

IAEA'S TRANSPORT REGULATIONS: TRANSITIONAL ARRANGEMENTS REQUIRING MULTILATERAL APPROVAL

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SUMMARY

This paper analyses regulatory provisions dealing with transitional arrangements, provided by both the 1985 Edition (As Amended 1990) and the 1996 Edition of the IAEA's Regulations for the Safe Transport of Radioactive Material (hereinafter "the Regulations"), particularly those requiring multilateral approval through a validation process.

From the status (expired and validated) point of view of the certificates, the information contained in the Directory of National Competent Authorities' Approval Certificates, IAEA-TECDOCs 903, 826, 758, 723 and 662, is analysed and the expected situation in the year 2001 is inferred.

Finally, difficulties encountered by applicants in obtaining multilateral approval as required by the current provisions of transitional arrangements are discussed, particularly in complying specific validation provisions imposed by Competent Authorities. In addition, eventual ways to overcome difficulties are described.

INTRODUCTION

The IAEA Regulations are used world-wide for regulating the safe transport of radioactive material; they establish technical, operational and administrative requirements. Such requirements are intended to control the exposure of persons, property and the environment, as well as to limit the risks due to criticality and heat generation, both in normal and accident conditions of transport.

The 1985, 1985 (As Amended 1990) and 1996 Editions of the Regulations provide transitional arrangements aimed at harmonising the Competent Authority's actions in the approval of packages and special form materials designed or approved under the provisions of previous editions, 1967, 1973 and 1973 Revised Edition (As Amended).

The first time that transitional arrangements were included in the Regulations was in the 1985 Edition. To allow continued operational use of packagings approved under previous editions of the Regulations was the main reason. If such kind of arrangements had never been

included, the only way in which the consignor could continue the use of a packaging would have been either to apply for the approval of the design according to the edition in force of the Regulations or that shipments be approved under special arrangement. It must be pointed out that special arrangement was never intended as mean of "grandfathering" (Explanatory Material for the IAEA Regulations, 1985 Edition (As Amended 1990), Safety Series No. 7).

Depending on the nature of the changes introduced in the provisions of a new edition of the Regulations and the features of the package design, in many cases the level of safety determined by both the current and the previous edition is quite similar. As a consequence, it is reasonable to permit the continued use of packagings manufactured according to a design approved under older editions of the Regulations, subject to suitable additional controls or limitations, as appropriate.

Regulatory changes are usually introduced either to improve the level of safety or to more clearly specify requirements. It should also be noted that an ongoing transport practice does not become more or less dangerous because of changes in the Regulations, that developments of new designs need time, and that new approvals can prove to be difficult. Therefore, it is entirely proper to allow, within their working lifetime, adequate exploitation of packagings manufactured to designs approved under previous editions of the Regulations. However, the trend is to gradually preclude the use of the oldest designs and to obligate that developments of new designs are made taking into account compliance with the last edition of the Regulations.

ANALYSIS OF THE STATUS OF APPROVAL CERTIFICATES

The Directories of National Competent Authorities' Approval Certificates, IAEA-TECDOCs 903, 826, 758, 723 and 662, include data collected by the IAEA's PACKTRAM Data Base for 1996, 1995, 1994, 1993 and 1992, respectively. Such data contain the details of the Approval Certificates declared by a representative number of Competent Authorities. The directories, among other information, reflects the status of the certificates (in force or expired) and lets know whether they were approved either by the Competent Authority of the country of origin of the design or by validation of the original certificate issued by other Competent Authorities.

Some of the data provided by the mentioned directories were summarised in Table 1 and Figure 1; they show the number of collected Approval Certificates every year since 1992 to 1996 classified according the edition of the Regulations under which they were approved, independently of their current status. The table also shows the percentages corresponding to each edition and the total number of certificates per year.

It seems to be of interest to analyse the decreasing rates of the number of certificates approved under old editions of the Regulations, which permits one to infer the situation at the time when the 1996 Edition (ST-1) will be in force world-wide. At the second IAEA's Transport Safety Standards Advisory Committee (TRANSSAC-II) meeting there were discussions addressed to co-ordinate the same target date for adoption of ST-1 in the different modes and it was concluded that is highly probable to be January the first, 2001.

