

The Advantages of Using Standardized Review Procedures in Certifying Type B Radioactive Material Packages

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The Advantages

- Clearly documented review processes and technical positions
- Flexibility to incorporate innovation
- Optimization of resources based on risk
- Helps ensure uniform application reviews



Current Review Process in the United States

- Standard Review Plans
- Standard Format for Package Approvals and Requests for Additional Information
- Standard Format and Content Guide
- Qualifications Journals



Current Review Process in Canada



- No application guide available; review based on IAEA paragraphs.
- Procedures developed on the review practices in effect prior to 2003 but not documented.
- Procedures assure that request for package approval, foreign or domestic, is reviewed in the same way.
- CNSC developed written procedures to assure that package approvals are consistent, clearly documented, and risk informed.



Current Review Process in Canada



- Risk based approach applied to assure that attention and resources are focused on package approvals that pose higher risk, while reducing burden for low risk categories of approvals.
- Guidelines for request for additional information and documentation of the review of an application are to be developed.



Risk based approach



- The level risk is based on the resources, the effort required to review the application and :
 - If the design has been previously approved by the CNSC,
 - The changes since the last approval, and
 - If other CA have approved the package or the changes.



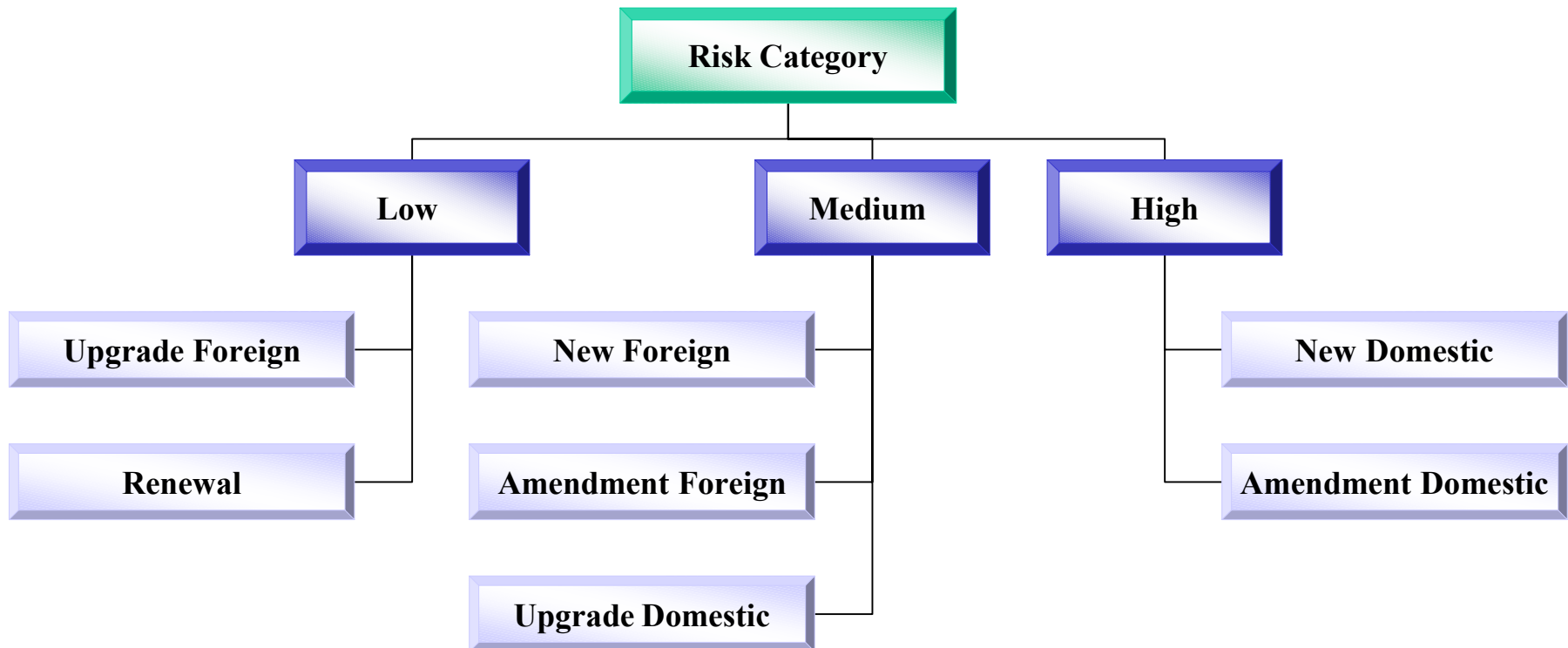
Risk based approach



- Stratified into three categories:
 - High risk: new domestic and amendment to domestic designs.
 - Medium risk: new and amendments of foreign packages, and upgrades of domestic packages approved more than fifteen years ago.
 - Low risk: renewal without changes to domestic and foreign packages and upgrades of foreign packages.



Risk based approach





Review Procedure and Process



- Review performed using criteria outlined in the procedure for the approval of certified packages.
- The procedure includes:
 - the assumptions used,
 - the boundary conditions,
 - the safety margins,
 - the material properties,
 - verification of calculations related to the safety of the package.



