governing the conduct of the hearing. The length of each presentation is limited to 20 minutes.

A DOE official will be designated to preside at the hearing. The hearing will not be a judicial or an evidentiary-type hearing, but will be conducted in accordance with 5 U.S.C. 533 and section 336 of the Act. At the conclusion of all initial oral statements at each day of the hearing, each person who has made an oral statement will be given the opportunity to make a rebuttal statement, subject to time limitations. The rebuttal statement will be given in the order in which the initial statements were made. The official conducting the hearing will accept additional comments or questions from those attending, as time permits. Any interested person may submit to the presiding official written questions to be asked of any person making a statement at the hearing. The presiding official will determine whether the question is relevant and whether time limitations permit it to be presented for answer.

Further questioning of speakers will be permitted by DOE. The presiding official will afford any interested person an opportunity to question, with respect to disputed issues of material fact, other interested persons who made oral presentations as well as employees of the United States Government who have made written or oral presentations relating to the proposed rule. This opportunity will be afforded after any rebuttal statements to the extent that the presiding official determines that such questioning is likely to result in a more timely and effective resolution of disputed issues of material fact. If the time provided is insufficient or inconvenient, DOE will consider affording an additional opportunity for questioning at a mutually convenient time. Persons interested in making use of this opportunity must submit their request to the presiding official no later than shortly after the completion of any rebuttal statements and be prepared to state specific justification, including why the issue is one of disputed fact and how the proposed questions would expedite their resolution.

Any further procedural rules regarding proper conduct of the hearing will be announced by the presiding official.

A transcript of the hearing will be made and the entire record of this rulemaking, including the transcript, will be retained by DOE and made available for inspection at the DOE Freedom of Information Reading Room as provided at the beginning of this notice. Any person may purchase a copy of the transcript from the transcribing reporter.

d. Issues for Public Comment

The Department is interested in receiving comments and data concerning the accuracy and workability of this methodology. Also, DOE welcomes discussion on improvements or alternatives to this approach. In particular, DOE is interested in gathering data on the following:

- The relevance of the data inputs and outputs of the Lawrence Berkeley Laboratory Residential Energy Model and Lawrence Berkeley Laboratory Manufacturer Impact Model models, whether these models could or should capture the cumulative effects of Federal energy conservation standards on multi-product appliance manufacturers and whether or not there are acceptable alternative models that could be used;
- Descriptive and performance characteristics for baseline models of each product class that are the subject of this rulemaking. These models should be those satisfying the appropriate standards;
- Proposed product classes for products in this rulemaking;
- Costs of baseline units and incremental costs of designs improving the energy efficiency of the products that are the subject of this rulemaking;
- Appropriateness of existing and proposed test procedures to the proposed design options;
- Methods of calculating the dollar value of reduced atmospheric emissions of SO_2, NO_x, and CO_2 from reduced energy consumption;
- Data on consumer financing of appliances useful for obtaining a weighted-average discount rate;
- Data on lifetimes of the appliances;
- Data on the distributions of locations of heating and cooling equipment relative to conditioned space and venting and air intake configurations for heating equipment; and
- Data on the possible adverse affects of standards on identifiable groups of consumers that experience below-average utility or usage rates.

The Department has been unable to identify the financial characteristics of small manufacturers. Nevertheless, for purposes of this analysis, small manufacturers' costs are assumed to equal those of medium manufacturers. The Department is especially interested in learning of the existence of small manufacturers and in obtaining costing data from such manufacturers of the products under consideration.

For the Lawrence Berkeley Laboratory Residential Energy Model, DOE requests interested parties to provide historical data on shipments and average efficiencies by class for the products subject to the proposed rulemaking. Data on consumer prices and on the installation and maintenance expenses of these appliances are also requested.

The manufacturer analysis needs financial data from the product division level. All of these data are available at the firm level; but since firms are typically much larger than the relevant division, the firm data may give a misleading indication of the division's finances.

An income statement and balance sheet at the division level would be most helpful. If this is not available, then data on the following variables are considered most essential: Net income, revenue, selling and general and administrative costs, engineering costs, costs of goods sold, interest, taxes, debt-to-equity ratio, net depreciable assets, net assets, capital investment, and long-term debt.

The Department also welcomes current data on unit sales and revenues for the industries as a whole.

Issued in Washington, DC., on August 30, 1993.

Frank M. Stewart, Jr.,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 93–21838 Filed 9–7–93; 8:45 am]

BILLING CODE 6450–01–P

federal register

Wednesday
September 8, 1993

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 314
New Drug and Abbreviated New Drug Applications; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 90N–0238]

New Drug and Abbreviated New Drug Applications; Preapproval Inspection Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revise its regulations governing the approval for marketing of new drugs and antibiotic drugs for human use to require the submission by applicants of new drug and antibiotic applications (for the purposes of this document, new drug and antibiotic applications will be referred to as NDA's), abbreviated new drug and antibiotic applications (for the purposes of this document, abbreviated new drug and abbreviated antibiotic applications will be referred to as ANDA's), and supplemental applications of an additional copy of the chemistry, manufacturing, and controls (chemistry) section of their NDA's and ANDA's and of certain supplemental applications. The additional copy will be used by FDA investigators during a preapproval inspection to audit application commitments and statements against actual manufacturing practices used by applicants. FDA is also requiring the submission in the chemistry section of an NDA or ANDA, if not ordinarily included, certain information concerning the batches used to perform bioavailability, bioequivalence, and stability tests and the proposed or actual master production record for a commercial lot. This rule is intended to improve FDA's surveillance and enforcement activities with respect to NDA's, ANDA's, and supplemental applications consistent with the agency's efforts to address certain fraudulent practices found during recent investigations of the generic drug industry.

EFFECTIVE DATE: October 8, 1993.

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of January 28, 1991 (56 FR 3180), FDA published a proposed rule to require the submission by applicants of NDA's, ANDA's, and supplemental applications of an additional review copy of the chemistry and human pharmacokinetics and bioavailability (biopharmaceutics) sections of their applications and of certain supplemental applications and an additional copy of the applicant's draft labeling. FDA also proposed to require the submission in the chemistry section of an NDA and ANDA, if not ordinarily included, certain information concerning the batches used to perform bioavailability, bioequivalence, and stability tests and the master production record for a commercial lot. The proposed new requirements would: (1) Provide to FDA field investigators information to be used during a preapproval inspection to audit application commitments and statements against actual manufacturing practices used by applicants and (2) provide to FDA headquarters reviewers additional information to be used in FDA's determination whether new drug products meet the statutory requirements for approval. FDA provided 60 days for public comment. The agency has revised portions of the final regulations in response to comments received on the proposal.

Highlights of the final rule are summarized below, followed by a summary and discussion of the comments.

II. Highlights of the Final Rule

A. Requirements

This final rule has been significantly revised to reduce the amount of information that an applicant would submit for a preapproval inspection and to permit a U.S. applicant to send the information directly to the appropriate FDA district office. Accordingly, the final rule requires U.S. applicants of NDA's and ANDA's to submit to the applicants' home FDA district office, at the time of submission of their application to FDA headquarters, a certified copy of the chemistry section of their NDA's and ANDA's, all amendments to that section, and certain supplemental applications. FDA has designated this copy as the field copy. Foreign applicants would submit the field copy to the FDA headquarters address specified under § 314.440 (21 CFR 314.440) for submission of original NDA's, ANDA's, amendments, and supplements. The field copy of an NDA and ANDA will be used by FDA's field investigators in conducting a preapproval inspection. Unlike the proposed rule, the final rule does not require the submission of an additional copy of the biopharmaceutics section of an NDA and an ANDA and an applicant's draft labeling.

