



WORLD NUCLEAR TRANSPORT INSTITUTE

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October 11, 2000

AD

Ms. Annette L. Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Rulemaking and Adjudication Staff

RE: MAJOR REVISION TO 10 CFR PART 71: COMPATIBILITY WITH
ST-1 - THE IAEA TRANSPORTATION SAFETY STANDARDS -
AND OTHER TRANSPORTATION SAFETY ISSUES

Dear Ms. Vietti-Cook:

I am writing further to my letter to you of September 29, 2000 in which I submitted World Nuclear Transport Institute (WNTI) comments on the Major Revision to 10 CFR Part 71: Compatibility with ST-1 - The IAEA Transport Safety Standards - and Other Transportation Safety Issues, as published in the July 17, 2000, *Federal Register*.

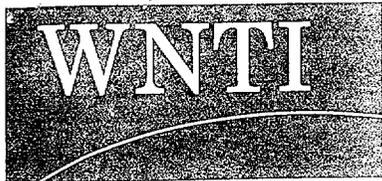
As indicated in that letter, I am forwarding herewith two papers produced by the WNTI on the continued safe use of packagings, and harmonization issues. These papers have been submitted to the IAEA for its consideration. We hope you will find them helpful in your consideration of ST-1 adoption.

Yours sincerely

Sten Bjurstrom
Secretary General

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SECY-02



World Nuclear Transport Institute

CONTINUED SAFE USE OF EXISTING PACKAGINGS

BY MELISSA MANN

CONTINUED SAFE USE OF EXISTING PACKAGINGS

The transport of radioactive materials – whether for medical and industrial use, fuel cycle applications or waste management activities – necessarily relies on the accessibility of approved packagings. IAEA Member States recognize the need to authorize existing package designs over a reasonable period of time. As a practical matter, however, differing approval processes and interpretations of regulatory provisions can hamper availability of suitable packagings for multinational shipments. These pressures are expected to increase as the IAEA moves to a two-year revision cycle.

Development of a viable system in which packagings that are properly maintained and continue to meet their original design intent may safely continue in use to the end of their useful design lives is a necessary precursor to the continued flow of radioactive materials in an increasingly international marketplace.

Consistent with development of transitional arrangements that are practical in a two-year revision cycle, evaluation of existing design reviews and validation processes may be undertaken to determine how better efficiencies can be introduced to the current system.

Continued Safe Use of Existing Packagings: An Overview

As initially incorporated into Paragraphs 713 and 714 of the 1985 Edition of the IAEA Regulations for the Safe Transport of Radioactive Material (as Amended 1990), the regulators recognized the need to allow continuing use of certain existing package designs subject to multilateral approval. These requirements, colloquially known as “grandfathering” provisions, provided for continuing use of packagings manufactured to a design approved under the two previous editions of the regulations (1967 and 1973 Editions).

This concept is extended in Paragraphs 815 through 818 of the 1996 Edition (ST-1 and TS-R-1). Again, the IAEA regulations provide for continuing utilization of packagings manufactured to designs approved under the two previous editions of the regulations (in this case, 1973 and 1985 Editions).

ST-1 allows further use of such packagings, provided that they:

- are properly maintained;
 - meet their original design intent;
-

- meet quality assurance requirements as outlined in ST-1 Paragraph 310.

The IAEA recognizes the need for packagings meeting these basic criteria to continue in use to “the end of their useful design lives” (please refer to ST-2 Paragraphs 816.1 and 817.1).¹ ST-2 Paragraphs 816.3 and 817.2 state,

“In the process of developing the 1996 Edition of the Regulations it was determined that there was no need for an immediate change of the Regulations following their adoption, but that changes aimed at a long term improvement of safety in transport were justified.”

In recognition of the continued safe use of existing packagings, the IAEA confirmed it is appropriate to accept the “continued operational use of certain packages” designed and approved under the 1973 and 1985 Editions (please see ST-2 Paragraphs 816.2 and 817.2).

Existing designs are not exempted from other provisions of ST-1. Specifically, packagings designed to earlier versions of the IAEA regulations are subject to the new activity limits and material restrictions outlined in ST-1 (please refer to Section IV) as well as the new requirements for transport of fissile material by air (please refer to ST-1 Paragraph 680).

ST-2 Paragraphs 816.2 and 817.1 reflect the regulatory intent in this regard:

“The reference to Section IV and para. 680 of the 1996 Regulations are included to ensure that only the most recent radiological data (as reflected in the A_1 and A_2 values), and requirements for fissile material by air, may be used to determine package content and other related limits. It should be noted that the scope of the transitional arrangements of the regulations only extends to the requirements for certain packagings and packages. In all other aspects e.g., concerning general provisions; the requirements and controls for transport including consignment and conveyance limits; and approval and administrative requirements, the provisions of the 1996 Edition of the Regulations apply.”

Provisions for the continuing safe use of existing packagings do not restrict the ability of individual Competent Authorities to authorize package designs under special arrangement provisions (please see ST-1 Paragraphs 824 through 826). Similarly, such provisions do not restrict the ability of regulators to restrict or cancel design approvals should they determine that such action is necessary to protect public health and safety.

