REGULATORY COMPLIANCE ASSURANCE: TWENTY-FIVE YEARS OF EXPERIENCE IN SHIPPING LARGE QUANTITY, LOW ACTIVITY RAM PRODUCTS

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Abstract

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A brief outline of one company's interpretation of the IAEA Safety Series No. 6 Regulations for Type A and excepted quantity package designs is outlined. The design route for new product packagings for these ranges and the controls introduced to ensure safety, consistency and regulatory compliance throughout the packaging range are explained. An outline of past and present regulatory problems that have been encountered is given, to demonstrate why greater conformity within the Regulations and greater understanding of the differing types of radioactive materials movements should be pursued to simplify their transport throughout the world. Statistical data on safety are given and it is confirmed that the standards of packaging for Type A and excepted quantities are more than adequate for normal conditions of transport. Regulatory bodies are encouraged to increase their existing efforts to unify their requirements and to educate the transport industry in the high level of safety inherent in the movement of radioactive consignments.

INTRODUCTION

This paper describes the experience of a UK company which has since 1948 been developing and producing medical, research and industrial products for life sciences and health care and currently exports to a large number of countries. The traffic in radioactive materials from the company has grown steadily over the years. Though estimated annual traffic for 1986-87 is around half a million packages and 1.5 billion (1.5×10^9) package kilometres, the number of incidents, all of a minor nature and involving only damage to packages with no release of material, has been maintained at about 5 per year. In the last 15 years only 2 incidents have involved the release of (small) quantities of radioactive material. For many years the design procedures used have been linked with the regulatory requirements.

All major modes of transport are used and often a consignment will involve two or more modes. Such movements are made more complex if not only the international and national requirements are at variance but also if the modal authorities introduce different interpretations of the same requirement.

Initial shipments from this company involved refined radium for luminous compounds and radium sources for clinical use. These were originally shipped only in the UK, but their movement internationally rapidly developed. In time, many other radioactive materials have been added (including labelled compounds for research and radiopharmaceuticals). To meet the needs of the various users of this wide array of materials, having a wide variation of half-lives and covering many countries throughout the world, the transport system used must be reliable and flexible. For example, for radiopharmaceuticals with relatively short half-lives, a combination of road and air transport is commonly used. Local distributors were added in high-use areas and direct deliveries by road from the UK to the European area are now common. Also, to expedite shipments, centralization of regional consignments for redistribution to local distributors is now quite common.

With a wide range of materials to be shipped (in excess of 18000) and a considerable number of packaging configurations (approaching 1000) it is necessary to ensure that each material be allocated to the correct packaging. Therefore, an approval system covering both packaging design and allocation of contents is used.

Because they are used in the health industry, the half-lives of the products are very short. It is therefore essential that these can be shipped quickly and efficiently, without the intervention of regulatory authorities, either governmental or commercial. In some cases even a few hours delay can render the product unfit for its purpose. Direct shipments by air to remote locations will always be required for certain radioactive products while others can use road, rail or sea alternatives. For this reason it is important that commercial organisations continue to maintain a high profile in the international world of radioactive transport and regulatory controls.

DESIGN CONTROLS

As in all design operations, control of standards is essential. A series of procedures has been developed to serve as guidelines to the package designer. The procedures

are structured to provide a clearly identified route through both the regulatory and company safety standards to ensure a consistency of quality throughout the packaging range. The system is centred on a work flow procedure which ensures that the basic classification questions are asked to define the type of package to be designed. The design route begins with the production of a design effort request (DER) form which clearly specifies the product and associated hazards as well as providing suggestions of existing package configurations that might be employed. The appropriate procedures dictate the steps to be taken to achieve a satisfactory design. In the case of Type A or excepted packages, these procedures take into account, among others, activity and shielding. One of the problems with operating a large international company is that packaging design facilities cannot always be centralized. Hence tests may need to be carried out at subsidiaries and the results forwarded for approval. To ensure consistency of standards throughout the group, we have developed a series of test procedures, outlining precisely how the test is to be carried out, the number and type of samples to be used and, most importantly, the criteria against which the results are to be judged in order to satisfy the regulatory and company safety standards. All tests are witnessed by two people, each of whom signs the report which is included in the approval submission.