In Figure 2 were plotted the percentages of certificates approved under every edition of the Regulations as a function of the year of collection of the data, in the period 1992-1996. In the same figure straight lines were extrapolated to indicate the decreasing rates of the number of

certificates approved under old editions and the increasing rate for the edition in force. From that figures can be extracted the following conclusions:

- (i) At the end of the period during which the 1985 Edition was in force in most of the countries, that is 1996, there were about 42 % of certificates approved under older Editions (1967 and 1973).
- (ii) The number of certificates approved under the 1985 and 1985 (As Amended 1990) Editions is increasing at a rate average of 13 % per year; those approved under the 1973 and 1973 (As Amended 1990) Editions are decreasing at a rate average of 12 % per year, and those approved under the 1967 Edition are decreasing at a rate average of 0.6 % per year.
- (iii) Considering such decreasing rates and assuming that such tendency will be maintained in the following years, it is highly probable that at the moment when the 1996 Edition enters into force, there will be practically no approval certificates issued under 1967 and 1973 Editions. However, this conclusion could be not entirely true because data from TECDOC-903 indicate that a few certificates have expiry date ending on or beyond the year 2001.

EDITION OF THE IAEA REGULATIONS Current, expired, original and by validation Certificates	IAEA TECDOC-662 - 1992 -		IAEA TECDOC-723 - 1993 -		IAEA TECDOC-758 - 1994 -		IAEA TECDOC-826 - 1995 -		IAEA TECDOC-903 - 1996 -	
	No. Certif.	%	No. Certif.	%	No. Certif.	%	No. Certif.	%	No. Certif.	%
1967	44	3.3	30	2.0	23	1.6	17	1.1	14	0.9
1973 & 1973AA	1 147	86.9	1 118	75.4	829	58.8	811	52.2	658	40.7
1985 & 1985AA '90	129	9.8	335	22.6	558	39.6	725	46.7	942	58.4
GRAND TOTALS	1 320	100	1 483	100	1 410	100	1 553	100	1 614	100

Table 1

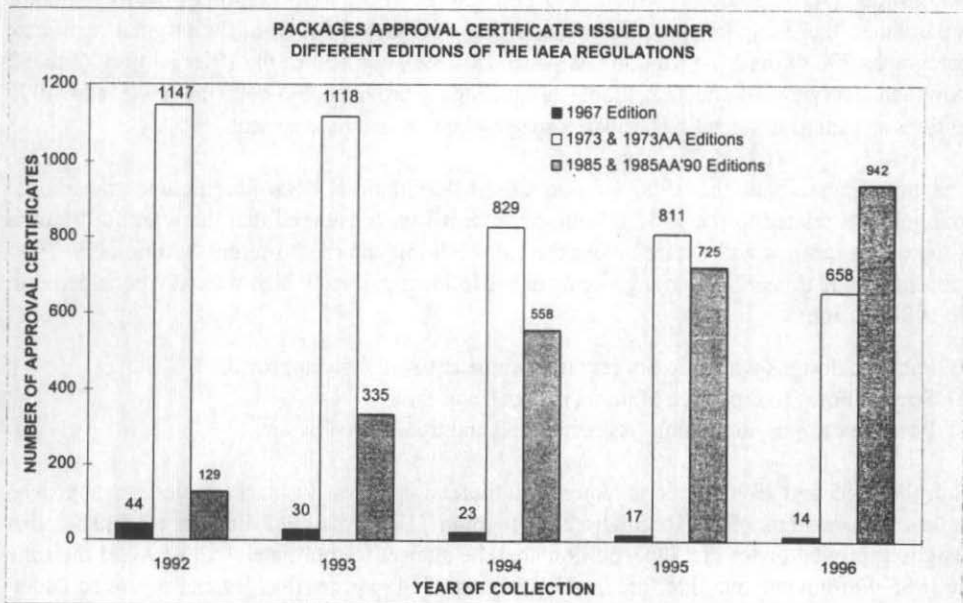


Figure 1

**INCREASING AND DECREASING RATES OF THE NUMBER OF APPROVAL CERTIFICATES
UNDER DIFFERENT EDITIONS OF THE IAEA REGULATIONS**

