

U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-04-16

To: NRC Management Directives Custodians

Subject: Transmittal of Management Directive 8.4, "Management of Facility-specific Backfitting and Information Collection"¹

Purpose: Directive and Handbook 8.4 are being issued 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 backfit provisions of 10 CFR 50.109 for nuclear power reactors and 10 CFR 70.76, 72.62, and 76.76 for nuclear materials facilities, as well as the provisions of 10 CFR Part 50, Appendix O; 10 CFR 50.54(f); and the corresponding requirements in Parts 70, 72, and 76, and 10 CFR 2.204.

Office and Division of Origin: Office of Nuclear Regulatory Research
Division of Systems Analysis and Regulatory Effectiveness

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¹Until a separate management directive is developed for generic backfitting, staff guidance for information collection will be retained in this management directive.

Directive: 8.4 Management of Facility-specific Backfitting and Information Collection

Availability: Rules and Directives Branch
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Management of Facility-specific Backfitting and Information Collection

Directive

(Formerly
Manual
Chapter 0514)

8.4

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U. S. Nuclear Regulatory Commission

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RES

Management of Facility-specific Backfitting and Information Collection Directive 8.4

Policy (8.4-01)

It is the policy of the U.S. Nuclear Regulatory Commission to have an effective program that will ensure that proposed facility-specific backfits to be imposed on NRC-licensed nuclear power reactors and selected nuclear materials facilities are appropriately justified on the basis of the backfit provisions of applicable NRC regulations and the Commission's backfit policy and guidance. Additionally NRC requires the staff to appropriately justify information requests to the licensees.

Objectives (8.4-02)

- To ensure that facility-specific¹ backfitting of a nuclear power reactor or materials facility is appropriately justified and documented and to specify that the Executive Director for Operations (EDO) is responsible for ensuring proper implementation of the backfit process. (021)

¹In 10 CFR 50.109, backfitting for a nuclear power reactor is defined as the modification of or addition to systems, structures, components, or design of a plant or a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a plant or 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). For certain materials facilities, the backfitting definitions in 10 CFR 70.72, 72.62, and 76.76 are slightly different.

Objectives

(8.4-02) (continued)

- To 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 either safety or security, beyond adequate protection, while avoiding any unwarranted burden on NRC, the public, or licensees when implementing such backfits. (022)
- To ensure that facility-specific backfits will be communicated to the licensee only if necessary to provide an adequate level of safety and security, or after the required backfit and regulatory analyses/documentated evaluations are completed and approved. (023)
- To specify that the backfit analysis and supporting regulatory analysis, if any, be approved by the appropriate office director or regional administrator, and forwarded for information to the EDO before communicating these analyses to the licensee. (024)

Organizational Responsibilities and Delegations of Authority

(8.4-03)

Executive Director for Operations (EDO)

(031)

- Is responsible for the NRC's backfit actions. (a)
- Reviews and modifies any proposed facility-specific backfit action on his or her own initiative or at the appeal of the affected licensee. (b)
- Authorizes deviations from this management directive when such action will be in the public interest and the deviation otherwise would comply with the applicable NRC regulations, public laws, and Executive Orders. (c)

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

General Counsel (GC)
(032)

- Identifies backfits and performs legal reviews of staff-initiated facility-specific backfits. (a)
- Provides legal advice and assistance during the backfit identification, justification, imposition, and licensee appeal processes. (b)

Committee To Review Generic
Requirements (CRGR)
(033)

- 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. This task is in addition to monitoring the overall effectiveness of the NRC's generic backfit management process. (a)
- Develops the necessary guidance to conduct audits of the NRC's administrative controls for facility-specific backfitting practices in various headquarters and regional offices. (b)
- Reviews new or 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 backfit rules. The CRGR review shall focus on the staff practices for facility-specific backfit management and assess the adequacy of management direction, programmatic and administrative controls, and interoffice coordination for processing backfits, as well as staff guidance and training. (c)

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Committee To Review Generic
Requirements (CRGR)
(033) (continued)

- Ensures that the offices and regions have adequate administrative controls to ensure that the backfit process is plainly communicated to the licensees and that the cognizant² staff promptly enters backfit decisions into the Agencywide Documents Access and Management System (ADAMS), which is accessible to the public. Any classified information or information deemed to be Safeguards Information pursuant to 10 CFR 73.21 shall not be placed in ADAMS. Additionally, any proprietary or sensitive information shall be excluded from the public domain in ADAMS. (d)
- Periodically meets with the stakeholders to fulfill CRGR's regulatory effectiveness responsibilities by soliciting direct feedback from the stakeholders and advises the EDO of any modifications that may be necessary. (e)

Director, Office of Nuclear
Regulatory Research (RES)
(034)

- Revises, as appropriate, this management directive to include pertinent CRGR recommendations, EDO decisions, and Commission directives for enhancing the NRC's facility-specific backfit control program. (a)
- Maintains and revises the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058,

²The office or the region that originated the backfit shall support the oversight office (the Office of Nuclear Reactor Regulation or the Office of Nuclear Material Safety and Safeguards) that has the statutory obligation to impose and dispose the backfits.

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Director, Office of Nuclear
Regulatory Research (RES)
(034) (continued)

and related documents and tools, as necessary. Furthermore, to formalize and define this responsibility, RES shall develop, maintain, and implement an office letter. (b)

- Provides administrative support for the routine CRGR activities. (c)
- Provides appropriate staff training and ensures that RES staff performance meets the requirements of this management directive. (d)

Director, Office of Enforcement (OE)
(035)

- Defines and implements appropriate administrative controls to support the office or regional staff in processing compliance backfits. (a)
- Consults with the cognizant office, as appropriate, on all proposed compliance backfits and advises on their imposition, including negotiating with the licensee a schedule for implementation of compliance backfits. (b)
- If an Order is issued, supports the oversight office in accordance with 10 CFR Part 2, Subpart B. (c)
- Provides appropriate staff training and ensures that the OE staff performance meets the requirements of this management directive. (d)

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Director, Office of Nuclear Security and
Incident Response (NSIR)
(036)

- Develops, updates, and maintains security-related backfit procedures and administrative controls to identify, justify, and process security-related facility-specific backfits, including appeals, for nuclear power reactors and certain materials facilities.³ The NSIR backfit procedures shall be coordinated with the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), and the regional offices. (a)
- Designates an NSIR manager (division director or higher) who coordinates with NRR or NMSS, as appropriate, to issue the nuclear power reactor and materials facility related backfit(s) to the licensee, after approval of the supporting documentation by the Director of NRR or the Director of NMSS, as appropriate, in accordance with this management directive. (b)
- Ensures consistency of the NSIR backfit procedures with pertinent inspection procedures. (c)
- Consults and coordinates, as appropriate, with either the Director of NRR or the Director of NMSS to resolve issues with proposed security-related facility-specific backfits. The Director of NSIR shall support the Director of NRR or the Director of NMSS, as appropriate, in processing security-related backfits, including resolution of licensee backfit appeals.⁴ (d)

³The Commission policy on post-9/11 security backfits is evolving and may warrant modifications to NSIR's role, responsibilities, and procedures in the future.

