

COMPETENT AUTHORITY APPROVAL OF PACKAGE DESIGNS IN THE UNITED KINGDOM

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SUMMARY

Type B packages and all packages containing fissile material, as well as special form materials, special arrangements and certain shipments, are required to be approved by the Competent Authority. In the United Kingdom this function is carried out on behalf of the Secretary of State by the Radioactive Materials Transport Division of the Department of the Environment, Transport and the Regions (RMTD).

Competent Authority approval is given only after a detailed assessment of the design by the specialist staff of RMTD. There are three facets to the assessment procedure, namely engineering, criticality and radiation protection, and quality assurance. The engineering assessor ensures that the designer has demonstrated the integrity of the containment and shielding systems under the regulatory conditions. The criticality assessor examines criticality safety in detail, and together with the engineering assessor, decides whether this is maintained under regulatory conditions. The quality assurance assessor verifies that the applicant has the necessary controls in place to ensure that the design and operational requirements are met.

The applicant is responsible for making the case for approval, but the assessment is facilitated if the Competent Authority is involved with the designer at an early stage in development and during the construction of the test prototype. Central to the approval process is the regulatory test programme, which is designed and carried out by the applicant, but agreed and witnessed by representatives of RMTD. Following the test programme, the applicant submits a formal application, supported by the Design Safety Report, which provides a full analysis of the design and the test results, including the behaviour of the package under normal and accident conditions of transport, the manufacturing and maintenance procedures, quality assurance and the emergency provisions for the operation of the package.

RMTD produces a comprehensive Guide to Applications, which details the information required in all types of application for Competent Authority approval in the United Kingdom.

INTRODUCTION

In Great Britain the role of the Competent Authority is fulfilled by the Radioactive Materials Transport Division (RMTD) of the Department of the Environment, Transport and the Regions, for all radioactive materials and for all modes of transport except post. Among its duties are the assessment and approval of package designs and related transport items including special form designs, operations under special arrangement and certain shipments. Assessments are carried out independently by the Division's team of specialist engineers and scientists for all packages and other items requiring Competent Authority approval under the IAEA regulations.

THE ROLE AND STRUCTURE OF RMTD

RMTD is the lead government body in the United Kingdom responsible for the regulation of the transport of radioactive materials. Accordingly it undertakes a wide range of regulatory functions in addition to assessment. Prominent among these is its extensive contribution to the development of international recommendations and regulations, for example the IAEA's ST-1 regulations (IAEA, 1996), and the incorporation of these into international modal regulations. Within the United Kingdom, RMTD develops and enforces the regulations for transport of radioactive materials by road, and advises the appropriate bodies on regulations for other modes of transport. Enforcement powers cover all transport of radioactive materials in the public domain, in both Competent Authority approved and lesser types of packages. RMTD monitors the transport emergency response plans established by the nuclear industry, and provides specialist input to national response plans, being the lead Department for response to transport incidents involving radioactive materials. Provision of support for government transport ministers in responding to questions in parliament and from the public is a further aspect of RMTD's responsibility.

It is the assessment of packages, however, which calls most upon the specialist technical knowledge of the Division, and RMTD is structured so as to facilitate the assessment of applications against the regulatory requirements. There are four branches as follows:

- Engineering -- which examines all aspects of package construction, including mechanical integrity, containment and radiation shielding, thermal performance and the response to the regulatory performance tests.
- Criticality and Radiation Protection -- which examines criticality safety cases for fissile material shipments, and ensures that requirements for radiation protection are fulfilled.
- Quality Assurance and Compliance Assurance -- which examines the applicants' quality assurance arrangements for package design, manufacture and maintenance, and conducts audits of organisations involved in transport of radioactive materials.
- Administration -- which is responsible for the provision of information, for the distribution of assignments within the Division, and for the production and issue of certificates of approval.

