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# RADIOACTIVE MATERIALS PACKAGING STANDARDS AND REGULATIONS — MAKING SENSE OF IT ALL

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## DISCLAIMER



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## ABSTRACT

Numerous regu -ions and standards, both national and interna:ional, apply to the packaging and transportation of radioactive material. These are legal and technical prerequisites to practically every action that a designer or user of a radioactive material transportation package will perform. The identity and applicability of these requirements and the bodies that formulate them are also not readily understood. This paper addresses the roles that various international bodies play in developing and implementing the various regulations and standards. It uses the U.S. regulatory and standards-making bodies to illustrate how international requirements feed the domestic control of packaging and transport. It explains the scope and interactions between domestic and international regulatory and standards agencies and summarizes the status and major standards activities at the international level. The overview provided by this paper will be valuable to designers and users of radioactive material packages for better understanding and use of both standards and regulations, and for complying with regulatory requirements in the radioactive materials transportation field.


## INTRODUCTION

It was recognized very early in the use of radioactive materials that if they were to be handled safely, stringent controls on their use needed to be established and implemented. This was especially true for the transportation of these materials because these activities generally occur outside of controlled areas or facilities where they can involve large segments of the public. The control of the transport of radioactive materials is further complicated because this is the only activity involving these materials where the material can actually move between different communities, states, or even different countries.

The first set of structured controls for the packaging and shipment of radioactive materials was produced in the U.S. in 1947 when a set of regulations was issued by the Bureau of Explosives.

In 1957, the newly formed United Nations (UN) created the International Atomic Energy Agency (IAEA) and shortly thereafter, following a recommendation of the Committee of Experts on the Transport of Dangerous Goods (TDG) of the UN Economic and Social Council (ECOSOC), the IAEA undertook to develop a set of safety rules that could serve as a model for Member States of the IAEA to use in developing their domestic regulations to control the packaging and transportation of these materials. With the help of qualified experts from a number of its Member States, the IAEA began its work on transport regulations in 1959. Initially, the synthesis of these regulations was based on the set of requirements embodied in the above-mentioned U.S. Bureau of Explosives regulations, as well as other requirements that existed in a few Member States.

The IAEA's activities in this area are currently carried out in the Radiation Protection Section of the Division of Nuclear Safety; therefore, the focus of these activities is, and always has been, to ensure safety, with special emphasis on those features of packaging and controls that will provide radiation protection for workers, the public, and the environment.

The IAEA worked in close cooperation with other international bodies, and the first edition of the Regulations for the Safe Transport of Radioactive Material, identified as Safety Series No. 6, was issued by the IAEA in 1961 (IAEA, 1961). In addition to being applied directly to the IAEA's operations and to IAEA-supported activities in its Member States, the regulations were (and still are):

> "recommended to Member States and to international organizations concerned as a basis for national and international transport regulations." (From Foreword to each edition of Safety Series No. 6).

Revised editions of these regulations, taking into account developments in technology and shipping practices, were issued in 1964, 1967, 1973 (amended in 1979), and most recently, in 1985. In all cases, these updated regulations have been given the identification of Safety Series No. 6.

With time, the IAEA's regulations have been adopted or otherwise implemented in most of the IAEA's Member States, including the U.S. and Japan, and they have served as models for, or have provided inputs to, various regulatory requirement documents or standards promulgated by a number of international bodies.

Concurrent with the development of the regulatory requirements that delineate basically what must be done, other documents have been developed that delineate how the requirements might be implemented. The latter, at both a domestic (i.e., a Member State) level, and an international level, are standards or are standard-like. For example, the IAEA has issued a document, identified as Safety Series No. 37 (IAEA, 1987), that defines ways in which the regulatory requirements in Safety Series No. 6 might be implemented; however, it is up to individual Member State regulatory authorities or Member State or international standards bodies to determine whether the methods described in Safety Series No. 37 are acceptable for a formal standard.

Although both Safety Series No. 6 and Safety Series No. 37 are utilized by the IAEA to control its own radioactive material shipment activities, they are only recommendations for other regulatory and standards bodies.

In parallel with the IAEA's advisory documentation, the International Standards Organization (ISO) has been working on providing internationally accepted standards relating to specific issues dealing with the packaging and transport of radioactive materials. The ISO, which was originally formed in 1946 following an initiative of the UN, formed Technical Committee 85 "Nuclear Energy" in 1956 (Becker and Smith, 1983). Under this committee, it has issued or is working on standards in areas such as lifting equipment, handling and storage, transportation and packaging, criticality safety, and material control and inventory.

The purpose of this paper is to provide an overview of how radioactive materials packaging standards and regulations tie together. It will be shown that not only are regulations and standards at the national level based on those originating at the international level, but that efforts at the national level feed upward to the international arena. The international structure of the agencies involved will be reviewed, and the specific application in one country, the United States of America, will be used to illustrate how these requirements and standards are utilized at the domestic level.

## DEFINITIONS

In order to provide a consistent basis for the following discussion, a few definitions are required. The definitions of many of the terms that follow may vary from one regulatory or standard organization to another, but only one definition is listed here to provide the basis for this paper. Also, often one defined term may be used to define another defined term. To guide the reader, the defined terms used in defining other terms are highlighted using bold print. The definitions are:

- **AUTHORITY:**

  "Body that has legal powers and rights" [International Standards Organization, International Electrotechnical Commission (ISO/IEC), 1986].

- **CARRIER:**

  "Any individual, organization, or government undertaking the carriage of radioactive material by any means of transport" (IAEA, 1985).

- **CONSENSUS:**

  "Consensus is reached when... substantial agreement has been reached by directly and materially affected interest categories" (ANSI, 1987).

- **CONSIGNEE:**

  "Any individual, organization, or government which receives a consignment" (IAEA, 1985).

- **CONSIGNMENT:**

  "Any package or packages, or load of radioactive material, presented by a consignor for transport" (IAEA, 1985).

- **CONSIGNOR:**

  "Any individual, organization, or government which presents a consignment for transport, and is named as a consignor in the transport documents" (IAEA, 1985).

- **PACKAGE:**

  "The packaging with its radioactive contents as presented for transport" (IAEA, 1985).

- **PACKAGING**

  "The assembly of components necessary to enclose the radioactive contents completely. It may consist of one or more receptacles, absorbent materials, spacing structures, or radiation shielding, as well as devices for cooling, absorbing mechanical shocks, or for thermal insulation" (IAEA, 1985).

- **REGULATION:**

  "Document providing binding legislative rules, that is adopted by an authority" (ISO/IEC, 1985).

- **REQUIREMENTS:**

  Actions, activities, or quantified rules which must be performed and are required by law, regulation, or voluntary adoption.

- **SAFETY:**

  "Freedom from unacceptable risk of harm" (ISO/IEC, 1986).

- **STANDARDS:**

  "Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context" (ISO/IEC, 1986).

## ROLES OF REGULATIONS AND STANDARDS

### The Legal Requirements

The transport of radioactive materials is a closely regulated activity. Recognition of the hazards of radioactivity early in the development of the nuclear industry resulted in the establishment of transportation restrictions to limit these hazards. The evolution of these regulations has formed the existing structure and relationships among the different levels of regulations. It is important for the radioactive materials package designers and users to understand the multitude of regulations as they apply to their activities.

The primary international regulatory body concerned with the transportation of radioactive materials is the IAEA. Under the auspices of the UN, the IAEA develops and promulgates regulations that apply to its own activities, in addition to recommending these regulations to Member States and other international organizations for adoption. The diligence and thoroughness of the regulations have resulted in their acceptance by all major international transport organizations, all major industrialized nations, and nearly all IAEA Member States (Rosen et al., 1987). As the originator of the almost universally accepted regulations, the IAEA is in a position to foster consistent regulations worldwide. The IAEA has used this position and responsibility to help achieve an exemplary level of safety and consistency in radioactive materials transportation regulations (O'Sullivan, 1988).

IAEA Member States have a variety of ways to implement their own transport regulations. These methods vary by any national law, custom, or international agreement that may apply. In some cases, exceptions or additions to the IAEA regulations are made as they are implemented by individual Member States, but the overall objective is to maintain as close an alignment with the IAEA regulations as possible. This results in good continuity among the regulations of the Member States. Therefore, with a few exceptions, most shipments of radioactive materials can move smoothly in international commerce once they are in compliance with the regulations of the country of origin, if these regulations are consistent with the IAEA regulations.

The United States has two regulatory agencies with jurisdiction over the transport of radioactive materials: the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC). The DOT is empowered by the Hazardous Materials Transportation Act (HMTA) to regulate both shipper and carrier activities for the transport of all radioactive materials (as defined by the HMTA, which is consistent with IAEA). The NRC is authorized by the Atomic Energy Act to only regulate the transportation of source, by-product, and special nuclear materials. These three groups, which are specifically defined in the Atomic Energy Act, essentially include all radioactive materials and are defined for transport purposes to be consistent with the IAEA.

It was recognized that the duplication of authority between DOT and NRC could be troublesome for shippers and NRC licensees if the activities and regulations of the two agencies were not closely coordinated. Fortunately, they are closely coordinated and the two agencies have entered into a memorandum of understanding (MOU) to ensure consistency in approach and to minimize duplication of effort. The MOU delineates the responsibilities for regulating these activities within the U.S. as follows:

#### DOT Responsibilities

- o all consignors (including actions such as marking, labeling, placarding, and packaging)
- o carrier regulations (those who actually transport the material)
- o packaging for smaller quantities of material and lower hazard materials
- o reliance on NRC for packaging regulations related to fissile materials and larger quantities of material (Type B quantities)

#### NRC Responsibilities

- o source, by-product, and special nuclear material
- o all NRC licensees
- o packaging for Type B and fissile materials
- o reliance on DOT for carrier requirements and packaging regulations related to smaller quantities of material and lower hazard materials.

The MOU also makes each agency's regulations mutually applicable and addresses accident investigation. While the MOU is not applied literally in all respects, it does establish the working relationship between the agencies. Understanding its provisions will help the regulated public understand which agency has jurisdiction over various transportation activities.

### Complying With the Legal Requirements

The regulations that are promulgated by both national and international authorities need to fulfill two goals which sometimes appear to conflict. The first goal is to state, as completely as possible, what the required action or responsibility is. The second goal is to present the requirements as simply as possible, in order to avoid confusion and to foster understanding of the

requirements, which results in greater compliance.

The IAEA has recognized that the regulations should address the actions that are required for safe transport, i.e., "what" must be done. There is also a recognized need for information on "how" the regulatory requirements can be fulfilled. In some cases, there are many possible ways to comply with a regulatory requirement and the regulated public needs to know which of these methods are acceptable to the cognizant authorities. In response to this need, the IAEA has separated the regulations (what must be done) from the advisory material (how these actions can be accomplished). This information is found in two Agency publications, Safety Series No. 6, the transport regulations (IAEA, 1985), and Safety Series No. 37, the advisory material for the application of the regulations (IAEA, 1987). Presenting the advisory material separate from the regulations has been very favorably received by the regulated public. This method provides clear guidance on certain aspects of the regulations and reduces the demands on regulatory authorities to supply this information on a repetitive basis.

Within the U.S., the NRC has taken a similar approach in separating guidance and regulatory requirements. In order to supply applicants with guidance that will enhance understanding of acceptable ways to comply with the regulations, and to speed the evaluation of their package design approvals, the NRC issues Regulatory Guides. These documents, known as "reg guides," are divided into categories according to subject and cover such topics as receiving packages, leaktesting packages, package design criteria, structural analysis, quality assurance, and formats for design approval applications. Public involvement is utilized in the development of the regulatory guides and NRC's application of the regulatory requirements in certifying package designs is influenced by the guides. Regulatory guides, like Safety Series No. 37 in the international arena, provide a way of applying regulations that will usually be accepted by the NRC staff if properly and consistently applied. The heading on NRC Regulatory Guides states:

> Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

The NRC also publishes Information Notices that alert licensees to potential problems that may affect them, as well as ways to avoid these problems. This provides an excellent mechanism for NRC to share information when events occur that may have implications for more than one licensee.

