

OTHER CHANGE CONTROL PROCESSES APPLICABLE TO TIER 2* INFORMATION

Executive Summary

The Tier 2* change control process in Section VIII.B.6 of the design certification rule for the AP1000 in 10 CFR Part 52, Appendix D, requires every change to information designated as Tier 2* be subject to NRC approval. The purpose of this paper is to evaluate whether there currently exist other appropriate methods for controlling changes to Tier 2* information for the AP1000. This paper demonstrates, given the existence of other change controls, there is no need to apply the stringent Tier 2* change control process to ensure changes which adversely affect safety are subject to NRC review and approval.

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OTHER CHANGE CONTROL PROCESSES APPLICABLE TO TIER 2* INFORMATION

1.0 Purpose

The Tier 2* change control process in Section VIII.B.6 requires every change to information designated as Tier 2* be subject to NRC approval through a license amendment. The purpose of this paper is to evaluate whether there currently exist other appropriate methods for controlling changes to Tier 2* information for the AP1000.

2.0 Regulatory and Procedural References

Tier 2* information is a subset of Tier 2 of the Design Control Document (DCD) for a design certification. Section VIII.B.6.a of 10 CFR Part 52, Appendix D, states “[a]n applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval.” There are separate change control processes for Tier 2 and Tier 2* information in the design certification rules, including Section VIII of the design certification rule for the AP1000 in Appendix D to 10 CFR Part 52. The following sections identify the change control process for Tier 2 and Tier 2* information.

2.1 50.59-like Change Process for Tier 2 Information (10 CFR 52, Appendix D, Section VIII)

The change control process for Tier 2 information for the AP1000 is contained in Section VIII.B.5 of Appendix D to 10 CFR Part 52. Because this process is similar to the change control process for final safety analysis reports in 10 CFR 50.59, the Tier 2 change control process is often called the “50.59-like change process.”

Section VIII.B.5 contains the following provisions related to the Tier 2 change control process. If the requirement for prior NRC approval for departures to Tier 2* information were to be removed, the information which is currently subject to the Tier 2* change control process would be subject to the Tier 2 change control process.

VIII.B.5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the TS, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

VIII.B.5.b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by 10 CFR 52.47(a)(28) to address 10 CFR 50.150, requires a license amendment if it would:

- (1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

- (2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;
- (3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;
- (4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;
- (5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;
- (6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;
- (7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or
- (8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

VIII.B.5.c. A proposed departure from Tier 2 affecting resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

- (1) There is a substantial increase in the probability of an ex-vessel severe accident such that a particular ex-vessel severe accident previously reviewed and determined to be not credible could become credible; or
- (2) There is a substantial increase in the consequences to the public of a particular ex-vessel severe accident previously reviewed.

The term “departure from a method of evaluation” as used in Section VIII.B.5.b.8 above has a specific definition, as provided in Section II.G of the design certification rule. That definition is as follows:

10 CFR 52, Appendix D, Section II.G. *Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses* means:

- 1. Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or
- 2. Changing from a method described in the plant-specific DCD to another method unless that method has been approved by the NRC for the intended application.

2.2 Tier 2* Change Control Process (10 CFR 52, Appendix D, Section VIII)

The change control process for Tier 2* information for the AP1000 is contained in Section VIII.B.6 of Appendix D to 10 CFR Part 52. Section VIII.B.6 contains the following provisions related to the Tier 2* change control process.

VIII.B.6.b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burn-up.
- (2) Fuel principal design requirements.
- (3) Fuel criteria evaluation process.
- (4) Fire areas.
- (5) Reactor coolant pump type.
- (6) Small-break loss-of-coolant accident (LOCA) analysis methodology.
- (7) Screen design criteria.
- (8) Heat sink data for containment pressure analysis.

VIII.B.6.c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except under paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are subject to the departure provisions in paragraph B.5 of this section.

