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EFFICIENT PREPARATION AND MANAGEMENT OF THE PACKAGE SAFETY CASE

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ABSTRACT

In recent years the requirements for safety case management for transport packages have increased greatly. Often the Package Design Safety Report (PDSR) itself has become a massive volume, in some cases greater than that of the package itself! Software and computer developments have led to an increasing use of finite element (FE) analysis, criticality and shielding codes to support the more complex aspects of package design and engineering, and the resulting reports inevitably bulk-up the PDSR.

PDSR compilers often have a lengthy and unenviable task, but by employing a consistent and logical approach, the job can be both simplified and made more reader-friendly. Those reviewing the Safety Report within the various Competent Authorities are frequently under-resourced and overworked. An ability to stand in the assessor's shoes when writing the document is a valuable asset, and one which will benefit the review and licensing process.

The Author has been involved in the preparation of PDSRs for many years, both in-house and increasingly on behalf of third parties. This has been a process of continuous improvement, learning from experience, both self and others. New techniques and approaches have been adopted, and continue to be developed, with the objective of smoothing and hastening the compilation and approval process. Additionally, a thorough appreciation of the position and difficulties faced by the Regulators has been gained through many interface meetings and professional contact, both at domestic and International levels.

'Applicant's Guides' produced by the Regulators themselves are helpful in formatting the PDSR, but much more can be done by adopting a structured and self-questioning approach. Many of the benefits are appreciated fully as and when the document has to be revised.

Management of the PDSR is an area where opportunities for lateral thought are often overlooked in the interests of following tradition or established formats. This rarely results in an optimised approach for the assessor, and the approval process becomes more complicated as a result. Following a number of key principles will result in significant improvements to this process.

INTRODUCTION

Preparation of a new Package Design Safety Report (PDSR) is an activity often approached with trepidation, due to the expectation of a resulting tome. Alternatively it can be viewed more positively, as the logical ordering and presentation of the key information supporting the safety aspects of a new design. This paper concentrates on that positive aspect, and tries to anticipate the needs and concerns of the Regulator or other approval authority in reviewing the document.

1 Key Principles

1.1 Meeting the requirements of the applicable regulations

The transportation of nuclear materials is necessarily a highly regulated business. Clearly any safety report addressing the subject must state how the IAEA Regulations are satisfied by the design and proposed operation of the package.

1.2 Clear and concise presentation

The PDSR will not be judged on weight alone, and although the author of this paper is aware of a number of instances where safety reports have run to multiple volumes and occupied considerable shelf space, the PDSR compiler is reminded that at 'the other end' the assessor employed by the Regulator will have to read and absorb the entire contents of the report before an Approval can be contemplated. It can be expected that the longer the volume, the more regulator effort will be expended in its approval. However, careful planning, and thought given to later comprehension of the document can give considerable aid to the reader.

1.3 Effective conveyance of information

The report should be comprehensive and 'self standing' wherever possible – that is, the reader is not left to search for obscure referenced information, which causes frustration and lengthens the time for approval. The assessor should be left in no doubt as to the purpose of the document and the requirements of the Applicant.

1.4 Safety-related focus

The prime concern of the Regulators is the assurance of public safety. To that extent, they are not interested in conditions of transport which have no bearing on that, or in the commercial concerns of the Applicant. The Applicant is well advised to refrain from incorporating arguments which relate, for example, to product quality or cost of transportation. If they are referred to, the assessor will require to read and understand them, and may be looking for a safety significance which fails to exist.

1.5 Reflect the confidence and comfort of the author / Applicant

The Applicant should not submit a PDSR for review and approval by the Regulator without complete confidence in the safety of the package described. This will almost certainly lead to a protracted approval period and may ultimately lead to a failure to gain the requested approval. Needless to say, the Regulator's assessors are well experienced in probing any perceived weaknesses of safety case submitted, and would be unprofessional to accept any argument without full conviction. So – in order to avoid wasting the time of the Regulator *and* the Applicant, an internal discipline and self-examining attitude is required. This is usually manifested in the Applicant's internal management procedures for design review, and for checking and approval of not only the final document but also the individual reports and calculations which are normally found incorporated therein. This requires the Applicant to employ staff with

suitable qualifications and experience to carry out these tasks, and furthermore to be able to demonstrate that this is the case, for audit purposes.

