

Licensing Basis and Backfitting Workshops – Summer 2018

Case Studies and Potential Answers

Note: The case studies in this document are simplified scenarios for training purposes. As such, they do not include all details that would be necessary to evaluate a situation in practice. The “answer” pages provide suggested answers for discussion purposes during the workshop and should not be construed as agency positions on situations that may be similar to these training scenarios. Any proposed action should be evaluated using the Six-Step Process, in consultation with the Backfitting Community of Practice as needed.

1. Compliance exception – original design issue
2. Compliance exception – original design issue with Regulatory Guide
3. System design problem – 10 CFR 50.59
4. System design problem – NRC approved
5. Cracking problem
6. Earthquake frequency problem
7. New fire protection feature
8. Regulatory Guide use in license amendment
9. Non-conservative technical specification
10. Hurricanes in design certification renewal
11. Electrical circuit faults (combined license)
12. Flow resistance error (combined license)
13. Instrument calibration issue (combined license)
14. Quality classification issue (fuel facility)
15. Seismic hazard update (fuel facility)
16. Onsite medical treatment (fuel facility)
17. Hot leg injection issue
18. Heat exchanger inspection concern
19. Component cooling water pipe break
20. Operator shift durations

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Case Study 1: Compliance Exception – Original Design Issue

Background:

- During an engineering inspection at a nuclear power plant, inspectors identify a design issue with a safety-related system that was reviewed and approved during initial licensing. Inspectors believe the licensee needs to modify the system to address the problem.
- The NRC's safety evaluation report (SER) states that the design meets General Design Criteria (GDCs) x, y, and z. The SER describes how the NRC reviewed the applicant's use of industry standard XXXX that is required by 10 CFR 50.55a. The SER further describes NRC's review of the design calculation, and explicit approval of the calculation that supported the design.
- The inspection team noted that the plant design was unique, and that no other plants had a similar design, even though those plants were designed using the same industry standard XXXX to meet the same GDCs x, y, and z, and were approved in the same time period. The inspection team also noted that NRC did not explicitly review and approve the design calculation for any of the other designs.
- The region requested NRR to determine whether the licensee is in compliance with its licensing basis through the Task Interface Agreement (TIA) process.
- The TIA process concluded that the licensee is in compliance with its approved licensing basis. The TIA response also noted an apparent calculation error made by the applicant during original design, and stated that this may be the cause for the unique design.
- Assume NRC determined that the calculation error is not an issue of adequate protection.

Activity:

Discuss with your small group the answer to Step 4b, using the attached checklist to assess whether the compliance exception can be used. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
4b	Does the <i>Compliance exception</i> apply?	

Licensing Basis and Backfitting Workshops – Compliance Exception Worksheet – Summer 2018

THE REQUIREMENT	
The NRC has identified an NRC requirement for which compliance is sought.	<i>[a compliance backfit requires that an applicable requirement be in place, and this requirement is not changing, so to continue, describe the requirement]</i>
The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	<i>[confirm timing of standard—if not contemporaneous, do not check the box]</i>
The NRC consistently interpreted and applied the identified requirement.	<i>[check the box if the NRC’s interpretation was consistent <u>at the time of approval</u>; if there was inconsistent interpretation, then it is much less likely that an error or omission can be shown to have occurred]</i>
The NRC approved the licensee’s method of compliance with the requirement.	<i>[note the approval type/date and describe supporting information that indicates the NRC’s interpretation and application of the standards]</i>
THE ERROR OR OMISSION	
The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	<i>[describe the error or omission of information]</i>

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	<p>The error must have occurred at or before the time that the NRC found that the NRC requirement was satisfied and a regulatory approval was issued.</p>	<p><i>[note the time of the error (e.g., approval date)]</i></p>
	<p>The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement or commitment was satisfied and a regulatory approval was issued.</p>	<p><i>[refer back to the standard noted above and describe how we now conclude there was an error or omission at the time of approval—for example, a calculational mistake or omission of clearly important information]</i></p>
	<p>The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).</p>	<p><i>[describe how fixing the error or considering the omitted information changes the conclusion previously drawn by the licensee/applicant or the NRC]</i></p>
	<p>The NRC would likely not have issued its approval had NRC known of the error or omission.</p>	<p><i>[describe how fixing the error or considering the omitted information might have caused the NRC to not grant approval at that time]</i></p>
THE COSTS		
	<p>Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.</p>	<p><i>[discuss briefly what the corrective action would cost, and how long the facility has been in the current situation]</i></p>

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Case Study 2: Compliance Exception – Original Design Issue with Regulatory Guide

Background:

- During an engineering inspection at a nuclear power plant, inspectors identify a design issue with a safety-related system that was reviewed and approved during initial licensing. Inspectors believe the licensee needs to modify the system to address the problem.
- The NRC's safety evaluation report (SER) states that the design meets an applicable Regulatory Guide (RG) XX. No requirement was referenced or cited in the approval. The SER further describes the NRC's review of the design calculation, including the NRC's explicit approval of the calculation that supported the design.
- The inspection team noted that the plant design was unique, and that no other plants had a similar design, even though those plants were designed using the same industry standard that is endorsed in RG XX, and were approved in the same time period. The inspection team also noted that NRC did not explicitly review and approve the design calculations for any other designs.
- The region requested NRR to determine whether the licensee is in compliance with its licensing basis through the Task Interface Agreement (TIA) process.
- The TIA process concluded that the licensee is in compliance with its approved licensing basis. The TIA response also noted an apparent calculation error made by the applicant during original design, and stated that this may be the cause for the unique design.
- Assume NRC determined that the calculation error is not an issue of adequate protection.

Activity:

Discuss with your small group the answer to Step 4b, using the attached checklist to assess whether the compliance exception can be used. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
4b	Does the <i>Compliance exception</i> apply?	

Licensing Basis and Backfitting Workshops – Compliance Exception Worksheet – Summer 2018

THE REQUIREMENT	
The NRC has identified an NRC requirement for which compliance is sought.	<i>[a compliance backfit requires that an applicable requirement be in place, and this requirement is not changing, so to continue describe the requirement]</i>
The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	<i>[confirm timing of standard—if not contemporaneous, do not check the box]</i>
The NRC consistently interpreted and applied the identified requirement.	<i>[check the box if the NRC’s interpretation was consistent <u>at the time of approval</u>; if there was inconsistent interpretation, then it is much less likely that an error or omission can be shown to have occurred]</i>
The NRC approved the licensee’s method of compliance with the requirement.	<i>[note the approval type/date and describe supporting information that indicates NRC’s interpretation and application of the standards]</i>
THE ERROR OR OMISSION	
The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	<i>[describe the error or omission of information]</i>

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	<p>The error must have occurred at or before the time that the NRC found that the NRC requirement was satisfied and a regulatory approval was issued.</p>	<p><i>[note the time of the error (e.g., approval date)]</i></p>
	<p>The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement or commitment was satisfied and a regulatory approval was issued.</p>	<p><i>[refer back to the standard noted above and describe how we now conclude there was an error or omission at the time of approval—for example, a calculational mistake or omission of clearly important information]</i></p>
	<p>The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).</p>	<p><i>[describe how fixing the error or considering the omitted information changes the conclusion previously drawn by the licensee/applicant or the NRC]</i></p>
	<p>The NRC would likely not have issued its approval had NRC known of the error or omission.</p>	<p><i>[describe how fixing the error or considering the omitted information might have caused the NRC to not grant approval at that time]</i></p>
THE COSTS		
	<p>Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.</p>	<p><i>[discuss briefly what the corrective action would cost, and how long the facility has been in the current situation]</i></p>

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Case Study 3: System Design Problem with 10 CFR 50.59

Background:

- The licensee performed a modification that increased the flow through the minimum-flow recirculation line (mini-flow) for an emergency core cooling system (ECCS) pump.
- The licensee screened this modification using 10 CFR 50.59 and determined that prior NRC approval was not needed.
- The delivered pump flows were reduced as a result of increased mini-flow, affecting the performance assumed in the 10 CFR 50.46 loss-of-coolant accident (LOCA) analyses.
- The licensee did not revise the pump performance curves or reevaluate the affected Chapter 15 LOCA analyses.
- NRC inspectors discover this condition. In discussing the issue with the licensee, the inspectors determine the licensee improperly used 10 CFR 50.59 to implement this change, and that it should have, at a minimum, evaluated the impact of the reduced ECCS flow on the affected LOCA analyses. This change may have warranted an amendment under 10 CFR 50.90. Reporting under 10 CFR 50.46 may also have been required. Specifically, the inspectors determine that the change could have caused a more than minimal increase in the consequence of a previously analyzed accident.

Activity:

Discuss with your small group this question: **If NRC wants to take action to require the license to correct this condition—is this a backfit?**

Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

Case Study 4: System Design Problem with NRC Approval

Background:

- In 2008, the NRC issued a license amendment for a licensee-requested design change for the emergency core cooling system (ECCS) at a nuclear power plant. The NRC approval included a technical specification (TS) change that was necessary to support a modification that increased flow through the minimum-flow recirculation line (mini-flow) for an ECCS pump.
- The delivered pump flows were reduced as a result of increased mini-flow, affecting the performance assumed in the 10 CFR 50.46 loss-of-coolant accident (LOCA) analyses. The licensee did not revise the pump performance curves or the Chapter 15 LOCA analyses. The NRC, during its review and approval of the associated TS, did not recognize the need for reevaluation or reanalysis of the affected Chapter 15 LOCA analyses and did not request any changes in granting the approval.
- NRC inspectors discover this condition in 2018 and are concerned with the discrepancy between the new system design and the pump performance curves and LOCA analyses.

Activity:

Discuss with your small group this question: **If NRC wants to take action to require the license to correct this condition—is this a backfit?**

Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

Case Study 5: Cracking Problem

Background:

- The licensee identifies, during visual inspections conducted during a refueling outage, a large number of small cracks in the reactor vessel. This is the first time this cracking has been observed.
- The cracking was caused by a corrosive environment created by a leak of borated water from nearby equipment.
- An analysis of the cracking leads to the conclusion that the probability of reactor vessel fracture (for some events during the previous operating cycle) was significantly greater than previously understood.
- The licensee is ready to restart from the refueling outage. The licensee indicates that it identified and repaired the source of the leak, repaired the cracking in the vessel where necessary according to the ASME *Boiler and Pressure Vessel Code*, and performed analyses that indicates that the vessel will maintain integrity for all postulated design basis events during the upcoming operating cycle.
- NRC inspectors and technical experts at Headquarters are concerned about the situation. They are not convinced the licensee has appropriately assessed the damage to the vessel. They want the licensee to perform additional crack growth sensitivity studies and additional nondestructive evaluation of the reactor vessel.

Activity:

Discuss with your small group this question: **If NRC determines it is necessary to direct the licensee that it cannot restart until these actions are taken, is this a backfit? If so, must the NRC wait for the completion of a backfit analysis to take action?**

Use the attached worksheet (steps 0-4a) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>

Case Study 6: Earthquake Frequency Problem

Background:

- Nuclear power plants are designed based on the seismic spectra for a “safe shutdown earthquake” (SSE) with a postulated 10,000-year return frequency (i.e., the design basis earthquake used to meet General Design Criterion 2 for all safety-related equipment).
- A major seismic event occurs in the Midwestern U.S. that is larger (in terms of the seismic spectra) than previously predicted.
- Analysis of the event causes seismic experts to conclude that there is greater uncertainty associated with the seismic spectra for the SSE.
- Based on seismic PRAs, plants in that region might have seismic core damage frequencies in the 1 in 1000 reactor-year range (where these were previously understood to be in the 1 in 10,000 to 100,000 reactor-year range).
- The NRC concludes through its process for ongoing review of external hazard information that, as a result of this new information, action must be taken to address the increased uncertainty.

Activity:

Discuss with your small group the questions in steps 0-4a of the attached worksheet. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>

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Case Study 7: New Fire Protection Feature

Background:

- New research findings and technological breakthroughs have resulted in advanced fire protection features that are much more effective than current systems.
- The new fire protection technology is estimated using fire risk assessments to reduce the core damage frequency (CDF) attributed to fires, on a mean basis, by 5×10^{-5} per reactor year, effectively removing fire sequences as a significant contributor to power reactor risk.
- The total risk reduction is estimated to be 3×10^{-5} per reactor year in CDF on a mean basis, since other core damage sequences remain unaffected
- The reduction in overall risk to the public (safety benefit/reduction in radiological releases due to fire events) is converted from person-rem into dollars and is estimated to be \$50 million (average) for each plant.
- The total cost of the new requirements, including new equipment, initial installation, downtime, continuing maintenance, and averted offsite damage, is estimated to be \$25 million (average) for each plant.
- The NRC's regulatory analysis guidance state that, with certain exceptions, regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least 1×10^{-5} per reactor year in the estimated mean value CDF (i.e., the CDF before the proposed regulatory change should exceed the CDF after the change by at least 1×10^{-5} per reactor year) to justify proceeding with further analyses.