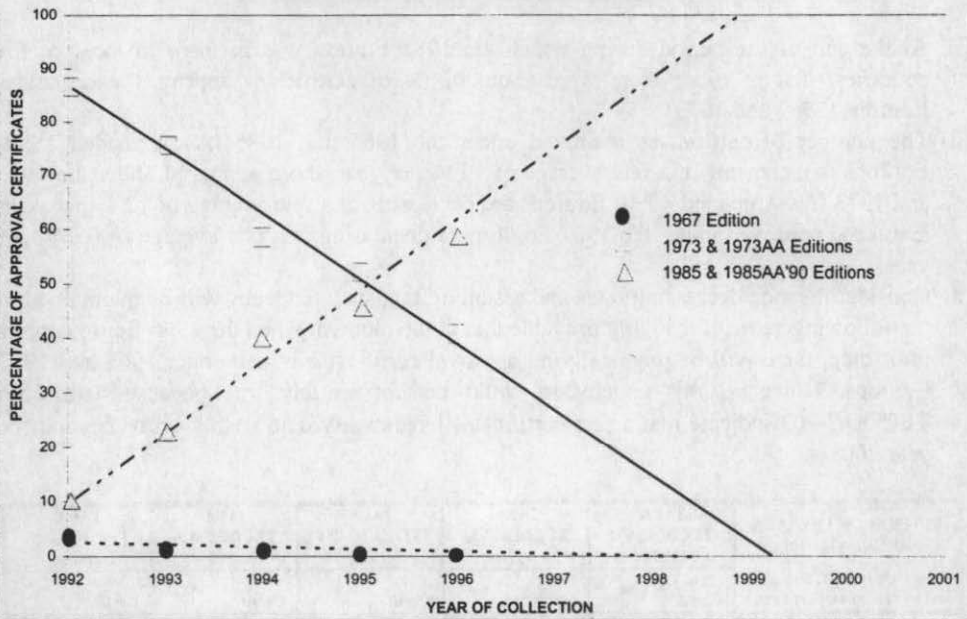


Figure 2

ANALYSIS OF TRANSITIONAL ARRANGEMENTS

It is of interest to analyse transitional arrangements provided in paragraphs 713 and 714 of the 1985 Edition (As Amended 1990) and 815 through 818 of the 1996 Edition of the Regulations. In particular, those requiring multilateral approval through validation of the original certificate (paragraphs 730 of the 1985 Edition (As Amended 1990) and 834 of the 1996 Edition). Table 2 shows an overview of the transitional arrangements provided by both the 1985 and 1996 Editions as well as the standing periods corresponding to each requirement.

It is noted again that the 1996 Edition of the Regulations does not include transitional arrangements related to the 1967 Edition because it was considered that the working lifetime of the oldest designs will expire before the 1996 Edition enters into force. Additionally, 1996 Edition include transitional arrangements in the following cases which were not considered in the 1985 Edition:

- (a) Package designs which do not require Competent Authority approval,
- (b) Special Form Radioactive Material designs, and
- (c) Package designs containing fissile material and transported by air.

Both the 1985 and 1996 Editions require multilateral approval for package designs approved under older versions of the Regulations. Paragraph 713 of the 1985 Edition establishes that designs approved under the 1967 Edition shall be subject to multilateral approval at the time the 1985 Edition entered into force, and paragraph 714 requires that designs approved under

