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Regulatory Experience of PNRA for Certification of Type B(U) Packaging

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Abstract

Radioactive material above a certain activity limit as defined in national and international regulations is transported in specific containers called B(U) packages. According to international standards, the design of such packages shall be approved by the competent authority of the country of origin of design which shall be capable to withstand the normal and hypothetical accident conditions during transportation.

In Pakistan, the shipments of high activity radioactive material are carried out in such packages which have design approval certificates issued by the competent authorities of the countries from where the material is imported. Pakistan Nuclear Regulatory Authority (PNRA) verifies the validity of certificate and allows only those shipments which comply with the certificate requirements and conditions received along with the package. In 2016, PNRA issued design certificate for type B(U) packages for transportation of radiopharmaceuticals for the first time.

PNRA regulatory framework on safe transport of radioactive material is mainly the adoption of IAEA TS-R-1(2003). To ensure compliance with the current international requirements for transport, the IAEA Transport Regulations (SSR-6) were also taken into consideration during the authorization of the B(U) package.

This paper presents PNRA certification process for type B(U) packages mainly comprising of review assessment of safety case and inspection of qualification tests on prototype of the package.

1. Introduction

Nuclear technology is used in Pakistan in the fields of research, medicine, agriculture, industry and power for more than a half century. Since then the history of the transport of radioactive material is safe. PNRA verifies the certificates issued by the competent authority of the country of origin of design along with the shipping documents. In 2011, Pakistan started production of radiopharmaceuticals indigenously. For the purpose of safe transport of these radiopharmaceuticals, the supplier planned to design & manufacture type B(U) package and applied PNRA for certification of package having model No. PRTP-001.

2. Regulatory Framework for Safe Transport of Radioactive Material

The nuclear regulatory regime in Pakistan dates back to 1970 when Nuclear Safety and Licensing Division (NSLD) was established within PAEC. The same was upgraded to a "Directorate of Nuclear

Safety and Radiation Protection" (DNSRP) with the promulgation of Pakistan Nuclear Safety and Radiation Protection Ordinance in 1984. In 1994, Pakistan became party to the Convention on Nuclear Safety (CNS), as a result, a quasi independent Pakistan Nuclear Regulatory Board (PNRB) was established to oversee the regulatory affairs. On January 22, 2001, with the promulgation of the Ordinance-III of 2001, an independent nuclear regulatory body namely 'Pakistan Nuclear Regulatory Authority (PNRA) was established.

The safety requirements for transport of radioactive material were initially established under Pakistan Nuclear Safety & Radiation Protection (PNSRP) Regulations 1990. After the inception of PNRA, a set of comprehensive requirements "Regulations for the Safe Transport of Radioactive Material-PAK/916" was issued in 2007 which is adoption of IAEA Regulations for the Safe Transport of Radioactive Material TS-R-1, 1996 Edition (As Amended 2003). Mainly, IAEA advisory material for transport regulations TS-G-1.1 is being used as guidance document. However, other technical safety guides issued by IAEA in the area of transport safety are also being followed.

3. PNRA Process for Certification of Transport Packaging

PNRA process for certification of transport packaging is based on PAK/916 i.e. IAEA TS-R-1, 1996 Edition (As Amended 2003) which comprises of the following steps:

i. Letter of intent from the applicant
ii. Agreement on Codes & Standards
iii. Submission of Application
iv. Review of applicant submissions
v. Regulatory oversight during manufacturing of prototype
vi. Witnessing of prototype testing
vii. Review of Functional Test Report
viii. Issuance of certificate

The same process was followed for the certification of PRTP-001 The brief detail of each step is as follows:

3.1 Letter of Intent

A person or organization who intends to design and fabricate a packaging for transport of radioactive material is required to communicate its intention to PNRA. The letter of intent provides PNRA a brief scope and purpose of the activity planned by the applicant. Considering the intent, PNRA starts necessary preparations like selection of codes and standards, and allocation of necessary resources. The applicant of PRTP-001 informed PNRA about its intention to design and fabricate a type B(U) package for transport of radiopharmaceuticals.

3.2 Agreement on Codes & Standards

After the receipt of letter of intent, a list of codes and standards is agreed by PNRA with the applicant. For transport packaging approval, major codes and standards other than the regulatory requirements to be followed are IAEA TS-G-1.1 "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material", USNRC Regulatory Guides 7.9 "Standard Format and Content of Part 71

Applications for Approval of Packages for Radioactive Material", 7.10 "Establishing Quality Assurance Programs for Packaging used in Transport of Radioactive Material" and NUREG-1609 "Standard Review Plan for Transportation Packages for Radioactive Material and ASME Boiler and Pressure Vessel Code Section III, Division 3".

To identify any additional requirements important to design safety of Type B(U) packages in the latest IAEA regulations, PNRA compared the requirements for type B(U) packages in PAK/916 i.e. IAEA TS-R-1, 1996 (as amended 2003) and IAEA latest regulations i.e. SSR-6 (2012 Edition).

For the certification of PRTP-001, the above codes were agreed with the applicant and extensive discussions were held on design requirements and acceptance criteria for prototype testing. For evaluation of design performance, combination of analysis and testing on full scale package was also agreed.