Activity:

Discuss with your small group step 5 in the worksheet below, assuming previous questions were answered sufficiently to proceed. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
5a	Would a substantial increase in public health and safety or common defense and security apply?	<i>[if the benefit is not judged to be "substantial," note this and stop work; if a substantial benefit would be gained, describe it and proceed]</i>
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	<i>[consider the costs of imposing the new requirement (briefly/qualitatively); note whether the benefit would justify the costs; note what action the NRC might take in either case]</i>

Case Study 8: Regulatory Guide Use in License Amendment

Background:

- In an original nuclear power plant licensing review, the NRC found the applicant's use of Regulatory Guide XX, Revision 0, acceptable in approving the design of a particular system.
- The nuclear power plant licensee wishes to modify the system and submits a Technical Specification (TS) amendment request under 10 CFR 50.90 that is necessary to support the proposed modification.
- The licensee's request related to the modification is based on Revision 0 of Regulatory Guide XX.
- Regulatory Guide XX was updated 1 year ago to Revision 1. The subject matter of the RG xx directly pertains to the proposed facility modification and addresses a design aspect key to NRC's approval of the TS amendment request and supporting modification.

Activity:

Discuss with your small group this question: **If NRC issues a request for additional information (RAI) regarding use of Revision 1 of RG XX (or otherwise requests its use) for the supporting modification, is that a backfit?**

Use the attached worksheet (steps 0-3) to support your discussion.

Then, discuss this follow-up question (no need to fill out the worksheet again): **As part of the TS amendment request review, if NRC requests the licensee make fixes to another system that is not part of, nor impacted in any way by, the modification supporting the TS amendment request, is that request/RAI a backfit?**

Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

Case Study 9: Non-Conservative Technical Specification

Background:

- A nuclear power plant licensee identifies a potentially non-conservative technical specification (TS). The TS for a particular system can be interpreted not to set any allowed outage time (AOT) for a key component. That is, the component could be out of service indefinitely.
- Administrative Letter 98-10 says, in part, that “discovery of an improper or inadequate TS value or required action is considered a degraded or nonconforming condition as defined in [Generic Letter] 91-18. Imposing administrative controls in response to an improper or inadequate TS is considered an acceptable short-term corrective action. The staff expects that, following the imposition of administrative controls, an amendment to the TS, with appropriate justification and schedule, will be submitted in a timely fashion. Once any amendment correcting the TS is approved, the licensee must update the final safety analysis report, as necessary, to comply with 10 CFR 50.71(e).”
- The licensee submits a license amendment request under 10 CFR 50.90 to amend the TS to include an AOT of 72 hours for the component in question.
- This AOT (72 hours) is the same as that used in the current Standard Technical Specifications (STS) (i.e., 72 hours). This STS outage time was developed based on engineering judgement of an acceptably short amount of time relative to the frequency of accident initiators that might occur, and not on any specific analysis.
- As part of the review of the license amendment request, the NRC requests the licensee to perform additional analyses to support the license amendment request.
- The licensee indicates that it does not wish to perform these analyses, that nothing has changed in the plant warranting this request, and it is simply adopting the STS AOT, which is clearly more conservative than the current TS (with no AOT).

Activity:

Discuss with your small group this question: **If NRC determines it is necessary for the licensee to conduct these analyses, is this a backfit?**

Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

Case Study 10: Hurricanes in Design Certification Renewal

Background:

Requirements and Guidance

- Nuclear power plants must be designed for extreme meteorological events (e.g., tornados, hurricanes) – General Design Criteria (GDCs) 2 and 4.
- Design certification (DC) applications must include site parameters postulated for the design and an analysis and evaluation of the design in terms of those site parameters – 10 CFR 52.47(a)(1).
- Prior to 2007, there was a general engineering assumption that tornado wind loads and missiles bounded those of hurricanes – Regulatory Guide (RG) 1.76, Revision 0.
- In 2007, RG 1.76, Revision 1 adopted a different tornado intensity methodology, resulting in a decrease in tornado wind speed. As a result, it was no longer clear whether tornado wind loads and missiles bounded hurricane wind loads and missiles.
- In 2011, new guidance concluded that, in certain U.S. locations, tornado conditions may not be bounding – RG 1.221.

Application

- Design “A” was certified via rulemaking in 2000.
- Consistent with then-current guidance, the designer assumed that tornado conditions bounded the site conditions and conducted associated wind load and missile analyses.
- In 2013, the designer submits a DC renewal application with no proposed changes to site parameters or analyses related to wind loads and missiles.
- The NRC is considering requiring the design be amended to specifically address the new guidance on hurricane wind loads and missiles. The staff’s concern is that at certain locations where tornado is not bounding, the design is not in compliance with GDCs 2 and 4, and adequate protection would not be demonstrated against hurricanes of credible intensity.
- Note: NRC can impose new requirements on the renewal, violating issue finality, if necessary for adequate protection, compliance, or cost-justified substantial increase in protection – 10 CFR 52.59(b). The renewal applicant can also request amendments in the renewal – 10 CFR 52.59(c).

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Activity:

Discuss with your small group this question: **If NRC determines it is necessary for the applicant to address the new hurricane guidance in the renewal, is this a violation of issue finality (similar to backfit)?**

Use the attached worksheet (steps 0-5b) to support your discussion.

Also, discuss with your group **whether there are other options available to address the issue without violating issue finality**. Use the box below to summarize your answer.

Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>

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Step	Question	Answer/Notes
4b	Does the <i>Compliance exception</i> apply?	<i>[use the attached checklist to assess whether the exception can be used; if so, recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
5a	Would a substantial increase in public health and safety or common defense and security apply?	<i>[if the benefit is not judged to be “substantial,” note this and stop work; if a substantial benefit would be gained, describe it and proceed]</i>
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	<i>[consider the costs of imposing the new requirement (briefly/qualitatively); note whether the benefit would justify the costs; note what action the NRC might take in either case]</i>

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Case Study 11: Electrical Circuit Faults (Combined License)

Background:

- Institute for Electrical and Electronics Engineers (IEEE) Standard XXX, developed in 1975, includes an assumption that one specific value used in designing electrical circuits would at least 1.5 times another value.
- For a design certification issued in 2011, the design control document (DCD) section on the direct current (dc) distribution system included use of IEEE XXX to calculate a particular maximum current for the components in the dc distribution system.
- The NRC accepted this approach in its safety evaluation report (SER) for the design certification.
- A COL issued in 2012 references this certified design and includes an item in the inspections, tests, analyses, and acceptance criteria (ITAAC) to verify (by calculation) that the dcC distribution system components can withstand the particular maximum current noted above without failure.
- Recent testing by Brookhaven National Labs using equipment invented in 2016 revealed that the IEEE XXX standard was non-conservative. The tests showed that the value could be as high as 15, not 1.5 as assumed in IEEE XXX.
- If this new contribution were considered in the design, the design analysis and potentially the affected components would have to be changed.
- Inspectors are concerned that the current situation may be unsafe given the new technical understanding of the design that was discovered by Brookhaven.

Activity:

Discuss with your small group the questions in steps 0-4a of the attached worksheet. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>

Case Study 12: Flow Resistance Error (Combined License)

Background:

- A design certification (DC) was issued in 2011 for Design X. A combined license (COL) was issued in 2012, referencing Design X.
- Tier 1 of the DC, as well as the COL for the facility, now under construction, includes an item in the inspections, tests, analyses, and acceptance criteria (ITAAC) to verify the calculated flow resistance in the passive core cooling system (PXS) piping between each core makeup tank and the reactor vessel. The calculated resistance must be between a value of 1.81 and 2.25 ft/gpm².
- The accident analysis calculations in Chapter 15 of the design control document for the certified design assume a PXS design-basis flow rate of 100 gallons per minute, to ensure safety provisions in General Design Criteria and 10 CFR 50.46 are met in a loss-of-coolant accident (LOCA).
- NRC inspectors look at the design calculations during an ITAAC inspection and identify that the PXS flow rate would be smaller than 100 gallons per minute if the flow resistance were greater than 2 ft/gpm².
- For the as-built plant, the calculated flow resistance is 1.9 ft/gpm².

Activity:

Discuss with your small group the questions in steps 0-4b of the attached worksheet, supported by the compliance exception worksheet for step 4b. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

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Step	Question	Answer/Notes
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
4b	Does the <i>Compliance exception</i> apply?	<i>[use the attached checklist to assess whether the exception can be used; if so, recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
5a	Would a substantial increase in public health and safety or common defense and security apply?	<i>[if the benefit is not judged to be “substantial,” note this and stop work; if a substantial benefit would be gained, describe it and proceed]</i>
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	<i>[consider the costs of imposing the new requirement (briefly/qualitatively); note whether the benefit would justify the costs; note what action the NRC might take in either case]</i>

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THE REQUIREMENT

	The NRC has identified an NRC requirement for which compliance is sought.	<i>[a compliance backfit requires that an applicable requirement be in place, and this requirement is not changing, so to continue describe the requirement]</i>
	The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	<i>[confirm timing of standard—if not contemporaneous, do not check the box]</i>
	The NRC consistently interpreted and applied the identified requirement.	<i>[check the box if the NRC’s interpretation was consistent <u>at the time of approval</u>; if there was inconsistent interpretation, then it is much less likely that an error or omission can be shown to have occurred]</i>
	The NRC approved the licensee’s method of compliance with the requirement.	<i>[note the approval type/date and describe supporting information that indicates the NRC’s interpretation and application of the standards]</i>

THE ERROR OR OMISSION

	The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	<i>[describe the error or omission of information]</i>
	The error must have occurred at or before the time that the NRC found that the NRC requirement was satisfied and a regulatory approval was issued.	<i>[note the time of the error (e.g., approval date)]</i>

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	<p>The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement or commitment was satisfied and a regulatory approval was issued.</p>	<p><i>[refer back to the standard noted above and describe how we now conclude there was an error or omission at the time of approval—for example, a calculational mistake or omission of clearly important information]</i></p>
	<p>The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).</p>	<p><i>[describe how fixing the error or considering the omitted information changes the conclusion previously drawn by the licensee/applicant or the NRC]</i></p>
	<p>The NRC would likely not have issued its approval had NRC known of the error or omission.</p>	<p><i>[describe how fixing the error or considering the omitted information might have caused the NRC to not grant approval at that time]</i></p>
<p>THE COSTS</p>		
	<p>Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.</p>	<p><i>[discuss briefly what the corrective action would cost, and how long the facility has been in the current situation]</i></p>

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Case Study 13: Instrument Calibration Issue (Combined License)

Background:

- For nuclear power plants, 10 CFR 50.36(c)(1)(ii)(A) requires that technical specifications (TS) include limiting safety system settings (LSSS), which provide automatic protection for variables having significant safety functions.
- As part of meeting this requirement, licensees calibrate safety-related instruments using a setpoint program required by TS and controlled under their quality assurance (QA) programs.
- For a current combined license (COL) holder, the TS require calibrations in accordance with the setpoint program. The NRC approved use of this program via a topical report during the design certification (DC) review and included this approval in the safety evaluation report (SER) for the DC. The COL was issued after the DC and referenced the DC.
- All operating reactor licensees use a similar approach, and the NRC has inspected the existing calibration control programs for years without identifying any concerns. All COL holders referencing the DC are also intending to use this approach.
- The NRC receives an allegation that the calibration approach in the approved setpoint program is flawed, and non-conservative setpoints are being used industry-wide for safety-related instruments. The NRC conducts a follow-up inspection and substantiates the allegation.
- To correct the issue, all licensees, including all operating reactor licensees and COL holders referencing the DC, would need to change their approved programs/procedures to restore compliance with TS.

Activity:

Discuss with your small group this question: **If NRC wants to take action to require licensees to correct this issue—is this a backfit? If so, on what basis should the NRC proceed?** Use the attached worksheet (steps 0-5b) to support your discussion.

