



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

RI 1620.1/0
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REGION I INSTRUCTION 1620.1, REVISION 0

PLANT-SPECIFIC BACKFIT PROCEDURES

Reference: NRC Draft Manual Chapter 0514, "A Program for Management of Plant-Specific Backfitting of Operating Power Reactors"

A. Purpose

To prescribe procedures for implementation of NRC plant-specific backfit policy in accordance with Draft NRC Manual Chapter 0514 (NRC-0514). Users of this instruction should familiarize themselves with NRC-0514. Any apparent conflict between this instruction and NRC-0514 should be brought to the attention of appropriate managers.

B. Discussion

It is the overall objective of this instruction to assure the plant-specific backfitting of nuclear power plants is justified and documented and that Region I senior management is responsible for the proper implementation of the backfit program in their area of responsibility. The specific objective of the backfit program is to provide for improvements in the levels of protection of public health and safety while avoiding any unwarranted burdens on licensees in implementing these backfits. We should assure to the extent possible that backfits to be issued will in fact contribute effectively and significantly to the health and safety of the public or the common defense and security.

It should be clearly understood that backfits are expected to occur and deemed an important part of the regulatory process to provide for the safety of nuclear power plants. However, it is important that backfitting be conducted in a controlled process if we are to have effective and consistent regulation. The management of plant-specific backfitting as described in this instruction in no way is meant to relieve licensees from complying with NRC requirements. The provisions of this instruction are intended to provide for a cogent regional review of new or changed positions that we may desire to impose on licensees who have already implemented previously applicable requirements or positions which were considered by the NRC to have provided acceptable levels of safety. The plant-specific backfit process described in this instruction will enhance both regulatory stability and safety by assuring that changes in staff positions do in fact provide substantial additional safety protection.

CONTACT:

J. Wiggins, DRP

Revision Responsibility:

DRP

that are warranted prior to imposing such changes on the licensee. This assurance will be provided through a regulatory analysis as described in Section D.3.

A plant-specific backfit is different from a generic backfit in that the former involves the imposition of a position unique to a particular plant, whereas a generic backfit involves the imposition of the same or similar position on two or more plants. Management of generic backfits is not governed by this instruction, but by the CRGR process.

C. Definitions

1. Licensee - Except where defined otherwise, the word licensee as used in this Regional Instruction shall mean that person that holds a license to operate a nuclear power plant, or a construction permit to build a nuclear power plant, or a Preliminary Design Approval or Final Design Approval for a Standardized Plant Design.
2. Plant-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 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 specified dates. Backfitting is "plant-specific" when it involves the imposition of a position that is unique to a particular plant.

It should be noted that to be a plant-specific backfit a staff position must meet conditions involving both (1) the substance of the elements of a proposed staff position and (2) the time of the identification of the staff position.

- a. A staff position may be a proposed backfit if it would cause a licensee to change the design, construction or operation of a facility from that consistent with an already applicable regulatory staff position. Applicable regulatory staff positions are described in NRC-0514.
- b. A staff position as described in C.2.a is a proposed backfit if it is first identified to the licensee after certain important design, construction or operation milestones, involving NRC approvals of varying kind, has been achieved. Those times after which a new or revised staff position will be considered a backfit are as follows:
 - (1) After the date of issuance of the construction permit for the facility (for facilities having construction permits issued after May 1, 1985); or

- (2) after 6 months before the date of docketing of the OL application for the facility (for facilities having construction permits issued before May 1, 1985); or
 - (3) after the date of issuance of the operating license for the facility (for facilities having an operating license on May 1, 1985); or
 - (4) after the date of issuance of the design approval under 10 CFR 50, Appendix M, N. or O.
3. Applicable Regulatory Staff Positions - Applicable regulatory staff positions are those already specifically imposed upon or committed to by a licensee at the time of the identification of a plant-specific backfit, and are of several different types and sources:
- a. Legal requirements such as in explicit regulations, orders, plant licenses (amendments, conditions, technical specifications). Note that some regulations have update features built in, as for example, 10 CFR 50.55a, Codes and Standards. Such update requirements are applicable as described in the regulation.
 - b. Written commitments such as contained in the FSAR, LERs, and docketed correspondence, including responses to IE Bulletins, Generic Letters, Confirmatory Action Letters, Inspection Reports, or responses to Notices of Violation.
 - c. NRC staff positions that are documented, approved, explicit interpretations of the more general regulations, and are contained in documents such as the SRP, Branch Technical Positions, Regulatory Guides, Generic Letters and IE Bulletins and to which a licensee or an applicant has previously committed to or relied upon. Positions contained in these documents are not considered applicable staff positions to the extent that staff has, in a previous licensing or inspection action, tacitly or explicitly excepted the licensee from part or all of the position.

Working level examples of staff positions which constitute backfits and those that do not constitute backfits are discussed in Appendix A to this instruction.

D. Procedure Implementation

The overall backfit process should be conducted in accordance with the following instructions.

1. Regional Backfit Identification - Any Regional staff member who identifies the need for imposition of a potential backfit will immediately verbally identify this need for imposition to his/her Section Chief. Licensees may also claim a staff action, not initially identified by the

staff, is a backfit, and this claim should be similarly treated under this section. If the issue is determined to be a backfit candidate by the Section Chief, in accordance with the guidance of Section C above, then a Backfit Identification Form (BIF) (Copy of Form attached as Appendix B) will be completed by the identifying staff member, within two working days, and forwarded by the staff member's Section Chief, through the Branch Chief, to the Division Director for disposition. Information copies of the BIF should also be forwarded to the responsible DRP Section Chief and Branch Chief.

2. Division Director Disposition - Each Division Director receiving a BIF will determine how to process the potential backfit within one week of receipt, as follows:
 - a. If the Division Director considers that the position, if imposed, would constitute a backfit, and that imposition of the backfit on the licensee appears to provide substantial additional safety protection, then the backfit will be processed by the originating section in accordance with Section D.3, 4, 6 and 7 below. If however the Division Director believes that immediate imposition of the position is required to protect the public health and safety or the common defense and security, then the Immediate Imposition Procedure of Section D.5 below should be implemented.
 - b. If the Division Director determines that the position, if imposed, would not constitute a backfit because the proposed modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee, no regulatory analysis is required. Instead, the Division Director is to provide a documented evaluation to support the proposed action to the Regional Administrator prior to taking the action. The evaluation shall include a statement of the objectives of and reasons for the modification.
 - c. If the Division Director determines that the position, if imposed, would constitute a backfit, but that imposition on the licensee would not provide substantial additional safety protection or is otherwise not necessary, then no further action on the issue should be taken beyond documentation of this determination on the BIF and in the Plant Specific Backfit System (PSBS), and the BIF should be filed.
3. Regulatory Analysis (RA)
 - a. If the originating staff's Division Director determines that the potential backfit constitutes backfitting, and it appears that imposition will provide substantial additional safety protection, then he is to direct that a RA be prepared. Preparation of the RA will be the responsibility of the Section Chief whose staff identified the backfit issue.