The final rule, like the proposed rule, provides that an applicant include in the chemistry section of its application certain information about the batches of the drug product used to conduct a bioavailability, bioequivalence, or stability study as follows: (1) The batch production record; (2) the specifications and test procedures for each component and for the drug product; (3) the names and addresses of the sources of the container and closure system for the drug product; (4) the name and address of each contract facility that performs an operation in the manufacture, processing, packaging, or testing of the drug product and identification of the operation performed by each contract facility; and (5) the components and drug product test results obtained under §§ 211.84 and 211.165 (21 CFR 211.84 and 211.165) (see § 314.50(d)(1)(ii)(*b*)). In response to comments, the final rule clarifies that these requirements apply only to the pivotal bioavailability and bioequivalence studies and to the primary stability studies, and that, for the components of the drug product used to conduct bioavailability, bioequivalence, and stability studies, an applicant is only required to submit the names and addresses of the sources of the active and noncompendial inactive components of the drug product rather than all components of the drug product.

In response to comments, the final rule modifies the proposed provision concerning submission of the master production record. For an ANDA and an application submitted under § 314.54, the final rule requires the applicant to provide the proposed or actual master production record to be used for manufacture of a commercial lot of the drug product (§ 314.94(a)(9)) (21 CFR 314.94(a)(9)) (§ 314.55(e)(2)(i) in the proposed rule) and § 314.54 (a)(1)(i) and (a)(2) (21 CFR 314.54 (a)(1)(i) and (a)(2)). However, for an NDA, the applicant may provide, in lieu of the proposed or actual master production record, a detailed description of the production process for a representative batch of its proposed product (§ 314.50(d)(1)(ii)(*c*)).

The final rule expands the proposed provision concerning supplemental applications. The final rule requires the submission by the applicant to the applicant's home FDA district office, or if a foreign applicant, to FDA headquarters, a field copy of all supplements to the chemistry section of an NDA and ANDA except labeling supplements (§ 314.71(b)).

In the **Federal Register** of April 28, 1992 (57 FR 17950), FDA issued final regulations on certain requirements that apply to ANDA's. These regulations implement title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417). That final rule, among other things, reorganized and revised 21 CFR part 314 to incorporate the new requirements. The revisions, in part, added new § 314.54 to subpart B and new §§ 314.92 through 314.99 to new subpart C. The agency is now conforming this rule to the new part 314 structure.

B. Relationship to FDA's Computer-Assisted New Drug Application (CANDA) Program

In the **Federal Register** of September 15, 1988 (53 FR 35912), the agency published a notice to give guidance to applicants interested in submitting CANDA's, including ANDA's and investigational new drug applications (IND's). The notice encouraged applicants to explore the use of CANDA's. The agency views computer technology as a promising means of making the new drug review process more efficient. FDA's long-range plans commit FDA's Center for Drug Evaluation and Research (CDER) to continue to explore the use of computer technology to enhance the timeliness, effectiveness, and efficiency of the new drug review process and reduce burdensome, nonessential hard-copy handling. Currently, the submission of a CANDA will generally not affect the required submission of an application in hard copy. Over time, there may be instances where no hard copy need be submitted. By fiscal year 1995, FDA expects that virtually all application submissions to CDER will either be full CANDA's or have major automated components.

Development and operation of an acceptable CANDA system require the acquisition and installation of appropriate computer hardware and software and orientation and training of employees in the use of the computer hardware, data file content and structure, and retrieval routines. Filing of a CANDA is also conditional on the reviewing divisions willingness to accept an application in the CANDA format used by the applicant. To date the agency has directed its efforts toward policies and procedures for CANDA submissions to headquarters. The agency's long-term goal is to extend the CANDA concept to its district offices. However, initiation of this goal will not occur before fiscal year 1995, and its completion will be conditioned on the availability of adequate budgetary resources. Therefore, for a preapproval inspection, unless otherwise instructed by the agency, applicants will submit the additional copy of the chemistry section of an application, all amendments to that section, and certain supplemental applications in hard copy.

III. Responses to Comments

FDA received 16 comments on the proposal. The comments came from pharmaceutical manufacturers and trade associations.

A. General Comments

1. One comment asked that the regulations define the respective roles in the new drug approval process of the FDA district offices and the reviewing divisions within CDER. Two comments expressed concern that inspectors in the districts will use the additional copy of the application to duplicate the review of an application already conducted by headquarters reviewers, and that this second, unnecessary review will not be limited to current good manufacturing practice (CGMP) issues but rather will overstep the intent of the rule and impinge on headquarters' role.

FDA advises that the roles of headquarters' personnel and FDA's district offices in the new drug approval process are necessarily distinct and different. The role of the reviewing divisions in FDA's CDER is to review the data submitted by an applicant in an NDA and ANDA to determine whether, for the drug product for which an applicant seeks approval, the NDA applicant has shown by adequate scientific evidence that the drug product is safe and by substantial evidence that the drug product is effective for the conditions prescribed, recommended, or suggested in the product's proposed labeling, and that the drug product will be manufactured properly; and the ANDA applicant has shown that the drug product is bioequivalent to its brand name counterpart, and that the drug product will be manufactured properly.

Under section 505(d)(3) and (j)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(d)(3) and (j)(3)(A)), the agency must deny approval of an NDA or ANDA if the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of the drug product for which the applicant seeks approval are inadequate to preserve the drug's identity, strength, quality, and purity. Therefore, before approval of an NDA or ANDA, FDA's reviewing chemists and microbiologists must determine that the data in an application about the composition, manufacturing methods, and specifications and test methods used for the drug substance and drug product are adequate to assure their identity, strength, quality, and purity.

The role of FDA's district offices is to determine whether all establishments that will participate in the manufacture, packaging, or testing of the drug substance or drug product are in compliance with CGMP regulations and with application commitments and statements. These determinations are made by inspections by field personnel. An FDA investigator evaluates a manufacturer's compliance with the requirements of the agency's CGMP regulations (21 CFR parts 210 and 211) that set forth comprehensive standards for drug manufacturing; determines whether the manufacturer has adequate facilities, equipment, procedures, and controls to manufacture the drug product for which an applicant seeks approval in conformance with application commitments and statements; and audits the accuracy of the manufacturing and testing data for the batches used to conduct bioavailability, bioequivalence, and stability studies submitted in an application. In short, an FDA headquarters' reviewer determines if the data in an application support the safety and effectiveness or bioequivalence of the applicant's proposed product, and if the manufacturing process described in an application can produce a consistent product; whereas an FDA field investigator determines if the data are accurate and authentic and support the commitments and statements made in the application, and if the manufacturing facilities are capable of manufacturing, packaging, controlling, and testing the applicant's proposed product as described in the application.