Also, discuss **what additional activities the NRC might wish to pursue in this circumstance, given the apparently generic nature of the issue.**

[notes on additional activities]

Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

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Step	Question	Answer/Notes
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
4b	Does the <i>Compliance exception</i> apply?	<i>[use the attached checklist to assess whether the exception can be used; if so, recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
5a	Would a substantial increase in public health and safety or common defense and security apply?	<i>[if the benefit is not judged to be “substantial,” note this and stop work; if a substantial benefit would be gained, describe it and proceed]</i>
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	<i>[consider the costs of imposing the new requirement (briefly/qualitatively); note whether the benefit would justify the costs; note what action the NRC might take in either case]</i>

Case Study 14: Quality Classification Issue (Fuel Facility)

Background:

- In licensing a fuel facility, the NRC approved a quality assurance (QA) program that includes a classification scheme.
- The license application stated that structures, systems, and components designated as items relied on for safety (IROFS) must have sufficient QA to ensure they are designed, installed, tested, modified, and maintained in accordance with approved procedures to guarantee their availability and reliability. 10 CFR 70.62(d) requires each licensee and applicant to have management measures to ensure that IROFS are designed, implemented, and maintained to ensure they are available and reliable to perform their functions when needed. The application identified different quality levels for IROFS that prevent and/or mitigate the consequences of the hazards evaluated as part of the facility's integrated safety analysis (ISA).
- Level "A" (High Consequence or "Crucial") was defined in the application as systems that ensure operation does not result in doses of more than 100 rem to workers or 25 rem to the public. These systems are subject to full QA requirements to maintain high reliability. Other IROFS have less strict, Level B QA requirements.
- NRC inspectors identified that the licensee modified an IROFS related to criticality safety, but used Level B controls rather than Level A. Inspectors noted that the IROFS was designed to control dose to workers and the public. Since before the time that the licensee submitted its renewal application, the NRC considered criticalities as "high consequence events" because criticalities produce worker doses in excess of 100 rem. The inspectors concluded that the IROFS related to criticality safety should have been classified as Level A.
- The licensee pointed out to the inspectors that the license renewal application included a list of all IROFS designated as Level A—which did not include the IROFS in question—and that the NRC's safety evaluation referenced this table and later concluded that the categorization of IROFS was acceptable.

Activity:

Discuss with your small group this question: **If NRC wants to require the licensee to treat this IROFS as Level A—is this a backfit, and how should the NRC proceed?**

Use the attached worksheet (steps 0-5b) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

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Step	Question	Answer/Notes
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
4b	Does the <i>Compliance exception</i> apply?	<i>[use the attached checklist to assess whether the exception can be used; if so, recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
5a	Would a substantial increase in public health and safety or common defense and security apply?	<i>[if the benefit is not judged to be “substantial,” note this and stop work; if a substantial benefit would be gained, describe it and proceed]</i>
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	<i>[consider the costs of imposing the new requirement (briefly/qualitatively); note whether the benefit would justify the costs; note what action the NRC might take in either case]</i>

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Case Study 15: Seismic Hazard Update (Fuel Facility)

Background:

- Fuel facility integrated safety analyses (ISAs) must be conducted *and maintained* in accordance with 10 CFR 70.62(c): “(c) Integrated safety analysis. (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:...(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena; (v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods”
- Credible events are also noted in 10 CFR 70.61, which requires: “(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely”
- A new U.S. Geological Survey (USGS) study shows an increased frequency for an earthquake at a particular facility location. The NRC issued an Information Notice to all licensees highlighting the study and emphasizing the 10 CFR 70.62(c) requirement to maintain the ISA.
- The licensee did not update its ISA to consider the new information from USGS, and did not have any documentation showing that the new information was evaluated at all for potential inclusion in the ISA.
- During a routine inspection, an NRC inspector raises a concern that the rupture of a process line—now credible under the increased frequency noted by USGS—could cause a high consequence event as defined by 10 CFR 70.61(b). The NRC inspector performs a calculation to confirm this potential. The NRC inspector determines that the licensee needs to update its ISA to consider this updated hazard.

Activity:

Discuss with your small group this question: **Should the licensee’s need to conduct an ISA update be handled through enforcement, or as backfitting?** Use the step 0 items below to support your discussion. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>

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Step	Question	Answer/Notes
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>

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Case Study 16: Onsite Medical Treatment (Fuel Facility)

Background:

- 10 CFR 70.50(b)(3) and 10 CFR 40.60(b)(3) require: “Twenty-four hour report. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material: An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual’s clothing or body.”
- NRC inspectors review the use of the onsite medical facilities at licensees’ facilities and note that employees with spreadable radioactive contamination had been treated. However, the licensee had not made any reports notifying the NRC of such instances.
- The licensees had interpreted the requirement to mean that only offsite medical facilities were the subject of the regulations.
- The inspectors review the history of this reporting requirement and find the following in the *Federal Register* (FR) notice associated with the final rule:
 - “The NRC has decided to require reports of any injured person introducing spreadable contamination into a medical facility regardless of who maintains the facility. The NRC must be aware of these incidents to ensure appropriate radiological controls are used and to ensure any radiological consequences are properly addressed. Since the exception for a licensee maintained facility has been removed from the rule, the above question, regarding interpretation of the rule, is moot.” (56 FR 40757 at 40763, response to Comment 35)
 - “The exemption for first aid at a licensee maintained medical facility for a superficial injury was deleted because the NRC agreed with commenters that a significant contamination event could still occur even if the injury was only superficial and the medical facility was licensed to handle radioactive material.” (56 FR 40747 at 40765)
- Inspectors are concerned that facilities licensed under 10 CFR Part 70 and 10 CFR Part 40 were not reporting the onsite medical treatment of employees with spreadable contamination as required by the applicable regulations.

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Activity:

Discuss with your small group this question: **Should the reporting issue update be handled through enforcement, or as backfitting?** Use the step 0 items below to support your discussion.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>

Also, discuss **what additional activities the NRC might wish to pursue in this circumstance, given the apparently generic nature of the issue.**

Take notes and report back to the large group when requested.

Case Study 17: Hot Leg Injection Issue

Background:

- In 2015, the licensee prepared a change package to proceduralize local manual actions for the hot leg injection (HLI) strategy, which is used after a loss-of-coolant accident (LOCA) to prevent boron from precipitating in the reactor core over the long term. The procedure was designed to address a single failure vulnerability and directed installation of electrical jumper cabling between a motor control center in one train and a motor-operated valve (MOV) in the opposite train that had lost power because of a single failure. The change made the procedure more specific—previously, jumper installation was a “skill of the craft” item. The 10 CFR 50.59 evaluation in the licensee’s change package concluded that no license amendment was required for the change.
- Inspectors were concerned that this jumper cable would be in conflict with separation and redundancy statements in the facility’s updated final safety analysis report (UFSAR), because the two power trains would be connected after jumper installation.
- In addition, the inspectors noted that the guidance in NEI 96-07 (to which the licensee is committed to using to perform its 10 CFR 50.59 determinations) states the following as an example of a change that would require prior NRC review and approval: “The change would reduce system/equipment redundancy, diversity, separation or independence.”
- The inspectors researched the issue, in consultation with NRR, and found that, because no standard review plan existed yet for this issue at the time of licensing, a publicly available NRR memo was used: “Concentration of Boric Acid in Reactor Vessel during Long Term Cooling—Method for Reviewing Appendix K Submittals,” dated January 21, 1976 (ADAMS Legacy Accession Number 8107020118).
 - Appendix I to this memo states: “The primary mode for maintaining acceptable levels of boron in the vessel should be established. Should a single failure disable the primary mode, certain manual actions outside the control room would be allowed, depending on the nature of the action and the time available to establish the back-up mode.”
- The inspectors also found that the NRC reviewed the licensee’s HLI strategy during initial licensing. The application was clear that the licensee needed both trains of electrical power to realign equipment, if no local manual actions were accounted for. Both the primary and alternate flow paths would be disabled by certain single electrical failures (for instance, a single battery or a single emergency diesel generator). Two NRC documents addressed the acceptability of the licensee’s HLI strategy:
 - Supplement No. 2 to the Safety Evaluation Report (SER) for the facility, dated March 1, 1976. SER Supplement 2 stated the plant met single failure criteria for its HLI strategy.
 - A letter dated March 29, 1982, which accepted the licensee’s responses to RAIs asked regarding the licensee’s strategy. The letter stated that the emergency procedure for LOCA was reviewed. The procedure in use at the time was reviewed by inspectors and was determined to have a step to install the jumpers, if needed. The letter concluded that the design and technical specifications for post-LOCA boron concentration control for the facility were acceptable.

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Activity:

Discuss with your small group this question: **Has a violation of NRC requirements been identified? If not, and if the NRC identifies the need for a new requirement, how should the NRC proceed?** Use the attached worksheet (steps 0-5b) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

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Step	Question	Answer/Notes
4a	Do one or more of the <i>Adequate Protection</i> exceptions to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
4b	Does the <i>Compliance</i> exception apply?	<i>[use the attached checklist to assess whether the exception can be used; if so, recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
5a	Would a substantial increase in public health and safety or common defense and security apply?	<i>[if the benefit is not judged to be “substantial,” note this and stop work; if a substantial benefit would be gained, describe it and proceed]</i>
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	<i>[consider the costs of imposing the new requirement (briefly/qualitatively); note whether the benefit would justify the costs; note what action the NRC might take in either case]</i>

Case Study 18: Heat Exchanger Inspection Concern

Background:

- At a nuclear power plant, the residual heat removal (RHR) heat exchangers (HX) are original plant equipment, operated intermittently for shutdown cooling over the 40 years of operation to date.
- Section E-4.1 of the vendor manual states that, “at intervals as experience indicates, an examination should be made of the interior and exterior condition of all tubes.” The licensee has never inspected the interior of the RHR HXs, and has not established a frequency for performing the HX inspections as recommended by the vendor manual.
- The licensee also has not tested the thermal performance of the RHR HXs. Because both water streams flowing through the HXs had chemistry controls in place, and because their shutdown cooling function was met, the licensee decided it was not necessary to perform the test.
- In 1989, the NRC identified concerns with closed-cycle cooling water systems in Generic Letter (GL) 89-13, “Service Water System Problems Affecting Safety-Related Equipment.” GL 89-13 stated, in part, that these systems “have the potential for significant fouling as a consequence of aging-related in-leakage and erosion or corrosion. The need for testing of closed-cycle system heat exchangers has not been considered necessary because of the assumed high quality of existing chemistry control programs. *If the adequacy of these chemistry control programs cannot be confirmed over the total operating history of the plant* [emphasis added] or if during the conduct of the total testing program any unexplained downward trend in heat exchanger performance is identified that cannot be remedied by maintenance of an open-cycle system, it may be necessary to selectively extend the test program and the routine inspection and maintenance program” for open-cycle cooling water systems to these closed-cycle systems.
- NRC inspectors are concerned that the licensee has not verified (via inspection or testing) the effectiveness of chemistry control programs in preventing degradation of the RHR HXs.
- NRC inspectors are also concerned that the licensee’s assumptions about thermal performance based on shutdown cooling may not be sufficient in design-basis accident conditions. Water temperatures and flow rates in the two situations are different, and the licensee does not monitor or trend the SDC performance of the HXs to detect degradation.

Activity:

Discuss with your small group this question: **Does the backfitting process need to be followed to address this issue?** Use the attached worksheet (steps 0-3) to support your discussion. You may find that more information is needed to reach a conclusion; discuss how the NRC could obtain that information. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

Case Study 19: Component Cooling Water Pipe Break

Background:

- In the original design of a nuclear power plant's containment support systems, containment heat removal could be provided by either two containment spray (CS) pumps cooled by component cooling water (CCW) or three containment air coolers (CACs) cooled by service water (SW). The design provided complete redundancy.
- In about 1982, as part of the Systematic Evaluation Program (SEP), the NRC identified that a pipe break could lead to a loss of both trains of CCW, inconsistent with General Design Criterion (GDC) 44. The SEP evaluation noted that the redundant CACs could provide the containment heat removal function.
- In the early 1980s, the licensee reanalyzed the MSLB design-basis event to address a newly identified issue in response to an NRC Bulletin. The revised analysis included the need for one CS pump to support the option with three CACs (not three CACs alone). On April 11, 1984, the NRC issued an SER relating to Bulletin 80-04. The SER accepted the plant's strategy of combining the CACs and CS systems to address an MSLB.
- The removal of CS/CAC system redundancy, as described in the original FSAR and SER, does not appear to have been explicitly considered during the 1980 reanalysis.
- On October 20, 1986, the facility submitted a license amendment request to remove a CAC fan from the TS. The licensee justified the change because the CAC was part of a redundant system to the CS credited in the accident analyses. The NRC issued the license amendment.
- In 2013, inspectors reviewed the CCW design and noted that a pipe break in the CCW system could make the plant not capable of providing post-accident containment cooling. As noted above, either option for post-accident containment cooling required at least one CS pump cooled by CCW.
- The licensee stated that postulating a passive failure (pipe break) of CCW concurrent with a design-basis accident is not within its licensing bases; the FSAR states that no active single failure would render CCW inoperable. The licensee considered a postulated failure of the non-safety-related portion of the CCW system inside containment as beyond-design-basis, except as result of a seismic event, which was not postulated to occur in conjunction with an accident.
- Inspectors, in coordination with Headquarters, determined that the risk of a total loss of CCW is a very small contributor to overall plant CDF and LERF, either as an initiating event or a subsequent failure after another initiating event. In the seismic PRA, this scenario is a more significant risk contributor, but overall seismic CDF is 4.2×10^{-6} per year and LERF is 7.2×10^{-7} per year, given other plant considerations.

