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(via e-mail)

February 27, 2019

Dr. David Rudland
Dr. Patrick Raynaud
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: White Paper on Suggested Content for PFM Submittals to the NRC

Dear Dr. Rudland and Dr. Raynaud,

During the October 23, 2018 NRC public meeting on "Discussion of a graded approach for probabilistic fracture mechanics codes and analyses for regulatory applications," EPRI provided a presentation containing suggested expectations for submittals to the NRC containing the use of probabilistic fracture mechanics (PFM). EPRI further identified that a white paper was under development which would contain additional detail regarding the recommendations made in the presentation. NRC Staff requested that the white paper be provided for their review. The white paper is attached to this letter, thereby satisfying that request. In providing this white paper, EPRI respectfully requests that the contents be considered by the NRC Staff as they develop guidance on PFM. It should lastly be noted that the attached white paper does not contain any commitments or NEI-03-08 requirements.

If you have any questions on this subject, please contact me by telephone at 724-288-4043 or by e-mail at npalm@epri.com.

Sincerely,

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SUGGESTED CONTENT FOR PFM SUBMITTALS TO THE NRC

1.0 Introduction

1.1 Background

In September 2018, NRC released a Technical Letter Report (TLR) [1] presenting a general framework to describe, perform, and evaluate a probabilistic fracture mechanics (PFM) analysis. The TLR states that the NRC intends to develop guidance to perform and evaluate PFM analyses in the form of a regulatory guide and a more detailed technical basis NUREG document. The NRC staff has concluded that such guidance is needed to ensure that NRC staff expectations for PFM submittals are sufficiently clear. NRC staff have emphasized that PFM analyses can be complex and thus require thoughtful, competent development, documentation, and regulatory review when applied in regulatory matters.

Expectations for PFM submittals were discussed at the May 2018 Industry / NRC Materials Programs Technical Information Exchange meetings ([2], [3], [4]). At this public NRC meeting, NRC staff discussed past cases in which they felt that industry PFM submittals did not include sufficient information and justification to support NRC review and acceptance. A relatively recent example is the topical report [5] submitted by EPRI MRP on peening mitigation of PWSCC. This topical report was accepted by the NRC primarily on the basis of its deterministic analyses, although PFM results informed the NRC review.

The industry generally concurs that the NRC TLR [1] provides a reasonable summary of the various aspects of probabilistic fracture mechanics analyses to be considered as the analyses are being developed and performed. However, the TLR does not make clear the minimum expectations for all PFM submittals, nor guidance for determining when more detail within specific areas is warranted. Instead, the TLR is a 50-page document that could be interpreted as a broad definition of all of the elements that must be explicitly evaluated and documented in the submittal. Moreover, there is substantial concern within industry that, once in the form of a regulatory guide accompanied by a NUREG, NRC staff in the future may interpret the guidance as mandatory requirements even though regulatory guides and NUREGs do not have the force of regulations. There is significant potential that without a more nuanced initial alignment of problem complexity with developmental and documentation level of detail, the NRC process could lead to inflexible, overly prescriptive, “one-size-fits-all” expectations for any PFM submittal.

1.2 Objectives

The goal of this white paper is to define a practical framework for the content of PFM submittals to maintain the effectiveness of NRC reviews of such submittals while improving review efficiency. It is proposed that the NRC staff consider the contents of this white paper as they develop guidance on PFM.

1.2.1 Suggest Minimum Content for PFM Submittals

As an alternative to the path the NRC outlined in their TLR and presented in the previous public forums, a main objective of this white paper is to identify the minimum content that should be provided for future PFM submittals to the NRC. The items suggested in this white paper are intended to provide traceability, appropriately detailed documentation, and instill confidence in PFM analyses without making PFM analyses cost- and schedule-prohibitive and to address the specific NRC concerns expressed in recent public meetings.

Table 1 summarizes the suggested PFM submittal content as recommended by EPRI. These are discussed in more detail in Section 2.0.

