

CLEAR REGULATIONS

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ABSTRACT

The need for clear and unambiguous regulations is essential in order to encourage their application. This paper discusses the reason for regulation and explores the difference between regulation and guidance, providing suggestions for future developments.

INTRODUCTION

The IAEA has produced Regulations related to the transport of radioactive material for around 50 years (The Regulations). The latest Edition [1] was published in 2009, and is based on several revisions of an Edition published in 1996. Changes have been incremental over this period, and significant rewrites have not taken place.

The Regulations provide a good technical basis for the safe transport of radioactive material worldwide, and as a result there is a strong justification that they should not change. Conversely, there appear to be areas of the regulations where competent authorities have different interpretations. Collaboration between these authorities leads to a greater common understanding, however the question as to whether the text of regulations could be improved so that all users might find it easier to understand.

An argument is put forward that changing the text might change the requirements, which in itself would suggest that the requirements might be subject to some interpretation.

REGULATION AND GUIDANCE

What would be the effect of having no regulation for the transport of radioactive material? Most existing carriers and consignors, if asked, would say they would continue to work in a safe manner. Regulations, if this is the case, serve the purpose of protecting safe industry from scrupulous, unsafe competition. Alternatively regulations could be seen as a permit from society for activities within boundaries.

In either case the reason for regulation is clearly not to assist people in doing “right” but to prevent people doing “wrong”. This then results in questions as to the purpose of guidance to the regulations. Is this to assist people not to do “wrong”, is it to assist regulators in identifying “wrong” or perhaps it is to assist people to do “right”. If the text seems to “assist” rather than compel or prohibit this is an indication that it is guidance. This needs to be examined when considering requirements, and conversely associated guidance material needs to be considered to ensure guidance does not include requirements.

CONTRIBUTION TO AMBIGUITY

Because the individual paragraphs in the regulations have been developed over many years by many different people there is obviously the scope for different styles to be inserted at different times. Some potential issues are set out here.

Shall, shall not, shall be and may – the benefits of a simple consistent structure

Should regulations tell you what to do or what not to do? There are different legal systems in the world and these will doubtless influence the views of individuals. It can be difficult to write regulations that can be applied equally in all legal systems in the world. However, in some states it is possible to do anything you wish unless legislation of some kind prohibits you. In these states it will be essential that any regulations produced should include a prohibition on unsafe transport as a minimum. In the regulations such a prohibition can be found in paragraph 310:

“310. *Consignments* for which conformity with the other provisions of these Regulations is impracticable **shall not** be transported except under *special arrangement*.”

Having placed a restriction that prohibits all transport (except as special arrangement) unless the regulations are complied with then there is scope to write the rest of the requirements as “shall” rather than “shall not”. However on examination there are different approaches with different paragraphs. Would the regulations be clearer if a consistent approach were used? Considering the additional words “may ... only if” and “may ... subject to” that are also used the answer would seem to be that consistency would be a benefit.

A good example of the different approaches can be seen in para. 423.

“423. *Radioactive material* which is ...**may be** classified under UN 2911, ... **only if**:

- (a) The *radiation level* ... **is not** greater than 0.1 mSv/h;
- (b) Each instrument or article **bears ... except**:
 - (i) Radioluminescent timepieces or devices; or
 - (ii) Consumer products **that have either ... or do not ... provided that .. that bears ...**;
- (c) .. **is ... enclosed** ... (a device ... **shall not** be ...);
- (d) The limits ... **are met** ...; and
- (e) For transport by post, the total activity ... **shall not** exceed ...”

In this case the “shall”, the requirement, is actually found in the overarching paragraph (401), and paragraph 423 is written as a permissive paragraph “may be”, with conditions “only if”. The level of conditions applied to paragraph 423 (b) (ii) results in a confusing list of negatives to the native English speaker. Examination of (d) and (e) reveals that these are similar requirements, but one is written as “limits ... are met” while the other is written as “shall not exceed”. Considering carefully the grammar of paragraph (e) the text in fact reads “may... only if ... shall not”, which is understandable, but not correct. The intent is obvious, it is “clear enough” in English, but can it be clear when translated?

In addition to the complex structure resulting from these multiple ways of expressing requirements it is also important to remember that the text will be translated into other forms, at least one of which uses “must” rather than “shall”. This causes a problem where the word “shall” is used with a meaning other than “must”. An example of this can be found in paragraph 420 (b) “where the *package* shall be used” does not mean “where the *package* must be used”.