- b. The regulatory analysis shall generally conform to the directives and guidance of NUREG 0058 and NUREG CR-3568, which are the NRC's governing documents concerning the need for and preparation of regulatory analyses. In preparing regulatory analyses, the complexity and comprehensiveness of an analysis should be limited to that necessary to provide an adequate basis for decision-making among the alternatives available. NUREG 0058, Section III.A.2, Scope of the Analysis, indicates that "The emphasis in (doing the analysis) should be on simplicity, flexibility, and common sense, both in terms of the type of information supplied and in the level of detail provided." The following information and any other information relevant and material to the backfit shall be included in the regulatory analysis, as available and appropriate to the analysis:
- (1) A statement of the specific objective that the proposed backfit is designed to achieve. This should also include a succinct description of the backfit proposed, and how it provides a substantial increase in overall protection.
 - (2) A general description of the activity that would be required by the licensee in order to complete the backfit.
 - (3) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements.
 - (4) Whether the proposed backfit is interim or final and if interim, the justification for imposing the proposed backfit on an interim basis.
 - (5) 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, and a qualitative assessment of benefits may be made in lieu of a quantitative analysis where it would provide more meaningful insights, or is the only analysis practicable. This statement should include consideration of at least the following listed factors:
 - (a) The potential change in risk to the public from the accidental offsite release of radioactive material.
 - (b) The potential impact on radiological exposure of facility employees. Also consider the effects on other onsite workers, due both to installation of procedural or hardware changes and to the effects of the changes, for the remaining lifetime of the plant.

- (c) The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay.
 - (d) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources.
- (6) A consideration of important qualitative factors bearing on the need for the backfit at the particular facility, such as, but not limited to, operational trends, significant plant events, management effectiveness, or results of performance reports such as the Systematic Assessment of Licensee Performance.
 - (7) A statement affirming appropriate interoffice coordination related to the proposed backfit and the plan for implementation.
 - (8) The basis for requiring or permitting 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 plant personnel, as appropriate. For those plants with approved integrated schedules, the integrated scheduling process can be used for implementing this step and the following two procedural steps.
 - (9) A schedule for staff actions involved in implementation and verification of implementation of the backfit, as appropriate.
 - (10) Importance of the proposed backfit considered in light of other safety-related activities underway at the affected facility.
- c. The completed RA and updated BIF will be forwarded for review by the cognizant Division Director, and after the concurrence of the Division Director is obtained, will be transmitted to the Regional Administrator for approval. The Division Director should not approve the proposed backfit unless the Regulatory Analysis supports the finding 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 the increased protection. If the Division Director determines that further staff action is not warranted the BIF and RA shall be filed. Disposition of the matter shall be entered in the PSBS.

4. Approval of Backfit Position

- a. The Division Director whose staff has initiated the backfit issue will forward the RA and BIF to the Regional Administrator for approval no later than four weeks from the identification of the backfit. At the same time, the completed RA will be forwarded to the Division Director of the appropriate headquarters office having program responsibility for the backfit issue (see Appendix C). The Program Office will in this manner be formally kept apprised of any backfit issues and will be given the opportunity to comment on the issue prior to its imposition on the licensee. Three workdays should normally be sufficient.

The Regional Administrator, or the Deputy Regional Administrator, will either approve or reject the backfit within one week from receipt of the RA and the BIF. Approval authority may not be redelegated. If approved, the BIF information will be provided to the DRMA, Programs Staff, Management Analysis for entry into the Backfit Data Base (BDB). If not approved, the BIF and RA will be filed.

- b. When a proposed backfit and supporting analysis are approved by the Regional Administrator, the documents (copy) must be forwarded to the EDO for information prior to transmitting the documents to the licensee. The Region shall forward the backfit and supporting regulatory analyses to the licensee without awaiting feedback from the EDO.
- c. If approved for issuance, the backfit position and the RA will be forwarded by the Cognizant Division Director to the licensee. The transmittal should clearly identify the position as a backfit.

5. Immediate Imposition Procedure

- a. If the Division Director whose staff has originated the backfit position believes that immediate imposition of the position is necessary to protect the public health and safety or the common defense and security, then the backfit may be processed without performance of the RA. In such cases, the EDO shall be promptly notified of the action and a documented evaluation as described in Section 042 of NRC-0514 will be performed, if possible, prior to the imposition of the backfit.
- b. In this instance a backfit panel will convene, chaired by the Regional Administrator or Deputy Regional Administrator, attended by the Projects Division Director or Deputy Director, and the Division Director and Branch Chief whose staff initiated the backfit. A representative from the headquarters office having program responsibility for the backfit requirement should attend the backfit panel meeting or participate via telecon. The headquarters representative

will be designated by the Office Director. The cognizant Section Chief will be responsible for presenting the issue including the rationale for immediate imposition.

- c. If the backfit panel agrees with the need for immediate imposition, the backfit will be forwarded, by the Regional Administrator, to the Office Director of the headquarters office having program responsibility for the backfit issue. The Office Director will be expected to act on immediate issuance of the backfit position within two working days from receipt of the request.
- d. If approval for immediate issuance is not given by the Office Director, then the backfit will be processed in accordance with Sections D.3, 4, 6 and 7.
- e. Whether approval is given by the Office Director or not, the BDB will be updated by the originating Section Chief by the forwarding of a completed BIF to the DRMA, Programs Staff, Management Analyst following the action by the Office Director.

6. Appeal Process

- a. The appeal processes are of two types:
 - (1) A licensee may appeal for withdrawal or modification of a staff identified backfit position in accordance with this section; or
 - (2) When a licensee is informed that a claimed backfit is, in the judgment of the NRC, not a backfit, the licensee may appeal this determination to the Director of the program office having responsibility for the program area relevant to the staff position. A copy of the appeal should be sent to the EDO.
- b. The rest of this section deals with the disposition of only staff-identified backfits. Licensees should address appeals to the Regional Administrator and should send a copy of the appeal to the EDO. When an appeal is received in the Regional Office, it should be forwarded to the Projects Division along with the other docket related mail. The initiating Section Chief will arrange and issue appropriate documentation for a first level appeals meeting in accordance with Regional Instruction 0550.1, Control of Significant Licensee Meetings, with the appealing licensee in order to attempt to resolve the issue. This meeting will be chaired by the cognizant Division Director and be attended by the applicable Projects Division Section Chief, and the Branch Chief and Section Chief whose staff initiated the appealed backfit position or staff action. A copy of the RA (if appropriate) will also be provided to the licensee, by the initiating Section Chief, in preparation for the appeals

meeting. The first level meeting should normally occur within 2 weeks of receipt of the appeal, or, in the case of a licensee identified backfit, within 2 weeks of the approval of the RA.

