

Response to Public Comments on Draft Regulatory Guide (DG)-1382
“Preparing Probabilistic Fracture Mechanics Submittals”
Proposed New of Regulatory Guide (RG) 1.245

On September 23rd, 2021, the NRC published a notice in the *Federal Register* (86 FR 52927) that Draft Regulatory Guide, DG-1382, (Proposed new Regulatory Guide (RG) 1.245), was available for public comment. The Public Comment period ended on October 25th, 2021. The NRC received comments from the organizations and people listed below. The NRC has combined the comments and the staff responses in the following table.

1. Matthew Walter, BWRVIP Senior Technical Leader Electric Power Research Institute (EPRI) 1300 West W.T. Harris Boulevard Charlotte, NC 28262-8550: ADAMS Accession No. ML21300A073	2. Cédric Sallaberry, Senior Research Mathematician Engineering Mechanics Corporation of Columbus 3518 Riverside Drive, Suite 202 Columbus, OH 43221-1735 ADAMS Accession No. ML21306A074
3. J. Brian Hall, Fellow Engineer Westinghouse Electric Company 1332 Beulah Road Pittsburgh, PA 15235-5082 ADAMS Accession No. ML21306A076	

Commenter	Section of DG-1382 or NUREG/CR -7278	Specific Comments	NRC Resolution
1. Walter	General Comment	<p>We believe that the overall plan for a graded approach, as identified in Regulatory Position C.1, as well as the set of items to be included in the PFM analysis and submittal as identified in Regulatory Position C.2 define a reasonable framework that meets the objective of having standardized content and a graded approach for PFM submittals to NRC. We also agree that key content from the EPRI white paper has been incorporated in DG-1382.</p> <p>Furthermore, we agree that presubmittal discussions will be key to ensure NRC and industry alignment regarding the choice of categorization within several of the tables shown in DG-1382.</p>	No change to the documents as a result of this comment.
2. Walter	A, page 1	Delete extra comma after “and holders of”	The NRC agrees with this comment. The extra comma was deleted.
3. Walter	B, page 6	The second of the two referenced sentences seem somewhat redundant with the first and generally provides little additional clarity. Consider deleting or revising the second sentence.	The NRC agrees with this comment. The two sentences were combined for simplicity and clarity.
4. Walter	B, page 6	The October 23, 2018 public meeting followed publication of NRC’s 2018 technical letter report, which is dated September 13, 2018. To clarify the chronology in this background section, it is suggested to discuss first NRC’s technical letter report, followed by the October 23, 2018 public meeting and BWRVIP Letter 2019-016, and finally this Draft RG-1382 and Draft NUREG/CR-7278.	The NRC agrees with this comment. The mention of the September, 2018 technical letter report was moved before the discussion of the October, 2018 public meeting.
5. Walter	B, page 6	Add reference for approved methodology	The NRC agrees with this comment. A reference has been added.

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6. Walter	C, page 8	We agree that identification of deviations from this RG would help streamline NRC’s review, as well as correspondence between NRC and industry as part of the review process.	No change to the documents as a result of this comment.
7. Walter	C, page 9	Sections 2.2, 2.4 and 2.5 should be included somewhere in this Figure. Sections 2.2. and 2.4 seem to fit under Step 1 and Section 2.5 seems to fit under Step 2.	The NRC agrees with this comment. Sections 2.2 and 2.4 were added as references to “Determine the suitability of the PFM code for the application.” Further, Section 2.5 is addressed in Comment 8.
8. Walter	C, page 9	Selection of appropriate models (Sec. 2.5) should be included in the ‘Plan’ step.	The NRC agrees with this comment. In response, “Selection of appropriate models (Sec. 2.5)” added as a bullet to Step 1 Plan in Figure C-1.
9. Walter	C, page 9	Since NRC is encouraging applicants to have pre-submittal discussions/meetings with NRC (Sec. 2.2), this should be part of the ‘Plan’ step.	The NRC agrees with this comment. Addressed in Comment 7.
10. Walter	C, page 9	Suggest referencing Sec. 2.2 and Sec. 2.4 for 3rd bullet in ‘Plan’ step.	The NRC agrees with this comment. Addressed in Comment 7.
11. Walter	C, page 9	Use lower case for ‘from’	The NRC agrees with this comment. The word “from” is revised as suggested.
12. Walter	C, page 11	Please specify that “direct access” entails access to the software executable not the source code.	The NRC agrees with this comment. The words “executable program” have been added to clarify.

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13. Walter	C, page 11	<p>We concur with this discussion of acceptance criteria, but we suggest that the discussion of acceptance criteria be extended to cover some specifics. We believe inclusion of some specific information would be productive and valuable for applicants who apply PFM. We suggest that the Reg Guide list acceptance criteria that were previously approved by NRC and remain acceptable to NRC, including the acceptable range of use for each set of approved acceptance criteria. The discussion should include the rationale that NRC applied to find that each set of acceptance criteria was acceptable. This information would be valuable to applicants who are considering whether derivation of new acceptance criteria is needed. Ideally, NRC would publish acceptance criteria for the most common types of expected PFM applications. For example, for xLPR applications related to leak-before-break, the acceptance criteria presented in ML21217A088 could be referenced.</p> <p>PFM is often used to investigate both structural integrity and leak tightness of pressure boundary components. Structural integrity is assessed in terms of the calculated frequency of unstable rupture, while leak tightness is considered through the calculated frequency of through-wall crack penetration and leakage. Risk-informed decision making principles in accordance with RG 1.200 and RG 1.174 do not appear suited for development of acceptance criteria for leak tightness and the calculated frequency of small pressure boundary leaks that do not have direct safety consequences. Could the Reg Guide discuss NRC's position on acceptance criteria for the calculated frequency of small pressure boundary leaks that do not have direct safety consequences?</p>	<p>The NRC agrees in part and disagrees in part with this comment. Although the NRC agrees that acceptance criteria are an important aspect of PFM regulatory applications, the RG purposely does not address acceptance criteria because it is too broad of a topic and would therefore detract from the specific purpose of the RG, describing acceptable best-practices for generating PFM submittals to the NRC. In fact, PFM could be applied to a large number of specific areas, thus it is not possible to comprehensively address and provide acceptance criteria. Acceptance criteria and QoI are problem specific, and the RG is by design a generic document. Some acceptance criteria may be found in relevant guidance for each application. The NRC may decide to address acceptance criteria separately in the future, on an application-specific basis. For example, for leak-before-break, NRC could develop a RG with acceptance criteria</p>

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14. Walter	C, page 12,13	<p>What are the limits of the approval for these three codes? Can references be added documenting NRC's approval of FAVOR and xLPR, along with the use case(s) and ranges of inputs for which these codes are considered approved? Considering that NRC has approved these codes, what additional actions would be required of a user to accept them to be exercised under their Appendix B QA program to perform analyses in support of a licensing submittal? Does the NRC approval process sufficiently assess the effectiveness of the developmental and maintenance SQA program such that the user may then cite NRC approval as the basis for code acceptance under their Appendix B program?</p> <p>The only NRC-approved codes mentioned are xLPR, FAVOR and SRRA. A question was asked during the August 10, 2021 ACRS meeting (ML21223A043): What constitutes an NRC-approved code? The response by the NRC was that the above-mentioned codes were included, but also codes where a safety evaluation report would have been written for a code for a specific application. There have been other PFM codes that have been used in reports where a NRC safety evaluation was written. These include:</p> <ul style="list-style-type: none"> • The VIPER code was used for RPV shell weld evaluations in BWRVIP-05 which has an NRC Safety Evaluation • The VIPER-NOZ code was used for RPV nozzle evaluations in BWRVIP-108-A and BWRVIP-241 A which both have an NRC Safety Evaluations 	<p>The NRC agrees in part and disagrees in part with this comment. There are no specific documents approving the NRC codes, but their validation regions are described in each code's manual. For clarity, references to the manuals for xLPR and FAVOR were added and the SE approving SRRA is now referenced as well.</p> <p>As long as applicants follow their Appendix B QA program, they meet the requirements of Appendix B. Applicants need to follow their implementation of Appendix B programs.</p> <p>The NRC did not write an SE approving the VIPER or VIPER-NOZ codes generally. The NRC allowed their use for a specific application. For Clarity, the following statement was added to the RG: "there may be instances where a code was approved just for a specific application, and these are considered approved for the same exact type of application". This sentiment is true for xLPR and FAVOR as well. Thus, other clarifying edits were made to Section 2.4 of the RG.</p>

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15. Walter	C, page 13	The intent of these tables when the comment column is subdivided into multiple entries for a given Category is potentially ambiguous. To ensure they are viewed as complimentary to each other rather than alternative selections, clarify the intent that the applicability of all listed comments should be considered when planning a PFM application.	The NRC agrees with this comment. The multiple entries were removed and bullet points were added to help reduce the ambiguity. All tables were adjusted to this format.
16. Walter	C, page 13	Can references be added documenting the validated range of use for the NRC-approved codes?	Yes. A reference has been added.
17. Walter	C, page 14	QV-1B is by definition outside a validated range; therefore, how can this be “within the same validated range”. The Submittal Guideline implies the model is within a validated range.	The NRC agrees with this comment. The language for M-1 and M-2 has been revised per the definitions of QV-1A and QV-1B.

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18. Walter	C, page 14	<p>Quantitative goodness-of-fit-analyses were not performed for all xLPR modules and should not be required for models in category M-2. For xLPR, module validation was performed to assess the predictive capability of modules relative to a combination of plant operating experience, laboratory data, alternative software/models, and/or engineering judgment. Although quantitative metrics were encouraged for xLPR module validation, visual assessment (e.g., plotting module predictions along with data being applied for validation) was also considered an appropriate technique. Thus, we believe similar flexibility should be included in the submittal guidelines for models in category M-2.</p> <p>Suggest updating guideline to: “document a comparison of model predictions for the entire new range to applicable supporting data, predictions made using alternative models, and/or using engineering judgment, optionally supported using quantitative methods such as goodness-of-fit analyses”</p>	The NRC agrees with this comment. The suggested language has been incorporated into the RG.
19. Walter	C, page 14	What are the criteria of a well-established model?	The NRC agrees that the criteria for a well-established model should be clearer. To clarify, a guideline was added that states, “Provide justification for model as being well-established by supporting references and engineering judgement.”
20. Walter	C, page 15	Should this be ‘sensitivity analyses’ or both?	No, this sentence is correct as written. The first sentence refers to sensitivity analyses; the second is correctly stated as sensitivity studies.

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21. Walter	C, page 15	Although the term “important variable” is defined in the glossary as a variable whose uncertainty contributes substantially to the uncertainty in the response, additional guidance on identification of “important variables” is needed. Such additional guidance may consist of either more objective criteria defining “important variables” or input regarding the NRC expectation for the number/fraction of included variables that are “important.” For example, if all inputs are considered to be important, one could also make the argument that none of the inputs are important.	The NRC disagrees with this comment. The NRC recognizes that there is subjectivity in what constitutes an ‘important variable’, and believes that specific criteria cannot be defined that would be applicable in all cases. Engineering judgement should be used by applicants when deciding which variables are important. No change was made to the RG.
22. Walter	C, page 16	Remove first line in the table caption. Also, update List of Tables in page 30.	The NRC agrees with this comment. Revisions were made as suggested.
23. Walter	C, page 16	In addition to listing distribution type and parameters, if applicable, sampling frequency (e.g., component-to-component, within-component, flaw-to-flaw) should also be listed.	The NRC agrees with this comment. Sampling frequency was added to table C-5 in the RG and Sections 3.2.2 and 3.3.2 of NUREG/CR-7278.

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24. Walter	C, page 16	<p>Depending on the application, some input values may be conservative for some QoIs while being nonconservative for other QoIs. For example, a larger bending moment tends to be conservative in that it results in a smaller critical circumferential crack size, but it also has nonconservative effects in that it results in larger leak rates that are more easily detectable for a given through-wall circumferential crack size. We suggest that the RG acknowledge this possibility.</p> <p>It is suggested to update the text to: “along with any known conservatisms or non-conservatisms in that numerical value and the rationale for such conservatisms or non-conservatisms.” and “including any known conservatisms or non-conservatisms in the specified input distributions and the rationale for the conservatism or non-conservatism.”</p>	<p>The NRC agrees with this comment. NRC defined “QoI” to be singular, so assessment of the conservatism in input values should be conducted for each QoI of interest.</p> <p>The proposed edits have been incorporated.</p>
25. Walter	C. page 16	<p>These two guidelines seem quite parallel and should be consolidated into one guideline. Suggested wording: “If applicable, list uncertainty classification (aleatory or epistemic) and provide the corresponding rationale.”</p>	<p>The NRC agrees with this comment. The suggested revision has been incorporated.</p>

