

An Introduction to IAEA Safety Series No. 112: "Compliance Assurance for the Safe Transport of Radioactive Material"

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INTRODUCTION

This paper will endeavour to introduce and briefly explore the IAEA's Safety Series No 112 "Compliance Assurance for the Safe Transport of Radioactive Material" in order to acquaint more people in the transport world with its existence and purpose. Future influences and developments in compliance assurance will be briefly looked at.

The 1985 Edition of the IAEA's Regulations for the Safe Transport of Radioactive Material (IAEA 1990) reinforced the requirement placed on Competent Authorities to establish Compliance Assurance (CA) programmes that aim to ensure that the Regulations are actually met in practice. A number of Member States subsequently requested help from the IAEA in fulfilling this requirement. As a response, in 1994 the IAEA published as a Safety Practice, an important new Safety Series No 112 (IAEA 1994), which addressed the subject of Compliance Assurance for the Safe Transport of Radioactive Material.

Safety Series No 112 was intended to be a useful book for all Member States and their Competent Authorities. Not only should it serve as a guide or manual for the newly created or existing Competent Authority responsible for a relatively small transport industry, but also be helpful to the more well-established authorities with large or wide-ranging Radioactive Material (RAM) transport industries to regulate. The book was also intended to be helpful to users of the Regulations in their interactions with Competent Authorities. The book is not mandatory for Competent Authorities or their industries, but it nevertheless brings together many recommendations and examples of good Compliance Assurance practice which should not be ignored.

STRUCTURE of SS No 112.

The book is formatted in the usual IAEA way, with a foreword, contents information, six sections, nine annexes and references. The six sections are titled as shown below:

SECTION I	Introduction
SECTION II	Responsibilities And Functions Of The Competent Authority
SECTION III	Regulations And Guides
SECTION IV	Compliance Assurance
SECTION V	Approvals And Approval Certificates
SECTION VI	International Co-operation Between Competent Authorities Concerning Packages And Shipments On Foreign Territory.

The titles and content of the nine annexes are relatively self-explanatory and are not discussed in this paper. Each of the Sections and their contents are outlined below.

SECTION I Introduction

This Section serves to introduce the book and discusses its purpose and scope. It confirms that the book is principally aimed at assisting Competent Authorities in the development and maintenance of CA programmes as well as assisting applicants, licensees, and other organizations in their interactions with Competent Authorities. Improvements in cooperation between Competent Authorities, and the promotion of a more uniform application of the International regulations, are also suggested as resulting from study of the book.

Readers are reminded that it is generally the responsibility of consignors, carriers, and other users of the regulations to actually comply with the relevant aspects of those regulations; and the responsibility of the Competent Authority to assure compliance with the regulations. It also serves to confirm that Competent Authorities should be concerned with all users of the regulations and their RAM transport activities.

SECTION II Responsibilities And Functions Of The Competent Authority

This Section responds to its title by covering all the various aspects of the Competent Authority's responsibilities and functions. It begins, logically, with establishing the legal basis for the Competent Authority to be able to carry out its duties. It recognises that within one country there may be more than one organization responsible for the regulatory control of all aspects of RAM transport and therefore close cooperation between those organizations involved is essential if total CA is to be achieved.

Clear guidance is given confirming that Competent Authorities should be independent, and not directly involved in those activities that it has to regulate. The capabilities of the Competent Authority to independently assess and verify the technical information it receives is specifically addressed; with various options for carrying out the necessary work being introduced. It is clearly established that the final responsibility

for such technical assessment work rests with the Competent Authority. Areas of expertise for which the Competent Authority should (consistent with the size and nature of its industry) be adequately resourced are listed.

The provision of information and guidance to all concerned by the Competent Authority is mentioned, as is the training of Competent Authority personnel. Section II recognises that liaison between the Competent Authority(s) and other government agencies is essential if total and consistent compliance assurance is to be achieved.

