

**Responses to Public Comments on Draft Regulatory Guide DG-1422
“Preparing Probabilistic Fracture Mechanics Submittals,” Revision 1 to Regulatory Guide 1.245**

On February 29, 2024, the U.S. Nuclear Regulatory Commission (NRC) published a notice in the *Federal Register* (89 FR 14782) that Draft Regulatory Guide, DG-1422 (Proposed Revision 1 to Regulatory Guide (RG) 1.245), was available for public comment. The public comment period ended on April 1, 2024. The NRC received comments from the individual and entity listed below. The NRC has combined the comments and NRC staff responses in this document.

Comment Submission

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NEI Comments on PFM and Risk-Informed Methodologies:

As communicated in our April 27, 2023, presentation, NEI disagrees with the position that the guidance in RG 1.174 applies to applications using PFM in situations where the application does not make use of the licensee’s probabilistic risk assessment (PRA).

DG-1422 would require that any regulatory application that uses PFM in support of a technical basis be submitted as a risk-informed application to satisfy the RG 1.174 integrated decision-making principles. The purpose of PFM is to model the behavior and degradation of systems more accurately than traditional deterministic fracture mechanics, and consequentially draw more precise and accurate conclusions about situations relative to performance criteria or design assumptions.

Simply because a probability is computed does not make PFM a risk-informed application. DG-1422 is inconsistent with the NRC’s own definition of a risk-informed approach:

A ‘risk-informed’ approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety.

In DG-1422, it seems as though the staff has conflated the computation of a probability with “risk”. DG-1422 says that PFM provides “risk insights” and therefore there is a need for an integrated decision-making process like RG 1.174. Yet, the NRC’s definition of “risk insights” is *“The understanding about a facility’s response to postulated accidents.”* PFM only provides an assessment of the likelihood of a failure of a component and does not address the facility response. Therefore, the application of the RG 1.174 integrated decision-making is inappropriate. NEI’s position is consistent with both the relevant EPRI technical guidance and the language of RG 1.174 itself, which cites these definitions. Industry acknowledges that PFM may be used with or in support of risk-informed decision-making for licensing basis changes. In those cases where risk insights are used, application of RG 1.174 principles make sense. However, when PFM methods alone are used, and the response of all plant structures, systems and components are not evaluated to calculate core damage frequency or large early release frequency, RG

1.174 should not be used. To that end, the approved guidance in RG 1.245 Rev. 0 makes no reference to either consequences or performance monitoring.

NRC Response:

The staff agrees that RG 1.174 guidance is applicable to licensee submittals that make use of the licensee's PRA, and that the guidance in RG 1.174 is not intended to cover all PFM applications. However, the staff believes PFM analyses do provide risk insights for passive component related changes.

The staff disagree with the assertion that DG-1422 would require meeting RG 1.174, because guidance is not a requirement, and thus licensees are not required to follow DG-1422, if finalized as RG 1.245 Rev. 1. Furthermore, DG-1422 does not state that licensees must follow the guidance in RG 1.174 for PFM applications, however, DG-1422 does clarify the meaning of the following sentence from RG 1.245, Rev. 0: "Applicants should be aware that the use of PFM in a regulatory submission is only one aspect of what is required for risk-informed decision making," as articulated by the revision to Staff Position 2.1 in DG-1422.

In view of the comment, the staff has decided to edit DG-1422 to remove some of the language pertaining to RG 1.174, and instead, to add language that more specifically clarifies the intent of RG 1.245. Specifically, the staff has added language to state that PFM applications should follow the PFM guidance in RG 1.245, and should also consider safety margins, defense in depth, and performance monitoring to ensure that the change proposed based on PFM analyses does not cause adverse safety degradation.

The commenter states that the staff seems to have conflated the computation of a probability with 'risk', and contests that PFM provides risk insights. The staff disagrees with this assertion. PFM analyses provide a probability of failure (or failure frequency) for passive components that may or may not impact the PRA results. For instance, for a component that is modelled in a PRA, if a proposed change causes the component failure frequency to fall above the initiating event frequency assumed in the PRA for the failure of that component, additional PRA analyses may be needed to determine the risk to the plant. If a proposed change causes very little change in the component failure frequency, no additional analyses are needed to understand the impact to plant risk. In both cases, PFM analyses are providing risk insights (either with or without additional PRA analyses) important to the risk-informed determination of the acceptance of the proposed change. Similar logic applies to passive components not modelled in the PRA. To clarify the issue, the staff has added language in DG-1422 to better explain the link between PFM and risk, which, in summary, is that PFM provides risk insights into the impacts of a proposed change.

The staff made the following changes to DG-1422 based on the comments and discussion above (new language in italics and deleted text with strikeout):

2.1. Regulatory Context

The staff typically reviews regulatory applications using engineering analyses that are consistent with currently approved staff positions (e.g., RGs, standard review plans, branch technical positions, the Standard Technical Specifications). For applications that leverage risk insights, such as PFM, the staff makes decisions in an integrated fashion that considers traditional engineering and risk information. Both of these may be based on qualitative factors as well as quantitative analyses and information. *PFM analysis results describe the impact of the proposed change modeled to the overall frequency of component failure. These values can also be interpreted as a change to initiating event frequencies, e.g., LOCA frequencies, typically used in probabilistic risk assessments (PRA). If the change in these frequencies is very small, it can be indirectly inferred that the impact to the core, i.e., core damage*

frequency, is small even if the passive component is not modeled in the PRA. If the change in these frequencies is large, further investigation on the impact to the core may be necessary. Either way, PFM results provide risk insights into the impacts of the proposed change, therefore, Since results from PFM analyses describe the impact of the conditions modeled to the overall probability of component failure, applicants using these tools to justify a submittal, such as an alternative to the codes and standards requirements, should consider not only the PFM analysis results but also other factors when developing the basis.

First, a licensee's proposed change may affect safety margins and defenses incorporated into the current plant design and operation. Therefore, the licensee should reevaluate the safety margins and layers of defense to support the proposed change. Second, careful consideration should be given to implementation of the proposed change and the associated performance monitoring strategies to ensure that they do not cause any unexpected adverse safety degradation. Therefore, an implementation and monitoring plan should be developed to ensure that the PFM analysis conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of the component evaluated. These considerations ensure that the conclusions drawn from the analyses remain valid.

~~For these types of applications, the risk informed guidance in RG 1.174 provides a framework for integrated decision making. The key to this framework is the integration of the five principles of risk informed decision making, which consider both traditional engineering and risk information. These principles include the following:~~

- ~~(1) — The proposed change meets the current regulations unless it is explicitly related to a requested exemption.~~
- ~~(2) — The proposed change is consistent with a defense in depth philosophy.~~
- ~~(3) — The proposed change maintains sufficient safety margins.~~
- ~~(4) — When proposed changes result in an increase in core damage frequency or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement (Ref.).~~
- ~~(5) — The impact of the proposed change should be monitored using performance measurement strategies.~~

~~In addition to addressing the principles items described above, regulatory submittals using PFM analyses should explain why a probabilistic approach is appropriate and how the probabilistic approach is used to demonstrate compliance with the regulatory criteria. When no specific regulatory acceptance criteria exist, the submittal should explain how the probabilistic approach informs the regulatory action and regulatory compliance demonstration. Applicants should be aware that this RG focuses *only* on the supporting PFM information needed for the staff to make an informed decision regarding the acceptability of the PFM methodology. Application specific guidance may be needed to develop the remaining basis needed for integrated decision making. For example, the staff developed a statistical approach to developing a performance monitoring plan for steam generator and pressurizer shell weld inspections (ADAMS Accession No. ML23272A168). Additional information in RG 1.174 on safety margins, defense in depth and performance monitoring may also be useful in developing a technical basis. Applicants should consult RG 1.174 for guidance on other information that may be needed to support the principles of risk informed decision making.~~

NEI Comments on Forward Fitting and previous approvals:

The NRC defines forward fitting as:

[T]he imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation.

The Regulatory Position C.2 communicated in DG-1422 is a “new or modified” interpretation of what is required to credit PFM in support of regulatory applications, including applications for use of alternatives to codes and standards requirements. Specifically, as stated in the regulatory analysis accompanying DG-1422, the current revision of RG 1.245 “does not include guidance on how risk-informed decision-making principles should be applied to regulatory applications that use PFM as part of their technical basis.” To remedy this situation, DG-1422 communicates a new position that RG 1.174 “is also applicable to regulatory applications that use PFM as part of their technical basis.” This position is not contained in revision 0 of RG 1.245, which simply contains the vague direction that “[a]pplicants should be aware that the use of PFM in a regulatory submission is only one aspect of what is required for risk-informed decision making.”

Indeed, the NRC has unconditionally approved four (4) plant submittals using PFM to support alternatives to codes and standards. The technical basis for these four applications was an EPRI white paper, “White Paper on Suggested Content for PFM Submittals to the NRC.” The NRC did not require application of RG 1.174 as a condition of approval of these applications. Specifically, the NRC did not require performance monitoring as a condition of those approvals, which is a principle made applicable to risk-informed decisions using PRA under RG 1.174. Imposing the need for performance monitoring, or other elements necessary pursuant to RG 1.174, in all applications supported by PFM would significantly expand the applicability of RG 1.174 and require licensees to modify their engineering evaluation and regulatory submittal processes as a condition of approval of licensee-initiated requests for use of alternatives to codes and standards.

Thus, if the NRC is proposing to require the use of the guidance contained in DG-1422 in lieu of the existing guidance provided in revision 0 to RG 1.245, then the changes in DG-1422 must be properly evaluated as forward fitting prior to the DG-1422 being finalized.

Specifically, MD 8.4 states that:

The NRC may condition its approval of . . . a licensing action on the use of a new or modified regulatory staff position only if: (1) there is a direct nexus to the licensee’s request, and (2) the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff’s determination of the acceptability of the licensee’s request. Staff must address these two elements in its analysis and adequately justify why each one is independently met.

There is no indication in either DG-1422, the associated Regulatory Analysis, or the associated Federal Register notice that the staff has addressed these required elements of forward fitting. In addition, MD 8.4 also points out that the Administrative Procedure Act requires some consideration of costs when a “forward fit is unrelated to adequate protection.”¹⁵ We do not believe, and there is no indication in DG-1422 or any of the supporting documents, that the forward fit imposed by DG-1422 is necessary to either ensure or redefine adequate protection. This conclusion is affirmed by the fact that, to our knowledge, the

NRC has not required backfitting of the four approved pilot plants to impose a performance monitoring requirement (or any other principle provided in RG 1.174).

While the Regulatory Analysis accompanying DG-1422 acknowledges that there will be costs associated with preparing and issuing the proposed revision to RG 1.245, it contains no meaningful discussion of those costs and does not attempt to quantify them. Also absent from the Regulatory Analysis is *any discussion* of costs imposed on applicants because of the revisions contained in DG-1422. Instead, the Regulatory Analysis asserts that applicant acquiescence to new position articulated in DG-1422 would *actually reduce costs* because such acquiescence “would reduce the number of requests for additional information and shorten review times, resulting in ongoing cost savings to the NRC and industry.”

NRC Responses:

Backfit and forward fit

The staff disagrees with the commenter’s assertion that DG-1422 is a forward fit, for the following reasons:

- RGs are not licensee-initiated requests, which is the prerequisite for a forward fit claim.
- The first sentence of the DG states that it “describes a framework to develop the contents of a licensing submittal that the [NRC staff] considers acceptable when performing probabilistic fracture mechanics (PFM) analyses in support of regulatory applications.” The DG does not suggest that this is the only framework acceptable. Additionally, as stated in the DG, regulatory guides are not NRC regulations and compliance with them is not mandatory. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.
- The DG specifies that the NRC does not intend to impose the DG on licensees, so issuance would neither be a backfit nor a forward fit.
- The DG deals with the content of an application. Even if the NRC required certain information to be in an application, such a requirement would not meet the definition of a backfit or forward fit.
- The DG, if finalized, would not invalidate previous approvals

The staff did not make any changes to DG-1422 as a result of this comment. However, since the issuance of DG-1422, the NRC staff has updated generic language for all DGs and RGs in “Purposes of Regulatory Guides,” as follows:

The NRC issues RGs to describe methods that are acceptable to the staff for implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if the applicant provides sufficient basis and information for the NRC staff to verify that the alternative methods comply with the applicable NRC regulations.