¹ All ST-2 citations reflected herein are based on the February 19, 1999 draft.

The Two-Year Revision Cycle

The approach in which package designs approved to the two previous Editions of the Regulations may be considered for continuing safe use has been feasible to date in that the time period covered by such authorization averages twenty years.

This approach is not workable, however, in a two-year revision cycle. Under a two-year cycle, the time period covered by two previous Editions of the Regulations would be less than five years. This time frame does not match the reality of the time required to design, test and obtain approval for modified and/or new package designs (please see further discussion below).

Failure to appropriately address the period for which packagings may be used following design approval and manufacture has the potential to greatly disrupt transport of all radioactive materials. The IAEA has expressed concerns about this topic, sufficient to justify additional and focused discussion during the scheduled November 2000 Technical Committee Meeting. At its June 21, 2000 public hearing, the European Parliament's Committee on Regional Policy, Transport and Tourism addressed this topic as one of fifteen priority issues related to the transport of radioactive materials. The U.S. Nuclear Regulatory Commission (NRC), in a July 17, 2000 request for public comment on the harmonization of ST-1 with its domestic regulations, specifically raised concerns about the impact of the two-year revision cycle on continued use of existing package designs. This topic was addressed in greater detail during an August 10, 2000 public meeting attended by U.S. NRC, U.S. Department of Transportation and U.S. Department of Energy officials.

Obtaining Design Approvals: A Multi-Year Process

Industry shares concerns about a viable system being developed under the two-year revision cycle. The process for obtaining and maintaining design approvals necessary for international transport already presents numerous challenges. While the experience of individual entities may differ on a package-by-package basis, obtaining package design approvals can routinely require five to eight years of effort before a packaging is introduced into actual service. This time frame includes the following steps:

- Design and development;
- Testing as required by national and international regulations;
- Preparation of the safety analysis report and related technical documentation;
- Review and approval of the design in the country of origination;

WNTI – Paper Prepared by M. Mann

- Foreign validation(s);
- Manufacture;
- Training on packaging handling and incorporation of relevant requirements into facility procedures and quality assurance programs.

As the movement of radioactive materials - whether for medical and industrial purposes, fuel cycle use or waste management - increasingly involves international transport segments, the foreign validation process is critically important. At present, the situation for validation of foreign designs is extremely challenging. Such difficulties are, in part, based on the following factors:

- National requirements prevent uniform implementation of IAEA recommendations.
- National policies and approaches toward regulatory requirements differ; these views often carry over into review of foreign designs. Two such examples are the differing approaches being taken with regard to criticality control and mechanical testing. In some cases, differing approaches may result in new reviews for foreign-designed packagings, including those holding unilateral approval certificates.
- In setting schedules for package reviews, countries often place a priority on designs being approved under national regulations over reviews for foreign-designed packages. Such priority schedules may be appropriate to meet national transportation requirements, but can complicate shipment planning as multinational entities increasingly rely on common sets of packagings.
- National Competent Authorities frequently function with few support staff. As the number of reviews increases (especially with the incorporation of ST-1 into national regulations), there is often a correlating increase in the time required to complete package reviews. These review periods are multiplied when package approvals and validations are required in multiple countries.
- The regulatory scheme applicable to package reviews and approvals differ from country-to-country, but often require that new certificates of approval be obtained whenever changes – even changes that have no impact on safety – are made. This proliferation of package approvals and related foreign validations means that licensees are caught in a seemingly never-ending chase for package approvals.

Against this backdrop, industry is currently evaluating existing package designs to ensure compliance with the significant new packaging and testing criteria contained in ST-1. ST-1 requirements are also being analyzed in conjunction with development of new designs. Packagings built to designs approved against the

1996 Edition of the Regulations may not come into use for several years hence; by this time, however, the 2003 and 2005 Editions of the Regulations could be in effect. Under a two-year revision cycle, package producers will effectively be developing designs against regulations not yet written or implemented.

Future revisions to the IAEA regulations may not involve the magnitude of changes contained in ST-1. It is important to note, however, that even a seemingly small change can have a dramatic impact on individual designs or on designs used to transport a class of radioactive materials. Hence, the impact of any change can be significant.

Even in cases where there are no changes required to the design itself, it is expected that there will be a substantial amount of work related to analyzing and updating existing safety analysis reports and related technical support documentation.

Harmonization

The two-year revision cycle presents additional challenges. As this process moves forward it will be important to understand how different regulatory authorities (international, regional and national) adopt updated Editions of the Regulations. Equally important is how each of these authorities interprets revised regulatory provisions.

As currently being experienced with ST-1, implementation schedules can vary greatly between the international modal organizations (ICAO and IMO), regional regulatory schemes (such as ADR/RID) and individual countries. While a number of countries will implement the 1996 Edition of the Regulations beginning in 2001, other countries will only incorporate ST-1 provisions into national requirements in 2002 or 2003.

In many cases, the varying implementation periods reflect national requirements applicable to the regulatory revision process. While harmonization with current revisions of the IAEA regulations is strongly desirable, it may not be feasible for these national systems to maintain pace with a two-year revision cycle. A package producer attempting to develop a new design consistent with the most current Edition of the Regulations will encounter difficulty if its national regulations do not yet recognize such requirements: it may not be possible to obtain design approval against the most current Edition. In such cases, the producer may find itself several versions behind the current regulations.