1.6 Consistency

A large document such as a PDSR is often compiled over a considerable period of time, and maybe by more than one compiler. It is unfortunately too often the case that this introduces inconsistencies within the document; earlier statements may be contradicted at a later stage. This again is frustrating and time wasting for the assessor, and places a heavy burden on the internal approval procedure before submission. Attention to a logical, planned and structured approach can be most productive in avoiding these problems.

1.7 Logic

Incorporated calculations and reports should be straightforward to follow, and with all references available.

1.8 'Written through the eyes of the reader' – constant self-challenge

To do this most effectively requires the skill of a good technical author. It may be appropriate to consider the engagement of such a person to assist with the final preparation and formatting of the document. They may have the advantage of a certain detachment from the design process which allows a degree of independent thought to benefit the readability of the final document. In effect, an additional level of review is incorporated, as the technical author should be required to understand the essence of what they are writing. However, the PDSR compiler has often to produce the document while carrying out other functions, and this places demands to write with the anticipation of challenge – to constantly put himself in the position of the assessor, who has to understand the significance of every statement made without the benefit of maybe having been involved in the design or development of the package.

2 CHARACTERISATION OF CONTENTS

The most fundamental requirement is to understand the nature of the package contents, and to be able to clearly express this within the PDSR, e.g.

2.1 Quantity

Obviously perhaps, but still an area where confusion has been experienced – the amount of radioactive material (RAM) to be carried should be established, and clearly tabled within the PDSR. This will have a strong influence on the radioactive dose external to the package.

2.2 Identification of radioactive isotopes present, and their individual concentrations

The characterisation of the contents should provide actual or 'bounding' quantities of radioactive isotopes present, and a full inventory of those isotopes with suitable reference data. Fissile isotopes must be identified as they may dictate the category of approval. In the case of isotopes with short half-lives, a reference date for the information is also required.

2.3 Calculation of activity

Knowing the quantity of each isotope, standard reference data can be consulted to produce a table listing and summing the package activity content. Reference to the appropriate A2 values from the IAEA regulations also allows calculation of the

individual and overall A2 values for the package content. This information is fundamental to a shielding calculation, which must be incorporated within the PDSR to demonstrate compliance with the dose limits contained within the IAEA regulations.

2.4 Calculation of decay heat

Where isotopes generate significant decay heat, as is the case with spent reactor fuel, for example, reference data should be consulted for each isotope to establish the heat generated according to the activity (typically, values used are Watts per Becquerel). The characteristics of decay products may also be relevant, and all should be included and incorporated and summed in an appropriate table. The calculation of decay heat is fundamental to a general thermal calculation to demonstrate the package surface temperature remains within regulatory guidelines, and that temperatures generated are compatible with the stability of materials incorporated in the construction of the package.

2.5 Detailed pin maps, in the case of spent or fresh fuel

Shipment of reactor fuel, spent of fresh (particularly for fresh mixed oxide or 'MOX' fuels) requires a knowledge of the geometry, fissile incorporation and disposition within the fuel assembly. This is provided in the form of a 'pin map' – a diagram showing a cross-section through the fuel element illustrating the pin array, together with the fissile enrichment incorporated in each pin. This assists the calculation of average fissile enrichment, activity and heat generation characteristics of the fuel element and thereafter the package contents.