Table 2

TRANSITIONAL ARRANGEMENTS' PROVISIONS				DATES AND STANDING PERIODS															
Edition	Para.	Designed under	Requirement	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
1985 (AA'90)	713	1967 Edition	Package Design shall require Multilateral Approval(*) + (‡). Changes in Package Design which would significantly and detrimentally affect safety shall be required to meet 1985 Edition in full + (‡).																
		1973 & 1973 AA Editions	Package Design shall require Multilateral Approval(*) + Packaging Serial Number. Changes in Package Design which would significantly and detrimentally affect safety shall be required to meet 1985 Edition in full. Construction of Packagings shall be required to meet 1985 Edit. in full.																
1996	816	1973 & 1973 AA Editions	Package Design shall require Multilateral Approval(*) + (‡) + QA (p. 310) + Activity Limits and Material Restrictions (Sec. IV) + Packages containing Fissile Material transported by Air (p. 680). Changes in Package Design which would significantly and detrimentally affect safety shall require to meet 1996 Edition in full (‡).																
		1985 & 1985 AA Editions	QA (p. 310) + Activity Limits and Material Restrictions (Sec. IV) + Packages containing Fissile Material transported by Air (p. 680). QA (p. 310) + Activity Limits and Material Restrictions (Sec. IV) + Packages containing Fissile Material transported by Air (p. 680) + Package Designs shall require Multilateral Approval. Changes in Package Design which would significantly and detrimentally affect safety shall require to meet 1996 Edition in full. Manufacture of Packagings shall meet 1996 Edition in full.																
	817	1985 & 1985 AA Editions	QA (p. 310) + Activity Limits and Material Restrictions (Sec. IV) + Packages containing Fissile Material transported by Air (p. 680) + Package Designs shall require Multilateral Approval. Changes in Package Design which would significantly and detrimentally affect safety shall require to meet 1996 Edition in full. Manufacture of Packagings shall meet 1996 Edition in full.																
		1985 & 1985 AA Editions	Excepted, Industrial and Type A Packages are required to meet QA (p. 310) + Activity Limits and Material Restrictions (Sec. IV). Changes in Package Design which would significantly and detrimentally affect safety shall meet 1996 Edition in full. Manufacture of Packagings and/or Packages Prepared for Transport shall meet 1996 Edition in full.																
818	73, 73 AA 85, 85 AA Editions	Special Form Radioactive Material shall meet QA Programme (p. 310). Manufacture of Special Form Radioactive Material shall meet 1996 Edition in full.																	

(*) Multilateral Approval may be by Validation of the original certificate issued by the Competent Authority of the country of origin of the design or shipment.

(‡) No new construction of such packagings shall be permitted to commence. A serial number shall be assigned to and marked on the outside of each packaging.

the 1973 Edition shall be subject to multilateral approval after 31 December 1992. In the same sense, paragraph 816 of the 1996 Edition requires that designs approved under the 1973 Edition shall be subject to multilateral approval at the time the 1996 Edition entered into force, and paragraph 817 requires that designs approved under the 1985 Edition shall be subject to multilateral approval after 31 December 2003. Table 2 summarises the dates and standing periods.

The 1985 Edition establishes that no new construction of packagings according to a design approved under the 1967 Edition shall be permitted. The same requirement is established by the 1996 Edition for package designs approved under the 1973 Edition. Additionally, the 1985 Edition requires that package designs approved under the 1973 Edition, for which construction begins after 31 December 1995, shall meet all the requirements of the edition in force. The same requirement is included in the 1996 Edition for package designs approved under the 1985 Edition, for which the construction begins after 31 December 2006. These requirements have as objective to gradually withdraw old designs from operation in a way to cause a minimum economic and technical impact allowing a smooth transition.

It is also interesting to infer two implicit requirements arising from transitional arrangements provided by the 1996 Edition of the Regulations:

- (1) After that edition enters into force, the only way to carry out transports involving package designs approved by the 1967 Edition is under Special Arrangement.
- (2) Changes approved under the 1985 Edition to package designs originally approved under previous editions, shall also require multilateral approval after 31 December 2003.

DIFFICULTIES IN FULFILING TRANSITIONAL ARRANGEMENTS

For international shipments, consignors shall obtain multilateral approval from the Competent Authorities of the countries through or into which the shipment is made, through a validation process which could be by either the endorsement on the original certificates or the issuance of a separate document. In the later case, the appropriate Competent Authority shall issue a new Approval Certificate to which must assign its own identification mark—paragraphs 730 (1985 Edition) and 834 (1996 Edition).

The criteria applied by the Competent Authorities of different countries to carry out such validation are not uniform and depends on several factors. Depending on the criteria of each Competent Authority, consignors and applicants must comply with strong or weak additional provisions as well as submit a substantial technical studies or few formal documents. Therefore, it is easy to infer that consignors and applicants will face many kind of difficulties for obtaining Multilateral Approval Certificates.