- (1) Nuclear Island structural dimensions.
- (2) American Society of Mechanical Engineers Boiler & Pressure Vessel Code (ASME Code) piping design and welding restrictions, and ASME Code Cases.
- (3) Design Summary of Critical Sections.
- (4) American Concrete Institute (ACI) 318, ACI 349, American National Standards Institute/American Institute of Steel Construction (ANSI/AISC)–690, and American Iron and Steel Institute (AISI), "Specification for the Design of Cold Formed Steel Structural Members, Part 1 and 2," 1996 Edition and 2000 Supplement.
- (5) Definition of critical locations and thicknesses.
- (6) Seismic qualification methods and standards.
- (7) Nuclear design of fuel and reactivity control system, except burn-up limit.
- (8) Motor-operated and power-operated valves.
- (9) Instrumentation and control system design processes, methods, and standards.
- (10) Passive residual heat removal (PRHR) natural circulation test (first plant only).

- (11) Automatic depressurization system (ADS) and core make-up tank (CMT) verification tests (first three plants only).
- (12) Polar crane parked orientation.
- (13) Piping design acceptance criteria.
- (14) Containment vessel design parameters, including ASME Code, Section III, Subsection NE.
- (15) Human factors engineering.
- (16) Steel composite structural module details.

2.3 Other Applicable Change Control Processes

In addition to the change control processes related to Tier 2 and Tier 2* information, there are other relevant change control processes. For example:

- Section VIII.A of the design certification rules requires NRC approval for any changes related to Tier 1 information (which is derived from Tier 2 information).
- 10 CFR 52.98, and 10 CFR 50.59 and 50.90, require a license amendment for any changes in the Technical Specifications attached to a license or the license conditions.

3.0 Screening Questions Based on NEI 96-07 for Tier 2 Departures

NEI 96-07, “Guidelines for 10 CFR 50.59 Implementation,” and NEI 96-07, Appendix C, “Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52,” provides guidance for implementing the 50.59-like change process. Pursuant to that guidance, a licensee should engage in a multi-step process to determine whether a departure from Tier 2 needs a license amendment. One of the first steps in the process is to conduct a “screen” to determine whether a full evaluation against the criteria in Section VIII.B.5.b and c is warranted. Typical questions asked during the screening are as follows:

Does the activity to which this screening applies represent:

1. Yes No A modification, addition to, or removal of a structure, system, or component (SSC) such that a design function as described in the plant-specific DCD, or Updated FSAR is adversely affected?
2. Yes No A change to procedures or method of control that adversely affects the performance of a design function as described in the plant-specific DCD, or Updated FSAR?
3. Yes No An adverse change to a method of evaluation or use of an alternate method of evaluation from that described in the plant-specific DCD, or Updated FSAR that is used in establishing design bases or in the safety analysis?
4. Yes No A test or experiment not described in the plant-specific DCD, or Updated FSAR which is outside the reference bounds of the design basis as described in the licensing document or is inconsistent with the analyses or descriptions described in the licensing document?
5. Yes No A modification, addition to, or removal of a structure, system, or component (SSC) such that a design feature credited in the ex-vessel severe accident assessment in the plant-specific DCD, or Updated FSAR is adversely affected?

If all of these questions are answered “No”, the change may be screened and a full evaluation against the criteria in VIII.B.5.b and c does not need to be performed. If any question is answered “Yes”, a full evaluation is needed.

4.0 Review of Tier 2* Matter

The following table lists each Tier 2* item for the AP1000, and provides a discussion of regulatory provisions other than the Tier 2* change control process which provides sufficient controls to ensure any safety significant changes to the Tier 2* information would be subject to prior NRC approval.

The Tier 2 references in this table are based upon AP1000 DCD Rev. 19 Table 1-1.