⁴For all facility-specific backfits concerning nuclear power reactors, the Director of NRR shall impose them and forward any licensee appeals on security-related backfits to the Director of NSIR for disposition. For all facility-specific backfits for nuclear materials facilities, the Director of NMSS shall impose them and forward any licensee appeals on security-related backfits to the Director of NSIR for disposition. If the licensee refuses to implement any imposed backfits, the Director of NRR or the Director of NMSS, as appropriate, shall issue an Order.

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Director, Office of Nuclear Security and
Incident Response (NSIR)
(036) (continued)

- Provides appropriate staff training and ensures that the NSIR staff performance meets the requirements of this management directive. (e)

Directors, Office of Nuclear Reactor
Regulation (NRR) and Office of Nuclear
Material Safety and Safeguards (NMSS)
(037)

- Develop, update, and maintain backfit procedures and administrative controls for nuclear power reactors, including decommissioning reactors, and certain nuclear materials facilities, including independent spent fuel storage installations (ISFSIs) licensed pursuant to the site-specific provisions of 10 CFR Part 72.⁵ Coordinate NRR backfit procedures with NSIR, NMSS, and the regional offices. (a)
- Designate an NRR and NMSS manager (division director or higher) who issues nuclear power reactor or nuclear materials facility related backfits to licensees after approval of the supporting documentation by the Director of NRR or NMSS in accordance with this management directive. (b)
- Ensure consistency between the pertinent inspection procedures and the backfit procedures. (c)
- Effectively communicate to the licensees the NRR and NMSS practices and staff guidance for handling facility-specific backfitting for nuclear power reactors. (d)

⁵Currently, the backfit requirements of 10 CFR 50.109 and 72.62 do not apply to the licensees of ISFSIs holding a general license pursuant to 10 CFR Part 72, Subpart K..

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Directors, Office of Nuclear Reactor
Regulation (NRR) and Office of Nuclear
Material Safety and Safeguards (NMSS)
(037) (continued)

- Consult and coordinate with regional administrators, NSIR, NRR, and NMSS, 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 certain nuclear materials facilities. The Director of NRR or NMSS shall also coordinate potential security-related backfits with the Director of NSIR and the appropriate regional administrator. (e)
- 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 program area of responsibility before communicating the backfit analysis and the regulatory analysis, if any, to the licensee. (f)
- Decide the licensee appeals on imposition of all backfits within the NRR or NMSS 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. (g)
- Ensure entry of all the backfit communications and decisionmaking, including the outcome of backfit appeals, into ADAMS. Exceptions are noted in Section 033(d) of this directive. (h)
- Provide appropriate staff training and ensure that the NRR and NMSS staff performance meets the requirements of this management directive. (I)

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Director, Office of Human
Resources (HR)
(038)

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

Chief Information Officer (CIO)
(039)

- Maintains backfit records in ADAMS. (a)
- Advises the offices and regions on implementing administrative controls to ensure that public accessibility of backfit information is restricted, as noted in Section 033(d) of this directive. (b)
- Assists in the design and development of the backfit Web page on the NRC's internal and external Web sites and ensures public access thereto. (c)
- Implements and maintains ADAMS online and ensures its accessibility of backfit information in the public domain to the stakeholders. (d)

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Regional Administrators (RA)
(0310)

- Develop, update, and maintain the backfit procedures and administrative controls for nuclear power reactors and certain materials facilities in accordance with this directive to ensure proper application of the provisions of NRC's backfit rules. Notwithstanding any region-specific administrative controls, ensure consistency of backfit procedures among the regions. Coordinate backfit procedures with NRR, NMSS, and NSIR. (a)
- Designate a manager for each region (division director or higher) who issues nuclear power reactor and materials facility related backfits to licensees after approval of the supporting documentation by the RA in accordance with this management directive. (b)
- Ensure consistency of the regional backfit procedures with the pertinent inspection procedures. (c)
- Effectively communicate to the licensees the regional practices and staff guidance for handling safety- and security-related backfitting for nuclear power reactors and materials facilities. (d)
- Consult and coordinate with the Director of NSIR, and with either the Director of NRR or the Director of NMSS, as appropriate, to develop resolutions of security-related facility-specific backfits. (e)
- Coordinate with NSIR, NRR, 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 and regulatory analysis, if any, to the licensee. (f)

Organizational Responsibilities and
Delegations of Authority
(8.4-03) (continued)

Regional Administrators (RA)
(0310) (continued)

- 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. (g)
- Ensure entry of all documents related to backfits originating in the region, including communications, decisionmaking, and the outcome of backfit appeals into ADAMS. Exceptions are noted in Section 033(d) of this directive. (h)
- Provide appropriate training for the regional technical staff and ensure that the staff performance meets the requirements of this management directive. (i)

Applicability
(8.4-04)

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

Handbook
(8.4-05)

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

References
(8.4-06)

Code of Federal Regulations

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

“Backfitting,” 10 CFR 50.109.

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

“Finality of Early Site Permit Determinations,” 10 CFR 52.39.

“Finality of Standard Design Certifications,” 10 CFR 52.63.

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

“Backfitting,” 10 CFR 70.76.

“Licensing Requirements for the Independent Storage of Spent
Nuclear Fuel, High-Level Radioactive Waste, and
Reactor-Related Greater Than Class C Waste,” 10 CFR
Part 72.

“Backfitting,” 10 CFR 72.62.

“Certification of Gaseous Diffusion Plants,” 10 CFR Part 76.

“Backfitting,” 10 CFR 76.76

Nuclear Regulatory Commission Documents

Charter of the Committee To Review Generic Requirements.

NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S.
Nuclear Regulatory Commission.”

References

(8.4-06) (continued)

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

United States Code

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

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Part I
Introduction

Backfitting (A)

Backfitting is the process by which NRC decides whether to impose new or revised regulatory requirements or staff positions on NRC-licensed nuclear power reactors or certain materials facilities. Currently there are no backfit rules applicable to test, training, or research reactors. Backfitting is an inherent part of the regulatory process and is expected to occur. However, it is to be implemented only after a formal and systematic review to ensure that the proposed changes are properly justified and suitably defined. (1)

The NRC's backfit rules relate to the agency actions that impose new or revised staff positions or requirements on operating nuclear power reactors and materials facilities; they do not apply to the NRC-requested actions that are optional or voluntary. Title 10 of the *Code of Federal Regulations* (10 CFR) contains the NRC's backfit rules for nuclear power reactors and the materials facilities. Specifically, 10 CFR 50.109, 70.76, 72.62, and 76.76 contain the backfit provisions for nuclear power reactors and certain materials facilities, including the fuel facilities, spent fuel and radioactive waste storage facilities, and the gaseous diffusion plants. (2)