3 AVOIDANCE OF DUPLICATION OF INFORMATION

Aided by Data Table approach

4 CLEAR STATEMENT OF WHAT'S WANTED – AND WHEN

4.1 Statement of package type, and category of approval required

Sometimes overlooked is a clear statement of the package type and category of approval required, such as 'Type B(U)F' to indicate a Type B package (a consequence of the nature of the contents), a Unilateral Approval (U) category (which imposes certain requirements on the package design – for example, a pressure limit), and a fissile content (F). Together with this information should be a clear reference to the date of application (usually the date of the covering Letter of Application) and when the Approval is required. Note that Competent Authorities issue guidance or requirements concerning the length of notice they require for an approval. This is necessary to ensure efficient prioritisation and work planning on their part, and to avoid disappointment to the Applicant. There may be special circumstances where early approval is required as a priority, which must then be the subject of a negotiation with the Regulator.

5 CLARITY TO BE PARAMOUNT AND ABSOLUTE

The information contained within the PDSR should be absolutely clear and unequivocal. This is one of the reasons behind the more extensive use of Data Tables – as explained later in this text. There should be no doubt left to the assessor concerning data or its application.

5.1 Avoidance of contradictions in the text

This is frustrating for the assessor and can be largely avoided by the use of data Tables

5.2 Avoidance of repetition

At some stage the PDSR may have to be revised. Revision is much more straightforward if multiple text references to the same piece of information can be avoided. This helps to eliminate inconsistencies and contradictions in the revised document.

5.3 Careful proof reading

An activity which needs to be carried out with dedication and with a minimum of interruption if it is to achieve full effectiveness.

6 USE OF DATA TABLES

Many errors can be avoided by the incorporation of information in tabular, rather than textual form. The author has been instrumental in the application of Data Tables – each table contains all the information relevant to a particular subject. The key principles are set out below:

6.1 Distillation of key information from supporting calculations and analysis

6.2 Laid out as table with cell references (e.g. columns A,B,C etc, rows numeric)

6.3 Provides a SINGLE REFERENCE in the main PDSR to a particular piece of information

e.g. the maximum activity in the package would only be found in 'Data Table 6, C-13', and all references in the text of the PDSR would state this, not the numerical value)

6.4 Source of information to be indicated clearly

6.5 Spreadsheet master with interactivity between tables as appropriate (see diagram)

6.6 Permits scaling of parameters between different tables, e.g. a change in pressure in one table will automatically update the consequences to stress, leak-tightness, etc in other tables

6.7 Ease of revision – parameter(s) changed in Excel master automatically updates all other master tables – then pasted into the revised PDSR

6.8 Transfer of Excel tables into Word document

6.9 Procedure for management of Data Tables

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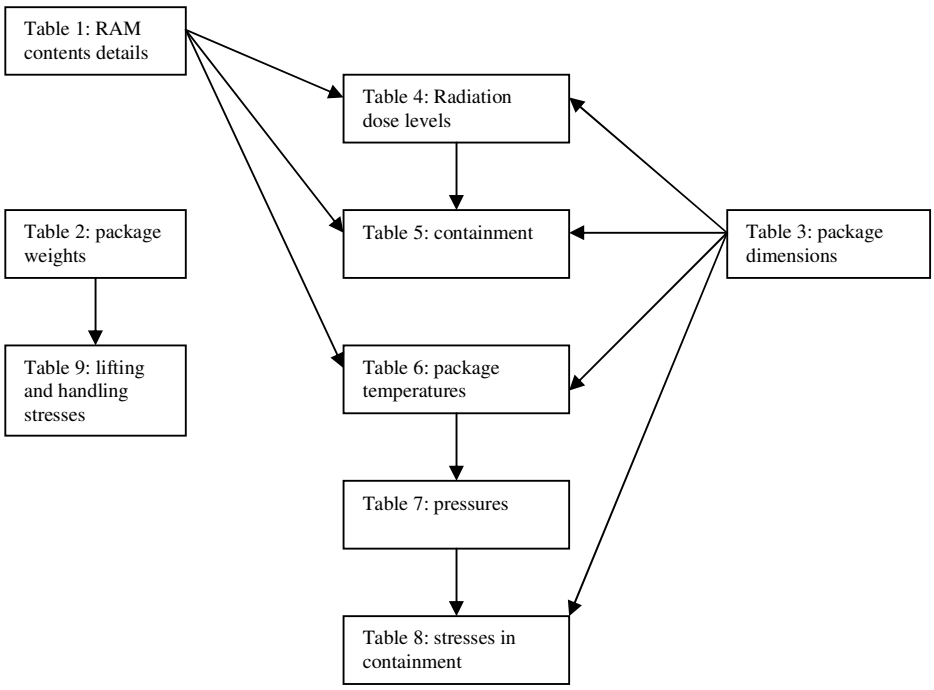