Apart from how individual regulatory systems coordinate adoption of new Editions of the Regulations, the manner in which provisions of each Edition are interpreted also has a significant impact on package design and approval. When individual authorities take conflicting approaches to testing requirements and what constitutes

appropriate pass/fail criteria, the package review cycle becomes further complicated and protracted.

One requirement in this regard is the early publication of guidance documentation – such as ST-2 – in final form. This type of advisory material provides a common basis for national regulators to implement new international requirements (especially where wholly new criteria and testing requirements are introduced). Increasing opportunities for Competent Authorities and other regulators to discuss, and hopefully address, differences would help to simplify the design approval and validation processes. Recognition of unilateral approvals without full reviews during foreign validations would also be beneficial.

What is needed

Development of a viable system for continued safe use of existing packagings is a necessary precursor to the continued flow of radioactive materials in an increasingly international marketplace. Consistent implementation and application of IAEA regulatory provisions is requisite to avoid significant disruption to consumers of radioactive materials (and their customers) as well as to government activities (many related to national and international nonproliferation objectives as well as decontamination and decommissioning activities).

Such a system should clearly delineate how long packagings are allowed to continue in use following design approval, taking into account subsequent revisions to the IAEA regulations. The existing IAEA system in which twenty years of use is allowed provides a good benchmark. As the IAEA transitions to a two-year revision cycle, this twenty-year time period could be carried through to future Editions. This time frame also matches that utilized by many national authorities in licensing fixed nuclear facilities (under such approval processes, facilities are typically authorized to operate over lengthy periods of time on an “as-built” basis subject to continuing regulatory oversight).

Such a time frame allows a package producer to justify the resource expenditures associated with package development, testing, design approval/validation and manufacture while also ensuring that resulting packagings can be used for a reasonable period. This system would allow for use of such packagings consistent with other relevant revisions to the IAEA regulations, such as further refinements of activity data, quality assurance provisions and related requirements. Regulators would also retain their ability to rescind design approvals or request other modifications in the case that specific information justified such responses.

It is also entirely feasible that packagings designed to previous versions of the regulations could be demonstrated to comply with more current versions. In such cases, pending technical justification and approval, the useful life of a particular packaging could be further extended.

Within a twenty-year window of use, the IAEA could also identify the types of activities that may be undertaken with regard to specific packagings. For example, what type and magnitude of design changes should be authorized before a packaging should be recertified under a more current Edition of the Regulations? To what extent can manufacture of new packagings or related components be undertaken within the twenty-year licensing period? It is anticipated that national authorities may have slightly different requirements, but IAEA language could serve as a common basis for such decision-making.

At the same time, IAEA member states may also wish to consider other activities that could help to reduce the challenges and time associated with existing design approval and validation processes. Potential areas for discussion include the following:

- An assessment of unilateral approval provisions to determine if such a system is workable as a practical matter;
- Evaluation of whether multilateral approval is necessary for continuing use of packagings designed to an earlier version of the regulations;
- Review of whether the identification mark assigned to each design should include the date reference to the regulations against which it was initially approved;
- Consideration of “timely renewal” provisions under which packagings manufactured to previously-approved designs may continue in use while design changes not involving significant safety issues are reviewed;
- Where well developed regional infrastructures such as the European Union exist, consideration of a single design approval valid within that region without the need for additional validation by member states.

Conclusion

IAEA member countries recognize that package designs and packagings manufactured and utilized in accordance with such design approvals become no less safe following amendment to the regulations. As one national regulator recently noted, “Package designs and packagings compliant with the existing regulations do not become “unsafe” when the regulations are amended (unless a significant safety issue is corrected in the revision).”² Existing provisions allow continued safe use of properly maintained packagings to the end of their useful design lives when linked

² U.S. Federal Register, Vol. 65, No. 137, July 17, 2000.

with compliance to appropriate quality assurance programs and compliance with radiological data and consignment and conveyance limits.

These types of mechanisms should be carried forward to future Editions of the Regulations. The existing twenty-year period can be maintained by specific reference in place of linking transitional arrangements to two previous versions of the regulations. This approach will provide package developers with assurance that packagings may be used for reasonable time periods following the development, testing and certification process while also retaining the firm ability for regulators to address specific concerns through existing regulatory authorities.

Consistent with this process, evaluation of existing design reviews and validation processes can be undertaken to determine how better efficiencies can be introduced in the system, allowing regulators and industry alike to focus on issues involving the highest level of safety concern.



World Nuclear Transport Institute

**HARMONISATION OF
TRANSPORT
REGULATIONS
FOR RADIOACTIVE
MATERIAL**

BY

BERND LORENZ &

BLACKWELL GRESLEY

Harmonisation of Transport Regulations

For Radioactive Material

1. Introduction

Transport of radioactive material (RAM) is worldwide, based on an international safety regime elaborated by the IAEA - the IAEA Regulations for the Safe Transport of Radioactive Material (ST-1). The IAEA Regulations do not have legal binding force beyond IAEA's own transport activities; rather, they are implemented through legal actions in each IAEA Member State. As the IAEA Transport Regulations cover all modes of transport, they are embodied in the corresponding modal regulations covering the different modes of transport (sea, air, road, rail) . International organisations and agreements see to the adoption of the IAEA recommendations in international and national law (IMO, ICAO, ADR/RID for Europe), and the national competent authorities fulfil this task if it is not covered by these organisations.