Both NRC and DOT are called on occasionally to issue interpretations of the regulations that they issue. These requests ask for clarification of specific requirements and are generally very narrow in scope, but the interpretations may affect a number of licensees or members of the regulated public. Therefore, forums such as the DOT Hazardous Materials Newsletter and specific letters to licensees are available to any interested person or group. In addition, interested parties can request to be added to the DOT mailing list in order to receive the newsletter and information on rulemaking actions by contacting the DOT Office of Hazardous Materials Regulation, Washington, DC 20590.

## Supplementing the Requirements

The radioactive material transport regulations present the minimum required actions that shippers and package designers must fulfill. In many cases, good practice deems that additional actions be taken on a "voluntary" basis, and these additional actions may make it easier to demonstrate compliance with the regulatory requirements. While the regulatory agencies may not be in a position to require these additional actions, they have often supported the development of them as consensus standards. Not all standards are supplements to the regulations, and standards should not be limited to supplements, but they do provide an excellent way to enhance the regulations. The regulatory agencies (NRC, DOT, and IAEA) have demonstrated a willingness to adopt standards that are suitable for supplementing the regulations.

There are several standards-setting organizations within the U.S. The American National Standards Institute (ANSI) has established the framework for the development and implementation of voluntary consensus standards related to the packaging and transport of radioactive and fissile material. The ANSI-accredited committee that has been given the overall responsibility for developing these standards is N14, "Packaging and Transportation of Radioactive Material." N14 has developed a number of standards that ANSI has approved and published, covering such areas as packaging, contamination control, leaktesting, modal requirements, and tiedowns.

The American Society of Mechanical Engineers (ASME) is also active in developing standards and codes that have direct bearing on the packaging of radioactive materials (Leatham and Warrant, 1987). While ASME standards relate primarily to design and construction, some of them have been incorporated (by reference) by the NRC and are applicable to packaging design. The American Society of Testing and Materials (ASTM) develops standards on materials specifications that are often incorporated into ASME standards. These, in turn, may be adopted by NRC — which then applies them to licensees and package designers. Consequently, there are three primary sources of standards in the U.S.: the N14 Committee and ASME (which are processed through ANSI), and ASTM.

The ISO is the major source of international radioactive material transport standards. ISO has not developed standards in as many areas as ANSI (through N14), but it is recognized as the appropriate source for international standards. Some provisions of ISO standards (e.g., those related to radioactive sources and packaging) have been incorporated by reference by the IAEA into Safety Series Nos. 6 and 37.

In summary, there are three major sources of

the regulations that are applicable to U.S. shippers and package designers. For purely domestic transport, NRC and DOT establish the regulations. For international transport, IAEA is the leader in developing the regulations and DOT is responsible for applying consistent regulations to import and export shipments involving the U.S. Numerous other international bodies follow IAEA's lead and there is considerable interaction between NRC, DOT, and IAEA in establishing the complete body of regulations.

Domestic standards, as voluntary requirements or as supplements to the regulations, are developed by ANSI through accredited bodies (N14 and ASME), and ASTM standards may also be incorporated. International standards are developed by ISO and involve interaction between ANSI and ISO. All of these interactions need to be clear if package designers and users are to understand how the requirements apply to them.

## THE U.S. STANDARDS ORGANIZATIONS

ANSI is the umbrella organization that oversees the development and publication of nuclear standards, relying on both N14 and ASME. N14 is an ANSI-accredited committee and ASME is an accredited organization. While ANSI does not develop the standards, it does verify that due process, consensus, and other criteria for approval have been met by the standards developer. However, because ANSI standards are based on consensus, they do not necessarily reflect unanimous approval by all participating parties. All that is required is that a concerted effort be made to resolve all conflicts and that a majority of the writing group approve of the draft of the standard after considering any negative comments. The ANSI Board of Standards Review is the final authority in assuring that the approval process has been fulfilled. Once a standard has been approved, ANSI publishes it, either as an ANSI or ANSI/ASME standard (depending on the source of the standard).

