DRAFT - For Discussion with NRC Staff

Reference #1	NRC Comment	NEI Response	Resolution
1	Assessing CCF Vulnerabilities		
a	Does the methodology described in draft NEI 20-07 require an assessment of potential common cause failure (CCF) vulnerabilities in a proposed system, prior to implementation of this methodology?	The CCF vulnerability assessment would be performed as part of, rather than prior to, applying the guidance in NEI 20-07. Results of the CCF vulnerability assessment would be provided in the Assurance Case. For example, SDO 10.1.3.2 requires use of a hazard analysis method to identify hazardous control actions that can lead to an accident or loss. SCCF would be a primary focus of the hazard analysis. Application software requirements and constraints will be derived from the identified hazardous control actions. It is possible that, as part of the standard digital design process, a CCF hazard analysis/CCF vulnerability assessment would have already been developed prior to implementation of NEI 20-07. If this is the case, then the results of the prior hazard analysis/CCF vulnerability assessment (if it meets the requirements of NEI 20-07) could be used and presented in the Assurance Case.	
b	How does the prescribed methodology in draft NEI 20-07 protect against potential CCF vulnerabilities in a generic sense, when different systems may have unique characteristics such as	The SDOs are independent of any platform technology and application software. The hazard analysis SDO, for example, performed for each system would consider integration of different systems from an application software perspective. Software development for each system would be	

Reference #1	NRC Comment	NEI Response	Resolution
Reference #1	NRC Comment different platforms, application software, architectures, etc.?	assessed separately following the guidance in NEI 20-07 using the information collected in the hazard analysis. NEI 20-07 focusses on addressing CCFs resulting from design defects in the internal platform software/hardware and application software. The SDOs address the level of quality needed to reach the conclusion that CCFs resulting from design defects in the platform and application software need not be further considered or postulated. NEI 20-07 does not address external system	Resolution
		architecture - only platform hardware/software and application software. Some aspects of the system architecture will be addressed by ensuring the platform is installed using the Safety Manual requirements (part of the SIL3/SC3 certification). However, it is not the intent of NEI 20-07 to address all CCFs resulting from other aspects of the system architecture (e.g., date communications).	
2	Executive Summary Comment – Alignment with Related Guidance		
a	Draft NEI 20-07 appears to leverage a 'frequency' argument to resolve CCF considerations in a similar manner to RIS 2002-22, Supplement 1, but for HSSSR systems. RIS 2002-22,	NEI 20-07 is not intended to be related to, consistent with, or parallel with RIS 2002-22 Supplement 1. One risk-informed aspect to NEI 20-07 is the	
	Supplement 1, allows for frequency	way an HSSSR system is determined. BTP 7-19	

Reference #1	NRC Comment	NEI Response	Resolution
Reference #1	(i.e. likelihood) arguments because it is focused on lower safety significant systems whose failure consequences of CCF is well understood and acceptable. It's not clear how the approach in draft NEI 20-07 is consistent with RIS 2002-22, Supplement 1 or BTP 7-19, Revision 8, SRM to SECY 93-087 as well as SECY 18-0090 with regard to using a frequency argument to remove CCF from further consideration, but for an HSSSR system.	allows for site-specific PRA, if available, to support the determination of a HSSSR system. NEI 20-07 is expected to be used for the highest safety-significant safety-related SSCs - the consequences of failure are therefore very high. NEI 20-07 adopts a level of quality to reach the conclusion that CCFs resulting from a design defect in the internal platform software/hardware or application software need not be further considered or postulated. Similar to what has been achieved for hardware (e.g., HW Equipment Qualification), NEI's intent is that there is an achievable level of software quality over and beyond what is currently required to meet the NRC endorsed IEEE software standards. The SDOs provided in NEI 20-07 were selected to achieve this next level of software quality.	Resolution
		Thus, NEI 20-07 is not based on failure likelihood or acceptable consequences. NEI 20-07 will be modified to remove the language that implies frequency of occurrence.	
b	Is it NEI's position that any CCF of a HSSSR has severe consequences and that the approach in NEI 20-07 is attempting to justify the safety system design through a very low likelihood of occurrence of software CCF?	NEI's position is that, by definition, the consequences of failure of a HSSSR SSC is high. NEI 20-07 provides guidance on platform selection and application software development where software quality is the focus.	

Reference #1	NRC Comment	NEI Response	Resolution
		Similar to HW qualification, NEI's position is	
		that it is possible to develop software with such	
		high quality that a CCF resulting from an	
		application software design defect or internal	
		platform software/hardware design defect no	
		longer needs to be postulated.	
		Note that CCFs resulting from the system	
		architecture will still need to be addressed (i.e.,	
		CCF resulting from other sources in the system	
		architecture other than application software or	
		platform hardware/software).	
3	Executive Summary Comment –		
	Current Processes versus NEI 20-07		
а	Is it NEI's position that existing,	The existing gap is between the level of	
	endorsed IEEE standards (e.g. IEEE	software quality required to postulate the	
	Std. 1012, IEEE Std. 7-4.3.2) have a	effects of a CCF as a beyond design basis (BDB)	
	potential gap that the methodology of	event (i.e., software quality level achievable	
	NEI 20-07 is addressing? This	using existing endorsed standards), vs. the level	
	statement seems to presume that	of quality required to conclude a CCF is	
	SDO concept are unique to IEC 61508.	adequately addressed and does not need to be	
		postulated (i.e., additional level of software	
		quality provided by NEI 20-07).	
		Note that if a licensee is committed to specific	
		IEEE standards for software development, then	
		that licensee would be expected to use these	
		IEEE standards in addition to NEI 20-07.	
		NEI 20-07 is not intended to replace the IEEE	
		standards - NEI 20-07 is intended to provide	

Reference #1	NRC Comment	NEI Response	Resolution
		guidance that results in raising the level of	
		quality beyond that provided by the IEEE	
		standards. NEI considers the SDO concept	
		unique to IEC 61508.	
b	Is it NEI's position that the	Yes. NEI 20-07 is expected to be used in	
	methodology described in NEI 20-07,	conjunction with the currently endorsed	
	when used in conjunction with the	software development standards. As stated in	
	currently endorsed standards, can	the response to Question 2a, NEI's position is	
	provide a lower likelihood of software	that there is a level of software quality over	
	CCF in HSSSRs than current processes	and beyond what is currently required to meet	
	alone?	the NRC endorsed IEEE software standards.	
		The SDOs provided in NEI 20-07 were selected	
		to achieve this next level of software quality.	
		The goal of NEI 20-07 is to provide guidance on	
		platform selection and application software	
	The present regulatory infrastructure	development with such high quality that a	
	for HSSSR systems acknowledges that	licensee no longer needs to consider the	
	it is possible to identify a potential CCF	internal platform software/hardware or	
	vulnerability due to a latent defect has	application software or as a source of CCF.	
	such a low likelihood of occurrence		
	that it may be treated as "beyond	Comparable to applying the testing criteria in	
	design basis", and therefore its	BTP 7-19 to eliminate software as a source of	
	consequences may be evaluated using	CCF, the SDOs provide a set of criteria that can	
	best-estimate methods. The use of	be applied to eliminate consideration of SCCFs	
	best-estimate methods was intended	resulting from internal platform	
	to be less burdensome for licensees	software/hardware and application software	
	and applicants than typical reactor	design defects in the D3 analysis.	
	safety thermal hydraulic analysis		
	methods. The consequences of very	There may be other sources of CCF that need to	
	low likelihood of occurrence of CCFs	be evaluated as part of the overall system	
	due to latent defects still need to be	architecture other than the platform	

Reference #1	NRC Comment	NEI Response	Resolution
	evaluated to demonstrate reactor	hardware/software and application software.	
	safety objectives and regulatory dose	NEI 20-07 only addresses CCFs resulting from	
	acceptance criteria limits are being	design defects in the application software and	
	met. As currently written, NEI 20-07	internal platform software/hardware. External	
	seems to suggest otherwise.	system architecture considerations such as	
		channel interconnections, network	
		communications etc. are not addressed in NEI	
		20-07. NEI recognizes that all potential sources	
		of CCF must be considered as part of the	
		overall system design and integration.	
4	Executive Summary Comment – EPRI		
	Research		
а	EPRI research appears heavily	NEI 20-07 is heavily leveraged on research	
	leveraged in this document. The staff	conducted by EPRI on the efficacy of SIL	
	would need to understand more	certification for nuclear power [EPRI Technical	
	details on this research and its	Report 3002011817, dated July 2019]. Some in	
	applicability and technical	the NRC staff have reviewed this EPRI report as	
	assumptions as it pertains to	it was used in the development of NEI 17-06,	
	addressing CCF in nuclear	Guidance on Using IEC 61508 SIL Certification	
	applications, types of	to Support the Acceptance of Commercial	
	devices/components considered,	Grade Digital Equipment for Nuclear Safety	
	software	Related Applications, which is currently under	
	applications, etc., and how they're	NRC review for endorsement. Some in the NRC	
	organized/configured. This is to	staff also conducted an audit of the SIL	
	ensure we have relevant comparison	certification process as part of development of	
	of data. For example, with regard to	NEI 17-06 and are familiar with the application	
	1.6 billion operating hours, how much	and requirements of IEC 61508.	
	of that		
	data is valid with respects to the	Regarding the 1.6 billion operating hours in the	
	components, systems, operating	EPRI research, all the EPRI harvested data is	
	system platforms, etc. that are	valid with respect to components, systems,	

Reference #1	NRC Comment	NEI Response	Resolution
	currently in use?	operating systems, platforms, etc. that are currently in use. The research evaluated the systematic process for programmable logic solvers (i.e., IEC 61508 based SIL certification), and evaluated the predictive reliability of that process to the actual failure rate data. The conclusion was that the systematic process can predict accurately the failure rate of the logic solver.	
5	Executive Summary Comment – IEC 61508		
a	Is it NEI's position that implementation of IEC 61508 in an adequate manner is sufficient to render SWCCF not credible (sufficiently low for platforms, not applications)? What about the application software?	Yes, it is NEI's position that IEC 61508 provides the level of SDOs for both platform and application software to eliminate their consideration as a source of CCF. The guidance in NEI 20-07 is intended to be used in the selection of platform software/hardware and for the development of high-quality application software such that SCCF due to a software design defect no longer needs to be considered or postulated.	
		As previously stated, NEI 20-07 only addresses SCCF resulting design defects in the internal platform software/hardware and application software. CCFs resulting from the system architecture other than the platform hardware/software and application software still need to be addressed. In other words, simply meeting the requirements of NEI 20-07	

Reference #1	NRC Comment	NEI Response	Resolution
		does not ensure that the entire integrated system is immune from all potential sources of CCFs.	
В	Standards are generally written to be followed in totality to achieve the stated goals within. In the context of NEI 20-07, is IEC 61508 being utilized in its entirety or are only certain portions of IEC 61508 being utilized? If only partially, what is that scope?	Per the guidance in NEI 20-07, platforms are required to meet SIL3/SC3 requirements as specified in IEC 61508. Thus, for platforms, IEC 61508 is being used in its entirety. The guidance in IEC 61508 was strategically synthesized to harvest only the necessary elements needed to develop high-quality application software.	
С	The methodology in NEI 20-07 appears to be a process that uses aspects of IEC 61508 without necessarily requiring the platform/application software to be compliant with IEC 61508. Is that the approach being taken by NEI 20-07? (Note: IEC 61508 is not a nuclear standard but an industrial standard. IEC 61513 is a nuclear though and it's not clear why this standard was not used).	To comply with the guidance in NEI 20-07, platforms would need to meet the requirements of SIL3/SC3 as specified in IEC 61508. Thus, internal platform hardware and software are required to be compliant with IEC 61508. As described in the response to Question 5B, the SDOs for developing application software were strategically synthesized from IEC 61508. Only portions of the guidance applicable to application software were taken from IEC 61508-3. EPRI research focused on platforms developed using IEC 61508. Results of their research indicate very high quality and reliability in	

Reference #1	NRC Comment	NEI Response	Resolution
		in applications where safety is a paramount concern. NEI 20-07 builds on the EPRI research. IEC 61513 was not considered when developing NEI 20-07. IEC 61513 is a system level standard whereas IEC 61508 is focused on single failures that can be consequential.	
6	Executive Summary Comment – Applicability to 10 CFR 50.59		
а	Is it the intention of this document to provide methodologies that are consistent with the guidance of RIS 2002-22 Supplement 1 and its definition of sufficiently low and requirements under 10 CFR 50.59?	NEI 20-07 is not intended to be related to, consistent with, or parallel with RIS 2002-22 Supplement 1 nor is NEI 20-07 intended to be used for SSCs implemented under 50.59. The reason for mentioning 50.59 was to indicate that, if desired, a licensee could use the guidance in NEI 20-07 for projects implemented under 50.59 - although it is not recommended. For clarity, NEI plans remove any reference to 50.59 in NEI 20-07.	
b	How does NEI envision this document being used under 10 CFR 50.59?	NEI does not envision NEI 20-07 being used for projects implemented under 50.59. NEI 20-07 is intended to be used on HSSSR SSCs that would typically require a LAR to implement. NEI intends to remove any reference to 50.59 in NEI 20-07.	
С	Is this document consistent with NEI 96-07, Appendix D? Does the document identify residual gaps between it and technical guidance	NEI 20-07 will be used for activities that will require a LAR to implement. The "Assurance Case" referred to in NEI 20-07 would be part of the LAR package.	

Reference #1	NRC Comment	NEI Response	Resolution
	that complements NEI 96-07,	The initial draft of NEI 20-07 mentioned 50.59	
	Appendix D?	in case a licensee desired to use the guidance in	
		a lesser safety-significant SSC. However, NEI	
		realizes that most, if not all, licensees will	
		continue to use the RIS Supplement on lesser	
		safety-significant projects. As such, NEI intends	
		to remove mention of 50.59 in NEI 20-07.	
7	Introduction Section Comment –		
	Software Development Process		
а	NRC staff already requires rigorous	The guidance provided in NEI 20-07 is based on	
	software development process (e.g.	a mature standard (IEC 61508) and years of	
	BTP 7-14) and has previously	EPRI research on quality platform and software	
	determined that a high-quality	development. Based on this research, NEI feels	
	software development process is	strongly that application of the guidance	
	sufficient to consider software CCF a	provided in NEI 20-07 will result in selection of	
	beyond design basis event, but not	the highest quality platform and development	
	necessarily sufficient to eliminate the	of the highest quality application software,	
	potential for CCF. NEI should describe	beyond that which can be achieved using	
	how the methodology in NEI 20-07 is	existing standards. As stated above, NEI 20-07	
	sufficiently different than current	is intended to be used in addition to the	
	processes such that potential software	existing NRC endorsed standards on software	
	CCF consideration can be eliminated.	development. There is overlap between the	
		two sets, but there are also SDOs not covered	
		by BTP 7-14, RGs and endorsed IEEE standards.	
8	Background Section Comment –		
	Additional Analysis		
а	Is it NEI's position that there is no	It is NEI's position that if a licensee provides an	
	evaluation/analysis needed if this	Assurance Case that provides the arguments	
	document is implemented?	and evidence that the SDOs are met, there is	
		no need to further consider or postulate SCCFs	

Reference #1	NRC Comment	NEI Response	Resolution
		resulting from design defects in the internal	
		platform software/hardware or application	
		software. The Assurance Case would be	
		provided as part of a LAR for the HSSSR system.	
		A licensee would still need to consider CCFs	
		resulting from other aspects of the system	
		architecture and plant integration.	
В	Is there any sort of evaluation/analysis	SDO 10.1.3.2 requires use of a hazard analysis	
	this document points to that is	method to identify hazardous control actions	
	performed to highlight potential CCF	that can lead to an accident or loss. SCCF	
	vulnerabilities?	vulnerabilities are the primary focus of this	
		hazard analysis.	
		The hazard analysis specified by SDO 10.1.3.2 is	
	Some analysis of the design	a global analysis considering all aspects of the	
	(architecture) beyond the "software"	system and architecture, including both	
	seems implied by SDOs relating to	hardware and software. Thus, the identified	
	6.3's 1 st principle. For example,	hazardous control actions will cover much	
	10.1.3.2 through 10.1.3.5. 10.1.3.2	more than application software. Some of the	
	identifies constraints derived from	hazardous control actions identified will not	
	hazardous control actions, which may	apply to the application software while others	
	imply something that enforces the	will. This SDO requires that results of the	
	constraint that is not the application	hazard analysis be used to generate specific	
	software itself. 10.1.3.4 identifies	application software requirements and	
	"hardware constraints." 10.1.3.5	constraints as they apply to the system - both	
	identifies "constraints imposed by the	hardware and software.	
	I&C system design."		
		SDO 10.1.3.4 requires identification of	
		hardware constraints that need to be	
		considered when developing the application	
		software are documented and complete. For	
		example, if a specific channel response time is	

Reference #1	NRC Comment	NEI Response	Resolution
		identified as a system requirement, then the time required for the application software to process a given input signal would need to be considered in addition to the field instrumentation (hardware) response time. This may place a constraint on the application software processing time due to the fixed hardware response time. Overall system and performance requirements will typically be developed through two separate sources - basic system functional and performance requirements and requirements discovered when applying the hazard analysis process. SDO 10.1.3.5 ensures that, in addition to requirements discovered through application of the hazard analysis process, system performance requirements and constraints are also documented and applied, as applicable, when developing the application software.	
9	Section 5 Comment – SRM to SECY 93-087 and Scope		
а	It's not clear how NEI 20-07 maps to SRM to SECY 93-087 and why SRM to SECY 93-087 is not referenced.	NEI 20-07 addresses Position 1 of SECY 93-087: Identify CCF vulnerabilities in the systems. NEI 20-07 is based on the position that internal platform software/hardware and application software can be selected/developed with such high quality that SCCF resulting from a design defect in the platform internal	

Reference #1	NRC Comment	NEI Response	Resolution
		software/hardware or application software no longer needs to be considered or postulated. There may be other CCFs that need to be postulated (e.g., due to various system architecture configurations), but SCCF due to a design defect in the application software or internal platform software/hardware would no longer need to be considered.	
b	BTP 7-19, Revision 8, includes sources of digital CCF to be both software and hardware, consistent with SRM to SECY 93-087. Is it NEI's position that NEI 20-07 provides adequate coverage with respect to the scope of CCF considerations in BTP 7-19, Revision 8?	BTP 7-19 provides an exclusion of software that meets the specified testing criteria. Similarly, NEI 20-07 is providing an exclusion for platforms and application software that meet the SDOs. NEI 20-07 focuses only on internal platform software/hardware and application software development. A SIL 3/SC3 platform certification does address internal hardware of the platform. Additionally, SDO 9.2.3.1 states that when platform elements are integrated at the system level, subsystem level, or among other elements, they are integrated in accordance with the Safety Manual that complies with IEC 61508-2 Annex D or 61508-3 Annex D. The Safety Manual does address some elements of external architecture hardware.	
10	Section 5 Comments – Gaps in		
	Current Regulatory Processes		
a	Is the approach of this document to "fill the gap" that is perceived within	It is NEI's position that the processes are complimentary and overlap but address	

Reference #1	NRC Comment	NEI Response	Resolution
	current NRC processes (e.g. BTP 7-14)	different objectives. The current set of NRC-	
	or is it attempting to be	endorsed software development standards	
	complimentary to current processes,	allow crediting a CCF as a BDB event. Applying	
	or both? Industry has not formally	the SDOs provided in NEI 20-07 would allow an	
	communicated of such a gap to the	applicant to deterministically assess that CCF	
	NRC. Industry has previously	associated with design defects in the platform	
	expressed concerns with the level of	and application software has been adequately	
	effort with current NRC practices and	addressed and need not be further considered	
	NEI 20-07 would appear to add an	or postulated.	
	additional layer of complexity to		
	licensing and design work.		
11	General Comments on Section 6,		
	titled "First Principles of Protection		
	Against Software CCF"		
a	The principles listed in this section	First principles do not need acceptance criteria.	
	have a description (with the	Rather, they provide a principle-based	
	subsection headers themselves acting	conceptual understanding of the phenomena.	
	as the principle itself) but do not	It is the SDOs that provide the analysis	
	appear to have guidance. It's not clear	guidance and acceptance criteria to meet the	
	how a licensee or application can	first principles. NEI 20-07 states, "This	
	apply them without specified	approach begins by establishing a set of first	
	acceptance criteria or similar type of	principles for the protection against software	
	consideration.	CCF in digital instrumentation and control	
		(DI&C) systems and then subsequently	
		decomposing these first principles into safe	
		design objectives (SDOs)."	
В	Without specified acceptance criteria,	See earlier comments regarding the term	
	it's not clear how a licensee or	"sufficiently low". Documented adherence to	
	applicant can	the SDOs provided in NEI 20-07 offers evidence	
	adequately determine whether the	that the acceptance criteria for selection of a	
	stated goals of this document (i.e.	high-quality platform and development of high-	

Reference #1	NRC Comment	NEI Response	Resolution
Reference #	sufficiently low finding with regard to software CCF) has been achieved.	quality application software at a level such that a CCF due to a design defects in the internal platform software/hardware and application software no longer needs to be considered or postulated has been met. For example, the acceptance criteria for a platform not being a source of CCF is evidence that the platform meets the SIL3/SC3 requirements identified in SDO 9.1.3.1 and is integrated within the requirements of SDO 9.2.3.1. For application software, the	Resolution
		acceptance criteria would be the documented evidence that all relevant application software SDOs were achieved. NEI 20-07 requires development of an "Assurance Case" to detail how the various SDOs were met for both the platform and application software.	
12	General Comments on Acceptance Criteria		
а	Does draft NEI 20-07 describe/provide general acceptance criteria for all portions of the methodology that are used to ultimately make a determination of "sufficiently low" with regard to the likelihood of	See earlier comments regarding the term "sufficiently low". NEI 20-07 is not intended to be related to, consistent with, or parallel with RIS 2002-22 Supplement 1.	
	with regard to the likelihood of software CCF?	To a degree, NEI 20-07 provides a deterministic approach for evaluating platform software/hardware and development of application software in that by applying the	

Reference #1	NRC Comment	NEI Response	Resolution
		prescribed SDOs, a CCF due to a design defect	
		in the internal platform software/hardware or	
		application software does not need to be	
		further considered or postulated.	
		NEI 20-07 will add the following statement:	
		"Documentation that the acceptance criteria	
		were met consists of documented evidence that	
		relevant SDOs were addressed adequately. A	
		licensee will build an Assurance Case as part of	
		a LAR package to clearly detail how the SDOs	
		were met."	
В	Does draft NEI 20-07 address relevant	Yes - If the SDOs in NEI 20-07 are applied, the	
	acceptance criteria in BTP 7-19,	design attributes/defensive measures that are	
	Revision 8, including Section 3.1.3?	used to meet those SDOs, will meet the	
		acceptance criteria in BTP 7-19, Revision 8,	
		Section 3.1.3.	
13	Section 6 Comment		
	Section 6 of the document states		
	the following: The first principles		
	listed in this section are considered		
	bounding and complete and		
	represent the starting point for		
	decomposition of SDOs.		
a	Clarify what is the basis for stating	NEI agrees that "bounding" is not an applicable	
	that the first principles in Section 6 is	term in describing the scope of the first	
	both "bounding" and "complete". On	principles. It is accurate to state that the first	
	the surface, with regard to software	principles are "complete." NEI's position is that	
	development, there would appear to	these first principles are complete. NEI	

Reference #1	NRC Comment	NEI Response	Resolution
	be more considerations than what's	welcomes NRC feedback regarding the first	
	currently listed.	principles provided in NEI 20-07.	
		NEI will revise NEI 20-07 to remove "bounding"	
		from the discussion on first principles.	
b	What is meant by the term	See response to Question 13a.	
	"bounding"? Bounding with current	·	
	regulations?		
14	Section 6 Comment		
	Section 6 of the document states		
	the following: The first principles of		
	protection against software CCF		
	will be achieved by executing the		
	SDOs.		
a	The principles listed in this section are	NEI is not taking the position that there are any	
	generally understood to be	identified gaps with IEEE standards. The IEEE	
	identified/covered within existing IEEE	standards have a different objective than NEI	
	standards the NRC staff has already	20-07 as expressed in the response for 10a.	
	endorsed and the subsections in	Rather, NEI's intent is that NEI 20-07 is a means	
	Section 6 are silent in this respect. Is it	to adequately address CCFs caused by latent	
	NEI's position that existing, endorsed	design defects in the platform	
	IEEE standards (e.g. IEEE Std. 1012,	software/hardware and associated application	
	IEEE Std. 7-4.3.2) have potential gaps	software.	
	that the methodology of NEI 20-07 is		
	addressing?		
15	Section 9 Comment		
	Section 9.1 of the document states		
	the following, in part: Use of IEC		
	61508 as a source for developing		
	SDOs to protect against software		
	CCF		

Reference #1	NRC Comment	NEI Response	Resolution
а	Does NEI intend to include the	NEI's intent is that NEI 20-07 has enough	
	relevant portions of IEC 61508 as part	information to facilitate the staff's review and	
	of this review or does NEI believe that	does not plan to submit any portions of IEC	
	NEI 20-07 has sufficient information	61508 for review and endorsement by the NRC.	
	contained therein to facilitate the		
	staff's review?	As stated in NEI 20-07, the SDOs are	
		synthesized from the relevant guidance in IEC	
		61508 and other industry standards.	
16	Software Quality Assurance		
	Argument of NEI 20-07 (B.1 Figure)		
	RIS 2002-22 Supplement 1, describes	NEI 20-07 is not intended to mirror the	
	the qualitative assessment concept	guidance in RIS 2002-22 Supplement 1. The	
	where the aggregate of considerations	next draft of NEI 20-07 will remove any	
	of deterministic design features,	connection to RIS 2002-22 Supplement 1.	
	software quality and operating		
	experience can be used to make a	NEI 20-07 does not rely solely on operating	
	sufficiently low determination. The RIS	experience when assessing a platform's	
	supplement is clear that operating	susceptibility to SCCF - the platform must meet	
	experience alone cannot be used as a	the requirements of a SIL3/SC3 system set forth	
	sole basis for a sufficiently low	in IEC 61508.	
	determination and isn't truly a		
	substitute for the two other aspects.	Additionally, operating experience, when used	
	NEI 20- 07 Section 6.4, 9.1.2 and other	in the context provided in NEI 20-07, only	
	sections would appear to make the	applies to internal platform software and	
	case that a focus on software quality	hardware. The concept of platform operating	
	and supplemental operating history	experience is derived from EPRI research on SIL	
	(presumably of the exact same	certified platforms. EPRI reviewed several	
	software package) alone are sufficient	platforms currently in operation and those that	
	to demonstrate a sufficiently low	were SIL3 certified and in operation for	
	likelihood of failure of an entire HSSSR	approximately 1.6 billion operating hours had	
	system. This appears to be the case in	no evidence of experiencing a SCCF. This	

Reference #1	NRC Comment	NEI Response	Resolution
	lieu of additional consideration of architectural design or deterministic design features (e.g. defensive measures) that can also demonstrate high reliability/dependability. This would not appear consistent with either the RIS supplement 1 or BTP 7-19, Revision 8, which both provide for reliance on these aspects to demonstrate system reliability/dependability to the effects of a digital CCF (hardware or software) or to prevent its occurrence, in addition to software quality.	supports the correlation between operating experience and quality. As stated previously, NEI 20-07 only addresses CCFs resulting from design defects in the internal platform software/hardware and associated application software (i.e., not the system architecture as a whole). The concept behind NEI 20-07 is that by applying the relevant SDOs, CCFs resulting from design defects in the internal platform software/hardware and application do not need to be further considered or postulated. NEI may consider to addressing the complete system architecture in NEI 20-07 in a future revision. However, at this time, NEI is focusing solely on SDOs for high-quality platform selection and application software development such that a software CCF does not need to be further considered or postulated.	
а	Is it NEI's position that software quality and operating experience (presumably of the same software package) alone, is sufficient to demonstrate a sufficiently low likelihood of failure for an entire system?	NEI position is that it is possible to develop such high-quality software that SCCF caused by software design defects no longer needs to be considered or postulated. As stated above, NEI 20-07 does not rely solely on operating experience when assessing a platform's susceptibility to SCCF - the platform must meet the requirements of a SIL3/SC3 system set forth in IEC 61508.	

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		Software defects are only one contributor to	
		CCF. Other aspects still need to be addressed,	
		such as the whole system architecture. NEI 20-	
		07 does not currently address whole system	
		architecture.	
		Therefore, it is not NEI's position that	
		adherence to the guidance in NEI 20-07 is	
		enough to conclude that a fully integrated	
		system is not susceptible to CCF.	
b	Are there any aspects of the	Yes - If architecture in this question is referring	
	methodology of NEI 20-07 that focus	to HSSSR digital system architecture. SDO	
	on architectural design and/or design	9.1.3.1 requires the platform to meet or exceed	
	features to also demonstrate high	a Systematic Capability of SC3 (as for a SIL 3	
	reliability/dependability?	system) as described in IEC 61508. Part of the	
		SC3 certification pertains to the internal	
		architecture of the platform, which includes	
		both hardware and software. SDO 9.2.3.1	
		addresses platform integration and states, in	
		part, that when platform elements are	
		integrated at the system level, subsystem level,	
		or among other elements, they are integrated	
		in accordance with the Safety Manual that	
		complies with IEC 61508-2 Annex D or 61508-3	
		Annex D. The Safety Manual requires	
		application of specific external architectural	
		design elements in order to maintain the SC3	
		certification.	
		With respect to both platform and application	
		software, NEI 20-07 presents specific design	

Reference #1	NRC Comment	NEI Response	Resolution
		objectives that, when met, will constitute a safe system that is, highly reliable and dependable.	
		Note that the focus of NEI 20-07 is on HSSSR platform and application software because these elements are the most probable cause of CCF in a HSSSR system.	