In 10 CFR 50.109, backfitting for nuclear power reactors 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 staff position interpreting the Commission rules that is either new or different from a

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Backfitting (A) (continued)

previously applicable staff position after certain specified dates.¹ The backfitting definitions in 10 CFR Parts 70, 72, and 76 are slightly different. (3)

Facility-specific² backfits are governed by this management directive. All regional offices and the Offices of Nuclear Regulatory Research (RES), Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), and Nuclear Security and Incident Response (NSIR) are required to develop, maintain, and implement procedures in accordance with this management directive. The NRC staff positions may be identified as potential backfits either by the staff or by licensees. The office director or the regional administrator having the responsibility to develop a staff position shall consider the issue at hand. This office director or regional administrator shall make the final determination as to whether the staff position is a backfit and whether the proposed backfit should be imposed on the licensee. For all security-related backfits, NSIR shall coordinate with NRR or NMSS, as appropriate. For all compliance backfits, the cognizant office or region shall consult and coordinate with the Office of Enforcement (OE) and seek advice from the Office of the General Counsel (OGC). (4)

Information Collection Requests (B)

The provisions of 10 CFR 50.54(f) require the nuclear power reactor licensees to respond to both generic and facility-specific

¹When a new or revised position is issued, it is considered a backfit if it is issued 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 Appendix M, N, or O of 10 CFR Part 52.

²Hereafter, the term “facility” will be used to mean either a nuclear power reactor or a materials facility, such as an independent spent fuel storage installation or a monitored retrievable storage installation.

Information Collection Requests (B) (continued)

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. The staff is also obligated to inform the licensee how NRC intends to use that information and in what time frame. Requests for information for nuclear power reactors to be licensed under 10 CFR Part 52 will be in accordance with the administrative requirements in Part 50, as proposed in the rulemaking to revise Part 52. The information collection requirements for certain nuclear materials facility licensees are contained in 10 CFR 70.22(d), 72.62(d), and 76.70(e). (1)

All facility-specific requests for information are governed by this management directive. (2)

Responsibilities and Authorities (C)

The Executive Director for Operations (EDO) is responsible for the NRC's backfit actions. All the headquarters and regional offices that are involved in backfitting shall be responsible for developing and maintaining the office and regional backfit procedures, implementing programmatic and administrative controls, and providing comprehensive staff guidance on implementing provisions of NRC's backfit 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 backfit control program, soliciting direct feedback from the stakeholders, and advising the EDO to enhance NRC's backfit controls.

Coordination and Communication (D)

For an effective implementation of the NRC's backfit program, the office directors and the regional administrators shall ensure— (1)

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Coordination and Communication (D)

(continued)

- Effective communication and coordination between their counterparts, as well as among the cognizant technical staffs within the headquarters and the regional offices, as appropriate. (a)
- That the office and regional backfit processes, including procedures as well as the programmatic and administrative controls, are written in plain language and made publicly available. (b)
- That a record of the backfit decisions, including the outcome of any licensee backfit appeals, shall be entered into the Agencywide Documents Access and Management System (ADAMS) and profiled as publicly available, with the exception of any proprietary, classified, or sensitive information or any Safeguards Information pursuant to 10 CFR 73.21. (c)
- That all backfit workshops or meetings with the stakeholders on the NRC's backfit control program are open to the public and are appropriately noticed. (d)

Recordkeeping and Reporting (E)

All the NRC offices and regions directly involved in backfitting shall be responsible for tracking the backfit actions originating in that office or region. Specifically— (1)

- The backfit-proposing office or region shall administratively manage each proposed facility-specific backfit by maintaining all records related to it. (a)
- All backfit-related information shall be entered into ADAMS,³ with the exception of any proprietary, classified, or sensitive

³The oversight office with statutory obligation will have precedence over all other offices and regions.

Recordkeeping and Reporting (E)

(continued)

information or any Safeguards Information pursuant to 10 CFR 73.21. 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 the NRC staff with respect to a facility-specific backfit. (b)

- Except as noted above, backfit records placed in ADAMS shall be accessible to the stakeholders by being profiled as publicly available. (c)

Figures 1 and 2 are flow charts that illustrate NRC's program for processing facility-specific backfits and backfit appeals. (2)

Part II

Overview of the Facility-specific Backfit Management Program

General (A)

The NRC's backfit rules relate to the agency actions that impose new or revised staff positions or requirements on licensees. They do not apply either to the NRC-requested actions the implementation of which are voluntary¹ or to the conditions of voluntary license amendments.² If the condition (or the proposed amendment) is directly related to and is necessary to ensure that (by implementing the proposed amendment) the facility provides adequate protection of public health and safety or common defense and security, it is a backfit. (1)

The current NRC regulations apply to backfitting nuclear power reactors and certain nuclear materials facilities; however, they do not apply to the test, research, or training reactors. (2)

Facility-specific Backfits (B)

The backfit rules apply to both generic and facility-specific backfitting of power reactors (including decommissioning reactors) and certain materials facilities. Facility-specific backfit is the result of the staff's attempt to ensure that a particular facility provides public health and safety and common defense and security, or complies with the Commission rules, policies, or guidance that are consistently applied to other licensees. This management directive covers only facility-specific backfitting. The Charter of the Committee To Review Generic Requirements (CRGR) covers the generic backfitting.

¹Optional for the licensee.

²Voluntary license amendments are those requested by the licensee, rather than those imposed on the licensee by NRC by rule or Order.

Facility-specific Backfits (B) (continued)

NRC's Backfit Regulations (1)

Title 10 of the *Code of Federal Regulations* (10 CFR) contains the NRC's backfit rules for nuclear power reactors and certain nuclear materials facilities. Specifically, 10 CFR 50.109, 70.76, 72.62, and 76.76 contain backfit provisions for the nuclear power reactors and certain materials facilities, including fuel facilities, spent fuel and radioactive waste storage facilities, and the gaseous diffusion plants. For new power reactor licensees who may wish to opt for one-step licensing, the backfit provisions are contained in 10 CFR 52.63, "Finality of Standard Design Certifications." These provisions apply to those utilities that reference design certification rules in their application, including construction permits, and operating licenses under 10 CFR Part 50. Furthermore, there are backfitting restrictions for Early Site Permits under 10 CFR 52.39, "Finality of Early Site Permit Determinations"; backfitting restrictions for design certifications under 10 CFR 52.63; backfitting restrictions for manufacturing licenses, duplicate design licenses, and design approvals in Appendices M, N, and O, respectively; and specific backfitting restrictions, applicable in the context of a specific design certification, in Appendices A, B, and C of 10 CFR Part 52.