- c. The initiating Section Chief will draft a memorandum by which the Regional Administrator will inform the EDO of the planned disposition of the appeal. The Regional Administrator is required to notify the EDO of the planned disposition within 3 weeks of receiving an appeal. A copy of this memorandum will be forwarded to the headquarters office having program responsibility for the backfit or staff action and the BDB updated accordingly. This action should normally be completed within 3-working days from the first level appeals meeting.
- d. A summary of the appeals meeting will be prepared by the initiating Section Chief and forwarded to the licensee with copies to the EDO and PDR. The result of the meeting with the licensee should take the form of one of the following:
 - (1) The licensee agrees with the NRC staff that the backfit should be implemented as imposed. In this instance, the appeal process in effect will be terminated pursuant to this instruction.
 - (2) The NRC agrees with the licensee that a backfit should be withdrawn or modified. If the backfit is to be modified, then the backfit should be reissued in accordance with Section D.4.c above, or if the Division Director whose staff originated the staff action determines not to pursue the issue as a backfit then it should be withdrawn.
 - (3) No agreement or final disposition is reached and a second level meeting is scheduled.
- e. If no agreement was reached at the meeting in Section 6.d above, then the applicable initiating Section Chief will arrange for a second level meeting with the appealing licensee in order to re-attempt to resolve the issue. Normally, it should be attempted to hold this meeting on the same day as the initial meeting. This second meeting will be attended by the applicable Projects Division Section Chief, the Division Director and Section Chief whose staff initiated the appealed backfit or staff action and the Projects Division Director or Deputy Director. The meeting will be chaired by the Regional Administrator or Deputy Regional Administrator.
- f. A summary of this second appeals meeting will be prepared by the initiating Section Chief and forwarded to the licensee with copies to the EDO and PDR. The results of this second meeting with the licensee should take one of the forms specified in step D.6.d above and the BDB will be updated accordingly.

- g. If no agreement was reached at the meeting in Section 6.e above, then the initiating Section Chief will arrange for and issue appropriate documentation for a third meeting with the appealing licensee in order to again attempt to resolve the issue. This third meeting will be held in headquarters and coordinated with the office having program responsibility for the backfit or staff action. This third meeting will be attended by the applicable Program Office Director or Deputy Director, the Regional Administrator or Deputy Regional Administrator, and other appropriate managers whose staff initiated the appealed backfit position or staff action. The meeting will be chaired by the cognizant Program Office Director or Deputy Director. The cognizant program offices are identified in Appendix C. The third level meeting should normally be conducted within two weeks of the second level meeting.
- h. A summary of this third meeting will be prepared by the initiating Section Chief and forwarded to the licensee with copies to the EDO and PDR.
- i. At the conclusion of this third meeting, the appeals process will be considered concluded, regardless of whether the position of the licensee or NRC staff was modified. All information regarding the appeals process will be updated in a timely manner and the results of appeals process updated in the BDB by the initiating Section Chief using revised BIFs.

7. Backfit Imposition

Following approval of the backfit position by the Regional Administrator, and issuance to the licensee, the licensee will either implement the backfit or appeal it. It should be noted that immediate effective Orders must be implemented by the licensee, and are not subject to the backfit appeal process since the licensee may request a hearing under 10 CFR Part 2. After an appeal and subsequent final decision by the NRC, the licensee may elect to implement a position resulting from the decision. If the licensee does not elect to implement the position, the position may be imposed by Order of the appropriate Program Office Director.

Implementation of plant-specific backfit positions will be accomplished on a schedule negotiated between the licensee and the Cognizant Division Director. Scheduling criteria should include the priority of the backfit relative to other safety-related activities underway or construction or maintenance planned for the facility, and schedules and reasonable constraints thereon to maintain high quality construction and operations. For plants that have integrated schedules, the integrated scheduling process can be used for this purpose.

A staff-proposed position may be imposed prior to completing any of the procedures set forth in this Regional Instruction, provided the appropriate headquarters Office Director determines that prompt imposition

is necessary to protect the health and safety or the common defense and security. In this instance, the procedures of Section D.5 above will be followed. In such cases, the EDO shall be notified promptly of the action.

If prompt imposition is not necessary, staff proposed positions shall not be imposed, and plant operation shall not be interrupted during the staff's initial evaluation and transmittal process, or a subsequent appeal process, until a final action is completed by either the licensee or by the NRC staff.

8. Information Requests Pursuant to 10 CFR 50.54(f)

A revision to 10 CFR 50.54(f) was issued with the September 20, 1985 revision to 10 CFR 50.109. The revision generally requires that the NRC prepare reasons for issuing information requests prior to issuance. Only information requests seeking to verify licensee compliance with the current licensing basis for the facility are exempt from the necessity to prepare the reason or reasons for the request. Requests for information to determine compliance with existing facility requirements including fact-finding reviews, inspections and investigations of accidents or incidents, usually are not made pursuant to Section 50.54(f), nor are such requests normally considered within the scope of the backfit rule.

All requests for information pursuant to 10 CFR 50.54(f) must be evaluated to determine whether the burden imposed by the information request is justified in view of the potential safety significance of the issue to be addressed. The information request and the staff evaluation must be approved by the Regional Administrator prior to transmittal of the request for information to a licensee.

The Division initiating the request shall prepare the evaluation, which shall include at least the following elements:

- a. A problem statement that describes the need for the information in terms of potential safety benefit.
- b. The licensee actions required and the cost to develop a response to the information request.
- c. An anticipated schedule for NRC use of the information.

E. Data and Recording Requirements

The data identified in the Backfit Identification Form shall be entered into the Backfit Data Base within 3 working days after any action which requires updating of the BIF. The cognizant Section Chief is responsible for providing the updated BIF to the DRMA, Programs Staff, Management Analyst for BDB entry.

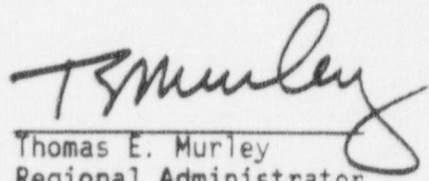
F. EDO Review

The EDO may review and modify any plant-specific backfit decision, at EDO initiative or at the request of a licensee, in accordance with NRC-0514.

G. Effective Date

This instruction supersedes Region I Instruction 1600.100 Revision 1 dated August 15, 1986 and is effective upon issuance.

Approved:


Thomas E. Murley
Regional Administrator

Date:

2/15/87

Enclosures:

1. Appendix A - Guidance for Backfit Determinations
2. Appendix B - Backfit Identification Form
3. Appendix C - Cognizant Headquarter Program Offices
4. Appendix D - Plant-Specific Backfit Flowchart

Distribution:

Office of the Regional Administrator
Division Directors
Chief, Administrative Management Branch (original)
Resident Offices

APPENDIX A

Guidance for Backfit DeterminationsGeneral

In this section selected regulatory activities or documents are discussed in order to enable regional staff to better understand the conditions under which a plant-specific backfit may be recognized. It is important to understand that the necessity for making backfit determinations should not inhibit the normal informal dialogue between the inspector and the licensee. The intent of this process is to manage backfit imposition, not to quell it. The discussion in this Appendix is intended to aid in identifying backfits in accordance with the principles that should be implemented by all staff members. This Appendix is not intended to be an exhaustive, comprehensive workbook in which can be found a parallel example for each situation that may arise. There will be some judgment necessary to determine whether a 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 when the actions result from normal discussions between staff and licensee concerning an issue, even though the change or additions may meet the definitions of Section C of this instruction.

Standard Review Plan (SRP)

The SRP delineates the scope and depth of staff review of licensee submittals associated with various review activities. It is a definitive NRC staff interpretation of measures which, if taken, will satisfy the requirements of the more generally stated, legally binding body of regulations, primarily found in title 10 CFR. Since October 1981, changes to the SRP are to have been 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 plants is defined. Consequently, application of a current SRP in a specific operating license (OL) review generally is not a plant-specific backfit, if the SRP was effective 6 months prior to OL review (i.e., 6 months prior to docketing of the OL application). Asking an applicant for an operating license questions to clarify staff understanding of proposed actions in order to determine whether the actions will meet the intent of the SRP is not considered a backfit.