2. Two comments discussed the economic impact of the proposed rule on NDA applicants. One comment noted that FDA's assessment of the economic impact was based solely on copying costs and such assessment was inadequate. Both comments expressed concern that experience during the initiation of FDA's new preapproval program demonstrated that there were delays in NDA approvals attributed to the preapproval plant inspections. One of the comments stated that an industry estimate conducted at the end of 1990 revealed that at least 14 NDA's were delayed 1 to 3 months resulting in an estimated economic impact of $280 million. The comments argued that the increased burden of the new requirements, the potential economic

loss from material delays in NDA approval, and the potential losses from the unavailability of new medicines should be accounted for in assessing the impact of the proposed rule. Another comment disagreed with FDA that submission of the additional copy would be a minimal burden on applicants because, if applicants are required to submit the copy to FDA, much time will have to be spent by applicants to track information to assure its proper and timely disposition to the applicable district.

FDA acknowledges that there were delays in application approvals during implementation of the expanded preapproval inspection program. New procedures, however, have been instituted to alleviate unnecessary delays in application approvals. Under the new procedures, inspections will be conducted earlier in the review process. By doing so, the inspection should be completed well before the application reaches the approvable stage based on review by CDER's scientists. Also, if the inspection identifies significant deficiencies that the firm is willing to correct promptly, there should be adequate time for the applicant to make the corrections before the scientific review is completed. In the past year, FDA has increased the number of its field investigators, which will provide more timely preapproval inspections and help alleviate unnecessary delays in inspections. Also, FDA's Office of Regulatory Affairs (ORA) has established a premarket approval management plan to ensure uniform implementation and efficiency of operations. Finally, FDA has conducted a series of Commissioner's exchange meetings on the preapproval inspection program to illicit suggestions and recommendations from the industry to further enhance the efficiency and effectiveness of these inspections. These meetings were held in Cherry Hill, NJ; San Francisco, CA; Chicago, IL; and San Juan, PR.

3. In the preamble to the proposed rule (56 FR 3180), FDA stated that an applicant's history of noncompliance with CGMP's may trigger a preapproval inspection. One comment asked how FDA determines that an applicant has a history of noncompliance and if the firm is advised of this.

The agency believes that responsible corporate officials in any firm know when they have a history of noncompliance with CGMP's. This is evidenced by FDA's numerous administrative and regulatory actions against a firm for failing to adhere to CGMP requirements. These actions may have included repeated failure to correct deficiencies reflected in a list of inspectional observations (Form FDA–483) left at the firm following an inspection, frequency of FDA inspections of a firm, numerous repetitive violations of CGMP regulations as evidenced by followup inspections by FDA, number of recalls, injunction proceedings, content and frequency of correspondence and meetings between FDA and the firm, settlement agreements, and consent decrees.

4. One comment asked that FDA clarify the effective date of this final rule. The comment argued that the final rule should not be applied to cover NDA's and ANDA's submitted before the effective date.

The requirements established in this final rule apply only to NDA's and ANDA's and their amendments and to supplemental applications submitted on or after the effective date of this rule.

B. Preapproval Inspections

5. One comment asked that FDA clarify whether preapproval inspections are mandatory or discretionary. The comment expressed the opinion that there is a potential that the standard for preapproval inspections contemplated by FDA's proposed rule is materially different from FDA's Compliance Program (CP) 7346.832.[1] The comment stated that the CP appears to make inspection mandatory for the listed categories of drug approvals, as assigned by CDER. For categories of drug approvals not assigned by CDER, the CP provides that CDER and the District will consult so that Districts may "exercise judgment as to whether preapproval inspections should be conducted * * *." If preapproval inspections are mandatory, the comment asserted that clear and identified criteria FDA will use in deciding when an inspection is warranted are essential, and that without such criteria the risks of favoritism, significant differences between and within districts, and unpredictability exist.

FDA does not agree that the proposed rule and CP 7346.832 contemplate different standards for preapproval inspections. Under section 505 (d)(3) and (j)(3)(A) of the act, FDA must deny approval of an NDA or an ANDA if the methods used in, or the facilities and controls used for, the manufacture, processing, and packaging of the drug product are inadequate to assure and preserve the product's identity, strength, quality, and purity. Therefore, before approval of an NDA or an ANDA, FDA must determine that the facilities involved in the manufacturing, testing, or other manipulation of the applicant's proposed drug product have been inspected and found to be in compliance with CGMP regulations. This determination is made by FDA's inspecting the involved facilities before approval of an NDA or an ANDA, or by relying upon results of recent on-site inspections of the applicant's facilities, which covered the same class of dosage form as the applicant's proposed product. Section 510(h) of the act (21 U.S.C. 360(h)) mandates on-site inspections for every registered drug establishment every 2 years. Because of certain fraudulent practices found during investigations of the generic drug industry, FDA expanded its preapproval inspection program beyond the statutorily required biennial on-site inspection to include additional criteria for triggering a preapproval inspection which is product and site specific and to include as part of a preapproval inspection an audit of the manufacturing and controls records concerning the batches used to conduct bioavailability, bioequivalence, and stability studies. The additional criteria cited by FDA in the proposed rule and in CP 7346.832 represent those situations most likely to trigger a preapproval inspection. For example, FDA must be assured that a manufacturer has adequate facilities, equipment, procedures, and controls to manufacture a new chemical entity or a new dosage form.

FDA's preapproval inspections are discretionary in that they are not statutorily mandated. Preapproval inspections may be requested by agency headquarters staff or conducted at the district offices' discretion. Factors considered by FDA and its district offices in determining whether a preapproval inspection is necessary include the date of the firm's last biennial inspection; the firm's CGMP inspection history; results of recent inspections that covered the same class of drug product, i.e., tablet, capsule; regulatory actions against the firm; recalls; and complaints against the firm. Because of the number and significance of the problems the agency is finding with both NDA's and ANDA's during preapproval inspections, the intensity of FDA's preapproval inspections will continue for both NDA's and ANDA's, and the inspections will be conducted for products meeting criteria such as those listed in the preamble and the CP.

6. One comment expressed concern that, if applicants are required to submit

[1] Compliance Program 7346.832 is available at cost from the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–30, 5600 Fishers Lane, Rockville, MD 20857.

review copies of each NDA, ANDA, amendment, and appropriate supplement, as well as the additional information that would be required in the chemistry section, FDA's reviewing chemists involved with the preapproval inspections will be burdened with tracking and compiling a complete record of the submission and all subsequent amendments and supplements. The comment argued that this would seriously detract from the FDA reviewers' ability to focus his or her efforts on the NDA/ANDA review and therefore interfere with FDA's current mandate to shorten NDA and ANDA review time. The comment suggested that FDA consider modeling the preapproval inspection requirements on a procedure used for methods validation packages in which the chemistry section and all related amendments would be sent, when the reviewing chemist requests an inspection, to the reviewing chemist for distribution, or, under appropriate circumstances, directly to the district office.

FDA believes that this comment misunderstood the process by which the agency would provide the additional copy to the district offices. FDA had envisioned a process that would impose minimal burdens on its reviewing personnel. Therefore, under the proposed rule, the additional copy of original submissions, amendments, and appropriate supplements submitted to FDA by applicants would be provided to the home FDA district office of the applicant by CDER's central document room. CDER's reviewing personnel would only be involved in the event it was necessary for them to assist in identifying whether an amendment or supplement did, in fact, affect either the chemistry or biopharmaceutics section of an NDA or ANDA. The concern expressed by the comment is now moot because, under the final rule, a U.S. applicant will send the additional copy of the chemistry section, amendments, and supplements directly to the appropriate district office.

