MEMORANDUM FOR: Wayne D. Lanning, Chief
Special Inspection branch
Division of Reactor Inspection and Safeguards
Office of Nuclear Reactor Regulation

FROM: Eugene V. Imbro, Section Chief
Special Inspection Branch
Division of Reactor Inspection and Safeguards

SUBJECT: MINUTES OF NRC/NUMARC MEETING ON DESIGN DOCUMENT RECONSTITUTION ACTIVITIES

On December 5, 1989, members of the NRC staff met publicly with representatives of NUMARC to discuss their activities in the area of Design Basis Documents (DBDs).

The NUMARC representatives stated that their Design Basis Issues Working Group had developed a draft guideline regarding the handling of technical concerns that are identified during a DBD reconstitution effort. The NUMARC document addressed how DBD issues should be handled with respect to reportability review, operability determination, and enforcement aspects.

The NRC participants were invited to attend a scheduled meeting of the DBD working group on January 16, 1990, to provide the NRC perspective and current thoughts regarding design document reconstitution and to provide any thoughts on the draft guideline. The NRC additionally was invited to address a NUMARC sponsored industry Design Document Reconstitution meeting on January 17, 1990. Both meetings will be held in Bethesda, Maryland.

Original signed

Eugene V. Imbro, Section Chief
Special Inspection Branch
Division of Reactor Inspection
and Safeguards
Office of Nuclear Reactor Regulation

Enclosures:
1. List of Attendees
2. NUMARC Material presented at December 5, 1989 meeting.

CONTACT:
Robert A. Gramm, NRR
492-0991

Distribution:

JMTaylor, EDO	TEMurley/JHSniezek, NRR	BKGrimes, NRR	EVImbro, NRR
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Meeting Attendees	Central Files	DRIS R/F	RSIB R/F

Public Document Room

RSIB:DRIS	SC:RSIB:DRIS	
RAGramm:rg	EVImbro	
12/18/89	12/18/89	

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ENCLOSURE 1

MEETING ATTENDEES

NAME	ORGANIZATION
Alex Marion	NUMARC
Tony Pietrangelo	NUMARC
Gene Imbro	NRR/DRIS/RSIB
Frank Akstulewicz	NRR/PTSB
Kamal Manoly	NRR/DET
Frank Miraglia	NRR/ADT
Wayne Lanning	NRR/DRIS/RSIB
Robert Gramm	NRR/DRIS/RSIB
Jim Dyer	OEDO
Brian Grimes	NRR/DRIS
A. Goalston	NRR/SELB
Mark Beaumont	Westinghouse
Brent Saclauskos	Bechtel

NUMARC/NRC Meeting

Design Basis Activities

December 5, 1989

AGENDA

I. Primary Objectives for Design Basis Programs

II. NUMARC Position Paper on Addressing Open Items

III. Definitions Adopted by NUMARC Working Group

IV. January 16, 1989 NUMARC Working Group Meeting

V. January 17, 1989 NUMARC Design Basis Meeting

NUMARC Design Basis Issues Working Group

PRIMARY OBJECTIVES FOR DESIGN BASIS PROGRAMS

1. Provide a documented reference for engineering personnel to use in the design process when considering future plant modifications.

2. Serve as a bases for technical reviews, safety reviews, and 10CFR50.59 safety evaluations.

3. Provide a documented reference to support operability evaluations and the development of justifications for continued operations (JCO's).

4. Provide a documented reference for licensing personnel in support of licensing analyses and updates to safety analysis reports.

5. Provide a documented reference to support the review of Technical Specifications changes.

NUMARC DESIGN BASIS ISSUES WORKING GROUP

DRAFT

Addressing
Open Items Identified
During The Implementation Of
Design Basis Programs

DRAFT

INTRODUCTION

This paper describes the approach developed by the NUMARC Design Basis Issues (DBI) Working Group to address open items identified during the implementation of design basis programs. Also described herein are positions relative to reportability of open items and the application of NRC enforcement policy to design basis programs. As discussed in this paper, design basis programs entail formal, self-initiated licensee design basis activities, such as system or topical design basis documentation efforts, field validations, or other related efforts that have a defined scope and timetable and are being diligently performed by utilities. Open items entail those items that are identified during the implementation of design basis program activities that are potential discrepancies and require disposition.

