



Council on Radionuclides and Radiopharmaceuticals, Inc.

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

9/15/08

73 FR 53286

November 10, 2008

(2)

Mr. Michael T. Lesar, Chief
Rulemaking, Directives and Editing Branch
Division of Administrative Services
Office of Administration
Mail Stop: T6D59
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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RULES AND DIRECTIVES
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**RE: NRC Enforcement Policy Revision. [NRC-2008-0497]
Federal Register Volume 73, No. 179, page 53286. September 15, 2008.**

Dear Mr. Lesar:

These comments concerning the proposed plan for revision of NRC's Enforcement Policy 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.

On March 23, 2007, CORAR submitted comments in response to NRC's Proposed Plan for Major Revision of its Enforcement Policy (FR Vol 72, No. 16, Page 3429, January 25, 2007). Many of those comments have not been addressed in the revised draft Enforcement Policy. CORAR therefore reiterates these and provides additional comments as follows:

General Comments

CORAR appreciates the opportunity to provide comments on the Policy. CORAR supports the primary purpose of the Policy, as stated by NRC, to protect the public health and safety, the environment and to assure the common defense and security. We agree that the Policy should deter non-compliance, encourage compliant behavior and programs, and encourage licensees to promptly identify and correct any violations of NRC requirements. CORAR companies have exemplary records of NRC compliance and employ radiation compliance management systems that are effective

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Call = J. Starkey (DRS)

in correcting self-identified compliance findings including those that may be reportable under the NRC regulations. Generally, we appreciate the consideration NRC gives to special circumstances in the civil penalty assessment process. CORAR recommends that the Enforcement Policy be more supportive of licensees who are proactive and effective in addressing self-identified compliance issues.

CORAR is concerned about the level of detail provided in the revised policy. There are numerous examples in NRC space where policy or regulation is less detailed but supplemented by more detailed regulatory guidance (e.g. NUREG-1556 series licensing guidance for materials licensees). We recommend that a similar approach be taken by abbreviating the policy to cover key expectations while deferring to the Enforcement Manual for additional detail and guidance. The Enforcement Manual should also be available to the regulated community, in a draft form for comment as well as in its final version. It is important for stakeholders to be consistent with NRC staff in their understanding of relevant roles and obligations in the enforcement process, and to avoid the potential for unilateral, subjective application of the policy by NRC. There is an additional concern that the Enforcement Manual does not reflect the current version of the revised policy and it is also our understanding that NRC does not intend to update the Manual. If that is the case, issuance of guidance that is not consistent with policy would be a disservice to NRC Staff as well as the stakeholders that are regulated.

Specific Comments

In the definition of Predecisional Enforcement Conference (PEC), it states that one *may* be conducted with a licensee or individual before the NRC makes an enforcement decision when escalated enforcement action appears to be warranted. CORAR strongly recommends that this position be revised to *always* provide the licensee the opportunity to have this conference in addition to the opportunity to respond initially to the apparent violation in writing.

The Policy should reconsider the position on public attendance at predecisional enforcement conferences. The revised policy currently states that the purpose of the PEC is to obtain information that will assist the NRC in determining the appropriate enforcement action, and that the conference is normally open to the public except when the proposed enforcement action involves discussions of safeguard, privacy, proprietary or other sensitive, non-public information. CORAR agrees but recommends that NRC also needs to consider whether the topic of the enforcement conference really has the potential to adversely impact the environment or public health and safety. If the compliance issue in question does not pose a threat to the environmental or public health and safety, then NRC should not open the conference to the public.

The Policy should address issues involving licensee disclosure of findings and other information as a result of audits conducted independent of NRC inspections. Similar to the US Environmental Protection Agency, with regard to audits conducted by or on behalf of licensees, NRC should not require that the results of such audits be disclosed nor should NRC inspectors request copies of audit reports or findings. In addition, audit reports or findings should not be used by NRC to trigger NRC enforcement investigations.¹ This protection from disclosure is an incentive for licensees to

¹ See US EPA Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations. Federal Register Vol. 65, No. 70. April 11, 2000.

rigorously audit themselves and to internally share audit findings and corrective actions. An open internal discussion of findings and underlying causes promotes for improved compliant behavior. Audits done under Attorney-Client protection organizationally have a more limited value as resulting information can only be shared on a limited basis.