N14 has a broad charter for developing standards related to the transportation of radioactive and fissile materials. A management committee assists in the formulation of N14 priorities, the identification of areas suitable for new standards, and coordinating writing group activities with the N14 Chairman and Secretariat (the writing groups do the actual development of the standards). A rigorous procedure has been implemented to ensure that N14-developed standards meet the ANSI specifications for consensus standards. This procedure requires (1) ensuring involvement of interested and affected parties, (2) utilization of due process in standards development, (3) consideration of all comments on draft standards, and (4) concerted effort to resolve negative comments. The majority of N14 standards have not been directly incorporated into regulatory requirements, but they are recognized by the regulatory agencies and industry to represent preferred ways of shipping these materials.

The N14 standards cover subjects that are pertinent to package designers, shippers, and carriers of radioactive materials. Some N14 standards, such as N14.5, "Leakage Tests on Packages for Shipment of Radioactive Materials," have been incorporated by reference into NRC reg guides that are of direct interest to package designers. Others, such as N14.1, "Packaging of Uranium Hexafluoride for Transport," have been incorporated into the DOT regulations and have direct bearing on shippers.

ASME standards and codes are also promulgated through ANSI and, in some cases, have been adopted by the regulatory agencies. For example, some aspects of Section III of the ASME Boiler and Pressure Vessel Code (BPVC) have been incorporated into NRC Regulatory Guide 7.6 as applicable to spent fuel casks.

Some ASME activities are specifically aimed at radioactive materials packaging. The Committee on Containment Systems for Nuclear Spent Fuel and High-Level Waste Transport Packagings (NUPACK) has been established as a Special Working Group under the purview of the Subcommittee on Nuclear Power (Section III). NUPACK's charter, as approved by ANSI, is to develop, maintain, and coordinate codes and standards for the construction and inservice requirements of containment systems for spent fuel and high-level waste transport packagings (Goldman, 1980). NUPACK's work has identified several areas where the traditional approaches to packaging approval used by ASME are different from those historically used by the NRC. These differences are being discussed with the NRC with the hope of developing mutually acceptable methods. It is anticipated that the NUPACK results will be published in the BPVC as a new subsection of Section III, Division I (for construction requirements), and as a new division in Section XI (for inservice requirements).

The ASTM is a source of materials specifications that are often incorporated into ANSI/ASME standards. The inclusion of a structural material into the ASME BPVC is a large step toward the acceptance of that material for use by NRC in packaging designs. Because the first step toward inclusion of a material in the BPVC is the publication of an ASTM material specification, the ASTM work can have direct bearing on radioactive materials package design. Currently, efforts are underway to develop ASTM specifications for ductile cast iron and borated stainless steel. There is considerable interest by spent fuel cask designers and manufacturers to have specifications for these materials developed as a precursor to inclusion in the ASME BPVC. If the materials are added to the code, then package designers may be better able to obtain NRC approval of designs that use the materials.

## INTERNATIONAL STANDARDS ORGANIZATIONS

As indicated in the Introduction of this paper, the ISO is the focal point for providing internationally accepted standards, and ISO's Technical Committee 85 (ISO/TC 85) has the responsibility to provide such standards that relate to the transport of radioactive material.

The secretariat for TC 85 was originally with the ANSI, but is now with the Deutsche (German) Standards Institute (DIN). ISO/TC 85 is divided into five subcommittees with secretariats in the U.S., France, Sweden, Poland, and Germany. ISO/TC 85 coordinates its activities closely with many international organizations, including the IAEA (Becker and Smith, 1983).

Subcommittee 2 (SC 2), dealing with radiation protection (Secretariat Sweden), and SC 5, dealing with nuclear fuel technology (Secretariat Germany), relate most closely with the transport of radioactive material.

