

Finally, part 21 establishes that a licensee or vendor should "immediately report" potential noncompliance or defects to the NRC in a telephonic "notification" (see § 21.3) within two (2) days of receipt of information identifying a noncompliance or defect in a basic component (see § 21.21(d)). In addition, part 21 requires that vendors/suppliers of basic components must make notifications to purchasers or licensees of a reportable noncompliance or defect within five (5) working days of completion of evaluations for determining whether noncompliance or defect constitutes a substantial safety hazard (see § 21.21(b)). Thus, Part 21 establishes a reporting scheme for immediate reporting of the most safety-significant noncompliances and defects, as contemplated by Section 206 of the ERA.

Section 50.69 would substitute a risk-informed approach for regulating nuclear power plant SSCs for the current deterministic approach. Therefore, it is necessary from the standpoint of regulatory coherence to determine: (1) What categories of SSCs (*i.e.*, RISC-1, RISC-2, RISC-3 and RISC-4) should be subject to Part 21 and § 50.55(e) reporting under proposed § 50.69, and whether changes to Part 21 and/or § 50.55(e) are necessary to ensure proper reporting of substantial safety hazards; and (2) the appropriate reporting obligations of licensees and vendors under proposed § 50.69, and whether changes to Part 21 and/or § 50.55(e) are necessary to impose the intended reporting obligations on these entities under proposed § 50.69.

III.4.1.1 RISC-1, RISC-2, RISC-3, and RISC-4 SSCs

After consideration of the underlying purposes of Section 206 and the risk-informed approach embodied in § 50.69 (which blends both deterministic and risk information), the Commission believes that RISC-1 SSCs should be subject to the reporting requirements in Part 21 and § 50.55(e) because of their high safety significance. The NRC should be informed of any potential defects or noncompliance with respect to RISC-1 SSCs, so that it may evaluate the significance of the defects or noncompliance and take appropriate action. The fact that properly-categorized RISC-1 SSCs in all likelihood fall within the Commission's definition of "basic components" and are currently subject to Part 21 and § 50.55(e) provides confirmation that the Commission's determination is prudent.

Similarly, the Commission believes that SSCs which are categorized as RISC-4 should continue to be beyond

the scope of, and not be subject to, Part 21 and § 50.55(e). SSCs properly categorized as RISC-4 have little or no risk significance, and it is highly unlikely that any significant regulatory action would be taken by the NRC based upon information on defects or instances of noncompliance in RISC-4 SSCs. Inasmuch as no regulatory purpose would be served by reporting for RISC-4 SSCs, the Commission proposes that RISC-4 SSCs should not be subject to part 21 or § 50.55(e). Again, the fact that SSCs properly categorized as RISC-4 do not otherwise fall within the definition of "basic component" and, therefore, are not subject to Part 21 and § 50.55(e), provides some confirmation of the prudence of the Commission's determination.

Thus, the most problematic issue from the standpoint of regulatory coherence, is determining the appropriate scope of reporting for RISC-2 and RISC-3 SSCs. For the reasons discussed below, the Commission proposes that neither RISC-2 nor RISC-3 SSCs be subject to part 21 and § 50.55(e) reporting requirements.

The Commission begins by considering the regulatory objective of Part 21 and § 50.55(e) reporting under Section 206, and believes that there are two parallel regulatory purposes inherent in these reporting schemes. The first objective is to ensure that the NRC is immediately informed of a potentially significant noncompliance or defect in supplied components (in the broad sense of "basic components" as defined in § 21.3), so that the NRC may make a determination as to whether such a safety hazard requires that immediate NRC regulatory action at one or more nuclear power plants be taken to ensure adequate protection to public health and safety or common defense and security. The second is to ensure that nuclear power plant licensees are immediately informed of a potentially significant noncompliance or defect in supplied components. Such reporting allows a licensee using such components to immediately evaluate the noncompliance or defect to determine if a safety hazard exists at the plant, and take timely corrective action as necessary. In both cases, the regulatory objective is limited to components which have the highest significance with respect to ensuring adequate protection to public health and safety and common defense and security, and whose failure or lack of proper functioning could create an imminent safety hazard such that immediate evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate

protection. In the context of a construction permit, the safety hazard is two-fold: First, that a non-compliance or defect could be incorporated into construction where it could never be detected; and second, that a noncompliance or defect would, upon initial operation and without prior indications of failure, create a substantial safety hazard.

The Commission believes that the regulatory objectives embodied in Part 21 and § 50.55(e) reporting remain the same regardless of whether the nuclear power plant is operating under the existing, deterministic regulatory system or the proposed alternative, risk-informed system embodied in § 50.69. In both cases, the reporting scheme should focus on immediate reporting to the NRC and licensee of potentially significant noncompliances and defects that could create a safety hazard requiring immediate evaluation and corrective action to ensure continuing adequate protection. Accordingly, in determining whether RISC-2 and RISC-3 SSCs should be subject to part 21 reporting, the Commission assessed whether failure or malfunction of these SSCs could reasonably lead to a safety hazard such that immediate evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate protection.

For RISC-2 SSCs, the Commission does not believe their failure or malfunction could reasonably lead to a safety hazard such that immediate licensee and NRC evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate protection. Although a RISC-2 SSC may be of significance for particular sequences and conditions, for the reasons discussed below, the Commission believes that no RISC-2 SSC, in and of itself, is of such significance that its failure or lack of function would necessitate immediate notification and action by licensees and the NRC.

The categorization process embodied in § 50.69 determines the relative significance of SSCs, with those in RISC-1 and RISC-2 being more significant than those in RISC-3 or RISC-4. This does not mean that any RISC-2 SSC would rise to the level of necessitating immediate action if defects were identified.

Those SSCs that are viewed as being of sufficient safety significance to require Part 21 reporting are RISC-1 SSCs. It is the capability provided by these RISC-1 SSCs for purposes of satisfying safety-related functional requirements that also leads to RISC-1 SSCs as being safety-significant, as these