

U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 8.4	MANAGEMENT OF FACILITY-SPECIFIC BACKFITTING AND INFORMATION COLLECTION	DT-13-19
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<i>Volume 8:</i>	Licensee Oversight Programs
<i>Approved By:</i>	Mark A. Satorius Executive Director for Operations
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EXECUTIVE SUMMARY

Directive and Handbook 8.4 are being revised to reflect NRC’s organizational responsibilities and authorities with respect to the management of facility-specific backfits. MD 8.4 establishes the roles and responsibilities of various offices and provides guidance for the NRC staff to implement the facility-specific backfitting provisions of 10 CFR 50.109 for nuclear power reactor licensees; 10 CFR 70.76, 72.62, and 76.76 for selected nuclear materials licensees; and 10 CFR 52.39, 52.63, 52.83, 52.98, 52.145, and 52.171 for new power reactor licensees; as well as specific provisions of 10 CFR 50.54(f) and the corresponding requirements in Parts 70, 72, and 76, and 10 CFR 2.204.

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I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to have an effective program that will ensure that proposed facility-specific backfits¹ to be imposed on nuclear power reactor licensees, new power reactor licensees,² and selected nuclear materials licensees are

¹ In Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.109, "Backfitting," backfitting for a nuclear power reactor is defined as 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 rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after certain date(s). The "issue finality" provisions in 10 CFR Part 52 are different from those in 10 CFR 50.109 and the wording and structure between the two groups of provisions differ significantly. For selected nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, 72.62, and 76.76 are slightly different. The term "backfit" is not normally used in discussions relevant to new power reactors; the concept of "issue finality" is used rather than "backfit." In this MD, the NRC uses the terms "backfit" and "backfitting" to mean backfits as defined in 10 CFR 50.109 and issue finality matters under 10 CFR Part 52.

² The term "new power reactor licensees" will be understood as referring to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and manufacturing licenses (MLs), and applicants for design certifications (DCs); applicants for COLs if the application references an ESP, design certification rule (DCR), or SDA; and applicants for MLs if the application references a DCR or SDA.

appropriately justified on the basis of the backfitting provisions of applicable NRC regulations and the Commission's backfitting policy and guidance. Additionally, NRC requires the staff to appropriately justify information requests to the licensees.

II. OBJECTIVES

- Ensure that NRC-licensed facilities provide adequate protection of the public health and safety and common defense and security, and allow for substantial improvements in both safety and security, beyond adequate protection, while minimizing any unwarranted burden on NRC, the public, or licensees when implementing a backfitting action.
- Ensure that facility-specific backfitting of a nuclear power reactor licensee or nuclear materials licensee is appropriately justified and documented.
- Ensure that NRC-proposed amendments or changes to previously approved ESPs, DCs, SDAs, COLs, and MLs (i.e., backfits for new power reactors) are appropriately justified and documented.
- Specify that the Executive Director for Operations (EDO) is responsible for ensuring proper implementation of the backfitting process.
- Specify that the backfit analysis be approved by the appropriate office director or regional administrator (RA) and forwarded for information to the EDO before communicating the analysis to the licensee.
- Ensure that a facility-specific backfit will be communicated to the licensee only if necessary to provide an adequate level of safety and security, or after the required backfit analysis or documented evaluation is completed and approved.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Executive Director for Operations (EDO)

1. Is responsible for the NRC's backfitting actions.
2. Reviews and modifies any proposed facility-specific backfitting action on his or her own initiative or at the appeal of the affected licensee or stakeholders.
3. Authorizes deviations from this MD when in the public interest and when the deviation otherwise complies with the applicable NRC regulations, public laws, and Executive Orders.

B. Office of the General Counsel (OGC)

1. Identifies backfits and performs legal reviews of staff-initiated facility-specific backfits.

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2. Provides legal advice and assistance during the backfit identification, justification, imposition, and licensee appeal processes.

C. Committee To Review Generic Requirements (CRGR)

1. Monitors the overall effectiveness of the NRC's generic backfitting management process.
2. Periodically conducts audits, typically every 5 years, to assess the effectiveness of the NRC's administrative controls for facility-specific backfitting as part of its regulatory effectiveness responsibility.
3. Develops the necessary guidance to conduct audits of the NRC's administrative controls for facility-specific backfitting practices in various headquarters and regional offices.
4. Reviews new and revised office and regional procedures developed in accordance with this directive to ensure consistency among the offices and regions in implementing the provisions of the NRC's backfitting rules. The CRGR review focuses on the staff practices for facility-specific backfitting management and assesses the adequacy of management direction, programmatic and administrative controls, interoffice coordination for processing backfits, and staff guidance and training.
5. Ensures that the offices and regions have adequate administrative controls that plainly communicate the backfitting process to the licensee. Also ensures that the responsible staff³ promptly enter the backfitting decision into the Agencywide Documents Access and Management System (ADAMS), and make it publicly available. (Classified information or information deemed to be Safeguards Information pursuant to 10 CFR 73.21 must not be placed in ADAMS and shall be kept in the appropriate facilities for handling and storage. Additionally, proprietary or sensitive information must be excluded from the public domain in ADAMS. All the above-mentioned records shall be managed in accordance with the appropriate agency policy and procedures.)
6. Periodically meets with the stakeholders to fulfill CRGR's regulatory effectiveness responsibilities by soliciting direct feedback from the stakeholders and advises the EDO when modifications to the backfitting process are necessary.

³ The office or the region that initiated the backfitting action supports the oversight office (the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Federal and State Materials and Environmental Management Programs, or the Office of New Reactors) that has the obligation to impose and dispose the backfit.

7. Participates in a backfit review panel at the request of the EDO.

D. Director, Office of Nuclear Regulatory Research (RES)

1. Revises, as appropriate, this MD to include pertinent CRGR recommendations, EDO decisions, and Commission directives for enhancing the NRC's facility-specific backfit control program.
2. Maintains and revises NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and related documents and tools, as necessary. (NRR is responsible for initiating the revision and requesting support for the needed technical basis from RES.)
3. Provides administrative support for the routine CRGR activities.
4. Coordinates with the Office of the Chief Human Capital Officer (OCHCO) to ensure that Human Resources Training and Development (HRTD) provides appropriate training for the RES staff and ensures that the RES staff performance meets the requirements of this MD.
5. Maintains the backfit implementation section of the NRC regulatory guides relating to all types of nuclear facilities and, working with OGC, revises the section as needed.
6. Designates a point of contact (POC) who is responsible for procedures and processes specific to relevant backfitting activities (generic and facility-specific). The POC updates procedures and processes as needed. The POC also ensures that the RES staff is proficient in the specific office training program relevant to backfitting activities.

E. Director, Office of Enforcement (OE)

1. Defines and implements appropriate administrative controls to support the office or regional staff in processing compliance backfits.
2. Consults with the responsible office, as appropriate, on all proposed compliance backfits and advises on their imposition, including negotiating a schedule with the licensee for implementing compliance backfits.
3. If an Order is issued, supports the oversight office in accordance with 10 CFR Part 2, Subpart B.
4. Coordinates with HRTD to provide appropriate training for the OE staff and ensures that the OE staff performance meets the requirements of this MD.

F. Director, Office of Nuclear Security and Incident Response (NSIR)

1. Develops, updates, and maintains security-related backfitting procedures and administrative controls to identify, justify, and process security-related facility-specific backfits, including appeals for nuclear power reactor licensees and selected nuclear materials licensees. The NSIR backfitting procedures are coordinated with the Office of New Reactors (NRO), the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of Federal and State Materials and Environmental Management Programs (FSME), and the regional offices.
2. Designates an NSIR manager (division director or higher) who coordinates with NRR, NRO, FSME, NMSS, and OGC, as appropriate, to issue nuclear power reactor and nuclear materials facility related backfits to the licensee, after approval of the supporting documentation by the Director of NRR, the Director of NRO, the Director of FSME, and the Director of NMSS, as appropriate, in accordance with this MD.
3. Ensures consistency of the NSIR backfitting procedures with pertinent inspection procedures.
4. Consults and coordinates, as appropriate, with the Director of NRR, the Director of NMSS, the Director of FSME, and the Director of NRO to resolve issues with proposed security related facility-specific backfits. The Director of NSIR shall support the Director of NRR, the Director of NMSS, the Director of FSME, and the Director of NRO, as appropriate, in processing security-related backfits, including resolution of licensee backfit appeals.⁴
5. Coordinates with HRTD to provide appropriate training for the NSIR staff and ensures that the NSIR staff performance meets the requirements of this MD.
6. Designates a POC who is responsible for procedures and processes specific to relevant backfitting activities (generic and facility-specific). The POC updates procedures and processes as needed. The POC also ensures that the NSIR staff is proficient in the specific office training program relevant to backfitting activities.

⁴ The Director of NRR imposes facility-specific backfits concerning nuclear power reactors and forwards licensee appeals on security-related backfits to the Director of NSIR for disposition. The Director of NMSS imposes facility-specific backfits concerning selected nuclear materials facilities and forwards any licensee appeals on security-related backfits to the Director of NSIR for disposition. The Director of NRO imposes all facility-specific backfits concerning new nuclear power reactors and forwards any licensee appeals on security-related backfits to the Director of NSIR for disposition. If a licensee refuses to implement an imposed backfit, the Director of NRR, the Director of NMSS, or the Director of NRO, as appropriate, shall issue an Order. NRC regulations concerning backfitting protection for nuclear materials licensees do not apply to FSME licensees, so FSME does not have any direct backfitting responsibilities. See Section III.I of this directive.