1.2.2 Identify Specific Circumstances When Additional Depth of Information May Be Needed

Depending on the scope and nature of a particular PFM analysis, it might be appropriate for additional information beyond the items identified in Table 1 to be included in an NRC submittal. Therefore, a second objective of this white paper is to identify specific situations when more detailed information is appropriate for inclusion in the submittal.

A prescriptive set of criteria covering all possible future situations is not practical nor necessary to ensure safe decision making. The organization responsible for the PFM analysis should consider the factors listed in Table 2 when establishing whether information beyond the minimum is needed in the submittal, as well as the level of detail of the information provided to the NRC. In recognition of the factors in Table 2, specific individual circumstances that may require additional details to be included in the submittal are discussed in Section 2.0.

Table 1 Summary of Suggested Content for PFM Submittals

#	Item	Suggested Minimum Content
1	Information Made Available to NRC Staff with PFM Submittal	• The submitter should have a plan for making the PFM software and supporting documents available to the NRC to enable their review of the PFM submittal
1.1	PFM Software	• In cases that a sufficiently similar PFM code is not available for NRC to perform a meaningful benchmarking comparison, propose a way to give NRC sufficient access to the PFM software, for example through an informal review meeting
1.2	Supporting Documents	• As appropriate, the supporting technical and quality assurance (QA) documents and procedures for the PFM software should be available for examination by NRC staff in an in-person review meeting
2	Models	• Document the model or models to a sufficient level of detail that a competent analyst already familiar with the relevant subject area could independently implement the model(s) • Provide a basis for all significant aspects of the model(s), including why the selected models are sufficiently reliable for the intended application, with identification of important uncertainties or conservatisms • Document any algorithms or numerical methods needed to implement the model(s) • Discuss any significant assumptions, approximations, and simplifications, including their potential impacts on the analysis
3	Inputs	• Document the inputs in detail, including specifying their values and whether they are treated as deterministic or probabilistic (and if probabilistic, document the distribution from which the inputs are sampled) • Provide the basis for the input values used, including why the input basis is considered sufficiently reliable for the application • Document use of interpolation, extrapolation, and truncation schemes, as well as curve fitting of data • Document the approach for treatment of correlation or statistical independence of inputs, along with the corresponding basis for the approach • Ensure that selected or sampled inputs remain consistent and physically valid if inputs are dependent on each other, e.g., due to physical processes • Present the method and basis for treating epistemic and aleatory uncertainties
4	Convergence	• Explicitly demonstrate convergence for all temporal and spatial discretizations, as well as statistical convergence of the Monte Carlo simulation

#	Item	Suggested Minimum Content
5	Input Importance and Sensitivity Studies	• Document an assessment of input importance, with the objective to identify the subset of inputs that have the greatest impact on the analysis results or conclusions • Revisit the most important inputs and discuss how the values or distributions for the most important inputs were confirmed to be treated appropriately
6	Verification and Validation	• Identify the applicable QA program, plan, and/or procedures, as well as the QA standards met • Include a basic description of the measures for quality assurance, including verification and validation of the PFM software as applied in the subject report • Include confirmation that the verification and validation cover the ranges of input values considered in the submittal • Document any benchmarking activities performed for the PFM software
7	Uncertainties	• Summarize the overall Monte Carlo sampling structure (or other probabilistic treatment) and simulation framework, including their basis • Include descriptions of the pseudo-random number generation, sampling methods, sampling frequencies, and applied spatial or temporal discretization (each as applicable) • Discuss the basis for any conservative treatments of input values or models • Include a summary discussion of key uncertainties or biases stemming from assumptions and simplifications to make real-world phenomena tractable, based, at a minimum, upon qualitative assessment
8	Acceptance Criteria	• Document the probabilistic acceptance criteria and their basis, for example a previous established precedent
9	Principles of Risk-Informed Decision-Making	• When information from the plant probabilistic risk assessment (PRA) is used along with the PFM results to propose a risk-informed change to the plant licensing basis, explicitly address each of the five items identified below, i.e., include sufficient discussion how each is ensured • In PFM submittals not making use of the PRA and/or not proposing a change to the plant licensing basis, optionally consider discussion of some of these risk-informed elements as warranted
9.1	Proposed change to licensing basis meets current regulations unless it is specifically related to a requested exemption	• Include a statement confirming this requirement, with explanation as needed

