

## NON-QUANTITATIVE SIGNIFICANCE DETERMINATION PROCESS USING INTEGRATED RISK-INFORMED DECISION-MAKING

DRAFT

## TABLE OF CONTENTS

1.0 PURPOSE.....	3
2.0 ENTRY CONDITIONS.....	3
3.0 APPLICABILITY.....	3
4.0 RISK-INFORMED DECISION-MAKING PROCESS.....	4
4.01 Characterize the Finding.....	5
4.02 Define the Effect on Each Decision Attribute.....	5
4.03 Perform Assessment on Each Decision Attribute.....	6
4.04 Integrate Assessment Results.....	7
4.05 Document the Decision.....	11
5.0 REFERENCES.....	11
Attachment 1 – Integrated Risk-Informed Decision-Making Flowchart.....	13
Attachment 2 – Quantitative Tool Not Available.....	14
Attachment 3 – Quantitative Tool Not Adequate.....	23
Attachment 4 – Additional SDP Tools Needed.....	29
Attachment 5 – Results Integration Matrix.....	30
Attachment 6 – Revision History.....	32

## 1.0 PURPOSE

This Appendix provides guidance for assessing the significance of inspection findings, identified through the cornerstones of Reactor Safety and Radiation Safety in the Reactor Oversight Program (ROP), using a formal Integrated Risk-Informed Decision Making (IRIDM) process. This Appendix should be used for these situations: (1) when the probabilistic risk assessment (PRA) methods and tools, including the existing significance determination process (SDP) appendices, are not available to assess the significance of the inspection finding, (2) when available PRA methods and tools or SDP appendices cannot provide a preliminary significance determination due to complexities that may affect a timely quantitative assessment (e.g., large uncertainties of modeling and other influential assumptions), or (3) when the significance assessment of inspection findings of unique complexities require the development of additional SDP tools that would involve extensive resources.

This Appendix M should not be used by decision makers when the preliminary significance determination results from an existing SDP appendix may provide anomalous decisions (e.g., the SDP assessment provides unexpectedly high or low significance outcomes). In these cases, the appropriate SDP method should be used and a deviation from the ROP Action Matrix should be pursued in accordance with Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program."

## 2.0 ENTRY CONDITIONS

When possible, the staff should use the appropriate available SDP appendices in IMC 0609 to determine the risk significance of an inspection finding. However, in certain situations and circumstances, the unique complexities of an inspection finding may challenge or prevent decision makers from making an objective and scrutable decision within the established SDP timeliness goals. These situations and circumstances are the Entry Conditions for which Appendix M should be used. The Entry Conditions are as follows:

- a. A quantitative SDP tool is not available and therefore, the significance assessment of the performance deficiency is not amenable to quantitative assessments for risk-informed decision making,
- b. The available quantitative SDP tools are not adequate to provide a preliminary significance determination due to complexities that affect a timely quantitative assessment (e.g., large uncertainties of PRA modeling and other influential assumptions),
- c. Additional SDP tools that involve extensive resources are needed to assess significance of inspection findings of unique complexities (e.g. findings associated with natural hazards).

If any one of Entry Conditions 2.a, 2.b, or 2.c is met, the staff should use the guidance in this Appendix M based on IRIDM principles to assess the risk significance of the inspection finding. However, if the Entry Conditions are not met, the staff should exit Appendix M and consult with

Headquarters (HQ) staff on the appropriate use of an available SDP tool in a separate Appendix of IMC 0609.

### 3.0 APPLICABILITY

In all cases, a clear and well understood inspection finding must be established in accordance with the guidance in IMC 0612. Appendix M may be used if the staff has determined that any one of the Entry Conditions defined in Section 2.0 is satisfied.

If explicitly directed to use Appendix M by SDP guidance, the staff should conduct a planning Significance and Enforcement Review Panel (SERP) to determine if Appendix M is an appropriate tool for characterizing the significance of a finding. The planning SERP members should carefully consider the Entry Conditions for using Appendix M, as defined in Section 2.0. Careful consideration is warranted in considering the use of this tool, especially if another SDP tool or method provides a suitable approach. For example, a degraded condition may be specifically modeled or uncertainties associated with an initiating event frequency or failure rate probability may not significantly affect the decision outcome. In these cases, an existing SDP tool may provide a suitable characterization of significance within the established SDP timeliness goals; therefore, Appendix M should not be used. The use of Appendix M is appropriate when another quantitative SDP tool is not available, is not adequate due to complexities affecting a timely quantitative assessment, or involves extensive study or analysis that cannot be completed within established SDP timeliness goals.

If a planning SERP has determined that Appendix M is appropriate, the staff should use this Appendix M in accordance with the IRIDM process described in Section 4.0. This process utilizes the methodology that combines insights from risk information and other decision-making attributes to provide risk-informed decision outcomes. The approach of using IRIDM process enables decision makers to consider additional decision attributes, factors, and other relevant insights that may influence the significance of the inspection finding.

When assessing significance of a finding with Appendix M, the intent is not to perform experiments or seek in-depth expert elicitation to support the decision making. The framework of this Appendix M is based on existing IRIDM principles that combine insights from risk information with deterministic engineering judgment relying upon in-house engineering knowledge and expertise, regulatory oversight experience, and any additional relevant factors and insights, to provide objective and scrutable risk-informed decisions.

### 4.0 INTEGRATED RISK-INFORMED DECISION-MAKING (IRIDM) PROCESS

The IRIDM process used in Appendix M is based on existing methodology as described in NRC Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," and NRR Office Instruction LIC 504, "Integrated Risk-Informed Decision Making Process for Emergent Issues." Once the staff has determined an Entry Condition in Section 2.0 has been met for a particular inspection finding, the staff will follow the general process:

- Characterize the Finding

- Define the Effect on Each Decision Attribute
- Perform Assessment of Each Decision Attribute
- Integrate Assessment Results
- Document the Decision

When implementing the process, the staff should utilize the IRIDM Process flowcharts in Attachments 2 through 5 in parallel with the guidance provided in Sections 4.1 through 4.5. This approach provides a consistent path and clear visual aid when making a risk-informed decision, and ensures that each applicable decision attribute is considered and its effect on the decision outcome is evaluated thoroughly.

#### 4.01 Characterize the Finding.

The purpose of this step is to determine the preliminary significance of the inspection finding from an initial bounding assessment, and to ensure that an applicable Entry Condition in Section 2.0 is met. The bounding assessment provides a bound on the significance outcome in the risk-informed decision making process. The initial bounding assessment should be performed with readily available information in accordance with guidance in IMC 0609 Attachment 1.4.1.1. A performance deficiency (PD) has been identified and defined in accordance with IMC 0612.

A bounding quantitative and/or qualitative evaluation (i.e., worst case analysis) should be performed. If feasible, use the readily available information to determine the preliminary significance of the PD. If the bounding evaluation shows that the PD is of very low risk significance (i.e., Green), the finding can be documented in accordance IMC 0612 and the staff can exit Appendix M. If the bounding evaluation indicates that the risk significance of the finding could be greater than Green, go to Attachment 1, “Appendix M Decision-Making Flowchart” to identify the applicable Entry Condition for implementing the appropriate IRIDM framework, and then proceed to Step 4.2 below.

#### 4.02 Define the Effect on Each Decision Attribute.

The purpose of this step is to identify the effect of the PD on each decision attribute considered in the IRIDM framework specialized for the applicable Entry Condition. Note that the decision attributes listed in this section are the minimum decision attributes that should be considered when making a risk-informed decision. For each Entry Condition defined in Section 2.0, a list of associated decision attributes is provided in a corresponding attachment. The associated decision attributes defined for each Entry Condition are provided in each attachment below:

- a. Attachment 2, “Quantitative SDP Tool Not Available”
  - Does the PD Significantly Affect Defense-in-Depth?
  - Does the PD Significantly Affect Safety Margins?
  - Did the Licensee Comply with Regulatory Guidelines?
  - Did the Licensee Use Effective Performance Monitoring Strategies?
  - Does the PD Result in Extent of Condition Impacts?

- Does the PD Result in Severe Degree of Degradation?
  - Does the Exposure Time Affect the Significance Determination of the PD?
  - Does the PD Significantly Affect Crediting Recovery Actions?
  - Are there Additional Relevant Decision Attributes to Consider?
- b. Attachment 3, “Quantitative SDP Tool Not Adequate”
- Identify the Influential Assumptions that Affect the Significance of the PD:
    - What are the Sensitivity Results that Affect the Significance Determination?
  - Does the PD Affect the Risk Contribution due to External Events?
  - Did the Licensee Comply with Regulatory Guidelines?
  - Did the Licensee Use Effective Performance Monitoring Strategies?
  - Does the PD Result in Extent of Condition Impacts?
  - Are there Additional Relevant Decision Attributes to Consider?
- c. Attachment 4, “Additional SDP Tools Needed”
- Did the Licensee Comply with Regulatory Guidelines?
  - Did the Licensee Use Effective Performance Monitoring Strategies?
  - Does the PD Result in Extent of Condition Impacts?
  - Are there Additional Relevant Decision Attributes to Consider?

After entering the applicable attachment, determine whether the PD is affected by each of the listed decision attributes by answering “Yes” or “No” to the questions. If the staff determines that the PD is affected by a specific decision attribute, the staff will assess the relative influence of the PD on the decision attribute (i.e., high, medium, or low) as described in Section 4.3.

The PD may not be affected by every listed decision attribute on the attachment associated with a specific Entry Condition. If there is no effect on a decision attribute, then proceed to determine the effect on the next decision attribute in the flowchart.

#### 4.03 Perform Assessment of Each Decision Attribute.

In this step, the staff will assess the relative influence of the PD on each specific decision attribute in the applicable attachment used from Section 4.2. For each decision attribute, several factors and criteria are provided in the form of questions to assess the relative influence of the PD on the decision outcome.

If any of these factors and criteria are found to be affected by the PD, the specific factor or criterion is assessed to determine its overall influence on the associated decision attribute. The staff should evaluate the influence of each specific factor that is affecting the decision outcome. Each specific factor may have low, moderate, or high influence, or the factor is not applicable. After assessing the influence of each factor, the next step is to assess the overall influence of

the applicable factors on the decision attribute under consideration. For example, the Decision Attribute for Defense-in-Depth in Attachment 2 contains influential factors 1.A through 1.F for evaluation. If one or more of these factors are assessed to have high influence, it is feasible to conclude that the Defense-in-Depth decision attribute has a high influence on the decision making.

After each decision attribute has been assessed, the next step is to continue to the next decision attribute as directed by the flowchart until all decision attributes are assessed. When this step is completed, the results are tabulated in the applicable Tables 1, 2, or 3 in Attachment 5, "Results Integration Matrix," to support integrated assessment of the overall significance of the PD. The approach for integrated assessment of results is described in Section 4.4. Detailed guidance on assessing each decision attribute is provided in the technical basis document, IMC 0308, Attachment 3, Appendix M, "Technical Basis for the Significance Determination Process Using Risk-Informed Decision Making."

#### 4.04 Integrate Assessment Results.

At this point, the assessment and evaluation of the effect of the PD on each decision attribute listed in the applicable Entry Condition attachment are completed. When making a decision on the risk significance of a PD, the decision maker should consider the importance of each decision attribute that would affect the safety of the plant, and how each decision attribute should be weighted for consideration in making the final decision. It is noted that a particular decision attribute identified for a PD may have less weight than the similar decision attribute identified for assessment of a different PD. Thus, an integrated approach that collectively considers the effect of the PD on each decision attribute would lead to a more objective decision outcome.

