PUBLIC SUBMISSION

As of: 3/8/22 11:48 AM
Received: March 07, 2022
Status: Pending_Post
Tracking No. l0h-65fy-vw9j
Comments Due: November 05, 2021
Late comments are accepted
Submission Type: Web

Docket: NRC-2019-0062
10 CFR Part 53: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

Comment On: NRC-2019-0062-0012
Preliminary Proposed Rule Language: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

Document: NRC-2019-0062-DRAFT-0232
Comment on FR Doc # 2020-24387

Submitter Information

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Organization: Hybrid Power Technologies LLC

General Comment

The attached Hybrid Power Technologies LLC letter contains comments, concerns, and observations on the proposed 10CFR53 subpart K, Quality Assurance provisions that nearly parallel Appendix B to 10CFR53.
In summary, subtle but profound alterations have been slipped into 10CFR53 Subpart K version of the existing Appendix B of 10CFR50, with attendant complexity introduced into quality measures by way of tentacles extending from various sections of the proposed 10CFR53. The ramifications of these action introduce major regulatory changes that:
1. Will inflict massively unbounded and unjustified costs on the design, construction, and operation of advanced reactors. These costs are not remotely proportional to risk, contrary to the risk informed expectations of the Nuclear Energy Innovation and Modernization Act.
2. Fail to develop the regulatory processes necessary to allow innovation and the commercialization of advanced nuclear reactors, as required by the stated purpose of the Modernization Act.
3. Create an unjustified major new expansion of NRC regulatory authority that will thwart innovation and the commercialization of advanced nuclear reactors, in direct conflict with the stated purpose of the Modernization Act.
We strongly advise that the proposed 10CFR53 simply employ, verbatim, the parent 10CFR50 Appendix B wording.

Attachments

HybPwr to NRC March 7 2022 10CFR53 QA Elements

Michael F. Keller
President
Hybrid Power Technologies LLC

March 7, 2022
Proposed 10CFR53: Quality Assurance (QA) Elements

hybridpwr.com

Mr. John Tappert
Director, Division of Rulemaking, Environmental, and Financial Support
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Hybrid Power Technologies LLC Input - NRC Rulemaking Plan Proposed 10CFR53.

Mr. Tappert:

REF. [1] was released in early February 2022 as a consolidated version of the proposed 10CFR53, including Subpart K – Quality Assurance Criteria General Provisions. The subpart nearly parallels Appendix B to 10CFR50, **REF. [2].**

We have reviewed the subject Subpart K and *Attachment (1*) contains our observations, comments, and concerns.

In summary, subtle but profound alterations have been slipped into 10CFR53 Subpart K's version of the existing Appendix B of 10CFR50, with attendant complexity introduced into quality measures by way of tentacles extending from various sections of the proposed 10CFR53. The ramifications of these actions introduce major regulatory changes that:

1. Will inflict massively unbounded and unjustified costs on the design, construction, and operation of advanced reactors. These costs are not remotely proportional to risk, contrary to the risk informed expectations of the **REF. [3]** *Act*.
2. Fail to develop the regulatory processes necessary to allow innovation and the commercialization of advanced nuclear reactors, as required by the stated purpose of the **REF. [3]** *Act*.
3. Create an unjustified major new expansion of NRC regulatory authority that will thwart innovation and the commercialization of advanced nuclear reactors, in direct conflict with the stated purpose of the **REF. [3]** *Act*.

We strongly advise that the proposed 10CFR53 simply employ, verbatim, the parent 10CFR50 Appendix B wording.

Regards,

Michael F Keller

Michael F. Keller Professional Engineer – State of Kansas

President
Hybrid Power Technologies LLC
A small US Business of the State of Kansas.

Michael F. Keller
President
Hybrid Power Technologies LLC

March 7, 2022
Proposed 10CFR53: Quality Assurance (QA) Elements

hybridpwr.com

Attachments:

(1) Detailed Review: Quality Assurance - 10CFR50 vs 10FR53, Rev 0

References:

[1] Risk-Informed, Technology-Inclusive Regulatory Framework; Proposed 10CFR53 circa January 2022.
[2] Title 10 of Code of Federal Regulations (CFR) Part 50, Domestic Licensing of Production and Utilization Facilities.
[3] Nuclear Energy Innovation and Modernization Act Public Law No: 115-439 (01/14/2019)