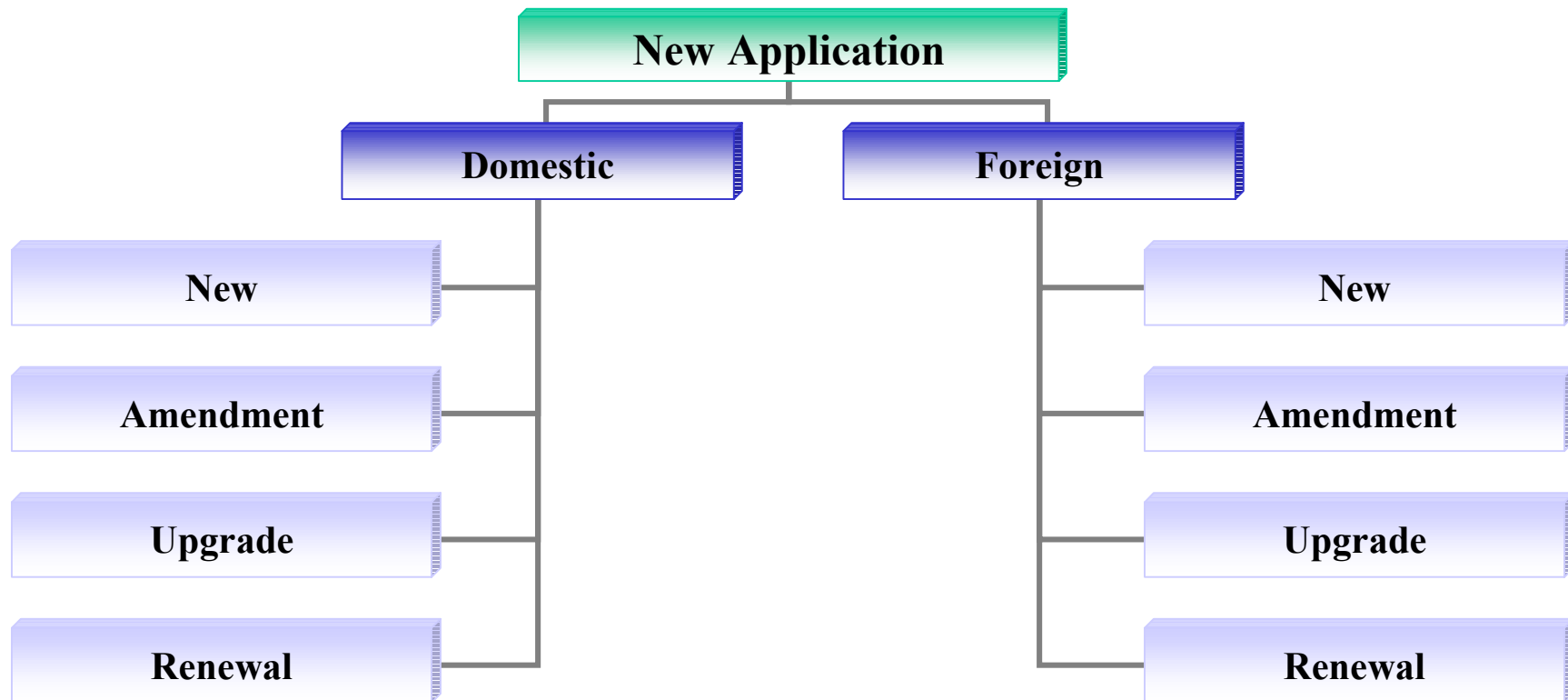
Review Procedure and Process



- Internal assessment document includes:
 - a description of the package and its contents,
 - a description of the area reviewed (structural, thermal ...),
 - a recommendation with regards to the approval of the package.
- High risk category and upgrade of domestic packages:
 - Peer review to ensure that the safety of the package has been adequately verified.

