U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

LICENSING BASIS AND BACKFITTING WORKSHOP

MODULE 2: BACKFITTING PROCESS

WHAT ARE THIS MODULE'S OBJECTIVES?

- Discuss the six steps for evaluating a proposed action (potential backfitting)
- Convey when backfitting requirements do and do not apply
- Differentiate the backfitting "categories"

WHY REVIEW THIS MATERIAL?

- You'll be more comfortable with backfitting concepts and know when we need to use them to support necessary actions—and which actions are not backfitting.
- Key points:
  - Safety and security come first.
  - If action is proposed to address a safety/security concern, we must consider backfitting.
  - These steps will help you decide if a proposed action is backfitting, and how to justify it.

NEW OR CHANGED REQUIREMENTS OR INTERPRETATIONS

- Backfitting is a *Code of Federal Regulations* requirement for the NRC
  - Structured approach for imposing a new requirement
  - Assumes affected entity is covered by these provisions
- Backfitting can occur after a regulatory approval if the action represents:
  - Changed or new requirement (regulation, technical specification, license condition, order)
  - Changed or new position **imposed** by the staff (including implied or inferred imposition)
- Backfitting affects:
  - Systems, structures, or components (design or the actual equipment)
  - Organization or procedures for design, construction, or operation

THE ENTRY CONDITION (STEP 0)

- An issue relevant to **public health and safety** or **common defense and security** has been raised.
  - Licensing review, inspection, operating experience, etc.
  - Includes identification of an issue during a licensing review that substantially increases risk (SRP 19.2, Appendix D)
- New requirements or NRC interpretations are needed to address the issue fully.
  - Note: The applicable requirements were confirmed in the facility-specific licensing basis (see Module 1).
- **How** should we address it?

SIX-STEP APPROACH FOR BACKFITTING AND ISSUE FINALITY

Step	Question
1	Is the proposed action *of the type excluded from* backfitting and issue finality provisions?
2	Would the proposed action affect any entity that is the subject of a backfitting or issue finality provision?
3	Would the proposed action constitute backfitting or involve a concern with issue finality?
4	a. Do one or more of the *Adequate Protection exceptions* to preparing a backfit analysis apply? b. If not, then does the *Compliance exception* apply?
5	Does the proposed action pass a backfit analysis or meet an issue finality criterion?
6	Should the NRC take action to avoid the effect of the backfitting or issue finality provision on the proposed action by invoking an *administrative exemption* from the backfitting provision?

STEP 1: IS THE PROPOSED ACTION OF THE TYPE EXCLUDED FROM BACKFITTING AND ISSUE FINALITY PROVISIONS?

- Information collection and reporting (facilitating NRC regulatory oversight)
- Requirements implementing mandatory statutory provisions, where the NRC has no discretion to implement the statute
- Administrative or organizational changes

References: SECY-93-086, SRM-SECY-93-086
Note: Non-public in ADAMS but documents are publicly available through PDR.

STEP 2: WOULD THE PROPOSED ACTION AFFECT ANY ENTITY THAT IS THE SUBJECT OF A BACKFITTING OR ISSUE FINALITY PROVISION?

- Backfitting does not apply to every entity
- Backfitting started with licensees of nuclear power plants (NPPs) (including holders of construction permits) under 10 CFR Part 50
  - Operating and decommissioning power reactors
  - Licensees under both 10 CFR Part 50 (10 CFR 50.109) and 10 CFR Part 52 (various *issue finality* provisions)
- NRC expanded backfitting applicability to certain materials licensees

MATERIALS ONLY

NRC BACKFITTING REQUIREMENTS

Affected Entities	Regulations
power reactors (operating and decommissioning)	10 CFR 50.109, 10 CFR Part 52
licensees authorized to possess special nuclear material (SNM) above a critical mass	10 CFR 70.76
independent spent fuel storage installations (ISFSIs)	10 CFR 72.62
gaseous diffusion plants (GDPs)	10 CFR 76.76

SPECIAL SITUATION: CERTIFICATES OF COMPLIANCE FOR SPENT FUEL STORAGE CASKS

10 CFR 72.62 does NOT apply to certificate of compliance (CoC) applicant and CoC holder (e.g., Holtec)

10 CFR 72.62 DOES apply to licensee using CoC-approved cask (e.g., NPP)

SPECIAL SITUATION: CERTIFICATE OF COMPLIANCE AMENDMENT VS. REVISION

CoC Holder (e.g., Holtec): not backfitting

CoC User (e.g., NPP licensee):

- Amendment: not backfitting – forward-fit for future voluntary applications
- Revision: backfitting – supersedes previous approval

Reference: RIS 2017-05 (ML17165A183)

EXAMPLE: RADIATION MONITORS

- In 2005, the NRC adopts a final regulation requiring entities licensed to possess special nuclear material to have a radiation detection monitor at each door where such material is stored. The regulation does not specify the sensitivity of the detector. Let's assume this applies to **NPPs, fuel cycle facilities, and two irradiators**.

- In 2018, the NRC proposes to amend the regulation by requiring the detector to have a minimum specified sensitivity.

- **Question: Does the NRC have to treat the 2018 rulemaking as potential backfitting?**

STEP 3: WOULD THE PROPOSED ACTION CONSTITUTE BACKFITTING OR INVOLVE A CONCERN WITH ISSUE FINALITY?

- Changed or new requirement
  - Regulation, technical specification, license condition, order
- Changed or new staff position
  - e.g., acceptability of a methodology
- Affecting:
  - Systems, structures, or components (design or the actual equipment)
  - Organization or procedures for design, construction, or operation
- **Imposed** after the entity has received the relevant regulatory approval

STEP 3: WOULD THE PROPOSED ACTION CONSTITUTE BACKFITTING OR INVOLVE A CONCERN WITH ISSUE FINALITY? (CONT'D)

HQ ONLY

- Backfitting steps should be followed for interpretive guidance (e.g., Regulatory Guides) if:
  - We intend the guidance to become (through further action) legally binding on a licensee OR
  - We expect licensees to voluntarily adopt the guidance as part of our basis for resolving a safety or regulatory issue
- "Forward fits" are not backfitting for currently licensed entities.
  - Application of guidance or requirements to future applicants
  - Requests by licensees for an exemption, other dispensation from compliance, or amendment—if
    - The new or revised guidance relates directly to the licensee's voluntary request; AND
    - The specific topic of the new or revised guidance is an essential consideration in the NRC staff's review of the licensee's voluntary request.

Reference: ML101960180

STEP 3: WOULD THE PROPOSED ACTION INVOLVE A CONCERN WITH ISSUE FINALITY? (CONT'D)

HQ RX / RII ONLY

- Part 52 entities ("issue finality")
  - Affects two types of entities
    - entity granted the license or approval
    - entity referencing the license or approval

STEP 3: WOULD THE PROPOSED ACTION CONSTITUTE BACKFITTING? (CONT'D)

MATERIALS ONLY

- Part 70 possessors of SNM (> critical mass)
- Part 72 CoCs for independent spent fuel storage installation (ISFSI) casks
  - Backfitting provision applies to licensee (e.g., NPP) users of ISFSI casks (e.g., changes in inspections of casks)
  - Backfitting provision does NOT apply to CoC holder (the designer/manufacturer/vendor of the cask)
- Part 76 gaseous diffusion plant (GDP)

EXAMPLE: NUMBERS OF WIDGETS

- In 1975, NRC adopts a final regulation requiring NPPs with operating licenses (OLs) issued after the effective date of the final rule to have two widgets.

- In 2018, NRC adopts a final regulation requiring all **new applicants** for OLs or combined licenses (COLs) to have three widgets.

- **Question: Does the 2018 regulation constitute backfitting or is it inconsistent with an issue finality provision?**

EXAMPLE: NUMBERS OF WIDGETS (MODIFIED)

- In 1975, NRC adopts a final regulation requiring NPPs with OLs **issued after the effective date of the final rule** to have two widgets.
- In 2018, NRC adopts a final regulation requiring **all NPPs with OLs or COLs on the effective date of the regulation** to have three widgets no later than 30 days after the effective date of the regulation. On the effective date of the 2018 regulation, there are 99 OLs and 2 COLs.
- **Question: Does the 2018 regulation constitute backfitting or is it inconsistent with an issue finality provision?**

STEP 4: CONSIDERATION OF ADEQUATE PROTECTION AND COMPLIANCE EXCEPTIONS

- Three exceptions to preparation of backfit analysis:
  - Needed for **adequate protection**
  - Defining or redefining **adequate protection**
  - Needed for **compliance** with requirements in effect at the time of regulatory approval
- Issue finality provisions do not refer to these as "exceptions"; they are just one of several criteria that would allow issue finality to be "violated"

References: COMSECY-16-0020 public summary (ML16355A258) and SRM (ML16334A462)

STEP 4A: DO ONE OR MORE OF THE ADEQUATE PROTECTION EXCEPTIONS TO PREPARING A BACKFIT ANALYSIS APPLY?

- Safety/security first!
  - The staff must first determine if one or both of the **adequate protection** exceptions apply.
  - If so, action is required under the Atomic Energy Act, and the staff should not consider the use of the compliance exception or develop a backfit analysis.
  - If not, then the staff should proceed to other steps.

References: COMSECY-16-0020 public summary (ML16355A258) and SRM (ML16334A462)

STEP 4A: DO ONE OR MORE OF THE ADEQUATE PROTECTION EXCEPTIONS TO PREPARING A BACKFIT ANALYSIS APPLY? (CONT'D)

- Backfitting requirements include two adequate protection exceptions:
  - Necessary to ensure adequate protection
  - Defining or redefining adequate protection

- May be sufficient to say that the proposed action **involves** adequate protection, and that the adequate protection exceptions in 10 CFR 50.109 apply

STEP 4B: IF NONE OF THE ADEQUATE PROTECTION EXCEPTIONS APPLY, THEN DOES THE COMPLIANCE EXCEPTION APPLY?

- Compliance exception was a subject of criticism from external stakeholders
  - Staff inconsistently applied the compliance exception over time.
  - Staff application of compliance exception was inconsistent with 1985 Statement of Considerations for the Backfit Rule stating that the exception was limited to mistake or omission of fact, and that new or revised interpretations of what was needed to comply with existing NRC requirements did not fall within the exception.

References: COMSECY-16-0020 public summary (ML16355A258) and SRM (ML16334A462)

STEP 4B: IF NONE OF THE ADEQUATE PROTECTION EXCEPTIONS APPLY, THEN DOES THE COMPLIANCE EXCEPTION APPLY? (CONT'D)

- Compliance exception **may** be used only where both of the following two elements are applicable:
  - The NRC (staff), whether by its own error or by licensee or third-party error or omission, at or before the time of its determination that a known and established standard of the Commission was satisfied, incorrectly perceived facts, performed or failed to recognize flawed analyses, or failed to properly draw direct inferences from those facts or analyses, as judged by standards and practices that were **prevailing among professionals or experts in the relevant area at the time** of the NRC determination in question, and
  - Those facts, analyses, or inferences have **now been properly perceived, performed, or drawn**.
- In short:
  - The NRC had a consistent interpretation of the requirements at the time of original approval.
  - If the error/omission had not occurred, we would likely have made a different decision.
  - Costs need to be considered.

References: COMSECY-16-0020 public summary (ML16355A258) and SRM (ML16334A462)

STEP 4B: IF NONE OF THE ADEQUATE PROTECTION EXCEPTIONS APPLY, THEN DOES THE COMPLIANCE EXCEPTION APPLY? (CONT'D)

Compliance exception may **NOT** be used for failures of the NRC to extrapolate conclusions from facts, analyses, and direct inferences in ways that were **not** commonly recognized under such prevailing professional standards and practices at the time of the original NRC determination.

Compliance exception may **NOT** be used for recharacterizations of whether a particular set of otherwise understood circumstances satisfies the standard at issue based upon professional standards and practices developed or accepted after the time of the NRC determination.

STEP 4B: COMPLIANCE EXCEPTION CHECKLIST – (I) THE REQUIREMENT

- ✓ The NRC has identified an NRC requirement for which compliance is sought.
- ✓ 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 consistently interpreted and applied the identified requirement.
- ✓ The NRC approved the licensee's method of compliance with the requirement.

STEP 4B: COMPLIANCE EXCEPTION CHECKLIST – (II) 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:
  - Incorrect perception or understanding of the facts
  - Failure to recognize flawed analyses
  - Failure to draw direct inferences form those facts or analyses
- ✓ 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.

STEP 4B: COMPLIANCE EXCEPTION CHECKLIST – (II) THE ERROR OR OMISSION (CONT'D)

- ✓ 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 facts, analyses, or inferences which are claimed to be an error are now properly perceived, performed, or drawn (determined).
- ✓ The NRC would likely not have issued its approval had NRC known of the error or omission.

STEP 4B: COMPLIANCE EXCEPTION CHECKLIST – (III) THE COSTS

- ✓ Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.

EXAMPLE: WIDGET METHODOLOGY

- In 1975, NRC adopts a final regulation requiring NPPs with OLs issued after the effective date of the final rule to have two widgets. The 1975 final rule notice states that two widgets will provide the desired level of performance based upon data analyzed by the Fine Methodology.
- In 2018, an NRC technical reviewer, running confirmatory calculations using **Super Methodology**, discovers that two widgets would not provide the desired level of performance and three widgets are needed.
- **Question: If backfitting is pursued, should the evaluation invoke one of the "exceptions" in the Backfit Rule?**

STEP 5: DOES THE PROPOSED ACTION PASS A BACKFIT ANALYSIS OR MEET AN ISSUE FINALITY CRITERION?

- Backfit analysis acceptance test consists of two sequential criteria:
  1. "Substantial increase" in safety or security

     Reasonable and documentable substantial increase in radiological public health and safety or common defense and security

  2. Cost of the safety or security increase is justified in light of the increase in safety or security (cost-beneficial)

STEP 5: DOES THE PROPOSED ACTION PASS A BACKFIT ANALYSIS OR MEET AN ISSUE FINALITY CRITERION? (CONT'D)

- **Substantial** means both:
  - Real; not speculative or illusory
  - Important or significant in a large amount, extent, or degree

References: 1985 Backfit Rule (50 FR 38097); SRM-SECY-93-086

Note: SRM is non-public in ADAMS but is publicly available through PDR.

STEP 5: DOES THE PROPOSED ACTION PASS A BACKFIT ANALYSIS OR MEET AN ISSUE FINALITY CRITERION? (CONT'D)

- Costs and benefits may be qualitative in nature
  - Quantifiable benefits and costs MUST be identified and presented to the extent possible
  - Non-quantitative factors inform decision making and, in limited cases, can be relied upon when quantitative analyses are not possible or practical

References: SRM-SECY-93-086, SECY-14-0087 (ML14127A458), SRM-SECY-14-0087 (ML15063A568)
Note: 1993 SRM is non-public in ADAMS but is publicly available through PDR.

STEP 5: DOES THE PROPOSED ACTION PASS A BACKFIT ANALYSIS OR MEET AN ISSUE FINALITY CRITERION? (CONT'D)

HQ RX / RII ONLY

Part 52 Approval	Part 52 Issue Finality Provision
Early Site Permit (ESP)	10 CFR 52.39 (term of ESP) 10 CFR 52.31 (renewal)
Standard Design Certification Rule (DCR)	10 CFR 52.63 (term of DCR) 10 CFR 52.59 (renewal)
Combined License (COL)	10 CFR 52.83 (referenced NRC approvals) 10 CFR 52.98 (term of COL)
Standard Design Approval (SDA)	10 CFR 52.145
Manufacturing License (ML)	10 CFR 52.171 (term of ML) 10 CFR 52.179 (renewal)

STEP 5: DOES THE PROPOSED ACTION PASS A BACKFIT ANALYSIS OR MEET AN ISSUE FINALITY CRITERION? (CONT'D)

HQ RX / RII ONLY

- Each 10 CFR Part 52 licensing process has different finality requirements
  - ESP – covers updates and variances
  - DC – restricts conditions for amending a DC rule; addresses standardization and material errors
  - COL – refers to 10 CFR 50.109; defines change processes when referencing other approvals
  - SDA – requires staff reliance on the SDA when referenced in an application absent new info
  - ML – refers to 10 CFR 50.109; restricts changes to the design
- Each finality requirement also places restrictions on information requests