All systems need some method of cross checking and in the present case, this is done through a so-called Stage 2 form, which is raised on receipt of the initiating DER form. The Stage 2 form provides a checklist of items to be considered and gives the approving authority an indication of how each requirement has been met.

APPROVAL SUBMISSION

Once the necessary tests have been completed the information is collated into an approval submission. It is often possible to use previous test results and an assessment rationale is included in the submission to guide the approving officer through it. The dossier also includes the DER and Stage 2 forms, engineering drawings and specific radiological requirements if applicable. The submission is reviewed firstly by the Transport Container Officer, whose main responsibility is for the engineering standards, the inherent safety of the package and compliance with regulatory requirements. It is then reviewed by the Safety Controller, whose main concern is for safety who is independent of commercial considerations. To record the acceptance of a package configuration into the company's range, a certificate

is raised and signed by both of them. The certificate outlines the package specification, its construction and refers to the applicable engineering drawings and purchase specifications. It should be made clear at this point that there is no legal requirement for such a certificate and the present paper should be interpreted as a call for such a requirement to be introduced. However, this method has been found suitable for maintaining records and providing evidence of the design and test work in the event of any queries. With the number of new products and packages being generated, some of which may only have a short life cycle, it is appropriate to limit the validity of a certificate to a determined period, currently five years. This ensures a continual review of designs. Finally, to define the package, a unique design number is allocated. To assist in the packing operation, the package is also given a unique alphanumeric code. The information is then logged into the packaging and order processing database of the computer system which allocates products to packages as orders are received.

PRODUCT ALLOCATION (EPM3)

A package that is suitable for a certain quantity of one nuclide may not be suitable for another. Checks of activity levels, surface dose rate and transport index must be carried out before a product can be approved to be shipped in a given package. This product allocation is controlled by a system of engineering package memoranda, known as EPM3's.

For every new product an EPM3 is produced and the necessary checks carried out to ensure the most appropriate package is used. The EPM3 is checked by the company health physics organisation and finally signed by the Transport Container Officer. The information is then entered into the computer system to enable the product to be allocated to a package. Without an EPM3, a product cannot be shipped. Thus an independent assessment is available for all packages and their products.

QUALITY ASSURANCE AND CONTROLS

It is all very well developing procedural and computerized systems but no system is infallible. To ensure high quality products and associated hardware, documented quality assurance inspections and audits are carried out throughout the packaging and transport operations from incoming raw materials through the entire packaging process to final despatch.

LOGISTICS

It is preferable that radioactive materials for in vivo medical diagnoses have short half-lives to ensure that after use they quickly reduce to safe levels within the body. Thus, a rapid transit time to the customer is desirable. The majority of products involved here contain only small quantities of radioactivity and fall mostly in the excepted or lower Type A ranges. Unfortunately, the transport world is relatively ignorant of such distinctions and treats all radioactive shipments with the same suspicion. The range of materials includes labelled products for bio-medical research, technetium generators and assay kits for diagnostic use and sources for use in radiotherapy or industrial processes. Radioactive consignments could therefore include various types of packaging in any number of different combinations.

To give some idea of the problems encountered on a normal shipment, we may consider a delivery to a customer in Australia. This is a reasonably complex shipping route but the basic elements are similar for the majority of movements. On leaving the warehouse, the package is transported by road (under UK regulations) to the freight forwarder's depot where it is checked and taken by road (under UK regulations) to Heathrow airport. It is then checked in for acceptance (under the internationally accepted regulations, of ICAO, the International Civil Aviation Organization, and the airline industry requirements of IATA, the International Air Transport Association). On arrival in Australia, it is taken, after customs clearance (under Australian regulations) to the subsidiary by road (under Australian regulations) and from there either by road (under the relevant state authority regulations) to its final destination or, again, by air (under both the relevant state regulations and/or the international regulations of ICAO and the requirements of IATA, both of which operate for internal domestic movements and both of which may be subject to different local derogations). Further complications may arise if part of the shipment needs to be transported by rail as several state variations may need to be considered.