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
b.1	Maximum fuel rod average burn-up.	4.3.1.1.1	As provided in Section 4.3.7 of NEI 96-07, fuel burnup limits are one of the design basis limits for the fuel cladding barrier. Any change in the limit would require a license amendment in accordance with Section VIII.B.5.b.7 of the design certification rule.
b.2	Fuel principal design requirements.	4.1.1	<p>Many of the fuel principal design requirements are also design basis limits. As provided in Section 4.3.7 of NEI 96-07, changes in the fuel design basis limits for the fuel cladding barrier would require a license amendment in accordance with Section VIII.B.5.b.7 of the design certification rule.</p> <p>To the extent the fuel principal design requirements are not limits themselves, changes in the requirements would need to be evaluated to confirm they do not result in a design basis limit being exceeded or altered.</p>
b.3	Fuel criteria evaluation process.	Table 1.6-1 4.1.3 4.2 4.2.1 4.2.1.1.2 4.2.1.1.3 4.2.1.5 4.2.1.6	Some of the Tier 2* information pertains to the design basis limits for the fuel. As provided in Section 4.3.7 of NEI 96-07, any change in the limits would require a license amendment in accordance with Section VIII.B.5.b.7 of the design certification rule. To the extent the fuel design parameters are not limits themselves, changes in the parameters would need to be evaluated to confirm they do not result in a design basis limit

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		4.2.3 4.2.6 4.3.1 4.3.1.1.1 4.3.5 4.4.8	<p>being exceeded or altered.</p> <p>Some of the Tier 2* information consists of methods of evaluation used in establishing the design bases or in the safety analyses. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p>
b.4	Fire areas	Figure 9A-1 Figure 9A-2 Figure 9A-3 Figure 9A-4 Figure 9A-5	<p>Changes to fire areas would need to be evaluated to determine the impact on accidents and malfunctions of SSCs. Depending upon the results of such an evaluation, several of the criteria in Section VIII.B.5.b of the design certification rule could be affected.</p> <p>Additionally, Table 3.3-3 of Tier 1 identifies fire areas and their associated Class 1E divisions. To the extent a change in a fire area represents a departure from that Table or associated Targeted ITAAC #1, it would require prior NRC approval pursuant to Section VIII.A.4 of the design certification rule.</p>
b.5	Reactor coolant pump type	5.4.1.2.1	<p>Any change in the reactor coolant pump (RCPs) information designated as Tier 2* would need to be evaluated to determine whether it would result in more than a minimal increase in likelihood of a malfunction of the pump. If yes, the change would require prior NRC approval pursuant to Section VIII.B.5.b.2 of the design certification rule.</p> <p>Additionally, Tier 1 Section 2.1.2 discusses some of the attributes of the RCPs. To the extent a change in a departure from those attributes, it would require prior NRC approval pursuant to Section VIII.A.4 of the design</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
			certification rule.
b.6	Small-break loss-of-coolant accident (LOCA) analysis methodology	15.6.5.4B.2.2 15.6.5.4B.2.3	The Tier 2* information pertains to methods of evaluation used in establishing the design bases or in the safety analyses. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.
b.7	Screen design criteria	6.3.2.2.7.1	<p>Some of this Tier 2* information pertains to methods of evaluation used in establishing the design bases or in the safety analyses. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>Most of the Tier 2* information pertains to design criteria on insulation and loose material which could clog the sump screens. Any change to one of the criteria would need to be evaluated for impact on performance of the passive core cooling system. To the extent the function of the passive core cooling system is adversely affected by the change in the design criteria, it is likely the change would require a license amendment pursuant to several of the criteria in Section VIII.B.5.b of the design certification rule.</p>
b.8	Heat sink data for containment	Table 6.2.1.1-10	Any change to the heat sink data would need to be evaluated for impact on the containment pressure. If the containment pressure limit is exceeded or