In addition, the NRC staff has updated the generic language for all DGs and RGs in Section D, “Implementation,” as follows:

Licensees generally are not required to comply with the guidance in this regulatory guide. If the NRC proposes to use this regulatory guide in an action that would constitute backfitting, as that term is defined in 10 CFR 50.109, “Backfitting,” and as described in NRC

Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests”; affect the issue finality of an approval issued under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”; or constitute forward fitting, as that term is defined in Management Directive 8.4, then the NRC staff will apply the applicable policy in Management Directive 8.4 to justify the action. If a licensee believes that the NRC is using this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may inform the NRC staff in accordance with Management Directive 8.4.

Previous approvals

Regarding the four plant submittals discussed by the commenter, the staff expressed how those submittals included the proper amount of performance monitoring in an April 27, 2023, public meeting (ADAMS Accession No. ML23114A034) in that those plants that requested an extension of their 10-year inspection interval to a 30-year interval were consistent with the performance monitoring approach in the staff’s white paper on the topic (ADAMS Accession No. ML23272A168). In addition, the staff notes that each individual application is evaluated based on its own merits, and that DG-1422 does not require performance monitoring. That said, DG-1422 clarifies the intent of RG 1.245 by stating that licensees should consider safety margins, defense in depth, and performance monitoring as part of their submittals that use PFM analyses as a basis.

To add clarity, the staff added the following paragraph to Section B of DG-1422 as follows:

During the development and after the publication of RG 1.245 Rev. 0, the staff had discussions with licensees pertaining to regulatory submittals that leverage PFM as a basis for ASME inspection relief. These discussions revolved around the topic of what additional information may be needed to support a regulatory application that utilizes PFM as a basis. A variety of public meetings were held (see ADAMS Accession Nos. for example see ML22053A171 and ML23115A138) where the staff clarified that items such as performance monitoring, safety margins, etc. may be needed to demonstrate continued applicability of the analysis results throughout the time period requested for the inspection relief. In addition, the staff published a draft white paper (ADAMS Accession No. ML23272A168) on performance monitoring to support these ongoing discussions and to clarify the staff’s initial consideration on performance monitoring issues. This revision to RG 1.245 provides clarification consistent with the aforementioned meetings and white paper.

Revised Regulatory Analysis

Regarding costs, this DG does not impose costs on industry because it is entirely voluntary. The staff did not make any changes to DG-1422; however, the staff has revised the previous regulatory analysis for DG-1422 as discussed below. Based on some of the comments above, the staff has revised the previous Regulatory Analysis (ADAMS Accession No. ML24312A310). In summary, the revised Regulatory Analysis concludes that the RG is justified from a quantitative standpoint because the benefits to licensees and the NRC from the averted cost of resubmitting applications outweigh the relatively minor cost to the NRC of issuing and implementing the RG. In addition, the NRC concludes that the RG is also justified when considering non-quantified costs and benefits because the increase in regulatory efficiency will provide benefits to both licensees and the NRC. This revised Regulatory Analysis and will be available for comment with the issuance of DG-1422, Revision 1.

NEI Recommendation:

NEI requests that the NRC either withdraw DG-1422, or revise and republish the draft guide for public comment with an adequate forward fit evaluation. The revised draft guide should limit the application of RG 1.174 principles to those submittals that use PFM in support of a risk-informed application since not all applications that may use PFM to support a technical basis are risk-informed.

NRC Response:

NRC has revised DG-1422 to clarify that safety margins, defense in depth, and performance monitoring should be considered by licensees in applications that use PFM, as identified above. In addition, the NRC has determined that the forward-fit claim is invalid for the reasons stated above.

The NRC is issuing DG-1422, Revision 1, and a revised Regulatory Analysis for an additional round of public comments.