Another example would be transport to customers via subsidiaries in Europe. The packages are loaded on to a lorry and driven by road (under UK regulations) to Dover, where they are accepted (not under IMO regulations as one might expect but under a special provision of the ADR/RID regulations). On arrival in France, the vehicle is then driven across the frontiers of Belgium, the Netherlands and the Federal Republic of Germany before reaching its final

destination . In each country, part of the load is removed and delivered to the local subsidiary (under the appropriate national regulations). Onward movement is then normally by road or rail (under the appropriate national regulations) to the customer in question.

PROBLEMS

It is now possible to understand the complexities involved in organizing a simple movement from the laboratories to the end user. What does it mean in practice? Here are some examples of problems that have been experienced in the past and that still exist today.

1. HAZARD WARNING LABELS. The minimum package dimension in the IAEA Regulations is 100 mm. The size of the side of the hazard warning label is also 100 mm. To fit on the package the label must be affixed with the sides parallel to the edges of the package or with the corners of the label folded around the package. According to ICAO, this second option is not permissible as "labels may not be folded". However, the IATA regulations clearly state that the labels must be fixed at 45 degrees, which means they must be folded if they are to fit a minimum dimension package. Unfortunately, it does not end there as the situation is further confused by IATA requiring that labels must not be folded.

Requests to IATA have subsequently resolved this anomaly.

2. MINIMUM DIMENSIONS. As stated above the minimum dimension for a package is 100 mm Except, of course, on a particular European railway system where the minimum standard is 150 mm! An insignificant difference perhaps, but the ramifications may be quite complex. Some products are prepacked in anticipation of incoming orders and subsequently labelled. Others are packed when the computer generated labels, based on the order processing system, are received. The packaging instructions are taken from the approved EPM3 listing, which is also held on the computer and which only recognizes product and activity, not destination. Thus, until recently, all products were packed and controlled irrespective of the customer's location. An insignificant change in one country's regulations has made it necessary to amend the entire computer system to recognize individual consignments (i.e. not overpacked or consolidated) which will at some time during their journey use the rail system.

3. REGULATION PRESENTATION. It is useful to be able to locate things quickly and efficiently and this is helped if layouts and presentation styles follow a similar format.

It is therefore disturbing to see how the various modal organizations have dealt with the incorporation of the IAEA Regulations. It is difficult enough confirming a complex regulatory issue within a single mode if one is not entirely confident with the regulations but when there are two sets for intermodal journeys, each laid out in its own way for its own way for its own historical reasons, the difficulties increase considerably. It is frustrating to receive annual copies of the ICAO and IATA regulations, each slightly different from the previous year and each approaching its interpretation of the radioactivity regulations in a slightly different way. The modal regulatory bodies are of course aware of the problem and some excellent work has been carried out by the various working parties that were set up by ICAO, ADR/RID and IMO in response to the publication of the 1985 Edition of Safety Series No. 6. However, more work could perhaps be done within the IAEA itself to reschedule the Regulations to conform more closely to the modal layouts.

4. TRADE ASSOCIATION INFLUENCE. It is only right and proper that trade organizations exist and the work carried out by IATA is excellent. However, with the appearance of the internationally recognized ICAO regulations, the presence of two sets of regulations can only lead to misunderstandings and problems for commercial organizations transporting dangerous goods. Hazard labelling is a clear example of the problems that can arise. What stand should be taken when, for example, the legal requirement is that called for in ICAO but the airline operates with the IATA manual?