7. One comment asked that FDA clarify what constitutes a drug with a narrow therapeutic range. The preamble to the proposal included as one of the grounds that may trigger a preapproval inspection those drug products that have a narrow therapeutic range, such as drugs used to treat epilepsy, asthma, high blood pressure, and heart diseases (56 FR 3180). The comment argued that this language suggests that all cardiovascular drugs, for example, have a narrow therapeutic range, and are subject to preapproval inspection.

FDA agrees that its description of narrow therapeutic range drugs may imply that all cardiovascular drugs have a narrow therapeutic range. This implication was not intended. The preamble language was intended only to give examples of the types of therapeutic classes to which the specific drug products belong. FDA has developed an informal list of drugs it believes may have a narrow therapeutic range. This list is used for various internal purposes only such as selecting drug products for preapproval inspection. FDA does not formally designate narrow therapeutic range drugs.

8. One comment noted that the preamble identified broad categories of drug products such as new chemical entities, new dosage forms for an applicant, and drugs that are difficult to manufacture and thus difficult to replicate that would be subject to the final rule. The comment asserted that it would be excessive for FDA to require preapproval inspections for all NDA's within these categories. The comment argued that, in the absence of a concern by the review divisions about the drug product, and in the absence of a concern by FDA's compliance officials about the manufacturer, a preapproval inspection should not be conducted and an NDA applicant should not have to submit the additional data that would be required by the proposed rule. Another comment noted that the criteria "are difficult to manufacture and thus difficult to replicate" and "generic versions of the top 200 most prescribed drugs" are obviously applicable to generic drugs and questioned their application to innovator companies.

The objective of FDA's preapproval inspection program is to evaluate a manufacturer's compliance with CGMP requirements, audit the manufacturing and control records for the batches used to conduct bioavailability, bioequivalence, and stability studies, and audit application commitments against actual manufacturing practices. This is intended to improve FDA's surveillance and enforcement activities with respect to NDA's and ANDA's consistent with the agency's efforts to address certain fraudulent practices found during recent investigations of the generic drug industry. FDA believes it is appropriate to apply this rule and its preapproval inspection program both to NDA's and ANDA's. As noted in section III.C.13., FDA cannot assure that NDA's are not susceptible to fraud. In addition, the agency is finding significant problems with both NDA's and ANDA's during preapproval inspections. Because of this, the intensity of FDA's preapproval inspections will continue for both NDA's and ANDA's. An important goal of FDA's preapproval inspection program is ensuring the integrity of the data submitted to FDA by an applicant. FDA intends to continue to conduct preapproval inspections of NDA's and ANDA's for products meeting criteria such as those set forth in FDA's proposed rule and in CP 7346.832.

FDA agrees that the criteria "are difficult to manufacture and thus difficult to replicate" and "generic versions of the top 200 most prescribed drugs" are applicable to generic drugs and would not apply to innovator companies.

9. One comment noted that FDA cited five criteria that may trigger a preapproval inspection but did not address the situation in which FDA requests, by force of habit, preapproval inspection of a firm submitting an application for a drug product that does not fall within one of the enumerated criteria. To prevent this situation from occurring, the comment asked that the final rule be amended to allow a firm to satisfy such an FDA preapproval inspection request by providing a written statement that its application does not fall within one of the five enumerated criteria.

FDA declines to make the change requested. The five enumerated criteria discussed in the preamble to the proposed rule were not intended to be all-inclusive. A preapproval inspection may be triggered by other events. As discussed in the preamble (56 FR 3180), FDA may also inspect applicants who have a history of noncompliance with CGMP's and new applicants, i.e., those applicants who have not previously submitted an NDA or an ANDA or who currently are manufacturers of over-the-counter drug products and are seeking approval of their first prescription drug product. In addition, for drug products not falling within one of the enumerated categories, an unsatisfactory inspection within the past 2 years will also trigger a preapproval inspection as will discrepancies warranting an investigation resulting from headquarters review of an application.

10. One comment asked that FDA amend the regulation to provide that the additional copy of the chemistry and biopharmaceutics sections be forwarded to the field investigative teams within 30 days following the decision by FDA to begin review of the chemistry section.

Under this final rule, a U.S. applicant will send the additional copy of the chemistry section directly to the home FDA district office of the applicant at the time of submission of an NDA or

ANDA to FDA. The final rule does not require submission of an additional copy of the biopharmaceutics section. Therefore, the comment's request is now moot.

11. One comment stated that the proposed rule provides that information contained in the drug master file (DMF) must be provided to FDA which will, in turn, provide the information to its field investigators. The comment asked that FDA clarify whether FDA is referring only to the applicant's facility DMF and not DMF's from companies other than the applicant, i.e., closure manufacturers, active ingredient suppliers, etc. The comment also asked that the final rule include a 30-day timeframe following the decision by FDA to begin its chemistry review within which FDA must provide this information to its field investigators.

In the preamble to the proposed rule (56 FR 3180 at 3181), FDA noted that the regulations at 21 CFR 314.420 permit certain information to be provided to FDA in a DMF and incorporated into an NDA or ANDA by reference to the DMF. If an applicant incorporates information in an NDA or ANDA by reference to its own DMF or to another person's DMF and that information or part of the information is relevant to a preapproval inspection, FDA will provide the information to its investigators.

FDA declines to impose a time period within which it must submit information in a DMF to its investigators. Contacts between appropriate headquarters reviewing personnel and FDA's district offices before and during a preapproval inspection will ensure that the field investigators have relevant information from a DMF in a timely manner.

12. One comment asked that the rule include a provision specifying that "field inspections must be initiated at least 30 days after receipt of information from headquarters and the field investigators must report back to headquarters within 10 days of receipt of the information. A failure to do so constitutes an agency waiver of the preapproval inspection need."

FDA declines to revise the rule to include the timeframes suggested by the comment. The scheduling of inspections is left to the discretion of the district offices. District preapproval activities are an inherent part of the agency's overall review process; therefore, districts are responsible for timely responses to headquarters assignments so as not to unduly delay recommendations concerning an application approval. As discussed in section III.A.2., FDA is streamlining its inspection scheduling and reporting procedures to allow for inspections to be conducted earlier in the review process and to avoid bottlenecks at clearance time, and is targeting increased resources for its preapproval inspection program.

C. Scope of Requirements

13. Some comments objected to imposing new requirements on NDA applicants because of instances of misrepresentation and fraud by some ANDA applicants. The comments argued that FDA's remedy for detection of fraud should not be extended to NDA's because of differences in the development sequences for original new chemical entity drug products and generic drug products and the very significant differences in the review of NDA's and ANDA's by FDA, and that the problems identified by FDA with respect to generic firms could be addressed without imposing additional burdens on NDA applicants. One comment viewed the new requirements as another tax on innovation. Another comment believed that there has been integrity in the approval process for NDA's and asserted that there is not an adequate basis for concluding that the new submission requirements by research companies will alleviate or prevent any problem.

The agency does not agree that the rule should apply only to ANDA applicants. FDA cannot assure that NDA's are not susceptible to fraud. This rule would allow FDA to prevent and remedy fraud wherever it occurs in the new drug product approval process.