The majority of nuclear utilities have initiated design basis programs. Based on industry experience, these activities can result in the identification of numerous open items with varying levels of significance. The types of open items identified have included documentation errors, inconsistencies of the as-built plant with the final design, and inaccurate translation of design basis information. To date, only a small fraction of the open items identified have proven to be potentially safety significant. Many questions remain, however, about a uniform manner or method to address these open items with regard to operability and reportability determinations.

The purpose of this paper is to provide a reasonable approach for addressing the spectrum of open items discovered during design basis programs. An open item resolution process is used to provide a framework for describing several key elements of the approach which focus on specific considerations and actions that comprehensively evaluate and disposition each open item.

This process may be applied independent of existing utility programs which address non-conformances or may be adapted to interact with such programs.

The underlying principle throughout this paper is to effectively manage the open item resolution process. Through this managed approach, both industry and regulatory concerns are addressed in an efficient, structured manner that is designed to promote diligent, self-initiated design basis programs.

OVERVIEW

A flow chart depicting a process for addressing open items is provided in Figure 1. The process is generally consistent with normal utility practices for treating non-conforming conditions identified during the course of day-to-day plant activities. The process applies to individual design basis program activities (e.g. system DBD efforts) that have a defined scope and timetable.

Following the identification of an open item, a screening element is applied to quickly distinguish the safety significance of the item. If the open item does not raise a safety concern based on the results of the screen, the open item would be held for final evaluation pending completion of the particular design basis activity. If the open item is determined to be potentially safety significant, the item would undergo both operability and reportability evaluations. The screening element should be completed within seven days of the identification of the open item.

The operability evaluation would determine if an operability issue is posed by the open item. If an issue is identified, the licensee would take the applicable Technical Specification action or other appropriate action deemed necessary to address the issue. If no operability issue is identified, the open item would be held for final evaluation pending completion of the

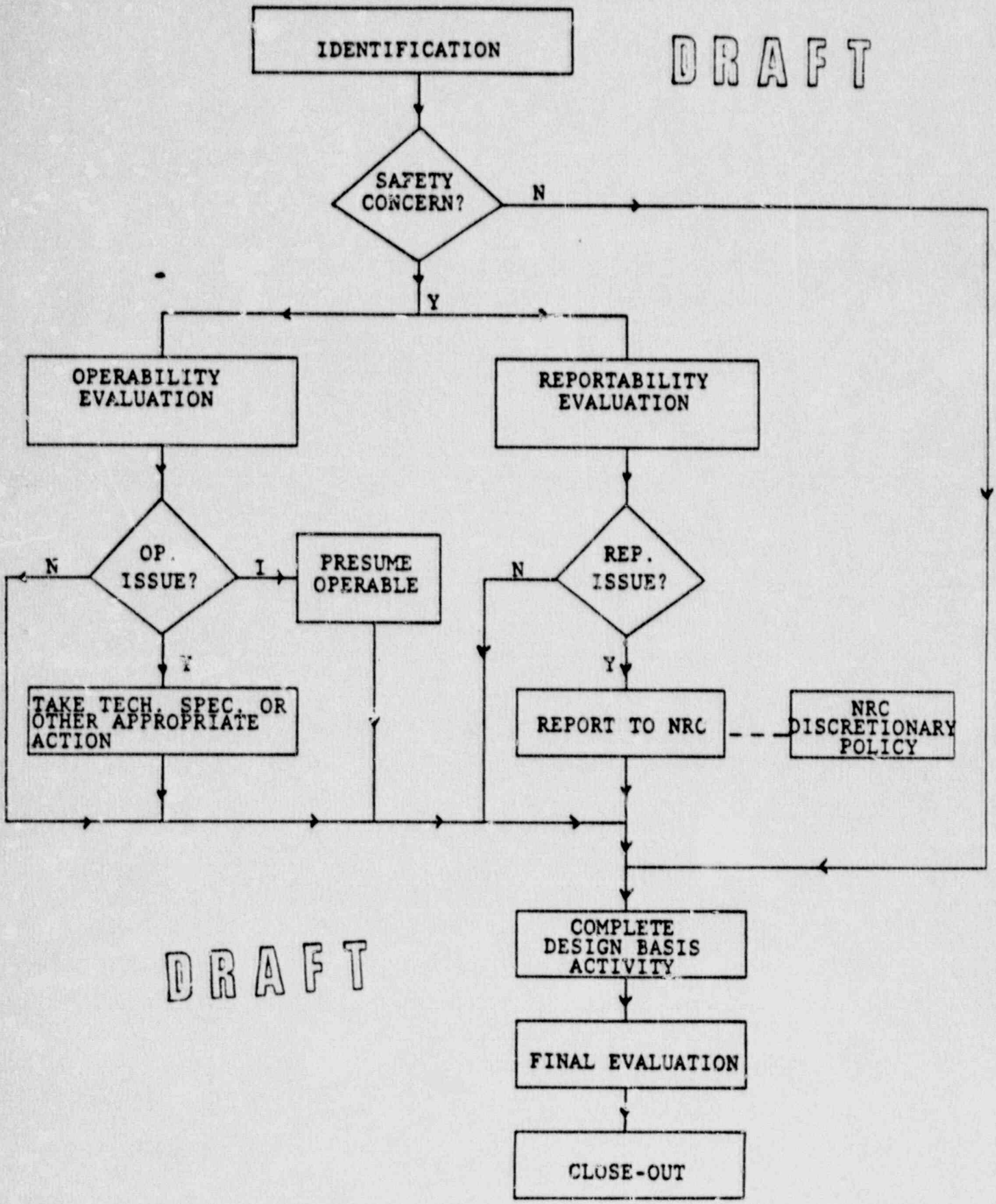
particular design basis activity. If the evaluation results are indeterminate, a presumption of operability would be made pending completion of the activity and the final evaluation. The operability evaluation should be completed within thirty days.