The process of implementation of the IAEA Transport Regulations involves many jurisdictions and represents a large number of interfaces; each of these can be the source of discontinuities in transport which are not in the interest of the nuclear industry and, in some cases, may or can cause deficiencies in safety, which is in no one's interest.

For the planned introduction of new, revised recommendations co-ordinated efforts of all concerned parties are necessary to minimise discontinuities and possible safety deficiencies. Due to the different structures, working and decision-making procedures of all involved, it obviously is difficult to achieve that objective. It is highly advisable to harmonise the transition period to the greatest possible extent, not only for the convenience of the consignors, carriers and consignees but also, in the interest of maintaining the desired level of transport safety and prevention of deviations from normal operations. By far the best solution would be the simultaneous transition to a new regulation for all modes of transport at exactly the same time and without transition periods¹, when old and new regulation can be used equally. This would not only be the clearest way for the transport organisations but it also would alleviate the task of the competent authorities which in all states have limited resources. These resource problems inevitably will increase when regulations are changing and new ways of work have to be found.

This ideal solution has not been achieved. There still are different dates when the new IAEA Transport Regulations ST-1 come into force for the different modes of transport and there also are different transition periods, when old and new regulations coexist. There is concern about the still non-harmonised transition periods and the problems for transportation which may result.

The situation becomes even more complicated when one takes into account the perennial problems of harmonisation between the (dangerous goods) transport regulations for RAM and national atomic law. In the future we are faced in several countries with the strange situation that one can release out of any control exemption quantities of material which are radioactive from a physics point of view, but non-radioactive from the legal point of view; but it will not be allowed to be transported unconditionally because, under the transport regulation it still is RAM (non-

¹ Transitional arrangements are needed of course for longer lasting transports, which start before the new regulations come into force and have not yet finished. This is the case especially for sea transport.

compliance of contamination limits) and thus to be transported under the provisions of transport regulations. The situation also can be *vice versa*, when national regulation does not follow the new exemption levels of ST-1.

And another topic of harmonisation arises; namely, the transfer of the modal regulations into the form of the model regulations of the UN Orange Book. Although this transfer has harmonisation of dangerous goods regulation in mind, it will cause practical problems, as nearly all people involved have to get used to the new formats. It is not a very advantageous coincidence with the introduction of new transport regulations. But on the other hand, harmonisation can only be achieved by going that route.

Problems related to the introduction of new regulations are becoming more critical now that the period of revision is shortened from the former ten years to two years. What was practical in the past with the relatively long revision cycle may now become impractical. There risks being a patchwork of regulations differing from mode to mode, area to area, attitude to attitude of consignee, carrier, consignor and authorities on which kind of regulations have to be applied, against the interest of harmonising the revision process.

2. Harmonisation of the modal regulations – the international time schedules

International time schedules

There are timing questions concerning the first introduction of ST-1, and the introduction of their revisions according to the new two year revision cycle. At the moment the time schedules for ST-1 implementation by the major modal organisations/agreements are as follows:

	ADR/RID	ICAO	IMO
ST-1 beginning	01.07.2001	01.07.2001	01.01.2001
SS6 ending	31.12.2001	01.07.2001	31.12.2001
Transition period	6 months	0	12 months

The transition periods recently have been synchronised; they formerly were much more inconvenient when transition periods of up to 18 months were foreseen. Strong efforts from the IAEA and the modal organisations have led to a much better situation today than pertained only months ago.