3.3 Submission of Application

The application is the principal document in which an applicant provides the information and basis for the PNRA team to determine that a given package meets the requirements of PAK/916.The formal application for package certification accompanies Safety Analysis Report (SAR) and Quality Assurance Program.

The applicant of PRTP-001 submitted the application along with the required submission and proposed design description. The proposed design description of the package mainly included packaging assembly, containment assembly, cork as insulation/vibration limiter, depleted uranium shielding, inner product container and flanges. The packaging assembly is shown in Figure 1.

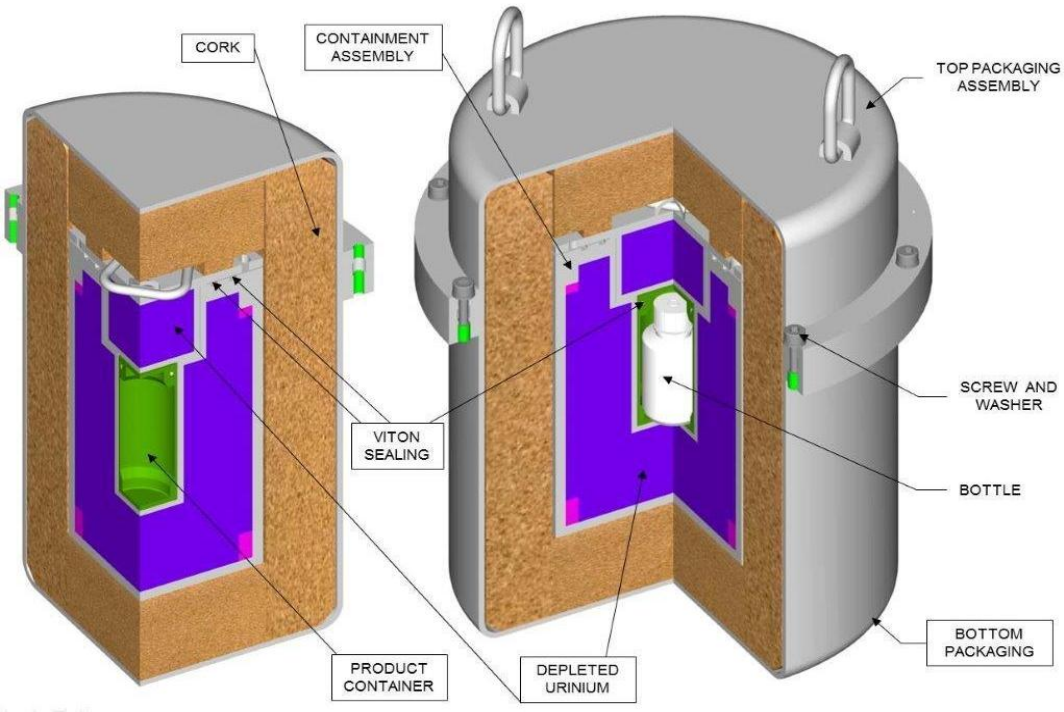

Figure 1: Schematic of PRTP-001

3.4 Review of Applicant Submissions

Upon receiving an application, PNRA performs a preliminary review to determine whether the application provides a reasonably complete information as required by applicable codes and standards. If the provided information is complete, the application is docketed by PNRA. A review team is formulated on the basis of considering required expertise. Upon completion of review, the team compiles a safety evaluation report which supports the regulatory decision.

Once the application of PRTP-001 was docketed, the review was initiated. A team of eighteen professionals with background in the areas of structure, thermal & shielding analysis, manufacturing, testing, quality assurance and regulations for transport of radioactive material was formulated.

As the review team was performing this activity for the first time so IAEA assistance was sought to built the capacity of the review team. PNRA arranged national workshops and scientific visits to testing facilities of other countries i.e. Italy, Brazil with the support of IAEA.

The review team performed review of a number of safety related aspects of package design like material properties, boundary conditions, safety margins and verification of calculations/analysis. After the completion of the review, safety evaluation report was prepared particularly reflecting recommendations for regulatory decision on package design approval.

3.5 Regulatory oversight during Manufacturing of prototype

PNRA has a well established regulatory oversight process for the manufacturers of safety class equipment and allows the fabrication of transport packaging by an organization having authorization for safety class equipment manufacturing. The manufacturer of the prototype was already licensed by PNRA to manufacture safety class equipment, therefore, only the quality plan was approved by PNRA and control points for inspection were communicated accordingly. A PNRA team performed inspections in the following major areas:

i. Material verification and identification
ii. Documents verification, fabrication specifications, Welding Procedure Specification, Welding Procedures Qualification etc.
iii. Non destructive examination of welded joints e.g. top pipe with flange, bottom pipe with flange, lifting hook etc.
iv. Dimensional inspections

3.6 Witnessing of Prototype Testing

As a step of certification process, PNRA witnesses the qualification tests performed on the prototype

For PRTP-001, a single full scale packaging was used for all prototype testing. The performance of prototype after each test was evaluated based on examination for integrity of shielding and containment system. The post test inspection techniques used were visual examination, recording through photography, dose mapping and leakage test.