On the other hand, using acceptance criteria more stringent than those contained in the SRP or proposing licensee actions more stringent than or in addition to those specified in the SRP, whether in writing or orally, are plant-specific backfits. During meeting with the licensee, staff discussion or comments regarding issues and licensee actions volunteered which are in excess of the criteria in the SRP generally do not constitute plant-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 is considered a plant-specific backfit whether or not the licensee agrees to take such action.

However, the staff should recognize that a verbally implied or suggested action should not be accepted by a licensee as an NRC position of any kind, backfit or not; only written and authoritatively approved statements should be taken as NRC positions.

Application of an SRP to an operating plant after the license is granted generally is considered a backfit unless the SRP was approved specifically for operating plant implementation and is applicable to such operating plant.

Regulatory Guides

As part of the generic review process pursuant to the CRGR Charter, it is decided which plants or groups of plants should be affected by new or modified Regulatory Guide provisions. Such implementation is therefore not governed by the plant-specific backfit procedures. However, any staff proposed plant-specific implementation of a Regulatory Guide provision, whether orally or in writing, for a plant not encompassed by the generic implementation determination is considered a plant-specific backfit. A staff action with respect to a specific licensee that expands on, adds to, or modifies a generically approved regulatory guide, so that the position taken is more demanding than intended in the generic positions, is a plant-specific backfit.

Plant-Specific Orders

An order issued to cause a licensee to take actions which are not otherwise applicable regulatory staff positions is a plant-specific backfit. An order effecting prompt imposition of a backfit may be issued prior to completing any of the procedures set forth in this instruction provided that the appropriate Headquarters Office Director determines that prompt imposition 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 plant-specific backfit provided the commitment was not solicited by the staff with the expressed or implied emphasis that such a commitment is necessary to gain acceptance in the staff review process. Discussion or comments by the NRC staff identifying deficiencies observed, whether in meetings or written reports, do not constitute backfits. Definitive statements to the licensee directing a specific action to satisfy staff positions are backfits unless the action is an explicit already applicable regulatory staff positions.

Inspections

NRC inspection procedures are to govern the scope and depth of staff inspections associated with licensee activities such as design, construction and operation. As such, they define those items the staff is to consider in its determination of whether the licensee is conducting its activities in a safe manner. The conduct of inspection establishes no new staff positions for the licensee and is not a plant-specific backfit.

Staff suggestions to the licensee that the contents of an NRC inspection procedure are positions that must be met by the licensee constitute a plant-specific backfit unless the item is an applicable regulatory staff position. Discussion or comment by the NRC staff regarding deficiencies observed in the licensee 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 previous staff positions applicable to the licensee are the only way to satisfy the staff. In the normal course of inspecting to determine whether the licensee's activities are being conducted safely, inspectors 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 is 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 the inspector does not indicate that the specific actions are the only way to satisfy the staff and the licensee freely volunteers to take such action. On the other hand, if the inspector indicates that a specific action must be taken, such action is a backfit unless it constitutes an applicable regulatory staff position.

For example, if the licensee commits to ANSI N18.7 in the SAR and the inspector finds the licensee's implementing procedures do not contain all the elements required by ANSI N18.7, telling the licensee he must take action to include all the elements in its implementing procedures is not a backfit. Likewise, if the inspector finds the licensee has included all the required elements of ANSI N18.7, but has not included certain of the optional elements in its implementing procedures, inspector discussion with the licensee regarding the merits of including the optional elements is not a backfit. On the other hand if the inspector tells the licensee that the implementing procedures must include any or all of the optional elements in order to satisfy the staff, inclusion of such elements is a backfit, whether or not agreed to by the licensee.

Notice of Violation (NOV)

A NOV requesting description of a licensee's proposed corrective action is not a backfit. The licensee's commitments in the description of 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 actions and requests that the licensee take additional actions, those additional actions (whether requested orally or in writing) are a backfit unless they are an applicable regulatory staff position.

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

Bulletins

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

Reanalysis of Issues

Throughout plant lifetime, many inspectors have an opportunity to review the requirements and commitments incumbent upon a licensee. Undoubtedly, there will be occasions when an inspector concludes the previously NRC approved licensee's program in a specific area does not satisfy a regulation, license condition or commitment. In the case where the staff previously accepted the licensee's program as adequate, any staff specified change in the program would be classified as a backfit.

For example, in the case of an NTOL, once the SER is issued signifying staff acceptance of the program contained in the SAR, the licensee should be able to conclude that his commitments in the SAR satisfy the NRC requirements for a particular area. If the staff was to subsequently require that the licensee commit to additional action other than that specified in the SAR for the particular area, such action would constitute a backfit. If there was tacit acceptance by staff, being silent on the issue for an extended period of time, then staff action to force change would be a backfit.

APPENDIX B

BACKFIT IDENTIFICATION FORMPerson Authorizing
Data Entry: _____

Date: _____

ENTER BACKFIT IDENTIFIER BELOW:

BACKFIT IDENTIFIER _____

123 4 5

Format (Starting position):

- 1 Office resp. for initiating backfit determination = R,S,E, or 1-5
- 2 Identifier of backfit = R,S,E,L, or 1-5
R=NRRL, S=NMSS, E=IE, L=Licensee, 1=Region 1 ... 5=Region 5
- 3 Plant abbreviation (5 positions)
- 4 Year initiated (must be numeric, 2 positions)
- 5 Sequential number of backfit (must be numeric, 3 positions)

IDENTIFYING BACKFIT INFORMATION

BACKFIT/PETITION DOCUMENT DESCRIPTION (360 CHARACTER MAXIMUM):

BACKFIT ISSUE SUBSTANCE (660 CHARACTER MAXIMUM):

BACKFIT DETERMINATION DATE (PREDICTED): (YYMMDD)

BACKFIT DETERMINATION INFORMATION

BACKFIT DETERMINATION DATE (COMPLETED): (YYMMDD)

WAS THIS DETERMINED TO BE A BACKFIT? (Y-YES, N-NO)

BACKFIT DETERMINATION SUBSTANCE (360 CHARACTERS MAXIMUM):

BACKFIT DETERMINATION ORGANIZATION (E.G. NRRL/DL):

BACKFIT DETERMINATION OFFICIAL (LAST NAME, 1ST INIT.):

REGULATORY ANALYSIS COMPLETION DATE: (YYMMDD)

PLANT-SPECIFIC BACKFIT PROCEDURES

Appendix B
RI 1620.1/0

Person Authorizing
Data Entry: _____

Date: _____

APPEAL INFORMATION

APPEAL DATE (PREDICTED): (YYMMDD)

APPEAL DATE (COMPLETED): (YYMMDD)

APPEAL DESCRIPTION/STATUS (360 CHARACTERS MAXIMUM):

APPEAL ORGANIZATION (E.G., NRR/DL):

APPEAL OFFICIAL (LAST NAME, 1ST INIT.):

CLOSING ACTION INFORMATION

CLOSING ACTION DATE (PREDICTED): (YYMMDD)