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Activity:

Discuss with your small group this question: **Does the backfitting process need to be followed to address this issue?** Use the attached worksheet (steps 0-4b), as well as the compliance checklist supporting step 4b, to support your discussion. You may find that more information is needed to reach a conclusion; discuss how the NRC could obtain that information. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

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Step	Question	Answer/Notes
4a	Do one or more of the <i>Adequate Protection</i> exceptions to preparing a backfit analysis apply?	<i>[if this appears to be a matter of adequate protection, note why and how the NRC might take action (e.g., an Order), recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>
4b	Does the <i>Compliance</i> exception apply?	<i>[use the attached checklist to assess whether the exception can be used; if so, recognize that the regulation requires NRC to provide a documented evaluation to invoke the exception, then stop work; if not, note this and proceed]</i>

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THE REQUIREMENT		
	The NRC has identified an NRC requirement for which compliance is sought.	<i>[a compliance backfit requires that an applicable requirement be in place, and this requirement is not changing, so to continue describe the requirement]</i>
	The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	<i>[confirm timing of standard—if not contemporaneous, do not check the box]</i>
	The NRC consistently interpreted and applied the identified requirement.	<i>[check the box if the NRC’s interpretation was consistent <u>at the time of approval</u>; if there was inconsistent interpretation, then it is much less likely that an error or omission can be shown to have occurred]</i>
	The NRC approved the licensee’s method of compliance with the requirement.	<i>[note the approval type/date and describe supporting information that indicates the NRC’s interpretation and application of the standards]</i>
THE ERROR OR OMISSION		
	The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	<i>[describe the error or omission of information]</i>
	The error must have occurred at or before the time that the NRC found that the NRC requirement or commitment was satisfied and a regulatory approval was issued.	<i>[note the time of the error (e.g., approval date)]</i>

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	<p>The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement was satisfied and a regulatory approval was issued.</p>	<p><i>[refer back to the standard noted above and describe how we now conclude there was an error or omission at the time of approval—for example, a calculational mistake or omission of clearly important information]</i></p>
	<p>The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).</p>	<p><i>[describe how fixing the error or considering the omitted information changes the conclusion previously drawn by the licensee/applicant or the NRC]</i></p>
	<p>The NRC would likely not have issued its approval had NRC known of the error or omission.</p>	<p><i>[describe how fixing the error or considering the omitted information might have caused the NRC to not grant approval at that time]</i></p>
<p>THE COSTS</p>		
	<p>Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.</p>	<p><i>[discuss briefly what the corrective action would cost, and how long the facility has been in the current situation]</i></p>

Case Study 20: Operator Shift Durations

Background:

- 10 CFR 55.53(e) states, in part: “To maintain active status, the licensee [licensed individual] shall actively perform the functions of an operator or senior operator on a minimum of seven 8-hour or five 12-hour shifts per calendar quarter.”
- NUREG-1021, revision 11, ES-605 further explains that: “[t]his requirement may be completed with a combination of complete 8- and 12-hour shifts ... at sites having a mixed-shift schedule, and watches shall not be truncated when the operator satisfies the minimum quarterly requirement (56 hours).”
- At one nuclear power plant, the operating crews generally stand 12-hour watches. “Administrative reactor operators” generally work outside the control room on 8-hour shifts. The licensee allows these operators to stand 8-hour watches in the control room to maintain an active license. When an administrative reactor operator completes an 8-hour “proficiency watch,” he/she turns over to another licensed operator who completes the remaining 4 hours of the typical 12-hour operating shift. This practice minimizes overtime costs to maintain the licenses for these individuals. The licensee began this practice within the past year and has not proceduralized it.
- Inspectors questioned whether the licensee’s approach met the 10 CFR 50.55(e) requirement and was consistent with the NUREG-1021 guidance. The inspectors identified two potential interpretations:
 - A “shift” is the length of time that an operating crew is assigned to stand watch, from the time the on-shift crew takes the watch to the time the on-shift crew is relieved. Using this interpretation, all licensed operators at the station would be required to stand five 12-hour watches per calendar quarter to maintain their licenses in an active status.
 - A “shift” is specific to an individual operator and refers to the distinct period of time during which a licensed operator is actively performing the functions of an operator or senior operator as defined by 10 CFR 55.4. Using this interpretation, the station’s administrative reactor operators would be required to stand seven 8-hour or five 12-hour shifts per calendar quarter to maintain their license in an active status.
- In consultation with NRR, the inspectors confirmed that there is no definition of “shift” in 10 CFR Part 55, NUREG-1021, or relevant technical specifications (TS).

Activity:

Discuss with your small group this question: **If the NRC wants to impose a 12-hour definition for the term “shift” in this context, would that be backfitting?** Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	<i>[summarize briefly the key issue and its relationship to safety/security]</i>
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<i>[if there is an enforceable requirement that (if the licensee returns to compliance) is sufficient to address the safety concern, state it here and stop work; if a new requirement is needed to address the concern fully, or if it appears NRC's approval against the requirements may be a result of an error or omission, describe the key points briefly and proceed]</i>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	<i>[if the action is excluded from backfitting and issue finality provisions (i.e., a recordkeeping and reporting requirement, administrative requirement, or statutory obligation without discretion), note this and suggest how the NRC could address the issue, then stop work; if it is not excluded, note this and proceed]</i>
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	<i>[if the licensee/applicant is the subject of a backfitting or issue finality requirement, note which requirement (e.g., 10 CFR 50.109) and continue; if the licensee/applicant is not the subject of any of these requirements, then note this and suggest how the NRC could address the issue, then stop work]</i>
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<i>[consider the definition of backfitting (e.g., modification to facility design/components/operation/procedures)—if the action does not meet the definition or might meet the definition, except is not being <u>imposed</u> (e.g., guidance), then stop work; if it meets the definition, describe it and proceed]</i>

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Case Study 1: Compliance Exception – Original Design Issue

Key Message: The compliance exception can be pursued when an issue is not significant enough for the adequate protection exception, and an error or omission is revealed that would have been understood at the time of approval and would have changed the NRC’s decision.

Background:

- During an engineering inspection at a nuclear power plant, inspectors identify a design issue with a safety-related system that was reviewed and approved during initial licensing. Inspectors believe the licensee needs to modify the system to address the problem.
- The NRC’s safety evaluation report (SER) states that the design meets General Design Criteria (GDCs) x, y, and z. The SER describes how the NRC reviewed the applicant’s use of industry standard XXXX that is required by 10 CFR 50.55a. The SER further describes NRC’s review of the design calculation, and explicit approval of the calculation that supported the design.
- The inspection team noted that the plant design was unique, and that no other plants had a similar design, even though those plants were designed using the same industry standard XXXX to meet the same GDCs x, y, and z, and were approved in the same time period. The inspection team also noted that NRC did not explicitly review and approve the design calculation for any of the other designs.
- The region requested NRR to determine whether the licensee is in compliance with its licensing basis through the Task Interface Agreement (TIA) process.
- The TIA process concluded that the licensee is in compliance with its approved licensing basis. The TIA response also noted an apparent calculation error made by the applicant during original design, and stated that this may be the cause for the unique design.
- Assume NRC determined that the calculation error is not an issue of adequate protection.

Activity:

Discuss with your small group the answer to Step 4b, using the attached checklist to assess whether the compliance exception can be used. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
4b	Does the <i>Compliance exception</i> apply?	It is likely that the compliance exception could be pursued, based on the attached checklist. The staff would need to confirm that the error would have been known to professionals at the time (if it had been revealed) and would have changed the NRC’s decision on approval (or on needing changes before granting approval). The staff would also need to consider the costs of addressing the error when documenting its evaluation.

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THE REQUIREMENT		
✓	The NRC has identified an NRC requirement for which compliance is sought.	Yes—10 CFR 50.55a, which requires application of industry standard XXXX. (This is a more specific requirement than the GDCs, which were used to establish the initial bounds of the design.)
✓	The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	Yes—both requirement and industry standard existed, and use of the standard is included in the UFSAR.
✓	The NRC consistently interpreted and applied the identified requirement.	Yes. For all other plants it appears that the industry standard XXXX was applied consistently. For this plant there was an explicit review and application of the standard that was unique.
✓	The NRC approved the licensee’s method of compliance with the requirement.	Yes—the SER explicitly approves the application of the standard and the specific calculation to meet the requirement.
THE ERROR OR OMISSION		
✓	The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	Yes—the applicant made a calculation error (details not known).
✓	The error must have occurred at or before the time that the NRC found that the NRC requirement or commitment was satisfied and a regulatory approval was issued.	Yes—during original design.
?	The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement was satisfied and a regulatory approval was issued.	May need additional detail to confirm this is the case.
✓	The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).	Yes—based on TIA evaluation
?	The NRC would likely not have issued its approval had NRC known of the error or omission.	Need additional detail to confirm this is the case.
THE COSTS		
?	Costs of the compliance backfitting are considered in the NRC’s documented evaluation of the backfitting action.	Need additional detail to confirm this is the case.

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Case Study 2: Compliance Exception – Original Design Issue with Regulatory Guide

Key Message: The compliance exception can be only be pursued when there is a specific requirement for which the NRC is seeking compliance, not in situations of nonconformance to a criterion the NRC considered during its approval.

Background:

- During an engineering inspection at a nuclear power plant, inspectors identify a design issue with a safety-related system that was reviewed and approved during initial licensing. Inspectors believe the licensee needs to modify the system to address the problem.
- The NRC's safety evaluation report (SER) states that the design meets an applicable Regulatory Guide (RG) XX. No requirement was referenced or cited in the approval. The SER further describes the NRC's review of the design calculation, including the NRC's explicit approval of the calculation that supported the design.
- The inspection team noted that the plant design was unique, and that no other plants had a similar design, even though those plants were designed using the same industry standard that is endorsed in RG XX, and were approved in the same time period. The inspection team also noted that NRC did not explicitly review and approve the design calculations for any other designs.
- The region requests NRR to determine whether the licensee is in compliance with its licensing basis through the Task Interface Agreement (TIA) process.
- The TIA process concluded that the licensee is in compliance with its approved licensing basis. The TIA response also noted an apparent calculation error made by the applicant during original design, and stated that this may be the cause for the unique design.
- Assume NRC determined that the calculation error is not an issue of adequate protection.

Activity:

Discuss with your table group the answer to Step 4b, using the attached checklist to assess whether the compliance exception can be used. Take notes and report back when requested.

Step	Question	Answer/Notes
4b	Does the <i>Compliance exception</i> apply?	No—see attached checklist for details.

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THE REQUIREMENT	
<p>The NRC has identified an NRC requirement for which compliance is sought.</p>	<p>No, unless the NRC can find some applicable requirement for this system cited somewhere else in the SER that supported issuance of the operating license.</p> <p><u>Compliance backfits do not change the governing requirement</u>, only the NRC's approval of the licensee's application or request against the governing requirement. As discussed in this training, this can only be done under limited circumstances when there was a mistake or omission made at or before the time of the issuance of the NRC's approval.</p> <p>In this case, no requirement was cited in the SER. A RG is not a requirement. It is simply one acceptable means for complying with a requirement. This conclusion for any situation where there is no governing requirement cited.</p>

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Case Study 3: System Design Problem with 10 CFR 50.59

Key Message: Requiring a licensee to correct a condition that violates requirements in effect for that licensee is not backfitting.

Background:

- The licensee performed a modification that increased the flow through the minimum-flow recirculation line (mini-flow) for an emergency core cooling system (ECCS) pump.
- The licensee screened this modification using 10 CFR 50.59 and determined that prior NRC approval was not needed.
- The delivered pump flows were reduced as a result of increased mini-flow, affecting the performance assumed in the 10 CFR 50.46 loss-of-coolant accident (LOCA) analyses.
- The licensee did not revise the pump performance curves or reevaluate the affected Chapter 15 LOCA analyses.
- NRC inspectors discover this condition. In discussing the issue with the licensee, the inspectors determine the licensee improperly used 10 CFR 50.59 to implement this change, and that it should have, at a minimum, evaluated the impact of the reduced ECCS flow on the affected LOCA analyses. This change may have warranted an amendment under 10 CFR 50.90. Reporting under 10 CFR 50.46 may also have been required. Specifically, the inspectors determine that the change could have caused a more than minimal increase in the consequence of a previously analyzed accident.

Activity:

Discuss with your small group this question: **If NRC wants to take action to require the licensee to correct this condition—is this a backfit?**

Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	With reduced pump flow, ECCS performance is reduced, and this may result in failure to meet 10 CFR 50.46 performance requirements (i.e., ECCS performance for LOCAs).
0b	Are new requirements or NRC interpretations needed to address the issue fully?	No—enforcement of the current requirements should be sufficient to correct this issue. There is an apparent violation of the 10 CFR 50.59 screening process. There may also be a violation of the underlying 10 CFR 50.46 LOCA requirements.