EXAMPLE: WIDGET BACKFIT ANALYSIS (PLANT-SPECIFIC)

- In 1975, NRC adopts a final regulation requiring NPPs with OLs to have two widgets.
- In 2018, NRC proposes to issue an Order to Facility X **requiring three widgets** on the basis of the new Super Methodology calculations. The backfit analysis shows that the safety benefit of three widgets is $100, which justifies the cost of $100.
- **Question: May the NRC impose this requirement on the basis of this backfit analysis?**

EXAMPLE: WIDGET BACKFIT ANALYSIS (GENERIC)

- In 1975, NRC adopts a final regulation requiring NPPs with OLs to have two widgets.
- In 2018, NRC proposes to adopt a final **regulation requiring all current and new NPPs to have three widgets**. The Backfitting and Issue Finality discussion in the draft final rule notice indicates that a backfit analysis shows that the safety benefits of three widgets is $10 million per plant, which justifies the cost of $1 million per plant.
- **Question: May the NRC adopt this final rule on the basis of this backfit analysis?**

EXAMPLE: GAUGE SENSITIVITY

- All NPPs, fuel cycle facilities, and research and test reactors are required to use a gauge that alarms at 100 Units of contamination to check their employees for radioactive contamination. Most licensees use the Fancy Gauge, which is very sensitive and alarms at 70 Units. Some use the less sensitive Standard Gauge, which alarms at 100 units.
- New medical information indicates that occupational exposure at a level of 80 Units of contamination, if received frequently, can cause health effects.
- The NRC proposes to require all licensees with the potential for occupational contamination to obtain and use the Fancy Gauge, which alarms at 70 Units.
- **Question: Which factors should be considered in approaching this problem?**

Step	Question
1	Excluded?
2	Covered entities?
3	Is it backfitting?
4	a. Adequate protection? b. Compliance?
5	Backfitting test met?
6	Admin exemption?

EXAMPLE: FUEL CYCLE FACILITY PROPOSED CYBER SECURITY REQUIREMENT

MATERIALS ONLY

- Under 10 CFR Part 73, Category I fuel cycle facilities (FCF) licensees must maintain a physical protection system designed to protect against the design basis threat, including a cyber attack. However, current NRC physical protection requirements do not set forth specific provisions for addressing cyber attacks at Category I FCFs.
- In addition, FCF licensees that hold classified information are required to meet the security requirements in 10 CFR Part 95. These requirements include protection against the loss or unauthorized disclosure of classified information, including from a cyber attack. However, 10 CFR Part 95 and related guidance do not provide specific cyber security provisions for the protection of digital assets for the required protection of classified information.

EXAMPLE: FUEL CYCLE FACILITY PROPOSED CYBERSECURITY REQUIREMENT (CONT'D)

MATERIALS ONLY

- The NRC is considering imposing cyber security requirements on FCF licensees.
- The proposed rule would require FCFs to create and maintain a cyber security plan, evaluate their digital systems, and deploy cyber security controls to detect, protect against, and respond to a cyber attack. FCF licensees would have to submit their security plans and security plan changes to the NRC for approval. They would have to report certain cyber security events to the NRC and compile and maintain certain information.
- The impacted licensees would include FCF licensees subject to: (1) 10 CFR 70.60; or (2) the requirements of 10 CFR Part 40 for operation of a uranium hexafluoride conversion or deconversion facility.
- **Question: Which factors should be considered in approaching this problem?**

Step	Question
1	Excluded?
2	Covered entities?
3	Is it backfitting?
4	a. Adequate protection? b. Compliance?
5	Backfitting test met?
6	Admin exemption?

KEY MESSAGES

- Use the 6-step process. Trust the process.
- Consult with the Backfitting Community of Practice point of contact for your office or region.
- Adequate protection issues require NRC action, and backfitting becomes a secondary consideration.
- A backfit analysis determines whether the proposed action would have a substantial increase in protection and, if so, whether the costs are justified–in that order.