Organization of Agreement States

DSI-5
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Robert Quillin, Chair
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October 21, 1996

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attn: Chief of Docketing and Services Branch
Washington, D.C. 20555-0001

Dear Mr. Hoyle:

As you know, there are currently 29 states that have entered agreements with the NRC under Section 274 of the Atomic Energy Act of 1954. The agreement state program is an excellent example of the ability of states to conduct regulatory programs in an effective and efficient manner. The Organization of Agreement States (OAS) provides a vehicle for Agreement States to interact on common issues that affect individual states or all 29 Agreement States.

The OAS has received comments from individual Agreement States on the Direction Setting Issue Papers issued as part of the NRC's Strategic Assessment of Regulatory Activities. These comments have been summarized for each of the Direction Setting Issue Papers and are attached for consideration in this matter. Many of the individual Agreement States will provide state specific comments as well.

If you have any questions, please contact me.

Sincerely,

Richard A. Ratliff for

Robert Quillin, Chair
Organization of Agreement States
Radiation Control Division
Department of Health
4300 Cherry Creek Drive South
Denver, Colorado 80222-1530

Acknowledged by card 10/31/96 DMO

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Organization of Agreement States

Comments on

U.S. NRC Strategic Assessment and Rebaselining Initiative

Direction Setting Issue Paper # 12
"Risk-Informed, Performance-Based Regulation"

Summary

The Direction Setting Issue (DSI)--"What criteria should the NRC use in expanding the scope in applying a risk-informed, performance-based approach to rulemaking, licensing, inspection and enforcement?"

We support a combination of certain aspects of all the options. Promulgation of regulations should be primarily as described in Option 1 because consideration of industry demand, safety benefit, ease of implementation, and available resources should always be considered in rulemaking. As described in Option 2, even when considering the items mentioned in Option 1, overall protection to public health and safety should be given the highest priority. In addition, cost/benefit of any rulemaking should also be one of the primary considerations, overridden only by protection of public health and safety. There are aspects of Option 2, notably to pursue concurrence with EPA on risk bases and models and assumptions to be used, that would be beneficial. Option 3, to perform a comprehensive assessment of NRC regulatory approaches, is a desirable goal and would go a long way in achieving regulatory coherence and consistency. As described in Option 4, the NRC should always be open input from the stakeholders. Licensee data concerning risk analysis, cost-benefit analysis, licensee need, and the licensee's ability to maintain an acceptable level of safety with innovative approaches must always be considered.

Discussion

In response to the first focus question as to whether important considerations may have been omitted from the issue paper, several important concerns were not addressed in the direction setting issue on risk-informed, performance-based regulation with regard to materials regulation. In coordination with the CRCPD, the NRC has agreed to participation in a parallel rulemaking process with the Agreement States, in which a participatory involvement among all involved parties is emphasized. No mention is made of this type of cooperative effort for the materials program.

The NRC describes the bases for rules and standards issued by the NRC. The issue paper describes the Atomic Energy Act, Congress and the Executive Branch, standards-setting organizations such as the ICRP, NCRP, and National Academy of Sciences, federal agencies, the nuclear industry, and the public. Conspicuously omitted are the CRCPD and the Agreement States. CRCPD, through its committee work and resolutions is a standard setting organization. The Agreement States have established standards through regulations that the NRC has used as

a model for its own regulations, specifically well-logging and industrial radiography rules.

In the discussion of risk-informed, performance-based regulation promulgation, the NRC again pointedly fails to acknowledge or discuss the impact of compatibility determinations by the NRC on regulations it promulgates. Agreement States often have distinct directives to consider in promulgating rules, including those NRC rules designated as compatibility items. These directives include emphasis on reducing regulatory burdens and that, in many instances, means deleting or revising existing rules if they do not have a direct effect on public health or safety. Most Agreement States must complete a cost/benefit analysis for any rule it introduces. The parameters for such an analysis are specified in both law and agency procedure. If the parameters and assumptions used by the NRC in completing a cost/benefit analysis for a compatibility regulation are different than those used by an Agreement State, this creates a significant conflict.