The reportability evaluation ensures timely reporting and regulatory compliance. If a reportable event is determined under the existing regulations, the licensee would report the event to the NRC. If no reportable events are determined, the open item would then be held for final evaluation pending completion of the particular design basis program activity. The reportability evaluation should be completed within thirty days.

The final evaluation determines whether the open items identified during the activity have any incremental or cumulative effects that would result in any operability issues or reportable events. Additionally, the open items are prioritized based on their relative significance, and their final dispositions are determined. This evaluation should be completed within 30 days.

The closeout program assures that the disposition of each open item is satisfactorily implemented.

FIGURE 1
DESIGN BASIS OPEN ITEM RESOLUTION PROCESS



INDIVIDUAL ELEMENT DESCRIPTIONS

The following is a discussion of the individual elements that form the open item resolution process.

Identification

This element includes the identification, logging, tracking and internal reporting of an open item discovered during the performance of a design basis program activity. To assist in establishing approximate time values for the expected duration of each block of actions in the resolution process, time "zero" for an individual open item is defined as the time that the open item is logged or entered into the tracking mechanism (e.g. punchlist, NCR, etc.) used to support this process.

NOTE: This is not to be construed as a "clock start" for 10CFR50.72 Notification or 10CFR50.73 Reportability

Screen for Safety Significance

Utility experience has shown that numerous open items may be identified during the performance of design basis program activities. A method is needed to quickly screen each of these items to determine its safety significance or the potential impact that the item may have on the continued safe operation of the plant. Without this initial determination, the process could easily become bogged down by giving equal priority to items of little or no significance. The following questions provide a screening method to initially determine the potential safety significance of each open item:

(1) Is the open item directly related to a system or component explicitly listed in the Technical Specifications?

(2) Does the open item compromise the capability of a system or component to perform as described in the FSAR?

(3) Does the open item appear to adversely impact any applicable licensing commitments?

If the answer to any of the above questions is yes, operability and reportability evaluations should be initiated expeditiously. (At this point in the process, the utility may elect to enter the open item into it's existing program that addresses non-conformances or may continue to address the open item separately.) If none of the above questions are answered yes, the open item would be held for final evaluation and disposition pending completion of the activity.

