DRAFT

OCT 16 1992

MEMORANDUM FOR: Raymond F. Fraley, Executive Director
Advisory Committee on Reactor Safeguards

FROM: Warren Minners, Director
Division of Safety Issue Resolution

SUBJECT: DRAFT COMMISSION PAPER ON RISK-BASED REGULATION

Enclosed for the Committee's review is a draft of the subject Commission paper. An advance copy of this paper had been provided to R. Savio of your staff on October 9, 1992.

We request Committee review and comments at the November 1992, Full Committee meeting and are prepared to brief the Committee on this paper at that time. Please note that Enclosure 1 to the paper is to be provided by NUMARC and will be given to the Committee as soon as it is received. The draft paper itself is considered predecisional and should, therefore, not be released to the public or put into the meeting record.

If you have any questions please contact Mr. T. L. King (492-3980) of my staff.

Original Signed By J. King

Warren Minners, Director
Division of Safety Issue Resolution

Enclosure: As stated

cc: R. Savio, ACRS

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PREDECISIONAL

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: RISK-BASED REGULATION

Purpose: This paper responds to the Staff Requirements Memorandum dated March 26, 1992, which directed the staff to provide their views on the practicality of risk-based regulation and on the feasibility of developing a transition strategy from deterministic based regulations.

Background: Risk can be used as a measure of safety and factored into regulatory actions, whether implicitly or explicitly. The consideration of safety impact, and therefore risk, has traditionally been a fundamental part of regulatory decision making.

In the early development of regulations, risk was implicitly considered through qualitative assessments and simple reliability principles and practices, such as worst case analysis, defense in depth and the single failure criterion. Following the accident at the TMI, the use of more quantitative risk information in regulation through probabilistic risk assessment (PRA) methods increased. The end result of this qualitative and quantitative consideration of risk in regulation has been a set of regulations and regulatory guides and practices that ensure adequate protection of public health and safety. Currently, the development of PRA techniques is such that the use of safety goals, expressed in terms of risk, have been established to help guide further regulatory decision making.

However, it is recognized that more explicit use of risk considerations in regulatory applications may be advantageous. Such use could help focus attention on the safety objective the Commission is intending to achieve by promulgating a regulation or guidance (in lieu of

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how to achieve it) and provide a means to systematically assess the importance of and need for various regulatory actions. This in turn would be expected to result in allowing licensees more flexibility and efficiency in meeting the intent of the regulations. This paper summarizes the use of risk today in regulation and staff plans for moving toward a more systematic use of risk-based information in regulatory initiatives in the future.

Discussion: Risk-based regulation is a broad term which can have a range of interpretations. Interpretations can range from one in which quantitative risk measures (e.g., core damage frequency) are used directly in regulations to one where risk considerations are used to develop prescriptive requirements and/or prioritize regulatory actions. In addition, the meaning of the term "risk considerations" itself can range from one of using detailed information developed using a PRA to one of qualitative judgments on the relative risk importance of safety issues and/or regulatory actions.

Risk has traditionally been the basis for NRC's regulatory actions. The degree to which this has been expressed quantitative (versus qualitative) has evolved with the state of development of PRA techniques and data bases. Early regulatory actions and requirements were the result of qualitative risk considerations and, accordingly, regulatory actions were not as integrated as they are today where quantitative information is available. For example, quantitative risk information is used in regulation development (e.g., prioritization and resolution of generic safety issues via the procedure documented in NUREG-0933) and to develop other regulatory actions where quantitative information is available. The requirements and regulatory actions resulting from the use of this more quantitative risk information have, in may cases, been prescriptive, although in some areas requirements related to performance of a system, structure or component have been and continue to be developed. In addition, at various times in the past the direct use of quantitative risk measures in the regulations has been considered, but not adopted. However, in general the use of quantitative risk information has allowed better integration among regulatory actions.

The discussion below summarizes the current regulatory structure and planned staff actions to continue to use risk information to improve regulation. These actions represent steps toward implementing evolutionary changes to our current regulatory structure and practices, not radical changes. It is our view that given the current regulatory structure, the state of the art in PRA technology, and the areas that would benefit most from improved use of risk

insights, evolutionary changes that involve more reliance on quantitative risk information are practical and could be beneficial in both improving safety and reducing unnecessary regulatory burden. For example, in updating proposed staff guidance on developing regulatory analysis supporting regulatory actions, increased emphasis has been placed on quantitative risk analyses.