CLOSING ACTION DATE (COMPLETED): (YYMMDD)

CLOSING ACTION DESCRIPTION (360 CHARACTERS MAXIMUM):

CLOSING ACTION ORGANIZATION (E.G., NRR/DL):

CLOSING ACTION OFFICIAL (LAST NAME, 1ST INIT.):

APPENDIX C

COGNIZANT HEADQUARTERS PROGRAM OFFICES

Inspection Related Backfit Positions - Office of Inspection and Enforcement

Enforcement Related Backfit Positions - Office of Inspection and Enforcement

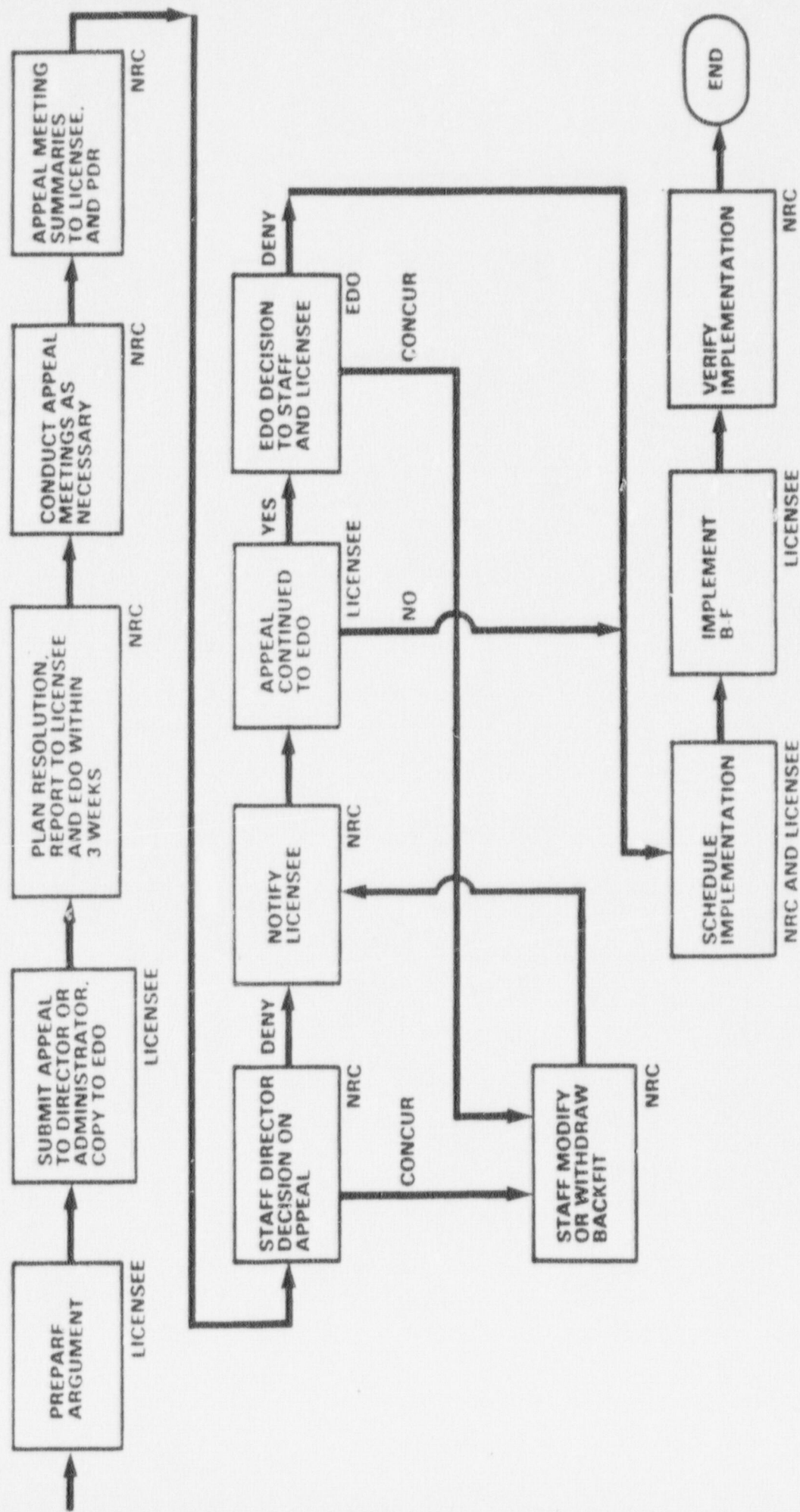
Licensing Related Backfit Positions - Office of Nuclear Reactor Regulation,
except for:

- Safeguards Issues - NMSS
- QA Issues - IE
- EP Issues - IE

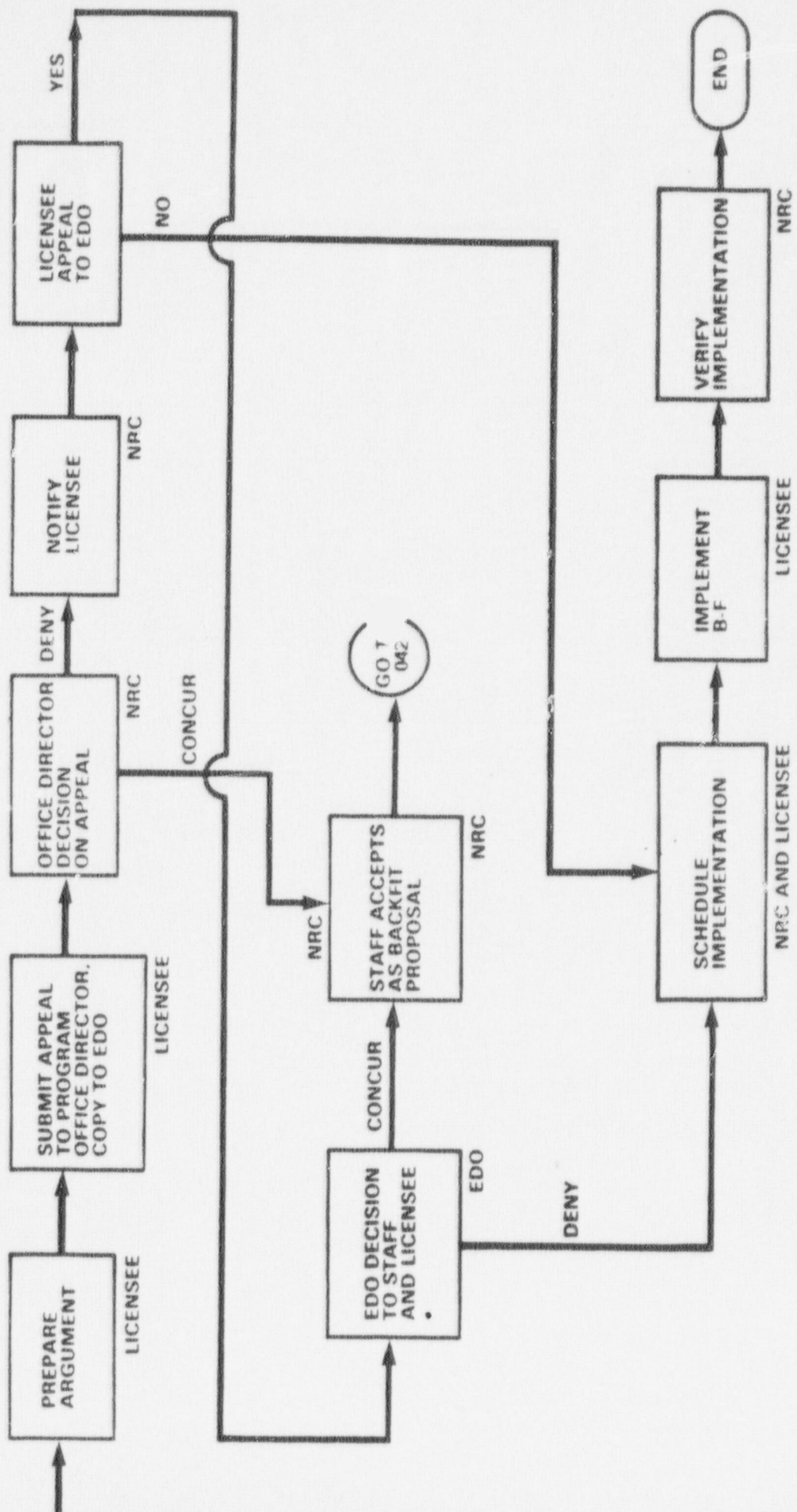

```

graph TD
    Start([START]) --> Q1{STAFF TAKES  
P S POSITION-  
IS BACKFIT?}
    Q1 -- NO --> Q2{NRC  
TAKES  
P S POSITION-  
IS BACKFIT?}
    Q1 -- YES --> Q3{IMPOSITION  
NECESSARY  
TO ENSURE  
NO UNDUCE RISK}
    Q2 -- NO --> Q4{NRC  
CONCURS  
THAT POSITION  
IS BACKFIT}
    Q2 -- YES --> Q3
    Q3 -- NO --> Q5{PREPARE P.G.  
ANALYSIS}
    Q3 -- YES --> Q6{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q4 -- NO --> Q7{NRC  
CONCURS  
THAT POSITION  
IS BACKFIT}
    Q4 -- YES --> Q8{DOCUMENT  
DETERMINATION  
AND BASIS,  
NOTIFY LICENSEE,  
COPY TO EDO  
WITHIN 3 WEEKS  
OF CLAIM}
    Q5 --> Q9{DIRECTOR OR  
ADMINISTRATOR  
DETERMINES  
BACKFIT JUSTIFIED}
    Q6 --> Q10{PREPARE  
EVALUATION  
(NOT A REG.  
ANALYSIS)}
    Q7 -- NO --> Q8
    Q7 -- YES --> Q9
    Q8 -- NO --> Q11{LICENSEE  
APPEAL}
    Q8 -- YES --> Q12{GO TO  
044 2}
    Q9 -- NO --> Q11
    Q9 -- YES --> Q13{TRANSMIT B.F.  
AND ANALYSIS TO  
LICENSEE, PDR  
AND EDO}
    Q10 -- YES --> Q14{PREPARE  
EVALUATION (NOT  
A REG. ANALYSIS),  
ISSUE PROMPTLY TO  
LICENSEE}
    Q10 -- NO --> Q15{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q11 --> Q16{APPEAL TO  
MODIFY OR  
WITHDRAW}
    Q12 --> Q17{GO TO  
044 1}
    Q13 --> Q17
    Q14 --> Q18{ISSUE TO  
LICENSEE}
    Q15 --> Q19{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q16 -- NO --> Q11
    Q16 -- YES --> Q17
    Q17 --> Q20{GO TO  
044 1}
    Q18 --> Q21{LICENSEE  
ELECTS TO  
IMPLEMENT}
    Q19 --> Q22{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q20 --> Q23{GO TO  
044 1}
    Q21 -- YES --> Q24{IMPLEMENT  
B.F.}
    Q21 -- NO --> Q25{ORDER  
ISSUED}
    Q22 --> Q26{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q23 --> Q27{GO TO  
044 1}
    Q24 --> Q28{SCHEDULE  
IMPLEMENTATION}
    Q25 --> Q29{ORDER  
ISSUED}
    Q26 --> Q30{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q27 --> Q31{GO TO  
044 1}
    Q28 --> Q32{SCHEDULE  
IMPLEMENTATION}
    Q29 --> Q33{ORDER  
ISSUED}
    Q30 --> Q34{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q31 --> Q35{GO TO  
044 1}
    Q32 --> Q36{SCHEDULE  
IMPLEMENTATION}
    Q33 --> Q37{ORDER  
ISSUED}
    Q34 --> Q38{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q35 --> Q39{GO TO  
044 1}
    Q36 --> Q40{SCHEDULE  
IMPLEMENTATION}
    Q37 --> Q41{ORDER  
ISSUED}
    Q38 --> Q42{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q39 --> Q43{GO TO  
044 1}
    Q40 --> Q44{SCHEDULE  
IMPLEMENTATION}
    Q41 --> Q45{ORDER  
ISSUED}
    Q42 --> Q46{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q43 --> Q47{GO TO  
044 1}
    Q44 --> Q48{SCHEDULE  
IMPLEMENTATION}
    Q45 --> Q49{ORDER  
ISSUED}
    Q46 --> Q50{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q47 --> Q51{GO TO  
044 1}
    Q48 --> Q52{SCHEDULE  
IMPLEMENTATION}
    Q49 --> Q53{ORDER  
ISSUED}
    Q50 --> Q54{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q51 --> Q55{GO TO  
044 1}
    Q52 --> Q56{SCHEDULE  
IMPLEMENTATION}
    Q53 --> Q57{ORDER  
ISSUED}
    Q54 --> Q58{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q55 --> Q59{GO TO  
044 1}
    Q56 --> Q60{SCHEDULE  
IMPLEMENTATION}
    Q57 --> Q61{ORDER  
ISSUED}
    Q58 --> Q62{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q59 --> Q63{GO TO  
044 1}
    Q60 --> Q64{SCHEDULE  
IMPLEMENTATION}
    Q61 --> Q65{ORDER  
ISSUED}
    Q62 --> Q66{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q63 --> Q67{GO TO  
044 1}
    Q64 --> Q68{SCHEDULE  
IMPLEMENTATION}
    Q65 --> Q69{ORDER  
ISSUED}
    Q66 --> Q70{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q67 --> Q71{GO TO  
044 1}
    Q68 --> Q72{SCHEDULE  
IMPLEMENTATION}
    Q69 --> Q73{ORDER  
ISSUED}
    Q70 --> Q74{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q71 --> Q75{GO TO  
044 1}
    Q72 --> Q76{SCHEDULE  
IMPLEMENTATION}
    Q73 --> Q77{ORDER  
ISSUED}
    Q74 --> Q78{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q75 --> Q79{GO TO  
044 1}
    Q76 --> Q80{SCHEDULE  
IMPLEMENTATION}
    Q77 --> Q81{ORDER  
ISSUED}
    Q78 --> Q82{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q79 --> Q83{GO TO  
044 1}
    Q80 --> Q84{SCHEDULE  
IMPLEMENTATION}
    Q81 --> Q85{ORDER  
ISSUED}
    Q82 --> Q86{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q83 --> Q87{GO TO  
044 1}
    Q84 --> Q88{SCHEDULE  
IMPLEMENTATION}
    Q85 --> Q89{ORDER  
ISSUED}
    Q86 --> Q90{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q87 --> Q91{GO TO  
044 1}
    Q88 --> Q92{SCHEDULE  
IMPLEMENTATION}
    Q89 --> Q93{ORDER  
ISSUED}
    Q90 --> Q94{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q91 --> Q95{GO TO  
044 1}
    Q92 --> Q96{SCHEDULE  
IMPLEMENTATION}
    Q93 --> Q97{ORDER  
ISSUED}
    Q94 --> Q98{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q95 --> Q99{GO TO  
044 1}
    Q96 --> Q100{SCHEDULE  
IMPLEMENTATION}
    Q97 --> Q101{ORDER  
ISSUED}
    Q98 --> Q102{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q99 --> Q103{GO TO  
044 1}
    Q100 --> Q104{SCHEDULE  
IMPLEMENTATION}
    Q101 --> Q105{ORDER  
ISSUED}
    Q102 --> Q106{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q103 --> Q107{GO TO  
044 1}
    Q104 --> Q108{SCHEDULE  
IMPLEMENTATION}
    Q105 --> Q109{ORDER  
ISSUED}
    Q106 --> Q110{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q107 --> Q111{GO TO  
044 1}
    Q108 --> Q112{SCHEDULE  
IMPLEMENTATION}
    Q109 --> Q113{ORDER  
ISSUED}
    Q110 --> Q114{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q111 --> Q115{GO TO  
044 1}
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IMPLEMENTATION}
    Q113 --> Q117{ORDER  
ISSUED}
    Q114 --> Q118{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q115 --> Q119{GO TO  
044 1}
    Q116 --> Q120{SCHEDULE  
IMPLEMENTATION}
    Q117 --> Q121{ORDER  
ISSUED}
    Q118 --> Q122{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q119 --> Q123{GO TO  
044 1}
    Q120 --> Q124{SCHEDULE  
IMPLEMENTATION}
    Q121 --> Q125{ORDER  
ISSUED}
    Q122 --> Q126{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q123 --> Q127{GO TO  
044 1}
    Q124 --> Q128{SCHEDULE  
IMPLEMENTATION}
    Q125 --> Q129{ORDER  
ISSUED}
    Q126 --> Q130{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q127 --> Q131{GO TO  
044 1}
    Q128 --> Q132{SCHEDULE  
IMPLEMENTATION}
    Q129 --> Q133{ORDER  
ISSUED}
    Q130 --> Q134{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q131 --> Q135{GO TO  
044 1}
    Q132 --> Q136{SCHEDULE  
IMPLEMENTATION}
    Q133 --> Q137{ORDER  
ISSUED}
    Q134 --> Q138{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q135 --> Q139{GO TO  
044 1}
    Q136 --> Q140{SCHEDULE  
IMPLEMENTATION}
    Q137 --> Q141{ORDER  
ISSUED}
    Q138 --> Q142{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q139 --> Q143{GO TO  
044 1}
    Q140 --> Q144{SCHEDULE  
IMPLEMENTATION}
    Q141 --> Q145{ORDER  
ISSUED}
    Q142 --> Q146{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q143 --> Q147{GO TO  
044 1}
    Q144 --> Q148{SCHEDULE  
IMPLEMENTATION}
    Q145 --> Q149{ORDER  
ISSUED}
    Q146 --> Q150{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q147 --> Q151{GO TO  
044 1}
    Q148 --> Q152{SCHEDULE  
IMPLEMENTATION}
    Q149 --> Q153{ORDER  
ISSUED}
    Q150 --> Q154{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q151 --> Q155{GO TO  
044 1}
    Q152 --> Q156{SCHEDULE  
IMPLEMENTATION}
    Q153 --> Q157{ORDER  
ISSUED}
    Q154 --> Q158{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q155 --> Q159{GO TO  
044 1}
    Q156 --> Q160{SCHEDULE  
IMPLEMENTATION}
    Q157 --> Q161{ORDER  
ISSUED}
    Q158 --> Q162{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q159 --> Q163{GO TO  
044 1}
    Q160 --> Q164{SCHEDULE  
IMPLEMENTATION}
    Q161 --> Q165{ORDER  
ISSUED}
    Q162 --> Q166{IMMEDIATE  
IMPOSITION  
NECESSARY}
    Q163 --> Q167{GO TO  
044 1
```