G. Directors, Office of Nuclear Reactor Regulation (NRR) and Office of Nuclear Material Safety and Safeguards (NMSS)

1. Develop, update, and maintain backfitting procedures and administrative controls for nuclear power reactors, including decommissioning reactors, and selected nuclear materials facilities, including independent spent fuel storage installations (ISFSIs) licensed pursuant to the general and site-specific provisions of 10 CFR Part 72, fuel cycle facilities licensed pursuant to the site-specific provisions of 10 CFR Part 70, and gaseous diffusion plants certified pursuant to the site-specific provisions of 10 CFR Part 76. Coordinate backfitting procedures with the other program offices (NSIR, NRO, RES, and FSME), and the regional offices.
2. Each designate a manager from their respective offices (division director or higher) who notifies the licensee of any nuclear power reactor or nuclear materials facility of backfits after approval of the supporting documentation by the Director of NRR or NMSS, as applicable, in accordance with this MD. Coordinate with NRO for information and/or applicability determination.
3. Ensure consistency between the pertinent inspection procedures and the backfitting procedures.
4. Effectively communicate to the licensees the applicable NRR or NMSS practices and staff guidance for handling facility-specific backfitting for nuclear facilities.
5. Consult and coordinate with RAs, NSIR, FSME, NRO, RES, and OGC, as appropriate, to resolve issues with proposed facility-specific backfits in the program areas for which NRR or NMSS has the oversight responsibility or whose activities may affect the security of nuclear power reactors or impact selected nuclear materials facilities. The applicable Director of NRR or NMSS also coordinates potential security-related backfits with the Director of NSIR and the appropriate RA. Coordinate with NRO for information and/or applicability determination.
6. Coordinate with NSIR and the affected regional office, as appropriate, and approve the supporting documentation for facility-specific backfits within NRR's or NMSS's, as applicable, program area of responsibility before communicating the backfit analysis to the licensee. Provide supporting documentation to NRO for information and/or applicability determination.
7. Decide licensee appeals on imposition of all backfits within the NRR or NMSS, as applicable, program area of responsibility and forward any appeals of security-related backfits to the Director of NSIR. These appeal decisions are subject to review by the EDO.

8. Ensure entry of all the backfitting communications and decisionmaking, including the outcome of backfit appeals, into ADAMS. Exceptions are noted in Section III.C.5 of this directive.
9. Coordinate with HRTD to provide appropriate training for their respective staffs and ensure that the respective staff performance meets the requirements of this MD.
10. Initiate revision of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (NRR only). (RES implements the revisions and maintains NUREG/BR-0058.)
11. Designate a POC for each office who is responsible for procedures and processes specific to relevant backfitting activities (generic and facility-specific). The POC updates procedures and processes as needed. The POC also ensures that the NRR or NMSS staff, as appropriate, is proficient in the specific office training program relevant to backfitting activities.

H. Director, Office of New Reactors (NRO)

1. Develops, updates, and maintains procedures and administrative controls for NRC-proposed amendments or changes to previously approved ESPs, DCs, SDAs, COLs, and MLs (i.e., backfits for new power reactor licensees).
2. Designates an NRO manager (division director or higher) who notifies the new power reactor licensee of NRC-proposed backfits after approval by the Director of NRO of the documentation addressing the applicable issue finality provision in accordance with this MD.
3. Ensures consistency between the pertinent inspection procedures and the procedures for proposing backfits for new power reactor licensees.
4. Effectively communicates to the licensees or applicants the NRO practices and staff guidance for NRC-proposed backfits for new power reactor licensees.
5. Consults and coordinates with RAs, NSIR, NMSS, FSME, NRR, and OGC, as appropriate, to resolve issues with NRC-proposed backfits for new power reactor licensees
6. Coordinates with NSIR, NMSS, FSME, NRR, RES, OGC, and the affected regional office, as appropriate, and approves the documentation addressing the issue finality provisions for backfits for new power reactor licensees before communicating the documentation to the licensee.
7. Decides licensee appeals on imposition of all backfits within the NRO program area of responsibility and forwards any appeals of security-related backfits to the Director of NSIR. These appeal decisions are subject to review by the EDO.

8. Ensures entry of all the backfitting communications and decisionmaking, including the outcome of backfit appeals, into ADAMS. Exceptions are noted in Section III.C.5 of this directive.
9. Coordinates with HRTD to provide appropriate training for the NRO staff and ensures that the NRO staff performance meets the requirements of this MD.
10. Designates a POC who will be responsible for procedures and processes specific to relevant backfitting activities (generic and facility-specific). The POC updates procedures and processes as needed. The POC ensures that the NRO staff is proficient in the specific office training program relevant to backfitting activities.

I. Director, Office of Federal and State Materials and Environmental Management Programs (FSME)

Supports NSIR and NMSS (and other program offices or regions) as stated in this MD. FSME does not have any direct backfitting responsibilities in this MD because no backfitting provisions exist in NRC regulations related to FSME licensees.

J. Chief Human Capital Officer (CHCO)

1. Develops, maintains, and updates, in consultation with OGC and in coordination with other offices and regions, a backfitting training program, including generic and facility-specific backfitting training modules and refresher courses, for the NRC's technical staff.
2. Consults and coordinates with the appropriate contact in the Office of Information Services (OIS) to maintain the training modules online.

K. Director, Office of Information Services (OIS)

1. Maintains backfitting records in ADAMS.
2. Advises the offices and regions on implementing administrative controls to ensure that public accessibility of backfitting information is restricted, as noted in Section III.C.5 of this directive.
3. Assists in the design, development, and accessibility of the backfit Web page on the NRC's internal and external Web sites.

L. Regional Administrators (RA)

1. As applicable, develop, update, and maintain the backfitting procedures and administrative controls for nuclear power reactor licensees and selected nuclear materials licensees in accordance with this directive to ensure proper application of the provisions of NRC's backfitting rules. Notwithstanding any region-specific

administrative controls, ensure consistency of backfitting procedures among the regions. Coordinate backfitting procedures with NRR, NRO, NMSS, FSME, and NSIR.

2. Designate a manager for each region (division director or higher) who notifies the licensee of any nuclear power reactor and nuclear materials facility of backfits after approval of the supporting documentation by the RA in accordance with this MD.
3. Ensure consistency between the pertinent inspection procedures and the regional backfitting procedures.
4. Effectively communicate to licensees the regional practices and staff guidance for handling safety- and security-related backfitting for nuclear power reactor licensees and nuclear materials licensees.
5. Consult and coordinate with the Director of NSIR, and with either the Director of NRR, NRO, FSME, or NMSS, as appropriate, to resolve security-related facility-specific backfits.
6. Coordinate with NSIR, NRR, NRO, FSME, and NMSS, as appropriate, and approve the supporting documentation for facility-specific backfits within the region's program area of responsibility before communicating the backfit analysis to the licensee.
7. Decide licensee backfit appeals within the regional area of responsibility and forward any security-related appeals to the Director of NSIR. These appeal decisions are subject to review by the EDO.
8. Ensure entry of all documents and records related to backfits originating in the region, including communications, decisionmaking, and the outcome of backfit appeals into ADAMS. Exceptions are noted in Section III.C.5 of this directive.
9. Provide appropriate training for the regional technical staff and ensure that the staff performance meets the requirements of this MD.
10. Designate a POC who will be responsible for procedures and processes specific to relevant backfitting activities (generic and facility-specific) and accomplishes updates as needed. The regional POC also ensures that the associated regional staff is proficient in a region-specific training program relevant to backfitting activities.

IV. APPLICABILITY

The policy and guidance in this directive and handbook apply to all NRC employees.

V. HANDBOOK

For effective regulation of NRC-licensed facilities, it is crucial that various control points in the backfitting management program be well defined, that staff members clearly understand their obligation for responsibly implementing all aspects of the backfitting program, and that managers ensure staff performance is in accordance with this MD. Handbook 8.4 explains the components of NRC's facility-specific backfitting management program.

VI. REFERENCES

Code of Federal Regulations

10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders."

10 CFR 2.204, "Demand for Information."

10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

10 CFR 50.12, "Specific Exemptions."

10 CFR 50.54, "Conditions of Licenses."

10 CFR 50.109, "Backfitting."

10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants."

10 CFR 52.31, "Criteria for Renewal."

10 CFR 52.39, "Finality of Early Site Permit Determinations."

10 CFR 52.57, "Application for Renewal."

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 Part 52, Appendix N, "Standardization of Nuclear Power Plant Designs; Combined Licenses to Construct and Operate Nuclear Power Reactors of Identical Design at Multiple Sites."

10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

10 CFR 70.22, "Contents of Applications."

10 CFR 70.76, "Backfitting."

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."

10 CFR 72.62, "Backfitting."

10 CR 73.21, "Protection of Safeguards Information: Performance Requirements."

10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

10 CFR 76.76, "Backfitting."

10 CFR 76.70, "Post Issuance."

Nuclear Regulatory Commission Documents

Charter of the Committee To Review Generic Requirements (ML110620618).

EDO Memorandum, "Implementation of an ADAMS-Based Record Access System for Facility-Specific Backfits," February 22, 2006 (ML052720147).

Memorandum to James M. Taylor and William C. Parler from Samuel J. Chilk, "SECY-93-086, Backfit Considerations," June 30, 1993 (ML003760758).

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (ML042820192).

NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook" (ML050190193).

NUREG-1409, "Backfitting Guidelines," July 1990 (ML032230247).

Staff Requirements Memorandum, SECY-98-185, Proposed Rulemaking, "Revised Requirements for the Domestic Licensing of Special Nuclear Material," December 1, 1998 (ML991880012).

United States Code

Energy Reorganization Act of 1974, as amended (42 U.S.C. 5801 et seq.).

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I. INTRODUCTION

A. Backfitting

1. Backfitting is the process by which the U.S. Nuclear Regulatory Commission decides whether to impose new or revised regulatory requirements or staff positions on nuclear power reactor licensees or selected nuclear materials licensees. Backfitting is an integral part of the regulatory process. To ensure that proposed changes are justified and defined, a backfit is implemented only after formal and systematic review.
2. Title 10 of the *Code of Federal Regulations* (10 CFR) contains the NRC's backfit and issue finality rules for nuclear power reactor licensees and selected nuclear materials licensees. Specifically, 10 CFR 50.109 applies to nuclear power reactor licensees, 10 CFR 52.39, 52.63, 52.83, 52.98, 52.145, and 52.171 apply to new power reactor licensees¹, and 10 CFR 70.76, 72.62, and 76.76 apply to selected nuclear materials licensees, including licensees of fuel facilities, spent fuel and radioactive waste storage facilities, and certificate holders for the gaseous diffusion plants. Currently there are no backfitting rules applicable to test, training, or research reactors licensed under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."
3. The NRC's backfitting rules relate to agency actions that impose new or revised staff positions or requirements on operating nuclear power reactor licensees and selected nuclear materials licensees. The backfitting rules do not apply to voluntary license changes, where "voluntary" is defined as any action by the licensee that was made of its own accord, without the force of a legally binding requirement or an NRC representation of a further licensing or enforcement action. Furthermore, the backfitting rules do not apply to NRC-requested actions with which licensees need not comply.
4. In 10 CFR 50.109, backfitting for nuclear power reactor licensees is defined as 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 rules or the imposition of

¹ The term "new power reactor licensees" will be understood as referring to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and manufacturing licenses (MLs), and applicants for design certifications (DCs); applicants for COLs if the application references an ESP, design certification rule (DCR), or SDA; and applicants for MLs if the application references a DCR or SDA.

