

# STABILITY OF REGULATIONS VERSUS CONFUSION

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## ABSTRACT

The stability of Regulations is essential to avoid confusion among their users: the competent authorities and transport operators. Consequently, any changes to the Regulations should be duly justified.

Modifications of Regulations are positive if they are really needed. Periodic review/revision cycles are necessary, since they provide opportunities to introduce changes, improving safety as soon as possible or adequately adapting the requirements to reality.

Changes in IAEA TS-R-1 imply successive modifications in the UN Recommendations (Orange book), international Regulations such as ADR (including their different language versions) and national Regulations. Finally, the users of the Regulations will have to modify procedures and carry out training to implement the changes. Thus, any major or minor change to TS-R-1 and/or the Orange Book starts a 'chain process' of modifications requiring heavy investments in resources until the change is finally implemented; therefore, it is very important, indeed essential, that the cost/benefit balance of any modification be as positive as possible.

However, sometimes review cycles are used to introduce modifications that are not clearly justified, where the frequently minor changes involve only movements of paragraphs or simple variations of wording in order to achieve a supposed improvement in the clarity of the text or a theoretical harmonisation among regulations.

For example, the 15<sup>th</sup> edition of the Orange Book introduced many changes specifically affecting radioactive material. As a result, the ADR 2009 edition, which is binding in the European Union, introduced some 120 changes, with around 100 being exclusively changes of paragraphs or structural changes. In short, approximately 85% of the changes were not new requirements or substantial modifications. In addition, many of them involved the review of cross references.

In addition to being a source of mistakes in Regulations, this kind of processes entails important disadvantages for the users, with confusion possibly being the main problem, leading to a low degree of trust in the Regulations among the users, insecurity in their application or/and a lack of compliance.

In conclusion, the instability of Regulations as a result of frequent unjustified changes may lead to confusion and to a lack of compliance and consequently to a problem of safety in the transport of radioactive material.

## INTRODUCTION

In the past the IAEA's Regulation on the safe transport of radioactive material, currently TS-R-1, was revised over cycles of 10 years. This long review period allowed for a more gradual process of analysis of the changes that provided the users with an understanding of such changes prior to the publication of new editions of the Regulation. Furthermore, the long cycle facilitated the process of

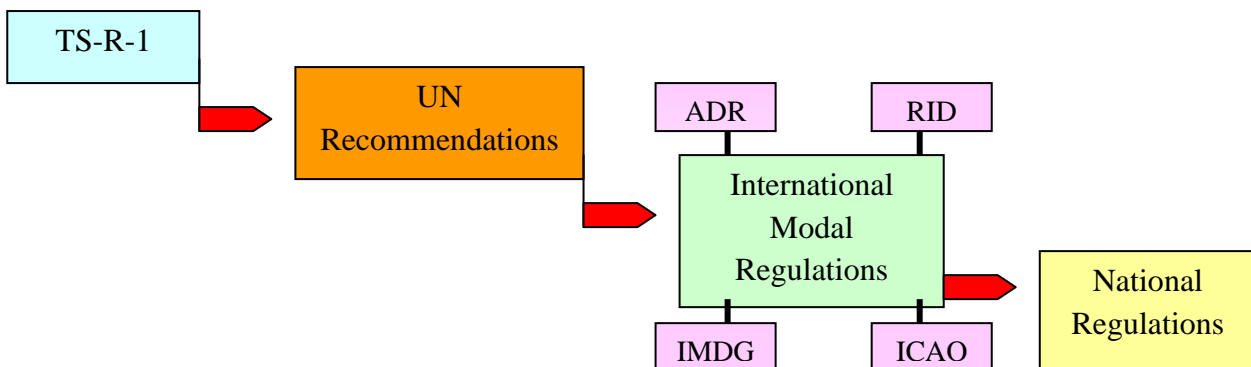
publishing new editions within the IAEA and their transfer to the national regulations of those countries that applied TS-R-1 directly. However, this type of cycle had the disadvantage of not allowing for the urgent incorporation of changes considered to be necessary to improve safety or to adapt requirements to practical reality and, especially, there was a lack of consistency with respect to the 2-year cycle of review of the Modal Regulations on the transport of dangerous goods, in which the requirements applicable to the transport of radioactive material are ultimately incorporated. This was the main reason for the IAEA deciding to change to 2-year review cycles for the Regulation, although these cycles do not necessarily imply the publication of a new edition.