14. A few comments requested clarification of the types of bioavailability and bioequivalence studies that are subject to § 314.50(d)(1)(ii)(*b*) of this rule. One comment asked whether the many types of clinical pharmacology, pharmacokinetic, and pharmacodynamic studies in which blood samples are routinely collected for analysis during clinical development of a dosage form would be considered within the scope of the regulation. The comment suggested that the regulation apply only to pivotal bioavailability and bioequivalence studies, i.e., those studies that define the absolute or relative bioavailability of a new drug and studies necessary to demonstrate the bioequivalence of a new formulation to that which was previously studied in clinical trials. One comment suggested that the scope of the submission requirements for NDA's be limited to records of "a batch representative of the batches used in studies of the bioequivalence or bioavailability of the drug product."

FDA agrees that clarification of the rule is necessary and has revised § 314.50(d)(1)(ii)(*b*) to clarify the bioavailability and bioequivalence studies to which this final rule applies.

In the **Federal Register** of April 28, 1993 (58 FR 25918), FDA published a final rule to amend its current bioavailability/bioequivalence regulations to require the retention for a specified period of reserve samples of the drug products used to conduct certain bioavailability or bioequivalence studies, and, when specifically requested, to release the reserve samples to FDA. In response to comments on the interim rule published in the **Federal Register** of November 8, 1990 (55 FR 47034), FDA revised § 320.38 (§ 320.32 in the interim rule) and § 320.63 to clarify the bioavailability and bioequivalence studies from which reserve samples are to be retained. Therefore, like the final rule on sample retention, for an NDA, this rule applies to those studies comparing the applicant's proposed product with that formulation studied during pivotal clinical trials to establish their equivalence; and for an ANDA, this rule applies to a bioequivalence study comparing the applicant's proposed drug product to the approved drug product upon which the applicant relies for approval of its product.

15. Three comments argued that submission of the biopharmaceutics section of an application is unnecessary because that section includes data such as statistical and raw laboratory data that would be of no use to the field investigator for a preapproval inspection. One comment suggested that the only portions of this section that are relevant to the field investigator's mission are: (1) Information about the drug product used to conduct a bioavailability or bioequivalence study such as composition of the test drug product, certificates of analysis for the test and reference products, and comparative dissolution profile for the test and reference products; and (2) the synopsis or summary of the bioequivalence study results. Another comment suggested that data identifying the lots used to conduct bioavailability or bioequivalence studies and the manufacturing site for the lots would be information needed for a preapproval inspection. The comments argued that a revision of the rule to provide for the submission of an additional copy of only these portions of the biopharmaceutics section would result in a saving of time and photocopy resources for applicants as well as

greater convenience and efficiency for FDA investigators in discharging their preapproval inspection duties. One comment expressed concern that, if the entire biopharmaceutics section was provided to the district offices, overzealous inspectors may attempt to conduct a pharmacokinetic review.

The agency has carefully considered these comments in light of the objectives of its preapproval inspection program and the regulatory requirements most appropriate to achieve these objectives. Based on this review, the agency has modified the final rule to remove the proposed provision requiring submission of an additional copy of the biopharmaceutics section of an application.

FDA considers an applicant's comparative in vitro dissolution data a critical component of FDA's approval of new drug products, especially generic drug products. For an ANDA, comparative dissolution data for solid oral dosage form drug products are necessary to show comparability of the applicant's proposed drug product to its brand name counterpart. For an NDA, comparative dissolution data for solid oral dosage form drug products are necessary to show comparability of the applicant's proposed drug product to the formulation used in conducting the pivotal clinical, bioavailability, and stability studies. Where comparative in vitro dissolution data are required in addition to an in vivo bioequivalence or bioavailability study or as the sole bioequivalence requirement, the data are included in the biopharmaceutics section of an NDA and an ANDA. During preapproval inspection, FDA investigators will audit an applicant's comparative dissolution data at the facility where the testing was conducted. If either FDA's headquarters reviewing personnel or FDA's field investigators question the integrity of the comparative dissolution data submitted to FDA by an applicant, FDA will arrange with its field investigators for additional audits. If, based on FDA's inspectional experience and headquarters reviews of applications, the agency believes additional requirements are needed to ensure the integrity of the data submitted in the biopharmaceutics section of an NDA or ANDA or to facilitate its preapproval inspections, it will again consider the issue and propose appropriate revisions to this rule.

16. A few comments asked that FDA clarify the types of stability studies that are subject to § 314.50(d)(1)(ii)(*b*) of this rule.

This requirement is limited to primary stability studies, i.e., those stability studies conducted with the proposed drug product in the container closure system proposed for marketing and under storage conditions that support the proposed expiration dating period. For an ANDA, generally the stability studies are conducted with the same batch of the drug product used to conduct bioequivalence studies.

17. Four comments argued that the explanation provided in the proposed rule describing the need for an additional copy of the applicant's draft labeling was inadequate because it did not define the role that the district office will have in label review, especially the package insert which is included in "labeling." The comments requested that the requirement for submission of a copy of the applicant's draft labeling be deleted.

FDA has reevaluated FDA's field investigators need for a copy of the applicant's draft labeling during a preapproval inspection and has concluded that its field investigators do not need to have access to draft labeling for every preapproval inspection. The agency is not finalizing the proposed revision of § 314.50(e)(2)(ii) that would have added the requirement for the submission of an additional copy of an applicant's draft labeling. The agency advises, however, that its field investigators may ask an applicant for a copy of its draft labeling to confirm consistency with application commitments. For example, an investigator may need to confirm that an applicant can meet the storage conditions contained in the labeling of its proposed drug product.

D. Number of Copies of an Application

18. Two comments asked that FDA clarify in the introductory paragraph of § 314.50 that extra copies are needed for only certain sections of a submission because the language of that paragraph implies that three copies of the entire application are required.

The agency does not believe that the language of the introductory paragraph of § 314.50 has the implication attributed to it by the comment. As proposed, an applicant would submit three copies of an application: An archival copy and two review copies. The content of the archival copy and of the two review copies is set forth at § 314.50 (h)(1) and (h)(2), respectively. The final rule, however, retains the current requirement for one review copy and requires an additional copy of the chemistry section of an NDA and ANDA, each amendment to that section, and each chemistry supplement, which is the field copy. FDA has added new § 314.50(h)(3) to describe the content of the field copy.

19. Several comments questioned whether one additional copy of the chemistry section of an NDA would be adequate in some instances to facilitate a preapproval inspection. The comments argued that, for new chemical entities, as many as 10 or more sites may be specified in an NDA, including those for the manufacture of bulk drug, drug product formulation, and packaging operations. Frequently, these sites and operations are located in geographically diverse areas covered by different FDA regional offices and may be separated from the company's research facility where stability data were generated and where the bioavailability study was conducted. As an alternative proposal, the comments suggested that the reviewing chemist determine the number of additional copies of the chemistry section and all amendments based on the number of inspections requested by the reviewing chemist. The additional copies could be checked for accuracy by the reviewing chemist before issuance to the field. Other comments suggested that, if the intent is to provide the district investigators with the additional information, the information could be provided by the applicant to the field investigator or the district office at the time of an inspection (or earlier, if requested). The comments argued that this would result in reduced need for storage space of documents at FDA, less possibility or probability of document loss or mismanagement at FDA, and reduced dollar cost to the agency. The investigator would be able to see the actual data and accompanying supporting data on site and be directed to the scientists involved with such data, resulting in a better evaluation. Another comment suggested submission to FDA at a time designated by the reviewing chemist of an updated final field copy or copies which would incorporate amended information and technical section revisions. This would reduce the volume of data requiring field review by eliminating superseded or obsolete references and permit the submission of an additional copy if more than one district will be conducting inspections. Still another comment, arguing for submission of the additional copy by the applicant to the applicable local district directly, asserted that FDA neither has the resources, manpower, nor systems in place in its review and documentation areas to comply with the proposal in an efficient and timely manner, and that experience indicates applications and

other submissions inevitably get lost, misplaced, or misfiled. The comment stated that verification of submission directly to the district could be made in cover letters with an applicant's NDA, ANDA, amendment, and supplemental application submission to FDA.