Other requirements are very long and incorporate multiple “shall” requirements. An example of this is found in paragraph 509.

“509. If it is evident that a *package* is damaged or leaking, or if it is suspected that the *package* may have leaked or been damaged, access to the *package* shall be restricted and a qualified person shall, as soon as possible, assess the extent of *contamination* and the resultant *radiation level* of the *package*. The scope of the assessment shall include the *package*, the *conveyance*, the adjacent loading and unloading areas, and, if necessary, all other material which has been carried in the *conveyance*. When necessary, additional steps for the protection of persons, property and the environment, in accordance with provisions established by the relevant *competent authority*, shall be taken to overcome and minimize the consequences of such leakage or damage.”

This paragraph can be deconstructed as follows:

{If it is evident ... **or** ... if it is suspected ... }

Then (*added for clarity*)

{{access to the *package* ... **and** ... a qualified person shall, {The scope of the assessment shall ... } }

and (*added for clarity*)

When necessary, ... shall be ... }

The initial “if” clause has, in fact, two separate requirements associated with it. One requirement is related to access control and assessment, the other requirement is related to competent authority instruction.

In addition, to add to the complexity of this paragraph, one requirement states “a qualified person shall ... assess”, when in fact the requirement should most probably read “an assessment ... shall be made ... by a qualified person”.

Again the text in English can be understood, however by confusing subjects and objects, and missing words (“then” and “and”) the potential for complexity in translation leading to confusion is all too obvious.

AMBIGUITY SQUARED

These issues are not restricted to the IAEA documents. The IAEA requirements find their way into other documents, which have their own particular means of expressing requirements. This leads to an added level of ambiguity. The IAEA regulations are incorporated into the UN Orange Book [2]. Although there are efforts to achieve harmony there are different traditions in expressing requirements in the two documents.

A good example of a requirement in the UN Orange Book that would be interpreted as being problematic by a typical IAEA requirement reader is paragraph 2.0.4.2.

“2.0.4.2 Samples of the substance shall be transported in accordance with the requirements applicable to the tentative assigned proper shipping name provided:

- (a) ...
- (b) The substance ... a radioactive material
- (c) ...
- (d) ... not exceeding 2.5kg ...and
- (e)”

First the inclusion of “radioactive material” in paragraph (b) clearly identifies this paragraph as applying to radioactive material. If a fuel sample, post irradiation, is packed in a heavy shielded container it is likely to exceed the 2.5kg specified in paragraph (d). Since the subsidiary clauses ((a) to (e)) are a logical “fail” then the requirement need not be met (that is to comply with the requirements applicable).

This would not seem to be the correct interpretation of this paragraph. Rather it would seem that this paragraph is in fact placing conditions on when dangerous goods may be carried as a sample. Reading this with “IAEA eyes” leads to a problematic understanding.

If the IAEA requirements start with a complex structure, and are then inserted into the UN structure, and then translated the potential for difficulty understanding is multiplied.

A SIMPLER STRUCTURE

Complexity of the requirements for the transport of radioactive material is one issue quoted as leading to carriers not accepting radioactive material. To start with a simple structure within the IAEA requirements would seem sensible.

A simple approach to a requirement is to say **who** shall do **what**, and **when** they shall do it. This can then be supplemented by **how** they shall do it. This approach is consistent with the concept of overarching paragraphs proposed as a standard for IAEA safety requirements.

An added benefit in respect to the transport requirements is that they clearly state that they do not specify the “**who**” leading to a very simple structure indeed. Nevertheless it is often a benefit to have a typical “**who**” in mind to assist in ensuring text is clear.

This is not a simple process, and the concerns that there is a potential for changing the requirements by accident are justified.

Paragraph 509 works; it may have constructions problems, but with years of use there is a good understanding of the text. Consider changing paragraph 509, initially simply in relation to the “when”

This paragraph has two conditions at the start:

Condition 1: If it is evident that a *package* is damaged or leaking

Condition 2: If it is suspected that the *package* may have leaked or been damaged

There are three differences between these conditions.

- A trivial difference is that the first condition has damage first, the second condition has leaked first. These differences are clearly unimportant, but they can cause delays, for example with translation.

- The first condition is considering now “is”, while the second condition is considering the past “may have ... been”.
- The first condition relates to “evident” while the second condition relates to “suspected”.

