

**International Conference on the Safe and Secure Transport of Nuclear and
Radioactive Material-2026**
Vienna, Austria

Theme: Safety and Security by Design – Regulatory and Industry Perspective

Associated Topic: Authorization (certification/validation/renewal) practices to ensure compliance with the code and standards including practices in regulation of non-approved packages.

Title: Pakistan's Experience Regarding Revalidation Experience of Type B(U) Package

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Synopsis

In Pakistan, the regulatory framework for safe transport of radioactive material (PAK/916 Rev. 1) requires designer of package for transport of radioactive materials (including Type B(U)), to obtain Design Approval Certificate (DAC) from Pakistan Nuclear Regulatory Authority (PNRA). To initiate this process, applicant must submit their case along with the necessary documentation to PNRA. The authority reviews the submissions and verifies compliance with the commitments made during manufacturing inspections (based on ASME code) and qualification testing of the prototype (based on PAK/916 Rev.1). Upon satisfactory compliance with the regulatory requirements, the PNRA issues a design approval certificate valid for a period of up to five (05) years.

If the certificate holder intends to continue using the approved package design after the expiry date and there have been no changes to the technical specifications, they must apply for revalidation to the PNRA at least six months prior to the certificate's expiry. This application undergoes evaluation by the PNRA, and if deemed necessary, verification through inspection is conducted. This synopsis outlines the PNRA's experience of evaluating application for revalidation of the already approved design, where certain issues were highlighted during this evaluation process. The licensee addressed the regulatory concerns, leading to the issuance of the design approval. The information presented in this synopsis emphasizes key focus areas regarding the issuance and revalidation of design approval certification for packages.

Pakistan Institute of Nuclear Science and Technology (PINSTECH) applied for design approval certificate for Type B(U) package with D(U) shielding from PNRA to transport radiopharmaceuticals including liquid form of Mo-99 (300 Ci), I-131 (250 Ci) and P-32 (150 Ci). The application was supported with safety analysis report and quality assurance program. The modes of transport applicable to the package were Air, Land and Sea. The packaging was granted DAC in 2016 which was revalidated in 2021, in compliance with "Regulations for the Safe Transport of Radioactive Material" PAK/916 (Rev .0) and IAEA "Regulations for safe Transport of Radioactive material" SSR-6 2012 edition. After obtaining the design approval certification the actual packages were manufactured and kept under control/storage by the

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user. Later, the applicant applied for revalidation of the said package design and submitted the documents as required by PNRA.

The submitted documents mainly outlined the details of maintenance and inspection history of the package and statement confirming that the operational and maintenance manual previously submitted to PNRA has not been changed. Furthermore, the applicant didn't propose any modification/change in already approved Safety Analysis Report, Quality Assurance Program and technical specifications. PNRA reviewed the submissions and conducted an inspection to verify the submitted information and the current physical condition of the packages after two years of storage. During the inspection some technical issues were highlighted which had contributing factors like ageing management, maintenance/handling errors and some manufacturing related issues. The applicant was required to comply with the deficiencies noted by PNRA. The detailed synopsis will describe the issues highlighted by PNRA during the revalidation process of the Type B(U) package and state approaches by which such issues can be avoided.