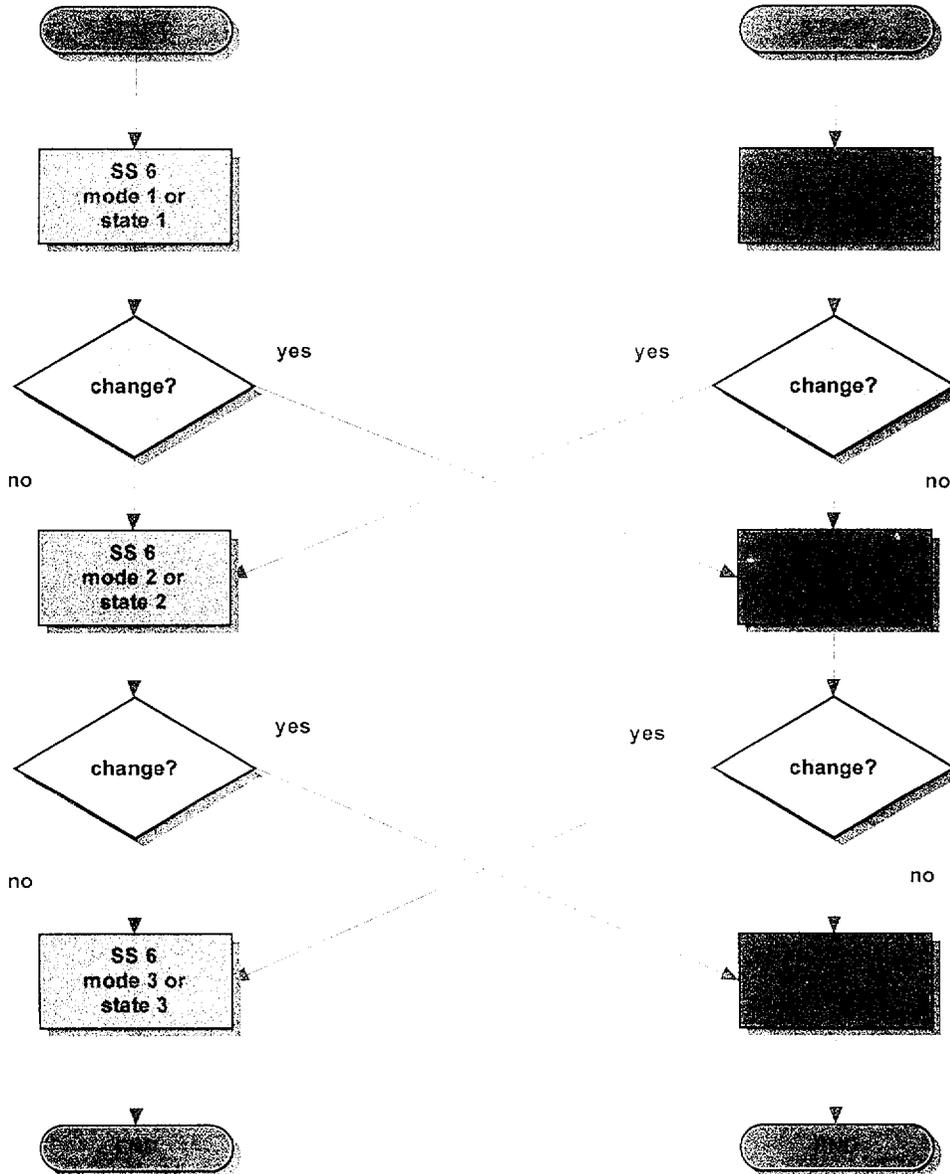
However there is the potential for confusion among the parties involved or at least a high degree of non-preparedness how to handle this transition period, as real experience with the practical problems is limited. This is to a certain extent true for the industry involved but also for the authorities, especially when taking into account their often already rather limited resources.

The ST-1 has been published in 1996 and it took quite a long time to incorporate it into the modal regulations. A more harmonised approach to future revisions of ST-1 is much to be desired.

Alteration between SS6 and ST-1

The time schedule poses an additional problem insofar as the modal regulations allow for transport either according the old SS6 or the new ST-1. The situation is illustrated by the following flow chart:

Flow chart 1: Alteration between SS 6 and ST-1



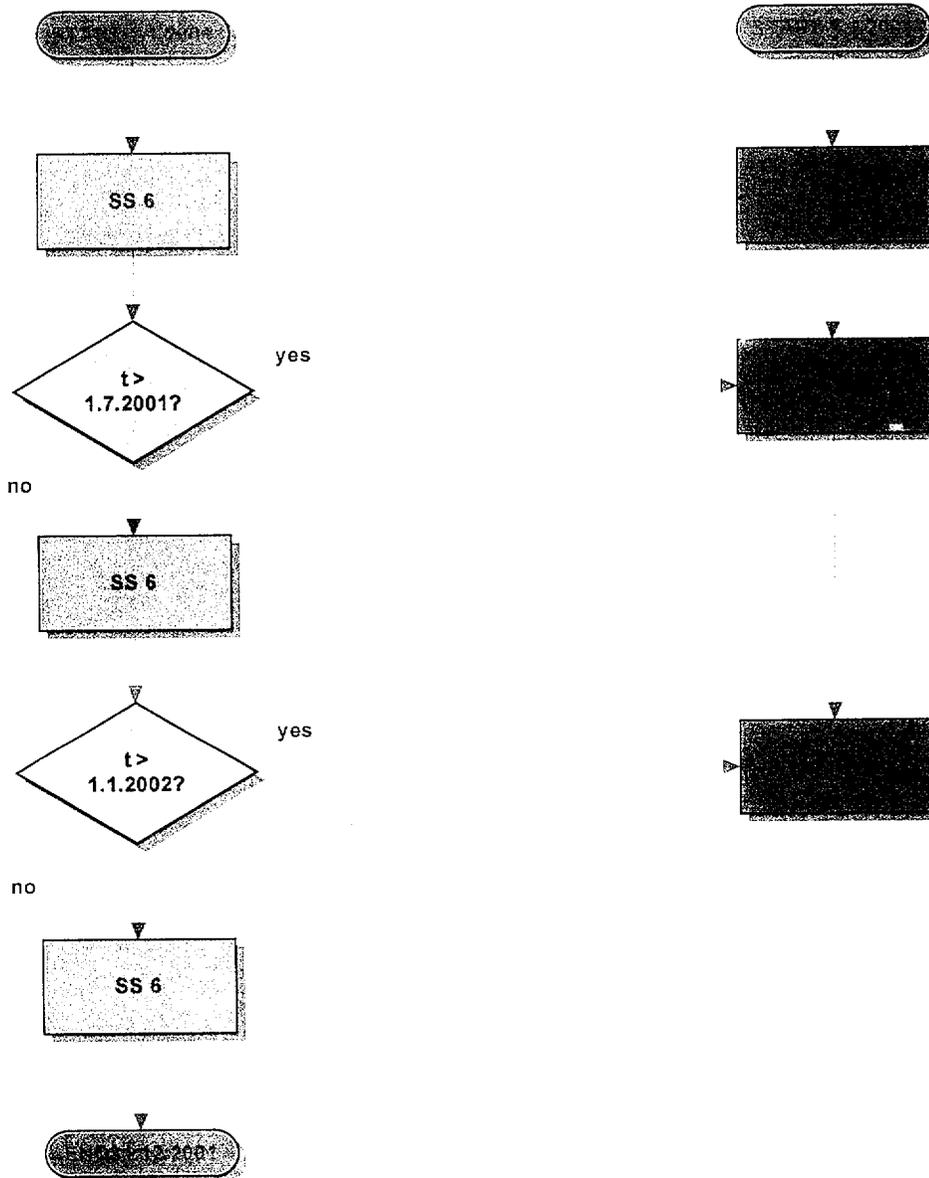
no = f(t,x) yes = f(t,x)

