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NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

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MAR 2 6 1979

MEMORANDUM FOR:

Roger Boyd, Director

Division of Project Management

FROM:

C. J. Heltemes, Jr., Chief Standardization Branch, DPM

THRU:

SUBJECT:

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W. P. Gammill, Assistant Director for Standardization and Advanced Reactors,

"INTEGRATION OF NEW REQUIREMENTS INTO THE STAFF REVIEW PROCESS"

The value of having a defined date in the staff's safety review of various applications as a "cut-off" of new requuirements has often been addressed. Such a concept was specifically addressed in the Commission's August 22, 1978 policy statement on standardization as follows.

"Staff approval of a design is based on a selected regulatory requirements cut-off date, which is a date near the end of the staff's safety review, after which the staff will not impose new requirements on the design unless they are essential to safety."

Additionally, in Information Report SECY 79-8 dated January 2, 1979, H. Denton discussed this concept as follows:

"One mechanism that might add stability to the licensing process would be to establish a regulatory requirements "cut-off date" for each project in review. The establishment of a "cut-off date" would permit only those changes that are necessary to provide substantial additional changes to be implemented. All other changes (that improve safety) would be accumulated and implemented at some future date (perhaps on a yearly basis). Such a mechanism would afford the industry and the public to have some advance notice of new requirements and not require projects in review to be impacted by changes of marginal significance."

In the past, such a "cut-off date" was, in some cases, explicitly defined. In other cases, there was an implicit "cut-off date." In general, this "cut-off date" corresponded to that point in time at which the Q-2's were issued to the applicant. Essentially, however, the only matters actually "cut off" were any new regulatory requirements that were not significant to safety issued after the "cut-off date."

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These can generally be thought of the RRRC Category I matters. Any new regulatory requirements considered to be significant to safety and issued after the "cut-off date" were merely deferred to the next stage of review. These can generally be thought of as RRRC Category II and III matters. It is important to note that only the Category I matters are actually being cut off while the Category II and III matters are only being deferred.

The need to develop the "cut-off date" concept in past reviews was developed in recognition of the difficulty in finalizing designs for approval purposes in the face of continuing new regulatory requirements. This situation was further complicated by the fact that (1) regulatory guide implementation plans did not reflect RRRC decisions and staff use of regulatory guides was often still different, (2) rarely, if ever, did the regulatory guide implementation plans or the RRRC decisions specifically identify the applicability of the requirements for all of the various types of applications and, (3) there was rarely any definition as to the time frame in which the staff had to verify the acceptability of the applicant's response to requirements that were to be backfit.

Although the problems discussed above are being alleviated by procedural changes, we believe there is still a need for the cut-off/deferral concept used in past reviews. However, we believe it should be modified slightly via new procedures. As we understand it, Category I matters issued after the docketing date of an application will not have to be considered in the review of that application. Thus, for the Category I matters, the "cut-off date" should be associated with the docketing date of the application as opposed to the Q-2 date. Obviously, there is still a need to establish a "deferral date" for new Category II and III matters. We believe it is still appropriate to keep this as the Q-2 date.

A key aspect of this situation is the misunderstanding and misconception associated with the term "cut-off date." Under the implementation proposals suggested by SB for plants referencing a PDA, and as discussed above, no matters classified as Category II, III, or IV would be "cut-off" i.e., not considered as applicable to the application under review. The staff review of the applicant's response/conformance to each such requirement is delayed to the next licensing action. For example, on PDA's, we believe that essentially all Category II, III and IV matters which are approved a Q-2's can be deferred until the review of the final design via a point FSAR or FDA application.

Thus, the term "cut-off" is misleading and we suggest that a new term be defined which would more accurately describe our intentions. Recently, Tom Cox suggested that the term should be the "Regulatory Requirements Deferral Date" or R2D2!

At the LSRC meeting on March 22, 1979, it was agreed that DSS, DSE and DPM would initiate action to define procedures governing how Category II. III, and IV matters are to be considered in the staff's safety reviews. This concept of a "deferral date" seems to us to be an important element to be considered.

Due to the length of the approvals for standard designs, this concept involving deferral to the FDA or FSAR stage is much more important. Without it we would have difficulties in completing our reviews. In addition, there would be uncertainties for any utility that referenced a standard design in that these matters potentially would have to be taken up on individual CP applications. Consequently, the handling of the Category II. III and IV matters can have an important and long-lasting effect on standardization, and thus, we see this subject as critical to our activities.

Original signed by: C. J. H. comes, A.

C. J. Heltemes, Jr., Chief Standardization Branch Division of Froject Nanagement

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