of NRC safety regulations, while requiring licensees with poorer track records to follow a more prescriptive approach.

4) I was pleased to note (from Jim Bongarra's presentation at the Human Performance/Root Cause/Trending June workshop in Philadelphia) that the NRC is attempting to validate whether the current performance measures and baseline inspections adequately capture the crosscutting issues of human performance and safety culture. Since such crosscutting issues can be critical to risk, it is important to determine whether they are in fact addressed by the current regulatory approach, or whether some modifications are needed.

I hope that the above thoughts are useful to you in your work on this issue. Please contact me if you desire more explanation of these comments.

--Vicki Bier
University of Wisconsin

Template: ADM 0-13

E-RIDS = ADM-0-3
Add: P Kadambi
(NPK)