Current Regulatory Structure

Figure 1 provides a simplistic illustration of the NRC's current approach to the development of regulations. Each regulation promulgated by the Commission results from some type of safety insight be it analytical or experience based. Those insights are then examined to determine the need for a regulation using the concept of adequate protection, or substantial increase in safety and the associated cost-benefit and Safety Goal considerations. This examination results in a rule basis. The rule basis is to be formulated using a PRA where practical, or if such application is not practical because of methodology or data limitations, then a qualitative risk analyses has to be provided. Thus, for the purposes of this paper we have defined a rule with a basis determined through the use of PRA as quantitative and one with a basis determined without the use of PRA as qualitative. During the development of a rule, a rule type is formulated. Rules can be prescriptive in which the Commission specifies a narrow set of acceptable solutions to a regulatory issue or performance oriented in which the Commission defines the goal or expectations for results without prescribing the methods or hardware to accomplish the results. The final attribute that characterizes a regulation is its use of acceptance criteria. The criteria may be defined in the regulation itself or may be part of regulatory guidance such as a regulatory guide, the Standard Review Plan or Standard Technical Specifications. If the criteria are stated in the rule itself usually they are deterministic in that they are fixed conclusively and can be arrived at by investigation, reasoning, or calculation. When the rule criteria are defined in regulatory guidance, they may be deterministic, probabilistic, or a combination of both. Figure 2 provides an example of an NRC regulation in the regulatory structure of Figure 1.

Figure 1 also shows the possibility of using probabilistic criteria in the rule itself. There are currently no NRC regulations which contain probabilistic criteria within the rule. (i.e., criteria that are stated in terms of quantitative values calculated or relied upon in a PRA such as core damage frequency or system availability/ reliability). A rule may indicate that a reliable system or component is required but does not specify what constitutes reliable in the rule.

Although it may be possible to develop rules containing quantitative probabilistic criteria, the staff does not believe that it is either practical or desirable at this time. In theory, such rules would provide greater flexibility to the industry in achieving safety, could potentially reduce regulatory burden, facilitate more objective decision making, and allow development of rules which would apply generically to many different designs, including revolutionary designs. However, in practice rules containing probabilistic criteria have considerable disadvantages including heavy reliance on evolving PRA technology, high uncertainty in the use of PRA for some phenomena and non-hardware issues, the potential for data manipulation, and, in many cases, very limited data to support decision making. In addition, careful attention would need to be given to implementation of quantitative risk criteria in regulations to ensure Commission policies with respect to defense-in-depth and the balance between accident prevention and mitigation are maintained. Nevertheless, there are several ongoing staff activities that are providing a greater risk orientation to the entire regulatory structure. For example, in the area of the basis for rules and regulatory guidance, SECY-91-270, "Interim Guidance on Staff Implementation of the Commission's Safety Goal Policy," proposed an implementation strategy that is primarily a quantitative-based analysis with respect to the Safety Goals. Future implementation of this guidance through the revised guidelines for Regulatory Analysis will result in increased use of quantitative risk information as the primary basis of future rules and regulatory action. In the area of existing regulation, the staff will seek to eliminate rules or rule criteria that are overly prescriptive and do not significantly contribute to enhanced safety. These plans are described in SECY-92-263 "Staff Plans for Elimination of Requirements Marginal to Safety." Finally, in order to support some of the more recent performance type rulemakings such as the maintenance rule and the station blackout rule, the staff is developing regulatory guidance that relies more on probabilistic criteria and insight.

The staff believes, however, that there are additional areas that can be improved in the staff's use of risk information in regulation. These areas fall into two broad categories:

1) those where risk insights can be used to improve or develop regulatory implementing guidance (for example Technical Specifications), and

2) those where risk insights can be used to change or develop new regulations whose objectives can be stated in terms of expected or needed performance. This

approach will provide many of the advantages of being less prescriptive in regulation (e.g., provides more flexibility to licensees) but which are not dependent on detailed PRA information for day to day implementation (for example, the maintenance rule).

Areas of regulation where the staff does not believe additional work is warranted at this time to further utilize risk information are those regulations which specify basic design attributes (e.g., 10 CFR 50, Appendix A "General Design Criteria"). Changes to regulations in these areas already consider quantitative risk information in their bases (regulatory analysis) and in backfit considerations and the staff proposes to continue this practice.