SECTION III Regulations And Guides

This short Section establishes that each Member State will have its own legislative system of which the national regulations for the transport of RAM will be part; and these national regulations must link in with the requirements of the various International Modal Regulations or Regional agreements that may also apply. The origin and links with the various International Modal Regulations, Regional Agreements and the IAEA's transport regulations are confirmed. Examples of these international regulations and agreements are given as well as references to other IAEA documents covering IAEA Safeguards, Physical Protection of Nuclear Material, and International Cooperation following a Nuclear Accident or Radiological Emergency.

SECTION IV Compliance Assurance

In contrast to the other Sections, this is by far the longest and most detailed, covering as it does all the many facets of CA. It aims to provide specific advice to Competent Authorities irrespective of the size and complexity of the RAM transport industry it has to regulate, or the size and capability of the Competent Authority itself. It begins with establishing that there are, as a minimum, three fundamental activities that any Competent Authority must engage in if a successful CA programme is to be maintained. These fundamentals are:

- Review and assessment activities, including the issue of approval certificates,
- Inspection and enforcement, and
- Emergency response.

Under the title "**Providing for Compliance Assurance**" is a listing of six criteria that must be addressed before a CA programme can be said to be operating shown below:

- Create a legal environment in which it can function effectively;
- Organize itself so as to be independent;
- Have an appropriate size and expertise for the activities in connection with RAM transport for which it is responsible;
- Issue or revise regulations appropriate to the activities for which it is responsible;
- Develop its own CA programme and work to it;
- Produce evidence that CA is being achieved.

The book confirms that any existing Competent Authority should periodically review its response to these criteria, to ensure that its CA programme is continuing to be effective and complete. Annex 1 Figure A-1 outlines the steps that can be followed in the development of a CA programme.

"**Methods of Assurance and Inspection**" are identified both in the text and in the "Compliance Assurance Circle" which is reproduced at Annex 1, Figure A-2.

"**Issue of Competent Authority Approvals**" covers the circumstances when the issue of such approvals is required, the relationship between the applicant and Competent Authority, the application assessment by the Competent Authority, and compliance by the Competent Authority itself when issuing the appropriate approval certificate.

The actions of the Competent Authority when considering "**Special Form Radioactive Material**" (SFRM) are highlighted, with specific attention being given to the application of quality assurance, testing variations, design and working life, and verification of manufacture.

The nine paragraphs under the heading "**Packages Requiring Competent Authority Approval and Package Design Assessment**" contain much useful advice for consideration during the pre-approval and assessment phases, before actual approval is given. Pre-approval development and testing and the interaction between the applicant and the Competent Authority are discussed, novel features or the use of scale model testing, inspection of test items and facilities, correlation and traceability between test items and final packages are also all dealt with. Information concerning what should appear in any application for approval to the Competent Authority is also given directly, as well as referring to Annex II of the book. The evaluation/assessment by the Competent Authority of the application is mentioned with particular emphasis on the necessary independence of such assessments. The design review concept is introduced, a particularly useful tool when evaluating older designs approved to earlier editions of the IAEA's Regulations for approval against the requirements of the current Regulations.

"**Approval of Special Arrangements**" is also covered in this section, with the reader being reminded that the compensatory measures to be put in place should restore the confidence levels to those equivalent to transport in full compliance with the Regulations. The Competent Authority is reminded that it should not directly participate in the control activities of the Special Arrangement, so as to maintain its independence and objectivity.

The CA programme must cover all packages and RAM in transport, and not just those subject to Competent Authority approval; consequently, "**Packages Not Requiring Competent Authority Approval**" is covered by two paragraphs which outline those aspects which should nevertheless be addressed by a CA programme.

"Identification of Packages and Serial Numbers of Packagings" are important features of the Regulations which contribute to transport safety; advice is provided about assignment, maintenance and inspection of package identification and serial numbers. Packages that can bear more than one identification mark by virtue of their construction and use of interchangeable components are discussed, as are problems involving the need to register a package serial number with more than one Member State and Competent Authority.

