

responsibilities under the AEA, as amended, including providing reasonable assurance of adequate protection of public health and safety or common defense and security.

The Commission does not believe that part 21 should apply to the early site permit holder after the early site permit has been issued, but before the holder has referenced the permit in a license application.² With one exception, the early site permit does not authorize any action by the holder with respect to the construction or operation of a nuclear power plant. The exception is when the early site permit authorizes the holder to conduct the site preparation activities permitted under 10 CFR 50.10(e)(1) (commonly referred to as limited work authorization-1, or LWA-1, activities). However, these activities are related to site clearing and preparation, and do not permit any construction (including subsurface preparation) for "structures, systems and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public." Thus, the conduct of LWA-1 activities do not appear to have any reasonable possibility of resulting in a "substantial safety hazard."

Furthermore, the inherent nature of an early site permit is site-specific and not susceptible to generic or wide-ranging applicability. For these reasons, the Commission proposes that part 21 should not apply to an early site permit holder until the permit is referenced by a license applicant.

Once an early site permit holder references the permit in a license application, the Commission believes that the holder should be subject to part 21. The Commission's safety review of a license application referencing an early site permit is limited in accordance with §§ 52.39 and 52.79 (proposed § 52.211), under the precept that the site parameters, terms, and conditions which define the envelope for safe siting of a nuclear power plant have been determined by the NRC in the early site permit proceeding. If the early site permit holder discovers a significant safety concern with respect

to its site (*e.g.*, that the specified site parameter for seismic acceleration is less than the projected acceleration due to new information), the concern should be reported to the NRC so that it may be considered in the review of the application referencing the early site permit. This reporting attains special importance given the Commission's proposal (see discussion in Section III.A.8 on referencing an early site permit) not to impose an updating requirement for early site permit information other than that related to emergency preparedness. Accordingly, the Commission concludes that the early site permit holder should be subject to part 21 once it references the permit in a license application.

The Commission believes that changes to part 21 are unnecessary to reflect these determinations with respect to early site permit applicants and holders. A licensee's reporting requirements in part 21 apply only with respect to "basic components" used or to be used in an NRC-licensed or otherwise regulated facility. The safety-related analyses and consulting services supplied to an applicant for an early site permit appear to fall within the definition of "basic component," in that they constitute "safety-related design [and] analyses * * * associated with component hardware" (See 10 CFR 21.3, "Basic component," paragraph (3)). Thus, part 21 could be interpreted as applying to the early site permit holder immediately upon the permit's issuance. However, there appears to be little reasonable likelihood of a "substantial safety hazard" unless and until the early site permit has been referenced by the permit holder in a license application. Once the early site permit has been referenced, the potential for a substantial safety hazard clearly exists if a known defect in site parameters, terms, or conditions defining the envelope for safe plant operation is not disclosed, and a plant is designed, constructed, and allowed to operate which does not reflect the actual limiting parameters and conditions of the site. Thus, no changes to part 21 are necessary to reflect the Commission's intent.

The Commission also proposes that part 21 apply to suppliers of safety-related analyses and services to an early site permit holder in the same manner and extent as part 21 applies to the early site permit holder. Such suppliers would be subject to part 21 only after the early site permit holder references the permit in a license application.

Design Certification Rules

Similar to the approach for early site permit applicants and holders, the Commission proposes that the requirements in part 21 should not apply to the applicant/vendor for a design certification (and/or its successors) during the pendency of its design certification application. During the pendency of the design certification application, the applicant/vendor would be required by 10 CFR 50.9, "Completeness and accuracy of information," to notify the Commission of any information having a "significant implication for public health and safety or the common defense and security" with respect to the matters covered in the application, pursuant to proposed § 52.111. Failure to abide by the completeness and accuracy requirements in § 50.9 would subject the applicant/vendor to potential criminal liability under § 52.113 (proposed § 52.403). In addition, under current § 52.9, the applicant for a design certification is subject to penalties for deliberate misconduct, including submission to the NRC of information known to be incomplete or inaccurate in some material aspect. Finally, during the pendency of a design certification application, the application has no operative effect with respect to issue resolution under current § 52.63 (proposed § 52.127); consequently, a design certification application itself could not result in a "substantial safety hazard" by virtue of the application being referenced in a nuclear power plant licensing proceeding. Therefore, the Commission does not believe that adopting the regulatory overlay of part 21 during the pendency of a design certification application is necessary to effectuate the Commission's regulatory responsibilities under the AEA, as amended, including providing reasonable assurance of adequate protection to public health and safety or common defense and security.

The Commission also believes that the reporting requirements in part 21 should not apply to the design certification applicant/vendor after the Commission issuance of a final design certification rule is referenced by at least one applicant/licensee (nor should either §§ 52.9 or 52.111 be modified to make them applicable to the design certification applicant/vendor). The Commission does not believe that a design certification rule would reasonably result in a "substantial safety hazard" so long as the design certification rule is not actually referenced in a license application (and

² The Commission would not permit a license applicant to reference an early site permit which it does not hold (or has rights to the permit contingent upon a NRC decision to issue a license whose application references the early site permit). To otherwise permit referencing of an early site permit by a non-holder would destroy the commercial value of the permit, and would prevent any entity from seeking an early site permit. This would frustrate the Commission's regulatory objective of providing early regulatory approval of siting, emergency preparedness, and environmental matters. Since the early site permit is a license, the relevant requirements of part 21 are those applicable to a licensee.