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26. Walter	C, page 18	It is possible that in exercising an NRC-approved code outside of the validated range, discretization may also be impacted. Suggest adding the following sentence to this bullet: “This verification should also be documented in cases where the use of a QV-1 code exercised outside of the validated range (i.e., QV-1B) may directly impact discretization convergence.”	The NRC agrees with this comment. The suggested revision has been incorporated.
27. Walter	C, page 18	These descriptions were initially difficult to follow. A decision tree/flowchart may be a more effective method for defining each of these categories (e.g., first split being acceptance criteria met with at least one order of magnitude of margin vs. less than one order of magnitude of margin).	The NRC agrees that the descriptions could be hard to follow. Figure C-2 was added for clarity to represent the decision tree.
28. Walter	C, page 19	Correct imbalanced square brackets.	The NRC agrees with this comment. The suggested revision has been incorporated.
29. Walter	C, page 20	Revise sentence to “...the applicant should determine the sensitivity analysis category for each PFM analysis and document...”	The NRC agrees with this comment. The suggested revision has been incorporated.
30. Walter	C, page 21	As QV-1 is a header, suggest only listing QV-1A.	The NRC agrees with this comment. The suggested revision has been incorporated.

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31. Walter	C, page 21,24	To ensure that the “same” inputs are applied, it is suggested to include a reference to the previously approved inputs for QV-1A codes. Please define what is intended by “same inputs”. As used, the context leaves it subject to interpretation. On one extreme, “numerically identical” inputs would make it impractical to evaluate a new problem. Alternatively, the intent may be that new inputs must not have been introduced to the input set of the NRC approved code version. Additional guidance to clarify the intent regarding the definition of “same” is needed.	The NRC agrees with the comment that the definition of “same inputs” should be clarified. Added language explaining that that Qol refers to the characteristic (not the actual numerical value) and the refers to the parameter chosen (not the actual parameter value).
32. Walter	C, page 21	Where would QV-1B fall? QV-1C should be identified as part of SA-3 and SA-4. QV-2 and QV-3 should be identified as part of SA-5 and SA-6.	The NRC agrees with the comment regarding QV-1C, QV-2, and QV-3 and the table was updated accordingly. QV-1A and QV-1B fall under SA-1 and SA-2.
33. Walter	C, page 21	What additional documentation should be included?	Based on the comment, the NRC believes that the guidance is not precise enough and should be further clarified. In response, the reference to ‘additional information’ was removed, and the guidance for category SA-5 was updated to say, “See the submittal guidelines for SA-3.”
34. Walter	C, page 22	'Or' for guideline directly above or the entire row above? It seems like submittal guidelines for O-1 should be included for O-3 regardless of the selection.	Based on the comment, the NRC believes that further clarification is needed. In response, brackets were added to clarify the reference to “or”.
35. Walter	C, page 24	This guideline is already included in Table C-2 and does not seem relevant for this table.	The NRC agrees with this comment. The subject guideline has been deleted.

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36. Walter	C, page 14	When the idea for what became xLPR was being refined, a modular approach that placed the relevant phenomenological models into generally self-contained modules was selected to facilitate code modification should analytical needs or knowledge in these individual areas evolve. However, Category M-1 highlights an unexpected benefit realized from this early modularity decision. Each xLPR module was independently verified and validated establishing confidence in the underlying models and investing them with a degree of portability beyond xLPR. Already several other PFM applications supported by EPRI have relied on the V&V pedigree of xLPR modules and repurposed them to address problems outside that for which xLPR is applicable. While clearly not relevant for every software development project, in a regulated environment where confidence in analytical models must be rigorously established, such a modular design approach can also have significant secondary benefits.	The NRC agrees with the comment that modular design approaches are beneficial. No action needed.
37. Walter	Draft NUREG/CR -7278, General Comment	There is no mention in this document about presubmittal meetings with the NRC. Presubmittal meetings are encouraged in Draft Guide 1382, Section 2.2. Guidance should be given in NUREG/CR-7278 as to the timeliness of these meetings. For example: Should they be done early in the project lifecycle or not until the submittal is ready to be sent to the NRC?	The NRC disagrees with this comment. Such guidance is not appropriate in the NUREG. With that said, language has been added in Section 2.2 of the RG to indicate that it may be desirable to have the presubmittal meetings early in the lifecycle of a project, but presubmittal meeting timing is ultimately left up to the applicant.
38. Walter	Draft NUREG/CR -7278, page xiii	This sentence on lines 47-48 appears to address a slightly different topic than the rest of this bullet. Should it be a separate bullet?	The NRC agrees with this comment. A separate bullet has been included.

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39. Walter	Draft NUREG/CR -7278, page xv	Insert missing carriage return between defined acronyms for BIC and CDF.	The NRC agrees that a return is missing. Revised as suggested.
40. Walter	Draft NUREG/CR -7278, page 3	Of the listed examples, “cold head cracking” appears to be a vaguely described subset of primary water stress corrosion cracking that is more fully described as the first example. Additional information should be included if cold head cracking is intended to describe something other than PWSCC. Otherwise consider deleting this example from the list.	The NRC agrees with this comment that cold head cracking is a subset of PWSCC. As a result, cold head cracking was deleted from the example list.
41. Walter	Draft NUREG/CR -7278, page 3	Consider also referencing the BWRVIP as well since several of their reports are also listed.	The NRC agrees that the BWRVIP should be added as a reference. Revised as suggested.
42. Walter	Draft NUREG/CR -7278, page 3,5	The latest revision of this report is MRP-335 R3-A (EPRI 3002009241). Suggest updating this reference to reflect the latest revision of this report.	The NRC agrees that the latest revision of the report should be referenced. The reference has been updated to latest version of the report.
43. Walter	Draft NUREG/CR -7278, page 7	Delete extra period at the end of the sentence.	The NRC agrees that the additional period should be deleted. Revised as suggested.

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44. Walter	Draft NUREG/CR -7278, page 7	This statement appears to be a bit broader than either the Purpose of the draft RG presented on page 1 or what this document actually contains. Preparing a thoughtful, competently documented PFM analysis is only one element in risk-informed decisionmaking. It is not by itself guidance on the overall RI decisionmaking process. Consider revising this statement.	The NRC agrees with the comment. Language has been added to clarify that this is “acceptable to use <u>as a piece of evidence</u> for design-basis changes.”
45. Walter	Draft NUREG/CR -7278, page 7	Table 2-1 was very useful in facilitating our review of DG-1382 and NUREG/CR-7278.	No action taken in response to this comment.
46. Walter	Draft NUREG/CR -7278, page 8	To be consistent with Table C-1 of Draft Guide 1382, add NUREG/CR-7278 Section 2.2.1 to RG Section 2.3, Section 2.2.2 to RG Section 2.4 and Section 2.2.3 to RG Section 2.5.	The NRC disagrees with this comment. Table C-1 is specific to mapping content to section 3 of the NUREG. Draft Guide 1382 included only the content related to section 2. This mapping is deliberately as-is and therefore no changes have been made.
47. Walter	Draft NUREG/CR -7278, page 8	For RG Section 2.1, EPRI White Paper Table 1 Item 9 and Table 2 Items 7 and 8 are relevant. For Section 2.9, EPRI White Paper Table 1 Item 5 is relevant. For Section 2.10, EPRI White Paper Table 1 Item 7 is relevant.	The NRC agrees in part and disagrees in part with this comment. For the lines corresponding to RG sections 2.1 and 2.9, NRC Agrees with the comment, and items were added in Table 2.1 of NUREG/CR-7278 as suggested in the comment. For the line corresponding to RG section 2.10 (output uncertainty characterization), NRC disagrees that EPRI white paper Table 1 Item 7 is relevant
48. Walter	Draft NUREG/CR -7278, page 9	Delete extra periods at the end of the sentence.	The NRC agrees that the extra period should be deleted. Revised as suggested.

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49. Walter	Draft NUREG/CR -7278, page 13	"Uncertain assumptions" sounds somewhat redundant. Consider whether this is the best wording to use here.	The NRC agrees with the comment. Updated "uncertain assumptions" to "various assumptions".
50. Walter	Draft NUREG/CR -7278, page 14	Leak detection does not impact the probability of leakage. Suggest changing the last sentence of this paragraph to: "For example, no mitigation and 10-year inspection intervals both impact the assessments."	The NRC agrees with this comment. – Leak detection has been deleted.
51. Walter	Draft NUREG/CR -7278, page 15	<p>10 CFR 50 Appendix B, which requires NQA-1, represents the highest level of QA for software development. The xLPR and FAVOR codes have not been developed to this standard. As noted in the Draft NUREG text, the SQA process should follow a graded approach. Thus, for some uses of PFM models, it may not be necessary to meet the most stringent requirements for all aspects of the software development.</p> <p>An explanation should be provided indicating that it is not the expectation that all SQA requirements per the currently NRC-approved versions of NQA-1 apply in all cases to PFM software that falls under the purview of this NUREG and Reg Guide.</p>	<p>The NRC agrees in part and disagrees in part with the comment. In general, applicants are required to follow their appendix B program. This RG does not exempt applicants from the requirements of 10 CFR 50 Appendix B.</p> <p>Whether NQA-1 applies depends on the applicant's Appendix B program. The guidance in section 2.4 of the RG does not require NQA-1 compliance, and instead describes a graded approach for SQA and V&V activities.</p> <p>The NRC agrees that FAVOR and xLPR were not strictly developed to NQA-1 standards.</p> <p>No change made in response to this comment.</p>
52. Walter	Draft NUREG/CR -7278, page 15	If there is no experimental data for validation of the current code, then there presumably wasn't any such data for that same problem aspect when other software reached the validation step.	The NRC agrees with this comment. The language has been revised to, "with comparable software that has been verified (and ideally validated) previously."

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53. Walter	Draft NUREG/CR -7278, page 15	The words “used in analysis” appear to add very little to this sentence. Consider deleting them.	The NRC agrees with this comment. –The words “used in analysis” have been deleted.
54. Walter	Draft NUREG/CR -7278, page 16	This bullet appears focused on the base code while the next bullet addresses problem-specific changes to that code. Therefore, it appears inconsistent to include the following sentence here: “Have the physics models been changed for the specific application?”	The NRC agrees with this comment. The sentence has been deleted.
55. Walter	Draft NUREG/CR -7278, page 18	This sentence mixes a general description "purely deterministic analysis" with a specific one - "PFM analysis". Not all probabilistic analyses are fracture mechanics so it would be more consistent to replace “PFM” with "probabilistic."	The NRC agrees with this comment. The language has been revised as suggested.
56. Walter	Draft NUREG/CR -7278, page 18	Consider deleting "These" from the sentence. It seems to imply a specific set or class of sensitivity studies that appears both unnecessary and potentially confusing.	The NRC agrees with this comment. The language has been revised as suggested.
57. Walter	Draft NUREG/CR -7278, page 19	KIC should be defined as the plane strain fracture toughness, consistent with ASME Code Section XI and other industry documents.	The NRC agrees with this comment. The language has been revised as suggested.
58. Walter	Draft NUREG/CR -7278, page 35	The broken cross-reference (Reference 0) should be re-linked with the intended reference.	The NRC agrees with this comment. The broken cross-reference has been updated.

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59. Walter	Draft NUREG/CR -7278, page 38	Although such different conclusions can be drawn when separating or when not separating epistemic and aleatory uncertainties, it is important to also point out that the mean results obtained using either approach should be the same (e.g., see the results and conclusions drawn from Case 1.1.23 documented in ML21217A088).	The NRC agrees in part and disagrees in part with this comment. The mean results obtained likely would not be identical due to sampling, but the results should be similar. Thus, a sentence has been added for clarity, which states, “Regardless of the approach for preserving the separation of uncertainties or not, the mean results using either approach should be similar.”
60. Walter	Draft NUREG/CR -7278, page 43	Please provide examples of goodness-of-fit hypothesis test, such as Student t-test	The NRC agrees that it would be helpful to add a few examples of goodness-of-fit hypothesis tests. A few examples have been added.
61. Walter	Draft NUREG/CR -7278, page 71	Row numbers 7 through 10 are not left justified.	The NRC agrees with the comment. However, the line numbers will not appear in the final document, so no correction is needed.
62. Walter	Draft NUREG/CR -7278, page 99	Suggest rewording this summary paragraph to indicate that the subsections of Section 2.2 only cover a handful of topics from DG-1382. The topics included are quantities of interest and acceptance criteria, software quality assurance and verification and validation, as well as models. Also indicate that the remaining topics (regulatory context, information made available to NRC staff, PFM software, supporting documents, inputs, uncertainty propagation, convergence, sensitivity analyses, output uncertainty characterization, and sensitivity studies) are discussed directly in DG-1382.	The NRC agrees with this comment. In response to this comment additional wording was added stating, “Section Error! Reference source not found. is intended for applicants of all experience levels. Each subsection introduces an element of content that would be expected in a PFM <u>submittal and only covers a handful of topics from [RG-1.245]. Topics include: QoI and acceptance criteria, software quality assurance, verification and validation, and models. Remaining topics are discussed directly in [RG-1.245].</u> It identifies representative circumstances for a submittal and describes a graded approach for the specific information to provide to the NRC.”

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63. Walter	Draft NUREG/CR -7278, page 101	Limiting this definition to only experimental data seems overly restrictive. Presumably experimental data will be better controlled and characterized but there are times where calibrating a model to well-characterized field data is appropriate as well.	The NRC agrees with this comment. The word 'experimental' has been removed.
64. Walter	Draft NUREG/CR -7278, page 106	Suggest replacing the "L SEP" symbols shown with regular spaces between the words "systematic method" and "for assessing."	The NRC agrees with this comment. The language has been revised as suggested.
65. Sallaberry	Draft NUREG/CR -7278, page 22	In page 22 first paragraph, it is said that LHS is considered a targeted sampling methods. My understanding of a targeted method is that the sampling density is changed to cover a specific region of the input space to better cover the statistics of one output of interest. LHS stratification is output independent and thus does not seem to match the definition of a targeted method (but maybe my definition is not correct).	In this context, 'targeted' simply implies a method selectively chosen to decrease the number of realizations for convergence, per the previous sentence - no change made.
66. Sallaberry	Draft NUREG/CR -7278	Furthermore, quasi-Monte Carlo Techniques (such as Halton Sequences and Lp-Tau) work similarly to LHS by trying to minimize the distance between two points and better cover the sample space without prior knowledge of the model and outputs of interest. Are these methods covered or are they considered to be too much specific to be included in the document?	The methods from this comment are considered to be too specific for this purpose. The references should be able to point the user to the appropriate method and a literature review is outside the context of this report.

Commenter	Section of DG-1382 or NUREG/CR -7278	Specific Comments	NRC Resolution
67. Sallaberry	Draft NUREG/CR -7278, page 44-48	In section 4.2.2 (p. 44-48) rank correlation and functional relationship are presented as methods to insure good representation of physical relations between inputs. Have copula been considered as potential method that relaxed some of the correlation constraints ?	These methods are not intended to be prescriptive, but merely examples for this report. No, copula has not been considered as a potential method to relax some of the correlation constraints.
68. Hall	C, page 9	Figure C-1: step 4: “Determine a set of sensitivity studies” could be performed in the analysis plan.	The NRC agrees with this comment. – Sensitivity studies could be part of the analysis plan, but this is not always the case. Language was added in parentheses in step 4.
69. Hall	C, page 9	Figure C-1: step 5: “Iterate on the analysis process to refine model results”; the analysis plan should have an established acceptance criteria. Suggest deleting this bullet. 2.3, 4th bullet: What does “rare probability” mean? e.g.: Value or distribution	The NRC agrees in part and disagrees in part with this comment. The analysis plan should have an established acceptance criteria, but this bullet emphasizes that it is likely to be an iterative process. In response to this comment, “rare probability” was revised to “a probability in the extreme tails of the distribution”
70. Hall	C, page 14	Table C-3: M-4: Does 'well-established' mean published in a peer-reviewed journal (see M-5)? Well established could be internal to a company and not necessarily to the entire industry. 2.8, 4th line “...would not change significantly, if...	No, ‘well-established’ does not <u>necessarily</u> mean published in a peer-reviewed journal (although publication in a peer reviewed journal <u>would</u> qualify as ‘well-established’). The NRC agrees with the comment that ‘well-established’ could be internal to a company and not the entire industry. No change was made in RG-1.245 as a result of this comment: the text in table C-3 of the RG for category M-4 provides the necessary flexibility as-is. The suggested addition of the word ‘significantly’ to Section 2.8, Line 4 has been incorporated in the RG.

Commenter	Section of DG-1382 or NUREG/CR -7278	Specific Comments	NRC Resolution
71. Hall	Glossary, page 26-27	<p>“Important variable” is not used in the text.</p> <p>“Random variable” is only used in other definitions.</p>	<p>The NRC agrees with this comment that “important variable” is not used in the text. Updated the glossary to instead define ‘important input variable.’ .</p>