TABLE 1: Quality Assurance Comparison – 10CFR50 versus 10CFR53

10CFR50 – REF. [1]	10CFR53 – REF. [2]	Ramifications of 10CFR53 Ratcheting
Item 1 Appendix B - Principal Design Criteria Criterion 1 Quality Standards "Structures, systems, and components {SSC} important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. Where generally recognized codes and standards are used, they shall be identified and evaluated to determine their applicability, adequacy, and sufficiency and shall be supplemented or modified as necessary to assure a quality product in keeping with the required safety function. "	***Item 1*** Subpart B—Technology-Inclusive Safety Requirements *{Relative to 10CFR50, 10CFR53 does not sanction graduated requirements involving the application of Quality Assurance and Standards}.* *{Relative to 10CFR50, 10CFR53 does not allow the use of recognized codes and standards}.* *{Relative to 10CFR50, 10CFR53 does allow modification of generally recognized codes and standards commiserate with the importance of the required safety function}.*	***Item 1*** The absence of recognition of explicit regulatory acceptance of graduated (AKA Risk Informed) QA requirements means the NRC can unilaterally impose the most rigorous requirements on SSC's and activities well removed from causing undue public risk. Further, all Quality Assurance Criteria can be construed to be rigorously applicable to all SSC, activities and human actions, irrespective of the safety significance of SSC functions. The absence of recognition of explicit regulatory acceptance of industry codes and standards means the NRC can unilaterally impose their own guidance that overrules the historical regulatory codified precedence of the acceptability of industry codes and standards.
Item 2 Appendix B Quality Assurance Introduction "… that prevent or mitigate the consequences of ***postulated accidents*** that could cause undue risk to the health and safety of the public."	***Item 2*** Subpart K – Quality Assurance Criteria General Provisions … that prevent or mitigate the consequences *of* ***licensing basis events, including design basis accidents, as described in § 53.240,*** that could cause undue risk to the health and safety of the public." 53-020 Definitions Design basis accidents (DBAs) mean postulated event sequences that are used to set functional design criteria and performance objectives for the design of safety related structures, systems, and components. DBAs are a type of licensing basis event and are based on the capabilities and reliabilities of safety-related structures, systems, Licensing basis events (LBEs) mean a collection of event sequences considered in the design and licensing of the advanced commercial nuclear	***Item 2*** Massive expansion of the reach of QA into huge areas significantly removed from the existing 10CFR50 postulated accidents arena. Postulated accidents are clearly a very small subset of the range of AOO's, unlikely & very unlikely event sequences, and DBA's. There is virtually no counterpart in 10CFR50 that extends licensing basis events in the unbounded and convoluted fashion specified by 10CFR53. These major new regulatory requirements will cause a massive expansion of the reach of QA into areas very distant from causing undue risk to the public.

	plant. LBEs are unplanned events and include AOOs, unlikely event sequences, very unlikely event sequences, and DBAs. 53.240 Licensing basis events. Licensing basis events must be identified for each commercial nuclear plant and analyzed in accordance with § 53.450 to support assessments of the safety requirements in this subpart. The licensing basis events must address combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards ranging from anticipated operational occurrences to very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the commercial nuclear plant. The analysis of licensing basis events must include analysis of one or more design basis accidents in accordance with § 53.450(f). The analysis of licensing basis events must be used to confirm the adequacy of design features and programmatic controls needed to satisfy safety criteria defined in §§ 53.210 and 53.220 and to establish related functional requirements for plant SSCs, personnel, and programs	
Item 3 Appendix B III Design Control … to assure that applicable regulatory requirements and the design basis, as defined in § 50.2, …" 50.2 Definitions *Design bases* means that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for	***Item 3*** Subpart K – Quality Assurance Criteria § 53.1815 Design Control … to assure that applicable regulatory requirements and the design basis, as specified in the license application, …" 53-020 Definitions *{Design basis is not explicitly defined by 10CFR53, but rather involves the limitless expanse of the entire license documentation}.* *Design basis accidents (DBAs)* mean postulated event sequences that are used to set functional design criteria	***Item 3*** The 10CFR53 term "Design Basis" can be readily construed to include all manner of activities as well as systems, structures and components (SSC) well removed from the existing design basis accident functional arena. This causes a massive expansion of the reach of QA into areas very distant from causing undue risk to the public. The stunningly massive expansion of the scope of Safety Related will cause an immense increase in the reach of QA into areas well removed from causing undue risk to the public. The

controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals. *Safety-related structures*, systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure: (1) The integrity of the reactor coolant pressure boundary (2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 50.34(a) (1) or § 100.11 of this chapter, as applicable. 10CFR 100.11 (a) As an aid in evaluating a proposed site, an applicant should assume a fission produce release[1] from the core, the expected demonstrable leak rate from the containment and the meteorological conditions pertinent to his site to derive an exclusion area, a low population	and performance objectives for the design of safety-related structures, systems, and components. DBAs are a type of licensing basis event and are based on the capabilities and reliabilities of safety-related structures, systems, and components needed to mitigate and prevent event sequences, respectively. *Safety-related (SR)* means those SSCs and human actions that warrant special treatment and are relied upon to demonstrate compliance with the safety criteria in § 53.210. *Safety criteria* means metrics that establish a level of safety based on requirements in § 53.210 and § 53.220. *Special treatment* means those requirements, such as measures taken to satisfy functional design criteria, quality assurance, and programmatic controls, that provide assurance that certain SSCs will provide defense-in-depth or perform risk-significant functions and that provide confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in § 53.210 and § 53.220 *§ 53.210* Safety criteria for design basis accidents. Design features and programmatic controls must be provided for each commercial nuclear plant such that analyses of design basis accidents in accordance with § 53.240 demonstrate the following: (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	convoluted 10CFR53 requirement logic: safety related (53.020 Definitions) to Safety Criteria (53.210) to Licensing Bases Events (53.240) to Special Treatment (Definitions 53.020) to Analysis Requirements (53.450). Relative to 10CFR53.220, there are no 10CFR50 design control (and by extension, QA requirements) of SSC or activities involving latent cancer deaths. The 10CFR53 requirements are major and unprecedented new considerations that are not warranted or justified from the standpoint of public risk. There are no existing QA requirements in 10CFR50 regarding programmatic controls involving plant personnel, and programs to maintain necessary reliability involving 10CFR53.220's vast range of licensing basis events. All of the preceding are major, unprecedented new requirements not warranted or justified from the standpoint of undue public risk.

zone and population center distance. For the purpose of this analysis, which shall set forth the basis for the numerical values used, the applicant should determine the following: (1) An exclusion area of such size that an individual located at any point on its boundary for two hours immediately following onset of the postulated fission product release would not receive a total radiation dose to the whole body in excess of 25 rem[2] or a total radiation dose in excess of 300 rem[2] to the thyroid from iodine exposure. [1] The fission product release assumed for these calculations should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products. *{10CFR50 Appendix A Criterion 63 and 64 address radioactive waste and associated releases}*	dose in excess of 25 rem (250 mSv) total effective dose equivalent; 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 (250 mSv) total effective dose equivalent. *§ 53.220 Safety criteria* for licensing basis events other than design basis accidents. Design features and programmatic controls must be provided to: (a) Ensure plant structures, systems and components (SSCs), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address licensing basis events in accordance with § 53.240 and provide measures for defense-in-depth in accordance with § 53.250; and (b) Maintain overall cumulative plant risk from licensing basis events such that the risk to an average individual within the vicinity of the plant receiving a radiation dose with the potential for immediate health effects remains below five in 10 million years, and the risk to such an individual receiving a radiation dose with the potential to cause latent health effects remains below two in one million years.	
Item 4 *Summary* *Reasonably straight forward, inherently risk informed.*	***Item 4*** *Summary* *Subtle but profound alterations have been slipped into the existing Appendix B of 10CFR50 with attendant complexity introduced into quality measures by way of tentacles extending from various sections of the proposed 10CFR53.*	***Item 4*** *Summary* In summary, the proposed 10CFR53 QA related requirements are major regulatory changes that: 1. Will inflict massively unbounded and unjustified costs on the design, construction, and operation of advanced reactors. These costs are not remotely proportional to risk, contrary to the risk informed expectations of the REF. **[3]** Act.

		2. Fails to develop the regulatory processes necessary to allow innovation and the commercialization of advanced nuclear reactors, as required by the stated purpose of the **REF. [3]** Act. 3. Creates an unjustified major new expansion of NRC regulatory authority that will thwart innovation and the commercialization of advanced nuclear reactors, in direct conflict with the stated purpose of the **REF. [3]** Act. Scrap the proposed 10CFR53 wording/approach slipped into 10CFR53 and revert, verbatim, to the existing 10CFR50 Appendix B wording.

References:

[1] Title 10 of Code of Federal Regulations (CFR) Part 50, Domestic Licensing of Production and Utilization Facilities.
[2] Risk-Informed, Technology-Inclusive Regulatory Framework; Proposed 10CFR53 circa January 2022
[3] Nuclear Energy Innovation and Modernization Act Public Law No: 115-439 (01/14/2019)