Throughout the issue paper, NRC references a probabilistic risk analysis to be used as a means for prioritizing regulatory activities. The risk analysis would consider cumulative impacts on safety, burden reduction, and efficiency. To consider these parameters, assumptions must be made and the risk "modeled." The assumptions made by NRC may not be applicable to specific Agreement State situations and by designating a rule an item of compatibility, the Agreement State is in effect forced to accept assumptions that are not applicable. An example of differing risk is the regulation of naturally occurring radioactive material (NORM). The predominant sources of NORM, concentrations of NORM, prevalence of NORM in the environment and workplace, industries that generate NORM and are thereby effected by NORM regulation, and risk to the general public vary greatly from state to state and region to region. Risk assumptions made about NORM in the phosphogypsum industry in Florida differ significantly from risk assumptions made about NORM in the oil and gas industry in Texas. Although the NRC does not have the authority to regulate NORM, the concept of differing risk applies to the regulation of other radioactive materials.

As a performance goal, dose limit standards have worked fairly well, suffering only from a lack of understanding by the public of the meaning of dose limits. In a transition to a risk-informed performance-based (RIPB) approach, risk information should begin with an explanation to the public that the dose limits have always included safety margins which keep risk as low as reasonably achievable. It may be that the real incentive for using a risk-based approach is an attempt to put exposure/dose information in a form which can be more readily understood by the public. The changes to the RIPB approach should be accompanied by and aggressive public education program.

An RIPB regulatory approach would necessarily be based on probabilistic calculations. Such calculations are usually accompanied by an uncertainty analysis. Problems can arise in uncertainty analyses when choosing input distributions which may, under very low probability circumstances, cause the output distributions to include the dose limit. It would be better to use as much site- or process-specific information as possible in a deterministic bounding calculation to show that compliance performance is achievable.

As with risk analyses, cost/benefit analyses must incorporate certain parameters and assumptions

that may be significantly different from state to state. Again, designating a rule an item of compatibility may force a state to either utilize inapplicable assumptions or not adopt an item of compatibility because an applicable cost/benefit analysis may not justify adoption of the rule.

Specific Comments

Option 1--Continue Current Process

Some aspects of this option are more amenable to the regulation of radioactive material. The flexibility to balance internal and external goals with available resources is necessary for any government agency. This must be tempered with the need for additional radiation standards to address emerging problems and new technologies.

Option 2--More Rigorously Assess Relationship to Public Health and Safety

Because the NRC is tasked with providing adequate protection for the health and safety of the public, it makes sense that they should focus on those areas that constitute the most risk to the public. It seems logical that the regulator would seek the best tools available to accomplish that task. If risk assessments can be relied on to identify the risk contributors, they should be used in the regulatory process where it makes sense to do so.

If risk assessments can not be relied on, then more conventional means, or some combination of analyses, will have to be used. Inherent in risk analyses are uncertainties caused by lack of objective data. The better the data, the more assurance we have that risks can be predicted. Data can be resource intensive to gather. Hence there is a cost/safety benefit tradeoff.

As the NRC did not require rigorous PRAs as part of the IPE process, and there is no other requirement to perform one, risk assessments vary in quality across the family of plants. This makes consistent application of them (regulatory coherence) difficult. In addition, use of generic data undermines the plant specific desirability of risk analyses. If the priority is the "greatest safety benefit"; and there is a potential for "substantial benefit and increases in overall public protection"; and it comes down to a safety/cost tradeoff for both the NRC and the regulated industry; and there is a safety goal policy in place to help determine the safety benefit side of the equation, how can it be argued that a rigorous safety analysis capable of measuring that benefit, or at least in understanding the uncertainties in the analyses, is not desirable, and that available resources should be a constraint?