There may be situations where the initial bounding assessment shows the initial significance of a PD is Greater than Green, yet the assessment of each decision attribute shows that the PD is not significantly affected by any decision attribute under consideration. In these circumstances, it is feasible to determine that the significance of the finding remains as it was initially assessed.

a. Integrated Assessment of Decision Attributes in Attachment 2, "Quantitative SDP Tool Not Available"

In general, a PD that is significantly affected by a decision attribute (i.e., high influence) warrants a change in significance by an order of magnitude. However, this change should not exceed the significance established by an initial bounding assessment. For example, the White significance established by an initial bounding assessment should remain the same because of an implicit assumption that most or all of the associated decision attributes have negative influences. Low or medium influential effect of a decision attribute should not warrant a change in significance color. In order to make an objective and scrutable regulatory decision, the effects of each decision attribute should be assessed in an integrated manner to determine the risk significance of the PD.

#### 1. Defense-in-Depth Decision Attribute

A PD that is significantly affected by the defense-in-depth decision attribute warrants a change in significance by an order of magnitude. However, the change should not exceed the significance established by an initial bounding assessment.

If the defense-in-depth decision attribute was assessed to have low or medium influential effect, the aggregate effect of every decision attribute should be evaluated before the decision to a change in significance of the PD.

## 2. Safety Margins Decision Attribute

A PD that is significantly affected by the safety margins decision attribute warrants change in increased significance. If the PD causes a loss of safety margins, then the plant is operating in a condition that increases the risk to the public.

If the influential effect is low or medium, then the plant is operating within safety margins and a change of increased significance may not be warranted. The aggregate effect of every decision attribute should be assessed to determine whether or not to change the significance of the PD.

## 3. Regulatory Compliance Decision Attribute

A PD that is significantly affected by regulatory compliance issues may justify a change in increased significance. If the licensee has repeatedly been in noncompliance with regulatory requirements or missed opportunities to correct a noncompliant condition associated with the PD, there is justification for a change in increased risk significance.

Low or medium influential effect of the regulatory compliance decision attribute may be considered to have minimal impact on overall risk significance. However, it is prudent to assess whether noncompliance issues would be affecting other decision attributes when making a decision on the overall significance of the PD.

## 4. Performance Monitoring Decision Attribute

A PD that is significantly affected by performance monitoring issues may justify a change in increased significance. If the licensee has significant performance monitoring issues which directly affects defense-in-depth or safety margins decision attributes, a change in increased risk significance should be considered.

## 5. Extent of Condition Decision Attribute



A PD that is significantly affected by extent of condition issues may justify a change in increased significance. If the extent of condition is significantly affecting other decision attributes, such as defense-in-depth and safety margins, a change in increased risk significance should be considered.

6. Degree of Component Degradation Decision Attribute

A PD that is significantly affected by the component degradation decision attribute may justify a change in increased significance. This depends on whether the component degradation significantly affects the defense-in-depth or safety margins decision attributes. If the component degradation affects an additional decision attribute, the aggregate effect on each of the other decision attribute should be assessed to make a final decision on risk significance.

7. Exposure Time Decision Attribute

A PD that is significantly affected by the exposure time decision attribute may justify a change in increased significance. If the PD has existed since the initial construction of the plant, then the long exposure time of a degraded condition warrants a change in increased significance.

8. Recovery Actions Decision Attribute

A PD that is significantly affected by the recovery actions decision attribute may justify a change in increased significance. This depends on whether the effect of recovery actions will directly affect other decision attributes in positive or negative ways. The aggregate effect on each of the other decision attributes should be assessed to make a final decision on risk significance.

9. Cross-Cutting Issue (CCI) Decision Attribute

A PD that is significantly affected by the CCI decision attribute may justify a change in increased significance. This depends on whether the effect of the CCI will directly affect other decision attributes in positive or negative ways. The aggregate effect on each of the other decision attributes should be assessed to make a final decision on risk significance.

b. Integrated Assessment of Decision Attributes in Attachment 3, "Quantitative SDP Tool Not Adequate"

In situations where the available quantitative SDP tools are not adequate to provide a preliminary significance determination due to complexities that may affect a timely quantitative assessment (e.g., large uncertainties of PRA modeling and other influential assumptions), the IRIDM framework for decision making is focused on insights from sensitivity analyses of influential assumptions and other decision attributes that are not inherently accounted for in the PRA model. Thus, the IRIDM framework applicable for this Entry Condition excludes several of the decision attributes related to deterministic

considerations as shown on Attachment 2. These “deterministic” decision attributes (e.g., Defense-in Depth, Safety Margins, Recovery Actions, etc.) are implicitly accounted for in a PRA model. The exclusion of these decision attributes from the IRIDM framework used here would prevent unintentional bias on the decision making.

1. Sensitivity Analysis Results of Input Assumptions Attribute

If the sensitivity analysis results show that one or more input assumptions have a significant effect (i.e., highly influential impact) on the decision outcome, this attribute should be considered when making a change in increased significance. In this case, the decision maker(s) should assess the “realism” of the influential assumptions to assure an objective decision is achieved, to the extent practicable.

If the sensitivity analysis results show that an input assumption has low or medium effect (i.e., negligible or small influence) on the decision outcome, this attribute may be considered to be neutral to a change in increased significance.

2. External Events Decision Attribute

This decision attribute addresses the sensitivity impact of external events risk contribution to the results of a significance assessment. It is noted that the outcome of quantitative assessments of risk from external events (e.g., floods, seismic events, and high winds) may have a large amount of uncertainty due to sparsity of data. If the external events risk contribution has a significant effect on the decision outcome, this attribute should be considered when making a change in increased significance.

If the external events risk contribution has low or medium effect (i.e., negligible or small influence) on the decision outcome, this attribute may be considered to be neutral to a change in increased significance.

3. Regulatory Compliance Decision Attribute

A PD that is significantly affected by regulatory compliance issues may justify a change in increased significance. If the licensee has repeatedly been in noncompliance with regulatory requirements or missed opportunities to correct a noncompliant condition associated with the PD, there is justification for a change in increased risk significance.

Low or medium influential effect of the regulatory compliance decision attribute may be considered to have minimal impact on overall risk significance. However, it is prudent to assess whether noncompliance issues would be affecting other decision attributes when making a decision on the overall significance of the PD.

4. Performance Monitoring Decision Attribute

A PD that is significantly affected by performance monitoring issues may justify a change in increased significance. If the licensee has significant performance

monitoring issues which directly affects defense-in-depth or safety margins decision attributes, a change in increased risk significance should be considered.

5. Extent of Condition Decision Attribute

A PD that is significantly affected by extent of condition issues may justify a change in increased significance. If the extent of condition is significantly affecting other decision attributes, such as defense-in-depth and safety margins, a change in increased risk significance should be considered.

6. Cross-Cutting Issue (CCI) Decision Attribute

A PD that is significantly affected by the CCI decision attribute may justify a change in increased significance. This depends on whether the effect of the CCI will directly affect other decision attributes in positive or negative ways. The aggregate effect on each of the other decision attributes should be assessed to make a final decision on risk significance.

c. Integrated Assessment of Decision Attributes in Attachment 4, "Additional SDP Tools Needed"

In situations where additional quantitative SDP tools are needed to assess significance of inspection findings of unique complexities (e.g., findings associated with natural hazards), the IRIDM framework for decision making is focused on insights from regulatory compliance, performance monitoring, extent of condition and other relevant decision attributes that are amenable to making a timely risk-informed decision without involving extensive resources. The IRIDM framework applicable for this Entry Condition requires decision makers to participate in a planning SERP to assess all of the relevant decision attributes needed to make a risk-informed decision.

1. Regulatory Compliance Decision Attribute

A PD that is significantly affected by regulatory compliance issues may justify a change in increased significance. If the licensee has repeatedly been in noncompliance with regulatory requirements or missed opportunities to correct a noncompliant condition associated with the PD, there is justification for a change in increased risk significance.

Low or medium influential effect of the regulatory compliance decision attribute may be considered to have minimal impact on overall risk significance. However, it is prudent to assess whether noncompliance issues would be affecting other decision attributes when making a decision on the overall significance of the PD.

2. Performance Monitoring Decision Attribute

A PD that is significantly affected by performance monitoring issues may justify a change in increased significance. If the licensee has significant performance

monitoring issues which directly affects defense-in-depth or safety margins decision attributes, a change in increased risk significance should be considered.

### 3. Extent of Condition Decision Attribute

A PD that is significantly affected by extent of condition issues may justify a change in increased significance. If the extent of condition is significantly affecting other decision attributes, such as defense-in-depth and safety margins, a change in increased risk significance should be considered.

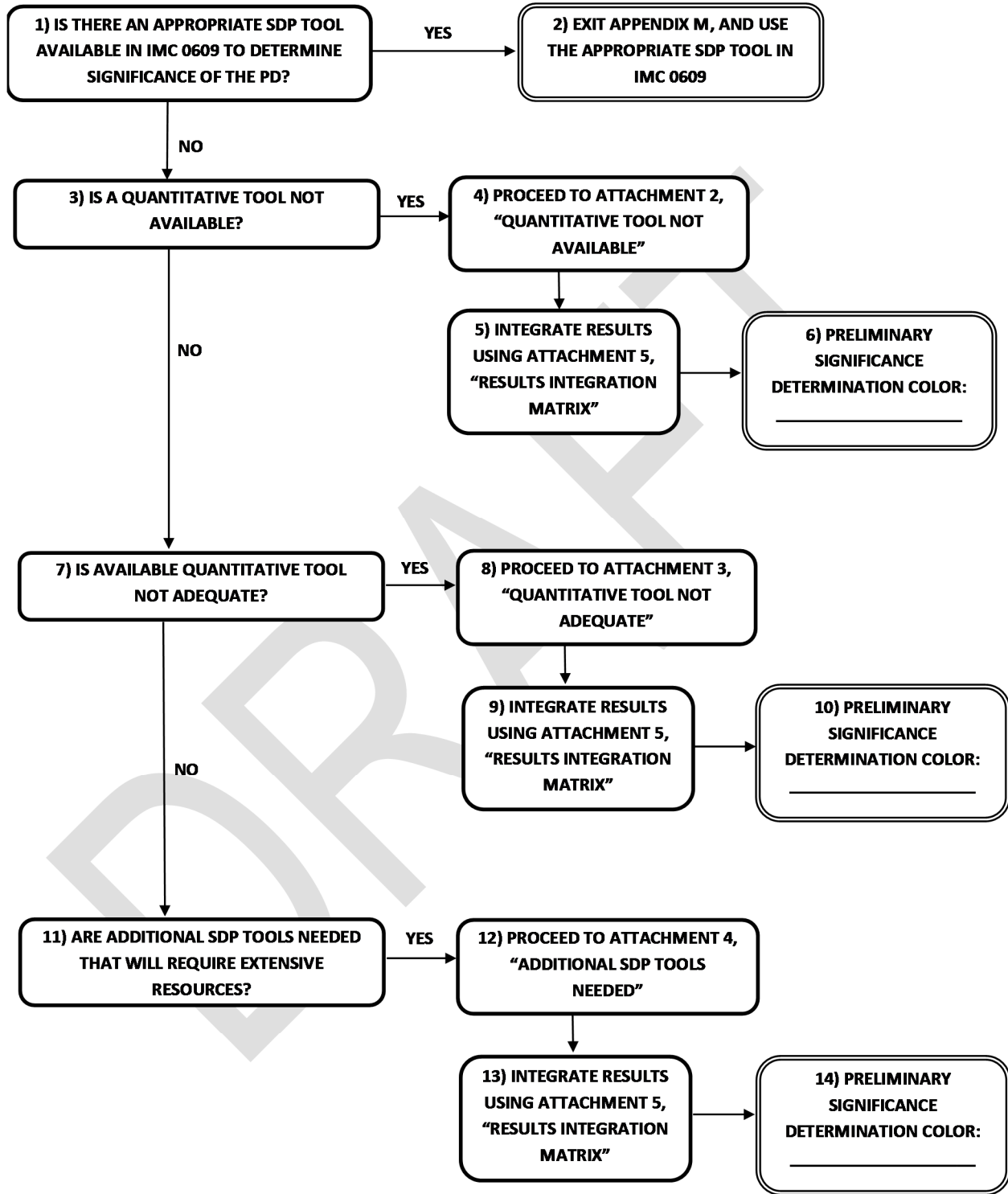
#### 4.05 Document the Decision.

