System Certification: Progress in Concept Recognition in IAEA Regulation

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DISCLAIMER

BACKGROUND[1]

System Certification is a regulatory concept which is intended to expand the scope of radioactive material transport regulations by allowing alternative means for proving compliance with the requisite standards of safety set out in transport regulations. In practice it may allow more stringent requirements in one aspect of the regulations to be substituted for less stringent application in other areas so long as the safety standard provided by regulation is preserved. The concept is widely perceived as the imposition of operational controls in exchange for relaxation of packaging standards, but that is only one possibility in the spectrum of potential actions under a System Certification provision in IAEA or national regulations.

The concepts and potential applications of System Certification have been explored in a number of recent papers:

> Luna et al. (1995) provided an overview of the potential application of System Certification to waste management issues and the ways in which trade-offs might be handled in the process. Attention was focused on the problems of trading off incident-free dose with accident dose and in trading either against costs likely to be saved if the operation were able to be undertaken in the context of a System Certification provision of regulations.
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> Lombard et al. (1995) discusses the concept of "Transport System Approvals" which is conceptually similar to System Certification. They examine application of the concept to LSA (Low Specific Activity) shipments that could be very costly and have higher radiation impacts without regulatory relief from a package limit of $100A_2$. Analysis is presented comparing risks from shipment methods, with and

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without System Certification, as examples of a means of demonstrating equivalent safety.

Luna and Jefferson (1992) provided a view of System Certification issues related to the definition of what equivalent safety, as defined in the Regulations, might be taken to mean. In particular, they considered the fact that incident free and accident risks are not perceived to be the same by the public, the non-equivalent relationship between risk and safety concepts, and the problems inherent in defining the current level of safety against which System Certification proposals might be judged.

IAEA ACTIONS

The IAEA has been a focus for attempts to include System Certification concepts in regulation, since it provides the model regulations upon which all National Regulations are based (Pollog 1994). Discussions of the need for, and advisability of, drafting and adopting System Certification enabling language in the IAEA's *Regulations for the Safe Transport of Radioactive Materials*, Safety Series 6 (1990a), have occurred frequently in the deliberations of SAGSTRAM[2] over the period from the adoption of the 1985 Revision of Safety Series 6 (SS 6). Deliberations on System Certification in the 1994 SAGSTRAM meeting (IAEA 1994) brought the issue to the point of decision.

The principal arguments for the concept were centered on the need for a flexible, but structured manner for handling situations outside the regulations in which there could be a documented case for equivalent safety. Particular situations in which a structured process was seen as likely to be needed were those dealing with waste shipments resulting from decontamination and decommissioning of large nuclear facilities.

The principal argument against the concept are that the Special Arrangement provisions in the Regulations already provide the Competent Authority with the ability to handle situations where transport was necessary and all aspects of the regulations could not be met. In addition, there is a significant fear that the inclusion of structured System Certification provisions would tie the hands of the Competent Authority in the effective exercise of its powers because it would be possible for those regulated to "write their own regulations" in a System Certification case.

SAGSTRAM in 1992 (IAEA 1992) recommended that the IAEA query the Member States on issues related to system certification. The results of the survey were presented to SAGSTRAM in March 1994 and showed that many Member States supported further IAEA work on system certification. As a result of the survey information and the general discussions of the issue outlined above, SAGSTRAM recommended that a consultant service meeting (CSM) be constituted to determine the need for including the concept of

[2]SAGSTRAM: Standing Advisory Group for the Safe Transport of Radioactive Materials

System Certification in SS 6, and if so, develop the proposed amendments to SS 6,7 & 37. SAGSTRAM also recommended that the CSM should be held before the Third Revision Panel for SS 6 which was already scheduled for October 1994. In this manner, a decision on any proposed amendments developed by the CSM could be made by the Third Revision Panel.

In September 1994, the CSM recommended that the concept of system certification should to be added to SS 6, and developed the proposed amendments incorporating system certification into SS 6. The recommendations of the CSM gave form to several ideas that had been often discussed as desirable extensions of the regulations to accommodate System Certification situations. In particular, they provided a working definition of operations eligible for System Certification:

> Transport of consignments as part of a planned shipment campaign for which compliance with all relevant requirements of the regulations is impracticable, but which, as a result of imposition of other requirements, satisfy the requisite standards of safety established by the Regulations.

The main thrust of the proposal was directed to three regulatory concepts currently embodied in the requirements for Special Arrangement which is used to control all non-compliant consignments. These proposed changes were intended to:

- distinguish between ad hoc situations (true Special Arrangements) and planned operations that could not be conducted without relief from some regulatory strictures;
- make clear that System Certification situations required demonstration that the overall level of safety is at least equivalent and make clear that Special Arrangement situations should only be required to demonstrate that there is a pressing need to protect public safety;
- specify the requirement that equivalent safety for System Certification must be demonstrated by quantitative analysis to the satisfaction of the Competent Authority; and
- consider reducing costs or increasing operational flexibility while maintaining requisite levels of safety and/or allowing shipment methods that are even safer than the regulations require.