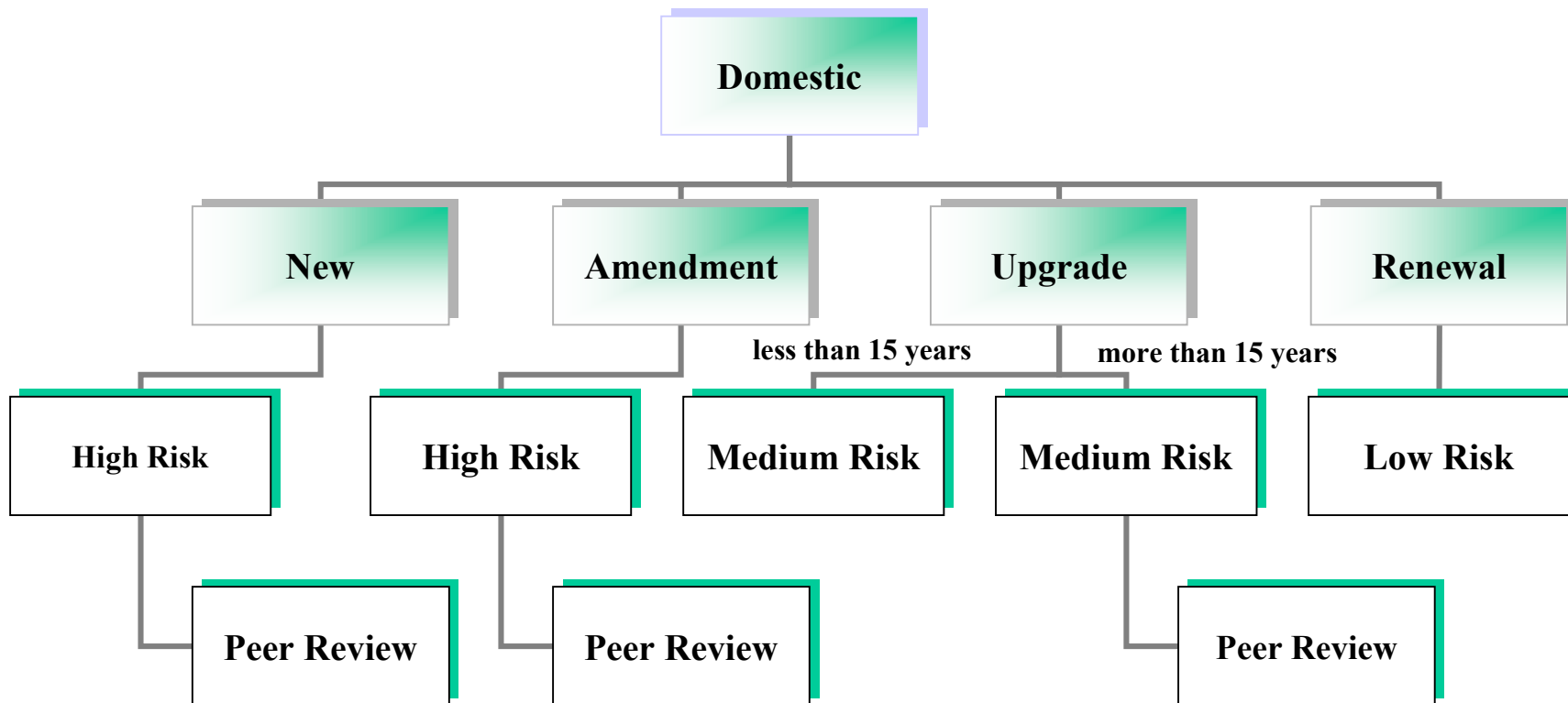


Categorization Based on Risk



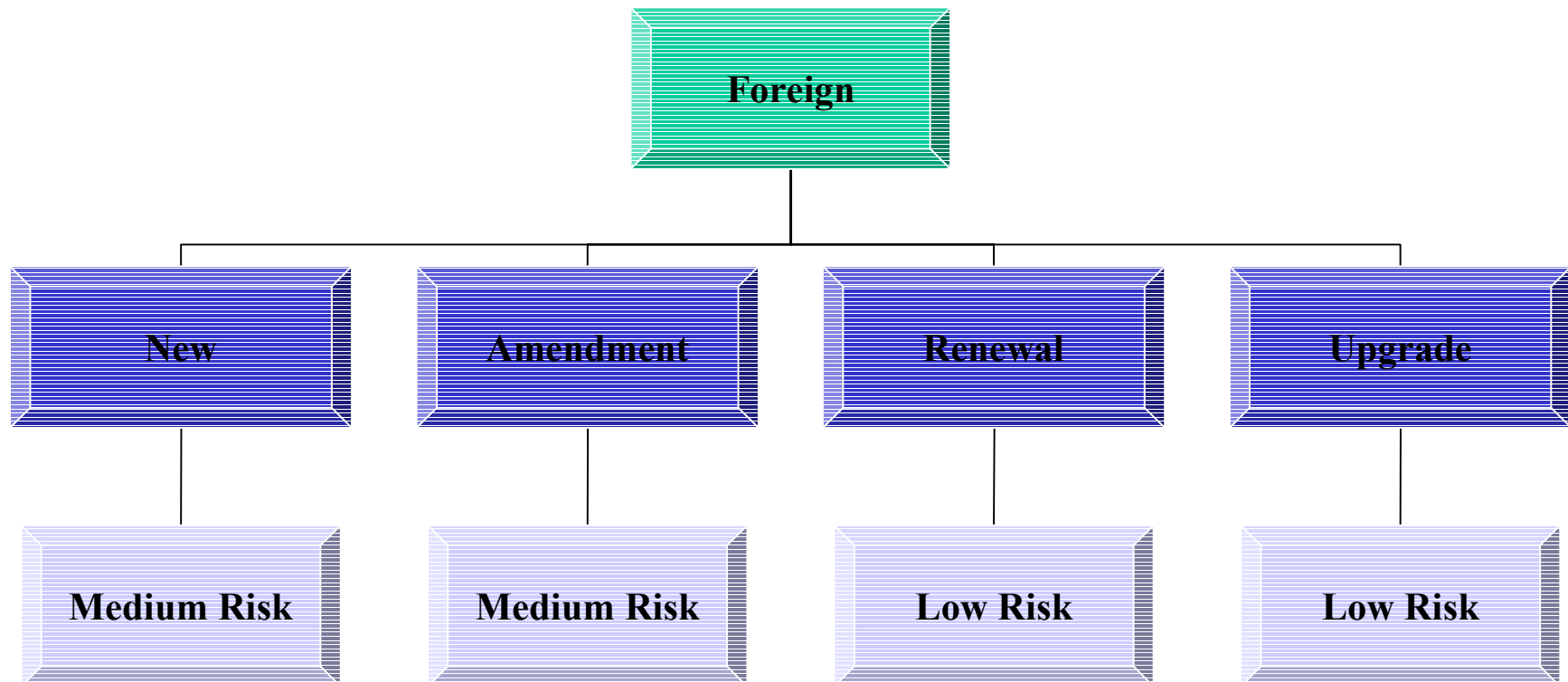


Categorization Based on Risk





Categorization Based on Risk





Format for Documenting Package Approvals and Requests for Additional Information



- No standard in place for dealing with request for additional information and to document the review of an application.
 - Request for additional information based on areas identified in the procedure for approval of certified packages.
 - Internal document describing the review of the application produce when the review is completed.



North American System

- **Unilateral Approval based on**
 - **Standard review plans or written procedures**
 - **Reviewer Qualifications**
 - **Consensus Technical Standards**