5. IMPLEMENTATION DATES. During the next few years there will be changes throughout the world as each country moves towards accepting the new requirements of Safety Series No. 6. There will also be a similar operation in the modal area as each authority sets out its rules for accepting both the new and the old standards during the period of transition. Following the introduction of the 1973 Regulations, major problems were encountered with differing package requirements for certain activity levels of nuclides and one had to be constantly aware of each country's and each mode's demands. Whilst the majority of changes in the 1985 regulations are not as fundamental as those set out in 1973 and whilst moves have been made by the IAEA to involve actively all modes in determining a suitable implementation date, problems are still foreseen as a result of the timetabling of meetings of the various approving bodies. The change most likely to cause concern for this organisation is undoubtedly the introduction of the SI system of units. Not only has the rounding process for curies apparently introduced two levels for the A1 and A2 values which are likely to be reproduced directly into all the

modal regulations, but the acceptance of these units internationally is likely not only to vary from one country to another but also to depend on the rate of acceptance of the IAEA Regulations within those countries. However, efforts have been made by the IAEA to unify implementation and it can only be hoped that these efforts will be continued.

6. NATIONAL DIFFERENCES. Rather like entropy, that ever increasing quantity, the influence of national bodies on international regulations is to make them ever more restrictive or complex. With the Australian shipment described above, this influence is extended, in a way similar to that in the United States of America, to the various states. It is difficult enough to be subjected to the vagaries of the modal derogations but when Member States of the IAEA cannot maintain the fundamental philosophies of the regulations within their own national boundaries it is remarkable that one can manage to ship anything anywhere. Why, for example, do some countries insist on radioactive labels on the outside of excepted packages? Or others restrict passenger aircraft to carrying medical RAM only? Why do some have different A1 and A2 values for certain nuclides? A recent example of the problems that arise was a consignment to Brazzaville from Heathrow which was delayed because the US air cargo company was trying to apply the US regulations in the UK!

EFFECTS

As each new regulatory change is introduced it is monitored, assessed and its impact determined. A decision has to be taken on how best to achieve compliance and invariably this involves changes to the order processing computer network. The system database has been historically structured around the IAEA requirements and package allocation is controlled by several different factors including:

(a) A1 and A2 values
(b) Transport index
(c) Package type
(d) Surface dose rate

In addition, categorization and labelling (both hazard and destination) are controlled. Transport Index accumulation on aircraft is automatically monitored and local regulatory differences are built in where possible. The system is understandably complex and the simplest changes create problems.

PERFORMANCE

The most telling test of quality is the effective track record achieved, so let us just recap. The total

number of packages shipped by this organisation per year has increased steadily from 100,000 in 1970, to the current total of over 500,000 for the financial year. During the same period, the distribution network has increased. Therefore, the rise in package kilometres has increased at a significantly higher rate than package numbers. This has the effect of increasing the probability of incidents occurring. Yet, despite this increasing probability, the actual number has been maintained at about 5 minor incidents per year in recent years. This effectively means that the safety record for packages of this type when expressed as a percentage of the package kilometers covered has continually improved in recent years.

CONCLUSIONS

The problems involved in the international transport of commercial radioactive products would be greatly reduced if the quality of inspection and policing were more consistent throughout the world and apparent dual standards were avoided. However, the main conclusions from the present paper are as follows:

(a) The evidence clearly shows that the standards of packaging for Type A and excepted packages are more than adequate for normal conditions of transport.
(b) The IAEA can and should try to influence modal authorities wherever possible to ensure that other regulations are both consistent and interpretable.
(c) The modal authorities themselves can and should create closer links to help reduce intermodal problems in international movements.
(d) The national authorities should involve themselves in and carefully consider the commercial implications of introducing variations to internationally accepted regulations.
(e) A greater awareness of the high level of safety in the movement of radioactive consignments should be induced into, at the very least, the transport industry in an attempt to educate workers and prevent problems caused by a basic mistrust of these materials.
(f) Such an awareness should be actively promoted not only by the IAEA but also by commercial organizations and the modal authorities who have a responsibility to their industry to help to ensure the continuing smooth and safe distribution of radioactive materials worldwide.