FDA acknowledges that a preapproval inspection may involve more than one facility per NDA or ANDA. The purpose of the requirement for the submission of an additional copy of the chemistry section is to provide FDA's field investigators with the information to audit application commitments and statements against actual manufacturing practices and to assure early detection of fraudulent practices by an applicant. FDA's objective is to achieve this purpose without imposing unnecessary burdens on the industry and FDA. In light of this objective and FDA's consideration of the comments, FDA concludes that it is appropriate to permit U.S. applicants to provide the additional copy of the chemistry section and all amendments to that section directly to the applicant's home FDA district office who will then provide the FDA district offices that cover the inspection site(s) with the information needed to conduct a preapproval inspection. The procedure set forth in the proposed rule was based on FDA's concern that if the additional copy was provided by the applicant directly to the district, there was a possibility that the copy provided to the district would differ from that submitted to FDA headquarters. To alleviate this concern under the revised procedure in this final rule, FDA's ORA will conduct periodic evaluations, with the cooperation of FDA's CDER, to assess whether the copies sent to the home district by the applicant are identical to the copies sent to FDA headquarters. ORA will prepare specific criteria for these evaluations. In the case of a foreign applicant, the final rule provides that the additional copy be sent with the applicant's original submission to the appropriate address designated under § 314.440. In addition, the final rule provides that this additional copy shall be a certified copy, i.e., a responsible corporate official must certify that the copy is a true copy of that submitted to FDA headquarters. The final rule also provides that a U.S. applicant include in its submission to FDA headquarters a statement certifying that the applicant has provided to its home FDA district office the required information.

FDA now furnishes colored binders to applicants free of charge for organizing their applications. FDA intends to use a specific color binder for the field copy of an application. Applicants may request supplies of the field copy binder (FDA Form 2626h) from Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

E. Batch Production Record

20. Three comments asked FDA to clarify what is intended to be included in the batch production record.

A batch production record is that record described under § 211.188 of the CGMP regulations.

21. Two comments argued that the information contained in the batch production records is directly related to CGMP requirements and that FDA would be able to verify the manufacturing procedures, batch size, and formulations used in bioavailability, bioequivalence, and stability studies during a preapproval inspection. Therefore, FDA should not burden the applicant by requiring that batch production records be submitted in an application.

FDA does not agree with these comments. The batch production records are significant to an FDA headquarters reviewer because they characterize the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of the product used to conduct the bioavailability, bioequivalence, and stability studies. FDA reviewers must be assured that the specific manufacturing process used to manufacture and control the batches used to perform the pivotal bioavailability and bioequivalence studies and the primary stability studies necessary for approval of an NDA or ANDA are comparable to those represented in the applicant's NDA or ANDA for production of the commercial batches. (Also, see discussion under section III.E.24. and III.I.33.)

22. Existing regulations at § 314.50(d)(1)(ii) require, in part, a description of the manufacturing procedures for the drug product for which the applicant is seeking approval. One comment asked whether the description of the manufacturing procedure required under § 314.50(d)(1)(ii) or the batch record will be considered the "official manufacturing procedure," asserting that, if the batch record, which is more detailed and may not reflect ranges established during the development of a product, is binding, it may be necessary to file supplements for variations within the description required by existing regulations.

The description of the manufacturing procedures required under § 314.50(d)(1)(ii) represents an applicant's proposed procedures for commercial production of the applicant's product and permits FDA to determine whether or not the procedures can produce the proposed drug product and whether the procedures are adequate to determine and preserve the product's identity, strength, quality, and purity. The level of detail required in this description will vary according to the nature of the drug product and FDA's familiarity with the product. This final rule requires an applicant to include in the chemistry section of an NDA either the proposed or actual master production record or a comparably detailed description of the applicant's production process for a representative batch, and for an ANDA, the proposed or actual master production record to be used for the manufacture of a commercial lot. (See section III.I.33.) The contents of a master production record are described at § 211.186 of FDA's CGMP regulations. On the other hand, a batch production record characterizes the precise methods used in, and the facilities and controls used for, the manufacture, processing, and packing of each batch of an applicant's proposed product. For ANDA's, except for changes that are necessary to accommodate the difference in size between the test and production batches, these same methods, facilities, and controls must be applied to the manufacture of production batches of the applicant's drug product to provide assurance that the applicant's product remains bioequivalent to its brand name counterpart. For NDA's, the specific manufacturing process used to manufacture and control the clinical batches and the batches used to conduct bioavailability and stability studies must be comparable with the manufacturing processes used for future commercial production to assure safety and effectiveness of the applicant's marketed product.

Under the CGMP regulations, a batch production record is required to include an accurate reproduction of the master production record for the size of batch, strength, and dosage form to be manufactured. FDA fully expects applicants to amend a pending application or submit a supplement to an approved application providing for significant changes to the manufacturing procedures described by an applicant in a master production record or, in the case of an NDA, in its detailed description of its manufacturing process if submitted in lieu of a proposed or actual master production record. Although neither the CGMP regulations

nor the regulations under § 314.50 use the term "official manufacturing procedure," FDA considers the master production record as representing the applicant's manufacturing process for a commercial lot.

23. One comment asked for clarification of a statement in the preamble which indicated that batches used for bioequivalence studies and those represented in the application differed; for example, in some instances batches were smaller. The comment read this passage in the preamble to imply that full commercial scale batches were needed for such studies and asked FDA to clarify the statement.

FDA believes the comment misunderstood the preamble statement. The preamble discussion described actual situations where information submitted in an ANDA about the batches of a drug product used to conduct a bioequivalence study (test batches) differed from the information at the manufacturing facility about those same batches. For example, the batch production record at the manufacturing facility showed manufacture of a smaller size batch than the batch production record for that batch submitted in the applicant's ANDA. The batch production record at the manufacturing facility for a test batch must be identical to that submitted to FDA in an application. This preamble discussion in no way implies that full commercial size batches are required as test batches.

24. One comment referred to a statement in the preamble that "FDA must also be assured that the batches used to perform bioavailability, bioequivalence, and stability tests necessary for approval do not differ from batches of the drug product represented in the applicant's NDA or ANDA and subsequently marketed" and asked FDA to define "do not differ."

The language "do not differ" means that the methods, facilities, and controls described in the batch production records for the batches used to conduct the pivotal bioavailability and bioequivalence studies and the primary stability studies must be comparable to those described in the NDA or ANDA for production of a commercial lot of the applicant's proposed drug product. For example, the equipment should be of the same design and operating principles, but may differ with respect to capacity because of the difference in size between a test batch and production batch. The standard operating procedures should be the same for the test batch and production batch except for changes necessary to accommodate the larger size of the production batch. (Also, see discussion under section III.I.33.)

F. Specifications and Test Procedures

25. Three comments contended that, for NDA's, specifications and test methods employed for the components and drug product evolve during the development of the dosage form. This information is routinely submitted to FDA as part of the IND process during development studies. The comments argued that the need to resubmit this information in the NDA is not warranted from a regulatory perspective and not adequately justified by the agency in the proposal.