Regardless of the length of the review cycle, it is essential that any change to the Regulation be fully justified, since this will save resources during the review process. Furthermore, in a short 2-year cycle it is especially important that changes to the regulations be optimised; in other words that the modifications, be they major or minor, be really necessary, since the frequent incorporation of numerous changes might make it difficult for the users to adapt to the regulatory changes and, therefore, apply them correctly.

### 1. CHANGES IN THE REQUIREMENTS RELATING TO THE TRANSPORT OF RADIOACTIVE MATERIAL, A ‘CHAIN PROCESS’

Any modification in the requirements of the IAEA’s TS-R-1 will be transferred to the world-wide or regional international Regulations on the transport of dangerous goods. Subsequently, the changes will be incorporated in the national Regulations.

Let us look at the process in Europe by way of an example. Compliance with the requirements of TS-R-1 is not obligatory in the European Union; rather these requirements must first be incorporated in the international regulations on different modes of transport that are applied in the EU: the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID), the Technical Instructions for the safe transport of dangerous goods by air (ICAO TI) and the International Maritime Dangerous Goods Code (IMDG Code). However, the requirements of TS-R-1 are not transferred directly to the ADR, RID, ICAO TI and IMDG Code. Previously, any change to TS-R-1 is incorporated in the UN Recommendations on the Transport of Dangerous Goods (UN Orange Book), which as its name indicates contains simply ‘recommendations’. Finally, in certain European countries it is necessary to make changes to the national regulations. This process of transferring regulatory changes is summarised schematically in figure 1.

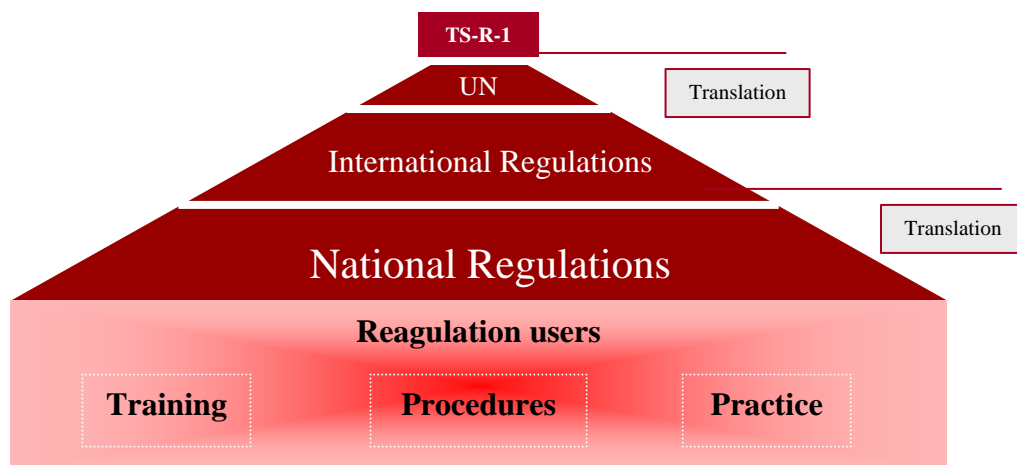


**Figure 1. Chain process of regulatory changes**

Furthermore, the process carries with it the translation of the regulation into the languages of the different countries that apply the international agreements. This implies an added difficulty and a complexity that is far from insignificant, which has occasionally proven to be an important source of errors.

Although we have focussed on the EU, other areas of the world have similar processes with the same degree of complexity.

However, the chain of change does not end with the purely regulatory process. It is very important to consider that any regulatory change must be implemented by the users of the Regulation: consignors, carriers, designers and manufacturers of packaging and, of course, the competent regulatory authorities in the different countries: nuclear and radiological protection authorities, port authorities, civil aviation authorities, the police and other authorities responsible for land transport, etc. All these users of the regulation must correctly interpret the changes occurring and train their personnel adequately in order for the changes to be suitably implemented. In addition to the training process, the regulatory changes will imply changes in the working procedures of the different organisations. The complete ‘chain process’ is summarised in figure 2.