THE APPROVAL PROCESS FOR PACKAGE DESIGNS

Design assessments are managed on a project basis and when an application is received, an assessor is assigned from each of the three technical branches, one of whom is the project officer, who manages and progresses the assessment and becomes the main point of contact with the applicant. The application and all supporting documentation are fully examined by the assessors for completeness and consistency, and to ensure compliance with all relevant regulatory requirements.

Although the Competent Authority does not take part in the design process, early discussions before formal application enable general advice to be given on the likely acceptability of schemes and testing procedures and on the preparation of the safety case. Provision of support for the safety case is the responsibility of the applicant, who will decide to what extent this will be based on testing, analysis or possibly comparison with similar packages. Discussion at the design stage enables the views of the Competent Authority to be obtained on the test prototype, if used, including any simplification or scaling, and simulation of the contents, or on the validity of analytical models or comparative data.

Package testing, where required, is carried out by the applicant, but witnessed by RMTD assessors to ensure that they are satisfied that the tests meet the regulatory requirements. Information on the proposed test programme should be provided to the assessor in advance to secure agreement on package preparation, drop attitudes, thermal test conditions if appropriate, recording and instrumentation systems, and the procedure for recording and assessing the test results. The regulations require that tests are carried out in the most damaging attitude, and if there is any ambiguity in this, the assessor may require the conduct of further tests to cover all possibilities. It is specified that some tests be carried out cumulatively, notably the tests for accident conditions of transport include the cumulative effects of two appropriate drops and the thermal test. Although the applicant may wish to examine the specimen between tests to obtain information on performance, any dismantling and re-assembly is allowed only at the discretion of the assessor and must not include any element of "repair".

Once the applicant has assembled all the necessary information to support the safety case, he will prepare a set of documentation in the form of a Design Safety Report. It is only when this has been completed that the applicant is in a position to submit a formal application for approval to RMTD. The information required in support of a design approval application is generally as specified in the IAEA regulations, Safety Series No. 6, (IAEA, 1990), and should be assembled according to RMTD's Guide to Applications which is described below.

In addition to the design itself, attention must be given to the maintenance and verification of the packaging integrity throughout its working life. Schedules for regular maintenance and for packing and handling must be available, the latter including instructions for closing and leak testing where necessary, and for tie-down and stowage.

The Competent Authority will look for evidence of quality assurance throughout the life of the package from design, testing and manufacture through to its use and maintenance. It is the responsibility of the applicant to ensure that his quality assurance systems are maintained and adhered to, and that the QA systems of sub-contractors and other parties involved in the

package and its transport are similarly in order. Applicants' quality assurance systems are audited periodically by RMTD's Quality Assurance Branch. It is a requirement for United Kingdom Competent Authority approval that emergency arrangements are in place. Provision of emergency cover during transport is the responsibility of the consignor and the carrier, and reference to the plan should be included where possible. Several industry-based emergency plans exist within the United Kingdom, e.g. the Nuclear Industry Road/Rail Emergency Response Plan (NIREP), (UKAEA 1996), and the Irradiated Fuel Transport Flask Emergency Plans (IFTFEP), (Magnox Electric 1996, Scottish Nuclear 1995), and where the consignor subscribes to one of these, it should be stated. Where the consignor's emergency arrangements are not known to the applicant, then the application should include a statement of the consignor's responsibilities for emergency provision. The National Arrangements for Incidents involving Radiation (NAIR), (NRPB 1995), are provided for use by the Civil Police in dealing with a wide range of radiation incidents. They should not be cited in lieu of the consignor's own provisions although they are often included in certificates against failure of the consignor's arrangements.