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- a staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after certain specified dates.²
5. The terminology and criteria associated with "backfit" for nuclear power reactor licensees under Part 50 are different from those used for new power reactor licensees under Part 52. Part 52 uses the concept of "issue finality" with regard to early site permits (ESPs), design certification rules (DCRs), combined licenses (COLs), standard design approvals (SDAs), and manufacturing licenses (MLs).
 6. Facility-specific backfits are governed by this management directive (MD).³ All regional offices and the Offices of Nuclear Regulatory Research (RES), Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), New Reactors (NRO), and Nuclear Security and Incident Response (NSIR) are required to develop, maintain, and implement procedures in accordance with this MD.
 7. NRC staff positions may be identified as potential backfits either by the staff or by licensees. The office director or the regional administrator (RA) having the responsibility to develop a staff position shall consider the issue at hand. The office director or RA makes the final determination as to whether the staff position is a backfit and whether the proposed backfit is imposed on the licensee.
 - (a) For all security-related backfits, NSIR shall coordinate with NRO, NRR, FSME, or NMSS, as appropriate.
 - (b) For all compliance backfits, the responsible office or region shall consult and coordinate with the Office of Enforcement (OE) and seek advice from the Office of the General Counsel (OGC).

² Applicable NRC action can be considered backfitting if the agency action occurs after—

- The issuance of the construction permit for the facility (for facilities with construction permits issued after October 21, 1985).
- Six months before the date of docketing of the operating license (OL) application for the facility (for facilities with construction permits 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 of 10 CFR Part 52.
- The issuance of a manufacturing license under Subpart F of 10 CFR Part 52.
- The issuance of the first construction permit issued for a duplicate design under Appendix N of 10 CFR Part 50.
- The issuance of a combined license under Subpart C of Part 52.

³ Hereafter, the term "facility" will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a new power reactor; or a nuclear materials facility such as an independent spent fuel storage installation, fuel facility, gaseous diffusion plant, or a monitored retrievable storage installation.

- (c) The RAs, NSIR, NRR, NMSS, and FSME should consult and coordinate, as appropriate, with each other to resolve issues with proposed facility-specific backfits that may impact security in an area of oversight responsibility of NRR or NMSS. The Director of NRR or NMSS shall also coordinate potential security-related backfits with the Director of NSIR and the appropriate RA.
8. Exhibits 1 and 2 to this handbook are flowcharts that illustrate NRC's program for processing facility-specific backfits and backfit appeals.

B. Information Collection Requests

1. The provisions of 10 CFR 50.54(f) require nuclear power reactor licensees to respond to both generic and facility-specific information requests from the staff. This rule stipulates that except for information sought to verify licensee compliance with the current licensing basis, NRC must prepare the reasons for the information request to ensure that the burden imposed on licensees is justified in view of the potential safety (or security) significance of the issue to be addressed.
2. Requests for information for nuclear power reactors to be licensed under 10 CFR Part 52 will be in accordance with the administrative requirements in 10 CFR Part 50, and as stated in 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c) as applicable. The information collection requirements for selected nuclear materials facility licensees are contained in 10 CFR 70.22(d), 72.62(d), and 76.70(e).
3. All facility-specific requests for information are governed by this MD (see Section IV of this handbook).

C. Responsibilities and Authorities

The Executive Director for Operations (EDO) is responsible for the NRC's backfitting actions. All the headquarters and regional offices that are involved in backfitting shall be responsible for developing and maintaining the office and regional backfitting procedures, implementing programmatic and administrative controls, and providing comprehensive staff guidance on implementing provisions of NRC's backfitting rules. As part of its regulatory effectiveness responsibilities, the Committee To Review Generic Requirements (CRGR) is responsible for assessing the overall effectiveness of the administrative controls for the NRC's backfitting control program, soliciting direct feedback from the stakeholders, and advising the EDO to enhance NRC's backfitting controls.

D. Coordination and Communication

For an effective implementation of the NRC's backfitting program, the office directors and the RAs shall ensure:

1. Effective communication and coordination between their counterparts, as well as among the responsible technical staffs within the headquarters and the regional offices.
2. That the office and regional backfitting processes, including procedures as well as the programmatic and administrative controls, are written in plain language and made publicly available.
3. That a record of the backfitting decisions, including the outcome of any licensee backfit appeals, shall be entered into the Agencywide Documents Access and Management System (ADAMS) and made publicly available, with the exception of any proprietary, classified, or sensitive information or any Safeguards Information. Proprietary or sensitive information must be excluded from the public domain in ADAMS. Classified and Safeguards Information shall be kept in the approved facilities for handling and storage. All the above-mentioned records shall be managed in accordance with the applicable agency policy and procedures.
4. That all backfitting workshops or meetings with the stakeholders on the NRC's backfitting control program are open to the public and are appropriately noticed.

E. Recordkeeping

All the NRC offices and regions directly involved in backfitting shall be responsible for tracking the backfitting actions originating in that office or region.

1. The backfitting proposing office or region shall administratively manage each proposed facility-specific backfit by maintaining all records related to it. Records will be maintained in accordance with NUREG-0910, "NRC Comprehensive Records Disposition Schedule."
2. All backfit-related information shall be entered into ADAMS and made publicly available, with the exception of any proprietary, classified, or sensitive information or any Safeguards Information pursuant to 10 CFR 73.21.⁴ Proprietary or sensitive information must be excluded from the public domain in ADAMS. Classified and

⁴ The oversight office will have precedence over all other offices and regions with regard to how the backfit-related information is classified in ADAMS.

Safeguards Information shall be kept in the approved facilities for handling and storage. Except as noted, ADAMS shall be the single repository of all the backfit decisionmaking, including the outcome of any licensee backfit appeals, as well as cross-references to all the communications issued or received by NRC staff with respect to a facility-specific backfit. All the above-mentioned records shall be managed in accordance with the applicable agency policy and procedures.

3. Except as noted above, backfitting records placed in ADAMS shall be accessible to the stakeholders by being profiled as publicly available. The records should be entered according to the instructions outlined in the EDO memorandum, dated February 22, 2006, titled, "Implementation of an ADAMS-Based Record Access System for Facility-Specific Backfits" (ADAMS Accession No. ML052720147).

II. INTRODUCTION TO THE FACILITY-SPECIFIC BACKFIT MANAGEMENT PROGRAM

A. Applicability

1. The NRC's backfitting rules relate to the agency actions that impose new or revised staff positions or requirements on licensees. They do not apply to the following:
 - (a) Implementation of NRC-recommended actions that are voluntary for the licensee and do not constitute the basis for resolution of a safety or regulatory issue.
 - (b) The conditions of voluntary license amendments, which are requested by the licensee, rather than those imposed on the licensee by the NRC by rule or order (including licensing).
 - (c) Non-mandatory relaxations to staff positions.
 - (d) Administrative changes such as number of Safety Analysis Report (SAR) copies submitted by a licensee.
 - (e) Changes to reporting and recordkeeping requirements.
 - (f) Changes mandated by statute without agency discretion in its implementation.
2. If the NRC staff expects any existing licensee to use or commit to using voluntary guidance (e.g., regulatory guides), then that guidance is considered a backfit. Additionally, if the NRC staff expects or plans to request licensees to adopt voluntary guidance to resolve a generic regulatory issue, then that guidance is considered a backfit.

3. If an existing licensee voluntarily seeks 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 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. This is not considered backfitting or a violation of any of the issue finality provisions.
4. A relaxation is a proposed or modified regulatory initiative reducing an existing requirement. If the implementation of this regulatory initiative is voluntary for the licensee, then this action is not a backfit. However, if a relaxation is mandatory, then the relaxation is considered a backfit.

B. Nonapplicability

The current NRC backfitting regulations apply to holders of licenses for nuclear power reactors, new power reactors, and selected nuclear materials facilities; however, they do not apply to the test, research, or training reactors licensed under 10 CFR Part 50.

III. OVERVIEW OF THE FACILITY-SPECIFIC BACKFIT MANAGEMENT PROGRAM

A. Facility-specific Backfits

The backfitting rules apply to facility-specific backfitting of nuclear power reactors, including decommissioning reactors and selected nuclear materials facilities. Facility-specific backfitting is the result of the staff's attempt to ensure that a particular facility provides adequate protection for the public health and safety and common defense and security, or complies with Commission rules or orders or the licensee's written commitments or license. This MD covers only facility-specific backfitting. The CRGR Charter (ADAMS Accession No. ML110620618) covers generic backfitting.

1. NRC's Backfitting Regulations

- (a) Sections 50.109, 70.76, 72.62, and 76.76 of the Commission's regulations contain backfitting provisions for nuclear power reactor licensees and selected nuclear materials licensees, including licensees of fuel facilities, spent fuel and radioactive waste storage facilities, and the gaseous diffusion plants.
- (b) Furthermore, there are "issue finality" provisions (similar to backfitting restrictions) found under the following provisions of 10 CFR Part 52:
 - (i) Early site permits under Subpart A, Section 52.39, "Finality of Early Site Permit Determinations";

- (ii) Design certifications under Subpart B, Section 52.63, “Finality of Standard Design Certifications”;
 - (iii) Applications for combined licenses and combined licenses under Subpart C, Section 52.83, “Finality of Referenced NRC Approvals; Partial Initial Decision on Site Suitability,” and Section 52.98, “Finality of Combined Licenses; Information Requests”;
 - (iv) Standard Design Approvals under Subpart E, Section 52.145, “Finality of Standard Design Approvals; Information Requests”; and
 - (v) Manufacturing Licensees under Subpart F, Section 52.171, “Finality of Manufacturing Licenses; Information Requests.”
- (c) Backfitting provisions are also applicable to standardized nuclear power plants of identical design at multiple sites as provided for in Appendix N to 10 CFR Part 52.