Operability Evaluation

An underlying premise throughout this element is a presumption of operability until a system or component is determined inoperable. Recognizing that open items discovered during the activity may have existed for some time and are surfacing due to a self-initiated effort that is more rigorous than what was industry practice when the plants were built, it is reasonable to pursue these items at a deliberate, managed pace. This would preclude a crisis atmosphere that could adversely impact the thorough evaluation of an open item. It would also reduce the potential for frequent plant perturbations

resulting from technical specification actions based on incomplete evaluations and premature determinations. For these reasons, the presumption of operability also serves to reduce potential disincentives to the aggressive performance of the program activity.

The operability evaluation should be consistent with normal utility practices that address non-conforming conditions that are discovered during the course of routine plant activities. If the evaluation determines that the open item poses an operability issue, the process would proceed to the "Actions" element. If the evaluation determines that the open item does not pose an operability issue, the basis for that conclusion should be documented, and the open item may be held for final evaluation and disposition pending completion of the design basis activity.

It is entirely possible that after thirty days the operability evaluation will be indeterminate. One of the primary objectives for initiating a design basis program is to enhance the ability to make accurate operability determinations. Should this case arise when evaluating a particular open item, the presumption of operability would continue until sufficient information is available to make a determination. Industry experience has shown that information uncovered during the course of a design basis activity may shed light on a previously identified open item. The approach described in this paper would allow this information to come to fore and would defer the operability determination in this case to the final evaluation element.

Take Technical Specification Action or Other Appropriate Action

When an operability issue is identified for an open item based on the preceding operability evaluation, immediate action should be taken to address the issue. The action should be consistent with normal utility practice.

Reportability Evaluation

In order to assure conformity to existing regulations and to keep the NRC informed in a timely manner, each open item captured by the screening element will receive a reportability evaluation. Current regulations 10CFR50.72 and 73 contain requirements for immediate notification and Licensee Event Reports respectively. The particular part of these regulations that has been the subject of much discussion and confusion is the interpretation of what constitutes a condition "outside the design basis of the plant". This confusion stems from differences of opinion on what documents or information constitute a plant's design bases.

Design bases as defined in 10CFR50.2 include information that identifies the specific functions to be performed by a structure, system or component, and the specific values or range of values chosen for controlling parameters as reference bounds for design. Applying this definition to determine what is "outside the design basis" would result in the following:

(1) A condition where a structure, system, or component is unable to perform its specific function(s), or

(2) A condition where a structure, system or component is beyond the

specific value or range of values that were chosen for controlling parameters as its reference bounds for design.

These two conditions serve to clarify what "outside the design basis" means with respect to the regulatory requirements noted above. When an open item is evaluated for reportability, the presence of either of these conditions would constitute a reportable event.

These conditions would seem relatively easy to detect when a plant's design bases are clearly understood and documented. However in many cases elements of the design bases are either unknown, not documented, or unclear, and the determination of an open item's reportability is difficult. In these cases, it is reasonable to use an approach similar to the "presumption of operability" discussed earlier. One need not automatically assume that a condition "outside the design basis" exists. Industry experience has shown that information is often identified during the course of an activity that contributes to the resolution of a previously identified open item. In this process, the element entitled "Complete DB Program Activity" is included so as to allow relevant information to come to fore, and is followed by a final evaluation where an open item can be reevaluated for both operability and reportability. That would be the appropriate time to make the final reportability determination for the open item in this particular case.

Report to NRC

When an open item is determined reportable under 50.73 criteria, a written LER shall be filed within 30 days of the determination. Should subsequent open items identified during the same activity result in additional reportable

events, it is proposed that written supplements to the initial LER be filed. Portions of the initial LER and its supplements (e.g. long term corrective action, safety significance, root cause) may be deferred until the activity is completed. When portions are deferred, a clear schedule for meeting all 50.73 requirements should be provided. Following completion of the activity, the final evaluation will comprehensively review the identified open items. At that point, a final supplement to the LER can be written that addresses the deferred areas of prior filings and fulfills the pertinent regulatory requirements.

The above position clearly reflects the managed approach to addressing open items during the implementation of design basis programs. An aggressive program may turn up a number of potential findings, and the LER process could quickly degenerate into a blizzard of submittals and revisions. For example, it makes little sense to propose long term corrective action in the first LER when subsequent findings may impact the decision regarding the appropriate corrective action. This would distract licensee resources with no safety benefit.