Once the integrated decision has been made, the decision should be documented and included in the SERP package as described in IMC 0609, Attachment 1, "Significance and Enforcement Review Panel."

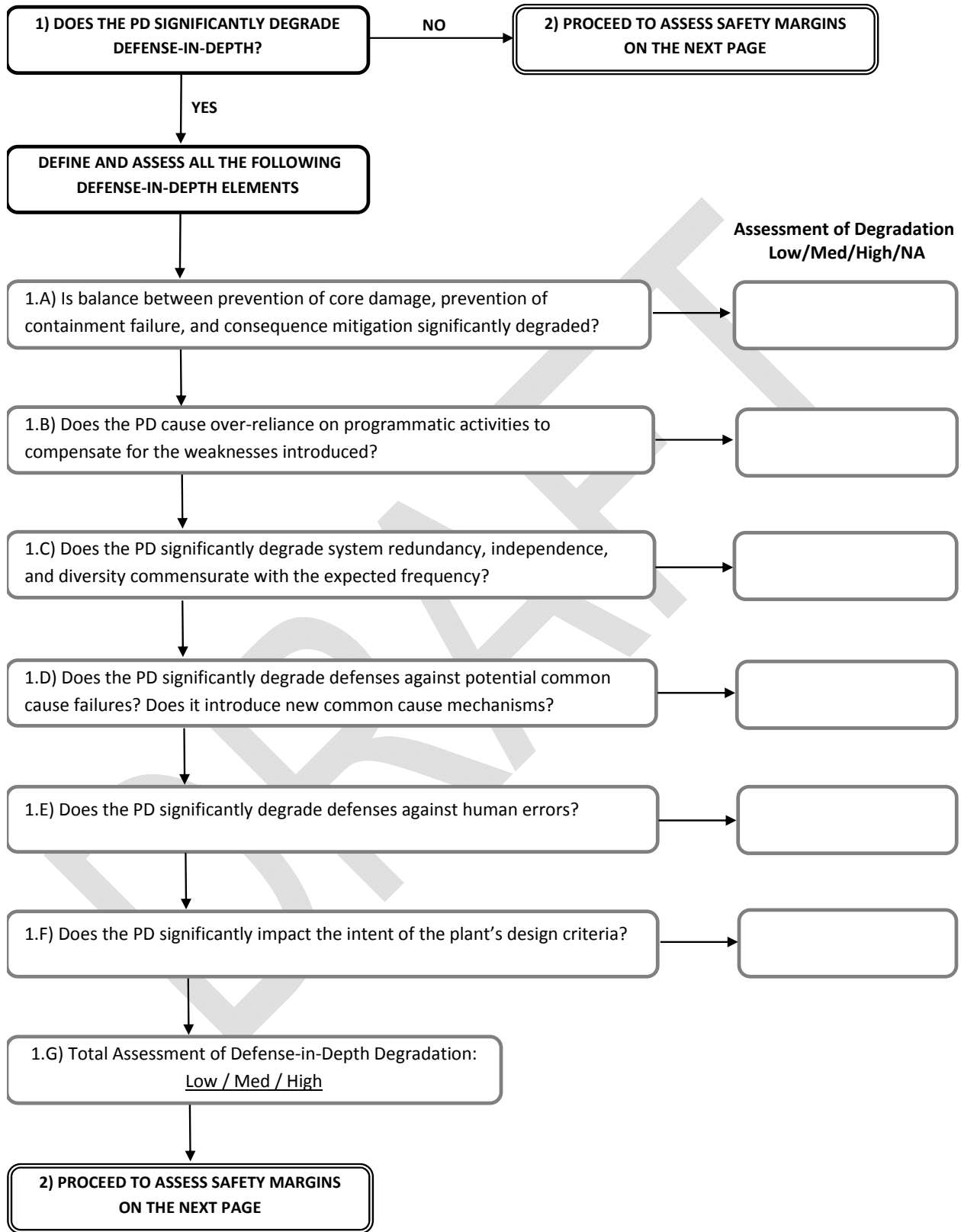
## 5.0 REFERENCES

1. IMC 0308 Attachment 3, Appendix M, "Technical Basis for the Significance Determination Process using Risk-Informed Decision-Making."
2. IMC 0609, "Significance Determination Process."
3. IMC 0609, Attachment 1, "Significance and Enforcement Review Panel Process."
4. IMC 0612, "Power Reactor Inspection Reports."
5. LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues."
6. Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."

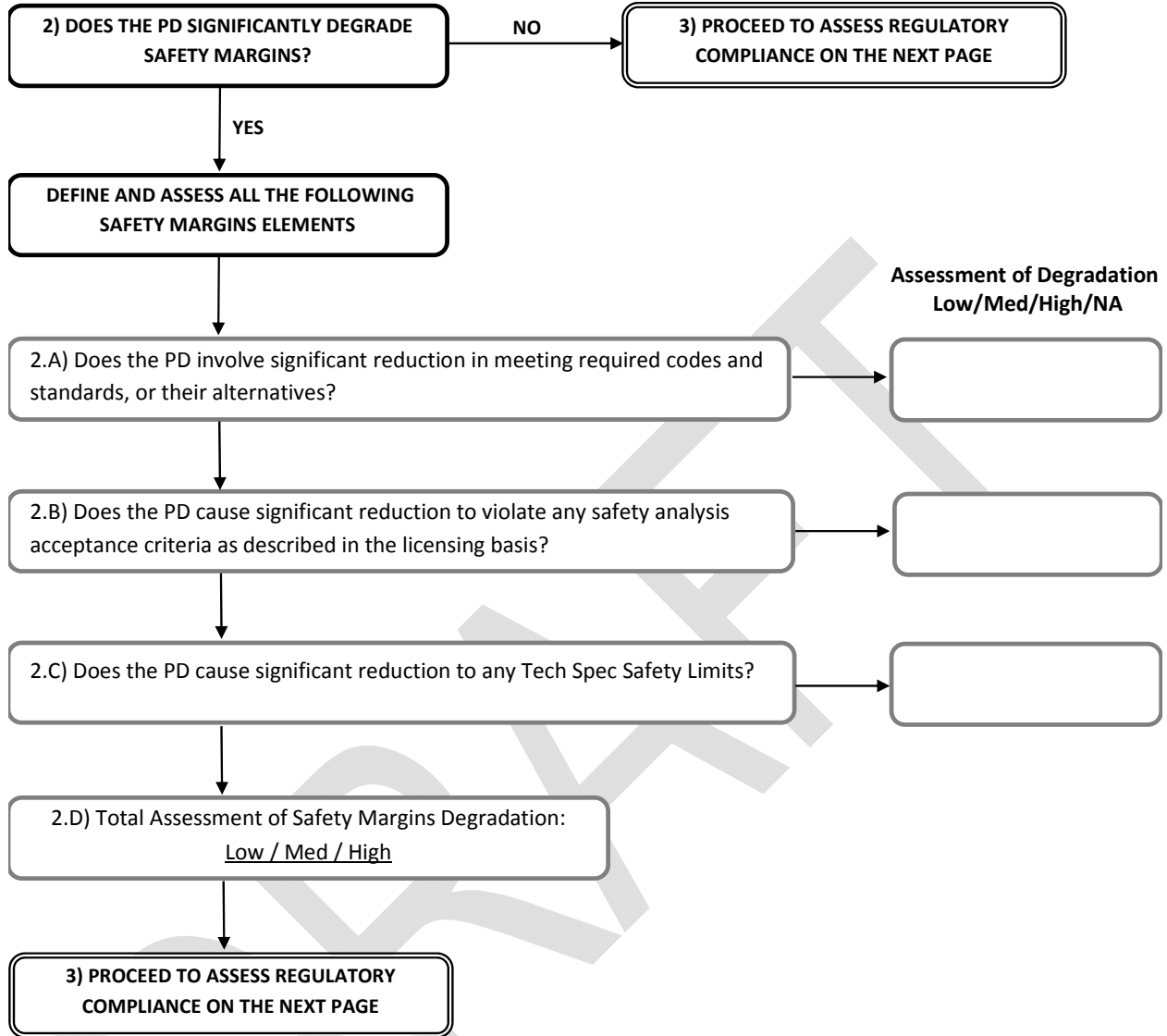
Attachment 1  
Appendix M Decision-Making Flowchart



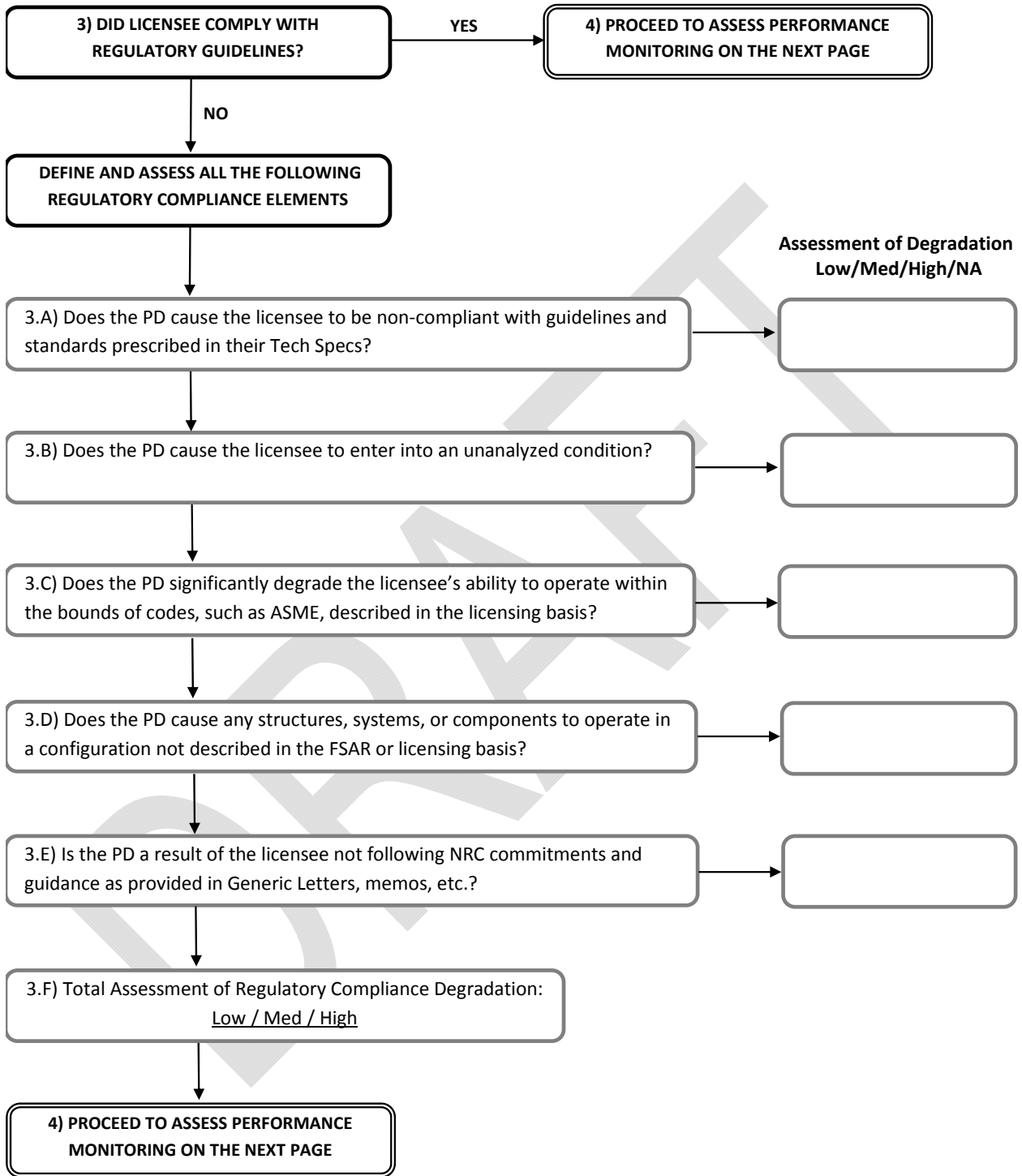
Attachment 2  
Quantitative SDP Tool Not Available



