

## U.S. NUCLEAR REGULATORY COMMISSION DIRECTIVE HANDBOOK (DH)

### DH 8.4 MANAGEMENT OF BACKFITTING, ~~FORWARD FITTING~~, ISSUE FINALITY, AND INFORMATION ~~COLLECTION~~REQUESTS DT-XX-XX

<i>Volume 8:</i>	Licensee Oversight Programs
<i>Approved By:</i>	[Name and Title of Approving Official]
<i>Date Approved:</i>	Month X, 200X [Date of Final Approval]
<i>Cert. Date:</i>	N/A, for the latest version of any NRC directive or handbook, see the <a href="#">online MD Catalog</a> .]
<i>Issuing Office:</i>	Office of Nuclear Reactor Regulation Division of Inspection and Regional Support
<i>Contact Name:</i>	Timothy Reed

#### EXECUTIVE SUMMARY

Management Directive (MD) 8.4, "Management of Backfitting, Issue Finality, and Information Collection," is retitled and revised to clarify ~~the agency's~~ roles and responsibilities for management of backfitting, ~~forward fitting~~, issue finality, and information ~~collection requests generically and on a facility specific basis~~. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) for nuclear power reactor ~~facilities-licensees~~; and selected nuclear materials ~~facilities-licensees~~; and the issue finality provisions of 10 CFR Part 52 ~~for~~ nuclear power reactor ~~s-licensees, design certification applicants, and holders of related NRC permits and approvals; and as well as~~ the ~~specific~~ provisions of 10 CFR 50.54(f) and the corresponding requirements in ~~Parts~~ 10 CFR ~~Parts~~ 52, 70, ~~10 CFR~~ 72, and ~~10 CFR~~ 76, ~~and 10 CFR 2.204~~.

Accordingly, MD 8.4 is retitled from "Management of Facility-Specific Backfitting and Information Collection" to "Management of Backfitting, ~~Forward Fitting~~, Issue Finality, and Information ~~Collection Requests~~" to clarify the intent and the objectives of the program.

#### TABLE OF CONTENTS

I. INTRODUCTION TO BACKFITTING AND INFORMATION <del>COLLECTION</del> <u>REQUESTS</u> .....	3
A. Backfitting .....	3

For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index ([YA-to-MD index](#)).

DH 8.4 MANAGEMENT OF BACKFITTING, FORWARD  
FITTING, ISSUE FINALITY, AND INFORMATION  
COLLECTION REQUESTS

Date Approved: XX/XX/XXXX

B. Information <u>Collection</u> Requests .....	15
C. Coordination and Communication .....	<u>16</u> <u>15</u>
D. Recordkeeping .....	16
<b>II. BACKFITTING APPLICABILITY .....</b>	<b><u>17</u><u>46</u></b>
A. Regulatory Changes Subject to the Backfit Rule .....	<u>17</u> <u>46</u>
B. Nonapplicable Regulatory Changes .....	<u>18</u> <u>47</u>
<b>III. BACKFITTING POLICY .....</b>	<b>20</b>
A. Adequate Protection Backfitting .....	20
B. Compliance Backfitting .....	<u>23</u> <u>22</u>
C. Cost-Justified Substantial Increase in Protection Backfitting .....	<u>29</u> <u>28</u>
D. Additional Considerations .....	<u>30</u> <u>29</u>
E. Scheduling of Backfitting Implementation .....	<u>31</u> <u>30</u>
F. Appeals of Backfitting Decisions .....	<u>32</u> <u>34</u>
G. Exceptions .....	<u>34</u> <u>33</u>
H. Assessment of the Overall Effectiveness of the NRC's Backfit Management Program .....	<u>34</u> <u>33</u>
<b>IV. INFORMATION <u>COLLECTION PROCESS REQUESTS</u> .....</b>	<b><u>34</u><u>33</u></b>
A. NRC Regulations for Information <u>Collection Requests</u> .....	<u>34</u> <u>33</u>
B. Justification .....	35
<b>V. TRAINING PROGRAMS FOR BACKFITTING AND INFORMATION <u>COLLECTION REQUESTS</u> .....</b>	<b><u>36</u><u>35</u></b>
A. Backfitting Training .....	<u>36</u> <u>35</u>
B. Backfitting Agencywide Training Coordination .....	<u>37</u> <u>36</u>
C. Information Collection Training .....	<u>37</u> <u>36</u>
<b>VI. ACRONYMS .....</b>	<b><u>37</u><u>36</u></b>

**EXHIBITS**

EXHIBIT 1	NRC Internal Backfitting and Issue Finality Flowchart .....	<u>40</u> <u>39</u>
EXHIBIT 2	NRC Internal Backfitting and Issue Finality Flowchart .....	<u>42</u> <u>44</u>
EXHIBIT 3	NRC Backfitting Requirements .....	<u>44</u> <u>43</u>

## I. INTRODUCTION TO BACKFITTING, **FORWARD FITTING**, AND INFORMATION **COLLECTION REQUESTS**<sup>1</sup>

### A. Backfitting

1. Under 10 CFR 50.109, backfitting is "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position."
2. Substantially similar definitions are provided in § 70.76, § 72.62, and § 76.76. Section 70.76 of 10 CFR defines the term backfitting for materials licensees authorized to possess greater than a critical mass of special nuclear material. Section 72.62 of 10 CFR defines the term backfitting for an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS). Section 76.76 of 10 CFR defines the term backfitting for a gaseous diffusion plant.
3. In 10 CFR Part 52, "issue finality" exists with respect to prior NRC approvals, which prevents the NRC from making changes to the approvals without meeting certain criteria as provided in the applicable issue finality regulation. The issue finality requirements are intended to accomplish the same objective as the backfitting requirements by limiting changes to final Commission decisions made as part of the 10 CFR Part 52 licensing process.
4. Backfitting is the process by which the U.S. Nuclear Regulatory Commission imposes new or revised regulatory requirements or new or revised staff positions on nuclear

<sup>1</sup> This section provides a high-level overview of the backfit and forward fit processes, and as such, may simplify some concepts for introductory purposes. If a provision of this section conflicts with a provision in a later section, the later section is controlling.

~~power reactor licensees or selected nuclear materials licensees.~~<sup>2</sup> Backfitting is an integral part of the regulatory process ~~and is expected to occur~~. To ensure that proposed changes are adequately justified and defined, a backfitting action is implemented only after formal and systematic review. Backfitting normally occurs ~~in one of two ways: when the agency imposes~~ a new or changed regulation or requirement ~~imposed upon a licensee's facility or facilities (through rulemaking or order).~~ ~~Backfitting concerns also arise when the agency communicates~~ a new or changed staff position interpreting applicable ~~regulations~~ requirements imposed on ~~facilities~~ licensees. A new or changed staff position may arise in a number of regulatory contexts including facility inspections, license amendment reviews, or issuance of guidance documents. In this Directive Handbook (DH), the terms "backfit" and "backfitting" mean backfitting as defined in 10 CFR 50.109, "Backfitting," 70.76, "Backfitting," 72.62, "Backfitting," and 76.76 "Backfitting," and ~~violations of changes affecting~~ issue finality under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The only parts of the NRC's regulations that contain backfitting or issues finality provisions are 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72, and 10 CFR Part 76. ~~The backfitting provisions typically do not apply to license applicants. There is no backfitting provision in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses of Nuclear Power Plants," however the scope of the NRC's review under 10 CFR Part 54 is limited.~~ The protections in the backfitting provisions further NRC compliance with the requirements of the Administrative Procedure Act regarding reasoned decisionmaking.

5. The backfit evaluation and analysis requirements ensure that the NRC demonstrates, before implementing the backfit, that the backfitting action meets certain standards that vary based on the type of facility. In accordance with the NRC Principles of Good Regulation and the Administrative Procedure Act, the backfitting rules provide the following:

- (a) Regulatory stability, by ensuring that the changes the NRC makes are necessary or provide a substantial safety enhancement;

<sup>2</sup>—For purposes of this DH, the term "licensees" includes the holders of power reactor construction permits (CPs) and operating licenses (OLs) under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities;" holders of licenses, permits or approvals under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;" holders of licenses for fuel facilities under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material;" Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material;" holders of licenses for spent fuel and radioactive waste storage facilities under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste;" and certificate holders for gaseous diffusion plants under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

(b) Reasoned and informed NRC decisionmaking, by requiring that the proposed action be properly justified; and

(c) Transparency of NRC decisionmaking, by requiring that the NRC document and make publicly available its analyses and evaluations.

6. The NRC's backfitting actions can be either generic or facility-specific.<sup>3</sup>

(a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised requirements through rulemaking or Orders or new or revised staff positions interpreting NRC regulations.

(b) Facility-specific backfitting issues typically arise through the NRC's inspection or licensing process. In these circumstances, the NRC's regional or headquarters staff may find that a change to a facility's licensing basis (LB) is appropriate.

4.7. There are three principal ~~types of backfitting that may be considered~~ justifications the agency relies on to impose a backfit: adequate protection ~~backfitting~~, compliance ~~backfitting~~, and a cost-justified substantial increase<sup>4</sup> in protection ~~backfitting~~.<sup>5</sup> If the NRC is considering a backfitting action, it must first consider whether regulatory action is necessary to ensure adequate protection ~~of public health and safety, and if so whether there is an imminent threat to public health and safety~~. If regulatory action is not necessary to ensure adequate protection, then the NRC needs to determine if the proposed action satisfies the compliance backfit criteria. If the proposed action does not satisfy the compliance backfit criteria, then the NRC must consider a cost-justified substantial increase<sup>6</sup> in protection backfit.

2. The Supreme Court's decision in *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015), reflects the view that, under the Administrative Procedure Act (APA), unless Congress has indicated otherwise, an agency's decisionmaking calculus should include at least some consideration of the cost placed on a licensee to comply with new requirements. In contrast, when the NRC has reached a new or changed position with

<sup>3</sup> Hereafter, the term "facility" will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or an MRS installation.

<sup>4</sup> See 50 FR 38097, September 20, 1985.

<sup>5</sup> The issue finality provisions of 10 CFR Part 52 include additional ~~backfitting actions~~ justifications for certain types of approval holders. For example, 10 CFR 52.63, "Finality of ~~s~~Standard ~~d~~Design ~~c~~Certifications," also allows backfitting to, among other things, correct material errors in the certification information for a design certification (DC) or to contribute to the increased standardization of the DC.

<sup>6</sup> See 50 FR 38097, September 20, 1985

respect to whether regulatory action is needed to ensure adequate protection under the Atomic Energy Act of 1954 (AEA), as amended, no further explanation, including consideration of cost, is necessary. Otherwise, the APA's reasoned decision making requirement compels some consideration of cost.

3.8. Regulations in 10 CFR 50.109, define the term backfitting for power reactors under 10 CFR Part 50 (i.e., construction permit (CP) holders and operating license (OL) holders) as the modification of or addition to systems, structures, components (SSCs); or design of a facility; or the design approval or manufacturing license (ML) for a facility; or the procedures or organization required to design, construct, or operate a facility, any of which may result from a new or amended provision in the Commission's regulations or the imposition of a staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain specified dates.<sup>7</sup> Provisions of 10 CFR 50.109 can also apply to power reactor licensees under 10 CFR Part 52,<sup>8</sup> but 10 CFR 50.109 is not applicable to non-power production or utilization facilities licensed under 10 CFR Part 50.

<sup>7</sup>—Applicable NRC action may be considered backfitting under 10 CFR 50.109 if the agency action occurs after the following:

- ▲ the issuance of the CP for the facility (for facilities with CPs issued after October 21, 1985);
- ▲ 6 months before the date of docketing of the OL application for the facility (for facilities with CPs issued before October 21, 1985);
- ▲ the issuance of the OL for the facility (for facilities having an OL on October 21, 1985);
- ▲ the issuance of the design approval under Subpart E, "Standard Design Approvals," of 10 CFR Part 52;
- ▲ the issuance of a an ML under Subpart F, "Manufacturing Licenses," of 10 CFR Part 52;
- ▲ the issuance of the first CP for a duplicate design under Appendix N, "Standardization of Nuclear Power Plant Designs: Permits To Construct and Licenses to Operate Nuclear Power Reactors of Identical Design at Multiple Sites," of 10 CFR Part 50; or
- ▲ the issuance of a COL under Subpart C, "Combined Licenses," of 10 CFR Part 52.

<sup>8</sup>—For purposes of this DH, the term "10 CFR Part 52 power reactor licensees" refers to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; DC applicants whose designs are certified in final DC rules (DCRs); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA.

~~4.9. In 10 CFR Part 52, power reactor licensees are granted "issue finality"<sup>9</sup> exists with respect to prior their NRC approvals, which prevents the NRC from making changes to the approvals without meeting certain criteria as provided in the applicable issue finality regulation. The issue finality requirements are intended to accomplish the same objective as the backfitting requirements by limiting changes to final Commission decisions made as part of the 10 CFR Part 52 licensing process. The standards vary for making changes to renewed and previously approved early site permits (ESPs) (10 CFR 52.31, "Criteria for Renewal," and 10 CFR 52.39, "Finality of Early Site Permit Determinations"), renewed and previously approved design certification rules (DCRs) (10 CFR 52.59, "Criteria for Renewal," and 10 CFR 52.63, "Finality of standard design certifications), previously approved combined operating licenses (COLs) (10 CFR 52.83, "Finality of Referenced NRC Approvals; Partial Initial Decision on the Site Suitability," and 10 CFR 52.98, "Finality of Combined Licenses; Information Requests"), previously approved standard design approvals (SDAs) (10 CFR 52.145, "Finality of Standard Design Approvals; Information Requests"), and renewed and previously approved MLs (10 CFR 52.170, "Criteria for Renewal," and 10 CFR 52.171, "Finality of Manufacturing Licenses; Information Requests"). The backfitting provisions in 10 CFR 50.109 apply to ~~ESPs,~~ ~~DCs,~~ COLs, SDAs, and MLs to the extent that they do not overlap the applicability of 10 CFR Part 52 issue finality provisions.~~

~~5.10. Section 70.76 of 10 CFR defines the term backfitting for materials licensees authorized to possess greater than a critical mass of special nuclear material as the modification of, or addition to, SSCs of a facility; or to the procedures or organization required to operate a facility. Either of these may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.~~

~~6.11. Section 72.62 of 10 CFR defines the term backfitting as the addition, elimination, or modification, after the license has been issued, of SSCs offer an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS), or the procedures or organization required to operate an ISFSI or MRS.~~

~~7.12. Section 76.76 of 10 CFR defines the term backfitting as the modification of, or addition to, SSCs of orf a gaseous diffusion plant, or to the procedures or organization required to operate a plant, any of which may result from a new or amended provision in the~~

<sup>9</sup>—Within this DH, the term "issue finality" encompasses the language of the regulations from ~~10 CFR 52.31, "Criteria for Renewal," 10 CFR 52.39 "Finality of Early Site Permit Determinations," 10 CFR 52.59, "Criteria for Renewal," 10 CFR 52.63, "Finality of standard design certifications," 10 CFR 52.83, "Finality of Referenced NRC approvals; Partial Initial Decision on Site Suitability," 10 CFR 52.98, "Finality of Combined Licenses; Information Requests," 10 CFR 52.145, "Finality of Standard Design Approvals; Information Requests," 10 CFR 52.171 "Finality of Manufacturing Licenses; Information Requests," 10 CFR 52.179, "Criteria for Renewal," and any other applicable discussion of finality in part 52.~~

~~Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.~~

8-13.

~~Sections 50.109(a)(4)(i) and (a)(7), 70.76(a)(4)(ii) and (a)(7), 72.62(b), and 76.76(a)(4)(i) of 10 CFR require compliance with "written commitments" and, in the case of 10 CFR 76.76(a)(7), "written Corporation commitments." Within the scope of backfitting, these written commitments mean those commitments that have been incorporated into the license as a means necessary to demonstrate compliance with requirements. This MD and DH reflect NRC policy direction and provide the process for implementing that policy. The MD and DH list the regulations and guidance documents that govern backfitting and describe how the NRC implements those regulations. Backfitting guidance for the NRC staff is available in NUREG-1409 and should be used by all offices and regions to ensure consistent implementation. Office or region-specific guidance is not required or desired. Consistency of implementation is assured by the staff's use of NUREG-1409.~~

14. ~~Any change to an NRC staff position that the NRC intends to communicate by any means to a licensee(s) as being applicable to their facility may be identified as backfitting either by the staff or by licensees. The means of communication can be through the issuance of regulatory guidance, inspection reports, generic communications, or staff interactions with licensee personnel. The NRR, NRO or NMSS office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities will make the determination as to whether the new or revised staff position constitutes backfitting and whether the backfit should be imposed on the licensee(s).~~

~~In support of the Commission's probabilistic risk assessment (PRA) policy statement<sup>10</sup> of August 1995, which encourages the use of PRA "in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy," risk insights must be considered, to the extent practical, as part of all backfitting and forward fitting actions. Risk information should be integrated in a manner that complements traditional regulatory approaches and supports the defense-in-depth philosophy, which would improve the technical basis, increase efficiency, and enhance effectiveness. All backfitting and forward fitting actions must be risk-informed.~~

~~Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits and backfit appeals. The licensing basis (LB) for power reactors under Parts 50, 52, and 54 is determined on a case-by-case basis and is commonly~~

<sup>10</sup> Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).



referred to as the set of NRC requirements applicable to a specific facility and that licensee's written commitments for ensuring compliance with applicable NRC requirements in the LB and the facility-specific design bases (including all modifications and additions over the life of the license).

9. Commitments that have been included in a licensee's updated final safety analysis report (UFSAR) that describe a method for complying with regulations or requirements are not enforceable unless they are part of the license. Commitments documented outside of the license only represent acceptable approaches for complying with the governing requirements.

1. If a licensee voluntarily submits a license amendment request (LAR) or license renewal application (LRA), the NRC, as a condition of its approval, may require that the licensee modify its submittal or adopt new or revised guidance, provided that 1) the new or revised guidance relates to the licensee's request, and 2) the subject matter of the guidance is essential to the NRC staff's determination of the acceptability of the licensee's request. This would not constitute backfitting. It is the licensee's burden to show that the submitted application enables the NRC to make the appropriate findings (e.g., in accordance with 10 CFR 50.40, 50.57, 50.92, or the other applicable regulations).

#### **B. Forward Fitting**

1. A forward fit is defined as the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. Such licensing actions may include a license amendment or a license renewal, although the normal application of the process in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," does not generally constitute forward fitting. The NRC may condition its approval of such a licensing action on the use of a new or modified regulatory staff position **only if 1) there is a direct nexus to the licensee's request and 2) the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff's determination of the acceptability of the licensee's request. Staff must address these two elements in its analysis and adequately justify why each one is independently met.** In deciding whether a forward fit is appropriate, the NRC staff should also take the following factors into account:

- a) As noted in paragraph I.A.5, when the NRC imposes new requirements or regulatory staff position interpreting requirements not needed to ensure adequate protection, the APA requires some consideration of cost. Thus, if

the forward fit is unrelated to adequate protection, the NRC must consider cost before implementing the new or modified requirement or interpretation.

b) In establishing or modifying the requirement or regulatory staff position interpreting the requirement, the NRC staff had the opportunity to consider whether the resulting position should be imposed as a backfit on existing licensees facilities. Under the mandatory backfitting provisions of §§ 10 CFR 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 72.62(b) regarding backfitting necessary to assure adequate protection of public health and safety, if such a change were necessary to ensure adequate protection of public health and safety when the new or modified requirement or regulatory staff position was made, the NRC would have been required to impose it as a backfit. Because such a backfit has not been imposed for cases where a forward fit is being considered, it is unlikely that a change could be justified to be necessary to ensure adequate protection of public health and safety.

c) NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," provides the following guidance on the development of regulatory staff positions:

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. Executive Order 12866 requires that a regulatory analysis be prepared for all significant regulatory actions. The NRC requires regulatory analyses for a broader range of regulatory actions than for significant rulemakings as defined in E.O. 12866. In general, each NRC office should ensure that all mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC or by a petition to the NRC. These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions and standard technical specifications.

If the agency issues a new or modified regulatory staff position (e.g., a revision to regulatory guidance) and the prior regulatory staff position is no longer available for use by current licensees, the new or modified regulatory staff position should include a regulatory analysis.

If the staff imposes a new or modified regulatory staff position as part of the approval of a licensing action for a current licensee, and the prior regulatory

staff position is available for use by current licensees and applicable to the licensing action under review, the staff should perform a site-specific regulatory analysis.

- d) If a licensee believes that the staff has incorrectly followed this process in imposing a forward fit, the licensee may use the backfitting and forward fitting appeals process described in Section III.F of this Management Directive to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors.<sup>11</sup>
- e) Forward fits generally do not include instances when an applicant files an initial licensing action for a new facility. For light-water reactor (LWR) facilities, § 50.34(dh), § 52.17(a)(1)(xii), § 52.47(a)(9), § 52.79(a)(41), § 52.137(a)(9), and § 52.157(f)(30) establish the version of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (the SRP) that applicants should be anticipated to reasonably rely upon in the development of their applications. Any change in requirements or regulatory staff positions from that version of the SRP interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

10. Under 10 CFR 50.40 Common standards, "in determining that a construction permit or OL in this part, or early site permit, combined license, or ML in Part 52 of this chapter will be issued to an applicant, the Commission will be guided by the following considerations: (a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in Part 20 of this chapter, and that the health and safety of the public will not be endangered."

11. A key aspect of 10 CFR 50.40 is the "collectively" aspect. The licensing (and amendment) finding allows consideration of the collective aspect of the proposed change. For example, if a licensee proposes longer outage time for SSC A, then the staff could rely on 50.40 to say that less outage time for SSC B is needed to give the overall collective reasonable assurance, and doing so is not necessarily a backfit.

The backfitting rules generally do not apply to voluntary licensee changes, where "voluntary" is defined as any action by the licensee that was made of its own accord,

<sup>11</sup> 50 FR 38097, 38101, September 20, 1985.

~~without the force of a legally binding requirement or NRC representation of further licensing or enforcement action. The licensee must not be compelled by the NRC staff to make the change. The NRC staff's requirement that the licensee adopt new or revised guidance that does not directly pertain to the licensee's voluntary request would constitute backfitting. Unless required by the NRC, confirmatory orders that are the result of participation in the alternative dispute resolution (ADR) process, LARs, and LRAs are considered voluntary, and the NRC review process and approval of an ADR, LAR, or LRA generally is not considered backfitting. Furthermore, the backfitting rules do not apply to NRC suggested actions with which licensees are not required to comply, but decide to voluntarily implement. The backfitting rules do not apply to any voluntarily initiated licensee installation of updated (or additional) equipment to the existing plant, to expand the plant, improve efficiencies, delay its obsolescence, or extend its capabilities.~~

~~Backfitting does not apply to actions that do not have a direct link to, and do not further a substantive radiological public health and safety, or common defense and security, objective. Nevertheless, the NRC must have legal authority to justify taking such actions.~~

- ~~12. For backfitting purposes, staff positions are documented interpretations of the regulations, already specifically imposed upon a licensee or "class" of licensees at the time of the identification of the proposed backfitting and may be contained in documents such as the Statement of Considerations for a final rule, Standard Review Plan (SRP), NUREG, interim staff guidance (ISG), and branch technical position (BTP). A licensee's commitment to guidance, such as regulatory guides (RGs) or NRC endorsed industry topical reports (TRs), through a licensing action is considered a voluntary action. However, RGs and NRC endorsed TRs do represent staff positions. Generally, the issuance of or revision to a staff position is considered forward-fitting and the revisions to staff positions do not, in isolation, impose anything, and are therefore not (in isolation) backfits. The applicable staff positions for each facility license application, LAR, or LRA includes the safety evaluation reports (SER),<sup>12</sup> and any NRC approvals based on licensees' docketed responses to requests for information. A change in the applicable staff position is referred to as a new or revised staff position.~~

- ~~13. The NRC's backfitting actions can be either generic or facility specific.<sup>13</sup>~~

<sup>12</sup>— Historically, the NRC has used two terms to describe the document approving a license, amendment, or license renewal: SER or safety evaluation (SE). Throughout this DH, the use of SE will indicate the SER (usually used for approving initial licensing or relicensing actions) or the SE (usually used for approving license amendments).

<sup>13</sup>— Hereafter, the term "facility" will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or an MRS installation.

~~(a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised regulations or requirements (through rulemaking or Orders) or new or revised staff positions interpreting NRC regulations. Generic backfitting actions can be initiated in a number of ways, such as by the staff in rulemaking, the Commission through a staff requirements memorandum (SRM), and the public through a petition for rulemaking. Regardless of whether a generic backfitting action is the result of rulemaking or a new or changed staff interpretation, the new or changed regulation or staff position must be documented, and stakeholders must have had an opportunity to review and provide comments in response to a *Federal Register* (FR) notice. However, time-sensitive, safety-significant, or security-significant NRC actions, such as Orders or Bulletins, do not require public notice and opportunity to comment. In addition, not all previously issued staff positions were provided to the public for comment.~~

~~(b) Facility specific backfitting issues typically arise through the NRC's inspection or licensing process. In these circumstances, the NRC's regional or headquarters staff may find that a change to a facility's licensing basis (LB) is appropriate. Facility-specific backfitting actions are normally a change in a staff position (the applicable SE) for a specific facility, based on an error or omission in the analysis (compliance backfit) for the implementation of that facility's LB, but they could also be a change to the facility specific LB deemed necessary to ensure that the facility provides adequate protection. For power reactors, in addition to single unit sites, facility-specific backfitting actions may apply to sites that have multiple units, sites that share a UFSAR, or sites that may have more than one reactor type but share common sections of a UFSAR. Any reference in this DH or in NUREG-1409, "Backfitting and Issue Finality Guidance," to facility-specific backfitting pertains to facility-specific backfitting actions in this context.~~

~~Unless an exception as described in Section I.A.10 applies, to justify a backfit under 10 CFR 50.109, 10 CFR 70.76, 10 CFR 76.76, and generally 10 CFR 72.62, or, in many cases, to justify a violation of issue finality under 10 CFR Part 52, the NRC must perform and document a backfit analysis in accordance with NUREG-1409 that shows the following:~~

~~The backfitting would result in a substantial increase<sup>14</sup> in overall protection of public health and safety or the common defense and security, and~~

<sup>14</sup>—As noted in the Statements of Consideration for the 1985 backfitting final rule (50 FR 38097; September 20, 1985), a "substantial" increase in protection means "important or significant in a large amount, extent, or degree." Under such a standard, the Commission would not ordinarily expect to

The direct and indirect costs of implementing the backfitting are justified in view of the increased protection.

The backfitting provisions generally contain three exceptions to the backfit analysis requirement described above, such that the analysis is not necessary when the backfitting action—

Is required for adequate protection,

Defines or redefines the level of protection that should be regarded as adequate, or is necessary to bring a facility into compliance with applicable requirements in the licensing basis, or into conformance with its written commitments.

14. Adequate protection backfitting, whether used to ensure that adequate protection is maintained or to define or redefine the level of protection that should be regarded as adequate, does not require a finding of substantial safety or security improvement, nor does it require that costs be considered. If a backfitting action is deemed necessary for adequate protection, it must be implemented, as required by Section 161 of the Atomic Energy Act of 1954, as amended (AEA). Compliance backfitting does not require a finding of substantial safety or security improvement, but does require some consideration of costs. Use of the adequate protection or compliance exception must be explained in a risk informed, documented evaluation.

15. The backfit analysis requirement, and the exceptions to that requirement, restrict the ability of the NRC to conduct backfitting by requiring the NRC to demonstrate, before implementing the backfit, that the backfitting action would meet certain standards that vary based on the type of facility. In this way, the backfitting rules provide the following:

- (a) Regulatory stability, by limiting the changes the NRC can make;
- (b) Reasoned and informed NRC decisionmaking, by requiring the proposed action to be properly justified; and
- (c) Transparency of NRC decisionmaking, by requiring the NRC to document and make publicly available its analyses.

16. This MD and DH reflect NRC policy direction and provide the process for implementing that policy. The MD and DH list the regulations and guidance documents that govern backfitting and describe how the NRC implements those regulations. Backfitting guidance for the NRC staff is available in NUREG-1400. Office or region specific

justify backfitting plant improvements that result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of costs.

guidance is not required or desired. Consistency of implementation is assured by the staff's use of NUREG-1409.

17. Any change to an NRC staff position that the NRC intends to communicate to a licensee(s) as being applicable to their facility by any means may be identified as backfitting either by the staff or by licensees. The means of communication can be through the issuance of regulatory guidance, inspection reports, generic communications, or staff interactions with licensee personnel. The NRR, NRO or NMSS office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities will make the determination as to whether the new or revised staff position constitutes backfitting and whether the backfit should be imposed on the licensee(s).
18. In support of the Commission's probabilistic risk assessment (PRA) policy statement<sup>16</sup> of August 1995, which encourages the use of PRA "in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy," risk insights must be considered, to the extent practical, as part of all backfitting actions. Risk information should be integrated in a manner that complements traditional regulatory approaches and supports the defense-in-depth philosophy, which would improve the technical basis, increase efficiency, and enhance effectiveness. All backfitting actions must be risk informed.
19. Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits and backfit appeals.

#### **B.C. Information Collection Requests**

1. The provisions of 10 CFR 2.204, "Demand for Information," require that a licensee respond to information requests from the Commission for the purpose of determining if an Order under 10 CFR 2.202, "Orders," should be issued, or whether other actions should be taken.
- 2-1. The provisions of 10 CFR 50.54(f) require power reactor licensees to respond to information requests from the staff NRC to enable the determination of whether a license should be modified, suspended or revoked. This rule stipulates that, except for information sought to verify licensee compliance with the facility's LB, the NRC must prepare the reasons for the information request to ensure that the burden imposed on licensees is justified based on the potential safety or security significance of the issue to be addressed. For additional information regarding appropriate use of 10 CFR 50.54(f), see Section IV, Information Requests.

<sup>16</sup>—Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).

~~3-2.~~ Requests for information for power reactors ~~to be~~ licensed under 10 CFR Part 52 will be in accordance with the administrative requirements in 10 CFR 50.54(f), and as stated in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable. The information ~~collection request~~ requirements for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).

~~4-3.~~ This MD and DH reflects the policy for ~~all~~ requests for information under these provisions.

#### ~~C-D.~~ Coordination and Communication

For effective implementation of the NRC's backfitting, forward fitting, and information ~~collection request~~ programs, the ODs and the RAs must ensure the following:

1. Effective communication and coordination are maintained between their counterparts and among the responsible technical staff within the headquarters and regional offices.
2. Processes, procedures, and programmatic and administrative controls are written in plain English.
3. Formal feedback from the Committee to Review Generic Requirements (CRGR) provided during the review of a proposed rule involving backfitting or forward fitting is addressed as part of the rulemaking package before its submittal to the Executive Director ~~of for~~ Operations (EDO).
4. No backfitting or forward fitting actions will be communicated to a licensee unless the appropriate OD or RA has determined whether the position involves backfitting or forward fitting and, if so, has ensured that the position is identified as backfitting or forward fitting, the appropriate material (i.e., documented evaluation or backfit analysis) has been prepared and approved, the CRGR was offered an opportunity to review the documentation, and written feedback was considered. NRR Program ODs shall ensure reactor backfitting and forward fitting actions are consistently implemented throughout the regions.

#### ~~D-E.~~ Recordkeeping

Offices and regions directly involved in backfitting, forward fitting, or information ~~collection~~ requests are responsible for tracking and maintaining associated records originating in that office or region. Documentation of the justification for backfitting or use of a backfit analysis exception is required by 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76. Documentation of the justification for information requests under 10 CFR Parts 50 and 52 are required by 10 CFR 50.54(f), 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable.



1. The office or region proposing information ~~collections requests, or~~ backfitting actions, ~~or forward fitting actions~~ must administratively manage each ~~collection request~~ or action by maintaining all related records. Records must be maintained in accordance with NUREG-0910, "NRC Comprehensive Records Disposition Schedule," issued March 2005.
2. Backfitting ~~and forward fitting~~ records placed in the Agencywide Documents Access and Management System (ADAMS) must be accessible to all stakeholders by being profiled as publicly available when appropriate, consistent with agency guidance on the release of information to the public.

## II. BACKFITTING APPLICABILITY

### A. Regulatory Changes Subject to the Backfit Rule

1. ~~As defined in Section I.A.1, a~~ An NRC action is considered backfitting when the NRC changes any requirements through rulemaking, ~~or an Order~~, or ~~the imposition of~~ ~~imposes~~ a new or modified staff position that interprets requirements and would result in the modification or addition to SSCs, or the design of a facility, or the design approval or ML for a facility, or the procedures or organization required to design, construct, or operate a facility, after the dates defined in the backfitting requirements.
2. If the NRC staff conveys an expectation that licensees change programs, processes, procedures, or the physical plant by using or committing to use voluntary guidance (e.g., RGs or NRC-endorsed industry ~~TR~~ ~~topical reports~~) that is not already within the LB for the identified purpose, then the staff's communication of that expectation ~~is may be~~ considered backfitting ~~or forward fitting~~. ~~As discussed above, in section I.A.11, forward fits do not constitute backfits but must meet additional, specified criteria and are subject to the backfit appeals process. Since there is generally more than one way to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there may be more ways to reach a level of protection that is adequate, the applicant or licensee is ordinarily free to choose the way which best suits its purposes. However, this does not apply during the review and consideration of any voluntarily submitted license application, LAR, or LRA, provided the issue in question is somehow associated with, and is within the scope of, the license application, LAR, or LRA under consideration.~~
3. A relaxation is the modification of a regulatory requirement or staff position that reduces ~~requirements the obligations of placed on~~ a licensee or class of licensees. A relaxation may provide licensees the option of continuing as previously licensed (status quo), or adhering to the new "relaxed" regulatory requirement or staff position. If a relaxation does not provide for the status quo option, it is mandatory, and the relaxation is considered backfitting. ~~However, if the implementation of the relaxation is voluntary for the licensee, in that it does provide for the status quo option, then the relaxation is not backfitting, even if the licensee decides to implement the relaxed requirement.~~

## B. Nonapplicable Regulatory Changes

1. The ~~NRC's backfitting rules do not apply to the~~ following ~~are is a non-exhaustive list~~  
~~of examples of regulatory actions that generally do not meet the definition for~~  
~~backfitting:~~
  - (a) Confirmatory action letters (CALs), because CALs involve voluntary actions a licensee commits to take, which are agreed to between the licensee and the NRC;
  - (b) Changes mandated by statute or other Congressional action that preclude agency discretion in their implementation;
  - (c) Changes required by other Federal agencies that preclude ~~agency-NRC~~ discretion in their implementation;
  - (d) Voluntary licensee submittals ~~of an LAR or LRA or subsequent license renewal (SLR) request,~~<sup>46</sup> subject to the limitations discussed above in Section I.A.104, ~~and the NRC's process (requests for information, licensee engagement, or modifications to the submittal) used during the review and consideration of the LAR, LRA, or SLR request;~~
  - ~~(e) A licensee's voluntary implementation of NRC recommended actions that do not constitute the basis for resolution of a safety, security, or regulatory issue (e.g., a licensee's decision to follow an NRC RC, or an NRC endorsed TR, or to make changes based on an NRC Information Notice);~~
  - ~~(f)(e)~~ Issuance of a notice of violation for an improper change ~~Overturning of an improper change implemented~~ under 10 CFR 50.59, "Changes, Tests, and Experiments" ~~resulting in a modification to a facility;~~
  - ~~(g)(f)~~ Licensee changes or plant modifications that expand the plant capabilities or improve plant efficiencies or performance that are not mandated by the NRC;
  - ~~(h)(g)~~ Non-mandatory relaxations of staff positions or regulations;
  - ~~(i)(h)~~ ~~New or changes to requirements that do not have a direct link to, and do not further a substantive radiological public health and safety or common defense and security objective, such as, reporting and recordkeeping requirements (e.g., 10 CFR 50.71, 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors") or appeals processes (e.g., 10 CFR 26.39, "Review~~

<sup>46</sup> The scope of the NRC's review of an LR or SLR and, thus, the backfitting of these applicants, is limited by the regulations in 10 CFR 54.30, "Matters Not Subject to a Renewal Review."

DH 8.4 MANAGEMENT OF BACKFITTING, ~~FORWARD FITTING~~, ISSUE FINALITY, AND INFORMATION COLLECTION~~REQUESTS~~

Date Approved: XX/XX/XXXX

~~Process for Fitness For Duty Policy Violations," 10 CFR 73.56(l), "Review Procedures";~~

~~(j)(i)~~ Changes or updates to American Society of Mechanical Engineers Boiler and Pressure Vessel (ASME) Code, Section XI, that are incorporated into 10 CFR 50.55a, "Codes and Standards";

~~(k)(i)~~ Plant or procedural changes to comply with industry or professional standards not mandated by the NRC;

~~(j)(k)~~ Current and future applications for an NRC license, with two exceptions described in Section II.B.4-2 below;

~~(m)(l)~~ Voluntary changes made to a plant based on national or international operating experience, including any changes as a direct result of NRC Information Notices;

~~(n)(m)~~ Changes as a result of a licensee's commitment management program;

~~(o)(n)~~ Licensee changes to its plant under 10 CFR 50.59 or other existing change control requirements ~~(see Section II.B.23 below); and~~

~~(p)(o)~~ Plant or procedural corrective actions to restore the LB or adherence to the license and thereby provide compliance with governing requirements;

~~2. The issuance of new or updated NRC RGs, as RGs are forward fitting, provided the RGs are not imposed on licensees;~~

~~3. The endorsement of new or updated industry-submitted TRs, because TRs are forward fitting and not imposed by the NRC; and~~

~~4. The staff use of documents, such as NUREGs, ISGs, and BTPs, during the review and consideration of any LAR or LRA, as the submission of the LAR or LRA is a voluntary action by a licensee applying for a change to its license, subject to the limitations discussed in Sections I.A.11 and I.A.14.~~

~~5. If an existing licensee voluntarily requests a license amendment or change, and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to an NRC guidance document (such as an RG) and (2) the specific subject matter of the guidance document is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow that guidance or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements in the licensing basis. This is not considered backfitting.~~

~~6. Power reactor licensee implementation of changes to its facility under 10 CFR 50.59 are not subject to the backfitting rules. The NRC has established a process under~~

~~10 CFR 50.59 that provides a licensee the authority to make certain changes without NRC approval if the change meets certain specified criteria. Unless the NRC determines that the licensee incorrectly used the 10 CFR 50.59 process, the licensee reasonably can implement the change without the NRC taking enforcement action. This is consistent with the underlying premise of regulatory stability established within the backfitting rules and the principles of good regulation. However if, during any inspection or review of licensee actions implemented in accordance with 10 CFR 50.59, the staff determines that 10 CFR 50.59 was not properly implemented, the staff shall issue a finding or violation in accordance with regulations, and the licensee may be required to "revert" to the previous plant or procedural configuration, or otherwise change the facility to a configuration acceptable to the NRC. This would not be considered backfitting.~~

~~7.2.~~ In general, backfitting provisions do not apply to current and future applicants for an NRC license. Backfitting is not intended to apply to every NRC action that substantially changes the expectations of current and future license applicants. There are two exceptions to this general principle. The first exception occurs when a 10 CFR Part 52 license applicant references a 10 CFR Part 52 license (e.g., an ESP) or NRC regulatory approval (e.g., a ~~DCRDC~~), or both, with specified issue finality provisions. The second exception occurs when a 10 CFR Part 50 power reactor OL applicant holds a CP or limited work authorization (LWA). ~~Section 10 CFR 50.109~~ would apply to the matters covered by the CP or LWA. See also the discussion on the use of the SRP for review of LWR applications in Section I.A.11 of this DH.

~~8. Actions proposed or voluntarily implemented by a licensee are not backfits, even though such actions may result from routine discussions between the staff and the licensee concerning an issue, provided that those discussions did not include an NRC expectation that the licensee must implement the action.~~

### III. BACKFITTING POLICY

#### A. Adequate Protection Backfitting

1. For all matters of potential backfitting, including forward fitting, the staff must first consider whether the issue is one of adequate protection.<sup>17</sup> If the NRC staff

<sup>17</sup> Like backfitting, for matters of potential forward fitting the staff must first consider whether the issue is one of adequate protection. Instances of adequate protection forward fitting should be extremely rare. This is because the NRC takes into account the potential for the imposition of backfits necessary for adequate protection under its mandatory backfitting provisions ((§§ 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 72.62(b) regarding backfitting necessary to assure adequate protection of public health and safety) when regulatory staff positions interpreting the Commission's requirements are developed. Once a new or revised regulatory staff position interpreting the Commission's requirements is finalized, the potential for backfitting that is necessary

determines that it must impose a backfitting action to ensure that a facility provides adequate protection to public health and safety and is in accord with the common defense and security, or if the Commission decides that it needs to define or redefine the appropriate level of protection of public health and safety or the common defense and security that should be considered as adequate, then the AEA requires that the backfitting action be implemented. ~~If a backfitting action is determined to be A backfit analysis to justify the determination that a backfitting action is necessary for adequate protection, a backfit analysis is not required and costs cannot be considered and a consideration of costs are not required~~ (unless the NRC staff identifies more than one means for implementing the new requirement, in which case costs could be considered in deciding which approach is appropriate). Whenever adequate protection is invoked, the NMSS, NRO or NRR OD must approve a risk-informed, documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to define or redefine adequate protection or to ensure adequate protection of public health and safety or the common defense and security.<sup>18</sup> The risk-informed, documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking adequate protection, and the safety or security risk if action is not taken. The NMSS, NRO or NRR staff should seek advice from the Office of General Counsel (OGC) on the imposition of all adequate protection actions, including the licensee's proposed implementation schedule. NUREG-1409 contains detailed guidance on how to prepare the documented evaluation. For generic backfitting actions that are part of rulemakings, the documented evaluation is provided as part of the rulemaking package that the Commission approves. Generally, adequate protection backfits are not included in rulemakings, and instead, result from the issuance of an Order. The rulemaking will subsequently be issued to include the previously imposed adequate protection backfits, given consideration to public comments provided on the proposed rule and to lessons learned through the implementation of the previous Order requirements.

2. To issue ~~the each~~ license, the Commission found that operating in accordance with the license would provide reasonable assurance of adequate protection of public health and safety and reasonable assurance that the licensee would meet the regulations. Therefore, licensee compliance with its LB is presumed to provide

for adequate protection of public health and safety would have been considered and accomplished as appropriate.

<sup>18</sup> It is the policy of the NRC that backfitting actions under 10 CFR 72.62 that are similarly justified must be documented in a manner similar to those under 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6).

reasonable assurance of adequate protection of public health and safety and the common defense and security. Thus, for the NRC to impose new or changed requirements on a licensee that are intended to provide for adequate protection of public health and safety or the common defense and security, the NRC must provide, within the documented evaluation, a clear explanation of why, despite the licensee's compliance with the applicable existing regulatory framework (LB), there is not (or will not be) reasonable assurance of adequate protection. This evaluation must include appropriate consideration of risk insights. Typically, a clear basis for invoking the adequate protection exception can be established when the NRC has new information regarding a safety or security issue that creates undue risk to public health and safety that is not addressed through compliance with the current regulatory framework. If the NRC can show that it must take action to provide reasonable assurance of adequate protection of public health and safety and the common defense and security, then the AEA requires the NRC to impose the new or changed requirements.

2.3. Upon determining that a backfit is necessary for adequate protection of public health and safety, the NRC must then consider whether the underlying safety issue presents an imminent threat to public health and safety. If so, the agency must take immediate action.

3.4. It is the NRC's position<sup>19</sup> that the agency cannot allow licensees to address issues of adequate protection by a voluntary initiative. Instead, the AEA requires the NRC to establish requirements that provide reasonable assurance of adequate protection of public health and safety and the common defense and security.

4. ~~5.~~ Under 10 CFR 50.109(a)(5), 52.39(a)(ii), 52.63(a)(1)(ii), 52.171(a)(1), 72.62 and 76.76(a)(5), the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of ~~occupational or~~ public health and safety.

5. Under 10 CFR 72.62, the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of occupational or public health and safety.

<sup>19</sup> In SRM-SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated ~~March 2~~ May 27, 1999 (ADAMS Accession No. ML003752062992810068) the Commission approved the staff's recommendation ~~agreed~~ that relying on voluntary industry initiatives to ensure adequate protection would be inappropriate "since they would be based on commitments rather than requirements."

## B. Compliance Backfitting

1. Compliance backfitting is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. New or modified interpretations of what constitutes compliance do not fall within the exception.

1-2. Before the staff uses the compliance exception, the staff must determine whether the conditions represent an issue of adequate protection. If the issue does not involve adequate protection, then the staff should determine whether the backfitting action is necessary to ensure compliance with regulatory requirements in the licensing basis, or written commitments on how the licensee will comply with a requirement that ~~were~~ was in place at the time of the decision at issue. ~~If the backfitting action ensures compliance, a backfit analysis is not required. Instead,~~ The appropriate program office or region prepares a risk-informed, documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to ensure compliance as the result of a ~~non~~ error or omission or mistake of fact (see item 6 of this section). The documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking the compliance exception, and the safety or security risk if action is not taken. NUREG-1409 contains detailed guidance on how to prepare this documented evaluation. The responsible office staff shall seek OGC and the Office of Enforcement (OE) advice on the imposition of all compliance backfitting actions, including the licensee's proposed implementation schedule. The NRC staff's compliance backfitting documentation should include risk insights, including safety margin<sup>20</sup>, to provide the staff sufficient information to determine an acceptable ~~acceptable~~ schedule for the licensee to implement the backfit. These risk insights may also indicate that it is appropriate to terminate consideration of a backfitting action as discussed in item 9 of this section.

2-3. The phrase "written commitments," as used within the backfitting provisions, refers to those commitments that have been submitted to the NRC on the docket, have become part of the license ~~been incorporated into the license~~, and directly relate to the means by which the licensee complies with a requirement.

<sup>20</sup> Safety margin may not be quantifiable. For example, meeting environmental qualification (EQ) requirements in 10 CFR 50.49 "Environmental qualifications of electrical equipment important to safety for nuclear power plants," results in safety margin, but this margin is not readily quantifiable, particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).



~~3.4.~~ Under 10 CFR 72.62, the Commission will require the imposition of a backfit if it finds that the backfit is necessary to bring an ISFSI or MRS into compliance with a license or the Commission's Orders or rules. ~~Under 72.62(b), "The Commission will require backfitting of an ISFSI or MRS if it finds that such action is necessary to assure adequate protection to occupational or public health and safety, or to bring the ISFSI or MRS into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by a licensee."~~

~~4.5.~~ ~~Because a compliance backfitting action does not require a backfit analysis, the staff need not demonstrate that the direct and indirect costs of implementation are justified in view of the increased protection from the backfit. However, As noted in paragraph I.A.5, when the NRC imposes new requirements not needed to ensure adequate protection, the APA requires some consideration of cost. Thus, the staff must include at least some consideration of costs in its documented evaluation- for a compliance backfit performed under 50.109(a)(4), 70.76(a)(4), or 76.76(a)(4).~~ Although the extent of the consideration required will necessarily be fact- and site-specific, one of the factors that may be relevant is the amount of time that has elapsed since the approval that is now claimed to be the subject of a mistake or omission. When the potential for compliance backfitting is identified relatively soon (within approximately 2 years) after the licensing decision or the imposition of a regulatory requirement, likely all that will be necessary is a simple estimate of the cost ~~of~~ imposing the backfitting action that does not quantify benefits or perform any balancing beyond that which was originally considered. However, when many years have passed (typically more than 10) before the staff determines that a regulation or requirement is not satisfied, identifying the benefits of compliance and comparing them to the cost of implementation will likely be appropriate to ensure that costs have been adequately considered. The staff is afforded ~~a high degree of substantial~~ flexibility, in accordance with Commission direction, to determine how much cost consideration is appropriate based on the specifics of each case and the identified risk.

~~5.6.~~ Use of the compliance exception is limited to the following situations that define "omission or mistake of fact":

- (a) 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, (1) incorrectly perceived facts, (2) performed or failed to recognize flawed analyses, or (3) failed to properly draw inferences from those facts or analyses, as judged by the standards and practices that were prevailing among professionals or experts in the relevant area at the time of the determination in question, and



- (b) Those facts, analyses, or inferences have now been properly perceived, performed, or drawn.
- (c) The error or omission may have been committed by any involved party and must be traced to—
  - (i) The original LB or to a change to the LB, and
  - (ii) The regulations ~~contained-reflected~~ in the LB at the time of implementation that were applicable to the particular licensee whose LB is at issue, and
  - (iii) Any standards and practices in existence at the time the original determination was made.

The understanding for what constituted proper implementation of the regulations, standards, and practices must have been widely known or understood by professionals at the time. This is not restricted to the regulatory positions of the NRC but includes any industry or professional standards and practices in existence at the time the original determination was made.

~~6-7.~~ The compliance exception should not be applied to the following:

- (a) Failure of the NRC staff 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 NRC determination; or
- (b) 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 determination.

~~7-8.~~ The following policy concerns the use of the compliance exception to mandate consistency with the general design criteria (GDC).

~~(a) The GDC are located in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 and 10 CFR Part 72, Subpart F, "General Design Criteria." Those design criteria help formulate a plant's design basis, and the design basis is reflected in the plant's final engineering drawings. The design basis must be documented in the UFSAR.~~

~~(b) The GDC establish "minimum requirements" for the development of the principal design criteria (PDC). The GDC are intended to provide guidance in establishing the PDC. The licensing process requires approval of an applicant's PDC as a condition for granting a CP. Before an OL is issued, and as a basis for its finding~~

~~of reasonable assurance of adequate protection of public health and safety and the common defense and security, the Commission must find that the facility has been built in accordance with the PDC and any NRC-approved changes. Thus, for 10 CFR Part 50 licensees with CPs issued since 1971 (when the GDC were promulgated), the Commission has already necessarily reached the conclusion that the design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria set forth in the GDC. The 1992 SRM approved the SECY that concluded that no GDC backfitting was needed, and that all pre-GDC plants meet the intent of the GDC.<sup>24</sup>~~

~~(e)(a)~~ The NRC must not rely on the GDC requirements for pre-GDC licensing actions (those licenses or CPs issued before the issuance of the GDC (before 1971)), unless the NRC has made the GDC a requirement for that licensee.

~~(d)~~ Under the provisions of 10 CFR 50.34, "Contents of Applications; Technical Information," an application for a CP must include the PDC for a proposed facility. Under the provisions of 10 CFR 52.47, "Contents of Applications; Technical Information," 10 CFR 52.79, "Contents of Applications; Technical Information in Final Safety Analysis Report," 10 CFR 52.137, "Contents of Applications; Technical Information," and 10 CFR 52.157, "Contents of Applications; Technical Information in Final Safety Analysis Report," an application for a DC, COL, SDA, or ML, respectively, must include the PDC for a proposed facility. The PDC establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.

~~(e)(b)~~ The license approval process will typically yield more specific requirements than those set forth in the GDC. However, the NRC is not precluded from reliance on GDC as the source of a "requirement" for purposes of invoking the compliance exception ~~in those cases where a GDC provides more than just a performance standard and has not been superseded through the approval of the PDC, and requirements derived from those PDC that are clearly meant to address the GDC at issue. Thus, a GDC can be regarded as a requirement in those circumstances in which~~ when the GDC is prescriptive in nature and the technical specifications and other licensee requirements derived

<sup>24</sup> SRM was in response to SECY-92-223 "Resolution of Deviations Identified During the Systematic Evaluation Program" and is dated September 18, 1992 (ML12256B290).

from the ~~principle~~principal design criteria, ~~PDC~~ do not speak to the matter in question.

~~(f) In some cases, conditions not in accordance with the GDC can be properly resolved as a matter of adequate protection if the matter creates undue risk to public health and safety or the common defense and security, without the need to invoke the compliance exception. The extent to which regulatory action is necessary to ensure adequate protection should be evaluated before invoking the compliance exception based on a requirement set forth in the GDC.~~

Use of the compliance exception to support a backfit should not be confused with routine inspection activities related to the LB, as determined by the reactor oversight process or other inspection activities. NRC inspections assess compliance with the requirements in the ~~licensing basis~~ LB, whereas compliance backfitting is pertinent to those issues where the staff has determined that it is necessary to modify the approved LB because of an ~~error or omission or mistake of fact~~. Thus, it is not expected that findings or violations documented as part of the NRC's inspection activities would result in compliance backfitting. However, the NRC staff must evaluate each circumstance to ensure the issue is properly assessed against the LB and resolved. For example, the NRC would take enforcement action when a licensee is not in compliance with the NRC-approved method of meeting a requirement, whereas compliance backfitting would occur when a licensee is in compliance with an NRC-approved method but the NRC subsequently determines that the licensee's method does not result in compliance with the requirement because of an ~~error or omission~~ or mistake of fact at the time of approval.

~~7.1 The NRC staff's compliance backfitting documentation should include risk insights, including safety margin,<sup>22</sup> to provide the staff sufficient information to determine an acceptable schedule for the licensee to implement the backfit.~~

~~8.9.~~ At any point during the process, the responsible program office or the region, in consultation with other appropriate offices, including OGC and OE, may decide not to

<sup>22</sup> ~~Safety margin may not be quantifiable. For example, meeting environmental qualification (EQ) requirements in 10 CFR 50.49 "Environmental qualifications of electrical equipment important to safety for nuclear power plants," results in safety margin, but this margin is not readily quantifiable, particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).~~

proceed with the backfitting action because further effort is likely to show either of the following:

- (a) Compliance backfitting would not provide any increase in safety or security as compared to the status quo. This is not to say that the increase in safety or security must be substantial, only that there must be some attributable increase.
- (b) An exemption from compliance with the Commission's regulation for which compliance is sought may be granted under 10 CFR 50.12, "Specific eExemptions;" 10 CFR 52.7, "Specific eExemptions;" 10 CFR Part 70 Subpart B, "Exemptions;" 10 CFR 72.7, "Specific eExemptions;" or 10 CFR 76.23, "Specific eExemptions."

9.10. Or, if In consultation with OE, the OD or RA may determine that enforcement discretion should be granted to enable the licensee to prepare a systematic and planned approach for implementing a compliance backfitting action. If the OD or RA and OE conclude that enforcement discretion is appropriate or necessary, based on a risk-informed analysis and in consideration of licensee outages and maintenance schedules, OE, with the OD or RA, will normally issue an enforcement guidance memorandum or seek Commission approval for an interim enforcement policy for multifacility compliance backfitting actions, as appropriate.

- (a) An enforcement guidance memorandum is usually the appropriate enforcement discretion for generic or industrywide compliance backfits.
- (b) For individual facility- or site-specific compliance backfitting actions, the exercise of enforcement discretion may be addressed in the Order associated with the compliance backfit.

~~10. If adequate protection is not involved, then a determination must be made to verify there is adequate safety margin with respect to the regulatory requirements. Therefore, consideration of cost is relevant in determining if a backfit is needed to recover the lost safety margin.~~

- 2. If, after careful consideration of the issue, risk to public health and safety or the common defense and security, safety margin, and licensee costs for implementation of the compliance backfit, the NRC determines that compliance should not be required, then the NRC will normally grant enforcement discretion until such time as the NRC initiates and issues an exemption in accordance with 10 CFR 50.12, an amendment in accordance with 10 CFR 50.90, a relaxation of an order, or other action as appropriate.

### C. Cost-Justified Substantial Increase in Protection Backfitting

For all backfitting that does not satisfy the adequate protection exception or compliance exception criteria, the NRC should determine whether to ~~perform~~ impose a backfit ~~analysis~~ by applying the facts of the proposed backfitting against the backfit standard as described below.

#### 1. Backfit or Issue Finality Standard

The backfitting provisions require, first, that the proposed action result in a substantial increase in the overall protection of public health and safety or the common defense and security. If either criterion is met, the standard then requires that the direct and indirect costs are shown to be justified in light of the substantial increase in overall protection. If the proposed action is not shown to result in a substantial increase in safety or security, or the costs are not justified, then the backfit cannot be imposed (unless the Commission exempts itself from the backfitting rule: although as noted in paragraph I.A.5, when the NRC imposes new requirements not needed to ensure adequate protection, the APA requires some consideration of cost).

In the statement of considerations for the 1985 reactor backfitting rule, the Commission said the following:

Substantial means "important or significant in a large amount, extent, or degree." Under such a standard the Commission would not ordinarily expect that safety improvements would be required as backfits that result in an insignificant or small benefit to public health and safety or common defense and security, regardless of costs. On the other hand, the standard is not intended to be interpreted in a manner that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided.

#### 2. Backfit Analysis

All backfit analyses must be performed in accordance with ~~40 CFR 50.109 or other the~~ applicable backfitting or issue finality regulations and NUREG-1409.

(a) Once the NRC determines that backfitting ~~must~~ should be pursued, and adequate protection or compliance backfitting are not appropriate, the NRC staff must develop a backfit analysis.

(b) The staff must demonstrate and document that the backfit standard is met. The staff must consider available quantitative and qualitative data in making this

determination. ~~If necessary, relevant, and consistent with SRM-SECY-14-0087, "Staff Requirements—SECY-14-0087 Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, qualitative considerations may be used to demonstrate a cost-justified increase in protection. As directed, q~~Qualitative factors should be used in a judicious and disciplined manner to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data). Accordingly, an analysis should be informed by applicable risk information, including a PRA, to the extent it is available and can be considered without undue use of NRC resources. The staff will also consider information available concerning any of the factors listed in 10 CFR 50.109(c), as may be appropriate, and any other information relevant and material to the proposed backfitting, including NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

- (c) ~~Relaxations may not show a substantial increase in safety or security; consequently, implementation of these relaxations are voluntary for the licensees.~~ In most cases, relaxations involve alternative regulatory approaches that licensees can choose to implement, may involve small decreases in safety or security, and are not backfitting actions if options for implementation are offered to the licensees. When such options are offered, the NRC verifies that compliance with the licensee's LB, including the relaxation (if it involves a small decrease in safety or security), continues to provide reasonable assurance of adequate protection.

3. Under 10 CFR 72.62, the Commission can require the backfitting of an ISFSI or MRS installation if it finds that the backfitting action would result in a substantial increase in protection to the occupational or public health and safety whose costs are justified in light of the increased protection.

#### D. Additional Considerations for Backfitting and Forward Fitting

1. For all backfitting and forward fitting actions, additional procedural factors required by the CRGR Charter for justification must be used if they apply to the issue. Furthermore, as additional administrative controls, the offices or regions may use reviews by special internal panels, and OE and OGC review and concurrence, as appropriate.
2. The NRC staff should recommend terminating a proposed agency action that would constitute backfitting when the staff concludes that the proposed action is not necessary for adequate protection; the compliance exception to the backfit analysis requirement does not apply; the backfitting action is not likely to result in a

substantial increase in safety or security; or, if a substantial increase in safety or security can be demonstrated, the direct and indirect costs of implementation are not likely to be justified. The responsible program OD or RA may approve closing the issue with appropriate notice sent to all applicable parties and recorded in ADAMS.

3. During the course of dispositioning a proposed finding, violation, or licensing action, a licensee may raise concerns that the proposed action is either backfitting or forward fitting. The staff will inform divisional management of the concern, before the proposed action is taken, and with ensuing discussions considering previous regulatory staff positions and enforcement precedents. A lack of historical staff position could be indicative of a new staff position and therefore subject to backfitting and forward fitting provisions and guidance. Informing divisional management and researching historical positions ensures appropriate consideration of licensee concerns and supports agency operation as a stable and reliable regulator.

#### E. Scheduling of Backfitting and Forward Fitting Implementation

1. After the appropriate OD (NMSS, NRO, or NRR) or RA has approved a facility-specific documented evaluation, or backfit analysis, or forward fit analysis, the responsible division director or above must issue the backfitting or forward fitting requirement to the licensee. The licensee may choose to implement the backfitting or forward fitting action or appeal the decision to the program OD or RA.
2. Implementation of a facility-specific backfitting action should be accomplished on a schedule based on the safety or security significance and overall risk of the issue, with the exception of any a Adequate protection backfits that should must be expeditiously imposed if the NRC finds that an imminent threat to public health and safety exists. Upon determining that a backfit is necessary for adequate protection to public health and safety, the NRC should prepare an imminent threat analysis that determines whether immediate action is necessary. The staff should consult with its regional and program office counterparts and OE to establish the implementation schedule, identify the implementation actions, and determine if and when enforcement action is appropriate. The responsible OD or RA, in collaboration with OE, must determine whether enforcement discretion is appropriate, and how it will be addressed in the facility specific backfit action.
- ~~3. In accordance with the backfitting provisions (e.g., 10 CFR 50.109(c)), scheduling criteria will include the importance of the backfitting action (i.e., safety or security significance, including risk) relative to other safety or security related activities underway, such as planned construction, outages, or other maintenance.~~
- ~~4.3.~~ For generic backfitting actions that are part of rulemaking, schedule considerations are addressed as part of the rulemaking process, and are typically included in the new regulations as implementation or scheduling provisions.

~~5.4.~~ A facility-specific backfitting action may be imposed by Order before completing any of these procedures if the OD who authorized the backfitting action determines that immediate imposition is necessary to ensure public health and safety or the common defense and security. In such cases, the appropriate OD must promptly notify the EDO of the action and, if possible, the staff must prepare a documented evaluation in time to be issued with the Order. If the documented evaluation cannot be issued with the Order, the evaluation must be completed as soon as possible after issuance of the Order and made publicly available.

#### F. Appeals of Backfitting ~~and Forward Fitting~~ Decisions

~~1.~~ As stated in Section I.B.1.c above, if a licensee believes that the staff has incorrectly followed the outlined process for imposing a forward fit, the licensee may use the backfitting appeals process described below to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors.<sup>23</sup>

~~1-2.~~ By NRC policy, the NRC affords licensees an opportunity to appeal any staff action that does not comport with the agency's backfit rules ~~backfitting action~~ at two levels: a First-Level Appeal to the OD or RA and a Second-Level Appeal to the EDO.

~~2-3.~~ The appeal process applies to the following two situations:

- (a) An applicable staff position that the NRC staff determined was not backfitting, but the licensee believes is backfitting, or
- (b) An applicable staff position that the NRC staff determined was backfitting, but the licensee believes was not properly justified, ~~including an appeal to modify or withdraw a backfitting action for which a backfit analysis was conducted or an appeal that a backfitting action justified by the adequate protection or compliance exception in fact must be justified through a backfit analysis.~~

~~3-4.~~ If at any time during an appeal process, the NRC determines the proposed action is unjustified backfitting, the responsible OD or RA, or designee, must document the decision and inform the licensee.

~~4-5.~~ The First-Level Appeal process must be ~~carried out-completed~~ before the Second Level Appeal process ~~begins~~. In the event a licensee addresses its initial appeal of a staff action to a level above the OD or RA, the appeal should be assigned to the OD of the program office that oversees the subject of the backfit, who will then oversee the First-Level Appeal process. ~~While a program OD or an RA can issue backfitting actions, a~~All backfitting appeals are overseen by a program OD, who will coordinate

<sup>23</sup> 50 FR 38097, 38101, September 20, 1985.



the review with the RA overseeing the affected facility, and ~~the OD for emergency preparedness or security issues, in the Office of Nuclear Security and Incident Response (NSIR), as applicable.~~

~~5-6.~~ First-Level Appeal:

- (a) The licensee may send a backfitting appeal in writing to the OD or RA whose staff proposed or issued the action. The program OD is responsible for deciding the appeal. This constitutes a First-Level Appeal.
- (b) During the review process, the OD may designate a panel to consider the appeal. A public meeting must be offered at which the licensee may discuss the appeal to ensure the NRC has a full understanding of the appeal. No determinations will be made at this public meeting.
- (c) During the review process and following any public meeting with the licensee, a meeting with the originating staff must be offered to discuss the backfitting action and supporting documentation to ensure a full understanding of the initial action in question.
- (d) After appropriate interoffice coordination and management review of the licensee's appeal, the program OD, working with the responsible RA and the NSIR OD, as applicable, must decide on the appeal. This process should be completed within 90 days of the date the NRC accepts the appeal.
- (e) The ~~applicable~~ Deputy EDO ~~responsible for the issuing office~~ must be informed of the decision before the program OD informs the licensee of the decision in writing.
- (f) If the backfitting action is ~~determined to be the correct regulatory path forward, following the written decision of the appropriate program OD~~ ~~sustained~~, the licensee may implement the action or submit a Second-Level Appeal.

~~6-7.~~ Second-Level Appeal:

- (a) If the licensee does not agree with the outcome of a First-Level Appeal, the licensee may file a second and final appeal to the EDO.
- (b) The EDO may designate a panel to consider the Second-Level Appeal. A public meeting with the licensee must be offered to discuss the licensee's appeal ~~documentation~~ and allow for a full understanding of the licensee's position.

- (c) The EDO's designated panel must consider all supporting staff analyses, submitted licensee analyses, and supplemented staff analyses, as well as any other information that is relevant and material to the appeal. Meetings with the staff involved in the original action in question and those involved in the First-Level Appeal must be offered to allow a full understanding of the staff position.
- (d) If the EDO determines that the action subject to a backfitting appeal is not considered backfitting, the action must not be treated further within the context of backfitting, but will be processed commensurate with the normal licensing or inspection appeal process.
- (e) If the EDO denies the appeal, the licensee must implement the action. If the licensee fails to implement the backfitting action, the appropriate OD must issue an Order. Once an Order is issued, whether or not it is immediately effective, MD 8.4 no longer applies. At this point, appeals are governed by the provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties."

#### G. Exceptions

The NRC staff is not required to make facility-specific backfitting findings when generic backfitting actions on the same issue(s) are, or have been, approved by the CRGR and EDO. This is also true for generic backfitting actions approved before November 1981, unless the EDO determines that significant facility-specific backfits were not considered during the prior reviews.

#### H. Assessment of the Overall Effectiveness of the NRC's Backfit and Forward Fit Management Program

The CRGR assesses, typically every 5 years, the effectiveness of the NRC's administrative controls for backfitting and forward fitting, as part of its regulatory effectiveness responsibility, and provides a report to the EDO.

### IV. INFORMATION COLLECTION PROCESS REQUESTS

#### A. NRC Regulations for Information Collection Requests

- ~~1. Demands for Information concerning alleged violations or potentially hazardous conditions or other facts are made pursuant to 10 CFR 2.204. Under Section 2.204, the NRC can require a licensee to respond for the purposes of determining if an Order under 10 CFR 2.202 should be issued, or whether other actions should be taken.~~

~~2.~~ Information requests to power reactor licensees are made pursuant to 10 CFR 50.54(f). Under 10 CFR 50.54(f), the NRC can require request its licensees to provide information to enable the Commission to determine whether or not a license should be modified, suspended, or revoked. This rule requires the NRC staff to justify these information requests with supporting analysis that demonstrates that the burden to be imposed on licensees is justified in view of the potential safety significance of the issue for which the information is requested. ~~The exceptions to this requirement to prepare a justification are as follows:~~

~~3.~~ No supporting analysis is required whenever there is reason to believe that public health and safety or the common defense and security may not be adequately protected, and information is needed to determine if this is the case and to take any necessary corrective actions.

~~4.~~ No supporting analysis is necessary if the staff seeks information of a type routinely sought as a part of the standard procedures for the review of applications for licenses or license amendments for facilities under construction, or the conduct of inspection activities for facilities under construction. However, if the request is not part of a routine licensing review (for example, if the staff seeks information to develop a new staff position), then the supporting analysis must include the reasons for the request and justify the estimated burden imposed on the licensee before issuance.

~~5-1.~~ No supporting analysis is necessary for licensing reviews or inspection activities for operating facilities, or for information requests sought to verify licensee compliance with the requirements in the LB for the facility. Requests for information made in connection with fact-finding reviews, inspections, and investigations of accidents or incidents are not usually made pursuant to 10 CFR 50.54(f). Furthermore, such requests are not normally considered within the scope of the backfitting rules.

~~6-2.~~ The requirements for information ~~collection~~ requests for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).

~~7-3.~~ The requirements for information ~~collection~~ requests for power reactor licensees under 10 CFR Part 52 are contained in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), and 10 CFR 52.171(c).

~~8-4.~~ The information request sent to the licensee should document the staff's evaluation of the applicable information collection requirements for the request.

#### **B. Evaluation Justification**

1. The program OD and the RAs must ensure that the staff establishes a reasonable basis for all information requests (except in cases that do not require justification). Specifically, the responsible OD or RA must do the following:

(a) Ensure that the staff has evaluated the request to determine whether the burden imposed on the licensee by the information request is justified, commensurate with the potential safety or security significance of the issue to be addressed. Such evaluation justification should consider the following:

- (i) Whether the NRC already has the information being requested,
- (ii) Whether the NRC can readily obtain the information absent a formal information request (for example, is the information available in the public domain),
- (iii) How to minimize the population of entities from whom information is being requested, and
- (iv) How to obtain the necessary information while minimizing the burden on requested entities.

(b) Approve the information request and the staff evaluation before transmittal of the request for information to a licensee.

2. The NRC staff's evaluations to demonstrate that an information request is justified must include at least the following elements:

- (a) A statement of the problem describing the need for the requested information in terms of its potential safety benefit,
- (b) The licensee actions required and an estimate of the cost to burden on the licensee to develop a response to the information request, and
- (c) An anticipated schedule for the NRC to analyze and act on the information.

## V. TRAINING PROGRAMS FOR BACKFITTING, FORWARD FITTING, AND INFORMATION COLLECTION REQUESTS

### A. Backfitting and Forward Fitting Training

The NRC ODs and RAs, informed by consultation with OGC and agency backfitting/forward fitting POCs, must plan for backfitting training for their staff that incorporates, at a minimum, the agency backfitting/forward fitting training program discussed below. NRC ODs and RAs may also provide additional backfit training that provides additional detail in areas pertinent to the region or office. ~~The agency backfitting training program should include beginner and advanced levels, as well as refresher courses.~~

#### B. Backfitting/**Forward Fitting** Agencywide Training Coordination

The Office of the Chief Human Capital Officer (OCHCO) must maintain and update a backfitting/**forward fitting** training program for the NRC staff. OCHCO will develop the backfitting/**forward fitting** training modules in consultation with OGC, CRGR, ~~and~~ program ODs, OE, RES, and NSIR. OCHCO will also consult and coordinate with the appropriate contact in the Office of the Chief Information Officer to ensure backfitting/**forward fitting** training modules are available online. The agency backfitting/**forward fitting** training program should include beginner, introductory and advanced levels, as well as refresher courses.

#### C. Information Collection Training

The NRC program offices should maintain information collection training and qualification for project managers with support from OGC. Regional inspection procedures and qualification do not apply to this training requirement.

### VI. ACRONYMS

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
BTP	Branch Technical Position
CAL	Confirmatory Action Letter
COL	Combined License
CP	Construction Permit
CRGR	Committee To Review Generic Requirements
DC	Design Certification
<del>DCR</del>	<del>Design Certification Rule</del>
DEDO	Deputy Executive Director for Operations
DH	Directive Handbook
EDO	Executive Director for Operations
ESP	Early Site Permit
GDC	General Design Criterion/criteria

ISFSI	Independent Spent Fuel Storage Installation
LAR	License Amendment Request
LB	Licensing Basis
LR	License Renewal
LRA	License Renewal Application
LWA	Limited Work Authorization
MD	Management Directive
ML	Manufacturing License
MRS	Monitored Retrievable Storage
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NSIR	Office of Nuclear Security and Incident Response
NUREG	NRC Technical Report Designation
NUREG/BR	NUREG Brochure
OCHCO	Office of the Chief Human Capital Officer
OD	Office Director
OE	Office of Enforcement
OGC	Office of the General Counsel
OL	Operating License
<del>PDC</del>	<del>Principal Design Criteria</del>
POC	Point of Contact
PRA	Probabilistic Risk Assessment
RA	Regional Administrator
RES	Office of Nuclear Regulatory Research
RG	Regulatory Guide

DH 8.4 MANAGEMENT OF BACKFITTING, ~~FORWARD~~  
~~FITTING~~, ISSUE FINALITY, AND INFORMATION  
~~COLLECTION~~REQUESTS

Date Approved: XX/XX/XXXX

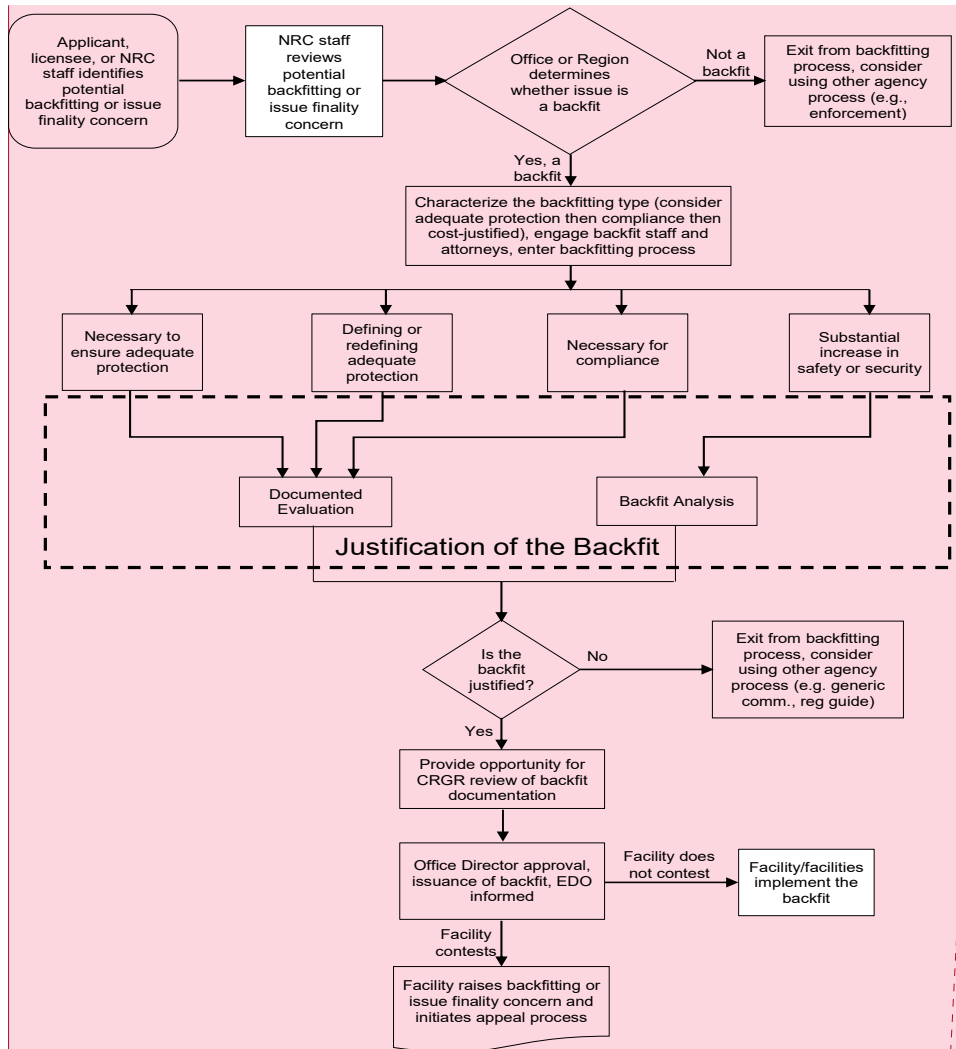
SDA	Standard Design Approval
SE	Safety Evaluation
SECY	Office of the Secretary
SER	Safety Evaluation Report
SLR	Subsequent License Renewal
SRM	Staff Requirements Memorandum
SSC	Structure, system, and component
<del>TR</del>	<del>Topical Report</del>
UFSAR	Updated Final Safety Analysis Report

## EXHIBITS

EXHIBIT 1 NRC Internal Backfitting and Issue Finality Flowchart

DRAFT

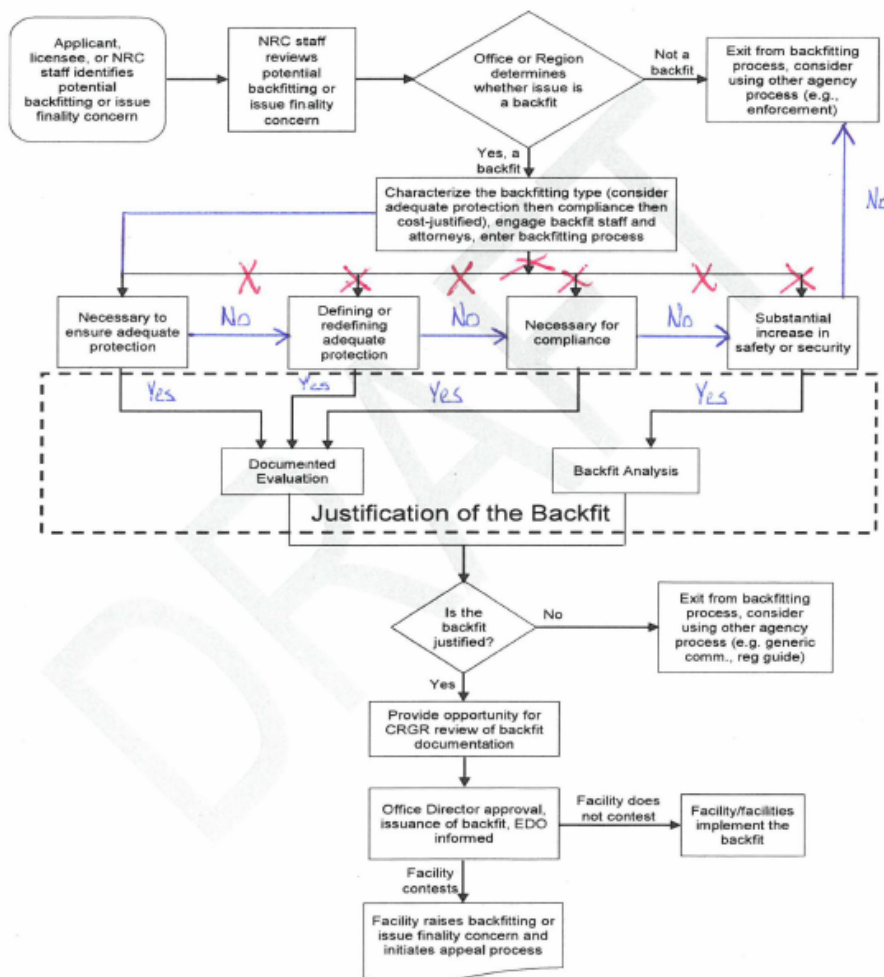




Commented [LR1]: See edits to exhibit on next page

## EXHIBITS

EXHIBIT 1 NRC Internal Backfitting and Issue Finality Flowchart



**Commented [LR2]:** Revise the two boxes that read: "Exit from backfitting process consider using other agency process (e.g. enforcement)" to read:

"Exit from backfitting process; document outcome."

**Commented [LR3]:** Delete the parenthetical from the box that starts with: "Characterize the backfitting type..."

EXHIBIT 2 NRC Internal Backfitting and Issue Finality Flowchart

[Revise octagon on far left to read "Issue dropped: document outcome."](#)

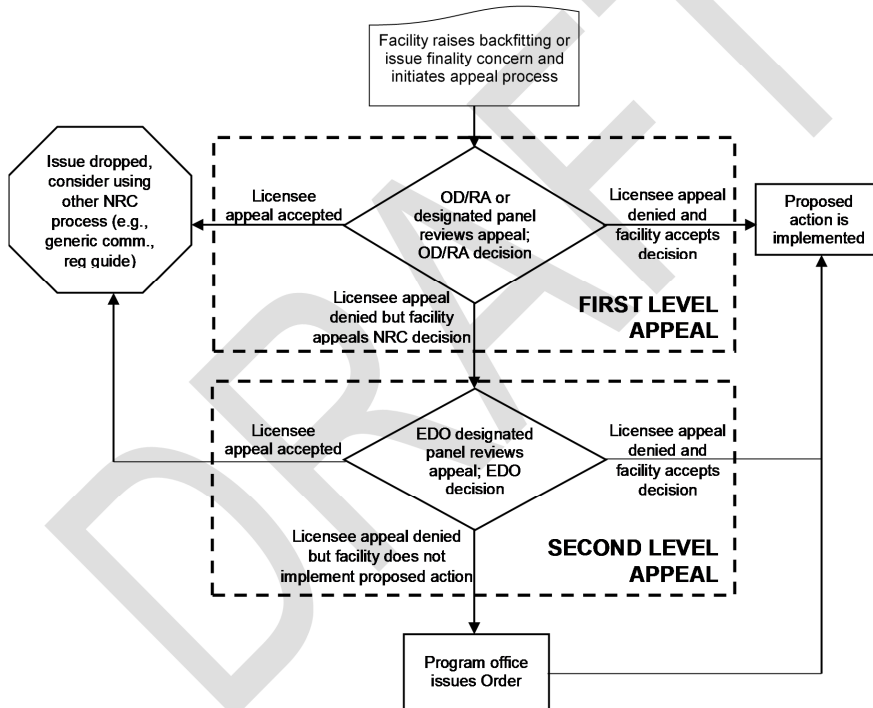


EXHIBIT 3 NRC Backfitting Requirements

Affected Entities	Backfitting/Issue Finality Regulation
Power Reactors (licensed under 10 CFR Part 50)	10 CFR 50.109
Power Reactors (permitted, certified, licensed or approved under 10 CFR Part 52)	10 CFR 50.109 and 10 CFR Part 52 (as noted below)
Early Site Permit (ESP)	10 CFR 52.39 (term of ESP) 10 CFR 52.31 (renewal)
Standard Design Certification <b>Rule (DCRDC)</b>	10 CFR 52.63 (term of <b>DCRDC</b> ) 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	10 CFR 52.145
Manufacturing License (ML)	10 CFR 52.171 (term of ML) 10 CFR 52.179 (renewal)
Licensees authorized to possess special nuclear material above a critical mass	10 CFR 70.76, Subpart H
Independent Spent Fuel Storage Installation	10 CFR 72.62
Gaseous Diffusion Plant	10 CFR 76.76