Backfit Determination (2)

The NRC staff positions may be identified as potential backfits either by the staff or by any stakeholder. Such identifications will be considered by the office director or the regional administrator having responsibility to develop the staff positions on the matter at hand. This office director or regional administrator shall determine if the staff position is a backfit and whether the proposed backfit should be imposed on the licensee. (a)

The NRC staff shall be responsible for identifying proposed facility-specific backfits. The staff at all levels shall evaluate any proposed facility-specific position with respect to whether or not the proposed position qualifies as a backfit. (b)

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Facility-specific Backfits (B) (continued)

Backfit Determination (2) (continued)

Exhibit 1 contains staff guidance for backfit determination. (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 and regulatory analysis, if any) has been prepared and approved. (d)

Backfit Types (3)

Generally, three types of backfits are recognized in the NRC backfit rules, namely, 10 CFR 50.109, 70.76, 72.62, and 76.76. They are compliance, adequate protection (including defining and redefining the level of adequate protection),³ and cost-justified substantial increase in safety. (a)

The first two types of backfits are termed as exceptions.⁴ They do not require findings of substantial safety improvements. Moreover, economic costs can never be a consideration in (i) either defining or redefining what is an adequate level of protection or in ensuring that an adequate level of protection is achieved and maintained or (ii) requiring compliance with regulations that ensure adequate protection (unless the alternative to compliance also ensures adequate protection). However, costs may be considered in selecting from various ways of ensuring adequate protection or compliance. (b)

³The term “adequate protection of the public health and safety, and common defense and security” means the same as “no undue risk and reasonable assurance of not endangering public health and safety, and common defense and security.” In the NRC regulatory practice, these standards are used interchangeably.

⁴Exception from the requirement for the staff to prepare a backfit analysis under the provisions of NRC’s backfit rules demonstrating that the backfit constitutes a cost-justified substantial increase in safety.

Facility-specific Backfits (B) (continued)

Backfit Types (3) (continued)

Relaxations,⁵ if the implementation of which is voluntary for the licensee, are not backfits. (c)

Backfit Analysis Not Required or Terminated (4)

A backfit analysis is not required when— (a)

- A backfit is necessary to bring a facility into compliance with the facility license, rules or Orders of the Commission, or written commitments by the licensee,

or

- Imposition of a backfit is necessary to ensure that the facility provides adequate protection of public health and safety or common defense and security.

When the staff invokes a backfit exception, the appropriate office director or the regional administrator must provide a documented evaluation that includes a statement of the objectives, the reasons for the modification, and the basis for the backfit exception. (b)

When a backfit is needed to ensure that the facility provides adequate protection, the documented evaluation shall also describe the significance and appropriateness of the action taken from the standpoint of public health and safety or common defense and security. When a backfit is needed to ensure compliance, the documented evaluation shall identify with specificity the regulatory requirement(s) (i.e., NRC regulations or Order(s), or the facility license conditions or technical specifications) for which compliance is to be required. (c)

Such an evaluation shall be issued with the backfit except when an immediately effective agency action is necessary because the

⁵A relaxation is a proposed or modified regulatory initiative reducing the existing requirement.

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Facility-specific Backfits (B) (continued)

Backfit Analysis Not Required or Terminated (4) (continued)

safety or security implications are urgent, and full documentation cannot be completed. In those cases, the documentation may follow the backfit imposition. (d)

Should it be necessary or appropriate for the Commission to prescribe a way to achieve adequate protection or compliance, the staff's evaluation can include a consideration of how costs contribute to selecting a solution among various acceptable alternatives. However, cost will not be a factor in determining whether to require adequate protection or compliance, or what constitutes an adequate level of protection. (e)

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 costs of implementation are not likely to be justified. The office director or the regional administrator having the program area responsibility may approve closing the issue, with appropriate notice sent to all parties and recorded in the Agencywide Documents Access and Management System (ADAMS). The exemptions are noted in Section 033(d) of the directive. (f)

Backfit Claim by a Licensee (5)

When a proposed staff position has not been identified by the NRC staff as a backfit but is claimed to be a backfit by the affected licensee, the staff shall promptly review the licensee claim. (a)

The licensee must submit the backfit claim(s) and supporting rationale in writing to the office director or the regional administrator of the NRC office that issued the position. A copy of this material should be sent to the EDO. The division director who issued the staff position shall review the licensee claim. If it is determined that the issue is indeed a backfit, the appropriate staff office should immediately reconsider the issue and proceed with

Facility-specific Backfits (B) (continued)

Backfit Claim by a Licensee (5) (continued)

the preparation of any required documented evaluation or supporting analysis, as appropriate, for interoffice coordination and management approval in accordance with this management directive. (b)

After reconsideration, 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. (c)

In either case, the cognizant⁶ office director or regional administrator shall report to the EDO and inform the licensee, within 90 calendar days after receipt of the written backfit claim, of the results of the staff's determination and the staff's plan for resolving the issue. (d)

When a licensee is informed that a claimed backfit is, in the judgment of NRC, not a backfit, then the licensee may appeal this determination, as described later in this management directive. (e)

Support for Backfit Justification (6)

Basic Backfit Justification (a)

The NRC staff is responsible for evaluating all proposed new or revised staff positions to determine whether the positions are backfits, and for identifying facility-specific and generic backfits.

Documented Evaluation (b)

For all backfits required to ensure either adequate protection of public health and safety or common defense and security, or compliance with Commission regulations or Order(s), or the facility

⁶The 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 (NRR or NMSS) that has the statutory obligation to impose and dispose the backfits.

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Facility-specific Backfits (B) (continued)

Support for Backfit Justification (6) (continued)

license conditions or technical specifications, the staff must prepare a documented evaluation to justify the proposed agency action.

Compliance Exceptions (i)

When ensuring 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, with a finding that the action is necessary to ensure compliance.

For compliance backfits, the staff need not consider the costs. Also, for compliance cases, if immediately effective agency action is needed, the required documented evaluation may follow the issuance of the agency action.

Such a 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 cognizant office staff should consult and coordinate with OE and seek OGC advice on imposition of all compliance backfits, including negotiating with the licensee the schedule for implementation.

At any point during the process, the cognizant 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—

- an exemption from compliance with the Commission's regulation for which compliance is sought may be granted under 10 CFR 50.12

Facility-specific Backfits (B) (continued)

Support for Backfit Justification (6) (continued)

or

- enforcement discretion may be exercised in accordance with applicable NRC guidance on the matter.

Adequate Protection (ii)

If imposition of a backfit is necessary to ensure that the facility provides adequate protection to the public health and safety or common defense and security, a backfit analysis to justify this determination is not required. Under these circumstances, the appropriate office director or regional administrator shall provide a documented evaluation 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.

This evaluation shall include a statement of the objectives and the reasons for the modification, and the basis for invoking this exception. 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.

If it is necessary or appropriate for the Commission to prescribe a way to achieve adequate protection, the evaluation can include a consideration of how costs contribute to selecting a solution among various acceptable alternatives.

Cost-Justified Substantial Safety Enhancement (iii)

For all the backfits other than compliance or adequate protection exceptions, the cognizant staff must perform a backfit analysis. Additionally, the staff may also 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. Often only one

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Facility-specific Backfits (B) (continued)

Support for Backfit Justification (6) (continued)

analysis is performed to meet both the backfit and the regulatory analysis requirements because the traditional cost-benefit analysis in the regulatory analysis satisfies the cost-justified safety enhancement requirement of the backfit analysis. The combined backfit and regulatory analysis is further discussed in Section II.B.6(f), and pertinent staff guidance is included in Exhibit 2.

Backfit Standard (c)

The backfit 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.”

In the statement of considerations for the 1985 reactor backfit 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

Facility-specific Backfits (B) (continued)

Support for Backfit Justification (6) (continued)

that would be provided (50 FR 38097, 38102, September 20, 1985).⁷

Backfit Analysis (d)

Many relaxations may not show a substantial increase in safety and their implementation should be optional for the licensees.

If necessary and relevant, qualitative considerations may also be used to demonstrate a cost-justified safety enhancement.

Regulatory Analysis (e)

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.

For a detailed description of the 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." The regulatory analysis must

⁷In 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), 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.)

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Facility-specific Backfits (B) (continued)

Support for Backfit Justification (6) (continued)

conform to the guidance and policies, including scope and format, as set forth in these documents.

Combined Backfit and Regulatory Analysis (f)

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 contain 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. (For example, in NUREG/BR-0058, Rev. 3, 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 50.109⁸ and identifies where that information should be discussed in the regulatory analysis.) Exhibit 2 also contains guidance on the scope of the combined backfit and regulatory analysis.

The regulatory analysis should be terminated with a final recommendation that no action be taken. However, if a positive finding 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 backfit 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, no agency action should be taken, 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

⁸For backfitting certain materials facilities, the staff must refer to the corresponding provisions in 10 CFR 70.76, 72.62, and 76.76, as appropriate.)

Facility-specific Backfits (B) (continued)

Support for Backfit Justification (6) (continued)

effort is needed to complete the analysis, it is deemed appropriate to produce a final regulatory decisionmaking.)

If, based on both quantitative and qualitative considerations, the combined regulatory and backfit analysis demonstrates a cost-justified substantial enhancement 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 regional administrator and a copy sent to the EDO before the analysis is transmitted to the licensee.

Further Justification (g)

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

Process for Imposing Facility-specific Backfits (7)

The imposition of facility-specific backfits is governed by this management directive, which establishes the staff requirements and provides guidance for implementation of this aspect of the backfit rules.

In this context, it should be noted that actions proposed by the licensee are not backfits, even though such actions may result

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Facility-specific Backfits (B) (continued)

Process for Imposing Facility-specific Backfits (7) (continued)

from normal discussions between the staff and the licensee concerning an issue.

The office director or the regional administrator shall approve the documented evaluation, the backfit analysis and the regulatory analysis, if any, prepared by the office or regional staff. The Director of NRR, the Director of NMSS, or the regional administrator, as appropriate, is responsible for final disposition of all backfits, including security-related backfits.

For backfits within the NRR [NMSS] program area of responsibility, which are proposed by the NRR [NMSS] staff, the Director of NRR [NMSS], without further delegation, shall approve the supporting analysis before communicating with the licensee.

After the appropriate office director or regional administrator has approved the documented evaluation, supporting regulatory analysis, if any, or backfit analysis, the cognizant division director shall issue the backfit requirement to the licensee. The licensee may choose to implement the backfit or appeal it.

Implementation of a facility-specific backfit is normally accomplished on a schedule negotiated between the licensee and NRC. The staff should consult OE and OGC for establishing the implementation schedule.

Scheduling criteria should include the importance of the backfit relative to other safety- or security-related activities under way, such as planned construction or maintenance that will allow the facility to maintain the schedule of construction or continue operations. The NRC actions should not interrupt or delay facility construction, licensing action, or operations. During the staff's evaluation and backfit transmittal process, or a subsequent licensee appeal process, the proposing office or region shall track

Facility-specific Backfits (B) (continued)

Process for Imposing Facility-specific Backfits (7) (continued)

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. Exceptions are noted in Section 033(d) of the directive.

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.

Licensee Claim of a Backfit and the Backfit Appeal Process (8)

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 regional administrator. A copy of the claim should be sent to the EDO.

For a staff position within NRR [NMSS] jurisdiction that is claimed to be a backfit by the licensee, the Director of NRR [NMSS] shall make the decision on imposition of the backfit. Claims on the security-related backfits shall be forwarded to the Director of NSIR. However, the Director of NRR or the Director of NMSS, as appropriate, is responsible for final disposition and imposition of backfits. The office director's decision is subject to the EDO's review.

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Facility-specific Backfits (B) (continued)

Licensee Claim of a Backfit and the Backfit Appeal Process
(8) (continued)

The cognizant staff shall promptly review the licensee's claim and re-evaluate the staff position in accordance with the backfit policies of this management directive. After management approval, the responsible director shall promptly communicate the backfit decision to the licensee.

The licensee may implement the backfit or appeal the backfit determination to the office director or the regional administrator, as appropriate. This is the first level of appeal. If dissatisfied with the decision of the office director or the regional administrator, the licensee may appeal to the EDO, which is the second level of appeal.

The appeals described in this section are of two types, which are applied to two distinctly different situations—

- Appeal to the cognizant office or region to modify or withdraw a proposed backfit for which a regulatory analysis had been prepared and transmitted to the licensee or
- Appeal to the cognizant 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
 - a backfit that the staff believes falls within one of the exceptions from the requirement for the staff to perform a regulatory analysis, in the licensee's view does not.

In the first type of appeal,

- The facility licensee must send an appeal of a proposed backfit in writing to the office director or the regional administrator whose staff has proposed the backfit. The office director or the regional administrator shall decide on the appeal.

Facility-specific Backfits (B) (continued)

Licensee Claim of a Backfit and the Backfit Appeal Process
(8) (continued)

- The licensee should send a copy of the appeal to the EDO.
- The written appeal should address the staff's supporting analysis and provide specific arguments against the staff's rationale for imposing a backfit.
- The office director or the regional administrator shall forward security-related backfit appeals to the director of NSIR.
- Within 90 days after receipt of the appeal, the office director or the regional administrator shall report to the EDO the staff's plan for resolving the issue.
- After the staff's re-evaluation of the licensee's appeal and appropriate interoffice coordination and management review, the office director or the regional administrator shall decide on the appeal and inform the licensee in writing. A copy of this decision will be sent to the EDO.
- If dissatisfied with the written decision of the office director or the regional administrator on a facility-specific backfit, the licensee may appeal to the EDO unless resolution is achieved at a lower management level.
- 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 EDO may review and modify the backfit decision either on his or her own initiative or at the request of the licensee.
- The cognizant staff shall prepare summaries of all appeal meetings, enter the summaries into ADAMS, and profile them as publicly available. Exceptions are noted in Section 033(d) of the directive.

