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NUCLEAR INNOVATION ALLIANCE

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Background

The Nuclear Innovation Alliance (NIA) is developing strategies and guidance to enable the efficient and effective licensing of advanced reactor technologies so that nuclear innovation can be put to work addressing national and global energy challenges. The NIA outlined key recommendations in its April 2016 report *Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing*.

One recommendation is that an applicant can use a staged approach to licensing to provide greater predictability and feedback. Figure 1 illustrates how existing mechanisms of the Nuclear Regulatory Commission (NRC) might be used to achieve this.

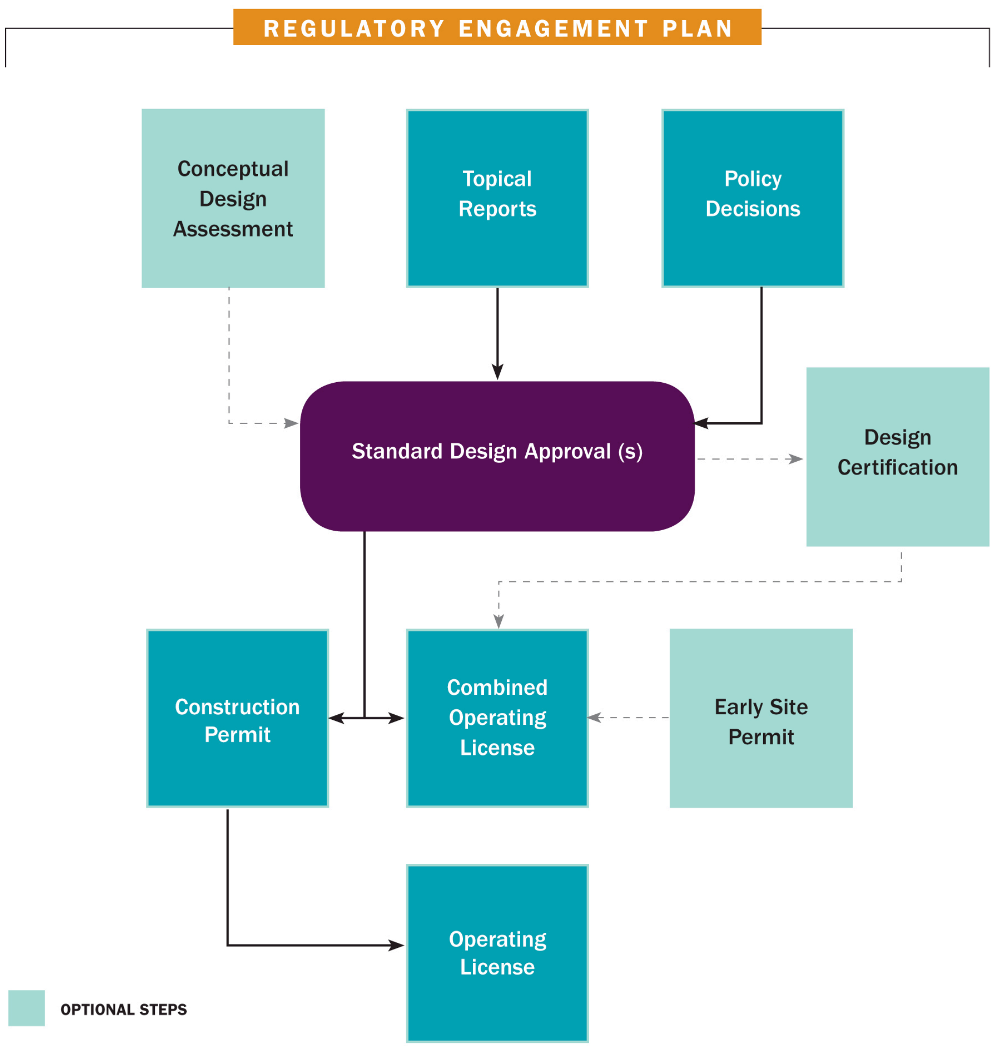

Figure 1: Elements of a Staged Licensing Approach

The standard design approval (SDA) can play a central role by enabling the review of "major portions" of a design. 10 CFR Part 52, Subpart E provides that an SDA may be "for either the final design for the entire reactor facility or the final design of major portions thereof," but does not define what constitutes "major portions."