**Figure 2. Chain process of regulatory changes and Regulation users actions**

In short, we are dealing with an enormous and complex ‘chain process’ that, regardless of whether the regulatory changes are major or minor in nature, may consume enormous quantities of resources before being finally implemented. It is easy to imagine the enormous difficulties that might be experienced by both the developers and the users of the regulations when there are frequent regulatory changes.

Consequently, it is essential for the cost/benefit balance of any regulatory modification to be as positive as possible; i.e., the advantages offered by the modification should be significant and truly assessable.

## **2. MINOR CHANGES: ENHANCED CLARITY OR A SOURCE OF CONFUSION?**

Consequently, whenever a proposal for the modification of TS-R-1 is made, then in addition to assessing the consumption of resources that it will imply as part of the IAEA review system, it is

necessary to be aware of the complex ‘chain process’ in which this change will subsequently be involved. Whenever a proposal for change is to be made, the proposer should first evaluate whether the radioactive material transport process could ‘live on’ without it and, therefore, ask himself the question: *Is this change really necessary?*

Despite the above, the review cycles have occasionally been used to introduce changes in the Regulation when the answer to the aforementioned question would very likely be negative. We should especially like to refer to the numerous minor changes (movement of paragraphs from one part of the Regulation to another or simple variations in the wording of the requirements) that have been carried out in order to achieve a supposed improvement in the clarity of the regulation or a ‘theoretical’ harmonisation between the modal regulations on the transport of dangerous goods and the TS-R-1.

In referring specifically to this issue we shall use as an example the modifications incorporated in the 2009 edition of the ADR, compliance with which is obligatory in the EU for the transport by road of radioactive material. However, this specific example might be illustrative of similar or identical problems in other international regulations.

Bearing in mind the chain process shown above, the modifications incorporated in ADR 2009 and relating directly to the transport of radioactive material arise from the modifications introduced in these requirements in the 15th edition of the UN Orange Book.

The 2009 ADR included around 120 changes only in the requirements relating specifically to the transport of radioactive material. However, a detailed analysis of these changes shows that the great majority, around 100, are merely movements of paragraphs from one position to another in the Regulation or changes that might be described as being ‘structural’, that is changes not affecting the content of the requirements and that might be considered as not being associated with safety-related aspects. In short, around 85% of the changes introduced were not new requirements or substantial modifications and furthermore many of them led in turn to the revision of numerous cross references to other paragraphs.

The original objective of these changes was supposedly to clarify the Regulation; however, the initial effect it had on users in Spain was one of great confusion. Indeed, the first impression it had on the competent authorities, consignors and transport companies not directly involved in the review process was that the number of changes in the 2009 edition of the ADR affecting the transport of radioactive material was enormous. The fact was that only 15% of these changes might be thought of as being substantial.

Consequently, an important informative effort was required to point out to these users that in fact the changes were not substantial but merely structural. The Nuclear Safety Council (CSN) drew up a table [1] identifying the changes made to the 2009 edition of the ADR with respect to the 2007 edition and underlining the objective of the change. This table may currently be found on the CSN website ([www.csn.es](http://www.csn.es)) in the section ‘Transport –Standards’. The table is included only in Spanish, but table 1 below shows a brief extract serving as an example of what is indicated here.

It is important to point out that the table drawn up by the CSN does not indicate the numerous changes to cross references that occurred at a subsidiary level as a result of the modifications introduced, and does not include changes resulting from simple modifications in the wording aimed at clarifying the text or due to changes or improvements to the Spanish translation.

**Table 1. Extract from the table published by the CSN to inform on changes to the 2009 ADR**

Subject	IAEA-2005	ADR - 2007	ADR - 2009	Objective of change in ADR
	Section IV Activity Limits			
<b>A<sub>1</sub>/A<sub>2</sub> and Exemption values</b>	401	2.2.7.7.2.1	2.2.7.2.2.1	Renumbering
“	402	2.2.7.7.2.2	2.2.7.2.2.2	Renumbering
“	403	2.2.7.7.2.3	2.2.7.2.2.3	Renumbering
“	404	2.2.7.7.2.4	2.2.7.2.2.4	Renumbering
“	405	2.2.7.7.2.5	2.2.7.2.2.5	Renumbering
“	406	2.2.7.7.2.6	2.2.7.2.2.6	Renumbering
<b>Package Content Limits</b>	407	2.2.7.7.1.1 4.1.9.1.1	2.2.7.2 4.1.9.1.1	Most of the contents of 2.2.7.7.1.1 move to the new section on <i>Classification of packages and materials</i> (2.2.7.2), which considers the limitations on the contents of packages and materials.  4.1.9.1.1. now includes numerous cross references due to the changes in position of the paragraphs that are now found in the new section 2.2.7.2.