This approach balances the need for prompt reporting to the NRC with a structured method that efficently addresses open items both individually and collectively. This method offers several advantages. Open items identified during an activity such as a system design basis documentation effort are closely related and should be reviewed for cumulative impact on the system's function(s). Additionally, this approach provides timely reporting when individual open item reportability determinations are made and minimizes, to the extent appropriate, the quantity of separately-numbered LERs which unavoidably seems linked to perceptions of licensee performance. In sum,

safety benefits would be attained through the comprehensive evaluation performed at the completion of the activity, while potential disincentives to the aggressive implementation of the program would be reduced.

NRC Discretionary Policy

Regulation 10CFR Part 2, Appendix C, Section G, "Exercise of Discretion" describes a portion of NRC enforcement policy designed to encourage and support licensee initiatives on self-identification and correction of problems. The application of this policy can help to promote the aggressive implementation of design basis programs.

As written, Section G lists several criteria used to determine when the exercise of discretion is warranted. These include criteria such as licensee identification of the problem, timely reporting and corrective action planned or taken to address the problem, and evidence that the problem is not willful, routine, or repeat. A primary objective of the approach described in this paper is to provide a systematic method that is consistent with the criteria noted above.

The NRC took a positive step towards promoting self-initiated licensee programs when the "Exercise of Discretion" policy was revised in October of 1988. In that revision, the option to refrain from proposing a civil penalty for a Level III violation was explicitly stated with regard to design basis programs. However, the fact that a violation may be issued as a result of a self-initiated activity provides a potential disincentive to the rigorous conduct of such activity. Violations are clearly regarded as being indicative of poor licensee performance both by the regulator and the general public. It is proposed that violations not be issued for problems identified by

licensees when all of the pertinent criteria in Section G are met. Further, the "Exercise of Discretion" policy should also be expanded to include Severity Levels I and II. These actions would greatly reduce disincentives and would serve to create a regulatory climate more conducive to sincere self-initiated efforts.

Complete Design Basis Program Activity

The main purpose of this element is to allow for all relevant information pursuant to the activity to be available for use in the subsequent "Final Evaluation" element.

As noted previously, industry experience has shown that an open item can often be resolved by information identified later in the related activity. Thus, it may be premature to disposition an item without allowing all pertinent information to come to fore. Additionally, by performing a final evaluation when the activity is completed, the cumulative effects of the items may be addressed in a comprehensive manner.

Final Evaluations

At this point, the design basis program activity has been completed and the open items associated with the activity have been identified, and those that were screened as safety significant have been evaluated individually for both operability and reportability issues. This element ties in the applicable information gathered during the activity and applies it toward the comprehensive review of the identified open items. There are three main objectives associated with this important element. The first is to look at the open items in total and determine if there are any cumulative effects

that impact operability. The second is to review the open items in total with respect to reportability. The third objective is to both prioritize and disposition the open items.

If an open item had previously resulted in an operability issue, the actions taken should now be reviewed in light of any additional open items or new information identified during the activity. Sufficient information should also now be available to resolve any previous operability evaluations that were indeterminate. The other important aspect of this particular evaluation is to determine if there are any cumulative effects associated with the open items. It is possible that several open items, when reviewed individually, did not result in any significant concerns or issues, but that together may impact the ability of a system or component to perform its intended function(s). If an operability issue is determined as a result of this comprehensive evaluation, then Technical Specification action, if applicable, or other appropriate actions should be taken.

The final evaluation for reportability should first address those open items for which the initial reportability evaluation was indeterminate. Sufficient information should now be available to make a final determination. Secondly, the cumulative effects of the open items should be reviewed to determine if any conditions result that may be reportable under existing regulations. Third, if any reportable events were concluded from the individual evaluations, a final supplement to the initial LER should be filed that fulfills any remaining 50.73 requirements and provides updates to corrective action plans based on new information identified.

The final task within this element is to prioritize and disposition the remaining open items discovered during the design basis activity. The

prioritization is important in that it distinguishes those items requiring more immediate corrective action from those that may be resolved through routine scheduling practices and from those that may not require any action.

Several utilities have developed methods to prioritize open items. Some have utilized probabilistic risk assessments (PRAs) for this application. Others simply route the open item for disposition to the appropriate engineering discipline through the routine process for addressing non-conformances, while others have employed a review committee to determine the priority of an item. All these options may be appropriate based on an individual utility's organization and culture.