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
	pressure analysis		altered as a result of the change, it would require a license amendment pursuant to Section VIII.B.5.b.7 of the design certification rule, as discussed in Section 4.3.7 of NEI 96-07.
c.1	Nuclear Island structural dimensions	3.7.1.4 Table 3.7.1-2 Figure 3.7.1-14 3.7.2 Figure 3.7.2-12	<p>Much of the Tier 2* information is also contained in Tier 1 Tables 3.3-1 and 3.3-5. Any change in that Tier 1 information or associated Target ITAAC #1 would require prior NRC approval pursuant to Section VIII.A.4 of the design certification rule.</p> <p>With respect to the remaining information, minor departures in those dimensions which do not affect the safety functions of the structures could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the structures would require prior NRC approval pursuant to several of the criteria in Section VIII.B.5.b.</p>
c.2	American Society of Mechanical Engineers Boiler & Pressure Vessel Code (ASME Code) piping design and welding restrictions, and ASME Code Cases	3.8.2.2 3.8.2.5 3.9.1.1 3.9.1.3 3.9.3.1.2 3.9.3.1.3 3.9.3.1.4 3.9.3.1.5 3.9.3.3 3.9.3.3.1 3.9.3.3.3 3.9.3.4 3.9.3.4.2 3.9.3.4.3 3.9.3.5	<p>In general, this Tier 2* information involves methods of evaluation used in establishing the design bases for piping systems. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>Additionally, any exceptions to the ASME Code would be subject to the change control process in 10 CFR 50.55a.</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		3.9.8.2 5.2.1.1 Table 5.2-3 5.2.1.2 3.7.3.2	
c.3	Design Summary of Critical Sections	3.8.3.5.8.1 3.8.3.5.8.2 3.8.3.5.8.3 Table 3.8.3-3 Table 3.8.3-4 Table 3.8.3-5 Table 3.8.3-6 Table 3.8.3-7 Figure 3.8.3-1 Figure 3.8.3-2 Figure 3.8.3-8 Figure 3.8.3-14 Figure 3.8.3-15 Figure 3.8.3-17 Figure 3.8.3-18 3.8.4.1.1 3.8.4.5.4 3.8.4.5.5 3.8.4.5.5.5 3.8.4.6.1.1 3.8.4.6.1.2 3.8.4.6.1.3 Figure 3.8.4-2 Figure 3.8.4-4 3.8.5.1 3.8.5.4 3.8.5.4.4 Table 3.8.5-3	<p>Some of the Tier 2* information pertains to methods of evaluation. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in the element of the method would require NRC approval unless the results of the analysis are the same or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>Other Tier 2* information involves dimensions. Some of that information is also contained in Tier 1 Tables 3.3-1 and 3.3-5. Any change in that Tier 1 information or associated Target ITAAC #1 would require prior NRC approval pursuant to Section VIII.A.4 of the design certification rule. Minor departures in those dimensions which are not in Tier 1 and which do not affect the safety functions of the structures could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the structures would require prior NRC approval pursuant to several of the criteria in Section VIII.B.5.b.</p> <p>As discussed in c.4, the Tier 2* information includes ACI-318, ACI-349, and other codes and standards applicable to the design and construction of structures. Given that information (which is more safety significant than the critical sections), it is not necessary to designate the critical sections as Tier 2*.</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		App 3H.1 App 3H.2.1 App 3H.3 App 3H.3.1 App 3H.3.2 App 3H.3.3 App 3H.3.4 App 3H.4 App 3H.4.1 App 3H.5 App 3H.5.1 App 3H.5.1.1 App 3H.5.1.2 App 3H.5.1.3 App 3H.5.1.4 App 3H.5.2 App 3H.5.2.1 App 3H.5.2.2 App 3H.5.3 App 3H.5.3.1 App 3H.5.4 App 3H.5.5 App 3H.5.5.1 App 3H.5.6 App 3H.5.6.1 App 3H.5.6.2 App 3H.5.6.3 App 3H.5.7.1 App 3H.5.7.2 Table 3H.5-1 Table 3H.5-2 Table 3H.5-3 Table 3H.5-4	