044.1 APPEAL TO MODIFY OR WITHDRAW BACKFIT



044.2 APPEAL TO REVERSE A DENIAL OF CLAIM OF BACKFIT



process as it stands (what with the existing Committee to Review Generic Requirements and the Commission's incontestable authority and ineluctable responsibility to instruct the staff), then I doubt that rule laid upon rule will do much to teach the Commission the virtue of self-discipline.

More specifically, the Commission majority presumably knows that the backfit threshold criteria applied to rulemaking would apply not just on a plant-specific basis (which it should be recalled was the intent of the original backfitting initiative), but to generic decisions that may affect dozens of plants, and in fact to rulemaking on *all* but procedural matters, rulemaking that may or may not have the remotest connection to what the public and our licensees normally consider a plant "backfit". The scope of Commission rulemaking responsibilities thus often involves broad public policy considerations, and those considerations can rise above elements as simple as cost-benefit analysis to reach issues as fundamental as fairness and individual rights. The Commission's backfit rule, if applied to rulemaking itself, will thus serve only to trivialize in appearance and confuse in practice the many factors to be weighed in rulemaking.

As one small example of the morass into which the Commission majority has wandered, consider (as the Commission currently is considering) whether there should be a requirement that radiation workers be provided their dose records annually. The "benefit" of this "backfit" of Commission rules may seem clear, but it might very well never pass the cost-benefit test. Indeed, it is difficult to imagine a rule that would involve the human-factors element of plant operations, and that would also be amenable to straightforward cost-benefit analysis.

Rulemaking as it exists involves numerous inherent procedural checks and balances to insure that each proposal is carefully considered prior to adoption. Indeed, rulemaking is the forum which provides the greatest number of checks against arbitrary action by the Staff or Commission. Much of the analysis (including cost-benefit) which the new backfitting rule would require is already done informally throughout the process of considering and adopting new regulations.

If the Commission wishes to insure still more structure in the rulemaking process, structure which could take into account every single factor set forth in the backfit rule and more, there are ample means of doing so by simple internal agency management. Such

methods would reaffirm existing Commission guidelines to the Staff without opening the door to additional needless litigation as a consequence of vague new, legally enforceable, Commission-created rights added to those already available to all parties under the APA.

The entire backfit rulemaking was undertaken to bring order and accountability to plant modifications heretofore sometimes imposed without the benefit of systematic evaluation and justification. In rulemaking *per se*, that objective has always been well within the Commission's grasp—it is, after all, the Commission that makes rules. For good measure, the Commission also has the Administrative Procedures Act as a matter of law, and its own Committee to Review Generic Requirements as a matter of internal administrative policy to assist it in carrying out such considered decision-making. Casting the net of the new backfit rule over Commission rule-making (almost as an afterthought, as it happened in this case) is thus at best an exercise in pointless symbolism, and at worst potentially destructive of the Commission's entire rule-making process.