Application of prioritization criteria may be dependent on the specific nature of the open item. It is important to exercise sound engineering judgement that takes into account the circumstances surrounding a particular open item. The following proposed criteria offer a methodology to prioritize open items based on general safety considerations and should be applied together with engineering judgement.

(1) Does the open item potentially impact the operability of a system or component that provides or supports a safety function?

(2) Does the open item question the validity or completeness of a design change undertaken on a system or component?

(3) Is resolution of the open item necessary to support a future design change planned for a system or component?

(4) Would resolution of the open item facilitate operability determinations on systems or components that have proven difficult based on past operating history?

If the answer to questions (1) or (2) is yes, then resolution of the open item should be pursued as a near term action item (i.e. resolved before startup from the next scheduled outage of sufficient duration). If the answer to questions (3) or (4) is yes, then resolution should be pursued as a long term action item (i.e. resolve the item by the completion of the next refueling outage, or if the outage is scheduled to begin in a timeframe that precludes the development of adequate corrective actions without adversely affecting the refueling outage, the resolution may be deferred to the next outage of sufficient duration). If none of the questions were answered yes, then the open items are considered non-priority items that should be pursued consistent with the utility's management guidance.

Industry experience has shown that a large number of open items discovered during design basis program activities are related to missing information. A main premise of the prioritization criteria is to determine whether there is a substantive reason or need that calls for pursuing the resolution of an item as a priority. With respect to missing information, this means that the reconstitution of design documents need not be pursued when the need does not exist. Additionally, reconstitution may not be necessary when other sources of data (e.g. test results, operating history, related industry experience) can provide reasonable assurance of continued safe operation. It is recommended, however, that a record be kept that identifies an area

where there is a lack of design documentation to avoid fruitless potential searches for this information in the future.

Closeout Program

Once the disposition of each open item is complete, a closeout program should be developed that effectively tracks the item to its successful resolution. The responsibilities of each plant/engineering organizational unit associated with the implementation of the disposition should be clearly understood. The program should verify that the corrective actions taken adequately address the open item and should preclude repetition of any condition adverse to quality. The program may include training, education, and programmatic reforms as applicable.