Case Study 4: System Design Problem with NRC Approval

Key Message: If the NRC wants to change a previous approval based on new information—even if the NRC made a mistake in its approval—the change must be evaluated as backfitting.

Background:

- In 2008, the NRC issued a license amendment for a licensee-requested design change for the emergency core cooling system (ECCS) at a nuclear power plant. The NRC approval included a technical specification (TS) change that was necessary to support a modification that increased flow through the minimum-flow recirculation line (mini-flow) for an ECCS pump.
- The delivered pump flows were reduced as a result of increased mini-flow, affecting the performance assumed in the 10 CFR 50.46 loss-of-coolant accident (LOCA) analyses. The licensee did not revise the pump performance curves or the Chapter 15 LOCA analyses. The NRC, during its review and approval of the associated TS, did not recognize the need for reevaluation or reanalysis of the affected Chapter 15 LOCA analyses and did not request any changes in granting the approval.
- NRC inspectors discover this condition in 2018 and are concerned with the discrepancy between the new system design and the pump performance curves and LOCA analyses.

Activity:

Discuss with your small group this question: **If NRC wants to take action to require the license to correct this condition—is this a backfit?** Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	With reduced pump flow, ECCS performance is reduced, and this may result in failure to meet 10 CFR 50.46 performance requirements (i.e., ECCS performance for LOCAs).
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. The NRC previously approved this change, so the licensee is in compliance with applicable requirements in its licensing basis.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes—correcting the condition would likely require a change to the facility (to change the system design or pump flow), or at least to the underlying documents and procedures that support operation, such as technical specifications.

Case Study 5: Cracking Problem

Key Message: New requirements must be considered for potential backfitting; exceptions to the need for a backfit analysis, such as the adequate protection exception may apply. Immediate action may be taken in areas of adequate protection, before a documented evaluation is done.

Background:

- The licensee identifies, during visual inspections conducted during a refueling outage, a large number of small cracks in the reactor vessel. This is the first time this cracking has been observed.
- The cracking was caused by a corrosive environment created by a leak of borated water from nearby equipment.
- An analysis of the cracking leads to the conclusion that the probability of reactor vessel fracture (for some events during the previous operating cycle) was significantly greater than previously understood.
- The licensee is ready to restart from the refueling outage. The licensee indicates that it identified and repaired the source of the leak, repaired the cracking in the vessel where necessary according to the ASME *Boiler and Pressure Vessel Code*, and performed analyses that indicates that the vessel will maintain integrity for all postulated design basis events during the upcoming operating cycle.
- NRC inspectors and technical experts at Headquarters are concerned about the situation. They are not convinced the licensee has appropriately assessed the damage to the vessel. They want the licensee to perform additional crack growth sensitivity studies and additional nondestructive evaluation of the reactor vessel.

Activity:

Discuss with your small group this question: **If NRC determines it is necessary to direct the licensee that it cannot restart until these actions are taken, is this a backfit? If so, must the NRC wait for the completion of a backfit analysis to take action?**

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	New cracking issue; source identified and corrected and analyses completed; concerned about restart without further evaluation of situation.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. Current requirements appear to have been met. Order or other mechanism would be needed to impose a new requirement (like disallowing startup).
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a	Yes—nuclear power plant.

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Step	Question	Answer/Notes
	backfitting or issue finality provision?	
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes—modification to procedures for operating (starting up) the facility. Inspection to assess whether the safety issue has been resolved (including inspecting physical situation, etc.) is <u>not</u> backfitting and should be pursued.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	Possibly—vessel (reactor coolant system barrier) integrity is in question. Note that the NRC must require backfitting if it is necessary to provide adequate protection to the health and safety of the public. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

Case Study 6: Earthquake Frequency Problem

Key Message: An event may reveal new information and cause the NRC to question the basis for a requirement. If there is undue risk, the NRC may use the adequate protection exception to support a backfit.

Background:

- Nuclear power plants are designed based on the seismic spectra for a “safe shutdown earthquake” (SSE) with a postulated 10,000-year return frequency (i.e., the design basis earthquake used to meet General Design Criterion 2 for all safety-related equipment).
- A major seismic event occurs in the Midwestern U.S. that is larger (in terms of the seismic spectra) than previously predicted.
- Analysis of the event causes seismic experts to conclude that there is greater uncertainty associated with the seismic spectra for the SSE.
- Based on seismic PRAs, plants in that region might have seismic core damage frequencies in the 1 in 1000 reactor-year range (where these were previously understood to be in the 1 in 10,000 to 100,000 reactor-year range).
- The NRC concludes through its process for ongoing review of external hazard information that, as a result of this new information, action must be taken to address the increased uncertainty.

Activity:

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Greater than anticipated frequency of serious earthquake, leading to concern about the design capability of the facility.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. Current requirements are met (design of facility to particular earthquake level).
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Maybe. If “action” is requesting more information, then no. If “action” is requiring improvements to facility design/operation, then yes.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	PRA information indicates that risk of particular event is 10-100x greater than expected. Core damage frequency of 1E-3 is high enough that adequate protection might be questioned.

Case Study 7: New Fire Protection Feature

Key Message: Risk information, such as the risk that would be averted if a modification were made, can be used to justify that a backfit would provide a substantial increase in protection of public health and safety.

Background:

- New research findings and technological breakthroughs have resulted in advanced fire protection features that are much more effective than current systems.
- The new fire protection technology is estimated using fire risk assessments to reduce the core damage frequency (CDF) attributed to fires, on a mean basis, by 5×10^{-5} per reactor year, effectively removing fire sequences as a significant contributor to power reactor risk.
- The total risk reduction is estimated to be 3×10^{-5} per reactor year in CDF on a mean basis, since other core damage sequences remain unaffected
- The reduction in overall risk to the public (safety benefit/reduction in radiological releases due to fire events) is converted from person-rem into dollars and is estimated to be \$50 million (average) for each plant.
- The total cost of the new requirements, including new equipment, initial installation, downtime, continuing maintenance, and averted offsite damage, is estimated to be \$25 million (average) for each plant.
- The NRC’s regulatory analysis guidance states that, with certain exceptions, regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least 1×10^{-5} per reactor year in the estimated mean value CDF (i.e., the CDF before the proposed regulatory change should exceed the CDF after the change by at least 1×10^{-5} per reactor year) to justify proceeding with further analyses.

Activity:

Step	Question	Answer/Notes
5a	Would a substantial increase in public health and safety or common defense and security apply?	Yes. First, a reduction in core damage of greater than 1×10^{-5} is essentially the entry condition to considering whether to proceed further. That is satisfied. Secondly, it is reasonable to conclude that a set of new requirements that can achieve a reduction in core damage frequency, on a mean basis, of 3×10^{-5} is a substantial additional protection. (Note: This is similar to the risk reduction from the station blackout rule, imposed as a cost-justified substantial safety enhancement.)
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	Yes. This example results in total costs that are less than the benefits. Note that, on the benefits side, these can only be human benefits (dose reduction to people). This example, being a generic backfit, would likely be an action that NRC would pursue through rulemaking.

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Case Study 8: Regulatory Guide Use in License Amendment

Key Message: NRC can require the use of new guidance as part of its review of a voluntary licensee/applicant request if (1) the guidance directly pertains to the request and (2) the specific subject matter in the guidance is essential to the NRC's decision on the request. This requirement is not backfitting.

Background:

- In an original nuclear power plant licensing review, the NRC found the applicant's use of Regulatory Guide XX, Revision 0, acceptable in approving the design of a particular system.
- The nuclear power plant licensee wishes to modify the system, and submits a Technical Specification (TS) amendment request under 10 CFR 50.90 that is necessary to support the proposed modification.
- The licensee's request related to the modification is based on Revision 0 of Regulatory Guide XX.
- Regulatory Guide XX was updated 1 year ago to Revision 1. The subject matter of the RG xx directly pertains to the proposed facility modification and addresses a design aspect key to NRC's approval of the TS amendment request and supporting modification.

Activity:

Discuss with your small group this question: **If NRC issues a request for additional information (RAI) regarding use of Revision 1 of RG XX (or otherwise requests its use) for the supporting modification, is that a backfit?**

Use the attached worksheet (steps 0-3) to support your discussion.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Newer guidance exists for the change being requested by the licensee, but the licensee is referring to old guidance.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes—the NRC is considering the imposition of new staff positions (guidance) in a licensing review.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant.

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Step	Question	Answer/Notes
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	<p>No. One fundamental backfitting consideration underlying backfitting is whether the action is voluntary or NRC is imposing an action. In this example the request is being voluntarily made by the licensee and is not the result of an explicit or implicit request by NRC.</p> <p>Notwithstanding the voluntary request, NRC can still make an imposition as part of its review of the request. In this case, (1) the RG directly pertains to the request and (2) the specific subject matter in the RG is essential to the NRC's determination/review of the submittal.</p>

Then, discuss this follow-up question (no need to fill out the worksheet again): **As part of the TS amendment request review, if NRC requests the licensee make fixes to another system that is not part of, nor impacted in any way by, the modification supporting the TS amendment request, is that request/RAI a backfit?**

Yes, imposing such a change would be backfitting. If the NRC asks the licensee to take actions that do not pertain to the NRC's review and approval of the request, those requests would be backfitting. This is really no different than the NRC simply making this request to the licensee without any licensing submittal, since it is entirely separate from the licensee's amendment request/review.

Case Study 9: Non-Conservative Technical Specification

Key Message: NRC can require additional information/analysis as part of its review of a voluntary licensee request if (1) the information directly pertains to the request and (2) the information is essential to the NRC’s decision on the request. This requirement is not backfitting. In keeping with the Principles of Good Regulation, the NRC staff should consider whether the information is already available through other means, and whether other licensees in similar situations needed to provide it.

Background:

- A nuclear power plant licensee identifies a potentially non-conservative technical specification (TS). The TS for a particular system can be interpreted not to set any allowed outage time (AOT) for a key component. That is, the component could be out of service indefinitely.
- Administrative Letter 98-10 says, in part, that “discovery of an improper or inadequate TS value or required action is considered a degraded or nonconforming condition as defined in [Generic Letter] 91-18. Imposing administrative controls in response to an improper or inadequate TS is considered an acceptable short-term corrective action. The staff expects that, following the imposition of administrative controls, an amendment to the TS, with appropriate justification and schedule, will be submitted in a timely fashion. Once any amendment correcting the TS is approved, the licensee must update the final safety analysis report, as necessary, to comply with 10 CFR 50.71(e).”
- The licensee submits a license amendment request under 10 CFR 50.90 to amend the TS to include an AOT of 72 hours for the component in question.
- This AOT (72 hours) is the same as that used in the current Standard Technical Specifications (STS) (i.e., 72 hours). This STS outage time was developed based on engineering judgement of an acceptably short amount of time relative to the frequency of accident initiators that might occur, and not on any specific analysis.
- As part of the review of the license amendment request, the NRC requests the licensee to perform additional analyses to support the license amendment request.
- The licensee indicates that it does not wish to perform these analyses, that nothing has changed in the plant warranting this request, and it is simply adopting the STS AOT, which is clearly more conservative than the current TS (with no AOT).

Activity:

Discuss with your small group this question: **If NRC determines it is necessary for the licensee to conduct these analyses, is this a backfit?**

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Question of validity of 72-hour STS allowed outage time (possibly too long based on plant-specific considerations)
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. Current requirements (no TS AOT) are met.

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Step	Question	Answer/Notes
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	If the additional analysis is directly relevant and essential to the staff determination, then this is not backfitting. NRC staff should consider the analyses used by other licensees in setting the AOT before deciding whether the analysis is necessary.

Case Study 10: Hurricanes in Design Certification Renewal

Key Message: In a design certification renewal, new requirements can only be imposed if they meet tests or exceptions similar to the 10 CFR 50.109 backfit rule—adequate protection, compliance, or cost-justified substantial safety enhancement.

Background:

Requirements and Guidance

- Nuclear power plants must be designed for extreme meteorological events (e.g., tornados, hurricanes) – General Design Criteria (GDCs) 2 and 4.
- Design certification (DC) applications must include site parameters postulated for the design and an analysis and evaluation of the design in terms of those site parameters – 10 CFR 52.47(a)(1).
- Prior to 2007, there was a general engineering assumption that tornado wind loads and missiles bounded those of hurricanes – Regulatory Guide (RG) 1.76, Revision 0.
- In 2007, RG 1.76, Revision 1 adopted a different tornado intensity methodology, resulting in a decrease in tornado wind speed. As a result, it was no longer clear whether tornado wind loads and missiles bounded hurricane wind loads and missiles.
- In 2011, new guidance concluded that, in certain U.S. locations, tornado conditions may not be bounding – RG 1.221.