In this report, the Nuclear Innovation Alliance is pursuing clarification of the meaning of "major portions" for an SDA under 10 CFR Part 52, Subpart E. A definition of "major portions" will make the SDA process more predictable for advanced nuclear technology developers. Further specification will be needed, but this report can serve as a foundation for more detailed guidance.

For a reactor developer intending to pursue an SDA for other than "the entire reactor facility," the following factors should be considered in defining "major portions."

1. Purpose/Benefit

The first question developers should address for their respective designs is what an SDA is intended to accomplish. From *A Regulatory Review Roadmap for Non-Light Water Reactors* (NRC, Oct 2016, ML16291A248):

> "A designer may submit a proposed preliminary or final standard design for a major portion of a nuclear power plant to the NRC for review. Unlike a standard design certification, the SDA documents staff conclusive findings but does not prevent issues resolved by the design review process from being reconsidered during a rulemaking for a design certification or during hearings associated with a construction permit or combined license application. An SDA can nevertheless be a useful tool within a licensing project plan in combination with preapplication interactions held during the conceptual and preliminary design processes. The SDA and related safety evaluation report documents staff findings, involves ACRS reviews, and provides a reference for subsequent applications. As such, the SDA can provide incremental progress towards the licensing or certification of a non-LWR design in what can be referred to as a 'staged-licensing process.'"

An SDA for major portions of a facility could be useful as part of the concept of "staged licensing," i.e., to demonstrate incremental progress on a limited portion of the design (with consequential reduction in licensing risk).

An SDA could serve to reduce initial development costs, i.e., by enabling an early, partial licensing determination and deferring NRC review of other portions of the plant to subsequent licensing steps (e.g., construction permit or combined license application) or where excluded portions are significantly site- or purpose-specific (e.g., process heat, desalination, or 50-Hz electrical generation).

An SDA could also be useful for achieving approval for the portion of a design for purposes such as: a developer pursuing an SDA in support of future customers planning deployment via a construction permit (note that the construction permit application would be required to address the entire design); deployment outside the US; deployment for demonstration purposes; or deployment (e.g., not involving electricity production) different from subsequent purposes.

These are several examples of scenarios in which an SDA might be sought. The intended purpose for an SDA will impact the scope of the "major portions" for which approval is sought.

2. Scope

"Major portions" are not defined explicitly in 10 CFR Part 52, so the SDA applicant is required to identify and justify the scope of the design for which approval is sought. The absence of a definition affords flexibility in defining this scope.

The extent of design required for a design certification (i.e., an "essentially complete design," or a design for essentially the entire plant scope) is not required for an SDA. As discussed above, the reason an SDA is sought could influence the scope of "major portions" for a given application. For example, an SDA could be sought for the structures, systems, and components (SSCs) associated with the "nuclear island," and these SSCs might be completed to a level of detail approximating that for a DCA. Alternatively, if the motivation for an SDA is early staff review of portions of the plant with more programmatic risk (e.g., because of novel design for fuel, security, seismic isolation, etc.), a different set of SSCs might be pursued, with level of detail varying as a function, for example, of the extent of interfacing systems or boundary conditions.

Whatever the scope selected for an SDA, developers should recognize the implications (e.g., future licensing and redesign risk) of a staff review and design that may be less fully integrated than it would be for an "essentially complete design." Developers also will need to understand the need to provide information on SSCs outside the "major portions" (e.g., functional or physical boundary conditions) so as to assess their risk significance to the portions for which approval is sought.

3. Criteria for Selection

The criteria used by the applicant to establish the scope of "major portions" are dependent, in part, on the scope of the approval being sought, which may, in turn, depend on the anticipated use of the SDA in subsequent license applications. Some possible examples are discussed below.

- If an applicant's intent is to seek approval of a significant portion of the plant's safety basis, the scope of the "major portions" for which approval is sought likely will need to include as many functional safety requirements as can be identified at that stage of design, which naturally will tend toward a broader scope of design.

- For a more limited "portion of the design," where only a limited portion of the plant's safety basis is presented in the SDA, the scope of approval would be limited accordingly, and a different set of boundary conditions would apply to the CP, DC, or COL application. This approach might apply where a set of SSCs carries a high regulatory risk that influences the business case for development.