2. Backfitting Determination

- (a) NRC staff positions may be identified as potential backfits⁵ either by the staff or by any stakeholder. Such identifications will be considered by the office director or the RA having the responsibility to develop the staff positions on the issue. This office director or RA shall determine if the new or changed staff position is a backfit, prepare the appropriate analysis required by the applicable backfitting rule, and decide whether the proposed backfit should be imposed on the licensee.
- (b) The NRC staff shall be responsible for identifying potential facility-specific backfits. The staff shall evaluate any proposed facility-specific position with respect to whether or not the proposed position qualifies as a backfit.
- (c) No staff position shall be communicated to the licensee unless the NRC official communicating that position has ascertained whether the proposed position is a backfit and, if so, ensured that the proposed position is identified as a backfit and the appropriate material (i.e., documented evaluation or backfit analysis) has been prepared and approved.
- (d) The staff may recommend terminating a proposed agency action that would constitute a backfit when the staff concludes that the proposed backfit is not likely to be a substantial increase in overall protection, or that the direct and indirect

⁵ The term “potential backfit” shall be applied to a new or changed staff position for which the NRC staff has not yet performed an evaluation to ascertain whether the staff position is a backfit or not.

costs of implementation are not likely to be justified. The office director or the RA having the program area responsibility may approve closing the issue, with appropriate notice sent to all parties and recorded in ADAMS (see also Section III.C.5 of this directive).

- (e) Exhibit 3 to this handbook contains staff guidance for determination of potential backfits.

3. Backfit Types

(a) Cost-Justified Substantial Increase in Protection

- (i) The NRC staff can impose a backfit if the staff prepares an analysis under the provisions of NRC's backfitting rules demonstrating that the backfit constitutes a substantial increase in protection to the public health and safety or common defense and security whose costs are justified in light of the increased protection.
- (ii) Under 10 CFR 72.62, the Commission can require the backfitting of an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS) installation if it finds that the backfit 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.

(b) Exceptions to requirement to prepare a backfit analysis

- (i) Three types of backfits are recognized in the NRC backfitting rules at 10 CFR 50.109, 70.76, and 76.76 as actions that do not require the NRC staff to prepare a backfit analysis:
- Action necessary to bring a facility into compliance with the facility license, rules or orders of the Commission, or written commitments by the licensee,
 - Action necessary to ensure that the facility provides adequate protection of public health and safety or common defense and security, and
 - Action that involves defining or redefining the level of adequate protection.
- (ii) Because a backfit analysis is not prepared, staff does not need to make a finding of substantial safety improvement and does not consider costs.
- (iii) Under Section 72.62, the Commission will require the imposition of a backfit if it finds that the backfit is necessary to:
- Assure adequate protection to occupational or public health and safety;

- Bring an ISFSI or MRS into compliance with a license or the Commission's orders or rules; or
- Bring an ISFSI or MRS into conformance with written licensee commitments.

(c) Special backfitting provisions for 10 CFR Part 52

- (i) 10 CFR Part 52 contains issue finality provisions applicable to ESPs, DCRs, COLs, SDAs, and MLs.
- (ii) The standards for making changes to previously-approved ESPs (10 CFR Part 52.39), DCRs (10 CFR Part 52.63), COLs (10 CFR Part 52.83 and 10 Part 52.98), SDAs (10 CFR Part 52.145), and MLs (10 CFR Part 52.171) vary. See Exhibit 4 to this handbook.
- (iii) The backfitting provisions in 10 CFR 50.109 can apply to COLs, SDAs, and MLs.

4. Process for Imposing a Facility-specific Backfit

- (a) The imposition of a facility-specific backfit is governed by this MD, which establishes the staff requirements and provides guidance for implementation of this aspect of the backfitting rules.
- (b) In this context, it should be noted that an action proposed by the licensee is not a backfit, even though the action may result from normal discussions between the staff and the licensee concerning an issue.
- (c) The office director or the RA shall approve the documented evaluation or the backfit analysis prepared by the office or regional staff. The Director of NRR, the Director of NMSS, the Director of NRO, the Director of NSIR, or the RA, as appropriate, is responsible for final disposition of all backfits, including security-related backfits.
- (d) For backfits within the NRR, NMSS, or NRO program area of responsibility, which are proposed by the NRR, NMSS, or NRO staff, respectively, the Director of NRR, NMSS, or NRO, respectively, without further delegation, shall approve the supporting analysis before communicating with the licensee. For all security-related backfits, NSIR shall coordinate with NRO, NRR, FSME, or NMSS, as appropriate.
- (e) After the appropriate office director or RA has approved the documented evaluation or backfit analysis, the responsible division director shall issue the backfit requirement to the licensee. The licensee may choose to implement the backfit or appeal it.

- (f) Implementation of a facility-specific backfit is normally accomplished on a schedule discussed between the licensee and NRC. The staff should consult OE and OGC for establishing the implementation schedule to identify the implemented actions and confirm when enforcement actions may be taken.
- (g) Scheduling criteria should include the importance of the backfit relative to other safety- or security-related activities underway, such as planned construction or maintenance. During the staff's evaluation and backfit transmittal process, or a subsequent licensee appeal process, the proposing office or region shall track each proposed facility-specific backfit. The staff shall include in ADAMS all the references to documents issued or received by NRC staff relative to facility-specific backfits, including requests, positions, statements, and summary reports (see also Section III.C.5 of this directive).
- (h) A staff-proposed backfit may be imposed by order before completing any of these procedures if the NRC official who authorizes the order determines that immediate imposition is necessary to ensure public health and safety or common defense and security. In such cases, the program office director shall promptly notify the EDO of the action; a documented evaluation shall be prepared, if possible, in time to be issued with the order.

5. Licensee Claim of a Backfit and Backfit Appeals

- (a) In some cases, a staff-proposed position that has not been identified by the NRC staff as a backfit position is claimed to be a backfit by the licensee. The licensee may also challenge the rationale for the staff-identified backfit. In either case, the licensee must submit the backfit claim in writing to the office director or the RA. A copy of the claim should be sent to the EDO by the office director or the RA that received the backfit claim. All backfit claims documentation (licensee and staff generated) shall be entered into ADAMS.
- (b) The division that issued the staff position shall review the licensee claim. If it is determined that the issue is a backfit, the appropriate staff office should immediately review the issue and determine the path forward. The staff shall proceed with the preparation of any required documented evaluation or supporting analysis for interoffice coordination and management approval in accordance with this MD.
- (c) For a staff position within NRR, NMSS, or NRO jurisdiction that is claimed to be a backfit by the licensee, the Director of NRR, NMSS, or NRO, respectively, shall make the decision on imposition of the backfit. Claims on a security-related backfit shall be forwarded to the Director of NSIR. However, the Director of NRR, the Director of NMSS, or the Director of NRO, as appropriate, is responsible for

final disposition and imposition of backfits. The office director's decision is subject to the EDO's review.

- (d) After the review, if it is determined that the staff position in question is not a backfit, the appropriate staff office shall document the basis for the decision.
- (e) In either case, the responsible office director or RA shall report to the EDO and inform the licensee, within 90 calendar days of receipt of the written backfit claim, of the results of the staff's determination and the staff's plan for resolving the issue.⁶
- (f) When a licensee is informed that a claimed backfit is not a backfit, then the licensee may appeal this determination, as described below in this MD (see Section III.A.6 of this handbook).
- (g) Silence or a lack of response to the licensee by the NRC staff shall not be considered tacit approval by the NRC staff unless the NRC's rules expressly provide for tacit acceptance.
- (h) The licensee may implement the backfit or appeal the backfit determination to the office director or the RA, as appropriate. This is the first level of appeal (see Section III.A.6 of this handbook). If dissatisfied with the decision of the office director or the RA, the licensee may appeal to the EDO, which is the second level of appeal.

6. The Backfit Appeals Process

- (a) The appeals described in this section are of two types, which are applied to two distinctly different situations:
 - (i) Appeal to the responsible office or region to modify or withdraw a proposed backfit for which a backfit analysis had been prepared and transmitted to the licensee, or
 - (ii) Appeal to the responsible office or region to reverse its denial of a prior licensee claim that—
 - a staff position not identified by NRC as a backfit is, in the licensee's view, a backfit, or

⁶ The office or the region that originated the backfit has the primary responsibility. However, whenever necessary, the office or region shall support, as appropriate, the oversight office that has the obligation to impose and dispose the backfits. NRC regulations concerning backfitting protection for nuclear materials licensees do not apply to FSME licensees, so FSME does not have any direct backfitting responsibilities. See Section III.I of this directive.

- a backfit that the staff believes falls within one of the exceptions from the requirement for the staff to perform a backfit analysis, in the licensee's view, does require a regulatory analysis.

(b) In the first type of appeal (see Section III.A.6(a)(i) of this handbook):

- (i) The facility licensee must send an appeal of a proposed backfit in writing to the office director or the RA whose staff has proposed the backfit. The office director or the RA shall decide on the appeal.
- (ii) The licensee should send a copy of the appeal to the EDO.
- (iii) The written appeal should address the staff's supporting analysis and provide specific arguments against the staff's rationale for imposing a backfit.
- (iv) The office director or the RA shall forward security-related backfit appeals to the Director of NSIR.
- (v) Within 90 days after receipt of the appeal, the office director or the RA shall report to the EDO the staff's plan for resolving the issue.
- (vi) After the staff's re-evaluation of the licensee's appeal and appropriate interoffice coordination and management review, the office director or the RA shall decide on the appeal and inform the licensee in writing. If applicable, this document shall also inform the licensee that an order may be issued if they pursue a second level appeal and are unsuccessful and refuse to comply with the staff's position. A copy of this decision will be sent to the EDO.
- (vii) If dissatisfied with the written decision of the office director or the RA on a facility-specific backfit, the licensee may appeal to the EDO unless resolution is achieved at a lower management level (see Exhibit 2 to this handbook). If the licensee appeals to the EDO and is unsuccessful and refuses to comply with the staff's position, an order may be issued.
- (viii) The EDO may appoint a special Backfit Review Panel to review the licensee's backfit appeal; this panel shall promptly resolve the appeal and document its resolution for the EDO's consideration. The Backfit Review Panel may be composed of the CRGR members.
- (ix) The EDO may review and modify the backfit decision either on his or her own initiative or at the request of the licensee. A backfit claim and resultant staff determination that is reevaluated by EDO initiative or in response to an appeal and that is again determined by the EDO not to be a backfit, or is excepted from the requirement for a backfit analysis, shall not be treated further in the context of this MD, but is dealt with within the normal licensing or inspection appeal process.