Attachment 2  
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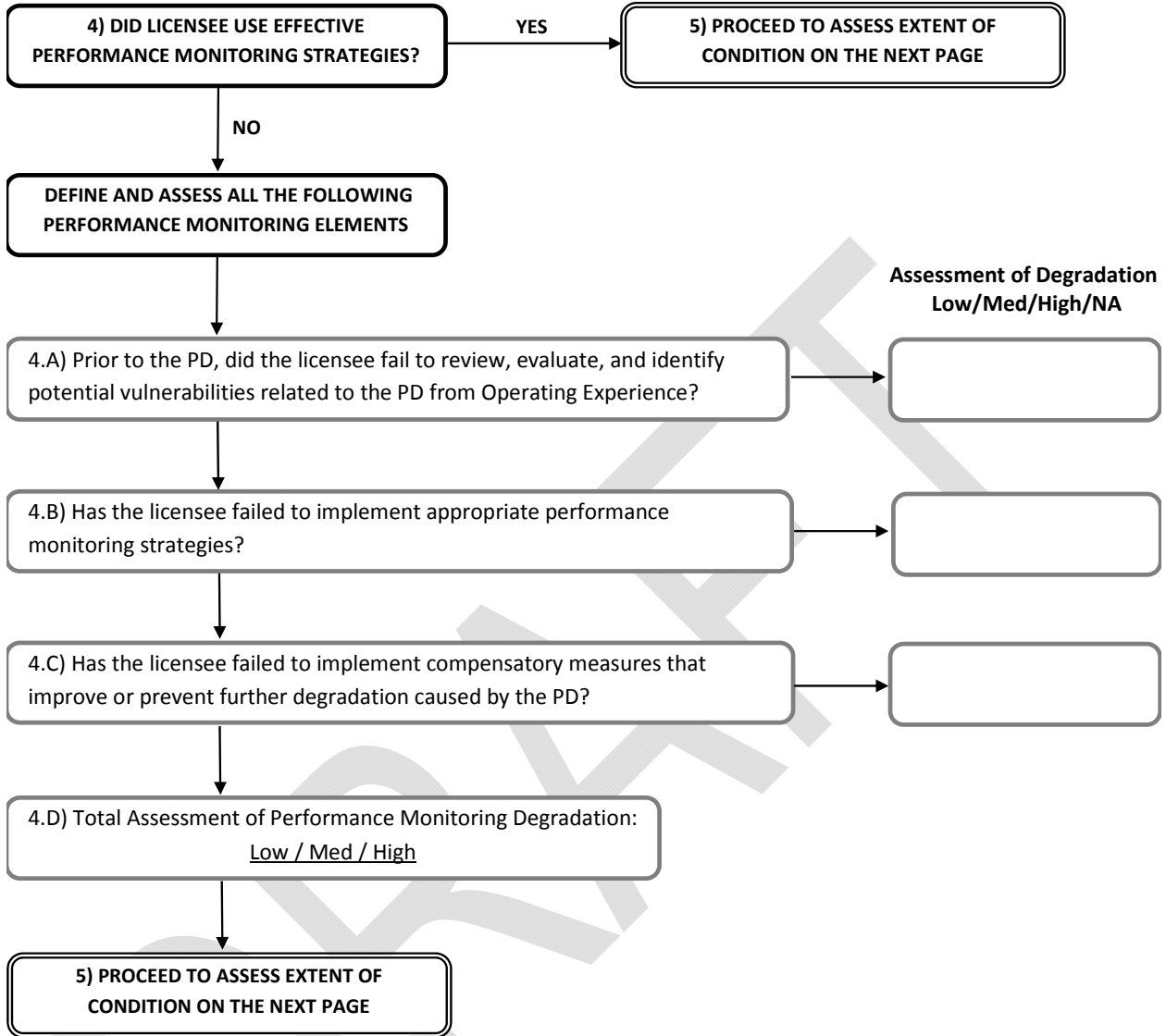


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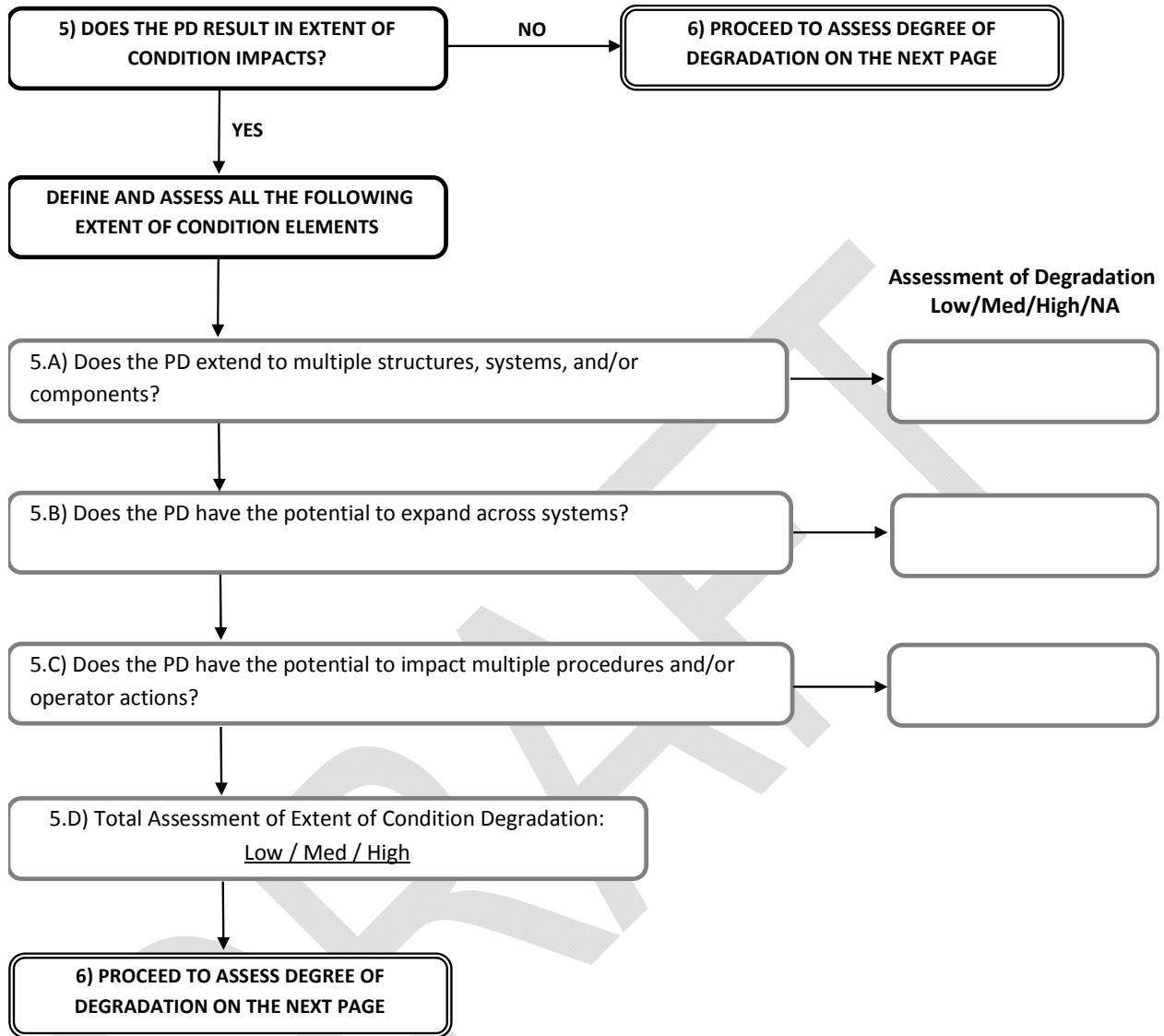