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Facility-specific Backfits (B) (continued)

Licensee Claim of a Backfit and the Backfit Appeal Process
(8) (continued)

- The staff should reconsider the supporting analysis as well as any other information that is relevant and material to the proposed backfit.

In the second type of appeal,

- The written licensee appeal must be addressed to, and will be decided by, the office director or the regional administrator, unless resolution is achieved at a lower management level (see Figure 2).
- 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.
- The licensee should send a copy of the appeal to the EDO.
- The office director or the regional administrator shall forward security-related backfit appeals to the director of NSIR.
- Within 90 days after receipt of the appeal, the office director or the regional administrator shall report to the EDO the staff's plan for resolving the issue.
- After the staff's re-evaluation of the licensee's appeal and appropriate interoffice coordination and management review, the office director or the regional administrator shall decide on the appeal and inform the licensee in writing. A copy of this decision will be sent to the EDO.
- If dissatisfied with the decision of the office director or the regional administrator, the licensee may appeal to the EDO, unless resolution is achieved at a lower management level (see Figure 2).

Facility-specific Backfits (B) (continued)

Licensee Claim of a Backfit and the Backfit Appeal Process
(8) (continued)

- The EDO may appoint a special Backfit Review Panel to review the licensee backfit appeal. This panel shall promptly resolve the appeal and document its resolution for the EDO's consideration.
- The EDO may review and modify the backfit decision either on his or her own initiative or at the request of the licensee.
- The cognizant staff shall prepare summaries of all appeal meetings and enter the relevant information into ADAMS, which shall be profiled as publicly accessible. Exceptions are noted in Section 033(d) of the directive.
- Backfit claims and resultant staff determinations that are reevaluated in response to an appeal and that are again determined by NRC as not to be backfits, or are excepted from the requirement for a regulatory analysis, shall not be treated further in the context of this management directive. Such matters are to be dealt with within the normal licensing or inspection appeal process.

Following approval of any required supporting analysis by the appropriate office director or regional administrator, and review, if any, by the EDO, and issuance of the backfit to the licensee, the licensee will implement the backfit or an Order will have to be issued.

Implementation of a Backfit (9)

If after losing an appeal the licensee does not agree to implement the backfit, it may be imposed by the Order of the appropriate office director. Once an Order is issued, whether or not it is immediately effective, this management directive no longer applies and appeals are governed by the provisions of 10 CFR Part 2, Subpart B.

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Facility-specific Backfits (B) (continued)

Implementation of a Backfit (9) (continued)

Implementation of a facility-specific backfit is normally accomplished on a schedule negotiated between the licensee and NRC.

Scheduling criteria should include the importance of the backfit at hand relative to other safety- or security-related activities under way, such as planned construction or maintenance that will allow the facility to maintain the schedule of construction or continue operations. The staff should consult OE and OGC for determining how long the backfit imposition can be deferred.

A staff-proposed backfit may be imposed by an Order before completing any of the requirements set forth in this management directive provided the office director issuing the Order determines that immediate imposition is necessary to provide adequate protection of the public health and safety (or the common defense and security). In such cases, the EDO shall be notified promptly of the action and if possible a documented evaluation, as described in this handbook, is performed in time to be issued with the Order.

If immediate imposition is not necessary, the implementation of staff-proposed backfits may be deferred. The staff should consult OE and OGC for determining how far the backfit imposition can be deferred.

Exceptions (C)

Nothing in this management directive 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.

**Assessment of the Overall
Effectiveness of the NRC's
Facility-specific Backfit
Management Program (D)**

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

Part III
Information Collection Requirements

NRC Regulations (A)

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 in 50 FR 38097) requires the NRC staff to justify such information requests by a supporting analysis, which should demonstrate 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— (1)

- 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. (a)
- 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), the supporting analysis shall include the reasons for the request and justify the estimated burden on the licensees imposed before issuance. (b)
- 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

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NRC Regulations (A) (continued)

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 management directive. (c)

The requirements for information collection requests for certain nuclear materials facility licenses are contained in 10 CFR 70.22(d), 72.62(d), and 76.70(e). (2)

Justification (B)

The Directors of the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Security and Incident Response, and the regional administrators shall develop internal office procedures to ensure that the staff establishes a rational basis for all information requests not clearly excepted from the finding, whether or not it is clear that a backfit action would result from staff evaluation of the information supplied by the licensee. Specifically, the cognizant office director or regional administrator shall—

- 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 (a)

and

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

The NRC staff's evaluations to demonstrate that an information request is necessary shall include at least the following elements:

- A statement of the problem describing the need for the requested information in terms of its potential benefit

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Justification (B) (continued)

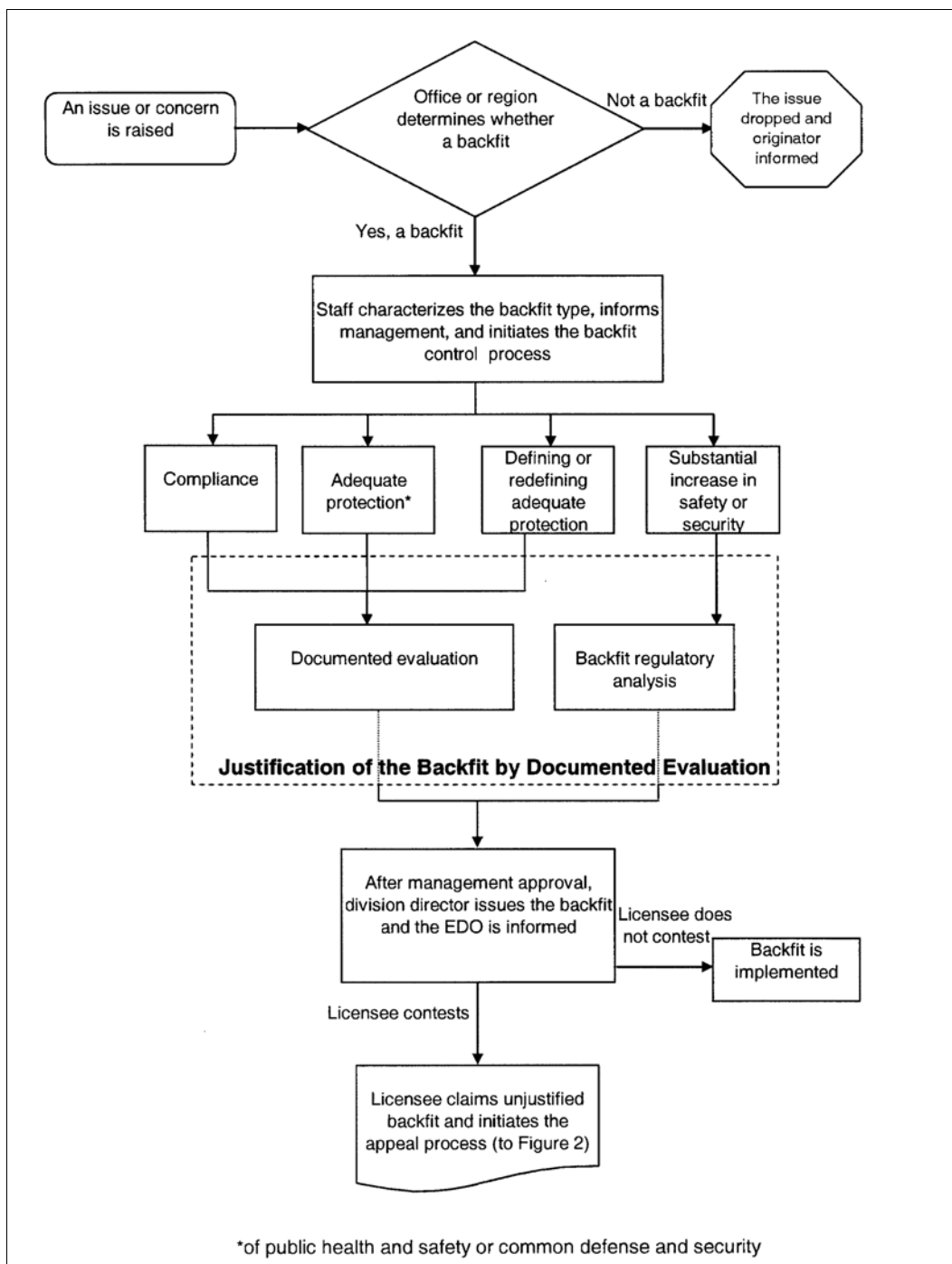
- The licensee actions required and an estimate of the burden on the licensee to develop a response to the information request
- An anticipated schedule for NRC to use the information