- (x) The responsible staff shall prepare summaries of all appeal meetings, enter the summaries into ADAMS, and profile them as publicly available (see also Section III.C.5 of this directive).
 - (xi) The staff should reconsider the supporting analysis as well as any other information that is relevant and material to the proposed backfit.
- (c) In the second type of appeal (see Section III.A.6 of this handbook):
- (i) The written licensee appeal must be addressed to, and will be decided by, the office director or the RA, unless resolution is achieved at a lower management level (see Exhibit 2 to this handbook).
 - (ii) The appeal must provide arguments against the staff's position, the licensee's response, and any other information that is relevant and material to the backfit determination.
 - (iii) The licensee should send a copy of the appeal to the EDO.
 - (iv) The office director or the RA shall forward security-related backfit appeals to the Director of NSIR.
 - (v) Within 90 days after receipt of the appeal, the office director or the RA shall report to the EDO the staff's plan for resolving the issue.
 - (vi) After the staff's re-evaluation of the licensee's appeal and appropriate interoffice coordination and management review, the office director or the RA shall decide on the appeal and inform the licensee in writing. If applicable, this document shall also inform the licensee that an order may be issued if they pursue a second level appeal and are unsuccessful and refuse to comply with the staff's position. A copy of this decision will be sent to the EDO by the office director or the RA.
 - (vii) If dissatisfied with the written decision of the office director or the RA, the licensee may appeal to the EDO unless resolution is achieved at a lower management level (see Exhibit 2 to this handbook).
 - (viii) The EDO may appoint a special Backfit Review Panel to review the licensee's backfit appeal; this panel shall promptly resolve the appeal and document its resolution for the EDO's consideration. The Backfit Review Panel may be composed of the CRGR members.
 - (ix) The EDO may review and modify the backfit decision either on his or her own initiative or at the request of the licensee.
 - (x) The responsible staff shall prepare summaries of all appeal meetings and enter the relevant information into ADAMS, which shall be profiled as publicly accessible (see also Section III.C.5 of this directive).

- (xi) A backfit claim and resultant staff determination that is reevaluated in response to an appeal and that is again determined by NRC as not to be a backfit, or is excepted from the requirement for a backfit analysis, shall not be treated further in the context of this MD, but is dealt with within the normal licensing or inspection appeal process.
- (d) Following approval of any required supporting analysis by the appropriate office director or RA, review by the EDO, and issuance of the backfit to the licensee, the licensee will implement the backfit. If the licensee fails to implement the backfit, the NRC will issue an order. Once an order is issued, whether or not it is immediately effective, this MD no longer applies. Appeals are governed by the provisions of 10 CFR Part 2, Subpart B.

B. Compliance Exceptions

1. When a proposed NRC action would ensure compliance with the existing regulatory requirements or written licensee commitments, a backfit analysis is not required. Instead, a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 70.76(a)(6), and 76.76(a)(6) is prepared by the appropriate office director or RA, with a finding that the action is necessary to ensure compliance.
2. For compliance cases, if immediately effective agency action is needed, the required documented evaluation may follow the issuance of the agency action.
3. For a compliance backfit, the staff need not consider the cost of the agency action; however, cost is a relevant consideration in performing the regulatory analysis for the NRC action.
4. Documented evaluation shall include a statement of the objectives, the reasons for the action, and the basis for invoking the compliance exception. Specifically, it must identify the regulatory requirements (e.g., Commission regulations or order(s), or the facility license conditions or technical specifications) for which compliance is required. The responsible office staff should consult and coordinate with OE and seek OGC advice on imposition of all compliance backfits, including the licensee's proposed implementation schedule.
5. At any point during the process, the responsible office, in consultation with other appropriate offices, including OGC and OE or regions, may decide not to proceed with the proposed backfitting because further effort is likely to show that either:
 - (a) an exemption from compliance with the Commission's regulation for which compliance is sought may be granted under 10 CFR 50.12, or
 - (b) enforcement discretion may be exercised in accordance with applicable NRC guidance on the matter.

C. Adequate Protection Exceptions

1. If imposition of a backfit is necessary to define or redefine adequate protection, or to ensure that the facility provides adequate protection to the public health and safety and is in accord with the common defense and security, a backfit analysis to justify this determination is not required. Under these circumstances, the appropriate office director or RA shall provide a documented evaluation⁷ of the type discussed in 10 CFR 50.109(a)(6), 70.76(a)(6), and 76.76(a)(6), with a finding that the action is necessary to ensure adequate protection of public health and safety or common defense and security.
 - (a) This evaluation shall include a statement of the objectives, the reasons for the modification, and the basis for invoking this exception.
 - (b) When a backfit is needed to ensure that the facility provides adequate protection, the documented evaluation shall also include the significance and appropriateness of the action taken from the standpoint of safety or security, as appropriate.
2. If it is necessary or appropriate for the Commission to prescribe a way to achieve adequate protection, the evaluation may include a consideration of how cost contributes to selecting a solution among various acceptable alternatives.

D. Cost-Justified Substantial Increase in Protection

For all backfits that do not satisfy the compliance or adequate protection exception criteria, the responsible staff must perform a backfit analysis. Additionally, the staff also may be required to prepare a regulatory analysis to show that certain improvements in safety or security are justified on the basis of the associated costs. This regulatory analysis is performed independent of the backfit analysis because most NRC and regulatory actions require a regulatory analysis. Often only one analysis is performed to meet both the backfit and the regulatory analysis requirements because, once the staff shows that the proposed action will result in a substantial increase in protection, the traditional cost-benefit analysis in the regulatory analysis satisfies the cost-justification requirement of the backfit analysis. The combined backfit and regulatory analysis is further discussed in Section III.D.1(d)(i) of this handbook, and pertinent staff guidance is included in Exhibit 5 to this handbook.

⁷ See note 6.

1. Backfit Evaluation

(a) Backfit Standard

The backfitting rules do not require a strict quantitative demonstration that benefits would exceed costs, but rather that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(b) Backfit Analysis

- (i) The staff shall demonstrate and document for new or changed staff positions that the backfit standard is met. However, if necessary and relevant, qualitative considerations may also be used to demonstrate a cost-justified increase in protection. The staff also will 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 backfit.
- (ii) Relaxations may not show a substantial increase in safety; consequently, implementation of these relaxations should be voluntary for the licensees.

(c) Regulatory Analysis

- (i) The regulatory analysis process is an integral part of NRC's decisionmaking and is designed to provide complete disclosure of the relevant information supporting a regulatory decision. In general, the regulatory analysis is designed to help ensure that NRC decisions are based on adequate information concerning the need for, and consequences of, proposed actions; appropriate alternative approaches are identified and analyzed; and no clearly preferable alternative is available to the proposed action.
- (ii) For a detailed description of the regulatory analysis requirements, the staff is directed to the latest version of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook." The regulatory analysis must conform to the guidance and policies, including scope and format, as set forth in these documents.

(d) Combined Backfit and Regulatory Analysis

- (i) Regulatory initiatives that are subject to the backfit analysis requirements may also be subject to regulatory analysis requirements. To some extent, each of these analyses contains similar information. Thus, to avoid duplication of effort and for regulatory efficiency purposes, the backfit analysis can be

included in the regulatory analysis. Specific guidance on incorporating backfit analysis requirements into the regulatory analysis appears in NUREG/BR-0058 and NUREG/BR-0184.⁸ Exhibit 5 to this handbook also contains guidance on the scope of the combined backfit and regulatory analysis.

- (ii) The regulatory analysis should only be terminated with a final recommendation that no action be taken. However, if a positive finding of a backfit is made, the staff must assess the direct and indirect costs of implementation to determine if these costs are justified in view of the increased protection. This cost justification test of the backfitting rules should be based on the “Estimation and Evaluation of Values and Impacts,” which is the final analytical section of the regulatory analysis. In the event the proposed agency action is shown not to be cost-justified, staff should consider not taking the agency action, and the regulatory analysis should be completed with that as its final recommendation. (Given that the analytical portion of the regulatory analysis has already been completed and only minimal effort is needed to complete the analysis, it is deemed appropriate to produce a final regulatory decision.)
 - (iii) If, based on both quantitative and qualitative considerations, the combined regulatory and backfit analysis demonstrates a cost-justified substantial increase in either safety or security and no clearly preferable alternative is available to the proposed action, the staff shall initiate the interoffice coordination and management approval process for all staff positions or agency actions identified as facility-specific backfits requiring a regulatory analysis. The combined backfit and regulatory analysis must be approved by the appropriate program office director or RA and a copy sent to the EDO before the analysis is transmitted to the licensee.
- (e) Further Justification

For facility-specific backfits, additional factors required by the CRGR Charter for justification of generic requirements may be used. In addition, the office or regional procedures may contain further justification requirements, including OE

⁸ For example, in NUREG/BR-0058, Rev. 4, and NUREG/BR-0184 (1997), this guidance appears in Section 2.3 and Section 2.2, respectively. In addition, Table 2.2 of NUREG/BR-0184 lists each of the reactor backfit analysis requirements pursuant to 10 CFR 50.109 and identifies where that information should be discussed in the regulatory analysis. This table is reproduced in Appendix 6 to this handbook. For backfitting selected nuclear materials facilities, the staff must refer to the corresponding provisions in 10 CFR 70.76, 72.62, and 76.76, as appropriate.

and OGC review and concurrence, as appropriate. Furthermore, as additional administrative controls, the offices or regions may use reviews by special internal panels. Details on these matters should be included in the office or regional backfitting procedures.

E. Exceptions

Nothing in this MD shall be interpreted as authorizing or requiring the staff to make facility-specific backfits or assessments for generic backfits that are, or have been, subject to review by the CRGR and approved by the EDO. This is also true for generic backfits approved before November 1981, unless the EDO determines that significant facility-specific backfits were not considered during the prior reviews.

F. Assessment of the Overall Effectiveness of the NRC's Facility-specific Backfit Management Program

The CRGR has the responsibility for assessing the effectiveness of the administrative controls for NRC's facility-specific backfitting. This MD designates the CRGR to periodically assess the overall effectiveness of the backfit controls, typically every 5 years.

IV. INFORMATION COLLECTION REQUIREMENTS

A. NRC Regulations

1. Information requests to power reactor licensees are made pursuant to 10 CFR 50.54(f). Section 50.54(f) authorizes NRC to require its licensees to provide additional safety information to enable the Commission to determine whether or not a license should be modified, suspended, or revoked. This rule, as amended on September 20, 1985 (50 FR 38097), requires the NRC staff to justify these information requests with supporting analysis that demonstrates that the burden to be imposed 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:
 - (a) No supporting analysis is required whenever there is reason to believe that the public health and safety or common defense and security may not be adequately protected and information is needed to decide if this is the case and to take any necessary corrective actions.
 - (b) 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 routine licensing review, for example, if it seeks information pursuant to development of a new staff position, then the supporting analysis shall include the reasons for the request and justify the estimated burden imposed on the licensee before issuance.