Examples of ISO standards that help guide the international application of transport regulations include:

| | |
|---|---|
| ISO 1677-1977 | Sealed Radioactive Sources - General |
| ISO 2855-1976 | Radioactive Materials - Packagings Test for Contents Leakage and Radiation Leakage |
| ISO 2919-1980 | Sealed Radioactive Sources - Classification |
| ISO 4826-1979 | Sealed Radioactive Sources - Leak Test Methods |
| ISO/TR 4815-1979 | Sealed Radioactive Sources - Leak Test Methods |

ISO standards, which are under development, include a guide on the packaging of uranium hexafluoride for transport; a set of performance requirements and testing procedures for criticality issues; and standardization of calculations, procedures, and practices related to criticality safety (Becker and Smith, 1983).

The next section discusses how the interactions between regulatory agencies and standards organizations can be viewed as being circular. Examples of this can be found in the 1985 edition of Safety Series No. 6 (IAEA, 1985). In assessing Special Form Radioactive Material, specific test methods are prescribed in paragraphs 607-10 of these regulations; however, alternate tests prescribed in ISO 2919-1980 can be used in place of those tests prescribed in paragraphs 607 (Impact test), 608 (Percussion test), and 610 (Heat test). Similarly, volumetric leakage assessments of sealed capsules are specifically defined in these regulations using ISO 4826-1979. Finally, freight containers, when used as certain types of industrial packages as specified in these Regulations, must satisfy requirements prescribed in ISO 1496/1-1978, "Series 1 Freight Containers - Specifications and Testing - Part I: General Cargo Containers." This latter situation is a case where an international standard was initially developed for application not related to the packaging of radioactive material, but where experts later agreed that this standard could be fruitfully used in the radioactive material transport regulations.

In a similar fashion, an alternative to tests required in Safety Series No. 6 (IAEA, 1985) for Industrial Package Type 2 is allowed by also adopting the tests specified for packaging group III in the "Recommendations on the Transport of Dangerous Goods," prepared in the United Nations Committee of Experts on the Transport of Dangerous Goods; and tank container requirements in these regulations now refer directly to the standards prescribed in Chapter 12 of the "Recommendations."

## HOW IT ALL FITS TOGETHER

It would be quite chaotic if the numerous regulatory and standards bodies that have been described were producing requirements without regard to one other. Fortunately, this is not the case and there is a concerted effort to coordinate all of their activities.

The regulatory authorities have evolved their relationships into a fairly well-defined set of interactions. As Fig. 1 shows, the IAEA plays the central role in setting international regulations for the transport of radioactive materials. The IAEA interacts with four other types of regulatory agencies in the establishment and implementation of transport regulations:

1. The UN is the umbrella organization for the international regulation of all hazardous material transportation. The IAEA has been delegated responsibility for radioactive materials, while the Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods is responsible for all other hazardous materials. That committee and IAEA must coordinate closely on matters of mutual impact, such as labeling, marking, and placarding. There are also some dual-hazard materials such as uranium hexafluoride, which come under the purview of both organizations and must be dealt with by mutual agreement. Consequently, the regulations of both parties are established with the interaction and participation of the other.

2. There are three international regulatory bodies that develop and implement modal regulations related to radioactive materials transport: (1) the International Civil Aviation Organization (ICAO), (2) the International Maritime Organization (IMO), and (3) the Universal Postal Union (UPU). All of these bodies rely on the IAEA for the establishment of the overall regulations and incorporate IAEA requirements as consistently as possible. They participate in IAEA's formulation process and IAEA, in turn, participates in theirs.