#	Item	Suggested Minimum Content
9.2	Proposed change to licensing basis is consistent with defense-in-depth philosophy	• Explicitly discuss how defense-in-depth is maintained under the proposed action (Section C.2.1.1 of NRC Regulatory Guide 1.174 discusses the relevant considerations)
9.3	Maintain sufficient safety margins	• Explicitly discuss how sufficient safety margins are maintained under the proposed action • A complementary deterministic analysis applying the structural (safety) factors of ASME Section XI might be one example of an acceptable approach
9.4	Proposed changes in risk are small and are consistent with the Commission's Safety Goal Policy Statement	• Ensure the submittal is clear concerning how the quantitative CDF or LERF results are compared to acceptance criteria, as well as how the acceptance criteria are appropriate
9.5	Use performance-measurement strategies to monitor change	• Explicitly discuss how future performance will be monitored to ensure that the conclusions of the PFM analysis continue to be valid, for example through ongoing examinations at the subject plant and more generally in the industry

Table 2 Considerations for Submittal of Additional Depth of Information

#	Consideration
1	The safety significance of the component being evaluated (e.g., pressure boundary components versus passive internals components, Class 1, 2, or 3 or Risk-Informed Safety Class (RISC) 4, high versus moderate energy) • Previous NRC approval of a PFM approach for a lower safety class may not apply to a higher safety class without further NRC consideration, possibly requiring further submittal of information
2	The “failure” mode being considered (e.g., rupture versus leakage versus flaw initiation)
3	The margin between the PFM results and the acceptance criteria
4	Plant-specific or generic scope
5	Emergent or ongoing issue
6	First-of-a-kind type applications or more routine application
7	Whether the submittal is a justification for a change to the plant licensing basis
8	Whether the PFM is the sole basis versus a supporting basis of the submittal
9	The extent of relevant plant experience available for reliably characterizing the degradation
10	The implications of potential unknowns
11	The code complexity (e.g., number of inputs and modules)
12	The extent of differences of the code to other codes previously reviewed by NRC
13	Whether the range of use for the application is outside that previously reviewed by NRC
14	Extent of difference between requested alternative and ASME Code requirements (e.g., single cycle relief or ongoing difference)

2.0 Items Needed for PFM Submittals

The following discussion of specific elements of a competent PFM submittal is presented in terms of topics that "must" or "should" be addressed, or similar phrasing. Given that the desired outcome is approval of the submittal, it is the responsibility of the submitter to communicate through the submittal with the appropriate level of detail for each element necessary for a knowledgeable reviewer to understand what was done and why it was considered technically defensible. Conversely, extraneous information and unnecessary detail may be distracting and potentially confusing, and its inclusion should be avoided. The following discussion attempts to provide guidance for balancing these competing priorities.

2.1 Information Made Available to NRC Staff with PFM Submittal

The submitter should have a plan addressing supporting information that may be necessary for competent review of the submittal. This may include information made available with the submittal, that which might be provided upon request, and that which maybe can't be directly transmitted but might be reviewed under specific agreed upon circumstances. Section 2.1.1 discusses a proposed approach for addressing NRC's stated desire for access to the PFM software in cases where a sufficiently similar code is not available to NRC. Section 2.1.2 discusses potential NRC access to supporting documents.

2.1.1 PFM Software

In the May 21, 2018, public meeting ([2], [3], [4]), NRC emphasized how, in past cases in which a PFM submittal was successful in gaining NRC acceptance, the PFM software was either available to them or NRC had a similar code that could be applied for benchmarking purposes. NRC staff emphasized from this practical experience that this item is key to NRC developing sufficient confidence in the PFM results. The benchmarking approach for gaining acceptance requires that a sufficiently similar PFM code already be available to NRC, preferably a code that has already been used in an application accepted by NRC (such as FAVOR).