- (c) No supporting analysis is necessary for licensing review or inspection activities for operating facilities, or for information requests sought to verify licensee compliance with the current licensing basis for the facility. Requests for information made in connection with fact-finding reviews, inspections, and investigations of accidents or incidents are usually not made pursuant to 10 CFR 50.54(f). Furthermore, such requests are not normally considered within the scope of the Backfit Rule or this MD.
2. The requirements for information collection requests for selected nuclear materials facility licensees are contained in 10 CFR 70.22(d), 72.62(d), and 76.70(e).
 3. The requirements for information collection requests for new power reactor licensees are contained in 10 CFR 52.98(g), 52.145(c), and 52.171(c).

B. Justification

1. The Directors of NMSS, NRO, and NRR and the RAs shall develop internal office procedures to ensure that the staff establishes a rational basis for all information requests (excluding those information requests in Sections IV.A.1(a)-(c) of this handbook), whether or not it is clear that a backfit action would result from staff evaluation of the information supplied by the licensee. Specifically, the responsible office director or RA shall:
 - (a) ensure that the staff has evaluated the request to determine whether the burden imposed on the licensee by the information request is justified in view of the potential safety significance of the issue to be addressed; and
 - (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 necessary shall include at least the following elements:
 - (a) a statement of the problem describing the need for the requested information in terms of its potential benefit;
 - (b) the licensee actions required and an estimate of the burden on the licensee to develop a response to the information request; and
 - (c) an anticipated schedule for NRC to use the information.

V. BACKFIT TRAINING PROGRAM

A. Training at the Headquarters and the Regional Offices

The NRC office directors and RAs shall plan for backfit training for their technical staff that incorporates the agency backfit training program. The agency backfit training program should include beginner and advanced levels, as well as refresher courses.

B. Agencywide Training Coordination

The Office of the Chief Human Capital Officer (OCHCO) shall maintain and update a backfit training program for the NRC's technical staff. In consultation with OGC and the appropriate staff in FSME, NMSS, NRO, NRR, OE, RES, NSIR, and the regional offices, OCHCO will develop the generic and facility-specific backfit training modules. The modules will include beginner to advance levels and OCHCO will plan for the refresher courses. OCHCO will also consult and coordinate with the appropriate contact in the Office of Information Services to make backfit training modules available online.

VI. DEFINITIONS

Applicable Staff Positions

Applicable staff positions are those staff positions already specifically imposed upon a licensee at the time of the identification of a facility-specific backfit. NRC staff positions that are documented, approved, explicit interpretations of the regulations and contained in documents such as the Standard Review Plan (SRP), branch technical positions, regulatory guides, generic letters, and bulletins, and to which a licensee or an applicant has previously committed to or relied upon, are called applicable staff positions. The applicable staff position for each plant includes the Safety Evaluation Reports (SERs) for that specific plant.

A change in the applicable staff position is referred to as a new or revised staff position.

Backfitting

Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; 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 rules or imposition of a staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after certain specified dates.

Facility-specific Backfit

Facility-specific backfit is the result of the staff's attempt to ensure that a particular facility provides adequate protection for the public health and safety and common defense and security, or complies with Commission rules or orders or the licensee's written commitments or license.

A new or revised staff position is a backfit if it is first identified to the licensee after certain important design, construction, or operation milestones involving NRC approvals of varying kinds have been achieved. (New or revised staff positions are described further in Section VI of this handbook under "Applicable Staff Positions.") Those times after which a new or revised staff position will be considered a backfit are as follows:

1. the date of issuance of the construction permit for the facility (for facilities having construction permits issued after October 21, 1985);
2. six (6) months before the date of docketing of the operating license application for the facility (for facilities having construction permits issued before October 21, 1985);
3. the date of issuance of the operating license for the facility (for facilities having operating licenses);
4. the date of issuance of the standard design approval under 10 CFR Part 52, Subpart E;
5. the date of issuance of a manufacturing license under 10 CFR Part 52, Subpart F;
6. the date of issuance of the first construction permit issued for a duplicate design under 10 CFR Part 50, Appendix N; or
7. the date of issuance of a combined license under 10 CFR Part 52, Subpart C, provided that, if the combined license references an early site permit, the provisions in 10 CFR 52.39 apply with respect to the site characteristics, design parameters, and terms and conditions specified in the early site permit. If the combined license references a standard design certification rule under 10 CFR Part 52, Subpart B, the provisions in 10 CFR 52.63 apply with respect to the design matters resolved in the standard design certification rule, provided however, that if any specific backfitting limitations are included in a referenced design certification rule, those limitations shall govern. If the combined license references a standard design approval under 10 CFR Part 52, Subpart E, the provisions in 10 CFR Section 52.145 apply with respect to the design matters resolved in the standard design approval. If the combined license uses a reactor manufactured under a manufacturing license under 10 CFR Part 52, Subpart F, the provisions of 10 CFR 52.171 apply with respect to matters resolved in the manufacturing license proceeding.

Licensee

Except where defined otherwise, the word “licensee” as used in this MD means an entity who holds any of the following:

1. a license to operate a nuclear power reactor, an independent spent fuel storage installation, or a monitored retrievable storage installation, or to own, acquire, deliver, receive, possess, use, and transfer special nuclear material,
2. a certificate of compliance approving a spent fuel storage cask design,
3. a construction permit to build a nuclear power reactor, or
4. under 10 CFR Part 52, an SDA under Subpart E, an ESP under Subpart A, a COL under Subpart C, or an ML under Subpart F; or is an applicant for a design certification under Subpart B; an applicant for a COL if the application references an ESP, DCR, or SDA; or an applicant for an ML if the application references a DCR or SDA.

The backfitting provisions of 10 CFR 52.83 apply to those applicants or licensees who reference an early site permit, a standard design approval, the design certification rule, and/or a manufacturing license in their application.

Substantial Increase

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

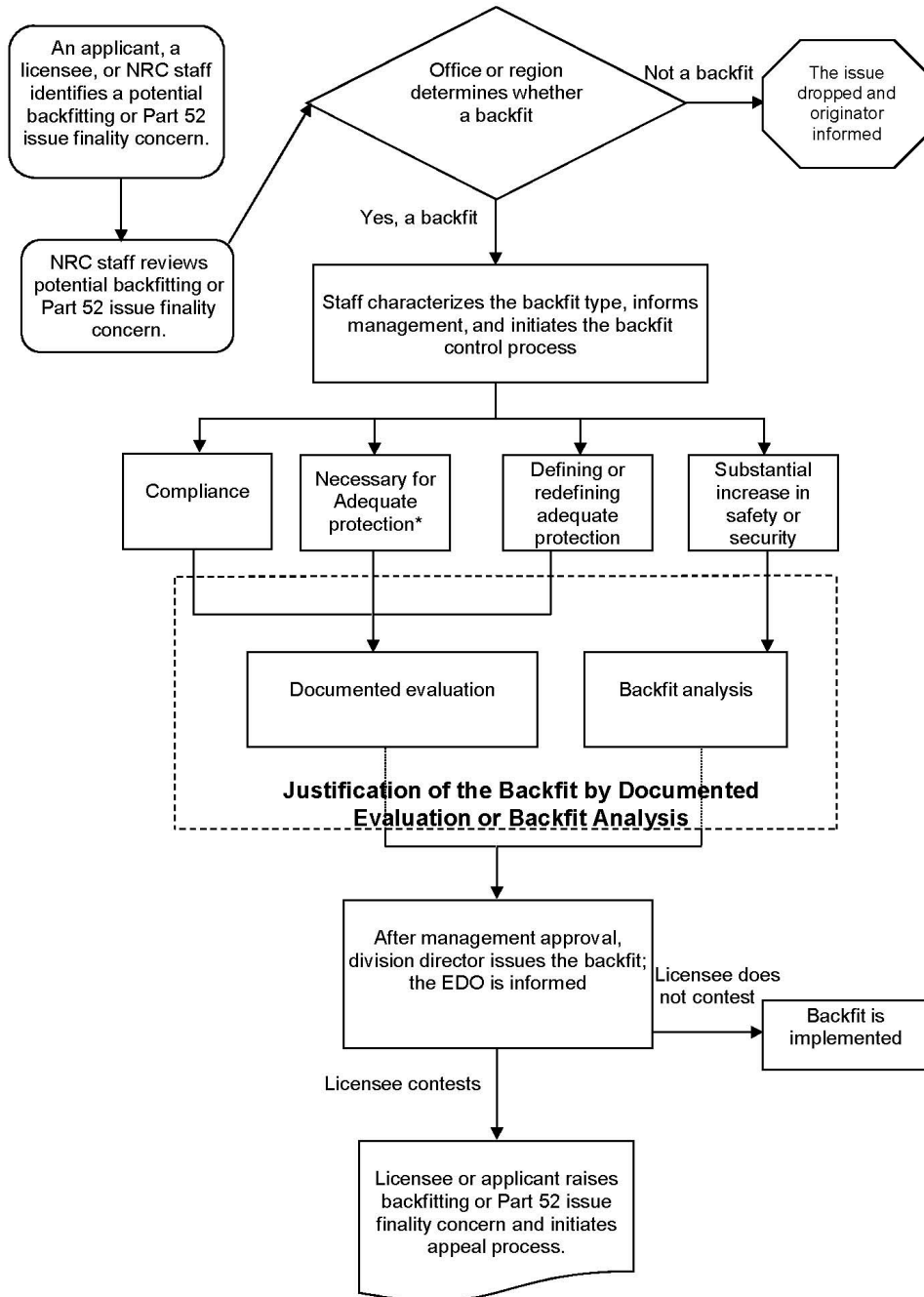
Substantial means “important or significant in a large amount, extent, or degree.” Under such a standard the Commission would not ordinarily expect that safety improvements would be required as backfits that result in an insignificant or small benefit to public health and safety or common defense and 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 (50 FR 38097, 38102, September 20, 1985).⁹

Tacit Acceptance/Approval

The NRC’s silence to a licensee’s request should not be regarded as tacit acceptance.