Unneeded law is bad law, and unneeded regulation is bad regulation. The Commission majority has imposed on this agency new regulatory obligations in rulemaking that are not only unneeded, but which the Commission majority itself hopes and trusts will be of little practical (i.e. legally enforceable) consequence. To the extent that this rule will affect rulemaking, it will therefore be a bad rule. In sum, the Commission majority has inexplicably insisted on fixing not only what is, but what ain't broke. I will not be a party to such poor judgment.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150-0011.

Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this final rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The affected facilities are licensed under the provisions of 10 CFR 50.21(b) and 10 CFR 50.22. The companies that own these facilities do not fall within the scope of "small entities" as set forth in the Regulatory Flexibility Act or the Small Business Size Standards set forth in regulation, issued by the Small Business Administration in 13 CFR Part 121.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Nuclear power plants and reactors, hazardous waste.

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Parts 2 and 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 162, 183, 186, 189, 66 Stat. 936, 937, 946, 953, 954, 955, 956, as amended; sec. 234 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 66 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Sec. 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.57(d), 40.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Section 50.78 also issued under sec. 122, 66 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 164, 66 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100-50.102 also issued under sec. 186, 66 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 66 Stat. 956, as amended (42 U.S.C. 2273), §§ 50.10 (a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 66 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10 (b) and (c) and 50.54 are issued under sec. 161, 66

B-3

Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 1810, 88 Stat. 950, as amended (42 U.S.C. 2201(c)).

2. In § 50.54, paragraph (f) is revised to read as follows:

(f) 50.54 Conditions of licenses.

(f) The licensee shall at any time before expiration of the license, upon request of the Commission submit written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

3. In § 50.109, paragraph (a) is revised, paragraph (b) is removed, paragraph (c) is revised and redesignated as (b), and new paragraphs (c), (d) and (e) are added to read as follows:

§ 50.109 Backfitting.

(a)(1) 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 the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position, after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985; or

(ii) Six months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985; or

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses; or

(iv) The date of issuance of the design approval under Appendix M, N or O of this part.

(2) The Commission shall require a systematic and documented analysis pursuant to paragraph (c) of this section for backfits which it seeks to impose. Imposition of a backfit pursuant to paragraph (a)(4)(ii) of this section shall not relieve the Commission of performing an analysis after the fact to document the safety significance and appropriateness of the action taken.

(3) The Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (c) of this section, 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.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standard does not apply where the staff finds and declares, with appropriate documented evaluation for its finding, either:

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That an immediately effective regulatory action is necessary to ensure that the facility poses no undue risk to the public health and safety.³

Such documented evaluation shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception.

(b) Paragraph (a) of this section shall not apply to backfits imposed prior to October 21, 1985.

(c) In reaching the determination required by paragraph (a) of this section, the Commission will consider how the backfit should be prioritized and scheduled in light of other regulatory activities ongoing at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

³For those modifications which are to ensure that the facility poses no undue risk to the public health and safety and which are not deemed to require immediately effective regulatory action, analyses are required. These analyses, however, should not involve cost considerations except only insofar as cost contributes to selecting the solution among various acceptable alternatives to ensuring no undue risk to public health and safety.

(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) Potential impact on radiological exposure of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(d) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(e) The Executive Director for Operations shall be responsible for implementation of this section and all analyses required by this section shall be approved by the Executive Director for Operations or his designee.

4. In Appendix O to 10 CFR Part 50, a new section (8) is added to read as follows:

Appendix O—Standardization of Design; Staff Review of Standard Designs

8. Information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be in accordance with 10 CFR 50.54(f) and shall be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

PART 2—(AMENDED)

5. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 161, 88 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 94-6*5, 76 Stat. 408 (42

U.S.C. 2241; sec. 201, 86 Stat. 1242, as amended (42 U.S.C. 5641); 5 U.S.C. 552.

Sec. 2.101 as issued under secs. 52.62, 63.81, 103, 104, 105, 86 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 86 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 86 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2136, 2239). Section 2.105 also issued under Pub. L. 97-415, 86 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 186, 234, 86 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 86 Stat. 1246 (42 U.S.C. 5846). Sections 2.300-2.306 also issued under Pub. L. 97-415, 86 Stat. 2071 (42 U.S.C. 2133). Sections 2.800-2.806 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 as amended (42 U.S.C. 4332). Sections 2.700a, 2.781 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 86 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.806 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91-580, 84 Stat. 1473 (42 U.S.C. 2135).

6. Section 2.204 is revised to read as follows:

§ 2.204 Order for modification of license.

The Commission may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) days from the date of the notice or such longer period as the notice may provide. The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. If the licensee requests a hearing during this 20-day period, the amendment will become effective on the date specified in an order made following the hearing. When the Commission finds that the public health, safety, or interest so requires, the order may be made immediately effective. If the amendment involves a backfit, the provisions of § 50.109 of this chapter shall be followed.

Dated at Washington, D.C., this 17th day of September, 1985.

For the Nuclear Regulatory Commission,
Samuel J. Chalk,

Secretary of the Commission.

[FR Doc. 85-22572 Filed 9-19-85; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulation No. 4]

Federal Old-Age, Survivors, and Disability Insurance; Listing of Impairments—Mental Disorders

Correction

In FR Doc. 85-20552 beginning on page 35038 in the issue of Wednesday, August 28, 1985, make the following corrections:

1. On page 35040, third column seventh line from the bottom, "of" should read "or".
2. On page 35044, first column, in the fourth *Comment*, sixth line, insert the word "only" between "if" and "one".
3. On page 35045, third column, in the third *Comment*, sixth line, "by" should read "be".
4. On page 35046, first column, in the fourth *Comment*, second line from the bottom, "patient's" should read "patients".
5. On page 35048, first column, in the second *Comment*, first line, "larger" should read "large".
6. On page 35049, first column, in the first *Response*, twelfth line, "necessary" should read "necessarily".
7. On the same page, second column, in the first *Response*, second line from the bottom, "individual" should read "individuals". Also, in the third column, "12.04 Mental Retardation" should read "12.05 Mental Retardation".
8. On page 35066, third column, first complete paragraph, "including" should read "include".

BILLING CODE 1505-01-0

20 CFR Part 404

Social Security Benefits; Coverage of Employees of Private Nonprofit Organizations, Work Outside United States, Etc.

Correction

In FR Doc. 85-21321, beginning page 36571 in the issue of Monday, September 9, 1985, make the following corrections:

On page 36572, first column, in the *DATES* paragraph:

1. In the first and second lines, "(insert date of publication)" should have read "September 9, 1985".
2. In the eleventh line "received" should have read "receive".

BILLING CODE 1505-01-0

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject To Certification; Flunixin Meglumine Paste

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering Corp., providing for flunixin meglumine paste. The paste is for oral use in horses to alleviate inflammation and pain from musculoskeletal disorders.

EFFECTIVE DATE: September 20, 1985.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: The Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033, has filed NADA 137-409 for Benamine® Paste (flunixin meglumine). Flunixin meglumine paste is for the alleviation of inflammation and pain associated with musculoskeletal disorders in horses. The NADA is approved and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-02, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs, oral use.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 520 is amended as follows: