

Date:

20 December 2012

From:

David Herrell

To:

Cindy K. Bladey, RADB

Company:

**USNRC** 

Fax:

(301) 492-3446

Phone:

Subject:

Comments on DG1206 DG1207 DG1208 DG1209 DG1210 DG1267

Total Pages: 21

## Message:

I hope these comments are not too late to be useful.

8/22/2012 77FR 50727

RECEIVED

RULES AND DIRECTIVE BRANCH USNRC

SUNSI REVIEW COMPLETE
TEMPLATE = ADM-013
E-RIDS = 03

ADD = m. Orr (mpo1)
m. Case (mje)

		Comments on Draft Regulatory Guide (DG-1206) Con	figuration Management Plans
ID	Section, Page, and Line #	Comment	Proposed Resolution
1	General	With the current emphasis on FPGAs, one would have thought that the topic would have at least been mentioned in this draft.	Incorporate sufficient guidance on software lifecycle techniques to support FPGA VHDL code development.
	General	This regulatory guide clearly defines the roles and responsibilities of licensees, applicants, and NRC staff for software processes. However, this reviewer's experience shows that most, if not almost all, safety software is not written by licensees or applicants. Rather, safety software and safety systems are designed and developed by various vendors. This regulatory guide does not define how software and system vendors are to apply the regulatory guidance. This regulatory guide does not define which version of the regulatory guide is to be applied by a software vendor, or the requirements for software vendors to maintain their programs current with regulatory guidance, which seems to be the NRC requirement, based on topical report submittals.	Consistently define the application of RGs 1.168 through 1.173 for software and system vendors, throughout all sections of each of the regulatory guides. Define the expectations for use of current regulatory guides, since software and system vendors do not have the capability to commit to a given version of regulatory guides and industry standards in a license. Define the expectations for use of current or older regulatory guides in topical report submissions, or point to other NRC documents that define these requirements.
2	A, page 1, last paragraph in the body of the text, 14 <sup>th</sup> line	The structure of the sentence is awkward and difficult to read.	Replace the wording "all activities, such as designing, purchasing, installing, testing, operating, maintaining, or modifying, that affect the safety-related functions of such structures, systems, and components" with "all activities that affect the safety-related functions of such structures, systems, and components, including such activities as design, purchase, installation, review, test, operation, maintenance, and modification."
3	A, page 1, last paragraph in the body of the text, 17 <sup>th</sup> line	The phrase "design changes shall be subject to design control measures commensurate with those applied to the original design" generates problems when updating from analog to digital systems, or updating an older digital system to a newer digital system.	Please provide clarification that current practices need to be used for current programs. This paragraph appears to require application of the analog or primitive software processes used in the last part of the 20 <sup>th</sup> century to current replacement digital systems, or to modification to existing systems. That cannot be the intent of this guidance.

4	A, page 2, third paragraph, fourth line	In the paragraph starting "The NRC issues regulatory" simplify the sentence structure.	Replace "applicants, however" with "applicants. However," for consistency with other regulatory guides.
5	A, page 2, third paragraph, next to last line	Please clarify the version of NUREG-0800 used in reviews.	After the phrase "The NRC staff uses the" add the phrase "latest version of" to provide guidance to industry.
	B, page 3, third paragraph, second sentence	In the paragraph beginning "Several criteria in Appendix B" the word "Criterions" is used. The plural form of criterion is criteria. While "criterions" shows up in several informal dictionaries, it should not be used in formal writing.	Suggest rephrasing the start of the second sentence to either "The listed criteria are only part" or "Each criterion listed below is only part" to use correct grammar.
6	C, page 8, Staff Regulatory Position 7, first paragraph, second line	The second line inappropriately eliminates any software developed by a vendor under a Research and Development (R&D) program from these regulatory requirements.	Delete the word "contractually" which will restore software developed by any vendor for safety related use back into the regulatory requirements.
7	C, page 8, Staff Regulatory Position 7, second paragraph, lines 6-7	While the comment made is correct (EPRI TR-106439 has never been endorsed by a regulatory guide), the technical report has been endorsed through an NRC SER.	Include a statement in the RG text that EPRI TR-106439 has been endorsed by the NRC through a Safety Evaluation Report, dated 17 July 1997.
8	C, page 9, Staff Regulatory Position 8, first paragraph, lines 2-3	Redundant information is provided in this sentence.	Delete the phrase "issued 2003" from the sentence, as the phrase is redundant to the reference to the IEEE Std. in the same sentence, which also includes the issue date with the standard number.
9	C, page 9 Staff Regulatory Position 10, only paragraph, lines 3-4	The phrase "commensurate with those applied to the original design" is problematic. This phrase generates problems when updating from analog to digital systems, or updating an older digital system to a newer digital system.	Please provide clarification that current practices need to be used for current programs. This paragraph appears to require application of the analog or primitive software processes used in the last part of the 20 <sup>th</sup> century to current replacement digital systems, or to modification to existing systems. That cannot be the intent of this guidance.
10	C, page 9 Staff Regulatory Position 11, only paragraph, next to last line	The phrase "activities authorized by the operating license" restricts the application of this guidance to applicants and licensees, eliminating vendors from this guidance. It is also not clear whether this guidance applies in the period before, or after, an operating license exists.	Please reword this statement for appropriate coverage of this standard to vendors, and to licensees and applicants who do not have an operating license.

12	References, page 12	The current note 6 states that this report must be purchased. Since this report is older and since the report did have a NRC SER issued, this report is freely available from the EPRI web site, at <a href="https://www.epri.com">www.epri.com</a> .	Please update the note to state that a PDF electronic version is freely available from EPRI, but that printed copies still require purchase, to be consistent with DG-1267.	
----	------------------------	---	---	--

		Comments on Draft Regulatory Guide (DG-120	7) Test Documentation
ID	Section, Page, and Line #	Comment	Proposed Resolution
1	General	With the current emphasis on FPGAs, one would have thought that the topic would have at least been mentioned in this draft.	Incorporate sufficient guidance on software lifecycle techniques to support FPGA VHDL code development.
2	General	This regulatory guide clearly defines the roles and responsibilities of licensees, applicants, and NRC staff for software processes. However, this reviewer's experience shows that most, if not almost all, safety software is not written by licensees or applicants. Rather, safety software and safety systems are designed and developed by various vendors. This regulatory guide does not define how software and system vendors are to apply the regulatory guidance. This regulatory guide does not define which version of the regulatory guide is to be applied by a software vendor, or the requirements for software vendors to maintain their programs current with regulatory guidance, which seems to be the NRC requirement, based on topical report submittals.	Consistently define the application of RGs 1.168 through 1.173 for software and system vendors, throughout all sections of each of the regulatory guides. Define the expectations for use of current regulatory guides, since software and system vendors do not have the capability to commit to a given version of the regulatory guides and industry standards in a license. Define the expectations for use of current or older regulatory guides in topical report submissions, or point to other NRC documents that define these requirements.
3	A, page 2, third paragraph, third line from end	Please clarify the version of NUREG-0800 used in reviews.	After the phrase "The NRC staff uses the" add the phrase "latest version of" to provide guidance to industry.
4	B, page 3, third paragraph, second sentence	In the paragraph beginning "Several criteria in Appendix B" the word "Criterions" is used. The plural form of criterion is criteria. While "criterions" shows up in several informal dictionaries, it should not be used in formal writing.	Suggest rephrasing the start of the second sentence to either "The listed criteria are only part" or "Each criterion listed below is only part" to use correct grammar.

5	B, page 4, first bullet on the page (last in the list), 2 <sup>nd</sup> and 3 <sup>rd</sup> lines	The sentence does not clearly state what must be "identifiable and retrievable."	Replace "specific itemized records for test documentation and controlled by the SCM as the software evolves with development and maintenance are identifiable and retrievable" with ""specific itemized records for test documentation are identifiable and retrievable, and that the records are controlled by the SCM as the software is developed and as the software evolves"
6	B, page 4, second paragraph, 3 <sup>rd</sup> and 4 <sup>th</sup> sentences	These sentences in the paragraph starting "The documentation identified" do not provide clear requirements that are consistent with practice.	Replace: "The test planning category consists of a test plan with key aspects of an integrity scheme level, which include a life-cycle phase and a traceability matrix for software projects. The overview test plan and report adds coverage for further control and details in the test process."  With text more like: "The test planning process creates a test plan based on the required integrity scheme.  Traceability shall be established from design documents and code to test specifications. The Master Test Plan, or a reference within the Master Test Plan, provides traceability between the all life cycle phases and test procedures. The Master Test Plan and Summary Test Report assure that test procedures have appropriate levels of detail and testing results are reviewed, summarized, and evaluated for completeness."

7	B, page 4, 4 <sup>th</sup> paragraph	The paragraph starting "The IEEE Std. 829-2008" requires interim status reporting, without defining the purpose or content of the "status reports" required. There are additional problems in the first four lines.	If the intent is to require phase summary test reports, then so state. Testing requirements should include test reports which provide results of testing, which are not clearly required by this section.  Replace: "The IEEE Std. 829-2008 test reporting category consists of an interim status report, an anomaly report, more test logs, along with the final test summary reports that allow the licensee to record and summarize test events and that follow the integrity scheme needed within the life-cycle and serve as the basis for evaluating test results."  With something more like: "The test documentation shall include phase summary test reports, anomaly report or reports, test reports, test logs, and the test summary reports. This test documentation will support the licensee by recording and summarizing test events. The test documentation shall follow the integrity scheme documented within the life-cycle. The test documentation shall serve as the basis for evaluating test results."
8	B, page 5, 3 <sup>rd</sup> paragraph, 6 <sup>th</sup> line	The word "associated" has specific meanings in IEEE standards and in regulatory space, which is not the meaning intended in this section.	Replace the word "associated" with another word, or, preferably, delete "associated" from the draft sentence.
9	B, page 5, 6 <sup>th</sup> paragraph, 3 <sup>rd</sup> line	For consistency, refer to IEEE standards in a consistent manner.	Replace "IEEE 829-2008" with "IEEE Std. 829-2008"
10	B, page 6, 1 <sup>st</sup> partial paragraph, last line	The phrasing makes it appear that there is a single "the SDOE."	Replace the phrase "the SDOE" with "an SDOE" to provide indication that SDOE is not a one-size-fits-all proposition.
11	B, page 6, 1 <sup>st</sup> paragraph, 3 <sup>rd</sup> line and C page 7, 1 <sup>st</sup> partial paragraph, 2 <sup>nd</sup> line	Simplify the sentence structure.	Break the existing sentence into two separate sentences. Replace ", however" with ". However"

12	General	DG-1207 now covers all aspects of testing, from unit through system validation/Factory Acceptance Test. DG-1208 only provides guidance for Unit Test.	Please provide guidance equivalent to DG-1208 that covers all aspects of testing to be consistent with the guidance provided in this document.
13	C 1, page 7, Item d	Item d extends the testing boundary for this regulatory guide well past the "Software" in the title, to include system, software, and hardware. It is not clear whether this item applies to all hardware or just hardware containing digital devices.	If this item is retained, then the title of the regulatory guide should be updated to include hardware to make it possible to identify this regulatory guide as applying to hardware.
14	C-2, page 8, first paragraph, last sentence	The sentence clearly defines the requirements for the licensee. The applicant's and the software vendor's responsibilities are not defined. In many cases, the licensee will not be provided with complete software records, making this statement difficult to meet.	Please revise the statement to one where the licensee or applicant is responsible for ensuring that software and system records are retained, including at a vendor's location.
14	C-3, page 8, first paragraph, last sentence	The timing required by the phrase "prior to implementation" is not clear, and can be interpreted in a manner that makes it impossible to write code in the Implementation Phase of the software life cycle, which is different from installation in the plant.	Change "prior to implementation" to "prior to being credited with performing one or more safety functions in a plant" for more appropriate guidance.
15	C-6, page 9, 2 <sup>nd</sup> paragraph, last sentence	There is a grammar issue with this sentence.	We believe that replacing " integrity level 4 and defined" with "" integrity level 4 as defined" conveys the intent.
16	C-6, page 9, 1 <sup>st</sup> paragraph, last sentence	It is not clear what should/shall be done based on "should consider" in the last sentence. Considering and implementing lead to two very different outcomes. We believe that the implementation is more important than consideration.	Replace "should consider" with "should implement" and replace "this annex" with "Annex C" for clarity.
17	C-10, page 10, first paragraph	Please correct the last sentence to reflect the endorsement of annexes.	Replace "These annexes are listed here as sources of information; they have not" with "Annexes B and C have been endorsed by this regulatory guide. Annexes A, D, E, F, G, and H are listed here as sources of information, which have not" and remove "unless otherwise noted"
18	C-10, page 10, Items 1, 4, 5, and 6	Rather than limiting the scope of applicability, provide guidance for software vendors as well.	Replace "applicants and licensees may find it useful" with "users of this regulatory guidance may find this annex useful"

~	Comments on Draft Regulatory Guide (DG-1208) Software Unit Testing			
ID	Section, Page, and Line #	Comment	Proposed Resolution	
1	General	With the current emphasis on FPGAs, one would have thought that the topic would have at least been mentioned in this draft.	Incorporate sufficient guidance on software lifecycle techniques to support FPGA VHDL code development.	
2	General	This regulatory guide clearly defines the roles and responsibilities of licensees, applicants, and NRC staff for software processes. However, this reviewer's experience shows that most, if not almost all, safety software is not written by licensees or applicants. Rather, safety software and safety systems are designed and developed by various vendors. This regulatory guide does not define how software and system vendors are to apply the regulatory guidance. This regulatory guide does not define which version of the regulatory guide is to be applied by a software vendor, or the requirements for software vendors to maintain their programs current with regulatory guidance, which seems to be the NRC requirement, based on topical report submittals.	Consistently define the application of RGs 1.168 through 1.173 for software and system vendors, throughout all sections of each of the regulatory guides. Define the expectations for use of current regulatory guides, since software and system vendors do not have the capability to commit to a given version of the regulatory guides and industry standards in a license. Define the expectations for use of current or older regulatory guides in topical report submissions, or point to other NRC documents that define these requirements.	
3	A, page 1, second paragraph, last three lines	The sentence structure is unnecessarily complex.	Replace "apply to all activities, including design, purchasing, installation, testing, operation, maintenance, or modification, that affect the safety-related functions of such systems and components" with ""apply to all activities, that affect the safety-related functions of such systems and components, including design, purchasing, installation, testing, operation, maintenance, or modification"	
4	A, page 2, third paragraph, next to last line	Please clarify the version of NUREG-0800 used in reviews.	After the phrase "The NRC staff uses the" add the phrase "latest version of" to provide guidance to industry.	
5	B, page 3, third paragraph, second sentence	In the paragraph beginning "Several criteria in Appendix B" the word "Criterions" is used. The plural form of criterion is criteria. While "criterions" shows up in several informal dictionaries, it should not be used in formal writing.	Suggest rephrasing the start of the second sentence to either "The listed criteria are only part" or "Each criterion listed below is only part" to use correct grammar.	