The different possible ways of transport are equally valid for changes in the mode of transport and the country in which or between which transport goes on. The variations are multidimensional and of any complexity, depending on how often the mode will be changed and

how many states are involved (for ease of demonstration only three changes have been chosen in the flow chart).

An endpoint exists only for the modal regulations by international organisations/agreements as demonstrated in the next flow chart.

Flow chart 2: time schedule for change from SS 6 to ST-1



no = f(t,x) yes = f(t,x)

The overall transition period now will be at least 1 year (in most of the European countries), when old and new regulations coexist. The possibility to choose between the old and the new regulation is an advantage only at first sight. The normal way of changing regulations is to have

only one date from which the new regulation is valid. Transition periods are regulated with the new law for certain items. The SS6 or ST-1 is a typical example for that procedure (see §§ 815-818 in ST-1).

Co-existence of the old and new regulation over a transitional period clearly is a matter of the regulations, but the policy of the transport organisation also plays a role. Each organisation has to define its policy, if there is the choice at all, whether to proceed along the old regulation line for whatever reasons or to go straight forward along the new regulations. Each organisation should plan its own transition period carefully. One question in this context is whether they are able to make this plan without response from the authorities. The situation becomes quite complex, when more than one country or more than one authority is involved and differences are to be observed in their attitudes.

Public opinion

Another aspect of transition is public opinion. Transport of RAM has come increasingly into public focus, especially the transport of high activity waste and spent fuel. At least in Western Europe many people believe after the huge media campaign on contaminated spent fuel casks that transport of RAM is a very dangerous matter and intrinsically unsafe. The mass media often shows little interest in presenting a realistic picture or highlighting the real safety achievements. Implementation of new regulations which are intended to provide an even greater degree of safety soon will attract media attention as the implementation date nears, and it is entirely likely that the public will expect a rapid adoption of the new, "better because more stringent" regulations.

3. Harmonisation of the legal adoption of the regulations – national time schedules and consistency

National time schedules

In addition to the transition problems related to modal regulations there is the necessity to adopt regulations by national law in the different countries. This process is not necessarily identical with the time schedule of the major modal regulations as outlined above. There are transition periods for a number of countries, where national regulation is guided by the aforementioned organisations/ agreements but will be determined exclusively by national legislation. The actual process of embodying IAEA Transport Regulations may differ significantly from those mentioned above. For example, in the United States ST-1 will be incorporated into 10 CFR Part 71, probably from 2003. For most European countries the adoption process is much earlier due to their commitment to ADR and RID. So in Europe the adoption process follows closely the line of the modal regulations as explained above and within one year the transition to ST-1 will be completed.

That full implementation can take much longer becomes clear when taking into account the fact that several countries follow their own lines of regulation. The recent survey on the implementation of transport regulations among IAEA Member States, the results of which to be presented to the IAEA General Conference this year, revealed that even the old pre-1985-SS6-versions still form the basis for transport regulations in about 8% of the 72 Member States which participated in the survey, 15 % do not regulate transport based on SS6 at all, whereas a similar percentage of states already are regulating according to the ST-1 1996 edition. The main stream of national regulations however is based on SS6 and probably the vast majority of RAM

transports is in or between these countries. These statistics reveal an unexpectedly broad range of different regulatory situations. With the new two year revision process, there will be a new version of the IAEA Regulations every two years. Doubtless, therefore, the landscape of different revisions which are in force in the various IAEA Member States will broaden significantly and transport between countries will become more and more complicated. The consignor and the carrier will have to maintain a database for all these revisions. Compared with the former SS6 regime in fifteen years seven(!) revisions can be expected - with the corresponding deviations forward and backward and the qualified personnel to keep track of the essentials. Even with the 1985-Edition of SS6 there were still moments of sudden recognition of facts or interrelations within this well known Regulations by experienced persons engaged in the matter for a long time.

