



# LICENSING BASIS AND BACKFITTING WORKSHOP

## MODULE 4: CASE STUDIES



# WHAT ARE THIS MODULE'S OBJECTIVES?

- Work through examples that illustrate the basic backfitting concepts
- Review concepts specific to your roles/responsibilities
- Understand key questions to consider when evaluating a potential backfitting

# CASE STUDY LOGISTICS

## General Timeframe:

- 15 minutes to review and discuss assigned case study with your group
- 10 minutes for large-group report-out on some of the case studies
- Repeat!

## Tips:

- You'll have access to written "answers" later, so keep your notes short.
- Cases are simplified for quick discussion. If you're missing information, make an assumption about what you would do if you had an answer.
- Try not to apply what you may know about any real situations from which some case studies were derived. Key details have been changed so the "answers" may be different than in real life.
- Ask the facilitators if you have questions.

# CASE STUDIES – ALL

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

## CASE STUDIES – MODULE BI (REACTOR LICENSING)

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
17. Hot leg injection issue
19. Component cooling water pipe break

# CASE STUDIES – REGIONS + MODULE B2 (REACTOR OVERSIGHT)

1. Compliance exception – original design issue
3. System design problem – 10 CFR 50.59
4. System design problem – NRC approved
5. Cracking problem
9. Non-conservative technical specification
11. Electrical circuit faults (combined license)
12. Flow resistance error (combined license)
13. Instrument calibration issue (combined license)
17. Hot leg injection issue
18. Heat exchanger inspection concern
19. Component cooling water pipe break
20. Operator shift durations

## CASE STUDIES – REGION II

### Large Group

- 5. Cracking problem
- 17. Hot leg injection issue
- 18. Heat exchanger inspection concern

### Breakout – Operating Reactors

- 19. Component cooling water pipe break
- 20. Operator shift durations
- 9. Non-conservative technical specification

### Breakout – Construction

- 11. Electrical circuit faults
- 12. Flow resistance error
- 13. Instrument calibration issue

### Breakout – Fuel Facilities

- 14. Quality classification issue
- 15. Seismic hazard update
- 16. Onsite medical treatment

## KEY MESSAGES FROM CASE STUDIES 1-5

1. 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.
2. 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.
3. Violations of requirements in effect for a licensee are not backfitting.
4. 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.
5. 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.



## KEY MESSAGES FROM CASE STUDIES 6-9

6. 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.
7. 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.
8. 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.
9. 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.

## KEY MESSAGES FROM CASE STUDIES 10-13

10. 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.
11. 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.
12. 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.
13. Allegations may identify generic issues that would need to be addressed through backfitting.

## KEY MESSAGES FROM CASE STUDIES 14-17

14. 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.
15. A requirement to update analyses on an ongoing basis is not backfitting.
16. 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.
17. 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.

## KEY MESSAGES FROM CASE STUDIES 18-20

18. 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.
19. 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.
20. 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.