- An SDA is independent of a site. An ESP or COL is site-specific and includes an environmental impact statement, whereas site information in an SDA – like a DCA – would be based on enveloping the site characteristics under which the design could be sited. A "major portion" could be defined, then, for a site-related parameter such as ground motion response spectra and certain aspects of structural design to ensure early NRC concurrence on novel techniques.

- "Major portions" could be used to seek approval of systems not traditionally captured within the scope of safety-related SSCs, such as molten salt processing systems (with or without fuel in the salt) to manage tritium, noble gases, etc. Waste or new fuel processing could be standardized as well, as could certain aspects of security design.

4. Interfacing Systems and Boundary Conditions

As discussed elsewhere in this paper, establishment of interfacing systems and boundary conditions is a critical consideration in defining "major portions." When an SDA is approved by the NRC staff, it will necessarily be associated with various conditions associated with those assumed interfacing boundary conditions, which in turn will have to be demonstrated to be satisfied if the SDA is incorporated into a subsequent CPA, DCA, or COLA. Additional guidance on establishment of interfacing boundary conditions as well as demonstration/ satisfaction of those conditions is beyond the scope of this document but should be addressed in future work.

5. Context

Recent discussions between industry and NRC staff regarding "staged licensing" have reinforced the concept that interactions with the NRC staff follow a continuum (see example in Figure 2), from early pre-application interactions, through progressively more detailed submittals, eventually resulting in NRC approval if successful.

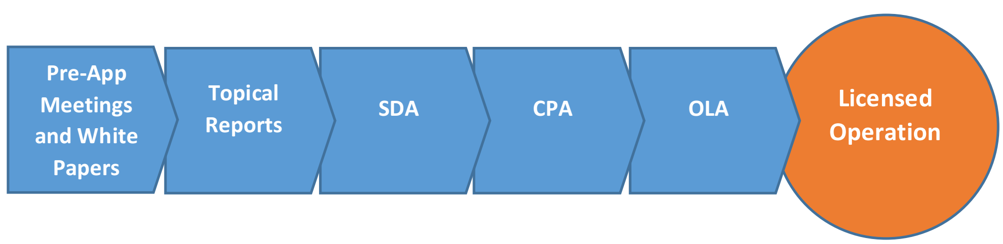

Figure 2: Example of NRC Interaction Continuum (Simplified)

As discussed above, an SDA can play a role in "staged licensing." As there is flexibility in defining "major portions," there is also flexibility in how much design information an SDA contains and in how an SDA is used. Where preliminary and conceptual design information are used, the applicant bears all programmatic risk in this regard (as is the case for any changes to design information that is the subject of NRC approval). An SDA should contain sufficient detail to support NRC safety conclusions at the level being sought. At least three "categories" for used of the SDA are envisioned:

a. The SDA can be thought of as similar to a design certification (DC), but covering fewer SSCs. In this situation the level of design detail for the selected "major portions" would be comparable to a DC application, and the interface requirements would be described in a manner analogous to a DC application with a significant amount of conceptual design information (CDI). See section 10.a. below for further explanation.

b. An SDA could be developed that sets forth major portions associated with concepts or design aspects that are novel relative to existing US technology. In this example, the SSCs might not be as fully developed as for a DC application; in this case, the NRC staff approval (i.e., safety evaluation report, or SER) also would be less substantive, but still could be useful (e.g., an NRC SER that approves fundamental operational and safety strategies would enable the design to proceed with reduced licensing risk). The corresponding NRC approval could incur downstream licensing risk in the event of changes to that design (e.g., to the extent an SDA contains "preliminary" design information, the risk of future changes is higher than if design information is "final"). In this case the applicant should consider whether a topical report is a preferable mechanism. See section 8.d. below.

c. The "mixed" category could reflect aspects of the two categories above. For example, an SDA could cover preliminary design information for an essentially complete design, equivalent to the level of design information and detail required for a construction permit, but without site specific considerations.

Preapplication interactions to ensure NRC understanding and receptiveness to the proposed scope will be essential to defining "major portions."

6. Regulatory Basis

The SDA is defined in 10 CFR Part 52, Subpart E. Important excerpts from 10 CFR Part 52 follow in Appendix A of this document.