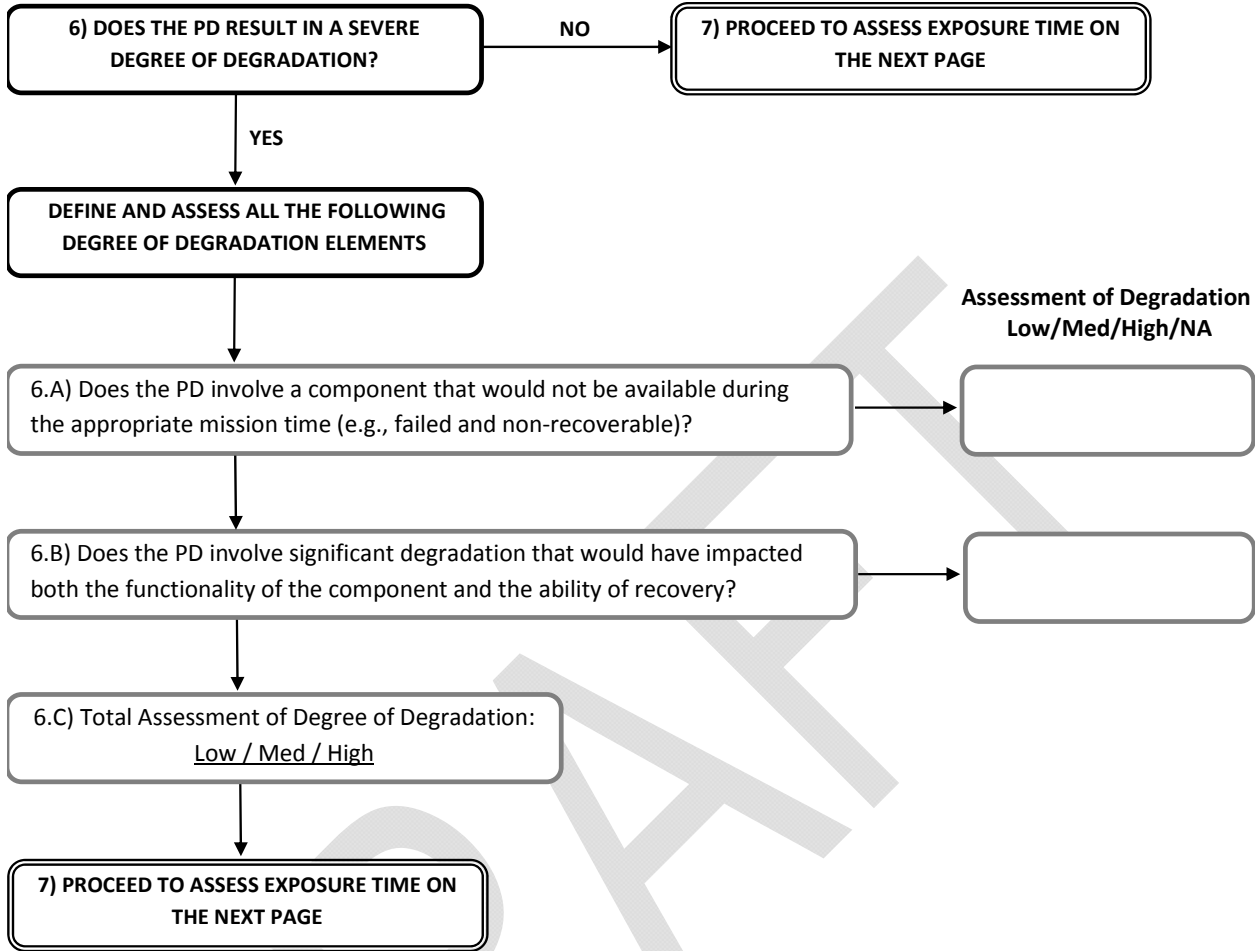
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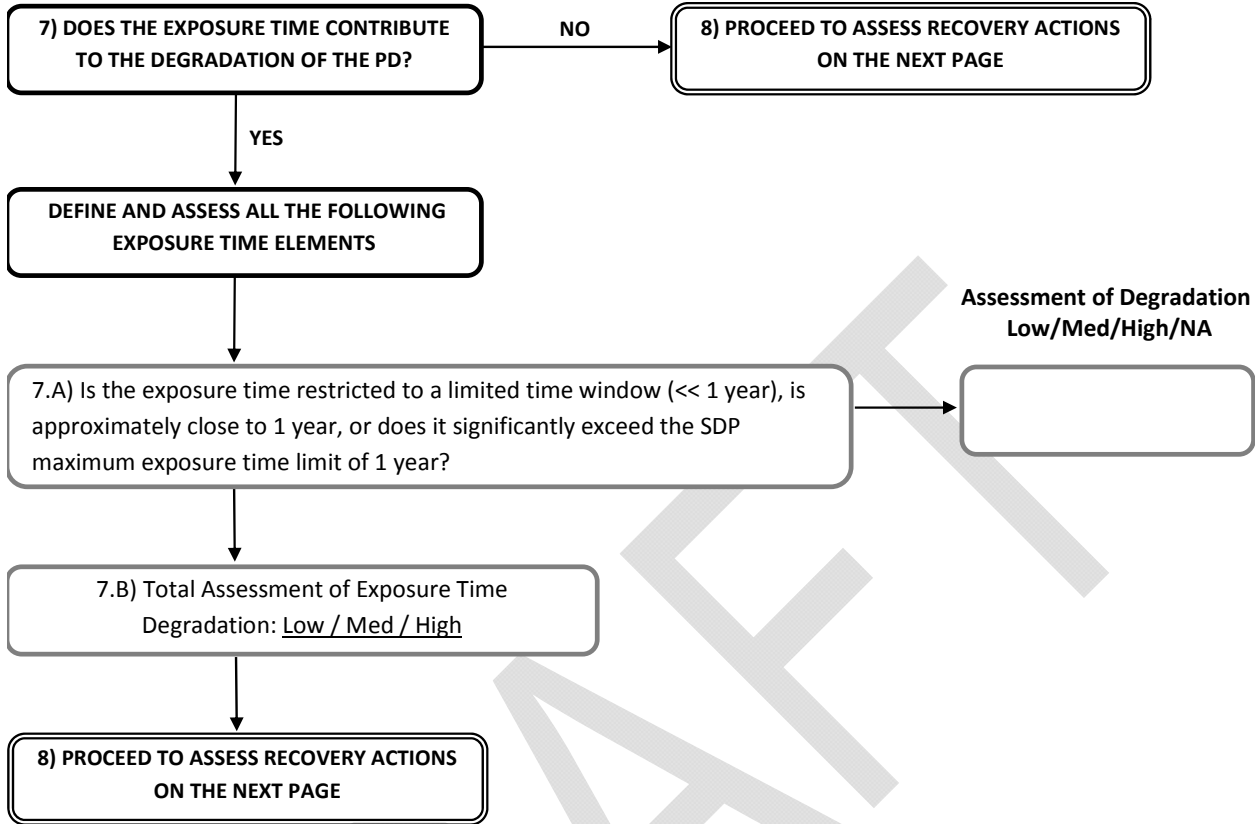
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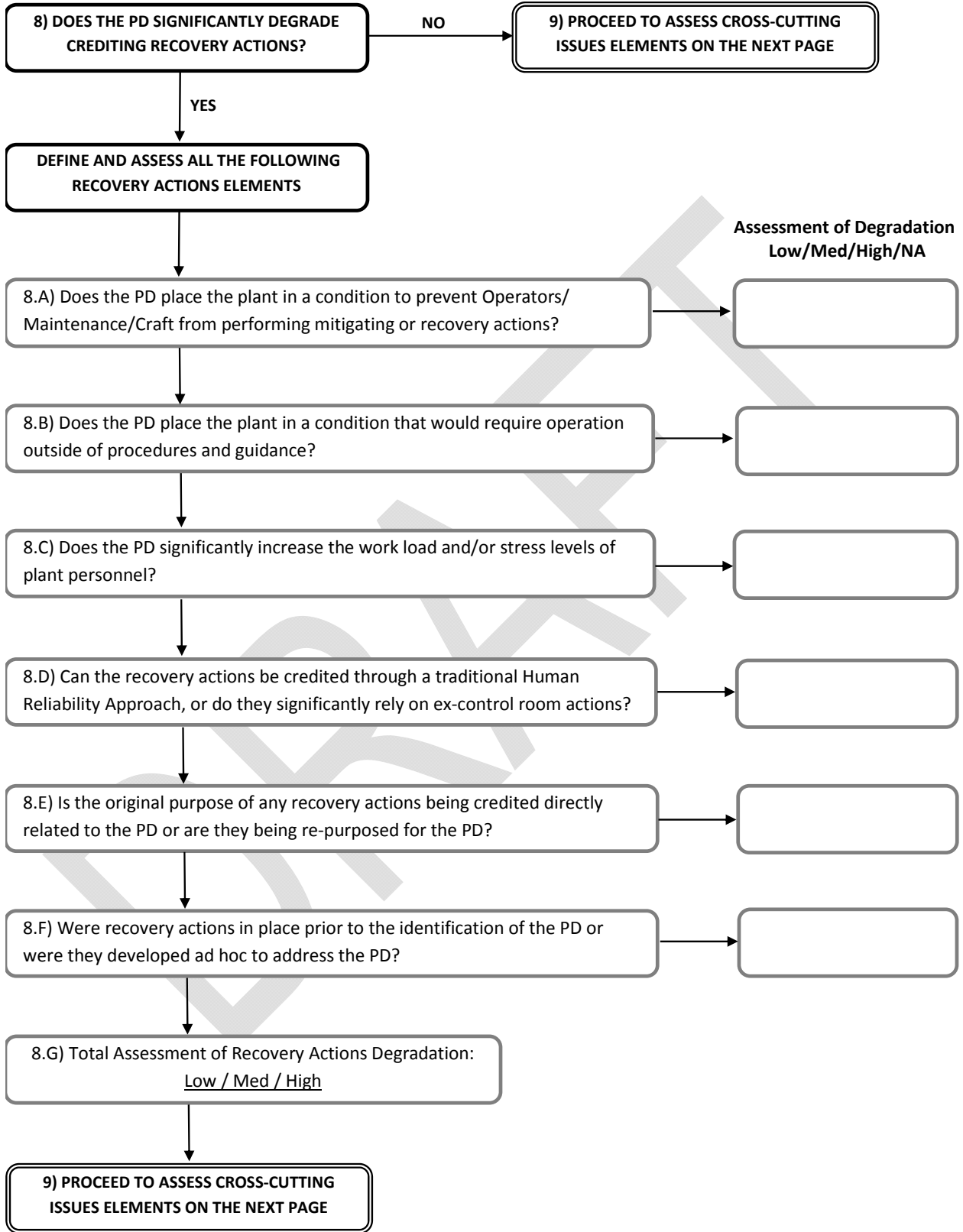
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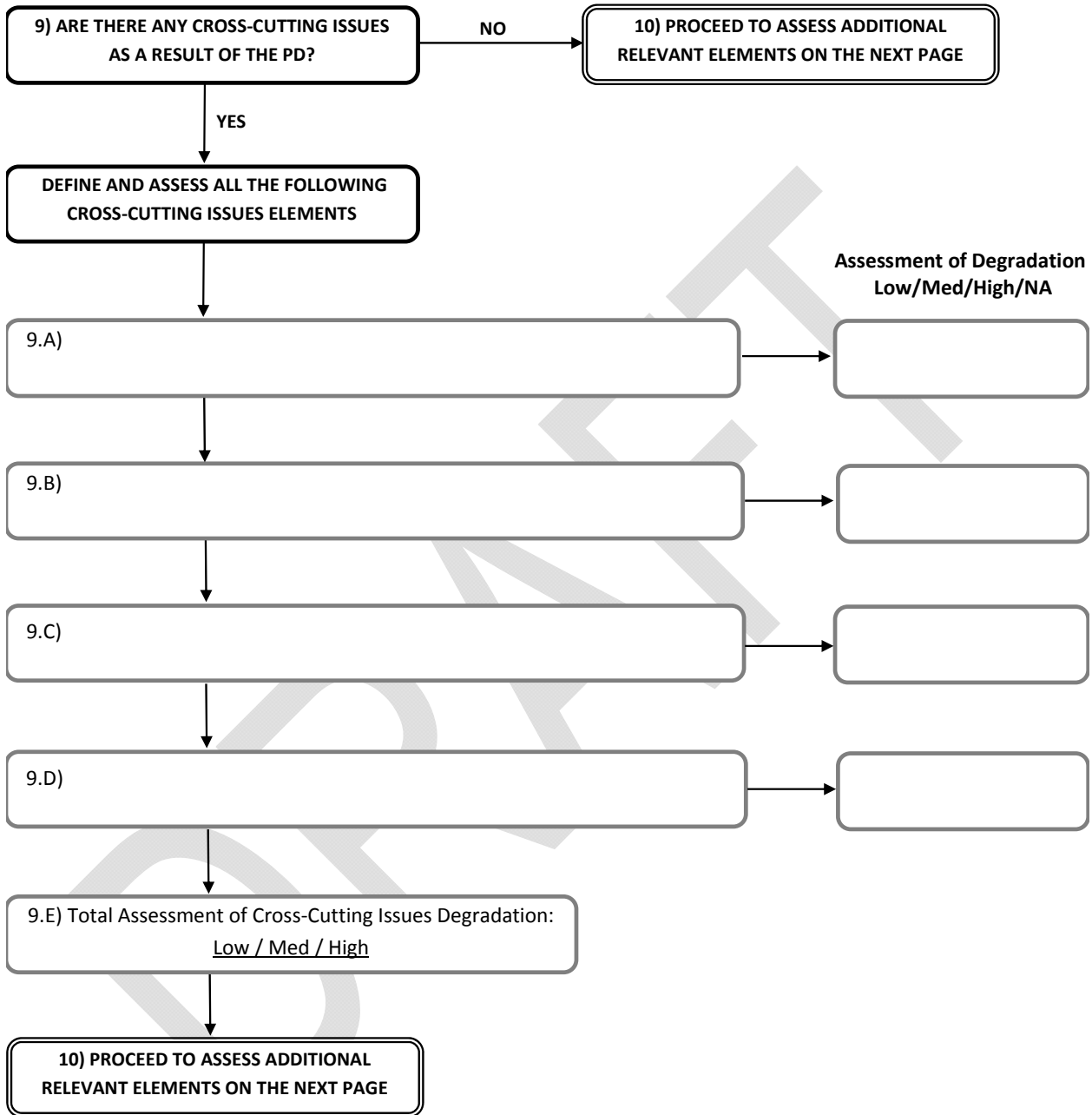