THE GUIDE TO APPLICATIONS

To ensure that all necessary aspects of the regulatory requirements are covered, it is helpful to both the applicant and the assessors for the safety information to be presented in a consistent form. To this end RMTD produces a Guide to Applications which sets out the requirements for all types of application in a standard format, (Department of Transport, 1992). The guide is available to all potential applicants and the applications are required to follow the format described. The guide is arranged in eight parts as follows:

Part I provides general information on preparing and submitting an application for UK Competent Authority approval. The confidentiality of information is affirmed and the system of priorities operated by RMTD is explained. Some general aspects of the IAEA Regulations are explained including the significance of unilateral and multilateral approvals, and the consignor's obligations in respect of designs not requiring Competent Authority approval. The importance of quality assurance programmes relevant to all aspects of transport is reiterated, and the obligation to facilitate access by the Competent Authority to all activities relating to package manufacture and transport operations is stated. This part of the guide includes a comprehensive list of national and international regulations, consistent with the IAEA regulations, which govern the transport of radioactive materials in the United Kingdom.

Part II of the guide gives a detailed description of the information required in an application for package design approval. All the requirements of the IAEA regulations are included, arranged to minimise repetition and grouped according to subject area. Administrative information comes first and includes details of the applicant and the type of approval sought, the modes of transport required, the date by which approval is required and the general specification of the quality assurance programmes. This is followed by the details of the radioactive contents - the radionuclides, their physical and chemical states, quantity and total activity, the heat load and any effects due to normal and accident conditions of transport. A statement of any other hazards, e.g. explosive, corrosive, pyrophoric, is required, as well as additional information relating to irradiated nuclear fuel if this is to be carried. The package is to be described next, with reference to the design, use, maintenance and inspections. A

detailed description of the packaging make-up is included here, with a list of drawings and an illustration to be included in the certificate.

The next section deals with the structural and procedural functions related to transport operations and calls first for a discussion of the handling and tie-down attachments. Specifically, for the tie-down system, the acceleration forces shown in Safety Series No. 37, (IAEA 1990), are to be applied for B(U) packages, although lower forces are allowable on B(M) packages for rail transport in the UK. Stowage provisions in relation to heat flux, and any actions required before and during shipment are included, followed by a statement of emergency instructions and any need for exclusive use conditions.

Justification of regulatory compliance is a major item in Part II and a statement is required of the methodology of design verification -- whether the design is verified by testing, comparison, calculation or reasoned argument, followed by test reports and other reference documents -- and for performance testing of the manufactured packagings. A detailed evaluation of the design follows, particularly where the applicant uses an analytical approach, covering structural integrity, radiation shielding, containment (including leak-tightness), thermal and pressure considerations and impact resistance. Finally, a detailed statement of the quality assurance programmes is required to cover both the production of the package and its maintenance and use.

Part III refers specifically to fissile material. The applicant is asked to state whether the package is excepted from the IAEA fissile requirements and under what grounds. If the package is not excepted, details of the distribution and masses of the fissile materials, moderators and neutron poisons are required, together with any irradiation history for which credit is being claimed. This information is to be followed by the detailed criticality assessment of packages, both singly and in array, and in undamaged and damaged conditions.

Part IV details the administrative requirements for Shipment Approvals.

Part V gives the procedure for an application for approval for special form radioactive material. Following administrative information, the specification of the special form includes reference standards, design principles, drawings, working life and quality assurance programmes. The description of the contents is to include the radionuclide, its maximum activity, and the nature of the radiation emitted. The heat output, temperature sensitivity, and details of any gas evolution and other dangerous properties are also specified. Finally, the demonstration of regulatory compliance is to include full details of testing and a justification of integrity throughout the working life.

Special Arrangements, **Part VI**, are issued only when a shortfall in a compliance feature is compensated for by alternative safety measures, and when no practicable alternative is available. Applicants are required to justify the reasons why the consignment cannot be made in full regulatory compliance and to demonstrate that the compensatory measures provide equivalent safety.

Part VII of the guide covers the application procedure for approval of foreign designs by validation. Validation is required in the UK for all designs requiring multilateral approval, and the following information and documentation is required:

- The approval certificate issued by the country of origin.
- The design drawings.
- A summary of test results or alternative demonstration of compliance.
- Materials specifications.
- References to relevant quality assurance programmes.
- References to emergency procedures applicable in the UK.
- For fissile materials, demonstration of criticality safety.
- For special arrangements, details of compensatory measures.
- In the case of B(M) packages, details of operational controls appropriate to transport in the UK.

All documentation should be supplied in English, and where summary and reference information is called for, the full documentation must be held for submission to the Competent Authority on request.

Part VIII Modifications to existing designs may be approved without a full re-appraisal of the safety case, and are categorised according to their effect on the safety of the package. Applicants must provide details of the modification on a sheet specified in the guide, and state, with justification, the modification category. The categories are defined in the guide and are summarised as follows:

Category A: A major change affecting safety. The request must include full supporting documentation. Approval is accompanied by a revised certificate, which must be issued before the modification is put into effect.

Category B: A significant change not primarily affecting safety. On approval the modification sheet is endorsed by the Competent Authority and returned to the applicant for attachment to the certificate. The applicant's documentation is updated within six months or prior to the next renewal of the certificate, whichever is the sooner.

Category C: A minor change to the package or the package design application, not primarily affecting safety. The modification sheet is endorsed as for Category B but the applicant's documentation is updated within one year or prior to the next renewal.

Amendment: A minor change or correction to documentation having no effect on safety.

Concession: Authorisation to use a package which deviates from specification in a way which does not affect safety and which is not intended to be introduced systematically. The applicant's documentation is to be updated within one year or prior to the next renewal.

CERTIFICATE ISSUE AND VALIDITY

Design approval certificates are normally issued for a period of three years, and renewed on application subject to further assessment if appropriate. Where significant modifications are made during the life of a certificate, that certificate is reissued, and the new issue supersedes and invalidates the earlier issue. This of course necessitates revalidation in the case of

multilaterally approved designs. It is clear that for complex designs which are subject to frequent change and used with different internal details, this could result in unacceptable delays and an excessive administrative burden. The UK Competent Authority has devised a number of ways to minimise the complexity of certificates and the need for modifications and to cope with the possible delays associated with revalidation. A summary of these is given below:

- Each variant of a design is assigned what is known as a "make-up letter". This gives a distinct design reference and an independent certificate to each assembly of an outer container, internal components and contents. Thus, for example, a hypothetical certificate number GB/7034A/B(U)-85 would refer to the outer container design number 7034 with a particular array of inner components plus contents. This certificate stands alone and may be renewed under the same design number, subject to Competent Authority scrutiny. If the applicant needs to use design 7034 with a different internal arrangement, then a separate application is made for design 7034B, without affecting the status of 7034A.
- If a change or addition of contents is required without any alteration to the internal structure of the packaging, then the certificate is normally adjusted and re-issued to accommodate the change. Where foreign validation procedures present a problem, then the Competent Authority can (and does) issue a separate certificate designated for example GB/7034A(1)/B(U)-85, with the same expiry date as the original 7034A certificate. This is a temporary designation which allows the continued use of the GB/7034A/B(U)-85 certificate alongside the new certificate. Upon expiry, the specification is updated to include the new or changed contents within the 7034A certificate, and the temporary 7034A(1) designation is discontinued.
- The modification procedure described earlier takes account of the scale of the modification. Although a major modification affecting safety necessitates a re-issue of the certificate and hence validation where appropriate, with lesser modifications, re-issue of the certificate may be deferred.
- Where a revised certificate is issued as a replacement for an earlier issue, the revised certificate may include an effective date in the future from which earlier issues cease to be valid and the new issue becomes effective. This allows time for the new issue to be validated by other competent authorities as necessary before the original issue lapses.

DISCUSSION AND CONCLUSION

The United Kingdom Competent Authority, RMTD, exists to ensure the safe transport of radioactive materials, and the approval of certain package types forms an important part of this function. RMTD encourages applicants to discuss designs throughout their development to expedite the assessment process. The Division itself is structured to reflect the several aspects of regulatory approval, and produces a detailed guide to enable applicants to present safety cases comprehensively and in a consistent format. A system for design identification and certificate issue has been developed to cover most eventualities and to provide for an optimum level of flexibility.

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