Part IV
Backfit Training Program

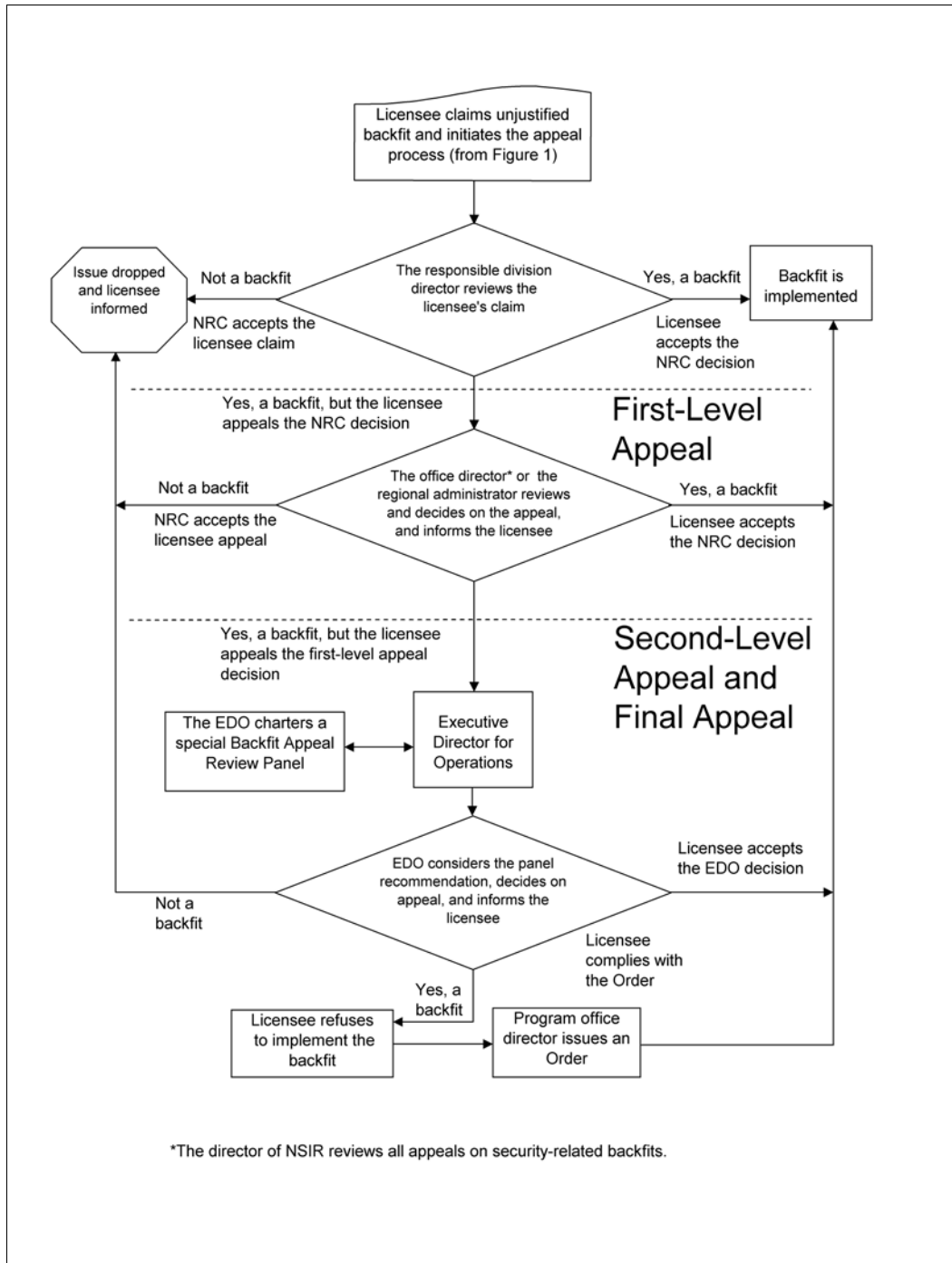
The NRC office directors and regional administrators shall plan for backfit training for their technical staff. The graded training will be provided at all levels—at the beginner and advanced levels—and will include refresher courses.

The Office of Human Resources (HR) shall maintain and update a backfit training program for the NRC's technical staff. In consultation with the Office of the General Counsel and the appropriate staff in the Office of Nuclear Regulatory Research, the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Security and Incident Response, the Office of Enforcement, and the regional offices, HR will develop the generic and facility-specific backfit training modules and also plan for the refresher courses. HR will also consult and coordinate with the appropriate contact in the Office of the Chief Information Officer to make some of the backfit training modules available online.

**Figure 1
 Facility-specific Backfit Process**



**Figure 2
 Facility-specific Backfit Appeal Process**



Glossary

Applicable Staff Positions. Applicable staff positions are those 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 are contained in documents such as the SRP (Standard Review Plan), 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.

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

Facility-specific Backfit. Backfitting 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 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 is the result of the staff's attempt to ensure that a particular facility provides public health and safety and common defense and security, or complies with the Commission rules, policies, or guidance that are consistently applied to other licensees.

It should be noted that to be a backfit, a staff position must meet the conditions involving both the substance of the elements of a proposed staff position and the time of the identification of the staff position:

- A proposed staff position may be a backfit if it would cause a licensee to change the design, construction, or operation

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Glossary (continued)

of a facility¹ from that consistent with already applicable staff position(s). Applicable staff positions are described in this Glossary.