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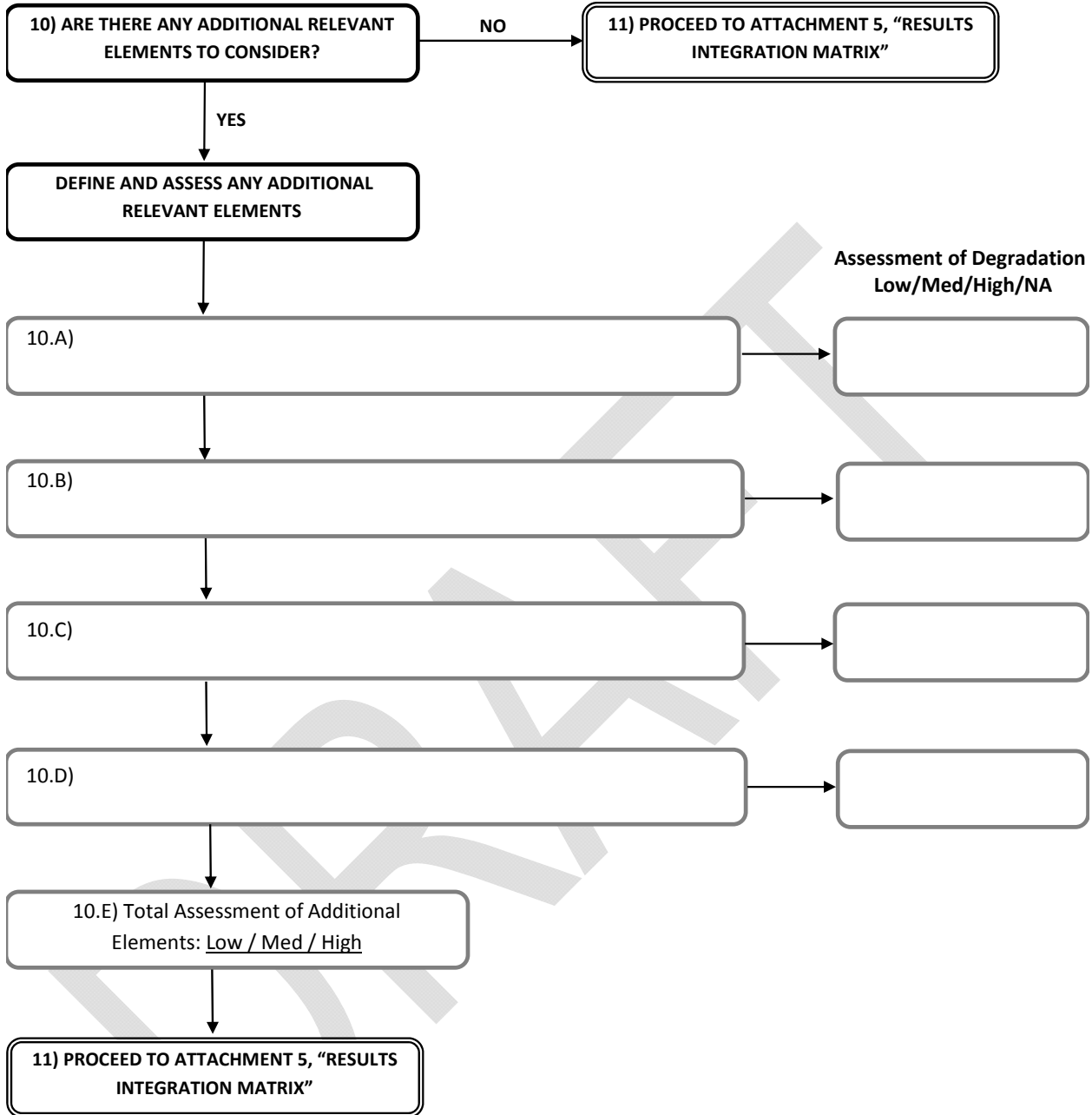
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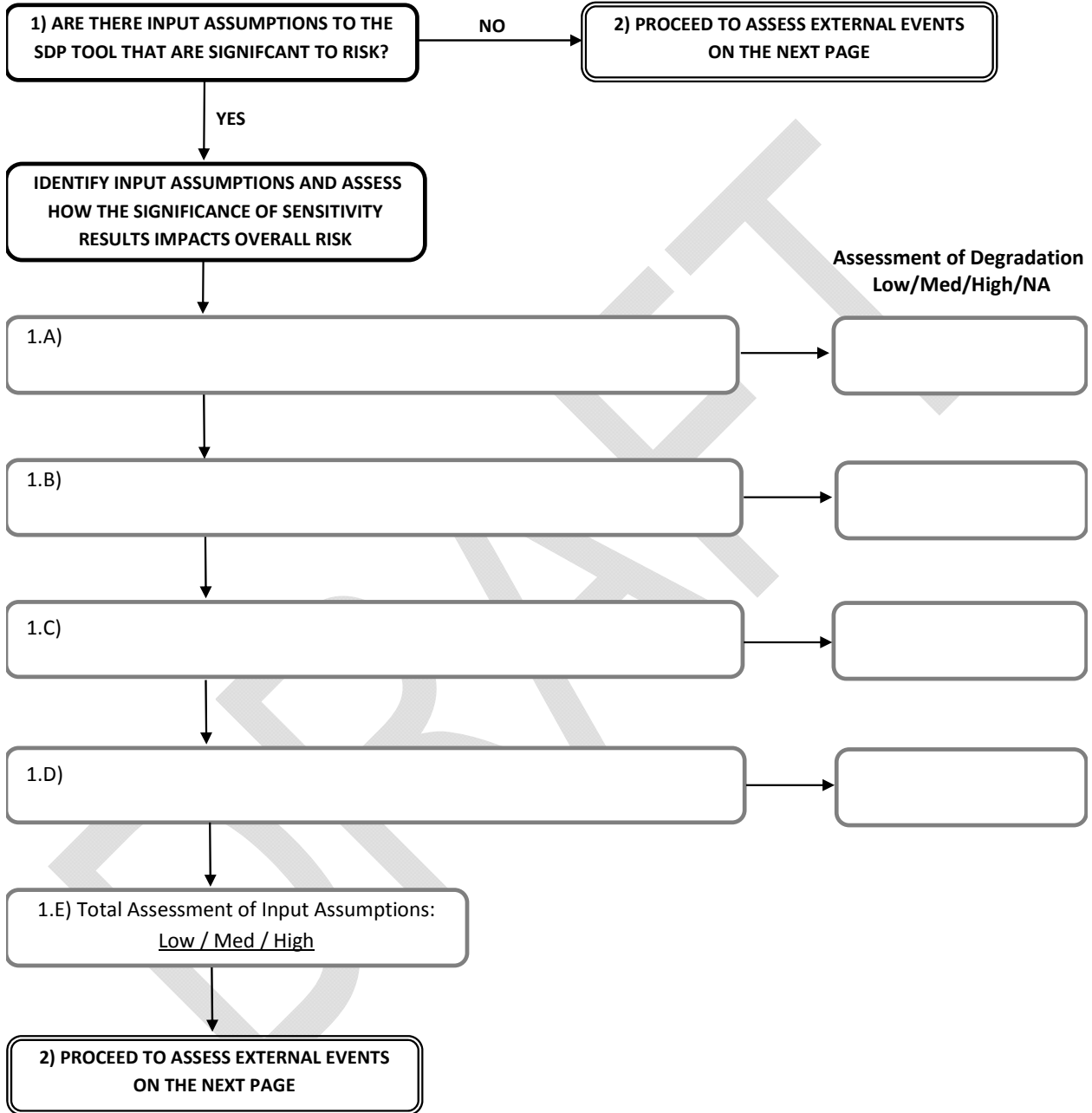
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Attachment 2  
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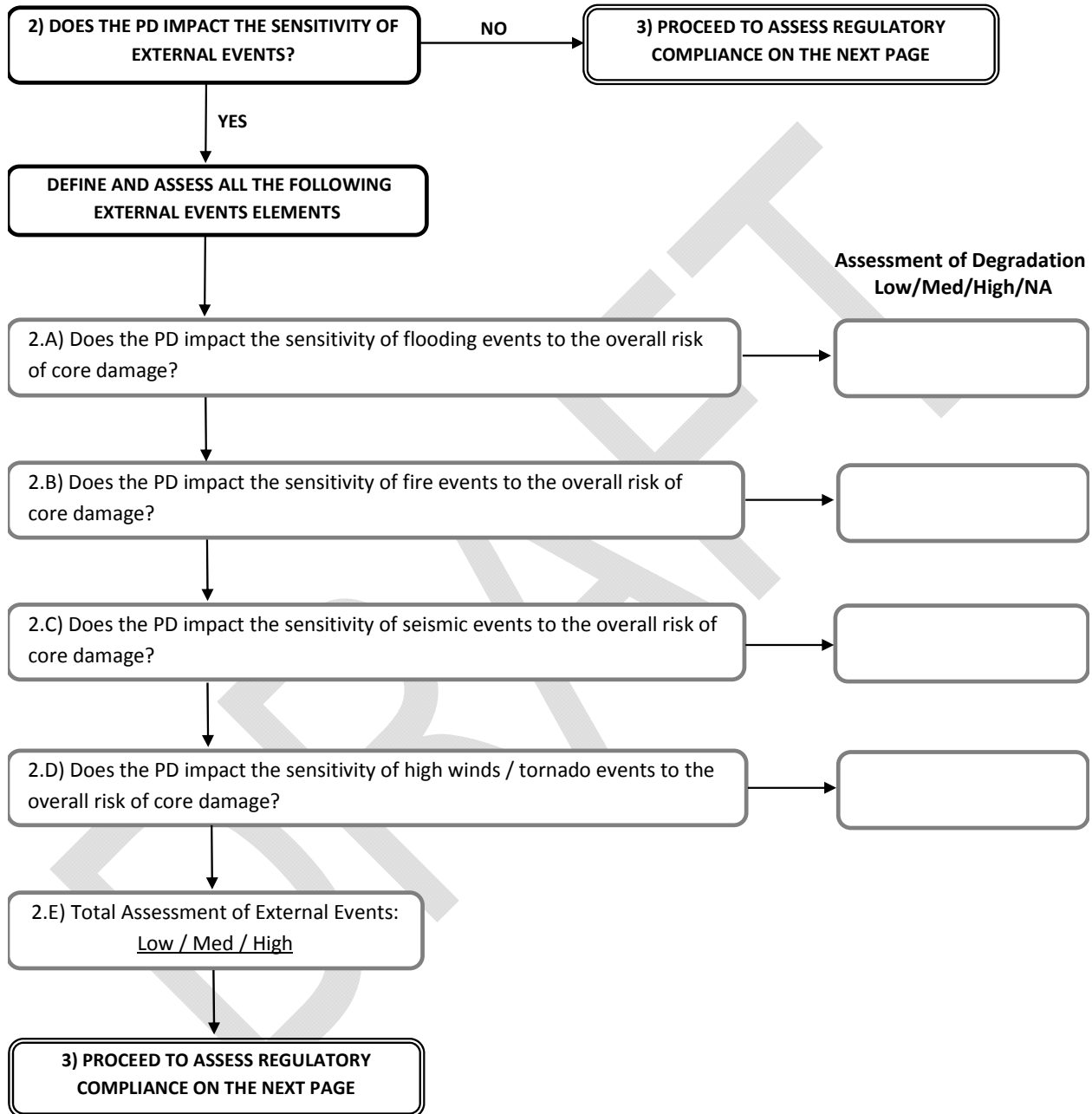