6	B, page 3, bullet for Criterion VI	The sentence provided is unnecessarily complex.	Suggest rephrasing the sentence from: "activities affecting quality, such as instructions, procedures, and drawings, be subject to controls that ensure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel" to "activities affecting quality be subject to controls that ensure that documents are reviewed for adequacy and approved for release by authorized personnel. These documents include instructions, procedures, and drawings. Changes to the documents are subject to at least the same controls."
7	C 1, page 5, last line	The sentence is overly restrictive, in that it requires the information to be provided in this document. At least for Item a in the list, providing reference to the document that contains these records should be sufficient.	Revise the text to allow at least Item A to be referenced from the testing documentation, rather than duplicated in each testing document.
8	C 3, page 6, third line	The phrase "design changes shall be subject to design control measures commensurate with those applied to the original design" generates problems when updating from analog to digital systems, or updating an older digital system to a newer digital system.	Please provide clarification that current practices need to be used for current programs. This paragraph appears to require application of the analog or primitive software processes used in the last part of the 20 <sup>th</sup> century to current replacement digital systems, or to modification to existing systems. That cannot be the intent of this guidance.
9	C 6, first paragraph, second line	There is no need for a semicolon in the text.	Break the sentence at the semicolon, making the single sentence into two separate sentences. Replace "they" with "The annexes"

	Comments on Draft Regulatory Guide (DG-1209) Software Requirement Specifications			
ID	Section, Page, and Line #	Comment	Proposed Resolution	
1	General	With the current emphasis on FPGAs, one would have thought that the topic would have at least been mentioned in this draft.	Incorporate at least some small amount of guidance on applicability of software lifecycles techniques to FPGA VHDL code development.	

Γ	T	<u> </u>	
	General	This regulatory guide clearly defines the roles and responsibilities of licensees, applicants, and NRC staff for software processes. However, this reviewer's experience shows that most, if not almost all, safety software is not written by licensees or applicants. Rather, safety software and safety systems are designed and developed by various vendors. This regulatory guide does not define how software and system vendors are to apply the regulatory guidance. This regulatory guide does not define which version of the regulatory guide is to be applied by a software vendor, or the requirements for software vendors to maintain their programs current with regulatory guidance, which seems to be the NRC requirement, based on topical report submittals.	Consistently define the application of RGs 1.168 through 1.173 for software and system vendors, throughout all sections of each of the regulatory guides. Define the expectations for use of current regulatory guides, since software and system vendors do not have the capability to commit to a given version of the regulatory guides and industry standards in a license. Define the expectations for use of current or older regulatory guides in topical report submissions, or point to other NRC documents that define these requirements.
2	A, page 2, first partial paragraph, line 5	Eliminate the ambiguous reference to "it" for clear, unambiguous requirements.	Replace the phrase "assure a quality product and that it will perform" with "assure a quality product that will perform" (delete "and" and "it") for clarity.
3	A, page 2, third paragraph, fourth line	In the paragraph starting "The NRC issues regulatory" simplify the sentence structure.	Replace "applicants; however" with "applicants. However," for consistency with other regulatory guides.
4	A, page 2, third paragraph, next to last line	Please clarify the version of NUREG-0800 used in reviews.	After the phrase "The NRC staff uses the" add the phrase "latest version of" to provide guidance to industry.
5	B, page 2, first paragraph, first line	Editorial style	For consistency with other standards, add a comma after "such as IEEE standards" to set off the phrase.
6	B, page 3, next to last paragraph, line 3	In the paragraph starting "The original regulatory guide" the third sentence is ambiguous, the word "venue" is being used incorrectly, and "IEEE 830-1998" is not consistent referencing of the standard (should be "IEEE Std. 830-1998").	Replace the sentence "Within this same venue is a new section to this regulatory guide called 'Unambiguity'." with "This regulatory guide provides a new section, 'Unambiguity' consistent with IEEE Std. 830-1998." If that is the intent of this sentence.

B, Page 3, "Description of Change" section, first paragraph	The last two sentences of the first paragraph are confusing as written. A few examples of the confusing statements include:  • The word "corrects" is misleading (suggesting something is wrong with IEEE Std. 830) and the word "enhancements" is opinionated. The actions being performed should be stated more precisely.  • The phrase "other perspectives" is vague – what are the "other" perspectives being referred to and why are the perspectives of the software attribute being changed and not the software attribute itself?  • "Nonapplicability" and "Unambiguity" are not software attributes, but the wording implies that they are.	The last two sentences of the first paragraph should be clarified. A suggested rewording is:  "This version of Regulatory Guide 1.172 endorses IEEE Std. 830-1998, addresses Annex B of IEEE Std. 830-1998, provides guidance on the "Unambiguous" characteristic of an SRS, provides clarification on the "Security" attribute of an SRS, and deletes the existing Regulatory Guide 1.172 section titled "Nonapplicability."
B, Page 3, "Description of Change" section, second paragraph	The first two sentences of the second paragraph are confusing as written. A few examples of the confusing statements include:  • The phrase "changes in the way software is viewed and documented" is confusing. What does it mean to say software is being viewed differently and whose viewpoint is being referred to, possibly the NRC staff? How is software being documented differently in a manner that justifies this argument? And does this mean "software development" as opposed to "software"?  • The second sentence is also confusing and it is unclear what value is being added by the sentence — if a subject is associated with the development of a safety system, then it is expected that it would be applicable for review. Is the purpose of the second sentence to mean that all sections in IEEE Std. 830-1998 are applicable to the development of software for safety-related systems?	The first two sentences of the second paragraph should be clarified. A suggested rewording, if it meets the NRC staff's intent, is:  "The section titled "Nonapplicability" in the previous version of this regulatory guide is being deleted because the NRC staff believes all sections of IEEE Std. 830-1998 are applicable to the development of software for safety-related systems."

B, Page 3,
"Description of
Change"
section, second
paragraph

The last sentence of the second paragraph is confusing as written. A few examples of the confusing statements include:

- The opening statement "This is also the case" is confusing because it is not clear what is also the case.
- The name "associated features" is never defined either in this RG or in RG 1.170. The use of the name in the third paragraph on Page 5 of DG-1207 implies associated features are safety system features that are exercised during testing but not identified. If this is the meaning, then it is unclear how making a requirement unambiguous will allow associated features to be identified. Or is this intended to be tied to the idea of "associated circuits" in IEEE 383?

The last sentence of the second paragraph should be clarified and the NRC staff should explain more clearly how making requirements unambiguous allows for "associated features" to be identified.

The term "associated features" should be defined. In addition, the word "associated" has very specific meaning when it comes to safety-related systems so the NRC staff should consider if this is the correct use of this word.

B, Page 3, "Description of Change" section, third paragraph and C, Page 8, Sub-section 6b, First Paragraph	In the third sentence, the statement is made that the NRC staff does not endorse Subclause 5.3.6.3 of IEEE Std. 830-1998 due to not "having sufficient detail for protecting software." This non-endorsement is re-iterated in Section C.6.b of this RG. Subclause 5.3.6.3 of IEEE Std. 830-1998 states the following:  "[Security Software Attribute] should specify the factors that protect the software from accidental or malicious access, use, modification, destruction, or disclosure. Specific requirements in this area could include the need to"  IEEE Std. 830-1998 is a standard on how to specify requirements, and it is not the source document for what the requirements must be. The NRC staff's non-endorsement of this section is written as if IEEE Std. 830-1998 is attempting to specify content, when it is only describing attributes. This would be similar to the NRC staff saying they do not endorse the "Availability" software attribute subclause because requirements for safety-system availability are provided in other documents. Even though the source of security requirements are located in other documents, the ability to specify these requirements for a specific software language and system design can be different with each application so providing software attributes of security requirements adds value. Requirements for software should always include cyber security requirements, which is all this portion of the IEEE standard attempts.	The NRC staff should clarify the guidance provided in Subclause 5.3.6.3 of IEEE Std. 830-1998, not state that the do not endorse the subclause and then point to the source documents for the requirements themselves (this standard is not specifying the source of the requirements, only the attributes of the requirements specification). In other words the NRC staff should clarify their position on Security with regards to Software Requirements Specification, not with regards to the source documents for those requirements.  Licensees and applicants know they are required to comply with RG 1.152 for SDOE and 10 CFR 73.54 for Cyber-Security – having to reiterate this fact in every software RG seems to be an unnecessary, burdensome approach and confuses the fact that, although RG 1.52 and 10 CFR 73.54 are the source of requirements, that does not mean they provide sufficient information on how to write the software specifications for those requirements.
B, Page 5, first paragraph	The opening sentence is unclear as written and states, "This regulatory guide is based on standards and describes methods acceptable for any safety system and discusses the required SRS activities."	Please clarify this sentence, which should likely read, "This regulatory guide is based on international consensus standards and describes methods and SRS activities acceptable for any safety system software."

C, Page 6, Sub-sectio First Parag		Recommend changing the title of this section to "Unambiguity" and combining discussion from Section 2.h in with this section. Also, the use of the word "traceability" should be replaced with a different word in this section to prevent confusion with the SRS characteristic "traceability."
C, Page 7, Sub-sectio First Parag	·	Recommend NRC staff replace "modified or restated" with "revised" so that the section reads more clearly. Specifically, it appears that the RG is saying that the IEEE standard requires unverifiable requirements to be removed or revise to be verifiable, but the NRC staff only endorses the option to revise to be verifiable.
C, Page 7, Sub-sectio First Parag		Recommend clarifying the last sentence in Section C.2.h. Specifically, the NRC staff should clarify what is means to say the "relationship" between a requirement and its end product should be unambiguous. This clarification should be sufficient to allow the applicant or licensee to know what is an acceptable "relationship" and what is not.  Also, recommend combining this section with Section C.2.a as mentioned in a previous comment.

C, Page 8, Sub-section 3, First Paragraph	The second and third sentences appear to be poor use of the words "should" and "may" in regulatory guidance. By using the word "should", the NRC staff is stating a preferred approach. It would be a better approach to use a format such as "either the licensee or applicant should or the licensee or applicant should" so that the NRC is not providing a preferred approach (without justification) if either approach is acceptable.  It is not clear why the NRC staff's preferred approach is that the licensee or applicant should have a separate change control process for the SRS. Why isn't the preferred approach to use a single software change control process that is part of the Configuration Management Program per RG 1.169? Incorrect software requirements are known to be a major contributor to the probability of latent errors in software, so it is not clear why the NRC staff does not require the SRS to be a Configuration Item per IEEE Std. 830-1998.  The last sentence of Section C.3 is a standalone statement of fact that does not provide any useful guidance for this section.	Any guidance related to change control and configuration management should be provided in RG 1.169. The guidance in Section C.3 should say that the NRC staff does not endorse Section 4.5 of IEEE Std. 830-1998 because guidance on change control and configuration management is provided in RG 1.169. If the NRC staff believes an exception should be made for the SRS, then this exception should be provided in RG 1.169 and Section 4.5 of IEEE Std. 830-1998 should be referenced there (or the wording from Section 4.5 of IEEE Std. 830-1998 placed directly in to RG 1.169 to prevent having to reference another standard and confuse the issue with IEEE Std. 828-2005).
C, Page 9, "Annex" Subsection, Header	This section has the same number as the previous section	Change this section number to Section 7.
C, Page 9, "Annex" Subsection, First Bullet	The bullet is poorly worded. What does it mean to say licensees may use non-endorsed Annex A "as an example"? What does it mean to say Subclause 5.3.7 "may be taken as advisory only"? Is it okay for licensees and applicants to use Annex A format – if not then why? The wording of this bullet implies that the NRC staff has a problem with the format in Annex A, as opposed to the NRC staff not endorsing Annex A because it is informative only.	The NRC staff should clarify their position on Annex A, because it is not clear what the NRC staff is saying they would do if the licensee or applicant provides an SRS in a format from Annex A. If it is okay for a licensee or applicant to provide an SRS in the format of Annex A, the NRC staff should say this.

	Comments on Draft Regulatory Guide (DG-1210) Software Life-Cycle Processes			
ID	Section, Page, and Line #	Comment	Proposed Resolution	
1	General	With the current emphasis on FPGAs, one would have thought that the topic would have at least been mentioned in this draft.	Incorporate sufficient guidance on software lifecycle techniques to support FPGA VHDL code development.	
2	General	This regulatory guide clearly defines the roles and responsibilities of licensees, applicants, and NRC staff for software processes. However, this reviewer's experience shows that most, if not almost all, safety software is not written by licensees or applicants. Rather, safety software and safety systems are designed and developed by various vendors. This regulatory guide does not define how software and system vendors are to apply the regulatory guidance. This regulatory guide does not define which version of the regulatory guide is to be applied by a software vendor, or the requirements for software vendors to maintain their programs current with regulatory guidance, which seems to be the NRC requirement, based on topical report submittals.	Consistently define the application of RGs 1.168 through 1.173 for software and system vendors, throughout all sections of each of the regulatory guides. Define the expectations for use of current regulatory guides, since software and system vendors do not have the capability to commit to a given version of the regulatory guides and industry standards in a license. Define the expectations for use of current or older regulatory guides in topical report submissions, or point to other NRC documents that define these requirements.	
3	A, page 1, last sentence	Separating "activities" from the modifying clause "that affect the safety function" makes the sentence more difficult to read than is necessary.	Replace "all activities, including design, purchasing, installation, testing, operation, maintenance, or modification, that affect the safety-related functions of such systems and components." With ""all activities that affect the safety-related functions of such systems and components, including design, purchasing, installation, testing, operation, maintenance, or modification."	
4	A, page 2, 2 <sup>nd</sup> paragraph, 2 <sup>nd</sup> line	Since the release year/version of the IEEE standard is already defined in the line above, it is not necessary to repeat the issue date.	Delete the phrase "issued 2006" that precedes "Ref. 4"	
5	A, page 2, third paragraph, third line from end	Please clarify the version of NUREG-0800 used in reviews.	After the phrase "The NRC staff uses the" add the phrase "latest version of" to provide guidance to industry.	

6	B, page 3, 2 <sup>nd</sup> paragraph, 2 <sup>nd</sup> sentence	In the paragraph beginning "Several criteria in Appendix B" the word "Criterions" is used. The plural form of criterion is criteria. While "criterions" shows up in several informal dictionaries, it should not be used in formal writing.	Suggest rephrasing the start of the second sentence to either "The listed criteria are only part" or "Each criterion listed below is only part" to use correct grammar.
7	B, page 4, 1 <sup>st</sup> paragraph, next to last line	Since "confirming the security accreditations" is not a phrase that seems to fit in either SDOE or RG 5.71, another phase is required.	Please replace "confirming the security accreditations" with a phrase more in keeping with NRC regulatory practices and guidance.
8	B, page 4, 2 <sup>nd</sup> paragraph, 2 <sup>nd</sup> line	The word "However" at the beginning of the sentence is superfluous. The phrase "be provided" on the second line is superfluous.	Please delete both "However," and "be provided"
9	B, page 4, 3 <sup>rd</sup> paragraph, 1 <sup>st</sup> line	This paragraph should apply to licensees and software vendors, not just applicants.	Please rephrase the requirements to include licensees and software vendors.
10	B, page 4, 5 <sup>th</sup> paragraph	The quality management process should also reference RG 1.169, in concert with RG 1.28.	Please add the Software Quality Assurance requirements to the Nuclear Quality Assurance requirements.
11	B, page 4, 5 <sup>th</sup> paragraph, third from last line	Software V&V is not normally considered something that is performed as "a software V&V."	Replace " performing a software V&V" with " performing software V&V"
12	B, page 5, 1 <sup>st</sup> paragraph, 2 <sup>nd</sup> sentence	The sentence is not clear.	Replace "It describes interrelationships among activities by defining the source activities that produce the inputs and the destination activities that receive the outputs." With "The IEEE standard describes how activities produce outputs, which are then used as inputs to the next activities in the life cycle."
13	B page 5, 3 <sup>rd</sup> paragraph	EPRI TR-106439 is also useful for the acceptance of pre- existing software, and has been referenced in other software draft guides.	Augment the end of the sentence by standing that " can be found in Regulatory Guide 1.152. Additional detailed information on acceptance processes appear in Electric Power Research Institute (EPRI) Topical Report (TR)-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," issued October 1996 (Ref. xx). EPRI TR-106439 has been endorsed by the NRC through a Safety Evaluation Report, dated 17 July 1997." This will require adding this to the References section, and providing a note that the TR is freely available from <a href="https://www.EPRI.com">www.EPRI.com</a> .

14	C, page 6, 1 <sup>st</sup> paragraph	The first sentence can be made more readable.	At least, consider placing a comma after "safety system software" and before "with the exceptions" to help.
15	C 1, page 7. Item c, 6 <sup>th</sup> from last line.	Regulatory Guide 1.152 does endorse IEEE Std. 7-4.3.2. However, RG 1.152 does not provide the information necessary to accept pre-existing software. In addition, IEEE Std. 7-4.3.2-2003 which is endorse does not provide sufficient information to accept pre-existing software.	Reference the as-yet-unendorsed IEEE Std. 7-4.3.2-2010 for a more complete version of the evaluation criteria.
16	C.1, page 7, Item C, last 5 lines	While the comment made is correct (EPRI TR-106439 has never been endorsed by a regulatory guide), the technical report has been endorsed through an NRC SER.	Include a statement in the RG text that EPRI TR-106439 has been endorsed by the NRC through a Safety Evaluation Report, dated 17 July 1997.
17	C 1, page 7, Item d, 4 <sup>th</sup> lìne	Failing to consider the operational environment while developing the software will result in security holes.	Add a third security objective "(ii) secure operational environment," and renumber existing (ii) to (iii).
18	C 1, page 7, Item d, 5 <sup>th</sup> and 6 <sup>th</sup> lines	Augment the discussion with the secure operational environment and simplify the sentence.	Replace "Guidance for secure software development is available in Regulatory Guide 1.152, whereas guidance for cyber security" With "Guidance for a secure software development and operational environment is available in Regulatory Guide 1.152. Guidance for cyber security"
19	C 2, page 8, next to last line	The pronoun "it" does not provide clear, unambiguous reference.	Replace " related properly to one another; it does not provide" with " related properly to one another. IEEE Std. 1074-2006 does not provide"
20	C 4, page 8, Item a, last line	The timing required by the phrase "prior to implementation" is not clear, and can be interpreted in a manner that makes it impossible to write code in the Implementation Phase of the software life cycle, which is different from installation in the plant. It may be necessary to install the software modification in the plant to test the modification adequately. The wording provided in this draft guidance makes that impossible.	Change "prior to implementation" to "prior to being credited with performing one or more safety functions in a plant" for more appropriate guidance.
21	C 4, page 8, Item b, last line	The guidance provided makes it necessary and required to take interfacing systems out of service and declare all interfacing systems inoperable. Properly designed and tested, this is excessively detailed and likely inappropriate requirements.	Change the sentence to allow properly designed, procedurally controlled, interfacing systems to be set to appropriate conditions, which could extend to placing all interfacing systems off line, or could be just as little as marking the data provided by that portion of the safety system as bad. This may require manual actions, or be included as part of the automatic actions included in the design for the interfacing system or the system being maintained.

22	C 6, page 10, 2 <sup>nd</sup> and 3 <sup>rd</sup> lines	The last sentence in this paragraph conflicts with the data provided in the list of annexes below this paragraph.	Change the second sentence to read: "Annex A is endorsed, as described in Item 1. Annexes B through F are not endorsed, but may provide useful information."
----	--	---	--

	Comments on Draft Regulatory Guide (DG-1267) Software Verification Validation Reviews and Audits			
ID	Section, Page, and Line #	Comment	Proposed Resolution	
1	General	With the current emphasis on FPGAs, one would have thought that the topic would have at least been mentioned in this draft.	Incorporate sufficient guidance on software lifecycle techniques to support FPGA VHDL code development.	
2	General	With the release of the 2012 version of IEEE 1012, one questions the value of approval of an 8 year old prior version of the standard.	While having standard revisions more close to the current standard is highly appreciated, use of current standards is more appropriate. When can we expect to see current guidance referenced and endorsed?	
3	General	This regulatory guide clearly defines the roles and responsibilities of licensees, applicants, and NRC staff for software processes. However, this reviewer's experience shows that most, if not almost all, safety software is not written by licensees or applicants. Rather, safety software and safety systems are designed and developed by various vendors. This regulatory guide does not define how software and system vendors are to apply the regulatory guidance. This regulatory guide does not define which version of the regulatory guide is to be applied by a software vendor, or the requirements for software vendors to maintain their programs current with regulatory guidance, which seems to be the NRC requirement, based on topical report submittals.	Consistently define the application of RGs 1.168 through 1.173 for software and system vendors, throughout all sections of each of the regulatory guides. Define the expectations for use of current regulatory guides, since software and system vendors do not have the capability to commit to a given version of the regulatory guides and industry standards in a license. Define the expectations for use of current or older regulatory guides in topical report submissions, or point to other NRC documents that define these requirements.	
4	A, page 2, third paragraph, fourth line	In the paragraph starting "The NRC issues regulatory" simplify the sentence structure.	Replace "applicants; however," with "applicants. However," for consistency with other regulatory guides.	
5	A, page 2, third paragraph, next to last line	Please clarify the version of NUREG-0800 used in reviews.	After the phrase "The NRC staff uses the" add the phrase "latest version of" to provide guidance to industry.	

6	B, page 3, third paragraph, second sentence	In the paragraph beginning "Several criteria in Appendix B" the word "Criterions" is used. The plural form of criterion is criteria. While "criterions" shows up in several informal dictionaries, it should not be used in formal writing.	Suggest rephrasing the start of the second sentence to either "The listed criteria are only part" or "Each criterion listed below is only part" to use correct grammar.
7	B, Page 5, first paragraph	The second-to-last sentence in the first paragraph reads, "elements of software V&V plan".	Change sentence to read, "elements of <u>a</u> software V&V plan"
8	B, Page 5, third paragraph	The opening sentence is unclear as written and states, "This regulatory guide is based on standards and describes methods acceptable for any safety system and discusses the required V&V activities."	Please clarify this sentence, which should likely read, "This regulatory guide is based on international consensus standards and describes methods and V&V activities acceptable for any safety system software."
9	C, page 6. first and second paragraphs	Second sentence of first paragraph states, "IEEE Std. 1012-2004 provides an acceptable approach to the NRC" while first sentence of second paragraph states, "The methods in IEEE Std. 1028-2008 provide an approach acceptable to the NRC staff"	Use "NRC staff" versus "NRC" consistently throughout document. It appears that "NRC staff" is the more consistent use as the document is currently written.
10	C.2, page 6	This section does not appear to clearly develop the guidance being promulgated by the NRC. The topic of the first paragraph is that IEEE Std. 1012-2004 discusses the measurement of software reliability as a method used to verify correct implementation of software requirements. The topic of the second paragraph is that quantitative reliability goals must be based on deterministic criteria. The measurement of software reliability as discussed in IEEE	If the NRC staff's position is that measurement of software reliability, as discussed in IEEE Std. 1012-2004, cannot be used to establish quantitative reliability goals because it is a nondeterministic method, then this position should be stated explicitly.  If the NRC staff's position is that measurement of software reliability, as discussed in IEEE Std. 1012-2004, in not a
		Std. 1012-2004 is not being used to establish quantitative reliability goals, so it is not clear what point the NRC staff is trying to make in this section. Moreover, measurement of software reliability could be used as a practical way to support quantitative reliability goals which, for software, will likely be established using a theoretical approach.	practice accepted by the NRC to help verify the correct implementation of software requirements, then this position should be stated explicitly. (If this is the only point being made, then there is no reason for the second paragraph in this section discussing quantitative reliability goals.)
11	C.6, page 8	This section never ties the requirements of software tools to either IEEE Std. 1012-2004 or IEEE Std. 1024-2008, which is the purpose of this RG.	The NRC staff should identify how the NRC's position on the V&V, review, and audit of software tools is different from (or similar to) the guidance provided in IEEE Std. 1012-2004 and IEEE Std. 1024-2008.
12	C.4, page 8, lines 6-7	While the comment made is correct (EPRI TR-106439 has never been endorsed by a regulatory guide), the technical report has been endorsed through an NRC SER.	Include a statement in the RG text that EPRI TR-106439 has been endorsed by the NRC through a Safety Evaluation Report, dated 17 July 1997.

13	C.8, page 10, last bullet, last line	The global statement that "Annex G is not endorsed by this regulatory guide" appears to conflict with Staff Regulatory Position 7. It is not clear whether the descriptive text found in Annex G is endorsed or not in Staff Regulatory Position 7.	Clarify in the RG text whether the portions of Annex G describing the implementation of those "optional" V&V tasks are endorsed or not endorsed. The "optional" V&V tasks are required by Staff Regulatory Position 7.
14	C.8, page 11, first bullet	We agree that the bibliography provides useful information.	Please clarify in the RG text whether the bibliography is endorsed or not endorsed by this RG.
15	C.8, page 11, last bullet under IEEE Std. 1028	We agree that the bibliography provides useful information.	Please clarify in the RG text whether the bibliography is endorsed or not endorsed by this RG.