Finally, it is interesting to indicate that these structural modifications introduced in the 15<sup>th</sup> edition of the UN Orange Book did not come from the TS-R-1 and, following an unusual inverse process, the IAEA regulations should be modified to introduce the changes. These modifications, inter alia, produced the 2009 edition of the TS-R-1.

### 3. PROBLEMS OF LOW STABILITY IN THE REGULATIONS

In general regulations of any type tend to be fairly stable. It is not normal for regulatory changes to be introduced continuously. Stability is important for the users of regulations because it allows them to gain detailed in-depth insight into the requirements and to acquire ample experience in their application. All this helps to ensure compliance with the regulatory requirements.

The specific case of the regulations governing the transport of dangerous goods, for which periods of periodic review are opened, should not imply the regulations being unstable. This ‘open doors’ system allows the requirements to be modified if this is actually necessary, but does not need to imply the ‘obligation’ to do so.

In view of what has been said in the previous sections, the problems deriving from the continuous incorporation of regulatory changes without sufficient justification are diverse and may be summarised as follows:

- Excessive consumption of the resources of the international organisations drawing up the standards, of the national regulatory authorities and of the transport operators (consignors, carriers and designers and manufacturers of packages).
- Source of errors in description of the requirements.
- Lack of understanding among the users of the regulations with sufficient promptness.

The main consequence of all these problems is confusion among the users and a low degree of trust in the regulations among the transport operators. This might lead to a lower degree of compliance with the regulatory requirements and ultimately to safety-related shortcomings in the transport of radioactive material.

In short, STABILITY in the regulations prevents CONFUSION and as a result favours SAFETY.

Talking of stability does not mean considering the regulations to be unmovable, but simply that the changes incorporated should be as few as possible, only those that are really necessary, such that the users have a set of regulations that is recognisable and that allows them to acquire experience. If it is thought that the regulations require greater clarity, the mechanism of development or explanatory Guidelines should be used, since these do not have to be as stable as regulatory requirements do.

## CONCLUSIONS

Review cycles are necessary since they provide the opportunity to introduce changes that improve safety conditions as soon as possible or to adequately adapt the requirements to the actual situation; however, modifications to the Regulations are positive only when they are really necessary.

The incorporation of numerous and frequent modifications in the IAEA’s TS-R-1 and/or in the Modal Regulation governing the transport of dangerous goods, causes instability in this Regulation and might lead to confusion among the users, a lack of understanding of the requirements, insecurity in application and a lack of trust in the regulation, this possibly leading in turn to inadequate compliance with the regulatory requirements and to shortcomings in relation to safety.

The review cycles should be looked upon as an opportunity to introduce changes that are absolutely necessary, but not as an ‘obligation’ to propose regulatory modifications. In addition to the necessary control of justifications of proposed changes in the review cycle, there should be a maximum self-regulation among those issuing the proposals, such that there be assurance of their real need before they are issued.

The regulations should be as stable as possible and explanatory Guidelines and similar documents should be used to clarify their requirements.

## REFERENCES

1. Modificaciones de requisitos específicos de la materia radiactiva (Clase 7) introducidas en el ADR-2009 respecto a la edición de 2007 y correlación con la edición 2005 del Reglamento de transporte de material radiactivo del OIEA (TS-R-1) (Modifications of requirements applying specifically to the radioactive material introduced in the ADR-2009 compared to the ADR-2007 and correlation with the TS-R-1 2005 edition). Consejo de Seguridad Nuclear. 2009.
2. European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). 2009 edition. Economic Commission for Europe, Committee on Inland Transport, United Nations.