Application

- Design “A” was certified via rulemaking in 2000.
- Consistent with then-current guidance, the designer assumed that tornado conditions bounded the site conditions and conducted associated wind load and missile analyses.
- In 2013, the designer submits a DC renewal application with no proposed changes to site parameters or analyses related to wind loads and missiles.
- The NRC is considering requiring the design be amended to specifically address the new guidance on hurricane wind loads and missiles. The staff’s concern is that at certain locations where tornado is not bounding, the design is not in compliance with GDCs 2 and 4, and adequate protection would not be demonstrated against hurricanes of credible intensity.
- Note: NRC can impose new requirements on the renewal, violating issue finality, if necessary for adequate protection, compliance, or cost-justified substantial increase in protection – 10 CFR 52.59(b). The renewal applicant can also request amendments in the renewal – 10 CFR 52.59(c).

Activity:

Discuss with your small group this question: **If NRC determines it is necessary for the applicant to address the new hurricane guidance in the renewal, is this a violation of issue finality (similar to backfit)?** Use the attached worksheet (steps 0-4a) to support your discussion.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	The DC renewal application does not address the most recent guidance on hurricane wind and missile loads. Staff believes the applicant should bring the DC up to date with the latest guidance.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes—a new requirement would need to be imposed for the DC renewal applicant to address this updated guidance.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes. DC renewal applicants are the subject of 10 CFR 52.59.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. The staff would be requiring a renewal applicant to amend its design to conform with a new Regulatory Guide.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	No. The staff found that the design complies with GDCs 2 and 4 and the principal design criteria, as well as conforms to RG 1.76, during initial certification. RG 1.221 was issued as a forward-fit and was not intended to backfit any existing licensees or approvals. The design was found to provide adequate protection during initial certification. Would not result in a condition of undue risk to the public.
4b	Does the <i>Compliance exception</i> apply?	No. Compliance with RGs is not required. There was no error or omission at or before the time of initial certification. The compliance exception cannot be invoked.
5a	Would a substantial increase in public health and safety or common defense and security apply?	Staff would need to perform an analysis to determine if there would be a substantial increase in safety/security. In this case, it probably would not pass the test on a <u>generic</u> basis, as the concern only involves hurricane conditions at very distinct areas of the U.S. The likelihood of a new reactor application locating a reactor at those locations is small. Staff would likely consider how the different wind fields would affect the analysis and whether it would involve a substantial increase in protection.
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	This consideration does not apply if a substantial increase would not be provided (step 5a). If there were a substantial increase, the costs of the analysis and any associated design changes would need to be considered.

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Also, discuss with your group **whether there are other options available to address the issue without violating issue finality.**

Although conforming to RG 1.221 might be a beneficial update to the design, absent passing the cost-justified, substantial increase test, the NRC has no regulatory means to require the DC applicant to address the concern. However, during the application review, staff could request the applicant to consider updating the DCD and associated analyses to specifically address hurricane wind loads and missiles. The applicant can request amendments to the design under 10 CFR 52.59(c). The staff should stress that this would be a voluntary action on the applicant's part, and they are free to make the change or leave the design as was previously certified. Applicants might find this change advantageous in certain circumstances—for example, if it were likely that applicants in affected regions of the country would reference the design and need to address site-specific questions during a licensing review.

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Case Study 11: Electrical Circuit Faults (Combined License)

Key Message: Issue finality provisions (similar to backfitting requirements) must be considered if new information reveals a safety concern with a certified design; depending on the issue, imposing a change under the adequate protection exception may be warranted.

Background:

- Institute for Electrical and Electronics Engineers (IEEE) Standard XXX, developed in 1975, includes an assumption that one specific value used in designing electrical circuits would at least 1.5 times another value.
- For a design certification issued in 2011, the design control document (DCD) section on the direct current (dc) distribution system included use of IEEE XXX to calculate a particular maximum current for the components in the dc distribution system.
- The NRC accepted this approach in its safety evaluation report (SER) for the design certification.
- A COL issued in 2012 references this certified design and includes an item in the inspections, tests, analyses, and acceptance criteria (ITAAC) to verify (by calculation) that the dc distribution system components can withstand the particular maximum current noted above without failure.
- Recent testing by Brookhaven National Labs using equipment invented in 2016 revealed that the IEEE XXX standard was non-conservative. The tests showed that the value could be as high as 15, not 1.5 as assumed in IEEE XXX.
- If this new contribution were considered in the design, the design analysis and potentially the affected components would have to be changed.
- Inspectors are concerned that the current situation may be unsafe given the new technical understanding of the design that was discovered by Brookhaven.

Activity:

Discuss with your small group the questions in steps 0-4a of the attached worksheet. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Electrical circuit faults were not conservatively analyzed, so if a fault occurs during an event or during normal operation, the plant may not respond as expected and previously evaluated. Specifically, DC distribution system components may fail, when they are expected to function, leading to an unsafe plant condition.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. The licensee is in conformance with its commitment to IEEE XXX, which was its approved method of satisfying the statements in the ITAAC.

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Step	Question	Answer/Notes
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes. The COL holder, and other COL holders as this issue is potentially generic, are entities affected by the proposed action, and these entities are afforded issue finality under 10 CFR 52.98.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. The proposed action involves a concern with issue finality as it would necessitate modification to the facility design and potential modification of the affected components. Under 10 CFR 52.98, to take the proposed action, the NRC must evaluate the proposed action under 10 CFR 52.103 or 10 CFR 50.109, as applicable.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	The NRC would need to analyze the consequences of the different plant response during an electrical circuit fault and determine whether it creates undue risk to the public health and safety. If the staff determines that it does, then the staff could pursue the backfitting action using the adequate protection exception. Staff must prepare a documented evaluation describing its invocation of the adequate protection exception.

Case Study 12: Flow Resistance Error (Combined License)

Key Message: Issue finality provisions (similar to backfitting requirements) must be considered if an error is identified in a certified design. If the NRC made an error in its approval (that would have been understood at the time the NRC approved the design and would have changed the NRC's decision), the compliance exception may be used to impose correction of the error.

Background:

- A design certification (DC) was issued in 2011 for Design X. A combined license (COL) was issued in 2012, referencing Design X.
- Tier 1 of the DC, as well as the COL for the facility, now under construction, includes an item in the inspections, tests, analyses, and acceptance criteria (ITAAC) to verify the calculated flow resistance in the passive core cooling system (PXS) piping between each core makeup tank and the reactor vessel. The calculated resistance must be between a value of 1.81 and 2.25 ft/gpm².
- The accident analysis calculations in Chapter 15 of the design control document for the certified design assume a PXS design-basis flow rate of 100 gallons per minute, to ensure safety provisions in General Design Criteria and 10 CFR 50.46 are met in a loss-of-coolant accident (LOCA).
- NRC inspectors look at the design calculations during an ITAAC inspection and identify that the PXS flow rate would be smaller than 100 gallons per minute if the flow resistance were greater than 2 ft/gpm².
- For the as-built plant, the calculated flow resistance is 1.9 ft/gpm².

Activity:

Discuss with your small group the questions in steps 0-4b of the attached worksheet, supported by the compliance exception worksheet for step 4b. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	The allowable flow resistance stated in the ITAAC would result in placing the facility in a condition beyond that in the Chapter 15 safety analyses. The safety significance / level of concern is low, at this point in time, since the facility under review did not need to assume flow resistance was as high as that allowed, and remains bounded by their analyses.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. The licensee is in compliance with the existing flow restriction limits stated in the ITAAC and has an expectation that the PXS system would function properly if called upon, as demonstrated by the analyses in the certified design. There appears to be an error made in the setting of the bounds on flow resistance.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes. The COL holder is an entity affected by the proposed action and the subject of issue finality provisions in 10 CFR 52.98.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. The proposed action involves a concern with issue finality as it would necessitate modification to the approved ITAAC in the certified design. The proposed action (changing the ITAAC) does not require modification of the affected system or components or the facility design analyses for the current licensee.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	No. This proposed action is not needed for adequate protection since the as-built design and expected system response would preserve public health and safety.
4b	Does the <i>Compliance exception</i> apply?	Yes. The NRC should change the acceptance criteria in the ITAAC for the certified design, as well as for any licensees referencing the certified design. The NRC committed an error in certifying the design with these bounds in the ITAAC, which affected all COLs referencing the DC that included the ITAAC. The staff would need to complete the compliance exception checklist (attached) and prepare a documented evaluation.

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THE REQUIREMENT		
✓	The NRC has identified an NRC requirement for which compliance is sought.	Yes—the relevant GDCs and 10 CFR 50.46 requirements, compliance with which is demonstrated through approved Chapter 15 analyses.
✓	The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	Yes. Requirements were in effect at the time of design approval.
✓	The NRC consistently interpreted and applied the identified requirement.	Yes. Requirements were uniformly applied to COLs referencing the certified design.
✓	The NRC approved the licensee’s method of compliance with the requirement.	Yes. The NRC approved the Chapter 15 analyses, as well as the ITAAC that defined appropriate system parameters to provide design-basis performance.
THE ERROR OR OMISSION		
✓	The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	Yes. The applicant made an error in its analysis of the maximum flow resistance value. The NRC did not identify this error in reviewing the application.
✓	The error must have occurred at or before the time that the NRC found that the NRC requirement or commitment was satisfied and a regulatory approval was issued.	Yes, part of the application review.
✓	The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement was satisfied and a regulatory approval was issued.	Yes, part of the application review.
✓	The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).	Yes.
✓	The NRC would likely not have issued its approval had NRC known of the error or omission.	Yes—would have requested a change to the maximum flow resistance.
THE COSTS		
✓	Costs of the compliance backfitting are considered in the NRC’s documented evaluation of the backfitting action.	Some costs—no physical modification, but NRC will incur costs to conduct rulemaking and impose licensee-specific changes.

Case Study 13: Instrument Calibration Issue (Combined License)

Key Message: Allegations may identify generic issues that would need to be addressed through backfitting.

Background:

- For nuclear power plants, 10 CFR 50.36(c)(1)(ii)(A) requires that technical specifications (TS) include limiting safety system settings (LSSS), which provide automatic protection for variables having significant safety functions.
- As part of meeting this requirement, licensees calibrate safety-related instruments using a setpoint program required by TS and controlled under their quality assurance (QA) programs.
- For a current combined license (COL) holder, the TS require calibrations in accordance with the setpoint program. The NRC approved use of this program via a topical report during the design certification (DC) review and included this approval in the safety evaluation report (SER) for the DC. The COL was issued after the DC and referenced the DC.
- All operating reactor licensees use a similar approach, and the NRC has inspected the existing calibration control programs for years without identifying any concerns. All COL holders referencing the DC are also intending to use this approach.
- The NRC receives an allegation that the calibration approach in the approved setpoint program is flawed, and non-conservative setpoints are being used industry-wide for safety-related instruments. The NRC conducts a follow-up inspection and substantiates the allegation.
- Correcting the issue would require changes to licensees' approved programs/procedures to restore compliance with TS.

Activity:

Discuss with your small group this question: **If NRC wants to take action to require licensees to correct this issue—is this a backfit? If so, on what basis should the NRC proceed?** Use the attached worksheet (steps 0-5b) to support your discussion.

Also, discuss **what additional activities the NRC might wish to pursue in this circumstance, given the apparently generic nature of the issue.**

As plant-specific approvals may have varied (i.e., the approach was explicitly approved for this licensee but possibly not for others) the backfitting and issue finality considerations may be complex to implement on a generic basis. A generic communication alerting licensees to the calibration issue may initiate voluntary action by licensees that addresses the safety concern, as long as adequate protection is not in question (in which case the NRC must take action).

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Incorrect calibration could affect setpoints that prevent safety limits from being exceeded. The safety significance could be high or low depending on how non-conservative the methodology is, since the setpoints determine when automatic protective functions occur which are needed for safety. It is assumed the methodology would be implemented the same way on all the safety-related equipment, so it could lead to common-cause failures of multiple trains of safety equipment.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. The licensee is in compliance with the setpoint program requirements stated in the facility TS and approved by the NRC.
1	Is the proposed action of the type excluded from of backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes. The COL holder is the subject of issue finality provisions in 10 CFR 52.98. Other 10 CFR part 50 licensees are the subject of the backfitting provisions in 10 CFR 50.109.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. The proposed action would constitute backfitting for operating plant licensees and involve a concern with issue finality for COL holders, as it would necessitate modification to the approved TS program. The proposed action would require modification of approved methods and modification to procedures that implement the program.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	Maybe. This proposed action might be needed to support adequate protection, given that it could affect multiple trains of safety-related equipment in an identical way. It depends on the severity of the non-conservatism that are introduced by the flaw in the methodology that was approved by the NRC.
4b	Does the <i>Compliance exception</i> apply?	It does not appear that it would—new information was revealed only through an allegation, and previous NRC inspections did not identify the issue. It would be challenging to justify that an error was made by the NRC in approving the setpoint program in reference to known and established standards at the time.
5a	Would a substantial increase in public health and safety or common defense and security apply?	Maybe. It depends on the degree of non-conservatism introduced. For instance, a delay in reactor core cooling injection by a small fraction of a second, which is caused by incorrect calibration of instrumentation, is not likely to affect core damage. However, major delays could result in more likely core damage and subsequent effects on the public.
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	Likely. Changes to procedures to implement a program or operate the plant generally are not expensive. It would not be expected that this would require significant physical plant modifications.

