
The Continuous Review and Periodic Revision Process for the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Materials—A Status Report

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INTRODUCTION

The International Atomic Energy Agency's (IAEA) Regulations for the Safe Transport of Radioactive Material, Safety Series No. 6 (hereinafter denoted as "the Regulations") have developed into the model for international modal organization and individual country regulations (and other regulatory-related documentation) controlling the packaging and transportation of radioactive materials. The Regulations were initially developed in 1961 and have been periodically revised since then. Revised editions of the Regulations, accounting for developments in technology and shipping practices, were issued in 1965, 1967, 1973 (also, an amended 1973 Edition was issued in 1979), and in 1985.

In addition to Safety Series No. 6, over the years the IAEA has produced various companion documents which supplement the Regulations. These currently include Safety Series No. 7, providing explanatory information; Safety Series No. 37, providing advisory material; and Safety Series No. 80, providing schedules of requirements by specific types of radioactive material consignments.

The process of developing these documents has been performed on a cooperative basis utilizing inputs from various member states of the IAEA and from other interested international organizations. The latest comprehensive revision of the Regulations and its supportive documents was initiated in 1979, and culminated in the 1985 Edition of the Regulations. This was the first complete revision to be published since 1973 (except for the amended Edition thereto being issued in 1979). During the process which led to the 1985 Edition of the Regulations and its supportive documents, it became apparent that changes needed to be made in this process. Not addressing issues related to transportation regulations on a continuing basis created many difficulties in trying to efficiently and acceptably review and revise these documents in a short period of time.

The purpose of this paper is to outline the review/revision process

which was established, to summarize the results from that process so far (in terms of changes that have been made to the 1985 Edition through supplements thereto), and to discuss current plans for carrying on with the review/revision process with slight modifications.

THE NEW REVIEW/REVISION PROCESS

The first step in changing the regulatory revision process was taken in January 1986 when the IAEA convened an advisory group to address the Transport Regulation Revision Process. The advisory group recommended a number of significant changes to the process, and these have been carried forward by the IAEA. Fundamentally it recommended that the IAEA commit, and take steps, to initiate a continuing review process with a periodic revision to the Regulations and its supporting documents. The process included periodic invitation to member states for proposals for amendments to the Regulations or identification of problems with the Regulations, review and comment by member states on proposed changes, and consideration of the proposed changes and comments by regularly scheduled review/revision panels. Oversight of the process was to be performed by the IAEA's Standing Advisory Group on the Safe Transport of Radioactive Materials (SAGSTRAM).

In summary, the process called for a cycle of approximately ten years consisting of two main phases: an initial review phase of the latest edition of the Regulations, and a phase of revision leading up to the next comprehensively revised edition; the entire cycle from edition to edition occupying 10 years. In the first phase, review panels were to convene in years 2 and 4, each resulting in a supplement to the Yth Edition of the Regulations. This is followed in the second phase by revision panels in years 6 and 8, leading to the publication of the (Y+1)th Edition of the Regulations in year 10 [Note: it is intended that any change made in the Regulations will also be properly and adequately reflected in corresponding changes in supporting documents].

As a result of this process, it was intended that formal supplements to the regulatory documents would be issued every two years during the first phase, and full revisions would occur approximately every 10 years (or at an appropriate time as determined and recommended by SAGSTRAM). SAGSTRAM reviewed and endorsed the process in March 1986, and the process was initiated by an editorial update to the 1985 Edition of the Regulations which was issued, in 1986, as the 1986 Supplement to the 1985 Edition. The full review/revision process was put into place during the latter part of 1986. The main objectives of the new process are:

1. Review of the Regulations should be continuous -- i.e., the need for changes and/or amendments of the Regulations should be assessed on a regular and continuing basis.
2. Included in the review should be the concurrent development of all amended text and provisions for all of the regulatory documents.
3. Agreed amendments to the regulatory documents should be suitably

- reflected in these documents on a timely basis.
4. Modal organizations and Member States have available or will implement an operationally suitable process whereby changes to the Regulations will be implemented in a timely fashion for international harmony in regulating the transport of radioactive materials.