Figure 1. Example of interactive spreadsheet master

7 INCLUSION OF ANALYSIS

7.1 Usually as appendices

Any supporting analyses necessary to the understanding of the arguments in the main body of the PDSR should be included, and it is usually in the form of appendices to the main body of the text (known as the 'Part 2'). The analyses should be clearly referenced, and within themselves clear in their appropriateness to the package being described, and the conditions of the analysis.

8 ADDRESS THE RELEVANT IAEA REGULATIONS

8.1 Role of Applicant's Guide

The assessor will be most appreciative of a clear path to follow through the review of the document. This is often aided by the availability of an 'Applicant's Guide' – a document prepared by the Regulator setting out a list of questions – generally following the order of the IAEA Regulation – which the Applicant is encouraged to follow.

8.2 Developments in harmonisation of guidance to Applicants from different CAs

Moves are current with respect to a degree of harmonisation to the approach between regulators from different countries. This has become apparent recently between the UK and France, and further work is ongoing to prepare a more enveloping European Guide to Applicants. This will have benefits in achieving abetter consistency of approach, particularly with those countries whose licensing bodies have less experience of the review process. However, the demands on the Applicant in terms of producing a clear and concise document are unlikely to be relieved!

9 'STAKEHOLDER MANAGEMENT'

A robust system should be followed to ensure the involvement and 'buy-in' of all relevant parties, or 'stakeholders' in the package design. This can be expanded under the following headings:

9.1 Design review

A process must exist to ensure the acceptability of the package to those that will interface with it, and to ensure its capability meets functional requirements. To this end it is normal procedure to hold a design review at various key stages throughout the development of the package and the preparation of the PDSR. This design review should include in its attendance, as appropriate, operators, maintenance personnel, designers, analysts and commercial representatives. A design review process is normally to be expected within corporate management procedures.

9.2 Operational input

Features of the package and the way that the PDSR addresses the package operation should be specifically addressed with those who will be responsible for operating the package, both at the point of loading and at the point of receipt. Weights of package and lid, for example, are to be considered carefully in conjunction with the facilities available to handle them.

9.3 Early brief for Regulator

In some cases it may be prudent to advise the competent Authority that a new design is in progress, a new PDSR being prepared, and the timescales of the project. This enables a considerable degree of forward planning by the CA and may be much appreciated. Additionally, it may provide a platform for advice to be given (such as impending regulation changes) that could favourably influence the design or PDSR preparation. It shows also a respect for the regulator's position and a commitment to their involvement which will be beneficial and may cultivate some necessary tolerance during the review process.

9.4 Establish and agree schedule for PDSR production

This is an early requirement of the project plan. Considerable manhours are expended in preparing the PDSR, and the availability of inputs such as test programmes, design information and analysis, are needed in a coordinated and timely manner.

9.5 Interface management

To be addressed as part of the Design review process, this requires the appraisal of customers and key users, in addition to regulators and commercial interests, to ensure that the expectations of these parties are met. For example, the availability of the licensed package to suit a commercial schedule is not possible to guarantee when certain activities – in particular review of the PDSR by the Regulator – is not within the control of the Applicant. However, while it may not be in 'control', it is certainly within the influence of the Applicant.. This is a common source of friction between the commercial teams and those responsible for managing the licensing process, and attention to the recommended practices herein should ensure the review process can continue broadly within the notional schedule advised by the Regulators.