7. Precedent

An SDA has not been sought since the process was defined in its current form in 2007. Lack of precedent or clarity in definition is also discussed earlier in this report. The regulatory precedent for 10 CFR Part 52 Subpart E is 10 CFR Part 50 Appendix O, which was first created in January 1975 to codify the Atomic Energy Commission's 1972 "Policy Statement on Standardization of Nuclear Power Plants."[1] The 10 CFR Part 50 Appendix O process was used to review designs for nuclear steam supply systems, balance of plant systems, a nuclear island, and a turbine island, but there is no regulatory precedent for using the SDA process for smaller portions of a plant design.[2,3] While past use of 10 CFR Part 50 Appendix O and supporting documentation suggest that initial interpretations of "major portions" applied

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[1] NRC Accession No. 8312270279.
[2] SECY-77-185A.
[3] White, R. Patrick. "The Historical Basis for Defining 'Major Portions' in 10 CFR 52 Subpart E."

principally to nuclear steam supply systems and balance of plant systems, it is possible that the term "major portions" was left undefined in order to afford flexibility to applicants in standardizing different portions of their designs.[4]

8. Practicality

In determining whether an SDA is desirable, and in defining "major portions," applicants will want to bear in mind various practicalities, including:

a. Is the amount of information required to support the desired NRC safety finding so large that it would be nearly as straightforward simply to pursue a full application, e.g., CP or DC?
b. In that an SDA may serve to partition the staff's review, how will other plant design issues be resolved if not as part of the SDA; what programmatic risks are incurred as a result?
c. Is the level of plant information and level of detail in design development for the "major portions" sufficient to support the desired NRC safety finding?
d. Is the extent of staff review being requested sufficiently discrete and compartmentalized that one or more topical reports could accomplish the same goal?
e. Can the SDA provide risk reduction or timing advantages (reduction in programmatic risk) in the design, manufacturing, or licensing process that are compatible with the program development needs?
f. While an SDA could yield an early, cost-effective licensing determination, total cost and schedule for NRC review and approval of an essentially complete design for DC or COL could increase. Is the additional overall cost of review justified?

9. Other Risks and Mitigation

a. An SDA results in an SER but not a DC rule, resulting in less finality and comparatively greater downstream licensing risk (see 10 CFR § 52.145 and § 52.79(c)(1)). This risk includes the potential loss of continuity in reviewers (e.g., new/different reviewers raising different questions in a subsequent review). However, this risk is mitigated by:

    i. The substantial NRC staff and Advisory Committee on Reactor Safeguards (ACRS) review that would otherwise be deferred owing to insufficient "complete design" development[5];

    ii. An SER, which provides substantial confidence in the NRC's position;

    iii. Constraints on the Staff regarding reinterpreting the SER absent a significant safety issue arising (as in 10 CFR § 50.54(f)); and

    iv. The ability to reference an SDA in a construction permit, DC or COL

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[4] Ibid.
[5] This discussion reflects the use of "complete" in terms of the extent of a plant's design (i.e., a "complete" plant in context of a DCA refers to the entire plant being designed), not necessarily the level of detail for any given SSC.

application, and the finality of the staff's review (i.e., in the absence of significant new information).

b. As discussed briefly above, a staged licensing approach including one or more SDAs can be more expensive overall if, for instance, a DC is sought later. This is mitigated by earlier NRC approval of "major portions," and by the possibility that an SDA may obviate the need for a DC, or may alone be sufficient for the designer's commercial purposes.

10. Analogues

Various analogues exist that could inform an applicant's definition of "major portions," as discussed below. These analogues can be explored in greater detail as the next step in developing industry/NRC guidance.

a. 10 CFR §52.47(a)(24) states that a DCA must include "A representative conceptual design for those portions of the plant for which the application does not seek certification, to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements in paragraph (a)(25) of this section." The use of CDI within a DC application could be considered analogous to deferring SSCs (i.e., not including in "major portions").

b. Similarly, 10 CFR §52.47(a)(25) states that a DCA must include "interface requirements to be met by those portions of the plant for which the application does not seek certification. These requirements must be sufficiently detailed to allow completion of the FSAR." Specifying interface requirements here is analogous to establishment of boundary conditions for an SDA.