The IAEA had earlier established rules for changing the Regulations. These rules were incorporated into the current review/revision process. The rules distinguish the following three categories of amendments and thereby facilitate accomplishing objectives three and four above:

- Minor Change Essentially limited to editorial corrections; this type of change may be implemented in the Regulations under the authority of the Director General of the IAEA.

- Change of Detail Limited to changes in the text, but only in so far as to make a previously agreed (and reasonably well documented) meaning or intention of a provision more clear or more readily interpretable, or to correct minor technical errors; this type of change can only be implemented after it has been circulated to all member states for a 90-day comment period and, following this period, no member state is in opposition to the change.

- Major Change Any change that does not fall into either of the above categories; this type of change can only be made during the next comprehensive revision of the Regulations, results from close scrutiny not only by the review/revision panels but also by SAGSTRAM, from a positive recommendation by the IAEA's Director General, and approval by vote of the IAEA's Board of Governors.

In practice, Minor Changes and Changes of Detail can only be instituted if there is no change to the paragraph structuring of the Regulations. Also, any change of substance (e.g., relaxing a requirement, making a requirement more limiting, or inclusion of a new requirement) to the Regulations is relegated to the category of Major Change, and will only be implemented in a full revision of the Regulations. Similarly, any Change of Detail which does not receive 100 percent agreement by Member States during the 90-day comment period, will either be delayed pending further review and consultation or will be relegated to a Major Change. This adds stability to the process and allows minor conflicts to be addressed in a timely fashion while also allowing the basis of the regulatory structure to remain fixed over reasonable periods of time.

It should be obvious that the main intent is stability, it is not to change the Regulations more frequently than previously done. Rather -- based upon the excellent history established with the Regulations -- any need to make major changes should occur less frequently in future

than in past. This implies (and the process has been thus structured) that the time span between major revisions should be at least 10 years. It is important to maintain stability in the Regulations, and to only introduce major changes when there is an established need. Concurrently, however, provisions have been made in the process for any needed clarifications or minor corrections on a more frequent basis.

The main emphasis in the new process is instead on the review of the regulations on a continuous basis to allow major issues to be addressed with sufficient time to properly resolve them, and to provide for an orderly entry into a major revision action. Stability is not meant to imply inactivity in terms of preparing for the next major revision. Need for change must be identified, justified, studied and fully discussed -- this is a time consuming process. The new process allows for concepts, solutions and agreements to develop over time. As soon as an agreement is established, the need to cover that issue again is conceptually eliminated (in practice it may only be minimized or delayed). The important point here is that much of the necessary "ground work" will have already been done when the time to start the major revision process arrives.

It is thus essential that both proposed amendments and identified problems be dealt with as they arise. In the event that an issue is resolved, leads to a proposed change, but is delayed until the next major revision rather being included in a supplement, this does not mean that the review/revision panel, or SAGSTRAM, or the review/revision process has failed. If, for whatever reason (major technical change, major paragraph restructuring, etc.) the resolved change can not appear in a supplement, the task has nevertheless been achieved. In fact, as long as safety is not compromised, the fewer changes made by way of supplements, the better.

The Continuous Review/Periodic Revision process also includes a number of administrative rules on the manner in which a proposed amendment or an identified problem can be appropriately brought to the review/revision panels. Standardized formats are used for these inputs to ensure basic quality requirements, with the goals of avoiding interpretation and/or comprehension difficulties, and to force the submitter to properly "think through" his submittal; both of which were problems with the somewhat free-form input previously allowed.

Each two-yearly review period is initiated by an IAEA request to Member States to submit proposals for amendment and problems identified.

A Proposed Amendment must be fully developed, including a clear identification of the shortcoming or deficit in the current version of the Regulations (or its supporting documents), justification for the amendment, priority, and fully developed draft text for both the Regulations and the supportive documents.

