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Rules, Announcements and Directives Branch (RADB),
Office of Administration,
Mail Stop: TWB-05-B01M,
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Washington, DC 20555-0001

Subject: **CORAR Comments on Incorporation of Risk Management Concepts in Regulatory Programs. Docket ID NRC-2011-0269.**

Reference: **Federal Register Vol. 76, No 225, November 22, 2011, Pages 72220-72223. Incorporation of Risk Management Concepts in Regulatory Programs. Request for public comments.**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)[1]. CORAR Manufacturers and Distributors are familiar with risk management concepts used in industry and appreciate the opportunity to provide stakeholder input in support of the NRC's update of the "risk-informed and performance-based approaches" in material licensee regulatory programs.

CORAR has provided the attached answers to each of the eight questions the NRC posed. However, it is difficult for licensees to provide comprehensive answers to these high-level questions. To provide meaningful feedback, we need to have a better understanding of the specific changes the NRC is considering. Because of this, we recommend that the NRC should invite stakeholders to one or more workshops on this topic, as was done to support the recent update to the NRC's Safety Culture Policy. However, there is a need for additional guidance concerning implementation of the Safety Culture Policy that includes specific examples of good practices. Similarly, licensees will be better able to contribute to NRC's update of risk management in regulatory programs if specific examples of effective risk management practices were discussed.

1. CORAR members include 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.

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CORAR appreciates the opportunity to submit comments 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.

Enclosure: CORAR Comments to the NRC on the Incorporation of Risk Management Concepts in Regulatory Programs.

01/04/2012

CORAR COMMENTS TO THE NRC ON THE INCORPORATION OF RISK MANAGEMENT CONCEPTS IN REGULATORY PROGRAMS

1. Do you believe there is a common understanding and usage of the terms risk-informed, performance-based, and defense-in-depth within the NRC, industry, and other stakeholders? Which terms are especially unclear?

In the radionuclide and radiopharmaceuticals industry, major material licensee radiation protection program managers and RSOs commonly appear to have the understanding of these terms that the NRC intends. However, other stakeholders with smaller licenses and the interested public are less likely to have this understanding. These stakeholders generally have difficulty understanding the "risk-informed" term.

A potential confusion is that radiation protection professionals are increasingly discussing the difference between "dose-based" and "risk-based" regulations. In this context "risk" is more narrowly defined than the "risk-informed" term used by the NRC.

2. What are the relevant lessons learned from the previous successful and unsuccessful risk-informed and performance-based initiatives?

The primary success of these initiatives for material licensees is the NRC's graded approach to radiation exposure. It supports material licensee exposure control practice, of primarily attending to higher dose and higher risk operations, which continues to reduce collective dose despite increasing use of radioactive materials during the past decade and ongoing. Both NRC and Agreement State regulatory inspectors are less inclined to issue citations for trivial deficiencies.

There have, however, been occasions when the NRC has initiated rules claiming to be risk-informed and performance-based but are perceived differently by material licensees. A recent example is the Decommissioning Planning Rule published in the Federal Register on June 17, 2011. The purpose of NRC decommissioning planning rules has always been to prevent the creation of legacy sites. However, this new rule imposes unnecessary surveillance for residual contamination and associated financial burdens on the vast majority of material licensees that have never created legacy sites and are unlikely to do so in the future. In this case material licensee performance has been excellent and there is essentially zero risk of creating a legacy site. There were six sites that were exceptions, however, they had unusual conditions, handling uranium and thorium, are easily identified and could be addressed by specific regulations and/or license conditions.

Another regulatory practice that could be more performance-based concerns licensee self-identification of radiation protection program deficiencies. Licensees that have exemplary programs and exceptionally proactive controls should be provided incentives to maintain their performance. These could be reduced frequencies of inspection, reduced fees and/or letters of commendation.