c. COL information items and Inspections, Tests, Analyses and Acceptance Criteria (ITAAC): these mechanisms provide for COL applicants or licensees to demonstrate compliance with assumptions made in the DC; similarly, if conservative assumptions are made about SSCs not included with "major portions," it is reasonable to presume some sort of reconciliation/validation of those assumptions would be required of a subsequent CP/operating license or COL applicant.

d. Plant parameter envelope: this option for an early site permit is analogous to possible assumptions regarding SSCs not included within "major portions." Likewise, a DC applicant is required to establish the site parameters postulated for a design, providing a similar analogue.

e. Major features of emergency plan: NRC guidance on defining "major features" of a partial emergency plan submitted as part of an early site permit can provide insight in subsequent efforts toward establishing boundary conditions.

f. Topical Reports: ample experience with topical reports can provide insight into establishing the scope of a submittal and evaluation that is not "the complete design."

g. Design-Specific Review Standard (DSRS): the recent revision of NUREG-0800 Chapter 7, via the mPower and NuScale DSRS, may provide insight into how to use criteria-based conditions in place of design information (i.e., for SSCs not within "major portions").

Appendix: Excerpts from 10 CFR Part 52

Standard design approval *or* design approval *means an NRC staff approval, issued under subpart E of this part, of a final standard design for a nuclear power reactor of the type described in 10 CFR 50.22. The approval may be for either the final design for the entire reactor facility* <u>*or the final design of major portions thereof*</u>*. [§52.1]*

§ 52.133 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design approval from the NRC staff separately from an application for a construction permit filed under 10 CFR part 50 or a combined license filed under subpart C of this part. <u>*An applicant for a construction permit or combined license may reference a standard design approval.*</u>

(b) Subpart B of this part governs the certification by rulemaking of the design of a nuclear power plant. <u>*Subpart B may be used independently of the provisions in this subpart.*</u>

§ 52.137 Contents of applications; technical information.

If the applicant seeks review of a major portion of a standard design, <u>*the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought*</u>*.*

(a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility, or major portion thereof, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification, upon which the requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Items such as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of

radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release 9 from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem 10 total effective dose equivalent (TEDE); and

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for watercooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria; and

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with adequate margin for safety;

(4) An analysis and evaluation of the design and performance of SSC with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of 10 CFR 50.46 and 50.46a;

(5) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter;

(6) The information required by § 20.1406 of this chapter;

(7) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(8) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii),

(f)(2)(ix), and (f)(3)(v) of 10 CFR 50.34(f);

(9) For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP is not a substitute for the regulations, and compliance is not a requirement;

(10) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e);

(11) The information pertaining to design features that affect plans for coping with emergencies in the operation of the reactor facility or a major portion thereof;

(12) An analysis and description of the equipment and systems for combustible gas control as required by § 50.44 of this chapter;

(13) The list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(14) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in 10 CFR 50.60 and 50.61;

(15) Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram (ATWS) events in § 50.62; (16) The coping analysis, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;

(17) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68(b)(2)–(b)(4);

(18) A description and analysis of the fire protection design features for the standard plant necessary to comply with part 50, appendix A, GDC 3, and § 50.48 of this chapter;

(19) A description of the quality assurance program applied to the design of the SSCs of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 were satisfied;

(20) The information necessary to demonstrate that the standard plant complies with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(21) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG–0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design;

(22) The information necessary to demonstrate how operating experience insights have been incorporated into the plant design;

(23) For light-water reactor designs, a description and analysis of design features for the prevention and mitigation of severe accidents, e.g., challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass;

(24) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear power plant; and

(25) A description of the design-specific probabilistic risk assessment and its results.

(26) For applications for standard design approvals which are subject to 10 CFR 50.150(a), the information required by 10 CFR 50.150(b).

(b) An application for approval of a standard design, which differs significantly from the light-water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions, must meet the requirements of 10 CFR 50.43(e).

§ 52.145 Finality of standard design approvals; information requests.

(a) <u>An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any individual facility license application that incorporates by reference a standard design approved in accordance with this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause</u>.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under part 2 of this chapter.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, <u>information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information</u>. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.147 Duration of design approval.

<u>A standard design approval issued under this subpart is valid for 15 years from the date of issuance and may not be renewed</u>. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a construction permit or an operating license under part 50 or a combined license or manufacturing license under part 52 that references the final design approval and is docketed before the date of expiration of the design approval.

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