Case Study 14: Quality Classification Issue (Fuel Facility)

Key Message: Inspectors should discuss identified issues with the licensee to ensure the full licensing basis and relevant contextual information (e.g., prior NRC approvals) is understood before proceeding with enforcement or backfitting.

Background:

- In licensing a fuel facility, the NRC approved a quality assurance (QA) program that includes a classification scheme.
- The license application stated that structures, systems, and components designated as items relied on for safety (IROFS) must have sufficient QA to ensure they are designed, installed, tested, modified, and maintained in accordance with approved procedures to guarantee their availability and reliability. 10 CFR 70.62(d) requires each licensee and applicant to have management measures to ensure that IROFS are designed, implemented, and maintained to ensure they are available and reliable to perform their functions when needed. The application identified different quality levels for IROFS that prevent and/or mitigate the consequences of the hazards evaluated as part of the facility's integrated safety analysis (ISA).
- Level "A" (High Consequence or "Crucial") was defined in the application as systems that ensure operation does not result in doses of more than 100 rem to workers or 25 rem to the public. These systems are subject to full QA requirements to maintain high reliability. Other IROFS have less strict, Level B, QA requirements.
- NRC inspectors identified that the licensee modified an IROFS related to criticality safety, but used Level B controls rather than Level A. Inspectors noted that the IROFS was designed to control dose to workers and the public. Since before the time that the licensee submitted its renewal application, the NRC considered criticalities as "high consequence events" because criticalities produce worker doses in excess of 100 rem. The inspectors concluded that the IROFS related to criticality safety should have been classified as Level A.
- The licensee pointed out to the inspectors that the license renewal application included a list of all IROFS designated as Level A—which did not include the IROFS in question—and that the NRC's safety evaluation referenced this table and later concluded that the categorization of IROFS was acceptable.

Activity:

Discuss with your small group this question: **If NRC wants to require the licensee to treat this IROFS as Level A—is this a backfit, and how should the NRC proceed?**

Use the attached worksheet (steps 0-5b) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	The issue relates to the QA activities applied to equipment that is designated as a criticality safety IROFS. The level of QA controls applied to the equipment could impact its reliability.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	The NRC would need to correct an error made in its approval. The licensee made an error in its classification of an IROFS, and the NRC made an error in issuing the renewed license with the classification error.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes. The fuel facility licensee is the entity that is affected by the proposed action, and is the subject of the backfitting provisions in 10 CFR 70.76.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. This action would impose a new regulatory staff position that could modify the IROFS and/or the facility's QA program, and the backfitting provisions of 10 CFR 70.76 would apply.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	Maybe. A criticality would likely cause only on-site consequences. The provisions of 10 CFR Part 70, Subpart H, include specific requirements for protection of on-site personnel. Historically, when performing the analysis associated with the appropriate backfitting provisions (i.e., 10 CFR 70.76), the NRC has considered these on-site protection aspects as part of the overall protection of public health and safety or the common defense and security. An adequate protection exception would be applicable if the increase in QA is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.
4b	Does the <i>Compliance exception</i> apply?	Yes.
5a	Would a substantial increase in public health and safety or common defense and security apply?	N/A
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	N/A

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THE REQUIREMENT		
✓	The NRC has identified an NRC requirement for which compliance is sought.	10 CFR 70.62(d) requires management measures to ensure IROFS will be available and reliable. The QA program is one such management measure.
✓	The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	As far as we know, 10 CFR 70.62(d) was known and established at the time the licensee submitted its application and the NRC issued the renewed license.
✓	The NRC consistently interpreted and applied the identified requirement.	As far as we know, the NRC consistently interpreted and applied 10 CFR 70.62(d).
✓	The NRC approved the licensee’s method of compliance with the requirement.	The NRC issued the renewed license, without requiring the licensee to correct the misclassification, thereby approving the licensee’s method of compliance with 10 CFR 72.62(d).
THE ERROR OR OMISSION		
✓	The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	The licensee did not properly classify an IROFS, and the NRC failed to recognize this flawed classification when it issued the renewed license.
✓	The error must have occurred at or before the time that the NRC found that the NRC requirement was satisfied and a regulatory approval was issued.	The error occurred at the time that the NRC issued the regulatory approval.
✓	The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement or commitment was satisfied and a regulatory approval was issued.	The NRC staff has identified an error in the license renewal application that was missed in the NRC’s review of the application. At the time of the review, the standard was for the particular IROFS to have been classified as subject to Level A QA requirements.
✓	The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).	The NRC concludes that the IROFS needs to be classified as subject to Level A QA requirements.
✓	The NRC would likely not have issued its approval had NRC known of the error or omission.	Had the NRC known of this error, the NRC would have conditioned its issuance of the renewed license on the licensee’s properly classifying the IROFS.
THE COSTS		
?	Costs of the compliance backfitting are considered in the NRC’s documented evaluation of the backfitting action.	The NRC would need to consider costs of correcting the classification and providing Level A QA controls for this IROFS before proceeding.

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Case Study 15: Seismic Hazard Update (Fuel Facility)

Key Message: A requirement to update analyses on an ongoing basis is not backfitting.

Background:

- Fuel facility integrated safety analyses (ISAs) must be conducted *and maintained* in accordance with 10 CFR 70.62(c): “(c) Integrated safety analysis. (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:...(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena; (v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods”
- Credible events are also noted in 10 CFR 70.61, which requires: “(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely”
- A new U.S. Geological Survey (USGS) study shows an increased frequency for an earthquake at a particular facility location. The NRC issued an Information Notice to all licensees highlighting the study and emphasizing the 10 CFR 70.62(c) requirement to maintain the ISA.
- The licensee did not update its ISA to consider the new information from USGS, and did not have any documentation showing that the new information was evaluated at all for potential inclusion in the ISA.
- During a routine inspection, an NRC inspector raises a concern that the rupture of a process line—now credible under the increased frequency noted by USGS—could cause a high consequence event as defined by 10 CFR 70.61(b). The NRC inspector performs a calculation to confirm this potential. The NRC inspector determines that the licensee needs to update its ISA to consider this updated hazard.

Activity:

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	New seismic hazard information has called into question the risk associated with certain systems at a fuel facility.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	No. In this case, inspectors identified an ongoing requirement, within the licensing basis of the facility, to maintain the ISA for the plant, including identification of accident sequences caused by credible external events. The licensee did not maintain its ISA to identify accident sequences caused by credible external events because it did not assess likelihood of the event on an ongoing basis.

Case Study 16: Onsite Medical Treatment (Fuel Facility)

Key Message: Contextual documents (e.g., *Federal Register* notices, NRC correspondence) contemporary to an NRC decision can be useful in supporting a later NRC determination that an issue is a matter for enforcement, not a change in agency position.

Background:

- 10 CFR 70.50(b)(3) and 10 CFR 40.60(b)(3) require: “Twenty-four hour report. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material: An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual’s clothing or body.”
- NRC inspectors review the use of the onsite medical facilities at licensees’ facilities and note that employees with spreadable radioactive contamination had been treated. However, the licensee had not made any reports notifying the NRC of such instances.
- The licensees had interpreted the requirement to mean that only offsite medical facilities were the subject of the regulations.
- The inspectors review the history of this reporting requirement and find the following in the *Federal Register* (FR) notice associated with the final rule:
 - “The NRC has decided to require reports of any injured person introducing spreadable contamination into a medical facility regardless of who maintains the facility. The NRC must be aware of these incidents to ensure appropriate radiological controls are used and to ensure any radiological consequences are properly addressed. Since the exception for a licensee maintained facility has been removed from the rule, the above question, regarding interpretation of the rule, is moot.” (56 FR 40757 at 40763, response to Comment 35)
 - “The exemption for first aid at a licensee maintained medical facility for a superficial injury was deleted because the NRC agreed with commenters that a significant contamination event could still occur even if the injury was only superficial and the medical facility was licensed to handle radioactive material.” (56 FR 40747 at 40765)
- Inspectors are concerned that facilities licensed under 10 CFR Part 70 and 10 CFR Part 40 were not reporting the onsite medical treatment of employees with spreadable contamination as required by the applicable regulations.

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Activity:

Discuss with your small group this question: **Should the reporting issue update be handled through enforcement, or as backfitting?** Use the step 0 items below to support your discussion.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	The issue relates to reporting requirements and not directly to facility safety or security.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<p>No. There are reporting requirements in 10 CFR 70.50(b)(3) and 10 CFR 40.60(b)(3). As long as prior consistent interpretation of the rule supports the issue as being a violation, no new interpretations are needed. In this case, the <i>Federal Register</i> notice shows the intent of the language in the regulation. So, the reporting requirement applies to both onsite facilities as well as those offsite such as local hospitals.</p> <p>Note: Reporting requirements are not under the purview of the backfitting requirements in 10 CFR Part 70, and 10 CFR Part 40 does not include backfitting requirements.</p>

Also, discuss **what additional activities the NRC might wish to pursue in this circumstance, given the apparently generic nature of the issue.**

The NRC may wish to issue a generic communication (e.g., Information Notice, Regulatory Issue Summary) to clarify its position and highlight recent issues/violations. In this case, the NRC's original intent is clear and unchanged, so this clarification would benefit licensees and be appropriate for such a communication.

Take notes and report back to the large group when requested.

Case Study 17: Hot Leg Injection Issue

Key Message: When following up on safety concerns, inspectors may need to explore background materials, possibly in coordination with NRR, to understand the licensing basis; backfitting processes should be followed if there are safety concerns with the licensing basis.

Background:

- In 2015, the licensee prepared a change package to proceduralize local manual actions for the hot leg injection (HLI) strategy, which is used after a loss-of-coolant accident (LOCA) to prevent boron from precipitating in the reactor core over the long term. The procedure was designed to address a single failure vulnerability and directed installation of electrical jumper cabling between a motor control center in one train and a motor-operated valve (MOV) in the opposite train that had lost power because of a single failure. The change made the procedure more specific—previously, jumper installation was a “skill of the craft” item. The 10 CFR 50.59 evaluation in the licensee’s change package concluded that no license amendment was required for the change.
- Inspectors were concerned that this jumper cable would be in conflict with separation and redundancy statements in the facility’s updated final safety analysis report (UFSAR), because the two power trains would be connected after jumper installation.
- In addition, the inspectors noted that the guidance in NEI 96-07 (to which the licensee is committed to using to perform its 10 CFR 50.59 determinations) states the following as an example of a change that would require prior NRC review and approval: “The change would reduce system/equipment redundancy, diversity, separation or independence.”
- The inspectors researched the issue, in consultation with NRR, and found that, because no standard review plan existed yet for this issue at the time of licensing, a publicly available NRR memo was used: “Concentration of Boric Acid in Reactor Vessel during Long Term Cooling—Method for Reviewing Appendix K Submittals,” dated January 21, 1976 (ADAMS Legacy Accession Number 8107020118).
 - Appendix I to this memo states: “The primary mode for maintaining acceptable levels of boron in the vessel should be established. Should a single failure disable the primary mode, certain manual actions outside the control room would be allowed, depending on the nature of the action and the time available to establish the back-up mode.”
- The inspectors also found that the NRC reviewed the licensee’s HLI strategy during initial licensing. The application was clear that the licensee needed both trains of electrical power to realign equipment, if no local manual actions were accounted for. Both the primary and alternate flow paths would be disabled by certain single electrical failures (for instance, a single battery or a single emergency diesel generator). Two NRC documents addressed the acceptability of the licensee’s HLI strategy:
 - Supplement No. 2 to the Safety Evaluation Report (SER) for the facility, dated March 1, 1976. SER Supplement 2 stated the plant met single failure criteria for its HLI strategy.
 - A letter dated March 29, 1982, which accepted the licensee’s responses to RAIs asked regarding the licensee’s strategy. The letter stated that the emergency procedure for LOCA was reviewed. The procedure in use at the time was reviewed by inspectors and was determined to have a step to install the jumpers,

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if needed. The letter concluded that the design and technical specifications for post-LOCA boron concentration control for the facility were acceptable.

Activity:

Discuss with your small group this question: **Has a violation of NRC requirements been identified? If not, and if the NRC identifies the need for a new requirement, how should the NRC proceed?** Use the attached worksheet (steps 0-5b) to support your discussion. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Single failures would limit the licensee's ability to accomplish long term core cooling following a large break LOCA, and potentially lead to core damage and associated offsite releases.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes. The licensee is in compliance with the requirements, as it intended to meet them, and the NRC accepted the licensee's approach.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. The change in NRC position would require the licensee to redesign and modify the as-built plant.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	Not likely. This issue is only a concern following a design basis accident concurrent with specific single failures.
4b	Does the <i>Compliance exception</i> apply?	No. No error or omission noted, even if review criteria have changed over time.
5a	Would a substantial increase in public health and safety or common defense and security apply?	Not likely, given the overall risk of the issue.
5b	Is the cost of implementing the proposed action justified by the substantial increase (5a)?	N/A given the answer to 5a.

Case Study 18: Heat Exchanger Inspection Concern

Key Message: When considering safety concerns that relate to a previously identified generic issue, review facility-specific information on how that licensee addressed the issue before proceeding with enforcement or backfitting.

Background:

- At a nuclear power plant, the residual heat removal (RHR) heat exchangers (HX) are original plant equipment, operated intermittently for shutdown cooling over the 40 years of operation to date.
- Section E-4.1 of the vendor manual states that, “at intervals as experience indicates, an examination should be made of the interior and exterior condition of all tubes.” The licensee has never inspected the interior of the RHR HXs, and has not established a frequency for performing the HX inspections as recommended by the vendor manual.
- The licensee also has not tested the thermal performance of the RHR HXs. Because both water streams flowing through the HXs had chemistry controls in place, and because their shutdown cooling function was met, the licensee decided it was not necessary to perform the test.
- In 1989, the NRC identified concerns with closed-cycle cooling water systems in Generic Letter (GL) 89-13, “Service Water System Problems Affecting Safety-Related Equipment.” GL 89-13 stated, in part, that these systems “have the potential for significant fouling as a consequence of aging-related in-leakage and erosion or corrosion. The need for testing of closed-cycle system heat exchangers has not been considered necessary because of the assumed high quality of existing chemistry control programs. *If the adequacy of these chemistry control programs cannot be confirmed over the total operating history of the plant* [emphasis added] or if during the conduct of the total testing program any unexplained downward trend in heat exchanger performance is identified that cannot be remedied by maintenance of an open-cycle system, it may be necessary to selectively extend the test program and the routine inspection and maintenance program” for open-cycle cooling water systems to these closed-cycle systems.
- NRC inspectors are concerned that the licensee has not verified (via inspection or testing) the effectiveness of chemistry control programs in preventing degradation of the RHR HXs.
- NRC inspectors are also concerned that the licensee’s assumptions about thermal performance based on shutdown cooling may not be sufficient in design-basis accident conditions. Water temperatures and flow rates in the two situations are different, and the licensee does not monitor or trend the SDC performance of the HXs to detect degradation.

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Activity:

Discuss with your small group this question: **Does the backfitting process need to be followed to address this issue?** Use the attached worksheet (steps 0-3) to support your discussion. You may find that more information is needed to reach a conclusion; discuss how the NRC could obtain that information. Take notes and report back to the large group when requested.

Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	Fouling, corrosion, or other degradation may impede the ability of the RHR HXs to perform their stated safety function.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	<p>Maybe. 10 CFR Part 50, Appendix B, Criterion XI, "Test Control," may require the licensee to establish an adequate test program for the RHR HXs to demonstrate they can perform as designed. In this case, enforcement of Criterion XI may be sufficient to address the issue.</p> <p>In developing a potential violation, the inspector needs to connect GL 89-13, how the licensee responded to the GL, and whether the licensee's current activities conform to those commitments. The inspector should ensure that the current interpretation is consistent with the interpretation of the GL in 1989. Coordination with the regional office enforcement officer would increase confidence in the proposed enforcement action.</p>
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	If the licensee's current activities conform to the commitments made in 1989 and those commitments were subject to NRC review with no documented concerns, the licensee's current HX testing activities may be appropriate and acceptable. If inspectors nonetheless believe that the current activities do not demonstrate appropriate viability of the HXs and further testing is required, such a regulatory position should be considered for backfit considerations.

Case Study 19: Component Cooling Water Pipe Break

Key Message: Inspection follow-up can reveal errors made many years ago in establishing the licensing bases of a facility; the backfitting process should be followed to assess how and whether to correct these errors.

Background:

- In the original design of a nuclear power plant's containment support systems, containment heat removal could be provided by either two containment spray (CS) pumps cooled by component cooling water (CCW) or three containment air coolers (CACs) cooled by service water (SW). The design provided complete redundancy.
- In about 1982, as part of the Systematic Evaluation Program (SEP), the NRC identified that a pipe break could lead to a loss of both trains of CCW, inconsistent with General Design Criterion (GDC) 44. The SEP evaluation noted that the redundant CACs could provide the containment heat removal function.
- In the early 1980s, the licensee reanalyzed the MSLB design-basis event to address a newly identified issue in response to an NRC Bulletin. The revised analysis included the need for one CS pump to support the option with three CACs (not three CACs alone). On April 11, 1984, the NRC issued an SER relating to Bulletin 80-04. The SER accepted the plant's strategy of combining the CACs and CS systems to address an MSLB.
- The removal of CS/CAC system redundancy, as described in the original FSAR and SER, does not appear to have been explicitly considered during the 1980 reanalysis.
- On October 20, 1986, the facility submitted a license amendment request to remove a CAC fan from the TS. The licensee justified the change because the CAC was part of a redundant system to the CS credited in the accident analyses. The NRC issued the license amendment.
- In 2013, inspectors reviewed the CCW design and noted that a pipe break in the CCW system could make the plant not capable of providing post-accident containment cooling. As noted above, either option for post-accident containment cooling required at least one CS pump cooled by CCW.
- The licensee stated that postulating a passive failure (pipe break) of CCW concurrent with a design-basis accident is not within its licensing bases; the FSAR states that no active single failure would render CCW inoperable. The licensee considered a postulated failure of the non-safety-related portion of the CCW system inside containment as beyond-design-basis, except as result of a seismic event, which was not postulated to occur in conjunction with an accident.
- Inspectors, in coordination with Headquarters, determined that the risk of a total loss of CCW is a very small contributor to overall plant CDF and LERF, either as an initiating event or a subsequent failure after another initiating event. In the seismic PRA, this scenario is a more significant risk contributor, but overall seismic CDF is 4.2×10^{-6} per year and LERF is 7.2×10^{-7} per year, given other plant considerations.

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Activity:

Discuss with your small group this question: **Does the backfitting process need to be followed to address this issue?** Use the attached worksheet (steps 0-4b), as well as the compliance checklist supporting step 4b, to support your discussion. You may find that more information is needed to reach a conclusion; discuss how the NRC could obtain that information. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	A postulated pipe break in the CCW system could render both trains unavailable to perform their function(s) of (1) removing heat from the reactor and containment to the ultimate heat sink after a design-basis event and (2) providing cooling to the ESS and CS pumps.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes—the licensee appears to be in compliance with applicable requirements. If after a thorough review of the licensing basis, the agency concluded that a change to the plant’s licensing basis would increase plant safety, backfitting provisions would apply.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	Yes—nuclear power plant.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	Yes. Requesting or requiring the licensee to modify the plant’s CCW design would constitute backfitting as such action would be in conflict with the approved facility design as discussed in the licensing basis.
4a	Do one or more of the <i>Adequate Protection exceptions</i> to preparing a backfit analysis apply?	No.
4b	Does the <i>Compliance exception</i> apply?	Possibly—as noted on the attached checklist, an error may have occurred that is appropriate for the compliance exception. The NRC would need to define clearly which requirement is not being complied with. Given the length of time that has passed and the potential costs, the NRC should carefully consider whether the compliance exception applies.

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THE REQUIREMENT		
?	The NRC has identified an NRC requirement for which compliance is sought.	Not yet defined. Only the GDCs are discussed in the scenario; a specific operational requirement should be identified.
?	The identified requirement must have been “known and established” (i.e., the requirement cannot be implied) at the time of the NRC’s approval.	The NRC would need to evaluate the requirements that led to initial design of the CACs and CS as completely redundant.
?	The NRC consistently interpreted and applied the identified requirement.	The NRC would need to review its application of the above requirements to other similar plants.
✓	The NRC approved the licensee’s method of compliance with the requirement.	Yes—in the SER on the 1980s MSLB re-evaluation.
THE ERROR OR OMISSION		
?	The NRC has identified an error or omission—either the NRC’s own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: <ul style="list-style-type: none"> • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses 	An error or omission may have occurred, in that the MSLB re-evaluation and the NRC’s approval did not explicitly address the loss of redundancy between the CACs and CS. Documentation would need to be reviewed to determine whether the NRC considered this point and found it acceptable based on the standards of the day (a decision that is now being questioned but would not be appropriate for the compliance backfit), or whether the topic was omitted or an error in judgment was made.
✓	The error must have occurred at or before the time that the NRC found that the NRC requirement or commitment was satisfied and a regulatory approval was issued.	Yes, at the time of the early 1980s SER on MSLB re-evaluation.
?	The existence of an error must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement was satisfied and a regulatory approval was issued.	See notes above.
✓	The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).	Yes—loss of redundancy is now identified.
?	The NRC would likely not have issued its approval had NRC known of the error or omission.	This point is not yet clear, as consistent application for other similar plants would need to be considered.
THE COSTS		
?	Costs of the compliance backfitting are considered in the NRC’s documented evaluation of the backfitting action.	The NRC would need to consider the costs. Another consideration is that the facility appears to have been in this situation for ~35+ years.

Case Study 20: Operator Shift Durations

Key Message: Not all requirements are subject to backfitting provisions. Even if backfitting provisions do not apply, careful review of regulatory history and completion of a regulatory analysis will support sound regulatory decisionmaking.

Background:

- 10 CFR 55.53(e) states, in part: “To maintain active status, the licensee [licensed individual] shall actively perform the functions of an operator or senior operator on a minimum of seven 8-hour or five 12-hour shifts per calendar quarter.”
- NUREG-1021, revision 11, ES-605 further explains that: “[t]his requirement may be completed with a combination of complete 8- and 12-hour shifts ... at sites having a mixed-shift schedule, and watches shall not be truncated when the operator satisfies the minimum quarterly requirement (56 hours).”
- At one nuclear power plant, the operating crews generally stand 12-hour watches. “Administrative reactor operators” generally work outside the control room on 8-hour shifts. The licensee allows these operators to stand 8-hour watches in the control room to maintain an active license. When an administrative reactor operator completes an 8-hour “proficiency watch,” he/she turns over to another licensed operator who completes the remaining 4 hours of the typical 12-hour operating shift. This practice minimizes overtime costs to maintain the licenses for these individuals. The licensee began this practice within the past year and has not proceduralized it.
- Inspectors questioned whether the licensee’s approach met the 10 CFR 50.55(e) requirement and was consistent with the NUREG-1021 guidance. The inspectors identified two potential interpretations:
 - A “shift” is the length of time that an operating crew is assigned to stand watch, from the time the on-shift crew takes the watch to the time the on-shift crew is relieved. Using this interpretation, all licensed operators at the station would be required to stand five 12-hour watches per calendar quarter to maintain their licenses in an active status.
 - A “shift” is specific to an individual operator and refers to the distinct period of time during which a licensed operator is actively performing the functions of an operator or senior operator as defined by 10 CFR 55.4. Using this interpretation, the station’s administrative reactor operators would be required to stand seven 8-hour or five 12-hour shifts per calendar quarter to maintain their license in an active status.
- In consultation with NRR, the inspectors confirmed that there is no definition of “shift” in 10 CFR Part 55, NUREG-1021, or relevant technical specifications (TS).

Activity:

Discuss with your small group this question: **If the NRC wants to impose a 12-hour definition for the term “shift” in this context, would that be backfitting?** Use the attached worksheet (steps 0-3) to support your discussion. Take notes and report back to the large group when requested.

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Step	Question	Answer/Notes
0a	How would you articulate the safety/security issue being considered?	The nexus to safety/security has not been completely defined. The issue at hand is whether the administrative reactor operator must stand the full 12-hour shift currently being completed by other control room operators.
0b	Are new requirements or NRC interpretations needed to address the issue fully?	Yes (if action is needed). Without a specific definition of “shift,” the licensee appears to be in compliance with the 10 CFR 55.53(e) requirement and facility TS, and not inconsistent with NUREG-1021.
1	Is the proposed action of the type excluded from backfitting and issue finality provisions?	No.
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?	No, because the proposed action of defining “shift” in 10 CFR Part 55 would not affect an entity that is the subject of a backfitting or issue finality provision (i.e., it would affect the individual licensed operator, not the licensee under 10 CFR Part 50). However, the staff would need to consider whether changes would affect 10 CFR Parts 26 and 50, as well as the facility’s TS, and whether backfitting provisions would apply to those changes.
3	Would the proposed action constitute backfitting or involve a concern with issue finality?	No. Based on item 2 above, a sole change to 10 CFR Part 55 would not constitute backfitting. However, the NRC would be well served by a thorough review of the issue and regulatory history, as well as potential unintended consequences of the change for other parts of the regulations. A regulatory analysis to consider the costs and benefits of the change should also be conducted.