3. What are the relevant lessons learned from the previous successful and unsuccessful deterministic regulatory actions?

Certain deterministic regulatory actions are both necessary and effective. These include the setting of possession, dose, concentration, etc. limits and exempt quantities. The concept of defining exclusion, restricted and controlled areas has also been very useful. Such deterministic actions are more useful when they harmonize with international regulatory actions.

However, setting constraints, that are significantly lower than limits, could be difficult for material licensees to implement. The constraint on public dose from airborne emissions has no technical merit because material licensees generally do not possess enough radioactive material to exceed the constraint. Administrative constraints that licensees establish in their radiation protection programs vary considerably due to the diversity of operational conditions and practices. It is unlikely that regulatory constraints could be established that are appropriate for all material licensee operations.

Certain deterministic regulatory actions are too broad, and consequently too conservative for most practical situations. For example, the LLRW Class system, while being appropriate for a LLRW disposal site in a wet climate region is unnecessarily conservative for the more numerous LLRW disposal sites in Western arid regions.

4. What are the key characteristics for a holistic risk management regulatory structure for reactors, materials, waste, fuel cycle, and security?

There needs to be a good understanding of the diversity of material licensee radiation protection program needs. Most material licensees maintain security programs and generate radwaste. To establish and maintain a holistic risk management regulatory structure there must be a quantitative understanding of licensee normal operating risks and potential risks. There needs to be risk limitation and minimization goals. These and associated operational requirements must be relevant to all licensees. This implies that the scope of the risk management structure must be limited to components that are relevant to all licensees and any additional requirements provided for specific operations or types of licensee in separate regulations or as license conditions. Examples of provisions that are appropriate for all material licensees are possession and dose limits, justification and optimization of operation, the ALARA principle, a graded approach to prioritizing limit resources and clear understanding of the qualifications and responsibilities of licensee staff.

For the risk management structure to be holistic there needs to be consideration of radiological and other risks including fire, hazardous materials, ergonomic and security risks. The regulatory structure must also be understandable to all licensees and practical and cost-effective for them to implement for those operations that society considers beneficial and needs.

5. Should the traditional deterministic approaches be integrated into a risk management regulatory structure? If so, how?

Certain deterministic approaches are necessary, for example possession and dose limits. However, another means of availing the licensee of deterministic provisions is to publish them in guidance documents like the NUREG 1556 series. Other deterministic approaches might also be integrated into a risk management regulatory structure if they were optional or if the licensing agency was allowed to waiver the provision for a licensee when there was a clear benefit.

6. What are the challenges in accomplishing the goal of a holistic risk management regulatory structure? How could these challenges be overcome?

A major challenge is how to understand what regulatory structures will be effective for all material licensees. This would need substantial input from a broad range of licensees. It would be helpful if the dialogue to achieve this was around specific provisions rather than concepts.

Another significant challenge is achieving an appropriate balance between the different types of risk. These risks include health, injury, property loss, environmental degradation, adverse publicity, and business interruption. Again input from a broad range of licensees should be helpful.

7. What is a reasonable time period for a transition to a risk management regulatory structure?

Firstly, there needs to be much more discussion on this topic between the NRC staff, other associated regulatory agencies and affected stakeholders including a broad range of material licensees. There is probably a need for workshops on this topic. Many licensees may not be familiar with risk management concepts and will need time to understand them before making a considered contribution. After there has been sufficient dialogue and regulatory changes are made, the time needed for material licensees to implement changes to their operations to accommodate the new requirements would depend greatly on the nature and extent of the regulatory changes. Usually industrial material licensees can implement changes to administrative procedures and associated documentation in one to two years. Major changes to facilities, operations and staffing are best integrated into the business cycle which varies from five to ten years or more.

8. From your perspective, what particular areas or issues might benefit the most by transitioning to a risk management regulatory approach?

Major material licensees could benefit from having more flexibility in updating operations to continuously improve performance and control risks. There is a clear benefit when certain licensees can be exempted from regulatory requirements that are not appropriate for their operations. When this occurs it opens the opportunity for the licensee to redirect resources to achieve the maximum benefit.