The initial actions of the October 1994 Third Safety Series 6 Revision Panel with regard to the proposal were somewhat at odds with the recommendations of the CSM. While their action seemed to endorse the need for a revision of the Special Arrangement provisions of Safety Series 6 to accommodate System Certification, their work was focused on refining the provisions for Special Arrangement. In Addition, they moved the requirement for demonstration of at least equivalent overall safety to the Explanatory Material contained in Safety Series 37 (IAEA 1990c). This shift changed the demonstration of equivalent risk from a requirement to a recommended method for meeting the requirements of Safety Series 6.

At the last meeting of the Safety Series 6 Revision Panels in the Fall of 1995, which was the last Revision Panel for this revision cycle, no substantial change was made to the text proposed in the Third Revision Panel. As a result, the text that will go to the IAEA Member States is shown in the boxed area below.

Assuming that no objections are raised to this text during Member State review, it will be presented to the Board of Governors for their approval in 1996.

Table 1: Comparison of Texts Related to Special Arrangement

211. [1] A **consignment** which does not satisfy all the applicable requirements of these Regulations shall not be transported except under **special arrangement**. Provisions may be approved by a **competent authority,** under which a **consignment,** which does not satisfy all of the applicable requirements of these Regulations, may be transported under **special arrangement**. These Provisions shall be adequate to ensure that the overall level of safety in transport and in-transit storage is at least equivalent to that which would be provided if all the applicable requirements had been met. for international **consignments** of this type, **multilateral approval** shall be required	312.[2] **Consignments** for which conformity with other provisions of these Regulations is impracticable shall not be transported except under **special arrangement**. Provided the **competent authority** is satisfied that conformity with other provisions of these Regulations is impracticable and that requisite standards of safety established by these Regulations have been demonstrated through means alternative to the other provisions, the **competent authority** may approve **special arrangement** transport operations for single or a planned series of multiple **consignments**. The overall level of safety in transport shall be at least equivalent to that which would be provided if all the applicable requirements had been met. For international **consignments** of this type, **multilateral approval** shall be required.

1. IAEA Safety Series No. 6 (IAEA 1990a)
2. Private Communication

ANALYSIS

The language adopted by the Revision Panels provides some modification of the existing definition of Special Arrangement. In particular:

- "**consignments**" makes clear that more than one consignment can be covered by a Special Arrangement;
- "**impracticable**" is made clear as the requirement to justify application for a Special Arrangement;
- "**means alternative**" makes clear that measures not included or required in the regulations may be substituted; and

- **"planned series of multiple consignments"** opens the door to multiple shipments under Special Arrangement with the Competent Authority.

This last feature may be a significant extension of Special Arrangement that meets much of the need for System Certification applications. Because of the reference to "a consignment" it was never quite clear under paragraph 211 that a shipment campaign spread over a period of time could be included in a Special Arrangement.

While the Revision Panels tried to honor the suggestions of the CSM to require demonstration of equivalent safety as part of the Special Arrangement process, its inclusion in the Advisory Material (Safety Series 37) makes it difficult to enforce. Moreover, the Revision Panel's proposed text to require it will be lost. The reasons for this are twofold:

- Advisory Material is intended to provide one possible way of meeting the requirements in Safety Series 6. It cannot present the only way to meet the requirements or it would be part of the Regulations itself.
- The Consultant Services Meeting recently held to define a process for revising and combining the texts of Safety Series 7 (IAEA 1990b) and 37 affirmed that the text of the combined documents should never use the word "shall" in the Advisory Material it contains.

As a result of the above, and the lack of change in the Approval and Administrative Requirements Section of the Regulations, implementation of the revised Special Arrangement requirements need not be much different than is currently practiced. While it is certainly possible for a Competent Authority to require documented proof of equivalent safety, it would not be required by the regulations as they are currently proposed. This may limit the application of Special Arrangement to situations that could benefit from System Certification because there may not be a sufficient documentation trail to support the decision to grant a Special Arrangement. This would not be a problem if there were no public questions to be answered, but in an increasingly litigious society there could be significant pressure to revoke a Special Arrangement without careful documentation. In the United States we are already in this situation with National Environmental Policy Act (NEPA) requirements overshadowing decisions made that nominally are completely within the scope of regulatory authority.

In total, the result of the IAEA's actions will be to aid in the use of System Certification concepts to some problem transport situations. However, it seems likely that application may be less frequent than would occur if it were not singled out as a "Special Arrangement" and clearly placed in the mainstream of regulatory practice. While the problem of the Regulations not requiring documentation that equivalent safety is being achieved is not a fatal flaw, it seems likely that significant deviations from the regulations and large-scale shipping campaigns are likely to be adequately documented through the actions of the Competent Authority.

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