Development of a Safety-based Cost-Justified Regulatory Development and Review Process for International Regulations

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It is truly a pleasure to have the opportunity to address so many people with the responsibility of meeting the daily challenges presented by the continued safe transportation of radioactive materials. Mr. Alan Roberts, the DOT's Associate Administrator of the Research and Special Programs Administration for Hazardous Materials Safety, could not be here today but asked me to express his best wishes for a successful conference. He also asked me to share with you what we in the Office of Hazardous Materials Safety see as two of the most important needs of the international nuclear transportation community: first, the need to better communicate with the public about the safety of radioactive materials transportation, and second, the need to improve the effectiveness and efficiency of the IAEA regulatory development, review, and approval process by adopting a formal regulatory analysis policy.

No matter what your individual transportation role or responsibility may be, I believe you sometimes cannot help feeling frustrated that the public does not support radioactive materials transportation. For a person knowledgeable of the IAEA transport regulations, the nuclear industry, and the exemplary safety record of the radioactive materials transportation industry, it is difficult to understand the active as well as the tacit opposition to industry's activities. When, however, we recognize that people tend to overestimate the risks associated with threats of which they have little knowledge and that the nuclear industry repeatedly faces the same challenges, we should also recognize the great opportunity we have to improve the general public's awareness and knowledge of the safety provided by the transport regulations.

In the United States, the Government has solicited public comment on many radioactive materials shipping campaigns. These efforts have produced mixed results because our audience does not have an adequate understanding of the basics of transportation and the nuclear industry. I do not believe we can fully satisfy all the critics of the nuclear industry, but we can increase the public's confidence and support in our ability to transport radioactive materials by communicating with them in terms they can understand and in media they use. The IAEA, individual member states, and corporations have started this work, but we as member states must continue to work with the IAEA to address these needs. We must work with IAEA to develop and distribute current information that first, explains the need and benefits of radioactive materials transportation; second, explains the IAEA transportation regulations and the level of safety they provide; and lastly, documents the exemplary safety record of radioactive materials transportation. This is not a new need or one that can ever be fully satisfied, but a need exists that we must continue to strive to satisfy.

As the Director of the Office of Hazardous Materials Technology, one of my top priorities is improving the safety of transportation of all hazardous materials, including radioactive material, on our air, water, and surface transportation systems. Even though the issue of radioactive materials is only a small part of the greater issue, it has often been the precursor of other hazardous materials issues. In the United States, a prime example is routing. The establishment of appropriate safety standards for transportation of hazardous materials, including radioactive materials, is an important element in further improvement of our transportation system. By developing international regulations that also meet our domestic requirements, we foster a safe, intermodal transportation system that allows shipments of radioactive materials to cross national borders without disruptions or delays that would result from conflicting regulatory requirements. Public confidence in the effectiveness of government's regulations and industry's careful compliance with them can go a long way to reducing the emotional concern over the transport of nuclear materials.

After participating in the IAEA's regulatory revision process and reviewing its proposed regulations, it is time to reexamine the effectiveness and the efficiency of the process the IAEA uses to develop, analyze, and approve international transport regulations. In the early 1960s it was practical for the IAEA member states drafting the transport regulations to consolidate existing modal and domestic regulations into a set of transportation regulations addressing all shipments and providing for the safe and economical transportation of radioactive materials. Over the years, however, the radioactive materials industry has grown, changed, and become more complex. The number of member states and their individual requirements has also expanded. The IAEA regulations have expanded to reflect the increasing complexity and scope of the nuclear industry. This complexity makes it increasingly difficult for industry and member states to accurately anticipate the cost and impact of regulatory revisions. Without my being prejudgmental, the apparent high costs and limited safety benefits of portions of the proposed transport regulations may make their adoption into domestic regulations a challenge for the United States and, possibly, other member states.

This potential for divergence between international and domestic regulation is of great concern. The public and the nuclear industry clearly deserve regulations that provide for safe, international, multimodal transportation at a reasonable cost. In order to preserve the effectiveness, uniformity, and usefulness of international regulations, we must subject them, and any proposed changes, to a formal regulatory analysis process—a process that adds more structure and analysis to the decision-making process. Before explaining the regulatory analysis framework and vision, let me be clear that the need for regulatory reform does not imply that the current or proposed transport regulations are inadequate. We are talking costs and process! I have complete confidence of the ability of the existing regulations, if followed, to provide safe transportation and to protect the public. I believe this confidence is well-founded when you examine the transport regulations, the industry's performance, and the resulting exemplary record of safe transportation.

The regulatory analysis process I am proposing is neither new nor a radical departure from current methods. Similar processes have been used in the United States for

regulatory development and review since the late 1970s. In the United States, it is a formal process mandated by our Executive Branch to ensure that our regulations and proposed regulations have been properly defined and analyzed. It is a method to demonstrate that the burdens the regulations place on shippers and the transport community are necessary to address specific hazards associated with the transport of radioactive materials and will provide the level of safety expected by the general public. Basically, the process consists of five points:

1. Formal identification and documentation of a regulation problem and associated safety or economic objectives.

2. Development and presentation of alternative solutions for meeting the objectives. The alternatives considered should include the status quo, no regulation, and other regulatory alternatives.

3. Analysis of alternative solutions with respect to safety benefits and the cost of implementation and continued application.

4. Selection of a preferred alternative. First, the safety benefits of an acceptable alternative should exceed its costs. In addition, of the acceptable alternatives, the lowest cost alternative should be selected.

5. Documentation of the problem, alternative solutions, and the benefit and cost analysis supporting a new or revised regulation. Documentation should also include a statement of what a regulation does in terms understandable by governments, industry, and the public.

I think you see that this is similar to the current process. The major differences are (1) the formal identification and documentation of a regulatory problem, (2) the requirement to document both the safety benefits and the regulatory burden associated with the proposed change, (3) the requirement that benefits exceed costs, and (4) the number of intermediate decision points involved in the process. I believe that such a system will better focus the established revision process and lead to a more concise and straightforward body of transport regulations. It will lead to early and clear identification of issues that truly affect safe transportation so that research and regulatory analysis necessary to make informed decisions can be completed early in the process. Subjecting our regulatory proposals to safety/benefit and cost/benefit analyses will lead to regulations that can be supported by the industry and the public, adopted by member states, and sustain challenges by interested parties. I suggest this is an opportune time, before we start the next revision cycle, to develop and adopt a formal regulatory development and review process. To facilitate adoption of such a process, the United States Competent Authority plans to submit a proposal at the inaugural meeting of the Transport Safety Series Advisory Committee (TRANSSAC) in early 1996. I ask that you consider the merits of a formal regulatory development and review process and consider adding your support to making it a reality.

I thank the organizing committee for inviting me to speak today. I also wish to invite anyone who is interested in improving the channels of communication or redefining the IAEA's regulatory development and review process to contact me and discuss these issues with me and any member of my staff.