Adoption problems

The varying time schedules for adoption pose one set of problems; the extent of adoption and the understanding of the particular provisions of the regulations by the competent authorities are others which influence the practical organisation and performance of transports. The IAEA Transport Regulations have to be “transformed” into the modal regulation or into national laws. It is to be hoped that with the harmonisation according the “model regulation” of the UN Orange Book, edition 11, this task will become easier in the future.

National adoptions have a potential for intended or unintended deviations from the original, which would not be in the interest of unimpeded international transport. On the other hand, there might be a better possibility to take care of the national atomic law and achieve better harmonisation between national atomic law and national transport regulation².

The introduction of new regulations creates extra work for all parties involved, but the resources are limited for any organisation, industry as well as authorities. A number of authorities already are hard pressed to guarantee a reasonable time for routine work such as issue of licenses or package approval certificates. Can the inevitable extra work in the wake of new regulations be done without further delay, and be responsive to the needs of safe, efficient transport?

Although the ST-1 was published several years ago it has to be recognised that an intensive process of study of the new provisions can be observed only recently. This is demonstrated by the great response to the ST-1 revision process. The large number of proposals for changes or identified problems makes clear that there is an expectation of practical problems from the viewpoint of industry as well as authorities.

Several of the proposals for ST-1 revision might well have been launched much earlier. Sometimes the proposal represents an effort to avoid misinterpretation of the rules. Some of the provisions of the IAEA Transport Regulations are open to interpretation and, in some cases, the official explanatory material either does not give sufficient clarity, or allows different interpretations. International transport needs harmonised interpretation.

A situation wherein a certain way of safety assessment is accepted in one country, but requires more explanations and calculations or testing in another is unsatisfactory. The validation of certificates, which is mandatory for a Type B(U)-F package and which is not necessary for a Type B (U) package, goes in very different ways in different countries, even in such a relatively small area as Europe.

² Harmonisation with the national atomic law could usefully start with a harmonisation of national laws based on IAEA Recommendations as e.g. their Basic Safety Standards for Radiation Protection.

The original idea for validation of F- packages was the individual way of criticality safety assessment in different countries. That means that all other conditions for the qualification as Type B(U) could be untouched. The reality of validation is different from this original intent. Several authorities prove nearly the whole safety assessment report a second time. The consequences are long validation times, misunderstandings often due to language problems, additional safety assessments or calculations.

Such problems occurred under the SS6 regime, which was the basis for a rather long time, i.e. was well known among all parties. There is concern about the potential for a number of new fields of disharmony between authorities of different countries when the new regulations come into force, where new technical and safety issues are still under discussion. This will be much more complex with a revision cycle of 2 years.

4. Examples for problem areas

To illustrate the practical consequences of the still not fully harmonised transition to ST-1 as outlined above the following examples are given:

Transport from/to an SS6/ST-1 regulated country/mode

Package design approval

New dose quantities in radiation protection

Radiation protection programmes

Transport from/to an SS6/ST-1 regulated country/mode

The following table lists some of the key points to be considered, when transporting from one kind of regulation to the other. The list is for illustration only and not exhaustive. The problem areas become more complicated when changing the regulation several times due to change of mode or touching other countries.

Transport starts under SS6		Transport received under ST-1	
package	SS6 design approval	No ST-1 design approval	Only by grandfathering; mind ambient dose equivalent H*(10)
	Multilateral approval on SS6 basis	Multilateral approval on ST-1 basis	Criteria unclear
labelling	SS6 label	ST-1 label	2 labels for the same package needed; potential for misunderstanding
activity	SS6 based	ST-1 based	Choosing the most restrictive (e.g. mind Tc99m)
contamination	SS6 based; relaxation for empty or excepted packages cannot be used	ST-1 based	Choosing the most restrictive
dose rate	SS6 based	ST-1 based; new dose quantity H*(10); measuring results differ	Choosing the most restrictive; potential for misunderstanding
TI	Includes criticality	TI plus CSI	Two sets of TI plus CSI needed; potential of misunderstanding
Radiation protection programme(RPP)	Not needed	Needed	
Exemption values	70 Bq/g	Nuclide specific	Detailed comparison before transport if it shall not be declared as radioactive

Transport starts under ST-1		Transport received under SS6	
package	ST-1 design approval	ST-1 design approval has to be accepted ("backward grandfathering)	legal basis ?
	Multilateral approval on ST-1 basis	Multilateral approval on SS6 basis	Criteria unclear
labelling	ST-1 label	SS6 label	2 labels for the same package needed; potential for misunderstanding
activity	ST-1 based	SS6 based	Choosing the most restrictive
contamination	ST-1 based	SS6 based; relaxation for empty or excepted packages cannot be used	Choosing the most restrictive
dose rate	ST-1 based; new dose quantity H*(10)	SS6 based measurement differs	Choosing the most restrictive; potential for misunderstanding
TI plus CSI		CSI does not exist	Two sets of TI needed; potential for misunderstanding