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		Table 3H.5-5 Table 3H.5-6 Table 3H.5-7 Table 3H.5-8 Table 3H.5-9 Table 3H.5-10 Table 3H.5-11 Table 3H.5-12 Table 3H.5-13 Table 3H.5-14 Figure 3H.2-1 Figure 3H.5-1 Figure 3H.5-2 Figure 3H.5-3 Figure 3H.5-4 Figure 3H.5-5 Figure 3H.5-6 Figure 3H.5-7 Figure 3H.5-8 Figure 3H.5-9 Figure 3H.5-10 Figure 3H.5-11 Figure 3H.5-12 Figure 3H.5-16 3.8.7 3H.5.8	
c.4	American Concrete Institute (ACI) 318, ACI 349, American National Standards Institute/American Institute of Steel Construction (ANSI/AISC)–690, and	3.8.3.2 3.8.3.5 3.8.4.2 3.8.4.4.1 3.8.4.5 3.8.4.5.1 3.8.4.5.2	The Tier 2* information includes methods of evaluation used in establishing the design bases. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
	American Iron and Steel Institute (AISI), "Specification for the Design of Cold Formed Steel Structural Members, Part 1 and 2," 1996 Edition and 2000 Supplement	3.8.5.5 Table 3.8.4-1 Table 3.8.4-2	by NRC for the intended application. The Tier 2* information also includes requirements related to design and fabrication of structures. Minor departures in those requirements (e.g., minor changes in dimensions) which do not affect the safety functions of the structures could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the structures would require prior NRC approval pursuant to several of the criteria in Section VIII.B.5.b.
c.5	Definition of critical locations and thicknesses	3.8.3.1 3.8.3.1.3 Table 3.8.3-3	The Tier 2* information involves dimensional requirements related to structures. Minor departures in those requirements (e.g., minor changes in dimensions) which do not affect the safety functions of the structures could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the structures would require prior NRC approval pursuant to several of the criteria in Section VIII.B.5.b. As discussed in c.4, the Tier 2* information includes ACI-318, ACI-349, and other codes and standards applicable to the design and construction of structures. Given that information (which is more safety significant than the critical locations and thicknesses), it is not necessary to designate the critical locations and thicknesses as Tier 2*.
c.6	Seismic qualification methods and standards	3.10.1.1 3.7.2.3.3 3.7.2.14 3.7.3.2 3.7.3.5 3.7.3.5.1 3.7.3.5.2 3.7.3.6	The Tier 2* information generally involves methods of evaluation used in establishing the design bases, and the results of the evaluations. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		3.7.3.7 3.7.3.7.1.1 3.7.3.7.1.2 3.7.3.7.2 3.7.3.8 3.7.3.8.1 3.7.3.8.2.1 3.7.3.8.2.2 3.7.3.8.3 3.7.3.8.4 3.7.3.9 3.7.3.11 3.7.3.12 3.7.3.13 3.7.3.13.4 3.7.3.13.4.1 3.7.3.13.4.2 3.7.3.13.4.3 3.7.3.15 3.7.3.17 Table 3.7.1-1 App 3G.4.3.3 Figure 3G.4-5X Figure 3G.4-5Y, Figure 3G.4-5Z Figure 3G.4-6X Figure 3G.4-6Y Figure 3G.4-6Z Figure 3G.4-	Additionally, numerous ITAAC require SSCs be designed to withstand applicable loads, including seismic loads. Any departure from those ITAAC would require prior NRC approval in accordance with Section VIII.A.4 of the design certification rule.

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		7X Figure 3G.4-7Y Figure 3G.4-7Z Figure 3G.4-8X Figure 3G.4-8Y Figure 3G.4-8Z Figure 3G.4-9X Figure 3G.4-9Y Figure 3G.4-9Z Figure 3G.4-10X Figure 3G.4-10Y Figure 3G.4-10Z	
c.7	Nuclear design of fuel and reactivity control system, except burn-up limit	Table 4.3-1 Table 4.3-2 Table 4.3-3	<p>As provided in Section 4.3.7 of NEI 96-07, in general the fuel principal design requirements are part of the design basis limits for the fuel cladding barrier. Any change in the limits would require a license amendment in accordance with Section VIII.B.5.b.7 of the design certification rule.</p> <p>To the extent the fuel principal design requirements are not limits themselves, changes in the requirements would need to be evaluated to confirm they do not result in a design basis limit being exceeded or altered.</p>
c.8	Motor-operated and power-operated valves	5.4.8.1.2 5.4.8.1.3 5.4.8.5.2	The Tier 2* information includes methods of evaluation used in establishing the design bases or in the safety analyses, including evaluation of test results. Under Section VIII.B.5.b.8 of the design certification rule,

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		5.4.8.5.3	<p>1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>The Tier 2* information also includes various design and testing criteria. Minor departures from those descriptions which do not affect the ability to confirm the valves can perform its safety function could be screened out. Departures which would adversely impact the ability to confirm the valves can perform their safety function would require a license amendment pursuant to Section VIII.B.5.b.1 and 2 of the design certification rule (and possibly other criteria). Additionally, numerous ITAAC require valves be bounded by the tests or type tests, and the valves appropriately change position during testing. Any departure from those ITAAC would require prior NRC approval in accordance with Section VIII.A.4 of the design certification rule.</p>
c.9	Instrumentation and control system design processes, methods, and standards	Table 1.6-1 7.1.7 7.1.2.14 7.1.2.14.1 7.1.2.14.2 7.7.1.11	<p>The Tier 2* information includes methods of evaluation used in establishing the design bases. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>The Tier 2* information also includes requirements related to design and fabrication of systems, including requirements for verification and validation. Minor departures in those requirements which do not affect the safety functions of the systems could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the systems would require prior NRC</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
			<p>approval pursuant to several of the criteria in Section VIII.B.5.b.</p> <p>Additionally, Targeted ITAAC ##11, 12, and 13 in Section 2.5.2 of Tier 1 addresses the processes used to design instrumentation and control systems. Any departure from those ITAAC would require prior NRC approval in accordance with Section VIII.A.4 of the design certification rule.</p>
c.10	Passive residual heat removal (PRHR) natural circulation test (first plant only)	14.2.5 14.2.10.3.7 14.4.6	<p>This test is subject to a license condition. Any decision not to perform such tests would require a license amendment.</p> <p>The Tier 2* information also includes some descriptions of the tests. Minor departures from those descriptions which do not affect the ability to confirm the system can perform its safety function could be screened out. Departures which would adversely impact the ability to confirm the system can perform its safety function would require a license amendment pursuant to Section VIII.B.5.b.1 and 2 of the design certification rule (and possibly other criteria).</p>
c.11	Automatic depressurization system (ADS) and core make-up tank (CMT) verification tests (first three plants only).	14.2.5 14.2.9.1.3 14.4.6	<p>This test is subject to a license condition. Any decision not to perform such tests would require a license amendment.</p> <p>The Tier 2* information also includes some descriptions of the tests. Minor departures from those descriptions which do not affect the ability to confirm the system can perform its safety function could be screened out. Departures which would adversely impact the ability to confirm the system can perform its safety function would require a license amendment pursuant to Section VIII.B.5.b.1 and 2 of the design certification rule (and possibly other criteria).</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
c.12	Polar crane parked orientation	3.7.2.3.2	Any departures to the orientation of the parked polar crane would need to be evaluated for its impact on the seismic analysis. Departures which could lead to a seismic failure would need to be approved by the NRC pursuant to several of the criteria in Section VIII.B.5.b of the design certification rule.
c.13	Piping design acceptance criteria	3.6.2.1.1.1 3.6.2.1.1.2 3.6.2.1.1.3 3.9.1.2 3.6.2.2 3.6.3.3 3.9.3.1.2 3.9.3.1.5 3.9.8.2 Table 3.9-5 Table 3.9-6 Table 3.9-7 Table 3.9-8 Table 3.9-9 Table 3.9-10 Table 3.9-11	<p>The Tier 2* information involves methods of evaluation used in establishing the design bases. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>Additionally, piping design is the subject of a number of ITAAC for various systems. Accordingly, the NRC will have an opportunity to determine whether licensees have properly implemented the piping design prior to operation of the plant. If the NRC determines the piping design ITAAC have not been satisfied, the plant will not be permitted to operate until appropriate corrective actions have been taken.</p>
c.14	Containment vessel design parameters, including ASME Code, Section III, Subsection NE	3.8.2.1.1 3.8.2.1.3 3.8.2.1.4 3.8.2.1.5 3.8.2.2 3.8.2.5 3.8.2.6 3.8.3.6	The ASME Code includes methods of evaluation used in establishing the design bases or in the safety analyses. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application. Additionally, any exceptions to the ASME Code would be subject to the change control process in 10 CFR

