

# Experience of Licensing Type B Packages

Issue	Typical Licensing Process in Europe	NRC Licensing Process
<b>Approval System</b>	The approval system is essentially the same for all countries: the applicant submits a safety report to the Competent Authority which carries out a review, followed by a series of questions and responses, and on being satisfied that the design meets the regulator requirements issues a Certificate of Approval.	
<b>Application for Approval</b>  As national regulations are all based on IAEA Regulations for the Safe Transport of Radioactive Materials, the information required for an application for approval is essentially the same for all countries.	It is usually acceptable and useful for the applicant to meet with the regulator at an early stage to discuss key issues before the DSR is completed and application for review made.  Applicant submits a Design Safety Report (DSR)  Each country has its own guide – which vary in detail.	An early meeting between the NRC review team and the applicant to facilitate completion of the SAR is encouraged by the NRC  Applicant submits a Safety Analysis Report (SAR).  NRC system in Reg Guide 7.9 is very detailed.  Complexity is initially daunting, but in fact it helps with providing the necessary information for review.
<b>Guidance</b>	Some guidance documents are provided by national Competent Authorities.  Use of international standards is useful	The NRC has produced a range of guides as follows:  Reg Guides NUREGs Information Notices  US standards such as ANSI, ASME, ASNT are not only advised but following these standards ensures acceptance and speedy review by the NRC.
<b>Review by regulator</b>	Queuing system  Time for review can be long, it can take 1+ years for the review to start with no schedule for completion.	A schedule is set for reviews as below.
<b>Review stages</b>	Meetings between the applicant and the reviewer no really help greatly in resolving issues.	Meetings between the applicant and the reviewer no really help greatly in resolving issues.
Initial completeness check	No formal initial completeness check, but applicant may be asked for further information.  No formal review schedule agreed.	Initial completeness check  Made within 3 months with request for information expected but missing from the application.
Principal review	Regulator issues questions relating to the whole application, but this does not preclude further new questions.  Response schedule not fixed	Once a SAR is accepted as “complete” the review is normally guaranteed with issue of RAIs within 6 months.  NRC issues questions in the form of Request for Additional Information (RAIs) relating to the whole application, but this does not preclude further new questions.  Response expected within 1 month.
2 <sup>nd</sup> review	Further questions can be related to initial questions or be on new topics.	Further questions, also in the form of RAIs, normally only relate to the topics of the initial questions.  Response expected within 1 month.
Completion of reviews	Question and answer process continues. Normally this ends when the DSR and supporting documents are fully accepted (after editing as required).	In carrying out the review, the NRC uses the data in the SAR to evaluate the design against its own guides and methods and compiles a Safety Evaluation Report (SER) that records the results of the NRC review. The SER is published when the certificate is issued.  The NRC does not always require the SAR to be modified regarding evaluations that are different to that of the NRC. Changes are normally only required where the input data for the NRC review has to be revised for correctness or completeness.
<b>Certificate</b>	The certificate is issued at the completion of the review process – with the certificate being valid for 3 to 5 years.	The certificate is issued at the completion of the review process – with the certificate being valid for 3 to 5 years.
<b>Time for review</b>	Indeterminate but can be several years	The certificate is issued at the completion of the review process (which should be within 2 years).
<b>Benefits</b>	The applications can be small for simple designs and the review can be quick.	Although the NRG applicants Guide (Reg Guide 7.9) requires extensive information to be provided even for relatively simple designs, the process can be quick if all the information is provided properly.  The NRC methodology of carrying out a review of the design and compiling its own SER, rather than working to agree and approve the application is seen as a major benefit. This is particularly true when it is decided during the review process to limit the review to certain requirements (a limited contents specification). The NRC does not require the applicant to edit the SAR to take out items not being reviewed.
<b>Costs</b>	Not all regulators charge for the review process.	The NRC charges for the review process according to the hours employed.  The NRC also charges for review of the QA system of the applicant.