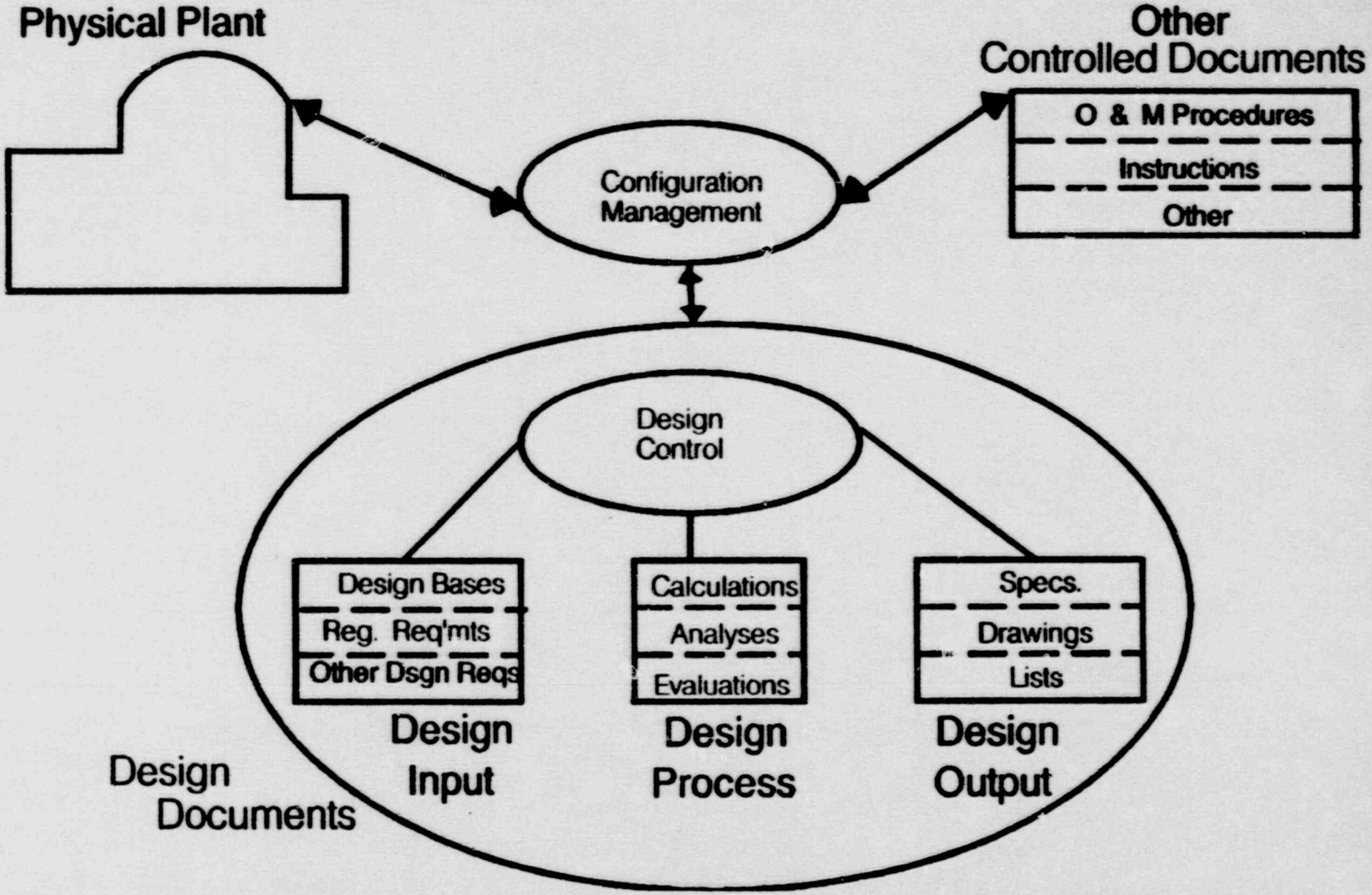
Most plants have a formal program to address the closeout of a non-conformance. Regulation 10CFR50, Appendix B, Criterion XV and XVI provide guidance on such a program. This guidance can be adapted to address the closeout process for dispositioning design basis program open items.

CONCLUSION

This paper describes a systematic, comprehensive approach to address open items identified during the implementation of design basis programs. This approach includes methodology to assess the safety significance of open items, evaluates significant open items for both operability and reportability issues and provides prioritization criteria to assist in the final disposition of each open item. This paper also clarifies reportability determinations, offers a reasonable method to communicate significant findings to the NRC and proposes enhancements to the NRC enforcement policy regarding the "Exercise

of Discretion". Additionally, a final evaluation is included following the completion of a design basis program activity that reviews the open items identified for any incremental or cumulative effects. The objective of this paper is to provide a managed approach to resolving open items that promotes diligent, self-initiated licensee efforts toward the aggressive implementation of design basis programs.

TERMINOLOGY RELATIONSHIPS



NUMARC Design Basis Issues Working Group

DEFINITIONS

1. **DESIGN BASES:** Information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or (2) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals. (10CFR50.2)

2. **DESIGN CONTROL:** Measures established to assure that the information from design input and design process documents for structures, systems, and components are correctly translated into the final design.

3. **CONFIGURATION MANAGEMENT:** Process of maintaining the physical plant and those controlled documents required to support plant operations consistent with selected design documents.

4. **DESIGN INPUT:** Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based. (ANSI N45.2.11)

5. **DESIGN PROCESS**: Documented design practices such as calculations, analyses, evaluations, technical review checklists, or other documented engineering activities that substantiate the final design.

6. **DESIGN OUTPUT**: Documents such as drawings, specifications and other documents defining the technical requirements of structures, systems, and components. (ANSI N45.2.11)

7. **FINAL DESIGN**: Approved design output documents and approved changes thereto. (ANSI N45.2.11)

8. **OPEN ITEMS**: Those items that are discovered during the implementation of design basis program activities that are potential discrepancies and require disposition.

9. **VERIFICATION**: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. (ANSI/ASME NQA-1-1986)

* Adopted by NUMARC Design Basis Issues Working Group on 11/30/89