The agency did not intend that an applicant resubmit information about the specifications and test procedures for each component and for the drug product used to conduct a bioavailability, bioequivalence, or stability study if the information was previously submitted in an IND. Section 314.50(g)(1) provides that an applicant may incorporate information submitted previously by reference. A reference to such information in accordance with § 314.50(g)(1) would satisfy the reporting requirement at § 314.50(d)(1)(ii)(*b*) of this rule.

26. One comment contended that the requirement for specifications and test procedures was too broad and unrealistic, and suggested that the requirement be limited by definition to the components of the product to be marketed (not including developmental forms of the product), and that there be no additional submission of specifications and test procedures for nonactive compendial items, when standardized procedures are used. The comment argued that the suggested limitation would avoid burdening the review process with the minutiae of the documentation which supports the manufacturing process.

As discussed previously in this preamble, the requirements of § 314.50(d)(1)(ii)(*b*) apply only to the components and the drug product used to conduct the pivotal bioavailability and bioequivalence studies and to the primary stability studies, and thus do not apply to developmental forms of the drug product. Reference to the current edition of the U.S. Pharmacopeia (U.S.P.) and the National Formulary (N.F.) may be made for compendial components to satisfy relevant requirements under § 314.50(d)(1)(ii)(*b*) of this final rule, and, as discussed above, an applicant may incorporate information submitted previously to FDA by reference.

G. Names and Addresses of Sources of Components and of the Container and Closure System for the Drug Product

27. Several comments addressed the requirement at § 314.50(d)(1)(ii)(*b*) to provide the names and addresses of the sources of the components and of the container and closure system for the drug product. The comments expressed concern that the requirement could be interpreted as restricting the source of excipients to those used in the bioavailability/bioequivalence batches or of the market container used for stability lots for the commercial product without the approval of a supplement. This would prevent the applicant from using components of equivalent quality from a new supplier until such approval is obtained. One comment argued that this is not current practice with NDA products and is totally inconsistent with the development of U.S.P. and N.F. specifications for inactive ingredients, which the agency has endorsed in the past. The comments asserted that, except for the drug substance, it is unnecessary to submit the name and address of each source of the raw materials or components. One comment suggested that the requirement apply only to suppliers of noncompendial inactive ingredients. The suppliers of compendial inactive components used to manufacture the drug product may change depending on the availability and price of the component. Thus, it is not economically feasible to restrict the source of these components to those suppliers identified in the application. For inactive components that comply with compendial specifications, the comment argued that it is sufficient for a sponsor to accept these materials based upon each supplier's certificate of analysis, and to periodically test representative material from each supplier to ensure compliance with compendial standards and CGMP principles.

The provision at § 314.50(d)(1)(ii)(*b*) has been revised to require that the applicant provide the names and addresses of the sources of only the active ingredient and noncompendial inactive ingredient components as suggested by the comments. The provision is not intended to require that an applicant submit a supplemental application for a change in the supplier of an inactive component. Because specifications for noncompendial components may differ among suppliers, FDA concludes that the information about the sources of noncompendial inactive ingredients is necessary to ensure that these components are properly controlled.

The final rule retains the proposed provision to provide the name and address of the source of the container and closure system.

H. Test Results for Components and Drug Product

28. On its own initiative, the agency has removed proposed § 314.50(d)(1)(ii)(*d*) and incorporated the requirement under § 314.50(d)(1)(ii)(*b*). The requirement for the submission of components and drug product test results was intended to apply only to the batches used to conduct the pivotal bioavailability and bioequivalence studies and primary stability studies. This corrects an inadvertent misplacement of the requirement in the proposed rule.

29. One comment asked that the FDA clarify the regulation at proposed § 314.50(d)(1)(ii)(*d*), which would require an applicant to include in its NDA or ANDA submission the components and drug product test results obtained under §§ 211.84 and 211.165, respectively, for the batches used to conduct bioavailability, bioequivalence, and stability studies. The comment argued that the language pertaining to § 211.84 appears to require testing of all inactive ingredients used to manufacture the bioavailability, bioequivalence, and stability batches; however, for inactive ingredients in particular, FDA reviewers have always accepted manufacturers' certificates of analysis provided that the manufacturer of the drug product has fully validated the data contained in a certificate of analysis.

FDA does not agree with the comment's interpretation of the language of proposed § 314.50(d)(1)(ii)(*d*) about component testing. The requirement in the proposed rule and in this final rule is consistent with the requirements at § 211.84. Final § 314.50(d)(1)(ii)(*b*) (proposed § 314.50(d)(1)(ii)(*d*)) only requires component test results as required by § 211.84(d). Section 211.84(d)(2) permits acceptance of, in lieu of component testing by the manufacturer, "a report of analysis * * * from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analysis through appropriate validation of the supplier's test results at appropriate intervals." Therefore, this final rule, consistent with § 211.84(d)(2), permits applicants to submit a supplier's report of analysis (certificate of analysis) provided the identity testing and validation as required by that provision have been performed by the manufacturer.

30. One comment argued that the requirement for component test results be limited to components of the product to be marketed (not including developmental forms of the product), and there be no additional submission of test results for nonactive compendial components, when standardized procedures are used. Another comment requested that the final rule be modified so that this requirement apply only to drug products used for pivotal bioavailability and bioequivalence studies and for primary stability study lots for the proposed drug product in the proposed market containers.

As discussed in sections III.C.14. and III.H.28., the requirement for the submission of components and drug product test results applies only to the drug products used to conduct pivotal bioavailability and bioequivalence studies and primary stability studies. The final rule has been revised accordingly. FDA does not agree that test results should not be submitted for inactive compendial components. These test results are critical to FDA's determination that the batches of the drug product used for conducting the pivotal bioavailability and bioequivalence studies and the primary stability studies were manufactured with components that meet compendial specifications.

31. One comment suggested that component testing information be required at the time of the preapproval inspection rather than at the time of an original NDA submission. Although the comment understood the agency's desire to obtain accurate information to detect fraudulent submissions, the comment believed that the proposed requirement to include results of component testing in an NDA would add considerably to the size of an NDA, but it would add little value. Two comments argued that the test results for the components and drug product for the batches used in the bioavailability, bioequivalence, and stability studies are already subject to CGMP requirements and are available for FDA's review when conducting preapproval inspections. The comments asserted that including such data in an application would unnecessarily increase the volume of information submitted without any benefit in value, and would likely contribute to confusion and lengthier reviews.

FDA does not agree with the comments. The requirement for the submission of component test results applies only to testing of the components of the drug product from the batches used to conduct pivotal bioavailability and bioequivalence studies and the batches used to conduct primary stability studies. (See discussion in sections III.C.14. and III.H.28.) This testing information is critical to FDA's determination that the bioavailability, bioequivalence, and stability batches were manufactured with components that met the applicant's specifications or compendial standards for identity, quality, strength, and purity. Thus, FDA does not agree that component test results are of little value and would likely contribute to confusion and lengthier reviews.