For the qualification tests, the packaging was instrumented with strain gauge, thermocouples and temperature indicating strips/liquids. The prerequisites of each test were verified by the PNRA team prior to the conduction of the test. The testing was performed in series without any repair or component

replacement. This maximized the cumulative damage to the packaging during testing. The maximum dose rate at 1m from the container simulated for the maximum radioactivity content comes out to be 15.7µSv/h which is well below the limits specified in regulations (i.e. 10mSv/h at 1 m with maximum contents).

The helium leak test was initially performed as fabrication test of prototype in order to demonstrate that the containment system will provide the required level of leak tightness. The test was performed using ANSI N14.5 (Leakage test on packages for shipment) and no leakage was observed. The helium leak test was repeated once more after the completion of all tests as a post test examination for the compliance with PAK/916 (IAEA TS-R-1, 2003) and no leakage was observed at containment assembly.

3.6.1 Free Drop and Penetration Tests

The container was dropped from a height of 1.2 meter onto a flat, horizontal, non-yielding surface. The free drop test was followed by penetration test. A bar of 6 Kg was dropped perpendicularly from a height of 1m on the top surface of the container. The impact was insignificant.

3.6.2 Mechanical Drop Tests

A series of drop tests were conducted. The drop-I test was comprised of dropping the container from 9m onto an unyielding surface in the vertical orientation having an angle of about 43^0. As a result the top packaging deformed by a dent of length 102.2mm, width 42.65mm at the corner and the impact was observed near circumferential weld seam.

In addition, the designer was also asked to provide design analysis simulation report. The designer submitted the analysis for explicit dynamic simulations and after evaluation the test was accepted by PNRA.

For the drop-II test, the package was dropped vertically from the height of one meter on a steel bar with bottom down end direction. The target circular bar was fixed on steel plate surface, normal to the horizontal plan through welding, to avoid displacement while striking the container. After execution of drop-I & drop-II tests, microstructure analysis, NDT (VT & PT) of impacted surface was performed as post test examinations to assess the material damage. The stress analysis also confirmed that the mechanical stresses under accidental conditions were below the allowable limits.

3.6.3 Fire Test

The test was performed in the electrical furnace at 820ºC having internal surface area 14 times larger than the envelope area of the package to compensate the lower values of emissivity and absorptivity. Initially the furnace was heated to 900ºC to compensate the drop in temperature while placing the specimen. The container was set onto a support and was allowed to stand for a period of 30 minutes after equilibrium. On cooling of the package to ambient temperature, it was unscrewed for the post test examination and inspection. The container sustained the effects of heat. There was loss of thermal insulation at outer periphery due to the fire but parts of the containment assembly like seals, plastic bottle, and inner product container were remained intact and leak tight. It was verified through dose mapping that no degradation of the shielding due to temperature has occurred.

3.6.4 Water Immersion Test

The prototype was inspected visually prior to test and then placed inside the water filled tank. The prototype was externally subjected to hydraulic pressure at 22 psig for 8 hours in leak tight tank. The pressure was maintained to ≥22 psig for the whole 8 hrs holding time. The test results showed that all components within the containment boundary remained intact during the test.

3.7 Review of Functional Test Report

A complete report is submitted on the tests performed to demonstrate compliance with the requirements defined in the regulations for normal and accident transport conditions to the Authority for review and approval. The report mainly includes a description of the test facilities, the procedure applied in each of the tests, the results obtained, photographic records of test performed. A similar report was submitted by the applicant which was approved by the authority after satisfactory review.

3.8 Issuance of Certificate

On completion of all the steps of the regulatory process, a certificate is issued by PNRA to allow the manufacturing of the package. A certificate was issued for PRTP-001 as Type B(U) package to transport radiopharmaceuticals in non special form by all modes.

4 Challenges

The challenges faced during the certification process by PNRA were associated with the technical interpretation of regulatory requirements and methodology to meet those requirements like orientation of the package , selection of most damaging position, selection of heating source, values of emissivity and absorptivity, implementation of acceptance criteria of loss of radioactive contents and meeting the requirement of heat flux in the thermal environment. PNRA took following measures to meet these challenges:

a. Capacity building of PNRA review teams with the assistance of IAEA through organization of a national workshop on design certification and scientific visits to Italian and Brazilian testing facilities. The designer/applicant was also involved in these activities to develop understanding of regulatory requirements;
b. Utilized IAEA Forum to get expert opinion on the technical issues raised while execution and acceptance of qualification tests;
c. Bringing improvements (technical upgrades) in the testing facility after inspections; and
d. Providing continuous guidance to the applicant on regulatory matters.

5. Conclusion

The design certification of PRTP-001/B(U) transport package was first ever regulatory experience for PNRA. Technical guidance from the IAEA documents & experts and USNRC regulatory guides provided a great support to perform this activity effectively. IAEA expert support during the process facilitated PNRA team to come out of the difficult situations. As a result of rigorous process of certification, it was concluded that the design of B(U) Package complied with the international requirements & standards. The experience gained by PNRA will be used to improve the quality and effectiveness of design certification process for future applications.

6. References

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