The NRC applied resources and strongly encouraged licensees to adopt the standard technical specifications for their design plant, to make the licensing functions more standard and less costly. Following the same line of reasoning, the NRC should follow a similar process in negotiating a satisfactory rigor for PRAs for plants. The NRC attempted to define adequate protection (how safe is safe enough) of the health and safety of the public in the safety goal policy. We believe that rigorous PRAs should be required of power plant licensees, so they can be relied

on as satisfactory tools to be used in the applications for which they are useful in satisfying that safety goal policy. Ideally, this would be done by a rulemaking. We believe that plant specific risk analyses should be required, should meet standards for accuracy and completeness, and should be kept current.

Option 3--Perform a Comprehensive Assessment of NRC Regulatory Approaches

Once the results of Option 2 are determined, Option 3 could be applied to verify and bound the rigor that needs to be applied to the risk analyses to ensure the safety goal policy is being met, and safety/cost tradeoffs are thoughtful and consistent. Prioritization of rulemaking activities, exemption of insignificant risk materials and uses, and application of limited resources to areas of higher risk would result from this approach.

As stated in the discussion of this issue with regard to the nuclear materials area, such a framework could be developed in which a systematic assessment of rules and regulations would result in identification of areas that are amenable to a RIPB approach. We encourage NRC to pursue the resolution of issues associated with dual regulation. This causes delays and additional frustration in establishing and implementing standards.

Agreement States can be and should be a partner in implementing such an approach. These regulatory programs regulate a majority of the materials licenses. Their experience in reviewing sources, developing licensing approaches, and implementing decommissioning standards should be utilized. Other stakeholders, such as industry groups and professional societies have developed initiatives that could be taken into account.

Option 4--Consider Risk-Informed, Performance-Based Approaches Primarily in Response to Stakeholder Initiatives

To give stakeholders a say in how they are regulated in a cost-conscious deregulated environment is desirable. A caution is not to abdicate regulatory responsibility to the stakeholders, or appear to put them in the position of self-regulators, when cost versus safety issues clash. There is good reason in both the regulatory and competitive environment for licensees to have a rigorous safety analysis to justify cost savings.

Subsumed Issues

1. What should be NRC's strategy and philosophy with respect to changing NRC's responsibilities and authority in areas of little public risk?

If the area falls inside the safety goal policy, regulate it. If it falls outside the safety goal policy, it is outside the NRC's adequate protection legislative jurisdiction.

2. What approach should NRC take in modifying the materials regulations to move toward risk-informed, performance-based regulation, recognizing the requirements will vary as a result of the range of products and the divergence of the licensees that use or possess byproduct nuclear material?

As described in the summary and discussion of the options above.

3. Should NRC revise its regulations to address the uses of materials resulting from technological advances and changing human factors? If so, to what extent should NRC articulate objectives to prevent or limit the effects of equipment failures and human factors/human performance?

Yes, the degree of risk and need for and type of regulation is dependent on the qualifications of the users (human factors) and the inherent safety of the material or device being used. Any additional regulations in these areas must be firmly justified by documentation of safety problems. For example, the requirement for certification of industrial radiographers was backed by documentation from NRC and Agreement States that assuring that individual radiographers were qualified to use the potentially hazardous sources decreased significantly the potential for incidents and overexposures. Likewise, development of certain inherently safe source/device combinations could and should result in their being exempted.

4. What should be the approach for licensing material uses with various levels of inherent risks?

The work of the joint Agreement State-NRC working group addressing the issue of generally licensed gauges has identified inconsistencies in terms of how certain sources and devices are regulated. Input from this group will be important to identifying a reasonable approach for licensing. Generally licensed gauge users should be either registered or have some mechanism for interaction with or notification from the appropriate regulatory agency in order for the material to be accounted for and not inadvertently disposed of as scrap. Certain sources that are currently specifically licensed could be generally licensed or exempt, based on risk factors. Likewise, certain multi-curie generally licensed devices should be specifically licensed. As discussed in subsumed issue 4 above, the approach must take into account human factors as well as technology.