- A proposed staff position, as described above, 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. Those times after which a new or revised staff position will be considered a backfit are as follows:
 - The date of issuance of the construction permit for the facility (for facilities having 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 having construction permits issued before October 21, 1985);
 - The date of issuance of the OL for the facility (for facilities having an OL on October 21, 1985);
 - The date of issuance of the design approval under 10 CFR Part 50, and Appendix M, N, and O of 10 CFR Part 52.

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

- a license to operate a nuclear power reactor, an independent spent fuel storage installation, or a monitored retrievable storage installation,
- a construction permit to build a nuclear power reactor,

¹Currently, the backfit requirements of 10 CFR 50.109 and 72.62 do not apply to the licensees of independent spent fuel storage installations holding a general license pursuant to 10 CFR Part 72, Subpart K.

Glossary (continued)

- a preliminary or final design approval, a design certification for a standardized plant design, Early Site Permit (ESP), Early Site Approval, a combined license, or a manufacturing license under 10 CFR Part 52.²

Tacit Acceptance/Approval. When the NRC's silence to a licensee request is, by rule, deemed to be approval. Instances of tacit acceptance are rare; silence or lack of comment by the NRC staff where the NRC's rules do not require an NRC response does **NOT** constitute tacit acceptance.

² The backfit provisions of 10 CFR 52.63 apply to those applicants or licensees who refer to the design certification rule in their application. These provisions also apply to applicants for construction permits and operating licenses under 10 CFR Part 50. Additionally, there are backfitting restrictions for ESPs, under 10 CFR 52.39, as well as general backfitting restrictions in Appendices M, N, and O, and specific backfitting restrictions, applicable in the context of a specific design certification, in Appendices A, B, and C of 10 CFR Part 52.

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Exhibits

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Exhibit 1 Guidance for Making Backfit Determinations

A. General

In this exhibit, selected regulatory activities and documents are discussed to help the NRC staff understand the conditions under which a staff position may be viewed as a facility-specific backfit. It is important to understand that the necessity for making backfit determinations should not inhibit the normal informal dialogue between the technical reviewer or inspector and the licensee. The intent of this process is to manage backfit imposition, not to quell it. The discussion in this exhibit is intended to aid in identifying backfits in accordance with the principles and the practices that should be implemented by the NRC staff. This exhibit is not intended to be an exhaustive, comprehensive workbook in which can be found a parallel example for every conceivable situation. As is evident from the definitions in the Glossary of Management Directive (MD) 8.4, a facility-specific backfit has the elements of a change from an already applicable staff position, which is defined as the applicable staff position established before certain defined milestones in the affected facility's licensing history. (See the Glossary of MD 8.4.) Some judgment will be necessary to determine whether a proposed staff position would cause a licensee to change the design, construction, or operation of a facility. In making this determination, the fundamental question is whether the staff's action is directing, telling, or coercing, or is merely suggesting or asking the licensee to consider a staff-proposed action.

Actions proposed by the licensee are not backfits under MD 8.4, even though such actions may result from normal discussions between the staff and the licensee concerning an issue, and even though the change or additions may meet the definitions in the Glossary.

B. Licensing

1. Standard Review Plan (SRP)

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 are being reviewed and approved through a generic review process involving the Committee To Review Generic Requirements (CRGR), and the extent to which the changes apply to classes of facilities is defined. 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

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actions so as to determine whether the actions will meet the intent of the SRP is not considered a backfit.

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

As part of the generic review process pursuant to the CRGR Charter, it is decided which facility or groups of facilities should be affected by the new or modified regulatory guide provisions. Such implementation is, therefore, not governed by the backfit procedures. Any staff-proposed facility-specific implementation of a regulatory guide 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 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

An Order issued to cause a licensee to take actions that are not otherwise applicable staff positions would be a facility-specific backfit. As described in the Glossary of MD 8.4, 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.

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 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.

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C. Inspection and Enforcement

1. Inspections

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.

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 such discussions the licensee agrees that it is appropriate to take action in response to the inspector's findings, such 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, such 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)

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.

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.

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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

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. Undoubtedly, 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.

For example, in the case of a near-term operating license (NTOL), once the safety evaluation report 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 was to subsequently require, after issuance of the license, that the licensee commit to additional action other than that specified in the SAR for the particular area, such action would constitute a backfit. A change in position prior to issuance of a license is not considered a backfit, inasmuch as the Safety Evaluation Report (SER) does not constitute the NRC's final position until the license is issued. Moreover, under 10 CFR 50.109, backfit protections do not become effective until the license is issued.

**Exhibit 2
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 backfit rules, the staff should consult with the Office of the General Counsel (OGC).

B. Scope

1. Regulatory Analysis

The regulatory analysis consists of six distinct sections:

- A statement of the problem and NRC objectives for the proposed regulatory action.
- Identification and preliminary analysis of alternative approaches to the problem.
- Estimation and evaluation of the values and impacts of selected alternatives, including consideration of the uncertainties affecting the estimates.
- 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.)
- The decision rationale for selection of the proposed regulatory action.
- A tentative implementation instrument and schedule for the proposed regulatory action.

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

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analysis should be limited to that necessary to provide an adequate basis for decision-making 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

With respect to the backfit analysis requirements, Table 1, which is reproduced from NUREG/BR-0184, identifies each of the information items identified in the reactor backfit rule (10 CFR 50.109) and its corresponding placement in the regulatory analysis format. For justification of backfitting of certain nuclear materials facilities, the staff should consider the corresponding provisions in 10 CFR Parts 70, 72, and 76.

Additionally, the following should be considered, as appropriate, for all proposed facility-specific backfits requiring cost-justified safety enhancement:

- 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.
- A general description of the activities that would be required by the licensee to implement the backfit.
- 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.
- 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.
- Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.
- 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.

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- 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 under way at the affected facility.
- A statement of consideration of the proposed facility-specific backfit for potential generic implications.

This combined analysis must be approved by the appropriate program office director or regional administrator and a copy must be sent to the EDO before the analysis is transmitted to the licensee.

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Table 1 Checklist for Combined Backfit and Regulatory Analysis
(Excerpted, except for the footnote, from NUREG/BR-0184)
(Table 2.2 Checklist for specific backfit regulatory analysis requirements)

CFR Citation ¹ (Title 10)	Information Item To Be Included in a Backfit Regulatory 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
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

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

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Table 1 Checklist for Combined Backfit and Regulatory Analysis
(Excerpted, except for the footnote, from NUREG/BR-0184)
(Table 2.2 Checklist for specific backfit regulatory analysis requirements)
(continued)

CFR Citation ¹ (Title 10)	Information Item To Be Included in a Backfit Regulatory Analysis	Section of the Regulatory Analysis Where the Item Should Normally Be Discussed
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

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