The upshot of these small differences is that certain conditions are not considered, for example:

While the current requirement states:

“If it is suspected that the *package* may have leaked or been damaged”

It does not state:

“If it is suspected that the *package* is damaged or leaking”

Remembering the purpose of regulation, it is important that it allows regulators to take action particularly if an unscrupulous person were involved. These minor gaps need to be avoided in regulation, although they may be acceptable in guidance. It is clear that the language could be improved, but it is not a simple exercise to rewrite even such a simple requirement in a manner which is precise, clear and unambiguous.

The “when” condition that this is trying to capture would initially appear to be:

If at any time it is suspected or evident – that a package is leaking or has leaked – or – is damaged or has been damaged.

However the inclusion of the past tense with no limit (i.e. it includes any leakage at any time in the past, even if it has been dealt with), although this is consistent with the current text, seems wrong.

The arguments for considering only the time range of the current consignment are strong, however the potential for damage to have gone un-noticed (even though this is a regulatory infringement in itself) would make some people argue that the condition should indeed be open ended in time.

In fact in order to ensure a revised text meets the needs it becomes necessary to have a more basic statement of what the concern is and how it is being addressed. The concern would seem to be that there is a need to have a requirement to address the potential for leakage during transport.

Why is damage the only consideration here? Are there any other conditions that could be precursors to leakage that we would wish to use as triggers for action? If a package seal is missing or if there is concern that the package may not have been closed properly then these would be conditions we might wish to add.

The outcome is that, in order to rewrite the text in a clear and unambiguous manner, while still maintaining the current level of safety we would need to carry out a fundamental review of the underlying principles of the requirements.

THE DANGERS OF MAKING TEXT BETTER

The adage that “the perfect is the enemy of the good” is certainly the case with clarification of text in the IAEA requirements. The long history of the requirements has both benefit and

problem. The problem is set out above. Many paragraphs are becoming overly complicated; the ability to interpret them clearly is being reduced. The benefits are that the text has a long history and through the close working of members of the transport community a common understanding is established in many cases. Training is effective at describing the requirements.

To change the requirements based on a full analysis to produce a complete re-write that is clear and unambiguous, while still maintaining the current level of safety is an acceptable way forward. However this would be very resource intensive, and as a result there is often a proposal to make small “improvements” to requirements as part of the review process for the regulations.

The danger of these part fixes is in part that they can introduce inconsistencies. However a greater danger is that they can lead to changes in interpretation leading to differences in application of the standards by different people. The benefits of the long stable history of the requirements would be negated while not fully addressing the problems. The result can be negative in terms of safety.

THE WAY FORWARD

There are clearly arguments for change and arguments against change. It is clear that a complete re-write of the requirements is not a task that is simple. However at the same time we should not add more levels of complexity to already complex requirements. The result is that the issue needs to be addressed in several different ways.

The first step is to discourage “improvements” in text where there is no clear safety benefit. This is being implemented through adherence to a simple filter on the review process. Unless there is a safety related benefit changes to requirements will not be made during a review/revision of the requirements.

The second step is to ensure we do not add to complexity. This involves an editorial review of all of the requirements where changes are being made for safety reasons. This has been initiated with the review cycle that is currently underway, and has met with mixed response. On balance it seems that this process provides benefits and is becoming more popular. Requirements ought to be formulated in a common manner where possible, and the benefits of extending the current use of overarching requirements (that exist in several parts of TS-R-1) should not be overlooked.

A third step is the analysis of a fundamental review of the underlying principles behind the requirements. This process is due to start in 2010, and will assist in identifying the key areas of the regulations that can be improved both for understanding and safety.

The fourth step is to review the incorporation of requirements in other standards to ensure a common understanding exists for all transport of radioactive material. The process for carrying out this work is currently under discussion between IAEA and UNECE, and may be initiated as early as the end of 2010.

CONCLUSIONS

The conclusion is clearly that the current requirements set out an acceptable level of safety for the transport of radioactive material. There are obviously improvements that can be made in the text to aid clarity, however partial “improvements” can lead to a worse situation. A comprehensive review is important to ensure any changes are indeed beneficial. Phasing in

improvements as paragraphs are changed for safety reasons seems to be an acceptable way forward.

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REFERENCES

[1] Regulations for the Safe Transport of Radioactive Material, Safety Requirements No. TS-R-1, INTERNATIONAL ATOMIC ENERGY AGENCY, Vienna, 2009.

[2] Recommendations on the Transport of Dangerous Goods, Model Regulations, Sixteenth revised edition, ST/SG/AC.10/1/Rev.16, UNITED NATIONS, New York and Geneva, 2009