General advice about **"Radiation Protection"** is contained in four paragraphs covering periodic assessments of radiation doses to workers and the public, optimization of radiation protection, use of appropriate monitoring and handling equipment, and the deployment of correctly qualified/trained personnel.

The recognition of other non-radiological hazards posed during the transport of RAM is briefly mentioned under the heading of **"Radioactive Materials Having Other Dangerous Properties."** Close liaison between the Competent Authority and those (other) authorities responsible for the safety and regulation of other categories of dangerous goods is positively encouraged.

Under the title of **"Quality Assurance in Support of Compliance Assurance,"** the close links between quality assurance and compliance assurance are reiterated. The Competent Authority is recommended to use the quality assurance practised by the industry to support its own CA programme. It is also clearly established that all organizations involved in "transport" must have appropriate QA arrangements. Appendix IV of the IAEA's Safety Series No 37 (IAEA 1990) is referred to for more specific guidance on the application of QA in transport. The Competent Authority is encouraged to have a meaningful audit programme that looks at the QA arrangements of those organizations transporting RAM.

The carrying out of **"Transport Inspections"** is similarly established as a cornerstone of any worthwhile CA programme, and advice is given on the objectives of inspections and some methodologies to be employed. Analysis and response (enforcement) actions are also introduced where cases of noncompliance are found.

The difference between assuring compliance and actually complying with the Regulations is clearly reaffirmed under a heading of **"Responsibilities and Actions of Consignors."** Actions (and examples) to be followed by the Competent Authority, as part of its CA programme, to confirm that the consignor (and others) is in compliance are prescribed under this heading.

A shorter but nevertheless important listing of carrier-related responsibilities and actions, together with examples of what the Competent Authority should be seeking to confirm, is featured under the title **"Actions and Operations of Carriers"**.

Seven detailed paragraphs describe those considerations and activities which, depending on the type of RAM package, packaging or SFRM, should be included in "**Design Assessments.**" Descriptions of what constitutes a design are followed by clear indications that there are varying degrees of design assessment, with the Competent Authority being responsible for conducting those relating to designs subject to their specific approval. However, the reader is also reminded that design assessments of packages not requiring Competent Authority approval should be carried out by the appropriate organization, and that the evidence of such assessments should be made available to the Competent Authority upon request. The qualities of a design assessor are discussed as well as the depth and scope of the assessment work.

"**Testing**" is an important activity, the results of which will often form part of a "safety case" or application for transport approval. The conduct and management of testing, as well as the principles to be adhered to in order to be able to confirm compliance with the regulatory test requirements, are explained.

Real safety in RAM transport rests with not only the design of a compliant package, but also the manufacture of a compliant package which reproduces the approved design. "**Control of Manufacture**" addresses the type of activity that needs to be carried out by a Competent Authority in order to confirm compliance in the manufacture of SFRM, packages and packagings.

Similarly, the design and manufacture of compliant packages must not be compromised in use by poor "**Maintenance and Servicing Arrangements.**" Problems arising from the international movement of packages, modifications to packages, maintenance periodicity, quality assurance and records are identified, and suitable CA arrangements are indicated.

"**Accident and Emergency Response**" and "**Distribution of Information**" recognise that Competent Authorities have a responsibility to plan and respond to accidents and emergencies; and should prepare and issue appropriate information to some or all users of the Regulations.

The importance of appropriate training and qualification for all people including consignor, carrier, Competent Authority personnel, etc., involved in RAM transport is established under the title of "**Training and Job Related Skills.**" The Competent Authority's CA related role in the training of its own and other persons is discussed.

Advice on "**Maintenance of Regulations and Regulatory Feedback**" is provided emphasising the need for review of international and national regulations, as well as the feedback and care which must be taken during the process.