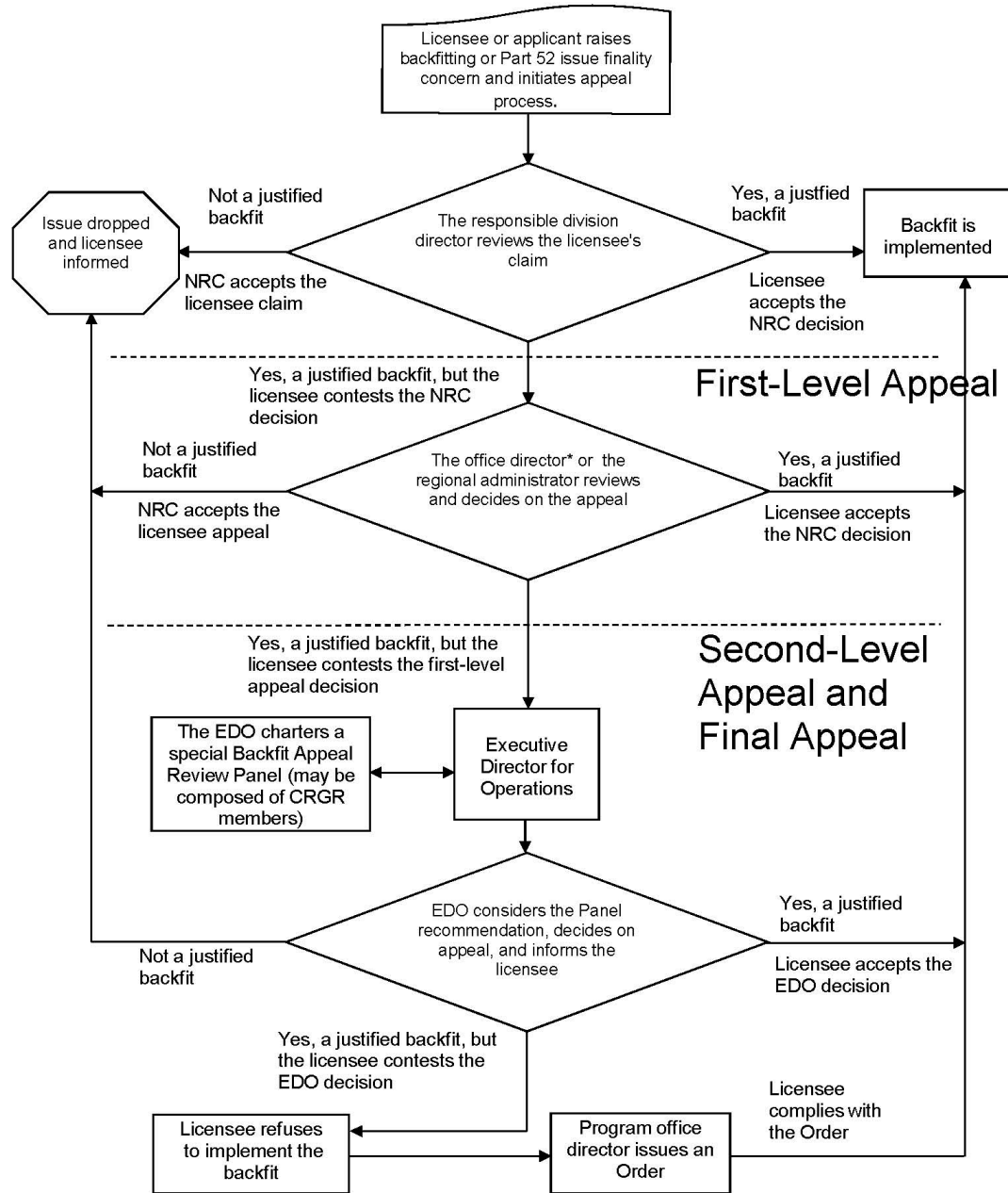
⁹ In a 1993 memorandum to the staff (memorandum to James M. Taylor and William C. Parler from Samuel J. Chilk, dated June 30, 1993, Subject: SECY-93-086, Backfit Considerations (ADAMS Accession Number ML003760758)), the Commission said that it continues to believe that these words embody a sound approach to the “substantial increase” criterion and that this approach is flexible enough to allow for qualitative arguments that a given proposed rule would substantially increase safety. Additionally, in the context of 10 CFR Part 70 licensing actions, the Commission supported the requirement that “any new backfit pass a cost-benefit test without the ‘substantial’ increase in safety test. The Commission believes that modest increase in safety at minimal or inconsequential cost should be justified on a cost-benefit basis.” (Staff Requirements Memorandum - SECY-98-185 - Proposed Rulemaking - “Revised Requirements for the Domestic Licensing of Special Nuclear Material,” dated December 1, 1998 (ADAMS Accession Number ML991880012).)

Exhibit 1 Internal NRC Facility-specific Backfit and Issue Finality Flow Chart



*of public health and safety or common defense and security

Exhibit 2 Facility-specific Backfit Appeal Process Flow Chart



*The director of NSIR reviews all appeals on security-related backfits.

Exhibit 3 Guidance for Making Backfitting Determinations

A. General

In this exhibit, the general steps are outlined to help the NRC staff identify the conditions under which a staff position may be viewed as a facility-specific backfit.

These steps are:

1. Identify the applicable staff position in the staff's regulatory history for the licensee;
2. Identify the current staff position;
3. Determine if there is a change or a new staff position;
 - (a) If there is a change or a new staff position, then confirm that there are no exceptions in applicability (see Section II.A of this handbook),
 - (b) If there are no applicable exceptions, then this position should be viewed as a facility-specific backfit.

An action proposed by the licensee is not a backfit under MD 8.4, even though the action may result from normal discussions between the staff and the licensee concerning an issue, and even though the change or addition may meet the definitions in Section VI of this handbook.

B. Licensing

1. Standard Review Plan (SRP)
 - (a) The SRP delineates the scope and depth of staff review of licensee submittals associated with various licensing activities. It is a definitive NRC staff interpretation of measures that, if taken, will satisfy the requirements of the more generally stated, legally binding body of regulations, primarily found in Title 10 of the *Code of Federal Regulations* (10 CFR). Since October 1981, changes to the SRP and the extent to which the changes apply to classes of facilities are being reviewed by the CRGR. The CRGR will review SRPs only if they expound a new staff position. Application by the staff of the guidance in a current SRP in a specific operating license (OL) review is not a facility-specific backfit, provided that the SRP was effective 6 months before the start of the OL review. Asking questions of an applicant for an operating license in order to clarify staff understanding of proposed actions so as to determine whether the actions will meet the intent of the SRP is not considered a backfit.
 - (b) During initial licensing, the staff's use of acceptance criteria more stringent than those contained in the SRP or taking positions more stringent than those

specified in the SRP, whether in writing or orally, is not a facility-specific backfit. During meetings with the licensee, staff discussion or comments regarding issues and licensee actions volunteered that are in excess of the criteria in the SRP generally do not constitute facility-specific backfits. However, if the staff implies or suggests that a specific action in excess of already applicable staff positions is the only way for the staff to be satisfied, the action would be considered a facility-specific backfit whether or not the licensee agrees to take such an action.

2. Regulatory Guides and NUREGs¹

As part of the generic review process pursuant to the CRGR Charter, the staff determines which facilities or groups of facilities should be affected by the new or modified regulatory guide (or NUREG) provisions. Such implementation is, therefore, not governed by the facility-specific backfitting process. Any staff-proposed facility-specific implementation of a regulatory guide (or NUREG) provision, whether orally or in writing, for example, for a facility not encompassed by the generic implementation, may be considered a facility-specific backfit. A staff action with respect to a specific licensee that expands on, adds to, or modifies a generically approved regulatory guide (or NUREG) such that the position taken by the staff is more demanding than intended in the generic positions may be a facility-specific backfit.

3. Facility-specific orders

- (a) An order issued to cause a licensee to take actions that are not otherwise applicable staff positions would be a facility-specific backfit. An order effective immediately for imposing a backfit may be issued before completing any of the requirements set forth in MD 8.4 provided that the appropriate office director determines that immediate imposition of a backfit is necessary.
- (b) An order issued to confirm a licensee commitment to take specific action even if that action is in excess of previously applicable staff positions is not a facility-specific backfit provided that the commitment was not obtained by the staff with the express or implied direction that such a commitment was necessary to gain acceptance in the staff's review process. An order intended to confirm a voluntary licensee commitment to specific action may involve a compliance backfit. Discussion or comments by the NRC staff identifying deficiencies observed, whether in meetings or written reports, do not constitute backfits. A

¹ Some licensees may commit to a particular NUREG and therefore the staff should consider facility-specific backfitting implications.

definitive statement or statements to the licensee directing a specific action, unless the action is an explicit and already applicable staff position, is a backfit.

C. Inspection and Enforcement

1. Inspections

- (a) NRC inspection procedures govern the scope and depth of the staff inspections associated with licensee activities, such as design, construction, and operation. As such, the inspection procedures define those items that the staff needs to consider in its determination of whether the licensee is conducting its activities in a safe manner. The conduct of inspections establishes no new staff positions for the licensee and is not a facility-specific backfit.
- (b) Staff statements to the licensee that the contents of an NRC inspection procedure are positions that must be met by the licensee do constitute a facility-specific backfit, unless the item is an applicable staff position. Discussion or comments by the NRC staff regarding deficiencies observed in the licensee's conduct of activities, whether in meetings or in written inspection reports, do not constitute backfits, unless the staff suggests that specific corrective actions different from previously applicable staff positions are the only way to satisfy the staff. In the normal course of inspections to determine whether the licensee's activities are being conducted safely, the inspector may examine and make findings in specific technical areas wherein prior NRC positions and licensee commitments do not exist. Examination of such areas and making findings are not considered a backfit. Likewise, discussion of findings with the licensee is not considered a backfit. If during these discussions the licensee agrees that it is appropriate to take action in response to the inspector's findings, the action is not a backfit provided that the inspector does not indicate that the specific actions are the only way to satisfy the staff. On the other hand, if the inspector indicates that a specific action must be taken, then the action is a backfit unless it is an applicable staff position. Furthermore, if the licensee decides to claim that the inspector's findings are a backfit, the staff must determine whether they are backfits under the guidance provided in MD 8.4.

2. Notice of Violation (NOV)

- (a) An NOV requesting description of a licensee's proposed corrective action is not a backfit. The licensee's commitments in the description of a corrective action are not backfits. A request by the staff for the licensee to consider some specific action in response to an NOV is not a backfit. However, if the staff is not satisfied with the licensee's proposed corrective action(s) and requests that the licensee

take additional actions, then those additional actions, if requested in writing, are a backfit unless they are an applicable staff position.

- (b) Discussions during enforcement conferences and responses to the licensee's requests for advice regarding corrective actions are not backfits. However, the staff's definitive statements to the licensee directing a specific action to satisfy the staff positions are backfits, unless the action is an explicit applicable staff position.