The Policy should also maintain its current position on civil penalty assessment for Severity Level I – III violations where relief from civil penalties is provided to licensees who identify and promptly and comprehensively correct violations, have no previous escalation enforcement actions, and are given credit for actions related to identification.

In addition to the relief from civil penalty provided for Severity Level I – III violations in the current Policy, NRC should not cite a Notice of Violation for any non-reportable compliance problems self-identified and promptly and effectively corrected by the licensee. It would be reasonable for NRC to expect the finding, identification of root cause, and corrective action to be documented by the licensee for future reference. Alternatively, NRC could disposition these as Non-Cited Violations.

The Policy needs to provide a process to allow for discussion in advance of the formal issuance of notices of violation. Citation of violations must be based on fact and licensees must be provided the opportunity to provide any additional facts surrounding potential compliance issues during an informal conference at the conclusion of the inspection and/or prior to issuance of a notice of violation. In addition, NRC inspectors must be granted authority to withdraw a notice of violation if the licensee provides adequate information to demonstrate compliance at the time of the informal conference.

Add consideration of an OSHA VPP type program² for NRC with accompanying enforcement benefits. For example, after demonstration of a healthy compliant program, OSHA has a reduced frequency of inspections (in order to focus on the other more likely non-compliant sites), and has a more liberal penalty policy for violations.

The revised policy states in its discussion of Enforcement Actions Involving Individuals that typically, the NRC will not take enforcement action against the individual if management's failures (e.g., improper training or inadequate procedures) are responsible for the individual's improper actions. NRC should reconsider this example. It may not be possible to determine whether training was adequate or the individual chose not to comply. If there is reasonable documentation in support of adequate training provided by the licensee, then at some point the individual must be held accountable for his actions.

In Section 6.8, the revised policy repeatedly refers "regulatory limits" in the examples used for the various Severity Levels. To avoid confusion, the specific limits or references to the regulations should be provided. Example d.1. cites as an example for Severity Level IV Transportation violations, failure to meet the transportation requirements that have more than a minor safety significance. Again, specification is needed as to what is meant by "transportation requirements" and "minor safety significance."

² See OSHA CSP 03-01-002, TED 8.4. Voluntary Protection Programs (VPP): Policies and Procedures Manual. Chapter VIII – Enforcement Activity at VPP Sites.

The revised policy refers in Section 2.2.1. (c) to licensee failures to notify NRC or receive prior approval for changes in licensed activities as grounds for a violation. The revised Policy should provide more objective guidance on what changes are to be considered "significant" and those that are not.

The revised policy states that loss of NRC regulated material is a significant regulatory concern. The definition of Lost Source Policy states that it is NRC policy to normally issue a civil penalty of at least the base civil penalty amount in the cases where regulated material is out of the control of the licensee for *any period of time*. It is the experience of this industry that, in the normal course of radiopharmaceutical supply chain distribution, control of regulated material will change hands and the licensee may not have immediate accountability of its location at a given point in time. However, there is a reasonable expectation that the material is under appropriate control of a general licensee. It is in this context that some clarification be provided to exclude material in distribution from consideration as "lost" material.

There is an urgent need for the revised NRC Enforcement Policy to be a matter of compatibility for Agreement States.

If you have any questions concerning these comments or would like additional explanation, please contact me at 314-795-6166

Sincerely,

A black and white scan of a handwritten signature, which appears to be "Roy W. Brown". The signature is written in dark ink on a light background.

Roy W. Brown
Senior Director, Federal Affairs
Council on Radionuclides and Radiopharmaceuticals