Planned Staff Actions

Following the briefing to the Commission on March 10, 1992, by representatives from NYPA and NUMARC on a risk-based regulation transition strategy, the staff has continued to have discussions with industry regarding their plans and interest in this area. Most recently, on October 14, 1992, members of the staff were briefed by representatives from NUMARC and industry on their interest in and effort to coordinate industry plans and activities on risk-based regulation. To help ensure coordination and serve as a point of contact for the staff, NUMARC has established an Ad Hoc Advisory Committee with membership from utilities, EPRI and NUMARC. Enclosure 1 summarizes the membership and purpose of this Ad Hoc committee. It is our understanding that the committee is discussing strategies for incorporating risk-based regulation and plans in the near future to recommend to the Commission certain initiatives directed at further implementation of risk-based regulation. From our preliminary discussions with the Ad Hoc Committee, we believe that the staff and industry agree in concept with the following:

1) ideally the regulations should be a mix of performance and prescriptive requirements and initial efforts assessing risk-based regulation should concentrate on those areas where it is clearly practical and feasible to make further use of risk information;
2) that significant technical and policy issues (see Enclosure 2) need to be discussed and agreement reached on how they are to be treated in order to establish the feasibility and practicality of further use of quantitative risk information in regulations (such as revising Technical Specifications or the implementation of quality assurance requirements); and
3) that some pilot programs would be useful as examples to explore further the issues associated with the expanded use of risk-based regulation and to help

assess the practicality and feasibility of the expanded use.

Accordingly, the staff proposes to establish an interoffice working group to interact with the NUMARC Ad Hoc Committee. This working group would be responsible for evaluating industry proposals, recommending actions in response to those proposals and coordinating staff work in this area. The working group would also be responsible for evaluating progress on any pilot programs and for providing recommendations to management regarding the practicality and feasibility of implementing risk-based regulation initiatives.

In addition to establishing a working group, it is our view that some of the activities proposed in the marginal to safety program (SECY-92-263) relate directly to risk-based regulation since they involve changes to certain regulations (e.g., 10 CFR 50, Append. J) to be more performance oriented. Accordingly, it is our plan to include in the marginal to safety workshop (currently scheduled for January 1993) discussion on options for making selected regulations more performance oriented. Through these examples we hope to solicit feedback from the public and industry on the interest in and ways to make regulations more performance-oriented using risk information.

Conclusion: The staff believes that the further use of quantitative risk-based information in regulation can lead to better integration of requirements and, in some areas, has the potential to improve implementation of requirements. In the short term, (one to two years) we intend to interact with industry (using the NUMARC Ad Hoc Advisory Committee) to identify and explore areas that could serve as pilot programs to assess the practicality and feasibility of an evolutionary transition to the use of more quantitative risk information in regulation. We will keep the Commission informed of industry proposals and staff actions in this regard. In the long term (beyond 2 years), the results of the pilot programs will be used to assess whether or not it is practical and feasible to continue application of the methods and processes developed to other areas and/or develop new initiatives. We believe these actions are consistent with the intent of the Commission's March 26, 1992, SRM.

Coordination: OGC has reviewed this paper and has no legal objections.

James M. Taylor
Executive Direcotr
for Operations

Enclosures:
1. Letter from NUMARC - TBD
2. Key Issues
3. Figure 1
4. Figure 2

Enclosure 2

Examples of Key Technical and Policy Issues Associated with Implementing Risk-Based Regulation

The PRA provides a systematic and objective method of studying risk significant contributors in a plant. The practicality of implementing risk-based regulation is dependent upon the practical utilization of PRA. Therefore, it is important that issues associated with utilization of the PRA be evaluated. The following topics are examples of key relevant issues that would need to be addressed and agreement reached on their treatment.

Technical Issues

a) Adequacy and use of analytical tools:

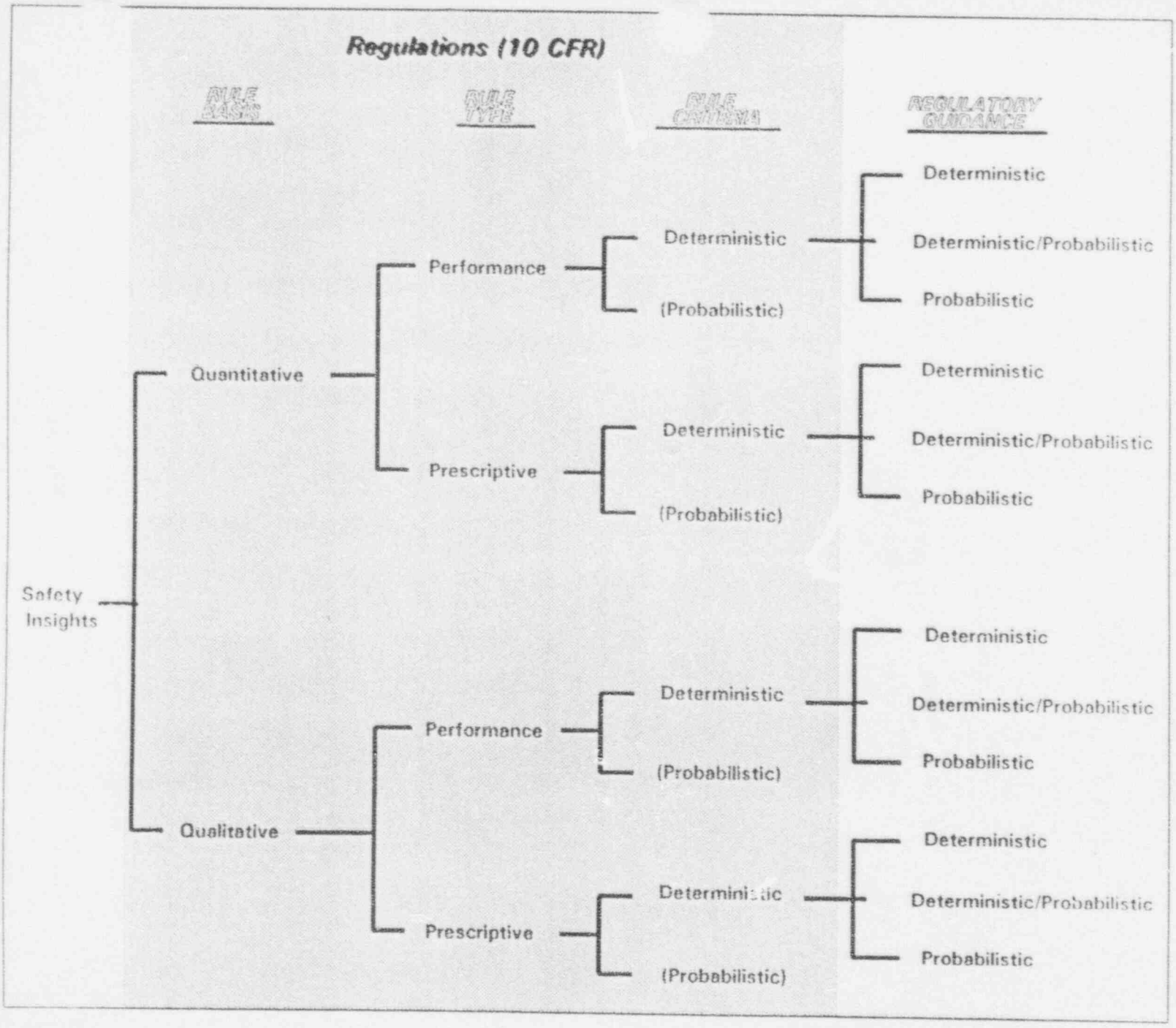
1. Level of analysis necessary (i.e., Level 1, 2, 3)
2. Adequate scope
   - level of detail modeled (e.g., should I&C be included?)
   - hardware failures (passive, active, partial)
   - system interactions
   - human interactions
   - common cause failures
   - effect of aging
   - recovery actions
   - adequacy and reliability of data base
   - external events
   - uncertainty analysis
3. Plant states needed (full power, low power, shutdown, etc.)
4. Adequacy of the importance ranking methods
5. Effect of uncertainty on the ranking process
6. Effect of human errors on the ranking process
7. Effectiveness of PRAs to quantify the risk significance of constant changes in plant configuration (configuration control)
8. Adequacy of methods for failure monitoring and updating the plant PRA
9. Adequacy of methods for accounting for maintenance, training, management effectiveness
10. Level of review necessary
11. Adequacy of IPEs for this purpose

b) Availability of Decision Criteria and Methods

1. Availability of decision criteria and analysis methods
2. Implications of selecting only the high ranking SSCs for regulation (e.g., address the overall safety implications of not regulating low ranked components and systems)
3. Role of uncertainties in decision criteria and methods
4. Dependency of PRA results on existing prescriptive regulations, criteria, guidance and how changes to be more risk based ensure safety is not unduly compromised

Policy Issues:

1. Consistency of risk-based regulation with standardization, backfitting, severe accident and safety goal policies
2. Consistency of risk-based regulation with the NRC's inspection and enforcement activities. Adequacy of methods to test compliance or noncompliance
3. Implications of risk-based regulation for traditional NRC deterministic practices, such as:
   - defense-in-depth
   - single-failure-criterion
4. How to best implement risk-based regulation in selected areas:
   - are license amendments required?
   - can 10 CFR 50.59 be used?


Regulations (10 CFR)
RULE BASIS
RULE TYPE
RULE CRITERIA
REGULATORY GUIDANCE
Safety Insights
Quantitative
Qualitative
Performance
Prescriptive
Performance
Prescriptive
Deterministic
(Probabilistic)
Deterministic
(Probabilistic)
Deterministic
(Probabilistic)
Deterministic
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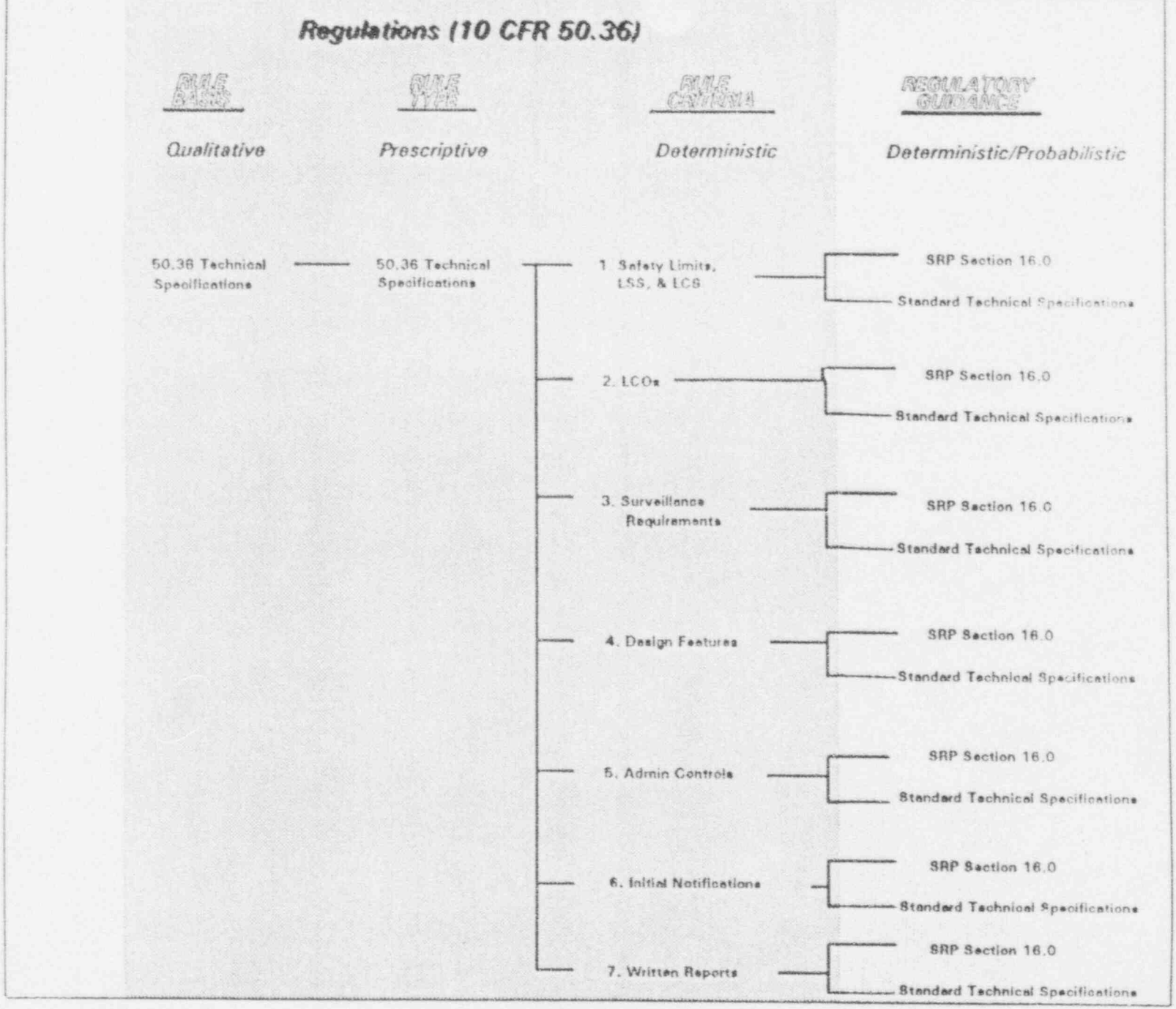
REGULATORY STRUCTURE EXAMPLE



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PRESENTATION TO ACRS

RISK BASED REGULATION

NOVEMBER 5, 1992

DRAFT

T. L. King
10/23/92

Purpose of Briefing

- To inform ACRS of staff proposal to interact with industry on the feasibility and practicality of further using risk information in regulation (draft SECY paper provided to Committee 10/16/92).

- ACRS comments requested

Background

- March 26, 1992, Staff Requirements Memorandum requested the staff, by 12/18/92, to:

  "provide their views on the practicality of risk-based regulations and the feasibility of developing a transition strategy from deterministic based regulations."

- Follow up to March 10, 1992, briefing by NUMARC and the New York Power Authority (NYPA) on a transition strategy to the use of risk-based regulations

WHAT IS RISK-BASED REGULATION?

- USING QUANTITATIVE RISK ~~CRITERIA~~ *measures* IN REGULATORY DOCUMENTS?
- USING QUANTITATIVE MEASURABLE SYSTEM/COMPONENT PERFORMANCE CRITERIA (DERIVED FROM RISK STUDIES) IN REGULATORY DOCUMENTS?
- USING QUANTITATIVE RISK INFORMATION TO ESTABLISH PRESCRIPTIVE-DETERMINISTIC REGULATORY DOCUMENTS?
- SOME COMBINATION OF THE ABOVE?

CURRENT CONSIDERATION OF RISK IN REGULATION

- NEW OR REVISED REGULATIONS AND OTHER REGULATORY DOCUMENTS ARE SUBJECT TO:
  - REGULATORY ANALYSIS
  - SAFETY GOALS ~~(IF REACTOR RELATED)~~
  - BACKFIT RULE ~~(IF REACTOR RELATED)~~

Reactor

- RISK INSIGHTS ARE BEING INTEGRATED INTO OTHER REGULATORY ACTIONS:
  - INSPECTIONS
  - TECH SPEC CHANGES
  - INTERNAL STAFF ACTIONS, SUCH AS PRIORITIZATION

- QUANTITATIVE AND QUALITATIVE RISK INFORMATION AND JUDGMENTS ARE USED TODAY.

TRANSITION STRATEGY

- ~~ON WHAT BASIS SHOULD~~ should ADDITIONAL USE OF RISK INFORMATION IN REGULATION BE CONSIDERED:
  - TO IMPROVE SAFETY
  - TO IMPROVE EFFICIENCY
  - TO IMPROVE INTEGRATION OF REQUIREMENTS

- BOTH NRC AND INDUSTRY RECOGNIZE POTENTIAL FOR IMPROVEMENTS:
  - NRC
    - MARGINAL TO SAFETY PROGRAM
    - RISK-BASED INSPECTION
    - TECH SPEC CHANGES
  - INDUSTRY
    - NUMARC AD HOC COMMITTEE
    - NYPA PROPOSAL USING FITZPATRICK

FEASIBILITY/PRACTICALITY

- PILOT STUDIES IN SELECTED AREAS ARE A GOOD WAY TO ESTABLISH FEASIBILITY/PRACTICALITY
- NUMARC - AD HOC COMMITTEE ESTABLISHED TO PROPOSE INITIATIVES
- NRC
  - TO ESTABLISH INTEROFFICE WORKING GROUP TO INTERACT WITH NUMARC ON INITIATIVES
  - MARGINAL TO SAFETY PROGRAM
  - PRA WORKING GROUP GUIDANCE
  - NMSS interaction with EPA
- DIRECTED TOWARD EVOLUTIONARY CHANGE

CHALLENGES

- GREATER USE OF QUANTITATIVE RISK INFORMATION REQUIRES:
  - AGREEMENT ON SCOPE AND DEPTH OF CALCULATIONAL METHODS, DATA BASES, DECISION CRITERIA
  - UNDERSTANDING OF IMPLICATIONS FOR DEFENSE-IN-DEPTH, ENFORCEMENT AND OTHER ASPECTS OF IMPLEMENTATION
  - ~~CONSIDERATION AND~~ Agreement on incorporating FEEDBACK OF OPERATING EXPERIENCE AND PLANT CONFIGURATION INTO RISK ESTIMATES AND REGULATORY ACTIONS.

Maintenance

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