3. Within Europe, several organizations establish regulations that not only apply to the region but may also be adopted outside of the region. Many of these regulations are established on a modal basis and are promulgated under that authority of the Economic Commission for Europe. These regulations are developed through the Commission's Inland Transport Committee (ITC) and include: (1) the European Agreement Concerning the International Carriage of Dangerous Goods on the Rhine (ADNR), (2) the European Agreement Concerning the International Carriage of Dangerous Goods on Inland Waterways (ADN), and (3) the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). Rail regulations are developed under the Central Office for International Railway Transport (OCTI), which is not a UN organization but meets in joint session with the ITC Group of Experts. Some Eastern European governments also incorporate the regulations of the Railroad Cooperative Organization (OSZhD) and the Council for Mutual Economic Assistance (CMEA).

4. The Member States of the IAEA form the fourth type of regulatory agency because

the international regulations must be implemented by the Member States of the IAEA if they are to be enforceable. Consequently, the Member States have the ultimate responsibility for the final regulations as they apply to their domain. Because Member States have a direct stake in the regulations, they interact very closely with the international regulatory agencies. In most cases, the representatives of the Member States actually comprise the majority of the international body and are, in essence, setting the regulations that will apply to them.

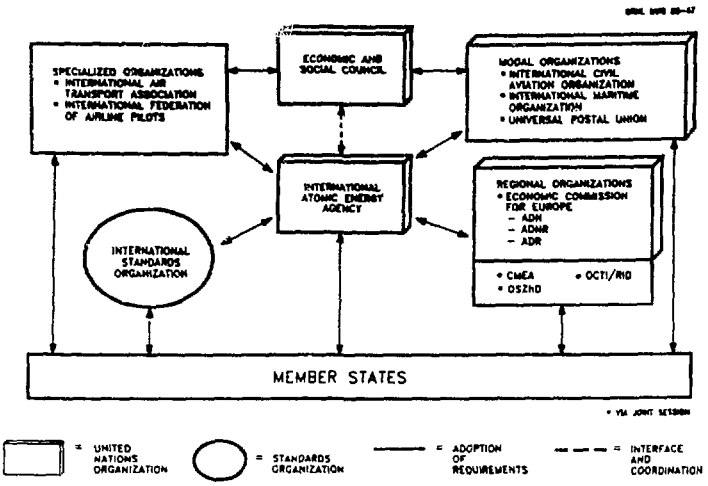


Fig. 1. Radioactive materials transportation regulations and standards: international interactions.

The IAEA also interacts with specialized international bodies which exercise control or influence on radioactive materials transport. These include the International Air Transport Association, the International Federation of Airline Pilots Association, and the International Cargo Handling Coordination Association.

As Fig. 1 shows, all of these bodies interact freely with each other. Interactions are not limited to those only proceeding through the IAEA. Member States participate directly with those organizations of interest to them. The fundamental principle, however, is that the IAEA is the source of international regulatory requirements for radioactive material transport.

The IAEA relies on the ISO for developing consensus standards that impact the packaging and transportation of radioactive materials. In some cases, the IAEA has identified a need where no ISO standard currently exists; this may result in the ISO expediting the development of a standard. The ISO, in turn, interacts with Member States to develop these standards, thereby closing the loop between the international regulatory and standards-setting bodies. Consequently, the interactions between Member States, ISO, and IAEA occur on a continuing basis. Therefore, not only do Member States have opportunities to participate in the development of regulations and standards, but also in the adoption of standards into regulations, whenever that occurs.

Within the U.S., there are a number of interactions that influence the development of standards and regulations. The DOT, the U.S. Competent Authority to the IAEA for the transport of radioactive materials, is the primary interface with the IAEA. As shown in Fig. 2, the interactions between NRC and DOT are covered by the MOU, and DOT provides the focal point for U.S. interaction with the IAEA. These are the primary interactions between the regulatory agencies for the development of regulations. Of course, the affected public, NRC licensees, and the Department of Energy (which has many activities regulated by DOT) have opportunities to interact with both NRC and DOT. It is crucial to an effective regulatory process to allow ample opportunity for continuing dialogue between the regulators and the affected parties. For NRC and DOT rulemaking, this process occurs through the publication of Federal Register Notices of proposed rulemakings and an opportunity to provide comments to the agencies. The comments are considered and addressed (if appropriate) in the notice of a final rulemaking.