The last facet of CA to be addressed is "**Enforcement Actions and Investigations of Incidents.**" The facility for enforcement action within a CA programme, is recommended and examples given of measures to be taken against the offender. Suitable inspection and enforcement programmes should be applied to all RAM

transport activities, not only those subject to specific Competent Authority approval. The investigation and reporting of incidents, and liaison with other involved authorities, are also confirmed as tools for improvement in CA.

SECTION V Approvals and Approval Certificates

This short section deals with approvals and approval certificates issued by Competent Authorities. It encourages early consultation between applicants and the Competent Authority, as well as the use of a formal Competent Authority produced guidance document for applicants. Advice is given on the different types of approval to be issued by the Competent Authority.

SECTION VI International Cooperation Between Competent Authorities Concerning Shipments on Foreign Territory

This key section introduces the need for international cooperation between Competent Authorities in order to support compliance assurance programmes. It draws out the point that many transport operations are international and there must be communication and confidence between involved Competent Authorities if total compliance assurance is to be achieved. Packages and shipments of foreign origin coming within the jurisdiction of a national Competent Authority or not, are defined, and suggestions for international cooperation are put forward.

ANNEXES I - IX

There are nine annexes within the book, some of which have been referred to in this paper; they are not individually mentioned in this paper due to space considerations. They are however worthy of study by the reader, and in the absence of any of the corresponding documents so exemplified, can be used as a basis for a Competent Authority to develop its own CA programme and support documentation.

The Impact of Safety Series No 112

It is difficult gauge the reception and impact of this particular document, because by the nature of the subject there is quite a numerically small direct interest readership. Apart from Competent Authorities themselves who have a direct interest in it, those others most likely to have an interest are all parts of the RAM transport industry and perhaps opposition pressure groups. While every Member State of the Agency has been advised of its publication, it is considered that many people in the RAM transport business are not aware of its existence. It is perhaps too early to assess its impact on national or international regulatory compliance, indeed its influence may not be seen for several years to come. However, it is possible to say that, in conjunction with the Regulations, it gives each of the Member States a common starting point or blueprint for achieving compliance assurance on both the national and international level.

In some quarters it is felt that the book goes too far in advising Competent Authorities what needs to be done in order to achieve full compliance assurance, and infringes on national sovereignty. But others suggest that the book fulfils a need in identifying many aspects of compliance assurance, and that it is for each Competent Authority to determine what is to be done, relative to the size and complexity of its RAM transport industry.

FUTURE DEVELOPMENTS IN COMPLIANCE ASSURANCE

Developments in compliance assurance are likely to arise from a variety of influences which could include:-

- a) Continued or increased pressure from outside the industry for more demonstrable assurance about regulatory compliance,
- b) Pressure from industry to relax the requirements on the grounds of cost and a good safety record,
- c) The occurrence of a major RAM transport accident with significant national or international repercussions.
- d) Increasing international design and manufacturing operations by multinational companies,
- e) The costs of providing the desired level of compliance assurance, and
- f) Proactive international cooperation by competent authorities, and
- g) IAEA initiatives in providing "TRANSART" (Transport Safety Advisory Review Team) support to member states.

As Competent Authorities develop and maintain their CA programmes, there should be an overall increase of confidence in compliance. This is of course assuming an actual desire on the part of individual Member States to fully support the IAEA's Regulations. Competent Authorities will have to be alert to the various industrial, economic and political pressures that will influence them, so as to be able to maintain effective and confidence-inspiring CA programmes. It is envisaged that no Competent Authority will be able to "stand still" in terms of compliance assurance, because it will soon find itself losing confidence and credibility, in the face of demands for higher standards of safety and compliance assurance.

REFERENCES

International Atomic Energy Agency, Compliance Assurance for the Safe Transport of Radioactive Material, Safety Series No 112, IAEA 1994.

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International Atomic Energy Agency, Advisory Material for the Safe Transport of Radioactive Material(1985 Edition), Third Edition(As Amended 1990), Safety Series No 37, IAEA 1990.