Radiation protection programme(RPP)	If needed	RPP on voluntary basis	
Exemption values	Nuclide specific	70 Bq/g	Detailed comparison before transport if it shall be not declared as radioactive

Package design approval

Package design approvals which already exist on the basis of the former regulations are regulated by the ST-1 transitional provisions of §§ 815 - 818. These transitional arrangements for packages, licensed under different revisions of the IAEA Transport Regulations, follow the basic philosophy, that " there was no need for an immediate change of the Regulations following their adoption, but that changes aimed at a long term improvement of safety in transport were justified." (see § 816.3/817.2 in ST-2) However this general line is contradicted by the conditions of the transitional arrangement, which are laid down in the same paragraph. As most of the licensed packages in use are licensed probably under the last SS6 edition, one can refer to the transitional arrangements for that kind of packages in § 817. The conditions for a continued use of existing packages are:

- quality assurance
- activity limits and materials restrictions of the new regulations only
- air transport of fissile material only according the new regulations.

But this is not all that has to be considered for continued use of the existing packages. Paragraph 816.2/817.1 of ST-2 states: "It should be noted that the scope of the transitional arrangements of the regulations only extends to the requirements for certain packagings and packages. In all other aspects, e.g. concerning the general provisions, the requirements and controls for transport including consignment and conveyance limits, and approval and administrative requirements, the provisions of the 1996 Edition of the Regulations apply."

Taking this into account the transitional arrangements have some pitfalls. The first task is that one has to clarify what are the differences in the general provisions and what are the differences in the activity limits and the materials restrictions. This clarification does not necessarily arrive at the same result when undertaken by the license holder or by the authorities of one or more countries. The acceptance of the authorities is, however, essential. The industry must not violate the regulations and a debate on suspected non-compliance should be avoided.

Another aspect which has to be taken into account, and which puts the transition arrangements into context, is the duration of package approval certificates. In most of the European countries package certificates expire after three years. The prolongation of certificate approvals may result in a 100% approval according to the new regulations. Due to that practically no credit is taken from the transitional arrangements.

For the transition to ST-1 there is a special issue, which makes it difficult to use old packages in the same conditions as before: the new quantities for dose measurement in radiation protection.

New dose quantities in radiation protection

At the beginning of the last decade the ICRP and the ICRU created a new system of dose quantities for radiation protection purposes. The key quantity for transport issues is the new "ambient dose equivalent $H^*(10)$ " and the corresponding dose rate. This quantity was via the IAEA Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources introduced into transport regulations as ST-1 refers to in its definitions to the

Basic Safety Standards. Unfortunately the new dose quantities would not be numerically equal to the old ones. The difference for photon radiation in a certain energy range can reach up to a factor of 1.5 and the same is true for neutron radiation of certain energies. One of the general provisions for transport is the compliance with dose rate limits. A measurement of the new dose quantities in radiation protection could result, when transporting the same contents of radioactive material, in dose rates above the limits and that could be interpreted as a violation of the regulation. This situation is probable for packages which have been designed up to the dose rate limits for the maximum possible content. Design of packages normally goes that way.

Dealing with this issue some authorities can put their emphasis on the transitional aspect, meaning a smooth transition with no need for abrupt changes because of the already achieved high safety standard(as mentioned above). Other authorities can go the more formal way and insist that a dose rate shall never be over the limit values. This would coincide with public expectations which probably could not understand why dose rate limits can be exceeded. The result is that, in the first case, a transport goes the same way and with the same contents of radioactive material and, in the second case, the contents of radioactive material have to be reduced to meet the demands of dose rate limits. The situation becomes more complex when authorities in more than one country are involved and have different points of view. The alteration of the regulatory basis for the forthcoming transition period has also to be taken into account.

Obviously we need a harmonisation between the authorities in charge of radiation protection and those in charge of transport regulation. And also there is a need for harmonisation between the authorities in charge of radiation protection in the different countries.

Radiation protection programmes (RPP)

One of the real changes from SS 6 to ST-1 is the provision of Radiation Protection Programmes (RPP). Such programmes are familiar to companies which already work in the nuclear field. Normally a nuclear license is needed for such activities and elements as personnel monitoring, radiation measurement including contamination measurement, dose such assessments, analysis of working places, training and education of workers are typical. The situation is different for companies not routinely working in the nuclear field. They now will need trained people, measurement equipment and software such as working instructions, test procedures etc. This is an added burden to these often smaller companies, and there is concern about the potential disincentive to companies willing to transport RAM. There is no experience with RPP in transport for smaller units so far and one should prepare some kind of standardised solutions for them, to keep the extra burden as low as possible and to maintain their engagement in nuclear transports.

5. Summary

The implementation of the IAEA Transport regulations is a complex area where several organisations, authorities and companies influence each other. Harmonisation of their activities is in the interest of safety and a continuous transport flow. The adoption of ST-1 and its revision process is a new challenge which needs joint efforts to achieve this objective. The implementation of ST-1, as shown above, still has several non-harmonised points which could well lead to some difficulties in the next few years. They should be overcome as the two year revision cycle proceeds; if not, there is concern about a deterioration of the situation.