3. Bulletins

Bulletins and resultant actions requested of the licensees undergo the generic review process pursuant to the CRGR Charter. Therefore, in general, it is not necessary to apply the facility-specific backfit process to the actions requested in a bulletin. However, if the staff expands the action requested in a bulletin to a specific licensee, such expansion is considered a facility-specific backfit.

4. Reanalysis of Issues

- (a) Throughout a facility's lifetime, many individuals on the NRC staff would have an opportunity to review the requirements and commitments incumbent upon a licensee. There will be occasions when a reviewer concludes that the licensee's program in a specific area does not satisfy a regulation, license condition, or the written licensee commitment. If the staff has previously accepted the licensee's program as being adequate, then any new or revised staff-specified changes in the program would be classified as a backfit.
- (b) For example, in the case of a near-term operating license (NTOL), once the Safety Evaluation Report (SER) is issued signifying the staff's acceptance of the programs described in the Safety Analysis Report (SAR), the licensee should be able to conclude that its commitments in the SAR satisfy the NRC requirements in a particular area. If the staff were to subsequently require, after issuance of the license and not in response to a licensee's voluntary request to amend its license, that the licensee commit to additional action other than that specified in the SAR for the particular area, such action could constitute a backfit depending on the specificity of the SER. A change in position prior to issuance of a license is not considered a backfit, inasmuch as the SER does not constitute the NRC's final position until the license is issued. Moreover, under 10 CFR 50.109, backfitting protections do not become effective until the license is issued.

Exhibit 4 Backfitting Provisions for Previously-approved ESPs, DCRs, COLs, SDAs, and MLs

10 CFR 52.39	<p>Notwithstanding any provision in 10 CFR 50.109, in general, when an ESP is in effect, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission:</p> <ul style="list-style-type: none"> (i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued; (ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security; (iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or (iv) Issues a variance requested under paragraph (d) of this section.
10 CFR 52.63	<p>Notwithstanding any provision in 10 CFR 50.109, in general, when a DCR is in effect, the Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that the change:</p> <ul style="list-style-type: none"> (i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued; (ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security; (iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security; (iv) Provides the detailed design information to be verified under those inspections, tests, analyses, and acceptance criteria (ITAAC) which are directed at certification information (<i>i.e.</i>, design acceptance criteria); (v) Is necessary to correct material errors in the certification information; (vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security; or (vii) Contributes to increased standardization of the certification information.
10 CFR 52.83	<p>If the application for a combined license references an ESP, DCR, SDA, or ML, the scope and nature of matters resolved for the application and any combined license issued are governed by the relevant Part 52 provisions addressing finality.</p>

<p>10 CFR 52.98</p>	<p>After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, or the inspections, tests, analyses, and acceptance criteria contained in the license, which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of § 52.103 or § 50.109.</p> <p>If the combined license does not reference a design certification or a reactor manufactured under a Part 52 manufacturing license, then a licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) under the applicable change processes in 10 CFR Part 50.</p> <p>If the combined license references a certified design, then—(1) Changes to or departures from information within the scope of the referenced DCR are subject to the applicable change processes in that rule; and (2) Changes that are not within the scope of the referenced DCR are subject to the applicable change processes in 10 CFR Part 50, unless they also involve changes to or noncompliance with information within the scope of the referenced DCR. In these cases, the applicable provisions of § 52.98 and the DCR apply.</p> <p>If the combined license references a reactor manufactured under a Part 52, subpart F manufacturing license, then—(1) Changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171; and (2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in 10 CFR Part 50.</p>
<p>10 CFR 52.145</p>	<p>An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any individual facility license application that incorporates by reference a standard design approved in accordance with this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause.</p>

10 CFR 52.171	Notwithstanding any provision in 10 CFR 50.109, during the term of a manufacturing license, the Commission may not modify, rescind, or impose new requirements on the design of the nuclear power reactor being manufactured, or the requirements for the manufacture of the nuclear power reactor, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.
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Exhibit 5 Guidance for Performing a Combined Backfit and Regulatory Analysis

A. General

Regulatory initiatives that are subject to backfit analysis may also be subject to the regulatory analysis requirements. For facility-specific backfits, other than adequate protection or compliance exceptions, the staff can prepare one supporting analysis that incorporates both the regulatory analysis and the backfit analysis requirements.

For a complete discussion of NRC's regulatory analysis requirements, the staff is directed to the latest versions of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook." For a thorough discussion of NRC's backfit analysis requirements, the relevant document is the latest version of NUREG-1409, "Backfitting Guidelines." Furthermore, to ensure consistency with the latest requirements of the NRC's backfitting rules, the staff should consult with the Office of the General Counsel (OGC).

B. Scope

1. Regulatory Analysis

(a) The regulatory analysis consists of six distinct sections:

- (i) A statement of the problem and NRC objectives for the proposed regulatory action.
- (ii) Identification and preliminary analysis of alternative approaches to the problem.
- (iii) Estimation and evaluation of the values and impacts of selected alternatives, including consideration of the uncertainties affecting the estimates.
- (iv) The conclusions of the evaluation of values and impacts and, when appropriate, the results of the safety goal evaluation. (Note: safety goal evaluation only applies to generic safety enhancements affecting power reactors.)
- (v) The decision rationale for selection of the proposed regulatory action.
- (vi) A tentative implementation instrument and schedule for the proposed regulatory action.

(b) The level of detail to be included in a regulatory analysis can vary, depending on the particular circumstances. In general, the complexity and comprehensiveness of the analysis should be limited to that necessary to provide an adequate basis for decisionmaking among the alternatives available. The emphasis should be on

simplicity, flexibility, and common sense, both in terms of the type of information supplied and the level of detail provided.

2. Backfit Analysis

- (a) With respect to the backfit analysis requirements, Exhibit 6, which is reproduced from NUREG/BR-0184, lists each of the information items identified in the reactor backfitting rule (10 CFR 50.109) and its corresponding placement in the regulatory analysis format. For justification of backfitting of selected nuclear materials facilities, the staff should consider the corresponding provisions in 10 CFR Parts 70, 72, and 76.
- (b) Additionally, the following should be considered, as appropriate, for all proposed facility-specific backfits requiring cost-justified safety enhancement:
 - (i) A statement of the specific objective(s) that the proposed backfit is designed to achieve. This statement should also include a succinct description of the proposed backfit and how it provides a substantial increase in overall protection of public health and safety or common defense and security.
 - (ii) A general description of the activities that would be required by the licensee to implement the backfit.
 - (iii) Factors that need to be considered to determine when the proposed backfit should be scheduled for implementation in light of other ongoing regulatory activities at the facility. The staff should consult with OGC or OE, as appropriate.
 - (iv) The potential safety or security impact of the proposed changes in plant design or operational complexity, including their relationship to the proposed and existing regulatory requirements.
 - (v) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit.
 - (vi) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.
 - (vii) A statement that describes the benefits to be achieved and the cost to be incurred. Information should be used to the extent that it is reasonably available. A qualitative assessment of benefits may be made in lieu of the quantitative analysis where it would provide more meaningful insights or may be the only analysis practicable. This statement should consider at least the following factors:
 - Potential change in risk to the public from accidental offsite release of radioactive material.

- Potential impact on facility employees from radiological exposures due to accidental releases and from exposures when implementing the backfit(s), if appropriate.
 - Installation and continuing costs associated with the backfit, including the estimated cost of facility downtime or the cost of construction delay.
 - Estimated resource burden on NRC associated with the proposed backfit and the availability of such resources.
 - A consideration of important qualitative factors bearing on the need for the backfit for a particular facility, such as, but not limited to, operational trends, significant facility events, and management effectiveness.
 - A statement affirming appropriate interoffice coordination related to the proposed backfit and the staff's plan for implementation.
 - The basis for requiring or permitting backfit implementation on a particular schedule, including sufficient information to demonstrate that the schedules are realistic and provide adequate time for in-depth engineering evaluation, design, procurement, installation, testing, development of operating procedures, and training of operators and other facility personnel, as appropriate.
 - A schedule for staff actions involved in implementation of and verification of implementation of the backfit, as appropriate.
 - Importance of the proposed backfit in light of other safety- or security-related activities underway at the affected facility.
 - A statement of consideration of the proposed facility-specific backfit for potential generic implications.
- (viii) This combined analysis must be approved by the appropriate program office director or RA and a copy must be sent to the EDO before the analysis is transmitted to the licensee.

Exhibit 6 Checklist for Combined Backfit and Regulatory Analysis
(Excerpted, except for the footnote, from NUREG/BR-0184)
(**Table 2.2** Checklist for specific backfit analysis requirements)

CFR Citation ¹ (Title 10)	Information Item To Be Included in a Backfit Analysis	Section of the Regulatory Analysis Where the Item Should Normally Be Discussed
50.109(a)(3)	Basis and a determination that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for the affected facilities are justified in view of this increased protection.	Basis - Presentation of Results Determination - Decision Rationale
50.109(c)(1)	Statement of the specific objectives that the proposed backfit is designed to achieve.	Statement of the Problem and Objectives
50.109(c)(2)	General description of the activities that would be required by the licensee or applicant to complete the backfit.	Identification of Alternatives
50.109(c)(3)	Potential change in the risk to the public from the accidental offsite release of radioactive material.	Estimation and Evaluation of Values and Impacts
50.109(c)(4)	Potential impact on radiological exposure of facility employees.	Estimation and Evaluation of Values and Impacts

¹ Use corresponding provisions in 10 CFR Parts 70, 72, and 76 for backfitting selected nuclear materials facilities.

CFR Citation ¹ (Title 10)	Information Item To Be Included in a Backfit Analysis	Section of the Regulatory Analysis Where the Item Should Normally Be Discussed
50.109(c)(5)	Installation and continuing cost associated with the proposed backfit, including the cost of facility downtime or construction delay.	Estimation and Evaluation of Values and Impacts
50.109(c)(6)	Potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements.	Estimation and Evaluation of Values and Impacts
50.109(c)(7)	Estimated resource burden on the NRC associated with the proposed backfit and the estimated availability of such resources.	Burden - Estimation and Evaluation of Values and Impacts Availability - Implementation
50.109(c)(8)	Potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit.	Presentation of Results Implementation
50.109(c)(9)	Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.	Decision Rationale
50.109(c)	Consideration of how the backfit should be scheduled in light of other ongoing regulatory activities at the facility.	Implementation