In cases that a sufficiently similar PFM code is not available for NRC to perform a meaningful benchmarking comparison, an alternate approach should be considered to address this NRC concern such as the following:

- Hold an informal review meeting with NRC staff in which the PFM submittal developers run analysis cases as requested by NRC staff.

- NRC staff could submit some analysis requests in advance of the meeting, or two separate meetings could be held to allow time between meetings for the PFM submittal developers to run cases.
- To address runtime concerns, developers could optimize runtime or consider a fast run mode that does not include all code features. Having some capability to perform runs during a review meeting would be advantageous.

Specific Circumstance in which Additional Depth of Information May Be Needed: The extent of the benchmarking or NRC staff review may depend on the factors outlined in Table 2. Specifically, more complex codes or new codes may warrant a more thorough review (e.g., more meetings or more cases run by request) than for codes with which NRC staff are closely familiar. Similarly, when a code previously reviewed by NRC is applied in a new way (i.e., outside the previously reviewed range of use for the code), a more detailed review to consider these differences may be warranted.

2.1.2 Supporting Documents

The quality assurance (QA) program or procedures to which the PFM analysis code is being developed (and thus also the standards to which that QA program or procedures comply) will define what additional supporting documents will need to be generated. It is not necessary or appropriate to transmit all such supporting documentation to NRC. However, if performed under a QA program, that supporting documentation will need to be retained by the organization(s) that developed the PFM analysis code. Depending on the application of the PFM code, different QA programs may apply, which in turn may impact the level of documentation required. Regardless of the QA program or procedures applied, the submitter of the PFM analysis might consider ways to facilitate making such supporting documents available for examination by NRC staff in an in-person review meeting.

2.2 Models

The submittal to the NRC must document the model or models applied in the PFM analysis code to a sufficient level of detail that a competent analyst familiar with the relevant subject area could independently implement the model(s) from the documentation alone. Model forms can either be theoretical, semi-empirical, or empirical.

A basis for all significant aspects of the model(s) should be provided and may consist of raw data or published references. Any algorithms or numerical methods (e.g., root-finding, optimization,

etc.) needed to implement the model(s) should also be documented or referenced. Furthermore, any significant assumptions, approximations, and simplifications made should be discussed, including their potential impacts on the analysis.

A summary of the model validation should also be provided to demonstrate that the selected models are sufficiently reliable for the intended application. Important uncertainties (e.g., bias, variance, noise) or conservatisms of the model(s) should be identified.

Separate deterministic fracture mechanics (DFM) analyses may be included to support other validation results, as appropriate for a given application.

Specific Circumstance in which Additional Depth of Information May Be Needed: Inclusion of increased detail regarding model development may be appropriate in cases where the applied model is relatively new (e.g., first-of-a-kind type applications), and the degree of detail should be commensurate with the safety-significance of the components being evaluated.

2.3 Inputs

The inputs to the PFM analysis must be documented in detail. This includes listing the inputs, specifying their numerical values, whether they are treated as deterministic or probabilistic (and if probabilistic, definition of the distribution from which the inputs are sampled), and the basis for the input values used. It should specify why the input basis is considered sufficiently reliable for the PFM analysis application, and if the input basis comes from another document, the reference should be clearly defined. . Use of interpolation, extrapolation, and truncation schemes, as well as curve fitting of data, should be documented.

If there is a lack of data to develop the needed input value or distribution, the basis should explain why engineering or expert judgment used to develop that input value or distribution is considered appropriate. Alternatively, through sensitivity analysis, it can be demonstrated that the given input does not have a sufficient impact on the results to affect the conclusions obtained from the analysis.

In some cases, correlation of sampled inputs is appropriate to address important relationships inherent across inputs. For example, material strength and fracture toughness are sometimes inversely correlated such that neglecting their relationship may produce non-physical results. The approach taken to correlation or statistical independence of inputs should be documented, along with the corresponding basis. Actions that are repeated in time (e.g., inspections) may be correlated temporally. For example, flaws located in areas challenging for detection would still

be expected to have reduced probabilities of detection for repeated examinations. Furthermore, if inputs are dependent on each other, e.g., due to physical processes, it should be ensured that selected or sampled inputs remain consistent and physically valid.

Separating sampled uncertainties into epistemic and aleatory uncertainties is not required in all cases, but may be considered as appropriate to obtain an improved understanding of the uncertainties in the analysis output. Classical (one-loop) Monte Carlo simulations have run-time advantages due to the significantly simplified sampling structure. As discussed in the NRC TLR [1], the choice of separating the two uncertainty categories in a PFM analysis depends on the nature of the problem and the intended outcome. Thus, selection of a two-loop Monte Carlo (separation of epistemic and aleatory uncertainties) versus a classical one-loop Monte Carlo simulation should be considered and discussed.

Specific Circumstance in which Additional Depth of Information May Be Needed: If certain inputs are found to be driving factors in the "failure" mode being considered (discussed further in Section 2.5), a more detailed and robust basis for those inputs or input distributions may be required.

2.4 Convergence

Convergence should be explicitly demonstrated for any discretization applied in the analysis. This includes temporal discretization (e.g., time-steps applied in model evolution), as well as spatial discretization (e.g., discretization of a component into multiple subunits). Furthermore, statistical convergence of the Monte Carlo simulation should be demonstrated. Convergence can be demonstrated by including summary results for a subset of cases showing that refined discretization and additional realizations have no significant impact on the analysis results and conclusions. If necessary, the uncertainty associated with incomplete convergence shall be estimated and applied when interpreting the probabilistic results.

Greater uncertainties associated with incomplete convergence may be more tolerable in cases where significant margin exists between the PFM results and the acceptance criteria, provided that the results are sufficiently converged to have confidence in that margin.

2.5 Input Importance and Sensitivity Studies

When reviewing the results of a PFM analysis, it is important to understand the input variables that have a major impact on the analysis results and conclusions. Multiple approaches and tools have been applied to assess input importance, or to determine if changing a given input has

significant impact on an analysis result or conclusion. Such methods include the following examples:

- Regression Analyses
  - multiple linear regression
  - rank regression
  - recursive partitioning
  - multi-adaptive regression spline (MARS)
- Machine Learning Algorithms
  - classification models
  - regression models
- Reliability Methods
  - directions cosines method
  - comparison of failure distributions with underlying distributions

Also included are classical sensitivity studies in which the input values or distributions are changed for one input at a time, followed by an assessment of the impact of those changes on the analysis outputs. Any approach or tool useful to evaluate input importance may be considered for use.

The PFM submittal should include an assessment of input importance, with the objective to identify the subset of inputs that have the greatest impact on the analysis results or conclusions. The analysist should apply one or more approaches or tools as appropriate for the specific PFM evaluation. The PFM evaluation should discuss the most important inputs and explain how the values or distributions for the most important inputs were confirmed to be treated appropriately.

Specific Circumstance in which Additional Depth of Information May Be Needed: More extensive sensitivity studies are likely needed for new codes, as well as for more complex codes. Cases where a code that was previously approved by NRC is modified, but still applied within a similar range of use, may require less extensive sensitivity studies.

2.6 Verification and Validation

The submittal should identify the applicable QA program, plan, and/or procedures, as well as the QA standards met. The submittal should also include a basic description of the measures for quality assurance, including verification and validation of the PFM analysis code as applied in the subject report. It should also confirm that the verification and validation cover the ranges of input values considered in the subject report.

Verification and validation may be performed on individual sub-models and the unifying framework, or can be directly performed on the overall code. Some QA programs also allow for checks using alternate calculation methods (e.g., spreadsheets or alternate implementations).

The applicable QA program, plan, and/or procedures define the supporting documents developed in conjunction with PFM analysis code development. A graded approach in QA requirements for software development, with different minimum requirements depending on the software application, such as outlined in IAEA TRS-397 [9], may be considered. Furthermore, as the applicable QA program may depend on the safety-significance of the component or system being evaluated, the corresponding rigor of verification and validation may also vary.

If a code is used for an application that is different than the one for which it was developed, the existing verification may still be valid, but the validation may need to be extended or redone if the previous validation was specific to a different range of use.

2.7 Uncertainties

The submittal should summarize the overall Monte Carlo sampling structure (or other probabilistic treatment) and simulation framework, including their basis. This should include descriptions of the pseudo-random number generation, sampling methods, sampling frequencies, and applied spatial or temporal discretization (each as applicable).

For probabilistic assessments, all aspects of the model and inputs should generally be defined to be best-estimate, with distributed inputs used to address uncertainties. A key advantage of the best-estimate probabilistic approach is that it directly quantifies the level of conservatism through comparison of the PFM results with the probabilistic acceptance criteria. However, use of conservative input values or models may be appropriate in some cases as a simplification to make the evaluation sufficiently tractable. In such cases, the submittal should discuss the basis for this approach being applied and for the specific inputs/models selected, including confirmation that these input values or models are conservative in all cases applied in the submittal. If there are cases where an individual model may be non-conservative, it should be confirmed that the impact, when combined with other models, is conservative.

Various assumptions and modeling simplifications are inherently applied when developing probabilistic models of real-world phenomena. An example of this type of assumption is modeling of cracks as idealized planar shapes, such as semi-elliptical flaws perfectly oriented in either the axial or circumferential direction. The PFM submittal should include a summary

discussion of key uncertainties or biases stemming from such assumptions and simplifications. At a minimum, the summary shall be based upon qualitative assessment of their implications.

Specific Circumstance in which Additional Depth of Information May Be Needed: In cases where there exists relatively little margin between the PFM results and acceptance criteria, assumptions and modeling simplifications will need to be more thoroughly justified and assessed than in cases where significant margin exists. The implications of potential unknowns may also warrant additional documentation of assumptions and modeling simplifications.

2.8 Acceptance Criteria

The submittal to NRC shall document the probabilistic acceptance criteria that are being applied for the PFM analysis. The basis for those acceptance criteria shall also be provided, for example a previous precedent established by NRC.

The applied acceptance criteria may be relative or absolute. Relative acceptance criteria refer to a relative comparison of probabilistic results under the proposed approach versus an already acceptable approach. In general, the rigor required in demonstrating that a relative acceptance criterion is met is lower than in demonstrating that an absolute acceptance criterion is met. Modeling and input uncertainties tend to affect the PFM results similarly when considering different analysis cases, for example for an extended inspection interval. Thus, the extent of information included addressing Sections 2.5, 2.6, and 2.7 may appropriately depend on the type of acceptance criteria applied, as well as the degree of margin.

Invoking previously approved acceptance criteria from a similar analytical process or evaluation framework must be done with appropriate care to ensure that inherent assumptions and requirements of the source activity are respected and any apparent differences are reconciled.

2.9 Principles of Risk-Informed Decision-Making

In some cases, information from the plant probabilistic risk assessment (PRA) may be used along with the results of PFM analyses to determine potential changes in plant core damage frequency (CDF) and/or large early release frequency (LERF). When these values are used to propose risk-informed changes to a plant licensing basis, the principles of risk-informed integrated decision-making as presented in NRC Regulatory Guide 1.174 [6] should be discussed.

Figure 1 summarizes those principles, with each of the subsections providing a discussion of that principle in the context of PFM submittals. For each PFM submittal making use of the PRA and

proposing a change to the plant licensing basis, each of these principles should be explicitly addressed. In many cases, it is expected that the principle can be sufficiently addressed with a relatively short discussion in the submittal.

In PFM submittals not making use of the plant PRA and/or not proposing changes to the licensing basis, the PFM submittal may optionally consider discussion of some of these risk-informed elements as warranted.

2.9.1 Change meets current regulations unless it is specifically related to a requested exemption

In the context of PFM submittals, this principle just states that the regulations other than those specifically covered by the scope of any relief request must continue to be satisfied. The PFM submittal needs to be clear in how it is being applied to the proposed change to the licensing basis and that regulations other than those for which an alternative is requested shall continue to be satisfied.

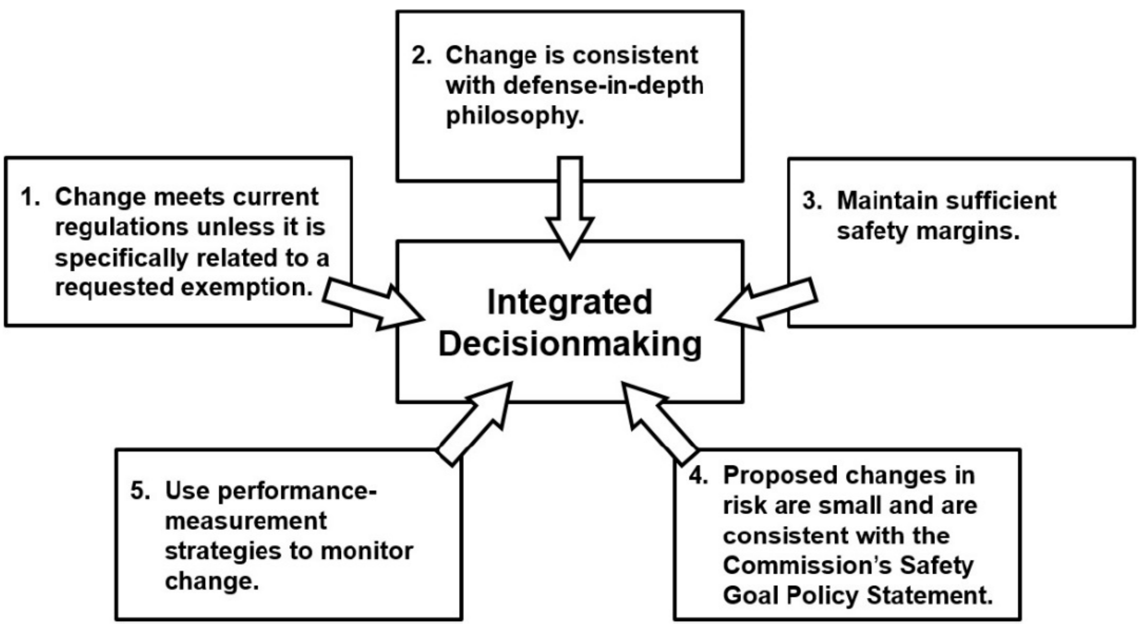

Figure 1 Principles of Risk-Informed Integrated Decision-Making, from RG 1.174 [6]

2.9.2 Change is consistent with defense-in-depth philosophy

To be consistent with NRC's risk-informed approach, PFM submittals should discuss how defense-in-depth is maintained under the proposed action.

Section C.2.1.1 of Regulatory Guide 1.174 [6] discusses the considerations that should be used to evaluate the impact of a proposed licensing basis change on defense-in-depth. This guidance can be applied in the context of a PFM submittal.

In some PFM contexts, showing a sufficiently low probability of pressure boundary leakage may be used to show that defense-in-depth is maintained. Defense-in-depth can also be supported by additional actions being performed on site. For example, per ASME Code Case N-729-4 [7], a demonstrated leak path assessment through all J-groove welds is performed in conjunction with volumetric or surface examinations performed for reactor vessel top head penetration nozzles.

2.9.3 Maintain sufficient safety margins

To be consistent with NRC's risk-informed approach, PFM submittals should explain how sufficient safety margins are maintained under the proposed action.

Section C.2.1.2 of Regulatory Guide 1.174 [6] discusses this topic in the context of a proposed licensing basis change. The licensee is expected to choose the appropriate method of engineering analysis to evaluate whether sufficient safety margins would be maintained. Regulatory Guide 1.174 states:

> *"With sufficient safety margins, (1) the codes and standards or their alternatives approved for use by the NRC are met and (2) safety analysis acceptance criteria in the licensing basis (e.g., FSAR, supporting analyses) are met or proposed revisions provide sufficient margin to account for uncertainty in the analysis and data."*

Similarly, in the context of PFM, the submittal should include a defensible analysis approach and defensible acceptance criteria for demonstrating that sufficient safety margins would be maintained. For example, a complementary deterministic analysis applying the structural (safety) factors of the ASME Code, Section XI might be an acceptable approach.

2.9.4 Proposed changes in risk are small and are consistent with the Commission's Safety Goal Policy Statement

This item flows directly from the quantitative PFM results. The submittal shall be clear regarding how the PFM results are applied and compared to acceptance criteria, as well as how the acceptance criteria are themselves appropriate. For example, Regulatory Guide 1.174 [6] discusses acceptance criteria for changes in core damage frequency and large early release frequency in the context of plant-specific changes to the licensing basis. Also, NRC staff has

considered PFM acceptance criteria in the context of xLPR [8]. One key challenge is that NRC has not issued acceptance criteria for the leakage frequency calculated in PFM submittals despite a clear need since at least the early 2000s. The need to document the acceptance criteria applied in PFM submittals is specifically addressed above in Section 2.8.

Specific Circumstance in which Additional Depth of Information May Be Needed: For cases in which the proposed changes in risk are considered non-negligible (even if sufficient margin exists between PFM results and acceptance criteria), the PFM analysis may need to be documented in greater detail within the submittal to NRC than otherwise.

2.9.5 Use performance-measurement strategies to monitor change

To be consistent with NRC's risk-informed approach, PFM submittals should discuss how future performance will be monitored to ensure that the conclusions of the PFM analysis continue to be valid.

Typically, individual licensees and industry issue programs track relevant operating experience and inspection results to check whether any new information is inconsistent with the assumptions or conclusions of existing PFM evaluations. Except for a limited number of cases, PFM analyses usually are not performed to support elimination of all relevant examinations. In the context of pressure boundary locations in PWRs, walk-downs for evidence of pressure boundary leakage are regularly performed regardless of any requirements for volumetric or surface examinations. Tracking of operating experience and ongoing examinations at the subject plant should be credited, as well as relevant experience at other plants in the industry.

3.0 Summary and Conclusions

The NRC staff has concluded that guidance is needed to ensure that NRC staff preferences for PFM submittals are sufficiently clear. Based on discussions that have taken place during recent NRC public meetings on this topic, it is evident that each PFM application is unique and prescriptive guidance will be difficult to develop and problematic to implement, even if developed in a graded or tiered approach. Based on the difficulties described by the NRC staff in performing review of past industry PFM submittals, industry believes that establishing the minimum expected content for PFM submittals, along with those factors that may motivate inclusion of additional content, would largely resolve the NRC staff concerns with PFM submittals while avoiding the development of inflexible and overly prescriptive guidance. Industry proposes that the minimum content for PFM submittals and considerations for including

additional information proposed in this white paper be strongly considered in the NRC's development of PFM guidance.

4.0 References

1. U.S. NRC, P. Raynaud, M. Kirk, M. Benson, and M. Homiack, "Important Aspects of Probabilistic Fracture Mechanics Analyses," Technical Letter Report TLR-RES/DE/CIB-2018-01. [NRC ADAMS Accession No.: ML18178A431]

2. Presentation by S. Cumblidge, "NRR Perspectives on Probabilistic Fracture Mechanics Calculations," Rockville, MD, May 21, 2018. [NRC ADAMS Accession No.: ML18141A393]

3. Presentation by D. Rudland, "Probabilistic Fracture Mechanics Technical Letter Report Discussion," Rockville, MD, May 21, 2018. [NRC ADAMS Accession No.: ML18141A394]

4. "PFM Report Review Summary," Rockville, MD, May 21, 2018. [NRC ADAMS Accession No.: ML18141A395]

5. *Materials Reliability Program: Topical Report for Primary Water Stress Corrosion Cracking Mitigation by Surface Stress Improvement (MRP-335, Revision 3-A)*, EPRI, Palo Alto, CA: 2016. 3002009241. [Publicly available at www.epri.com]

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7. ASME Code Case N-729-4, "Alternative Examination Requirements for PWR Reactor Vessel Upper Heads With Nozzles Having Pressure-Retaining Partial-Penetration Welds, Section XI, Division 1," American Society of Mechanical Engineers, New York, Approval Date June 22, 2012.

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