

conditions. Typically, the regulations establish the scope of SSCs that receive special treatment using one of three different terms: "safety-related," "important to safety," or "basic component." The terms "safety-related" and "basic component" are defined in the regulations, while "important to safety" (used principally in the general design criteria of Appendix A to 10 CFR part 50) is not explicitly defined.

These prescriptive requirements as to how licensees were to treat SSCs, especially those that are defined as "safety-related," are referred to in the rulemaking as "special treatment requirements." These requirements were developed to provide greater assurance that these SSCs would perform their functions under particular conditions (e.g., seismic events, or harsh environments), with high quality and reliability, for as long as they are part of the plant. These include particular examination techniques, testing strategies, documentation requirements, personnel qualification requirements, independent oversight, etc. In many instances, these "special treatment" requirements were developed as a means to gain assurance when more direct measures, e.g., testing under design basis conditions or routine operation, could not show that SSCs were functionally capable.

Special treatment requirements are imposed on nuclear reactor applicants and licensees through numerous regulations that have been issued since the 1960's. These requirements specify different scopes of equipment for different special treatment requirements depending on the specific regulatory concern, but are derived from consideration of the deterministic DBEs.

Treatment for an SSC, as a general term and as it will be used in this rulemaking, refers to activities, processes, and/or controls that are performed or used in the design, installation, maintenance, and operation of structures, systems, or components as a means of (1) specifying and procuring SSCs that satisfy performance requirements; (2) verifying over time that performance is maintained; (3) controlling activities that could impact performance; and (4) providing assessment and feedback of results to adjust activities as needed to meet desired outcomes. Treatment includes, but is not limited to, quality assurance, testing, inspection, condition monitoring, assessment, evaluation, and resolution of deviations. The distinction between "treatment" and "special treatment" is the degree of NRC specification as to what must be

implemented for particular SSCs or for particular conditions.

Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Defense-in-depth is a philosophy used by the NRC to provide redundancy as well as the philosophy of a multiple-barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

A probabilistic approach to regulation enhances and extends the traditional deterministic approach by allowing consideration of a broader set of potential challenges to safety, providing a logical means for prioritizing these challenges based on safety significance, and allowing consideration of a broader set of resources to defend against these challenges. Until the accident at Three Mile Island (TMI), the NRC only used probabilistic criteria in specialized areas, such as for certain man-made hazards and for natural hazards (with respect to initiating event frequency). The major investigations of the TMI accident recommended that probabilistic risk assessment (PRA) techniques be used more widely to augment traditional nonprobabilistic methods of analyzing plant safety.

In contrast to the deterministic approach, PRAs address credible initiating events by assessing the event frequency. Mitigating system reliability is then assessed, including the potential for common cause failures. The probabilistic treatment goes beyond the single failure requirements used in the deterministic approach. The probabilistic approach to regulation is therefore considered an extension and enhancement of traditional regulation by considering risk in a more coherent and complete manner.

The primary need for improving the implementation of defense-in-depth in a risk-informed regulatory system is guidance to determine how many measures are appropriate and how good these should be. Instead of merely relying on bottom-line risk estimates, defense-in-depth is invoked as a strategy to ensure public safety given there exists both unquantified and unquantifiable uncertainty in engineering analyses

(both deterministic and risk assessments).

Risk insights can make the elements of defense-in-depth clearer by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of, or the necessity for, elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

The Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA) on August 16, 1995 (60 FR 42622). In the policy statement, the Commission stated that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that supports the NRC's traditional defense-in-depth philosophy. The policy statement also stated that in making regulatory judgments, the Commission's safety goals for nuclear power reactors and subsidiary numerical objectives (on core damage frequency and containment performance) should be used with appropriate consideration of uncertainties.

To implement this Commission policy, the staff developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1.174. This RG provided guidance on an acceptable approach to risk-informed decision-making consistent with the Commission's policy, including a set of key principles. These principles include:

- (1) Be consistent with the defense-in-depth philosophy;
- (2) Maintain sufficient safety margins;
- (3) Any changes allowed must result in only a small increase in core damage frequency or risk, consistent with the intent of the Commission's Safety Goal Policy Statement; and
- (4) Incorporate monitoring and performance measurement strategies.

Regulatory Guide 1.174 states that consistency with the defense-in-depth philosophy will be preserved by ensuring that:

- (1) A reasonable balance is preserved among prevention of accidents, prevention of barrier failure, and mitigation of consequences;
- (2) An over-reliance on programmatic activities to compensate for weaknesses