Attachment 3  
Quantitative SDP Tool Not Adequate

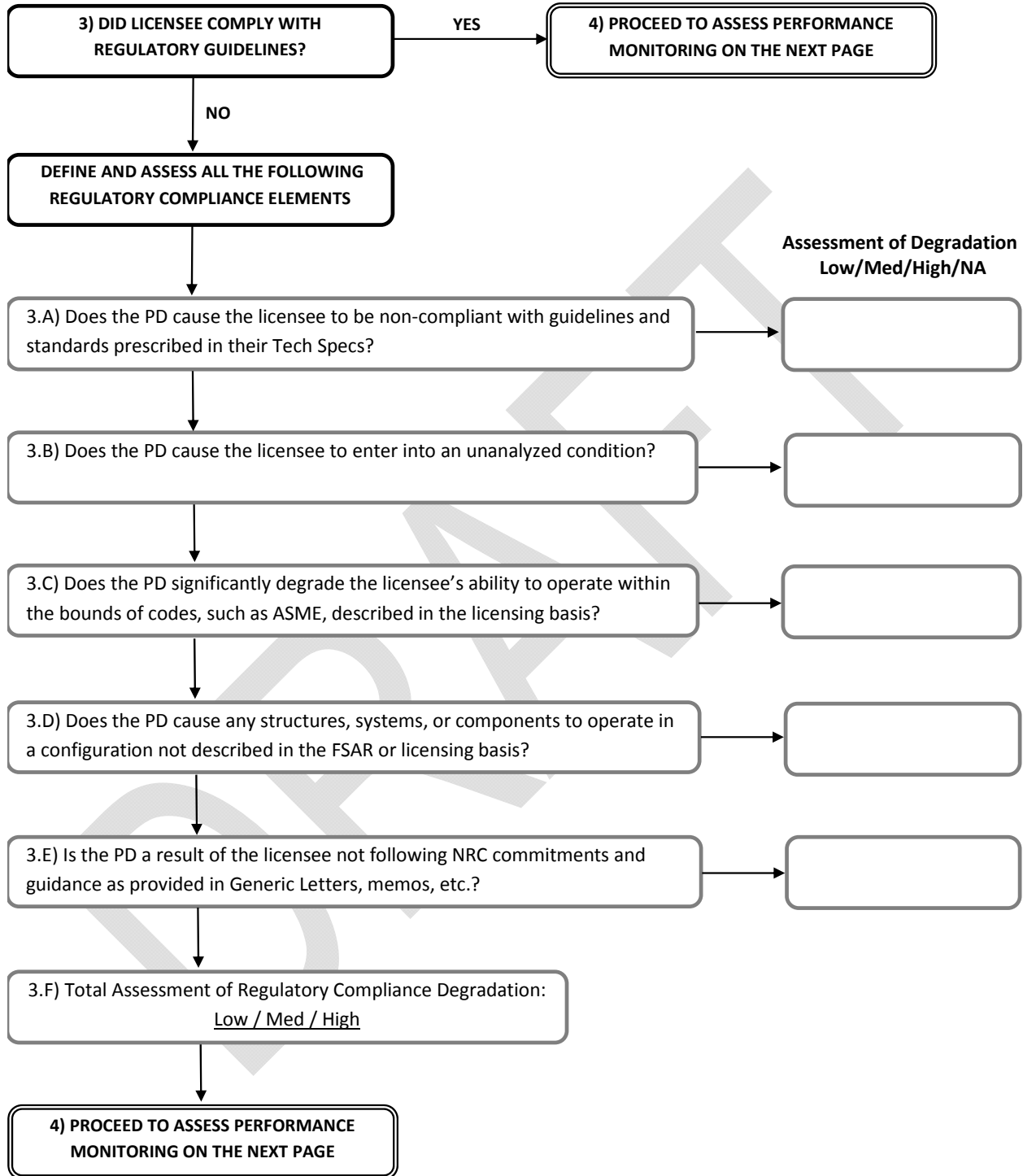




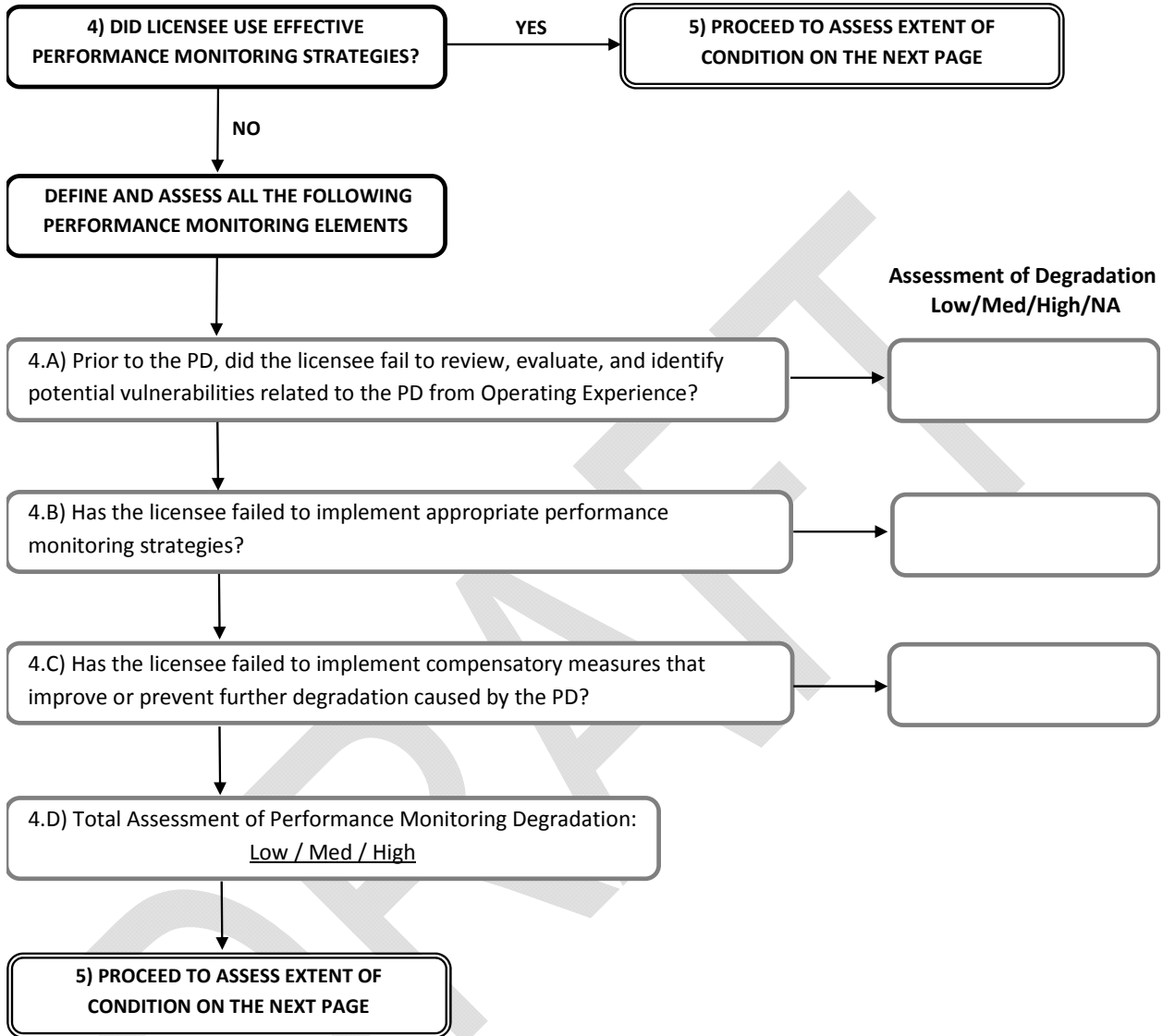
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Quantitative SDP Tool Not Adequate



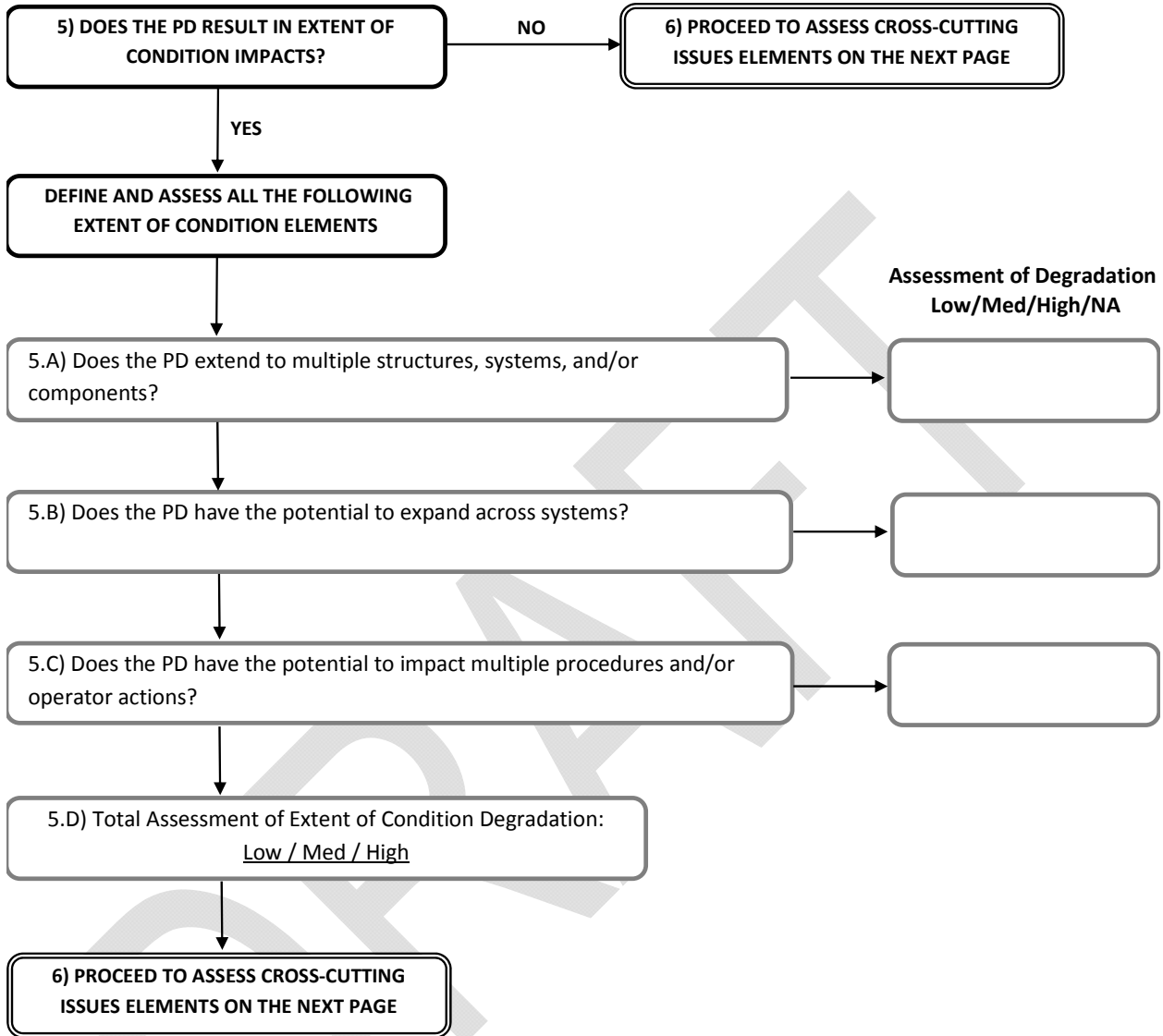
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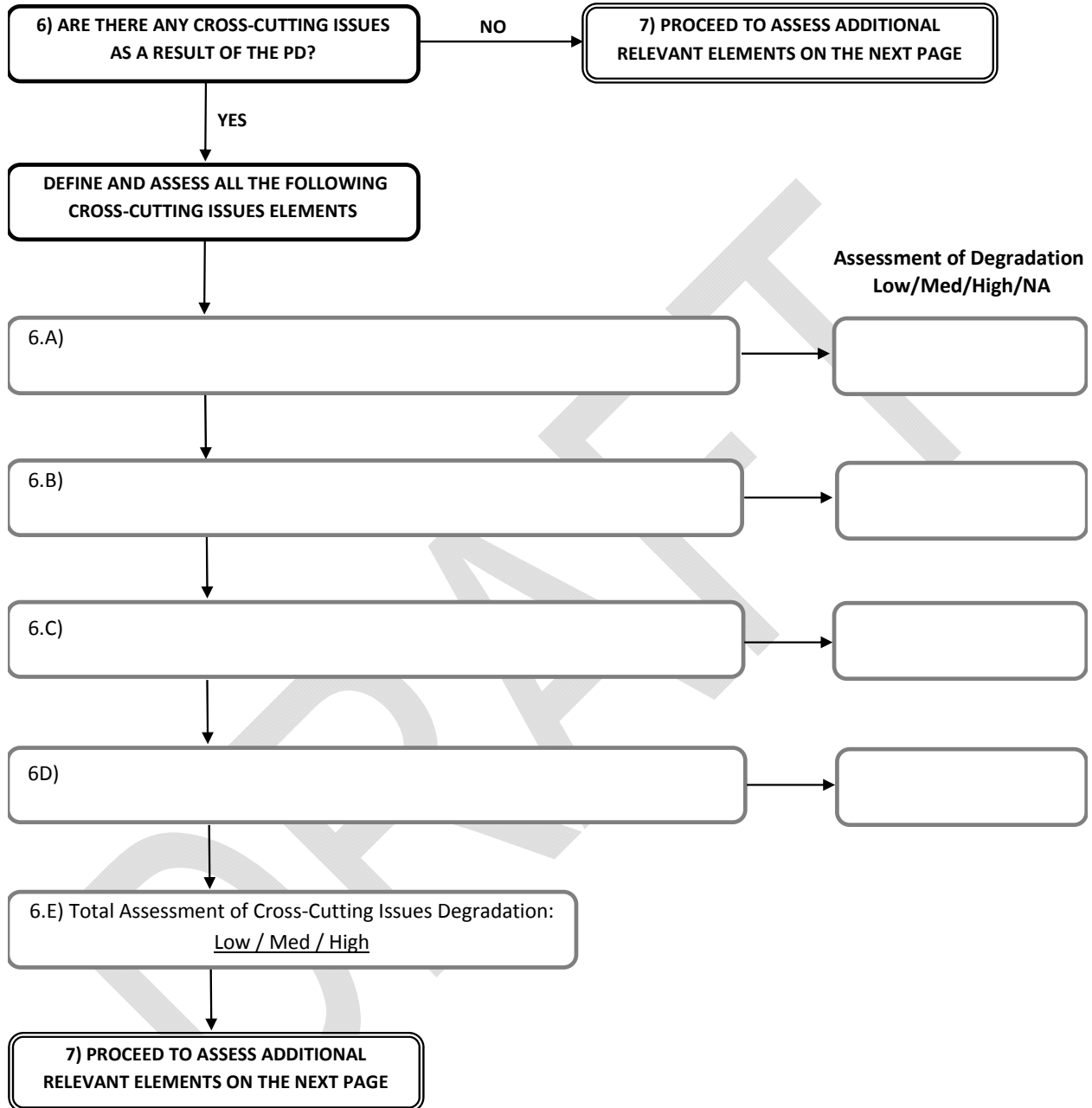
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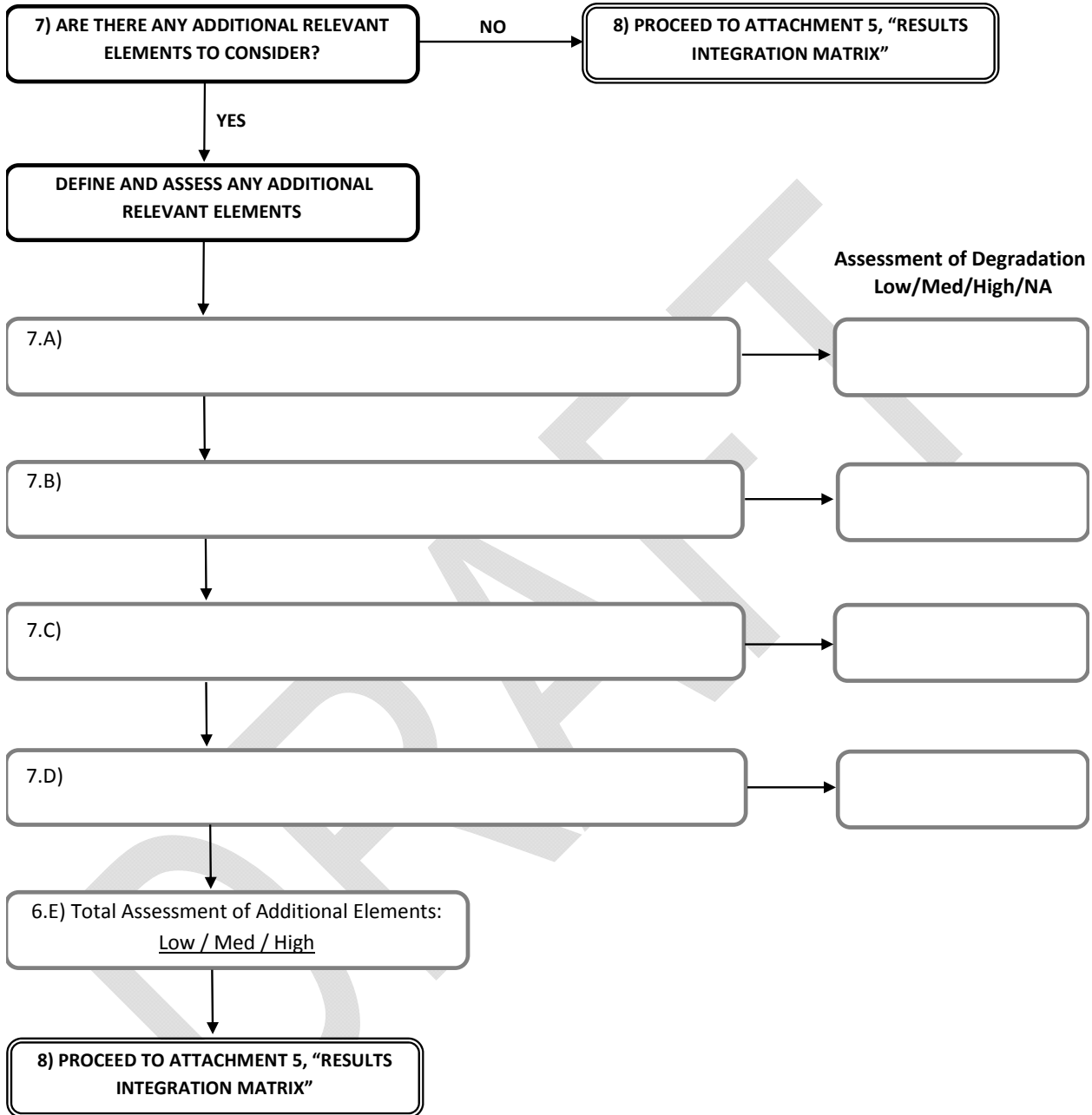
Attachment 3  
Quantitative SDP Tool Not Adequate



Attachment 3  
Quantitative SDP Tool Not Adequate



Attachment 3  
Quantitative SDP Tool Not Adequate



Attachment 4  
Additional SDP Tools Needed

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Attachment 5  
Results Integration Matrix

<b>TABLE 1 DECISION ATTRIBUTES FROM ATTACHMENT 2, "QUANTITATIVE TOOL NOT AVAILABLE"</b>		
<b>DECISION ATTRIBUTE</b>	<b>DEGREE OF DEGRADATION (Low/Med/High/NA)</b>	<b>JUSTIFICATION</b>
Defense-in-Depth		
Safety Margins		
Regulatory Compliance		
Performance Monitoring		
Extent of Condition		
Degree of Degradation		
Exposure Time		
Recovery Actions		
Cross-Cutting Issues		
Additional Relevant Factors		
<b>RESULTS (Number of Low/Med/High)</b>	<b>COLOR DETERMINATION</b>	<b>JUSTIFICATION</b>

<b>TABLE 2 DECISION ATTRIBUTES FROM ATTACHMENT 3, "QUALITATIVE TOOL NOT ADEQUATE"</b>		
<b>DECISION ATTRIBUTE</b>	<b>DEGREE OF DEGRADATION (Low/Med/High/NA)</b>	<b>JUSTIFICATION</b>
Sensitivity Results from Input Assumptions		
External Events		
Regulatory Compliance		
Performance Monitoring		
Extent of Condition		
Cross-Cutting Issues		
Additional Relevant Factors		
<b>RESULTS (Number of Low/Med/High)</b>	<b>COLOR DETERMINATION</b>	<b>JUSTIFICATION</b>



Attachment 5  
Results Integration Matrix

<b>TABLE 3</b>		
<b>DECISION ATTRIBUTES FROM ATTACHMENT 4, "ADDITIONAL SDP TOOLS NEEDED"</b>		
<b>DECISION ATTRIBUTE</b>	<b>DEGREE OF DEGRADATION (Low/Med/High/NA)</b>	<b>JUSTIFICATION</b>
Regulatory Compliance		
Performance Monitoring		
Extent of Condition		
Additional Relevant Factors		
<b>RESULTS (Number of Low/Med/High)</b>	<b>COLOR DETERMINATION</b>	<b>JUSTIFICATION</b>

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Attachment 6  
Revision History For  
IMC 0609 Appendix M

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number
N/A	12/22/06 CN 06-036	This new document has been issued to provide guidance to NRC management and inspection staff for assessing significance of inspection findings.	This procedure was developed by involved stakeholders. No training on the procedure recommended at this time. However, additional guidance may be developed based on experience gained.	ML063050646
N/A	ML101550365 04/04/12 CN 12-005	Provided clarification in the Scope and Applicability sections to articulate the Appendix M entry conditions and that Appendix M is not intended to be used to develop new models or acquire in-depth expert elicitation. In addition, ROPFF 0609M-1412 was incorporated to clarify that Appendix M applies to all the safety cornerstones of the ROP.	None	N/A