An Identified Problem input is more limited in scope, and consists only of a description of the problem, and a discussion of how the problem might be studied and/or resolved through the IAEA, or it may only provide a pointer towards the preferred end result. For an Identified

Problem, a proposed resolution is not required. Once the deadline for submissions is past, the proposals are compiled by the IAEA Secretariat and circulated to Member States and international organizations for comment. A standard comment form has been included in the process. The intent is again to structure comments from Member States and other participating organizations where support or lack of support is shown, and additional comments can be provided.

Finally, the comments received by the IAEA by a specified date are then compiled and issued to participants of the review panel at a time suitably in advance of the meeting. The review panel will have the initial task of sorting the issues into categories (Minor, Change of Detail, Major). Issues which will result in a major change are referred to SAGSTRAM for advice on further action needed such as studies which may need to be undertaken (this allows for input from the review/revision process into the IAEA's planning activities).

To date there is only limited experience with the process. One review panel meeting was convened in June 1987 (resulting in the 1988 Supplement), and the next review panel will be convened in July 1989. However, based upon the experience to date, the general soundness of the process has already been established. The utility of submittals being in standard form is readily apparent (although not all submitters are following the rules). The concept of being able to identify problems on a continuing basis is also proving very helpful in allowing discussions on such issues to be initiated early, in allowing priorities to be established, in allocating time for discussions, and in guiding the IAEA in budgeting its activities with its limited resources.

One difficulty appears to be the interface between the review process particularly as it applies to the every two-year issuance of a supplement, and the implementation of these changes by Member States and modal organizations. Many Member States and modal organizations do not have the capability to publish their modal regulations in a timely fashion to respond to these changes. This is a continuing problem which needs to be addressed and resolved. However, despite this problem, the review process needs to be continued as outlined above to avoid the difficulties encountered in producing the 1985 Edition of the Regulations.

STATUS OF THE REVIEW PROCESS

Supplement 1986

The first Supplement to the 1985 Edition, produced by the review/revision process outlined above, was issued in 1986. In actuality, this was an additional product of the advisory group convened to define the new process. The group recommended 22 minor changes and 3 changes of detail, and 14 issues were identified which could lead to major changes in the next major revision. All of the changes were implemented through the process outlined above, and the 1986 Supplement constituted 30 pages, corresponding to those in Safety Series No. 6,

with alterations marked by vertical bars in the margin. Pages were printed on one side only to enable users to correct their copies by "cutting and pasting" if they so desired. The supporting documents were in varying stages of publication, and these changes to the Regulations were reflected in the corresponding editions of these documents as they were finalized. As far as can be judged, user reaction to Supplement 1986 was favourable.

Supplement 1988

A review panel convened in June 1987, considered 64 proposals for amendment (to both the Regulations and to the supporting documents), and also addressed 18 identified problems. Nineteen items were agreed as Changes of Detail; they affected 25 paragraphs and 3 tables in Safety Series No. 6. Nine items were agreed as Minor Changes and were implemented; they resulted in changes to the Foreword, to headings, and to 12 paragraphs and tables of Safety Series No. 6, and to complementary and independent changes to all of the supportive documents.

As a result of the ninety-day consultation on the Changes of Detail, and of informal exchanges with Member State Competent Authorities, 8 of the 19 Changes of Detail were not approved. The Changes of Detail which were not approved will be referred back to the next review panel at its next meeting in July 1989. The review panel may amend them and resubmit to the the ninety-day approval process, may identify them as Major Changes for the attention of SAGSTRAM, or may abandon them entirely.

Supplement 1988 comprised 150 pages, 60 for the Regulations, 23 for the Explanatory Material, 29 for the Advisory Material, and 35 for the Schedules. As regards the Regulations alone, the increment added in the new supplement (i.e., including the 30 pages of changes from the 1986 Supplement) just equalled the size of the previous one -- this was a very reasonable outcome. The changes to the other documents, however, produced an alarming inflation in the overall size of the supplement.

THE FUTURE OF THE REVIEW/REVISION PROCESS

SAGSTRAM 7 convened in April, 1989 and noted that the Member State proposals for change and identified problems which had been circulated by the IAEA Secretariat in preparation for the July 1989 review panel comprised 124 separate items. It must be noted that not all submittals satisfied the format requirements established for the process.