9.6 PDSR as part of larger project schedule –critical path activity?

The PDSR production will often, at some stage, fall on the critical path of the project plan. This is most likely to occur after completion of the physical test programme for

the package. Usually at this stage other analysis and much of the compilation has been completed, but a large volume of information and results may now require to be interpreted and written up. Timely availability of the test reports has been a common source of complaint in the past, and it is worth addressing the completion schedule of these with the test facility at an early stage of the contractual negotiations to avoid subsequent disappointment and embarrassment.

10 QUALITY ASSURANCE

The Applicant must be able to demonstrate adequate measures for quality assurance throughout the design, development and subsequent manufacturing processes.

10.1 Manufacture

Demonstration of adequate quality assurance processes during manufacture may require the adherence to national or international codes, and requires careful specification within the contract for manufacture. This is likely to involve the maintenance of a detailed and auditable manufacturing quality plan.

10.2 Design

Design processes also need to demonstrate a robust approach. The design review system and the early agreement of a functional specification for the package are early steps towards this. Documents generated require to be maintained within a controlled system, with established levels of authorisation and approval.

10.3 Lifetime Quality Records (LQRs) / Post-Manufacturing Dossiers (PMDs)

Many packages have their operational life terminated on an early and possibly unnecessary basis because attention to the generation and retention of production records has fallen short of that required. For example, unless records are kept to demonstrate the grade of steel used in construction, it may be impossible to demonstrate the ability of the package to withstand impact at low temperatures. It must be said that regulatory change has also a role to play in the termination of the useful life of packages, but this is outside the control of the Applicant. The production and retention in a controlled system of comprehensive manufacturing dossiers is a key requirement to ensure the maximum possible safe package life.

11 MANAGEMENT OF LICENSING

11.1 Formal contact with the Regulator: progress meetings

The Applicant and the Regulator will both normally maintain schedules of their licensing activities, on the one hand submission and approval requirement, on the other, the review timescales. Some forum for comparison of these schedules would ensure that expectations can be efficiently managed.

11.2 Appropriate timescale allowance

To be established on a notional basis and updated during the review process. Understandably the regulators will not give any firm commitment in advance as they have yet to judge the quality of the application and the degree of interaction required with the Applicant.

11.3 Prompt response to questions

To ensure the assessor can remained focused on the job in hand, (i.e. ‘your’ application!) requires a prompt response to questions. Where research is involved, a

prompt acknowledgement of the question and an indication of the timescale for the response would be much appreciated by the assessor.

11.4 Appreciation for Regulator workload

You are not the only Applicant – your application is one among many which the Regulator has to manage. Your red-hot priority must be weighed against similar prioritisation by others. Anything that can be done to maintain continuity and efficient working by the assessor during the review period is a considerable advantage.

11.5 Programme management / programme for approval

Normal and recommended practice for the Applicant is to maintain a programme for the compilation, submission and approval of the PDSR as part of a larger programme of approval work with the Competent Authority, and cross-referencing the project master schedule.

12 COMPETENT AUTHORITY APPROVAL

Until now we have focused on approval by the Competent Authority as a governmental body – but packages with a less onerous duty (low activity, no fissile content) can be categorised, for example as 'Industrial Packages (IP1, 2 or 3) and their approval may be by other approved Industry organisations. However, all the same criteria apply to preparation of the PDSR, and the requirements of the competent authority.

CONCLUSION

Effective authorship of the Package Design Safety Report can be a valuable aid to gaining timely approvals, and can make best use of both the Applicant's and the Regulator's time. Adherence to the principles of conciseness and clarity highlighted in this paper, together with the use of appropriate Data Tables, will go a long way to achieving this ideal.