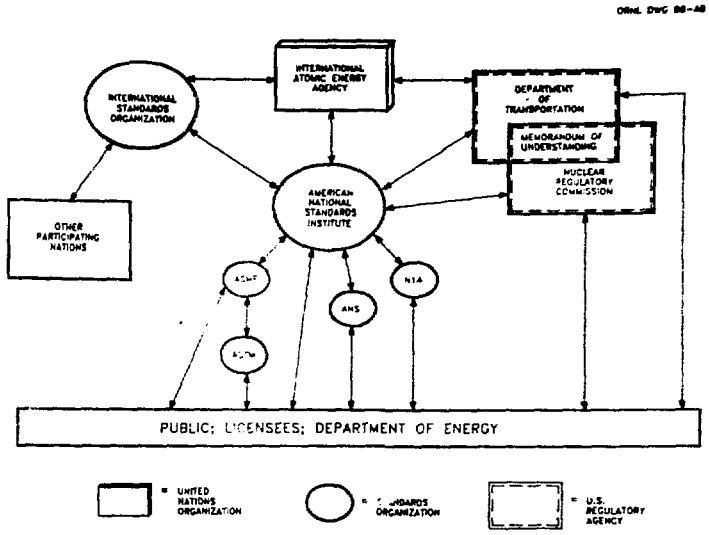


Fig. 2. Radioactive transportation regulations and standards: interactions of the United States.

Standards developed under the auspices of ANSI are published and are available for use by the public at large. If NRC or DOT believes that the standard is appropriate for incorporation into regulation, they are free to do so. In some cases, these agencies even encourage and directly support the development of specific standards. If a voluntary consensus standard can be developed on a topic that the agencies have found to be technically controversial, it simplifies implementing the requirements into regulation. It is generally easier for an agency to incorporate an ANSI standard than to independently develop and justify specific requirements. Consequently, Fig. 2 shows the relationship between NRC, DOT, and ANSI as a two-way relationship. Of course many areas of regulation are not amenable to consensus standards, and vice versa.

As the primary U.S. interface to ISO, ANSI serves to channel input from all interested parties, including the public and the regulatory agencies. International standards are developed under the ISO charter with the participation of other national organizations and interested parties. These standards are then available for adoption by nations, international organizations, and the IAEA. In some cases, the ISO standards have been adopted by IAEA; in other cases, IAEA is

interested in standards that are under development.

The interactions between the regulatory agencies (IAEA, NRC, and DOT) and the standards organizations (ISO and ANSI) are ongoing and can be viewed as circular. A requirement may be developed in any one of these arenas and eventually be adopted or addressed in any of the others. As a result, package designers and users should maintain awareness of the activities in all of these organizations.

## CONCLUSION

This paper has provided an overview of the interrelationships between radioactive material transport regulations and standards on both an international and a national level. The overview at the national level has been confined to consideration of the situation in the United States.

It has been demonstrated that, as the development of transport regulations and standards has matured, the interrelated nature of the two has also matured. At the international level, a great deal of "crossbreeding" is now occurring where standards are feeding regulations. This indicates that it is important for those responsible for developing regulations to remain abreast of development in the standards area, and if possible, participate actively in the development of these standards. It is becoming apparent that not only are regulations influencing standards, but that standards are now influencing regulations.

To assist the readers in obtaining necessary standards, the following information is provided:

- All ISO International Standards, Draft International Standards, Catalogues, and other publications may be purchased through associated national standards institutes in various countries. For example, in the U.S., ANSI should be contacted; in the United Kingdom, BSI should be contacted; and in the Federal Republic of Germany, DIN should be contacted (Becker and Smith, 1983).

- The address for ANSI is:

  American National Standards Institute, Inc.
  1430 Broadway
  New York, New York 10018, USA

- The address for BSI is:

  British Standards Institution
  2 Park Street
  London W1A 2BS

- The address for DIN is:

  DIN German Standards Institute
  Burggrafenstrasse 4-10
  D-1000 Berlin 30

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