SAGSTRAM 7 indicated that the July 1989 review panel should strive to keep the number of additional Minor Changes and Changes of Detail to the 1985 Edition of the Regulations to a minimum. Changes that might be desirable but not essential should be filed for further consideration during the second phase, i.e., the revision process. SAGSTRAM 7 also noted that a number of changes proposed could have the undesirable effect of introducing further modal diversity into the regulatory

provisions and that the need for such changes should be carefully weighed against the benefits of the multi-modality in the Regulations.

When the 1990 phase of the continuous review is complete, the 1985 Edition of the Regulations will have been in circulation for five years, and will have been subjected to three reviews. By then, any real need for minor amendments should have been satisfied. From approximately 1990 onwards, until 1995, the Regulations will be in force throughout the world and will be being tested in service. Thus, from 1990 to 1995, minor amendments should be avoided.

SAGSTRAM 7 endorsed its previous recommendation to maintain the 10-year interval between major revisions of the Regulations, and recommended that the current 2-year period for reviews, during the first phase, be maintained. Following the July 1989 review panel, and the changes resulting therefrom, activities should initiate in the second phase preparing for the 1995 Edition of the Regulations. By this time, any need for "urgent" changes should have been identified. For the future, maintaining the two-year interval between review panels should help to prevent an undue build-up of work before the next major revision.

SAGSTRAM 7 received the following feedback: (1) the 1988 Supplement is not popular with users, and it was not popular with the IAEA's publishing section; (2) since revisions are not foreseen after 1990, users would like to have available a "clean" version rather than a significantly "cut and pasted" version; (3) 1990 would be a convenient time to place the Regulations in electronically typeset form; and therefore (4) a completely revised publication, in 1991, of the Regulations (rather than a supplement) is desirable. Various alternatives are also available for updating the supporting documents in 1990, and these are under consideration by the IAEA.

Finally, SAGSTRAM 7 recommended that, in future cycles of the review process, publication should proceed as follows:

- year 0: Major revision and publication of new edition of Safety Series Numbers 6, 7, 37 and 80.
- year 2: Publication of supplement to all documents
- year 4: Publication of further supplement if necessary
- years 5-6: Reprints of Safety Series Numbers 6, 7, 37 and 80 to embody all changes including the contents of the first supplement
- year 10: Major revision and publication of new edition of Safety Series Numbers 6, 7, 37 and 80.

All changes identified following year 5 would be "stored" for the next major revision.

CONCLUSION

The IAEA issued the 1985 Edition of the Regulations for the Safe Transport of Radioactive Material. It also issued supporting explanatory, advisory and schedule documents in 1986, and has followed this up with a 1986 Supplement to the Regulations and a 1988 Supplement to all of the documents. The importance of the Regulations can be illustrated by noting that approximately 40,000 copies of the 1985 Edition of the Regulations have been distributed worldwide.

The development of the follow-on supplements to the 1985 Edition of the Regulations is part of a process of "fine tuning" the 1985 Edition so that as Member States and international organizations adopt the Regulations into their regulatory documents in the 1989 to 1991 time period, the resulting products will be as accurate and acceptable as possible. The IAEA's revision cycle occurring mid-decade to mid-decade ties in with adoption at the national and international level at the end-of-decade time periods.

The IAEA's new, continuous review and revision process has now functioned successfully for most of the initial, first phase (i.e., the implementational phase) of the existence of the 1985 Edition of the Regulations and its supportive documents. The need has been identified for only minor changes to the process as initially envisioned; and these will be implemented in the second phase of the process which will lead to the planned 1995 Edition of the Regulations.

From 1990 onwards, a phase of stability of the existing provisions of the Regulations will exist, based upon the 1985 Edition of the Regulations and the supporting documents, while preparations are being made for issuing a new Revised Edition in 1995. The latter will, of course, probably not be fully implemented in national and international regulations until approximately the year 2000. On current evidence and expectations, and subject to the further guidance of SAGSTRAM, the continuous review/revision process should be fully capable of ensuring that the Regulations remain adequate and appropriate for their purpose.

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