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
			<p>50.55a.</p> <p>The Tier 2* information also includes requirements related to design and fabrication of systems. Minor departures in those requirements (e.g., minor changes in dimensions) which do not affect the safety functions of the containment could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the containment would require prior NRC approval pursuant to several of the criteria in Section VIII.B.5.b.</p>
c.15	Human factors engineering (HFE)	<p>Table 1.6-1</p> <p>18.1</p> <p>18.1.1</p> <p>18.2.1.2</p> <p>18.2.1.3</p> <p>18.2.1.4</p> <p>18.2.1.5</p> <p>18.2.1.6</p> <p>18.2.2.1</p> <p>18.2.2.3</p> <p>18.2.3.1</p> <p>18.2.3.5</p> <p>18.2.4</p> <p>18.2.5</p> <p>18.2.7</p> <p>Figure 18.2-1</p> <p>18.5</p> <p>18.5.1</p> <p>18.5.2</p> <p>18.5.2.1</p> <p>18.5.5</p> <p>18.7</p>	<p>Much of this Tier 2* information pertains to method of evaluation used in establishing the design bases. Under Section VIII.B.5.b.8 of the design certification rule, 1) any change in an element of a method would require NRC approval unless the results of the analysis are conservative or essentially the same; and 2) any change to use a new method would require prior NRC approval unless the new method has been previously approved by NRC for the intended application.</p> <p>Some of the Tier 2* information consists of design criteria. Changes to those criteria would need to be evaluated for impacts on safety functions. To the extent a safety function is adversely affected, evaluations would need to be performed to determine the impacts on the frequency of occurrence and the consequences of an accident, with more than a minimal increase requiring NRC approval pursuant to Section VIII.B.5.b.1 and 3 of the design certification rule.</p> <p>Finally, HFE is the subject of Tier 1 Section 3.2, including associated ITAAC. Accordingly, the NRC will have an opportunity to determine whether licensees have properly implemented HFE prior to operation of the plant. If the NRC determines the HFE ITAAC have not been satisfied,</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
		18.7.2 18.8 18.8.1.2 18.8.1.4 18.8.1.7 18.8.1.8 18.8.1.9 18.8.2 18.8.2.1 18.8.2.2 18.8.2.5 18.8.2.6 18.8.3.2 18.8.3.4 18.8.3.5 18.8.6 Table 18.8-1 18.11.2 18.12.1 18.12.2 18.12.3 18.12.5	<p>the plant will not be permitted to operate until appropriate corrective actions have been taken.</p> <p>The amount of material considered Tier 2* in the five HFE reports referenced in Section 18.11 has subsequently clarified via license amendments.</p>
c.16	Steel composite structural module details	3.8.3.6	<p>The Tier 2* information involves requirements for steel composite structural modules, including some requirements related to materials. Minor departures in those requirements which do not affect the safety functions of the structures could be screened out under the 50.59-like change process. More significant changes resulting in more than a minor increase in likelihood of failure of the structures would require prior NRC approval pursuant to several of the criteria in Section VIII.B.5.b.</p>
N/A	Hard-wired manual actuation	7.7.1.11	<p>Removal of this requirement would likely be viewed as involving more than a minor increase in the likelihood of occurrence of a malfunction of a</p>

Number (VIII.B.6)	Tier 2* Matter	Tier 2 Reference	Non Tier 2* Regulatory Control
	function		<p>system, requiring prior NRC approval in accordance with Section VIII.B.5.b.2.</p> <p>Additionally, the diverse action system is addressed in Section 2.5.1 of Tier 1 (including ITAAC #2.c). Any departure from this Tier 1 information would require prior NRC approval in accordance with Section VIII.A.4 of the design certification rule.</p>

5.0 Conclusions

This paper demonstrates, given the existence of other change controls, there is no need to apply the stringent Tier 2* change control process to ensure changes which adversely affect safety are subject to NRC review and approval.