As a first instance, the two following situations produce a big difference in the level of difficulty faced by a consignor trying to carry out an international shipment with a packaging designed, manufactured and approved under older editions of the Regulations: (i) the designer, the manufacturer, the licensee and the Competent Authority which approved the original design are from the same country as the consignor or; (ii) they are from different countries. Of course, the level of fluidity in the interaction between the parts involved are quite different in both cases.

In either case the first action to be performed by the consignor seems to be to ask the licensee to update the approval of the package design. The first step for the licensee seems to be to evaluate if the package design could satisfy the new or modified requirements of the Regulations in force and, if it is the case, to apply to the corresponding Competent Authority. If this is not the case, a multilateral approval application to the Competent Authorities involved will be the only option.

Practical difficulties appear, as for example:

- (a) The designer, manufacturer or licensee do not exist any more. In such case is quite difficult for the consignor to comply with any regulatory requirement and consequently to apply either for the approval under the 1985 Edition of the Regulations or for a multilateral approval. Therefore, the only option seems to be to apply for a shipment under special arrangement.
- (b) The design is approved according the 1985 Edition but its serial number was not included in the current approval certificate. In this case, as the 1985 Edition requires that all the specimens manufactured according an approved design shall be covered by the approval certificate, the consignor will have other kind of difficulties to demonstrate compliance of such specimen with the 1985 Edition. This kind of situations are mainly produced when the specimen is used in a country different from the one of the origin of the design, and of course its solution may be much more complicated. That is because it is really difficult for the Competent Authority which issued the original certificate to make arrangement to know the actual condition of the packaging. However, there are some evidence which seems to indicate that the situations of non-inclusion of a serial number in an approval certificate were not only due to technical reasons but to commercial ones.

It is evident that multilateral approvals usually have associated a significant level of difficulty which implies the investment of economic and human resources to solve it.

Since August 1996 the validation process in Argentina requires that the consignor or applicant must submit for analysis: a copy of the original Approval Certificate, descriptive drawings and at least a summary of the Safety Analysis Report of the package design, a certification of the application of a Quality Assurance Programme, as well as the Manuals or Procedures for Operation, Inspection & Maintenance and Emergency. These requirements were established by the National Regulatory Authority (ARN in Spanish) after a carefully analysis which indicated that they were the minimum and reasonable ones. However, Argentine users of foreign designs who applied to the ARN for a Multilateral Approval, in most cases had serious problems (or in extreme cases were unable to) to obtain from the original designer an appropriate summary of the Safety Analysis Report of the package design, a certification of compliance with a QA Programme as well as updated Manuals or Procedures of Operation and Inspection & Maintenance as they are referenced in the in-force original Approval Certificate. Consequently, the ARN is forced to require to the consignor or applicant the use of an equivalent package design approved according the 1985 Edition (As amended 1990) of the Regulations or, if that is no possible, to carry out the shipment under a special arrangement. That option is often not the best solution for a shipment that can be made with an approved design and the provisions associated to a special arrangement many times have a significant economic impact on the consignor.

CONCLUSIONS

In order to facilitate the life of the applicants the following suggestions are made:

- (1) The transport-related community should invest more effort in improving future transitional arrangements' provisions. In that sense, it would be necessary that such provisions include, in addition to the pertinent dates and standing periods, pragmatic rules or advice to their comprehensive understanding and appropriate implementation. That could assure better harmonisation among Competent Authorities when different cases are analysed.
- (2) As far as possible the Competent Authorities should adopt uniform criteria for the validation processes: clear requirements, exchange of views on particular cases and personal contacts would help to harmonise the actions of Competent Authorities.
- (3) Competent Authorities, as well as users, should speed up the processes and studies needed to issue Approval Certificates under the provisions of the 1985 Edition (As Amended 1990) of the Regulations for designs approved under previous editions or, if that is not possible, to gradually qualify such designs only for a shipment under special arrangement.
- (4) Taking into account the experience gained during the implementation of the 1985 Edition (As Amended 1990) and in order to facilitate the commercial relationships between countries it is strongly recommended that, as far as possible, the international community as well as international transport organisations agree on the same target date to enter into force the 1996 Edition of the Regulations, for example not later than 1 January 2001.
- (5) A joint effort between the IAEA Transport Unit, TRANSACC, Member States and International Transport Organisations would seem to be the only and proper way to reach the necessary agreements related to the points above.

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