32. Two comments asked that FDA define the term "component" as used in proposed § 314.50(d)(1)(ii)(*d*).

The term "component" in proposed § 314.50(d)(1)(ii)(*d*) and § 314.50(d)(1)(ii)(*b*) of this final rule is used as FDA has defined the term in § 210.3(b)(3) of FDA's CGMP regulations (21 CFR 210.3(b)(3)). The agency notes that the term is used in existing § 314.50(d)(1)(ii) (redesignated in this final rule as § 314.50(d)(1)(ii)(*a*)), and that use is consistent with the definition of the term in § 210.3(b)(3).

I. Master Production Record

33. Several comments addressed the proposed provision in § 314.50(d)(1)(ii)(*c*), which would require an NDA and an ANDA to include the master production record to be used for the manufacture of a commercial lot of the drug product for which the applicant is seeking approval. The comments argued that the application of this proposed provision as part of the preapproval inspection program does not recognize the distinction between an NDA and an ANDA. Typically, an NDA is submitted at an earlier development stage than an ANDA. The comments asserted that, in the development of a new drug, the batches of the drug product used in the bioavailability, bioequivalence, and stability studies will not necessarily have been manufactured using a fully validated process. Only after full validation is completed is the final master production record generated. Some comments expressed concern that submission of the master production record with the NDA submission would constitute a firm commitment for the final manufacturing process which could not be modified as a result of final scaleup and validation. The comments argued that to wait for final scaleup and validation to be completed before submission of an NDA is impractical and would result in significant submission delays and would result in

the loss of opportunity to continue process development and achieve process improvement. Some comments suggested that the regulation require the development of master production records for NDA's coincident with the creation of validation protocols that can be reviewed just prior to NDA approval. Any differences between these initial master production records and the documents describing the manufacturing of the drug product for bioavailability, bioequivalence, and stability studies would be fully justified and recorded in the respective batch record file under the CGMP regulations. A few comments suggested that the information in an NDA about the applicant's manufacturing process should conform to the current FDA "Guideline for Submitting Documentation for the Manufacture of and Controls for Drug Products," which allows for manufacturing process information to be provided as a suitably detailed description together with a schematic diagram.

FDA recognizes the differences between NDA's and ANDA's with respect to the drug approval process as discussed by the comments. Given these differences, FDA has reevaluated the objectives of the preapproval inspection program and the regulatory requirements most appropriate to implement them. The ANDA approval process necessarily focuses on the applicant's ability to manufacture a product of acceptable quality that will be bioequivalent to the drug product it is copying, whose safety and effectiveness are established. Ordinarily, at the time of submission of an ANDA, a generic applicant will have manufactured a single batch of its proposed drug product for conducting the required bioequivalence and stability studies. Thus, the applicant has little experience in manufacturing its proposed drug product. This test batch must be produced using equipment appropriate for production of a commercial lot. In addition, the same standard operating procedures and controls for the manufacture of the test and commercial lots and the formulation must be the same except for changes necessary to accommodate the difference in size between a test batch and commercial batch. FDA's interim policy on batch size and production conditions for test batches for nonantibiotic, solid oral dosage form drug products is set forth in CDER's Office of Generic Drugs' (OGD) Policy and Procedure Guide 22–90 (Revised) dated September 13, 1990.[2] In reviewing an ANDA, FDA needs to be assured that the bioequivalence batches and the production batches are made by comparable procedures and equipment. A change in the applicant's manufacturing procedure and/or equipment for the production batches may affect the bioequivalence of the applicant's proposed product.

On the other hand, an NDA applicant has from 1 to 5 years experience manufacturing a series of pilot plant production batches during the IND phases for clinical, bioavailability, and stability studies. Pilot plant production simulates full scale production. FDA recognizes that as the clinical trials proceed, manufacturing procedures, specifications, and test methods may need to be modified or refined. It is appropriate that the processes by which a drug product is manufactured in the development stage be well documented and controlled in order to assure the reproducibility of the product for further testing and for ultimate commercial production. When drug development reaches the stage where a drug product is produced for clinical trials, compliance with the CGMP regulations is required. Thus, compliance with CGMP regulations mandates that applicants document the specific manufacturing process used to manufacture and control the clinical batches as well as the pivotal bioavailability and primary stability batches. This is necessary to ensure that a product's performance characteristics that influence its safety and efficacy are maintained throughout the manufacture of the clinical, bioavailability, and stability study batches. Such data in an NDA will be used to demonstrate the comparability of the manufacturing processes used for the clinical, bioavailability, and stability batches with manufacturing processes to be used for future commercial production. At the time of submission of an NDA, FDA would expect that enough would be known about the proposed product's physical and chemical properties, stability, and product performance characteristics that any subsequent changes, if necessary, in the manufacturing process, specifications, and test methods for production of the commercial lot would be minimal.

Because of the differences in manufacturing experience between NDA and ANDA applicants, as discussed above, FDA concludes that it is appropriate to permit the submission of different information by NDA applicants than by ANDA applicants with respect to the type of information needed by FDA to ensure that an applicant has demonstrated comparability of its manufacturing processes used for the bioavailability, bioequivalence, and stability studies with manufacturing processes to be used for a commercial lot. Therefore, for an NDA, § 314.50(d)(1)(ii)(*c*) of this final rule requires the submission of either a proposed or actual master production record or a comparably detailed description of the production process for a representative batch. This continues the current practice set forth in FDA's "Guideline for Submitting Documentation for the Manufacture of and Controls for Drug Products" as suggested by one comment. For ANDA's, § 314.94(a)(9) of this final rule (proposed § 314.55(e)(2)(i)) and for applications submitted under § 314.54, § 314.54(a)(1)(i) and (a)(2) require the submission of either a proposed or actual master production record. A detailed description of the production process for a representative batch, in lieu of a proposed or actual master production record, would not be acceptable. This is because, as noted above, at the time of submission of an ANDA, most generic applicants have little experience in manufacturing its proposed product. Therefore, at the time of submission of an ANDA, an applicant must document in either a proposed or actual master production record that scaleup will not result in a product quality difference between the batch used for bioequivalence and stability testing and the production batch. For both NDA's and ANDA's, the final rule requires that a proposed or actual master production record include a description of the equipment to be used in the manufacture of the commercial lot. Process validation, except sterilization process validation, need not be completed at the time of submission of an NDA and ANDA in those cases where a proposed master production record is submitted or in the case of an NDA where a detailed description of the production process is submitted in lieu of a proposed or actual master production record. In any event, an applicant is expected to amend a pending NDA or ANDA or submit a supplement to an approved NDA or ANDA to provide for changes in its manufacturing process. The types of changes requiring a supplement are described under § 314.70(b) and (c). These are the types of changes that may affect adversely the agency's previous

[2] OGD Policy and Procedure Guide 22–90 (Revised) is available from CDER's Executive Secretariat Staff (HFD–8), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

conclusions about the safety and effectiveness or bioequivalence of a drug product. For ANDA's, applicants may refer to OGD Policy and Procedure Guide 22–90 (Revised) for further guidance. Applicants may also consult with the appropriate reviewing chemist if further guidance is needed about the types of changes that would require submission of an amendment or supplement.

J. Supplements

34. In the preamble to the proposed rule (56 FR 3180 at 3182), FDA noted certain types of changes requiring a supplemental NDA or ANDA under § 314.70(b) that may require a preapproval inspection of the applicant's facilities. One comment noted that FDA requires that manufacturers of active ingredients rather than suppliers or distributors be included in NDA's and ANDA's, and suggested that in FDA's list of changes that may require a preapproval inspection, the wording "supplier of bulk active ingredient" be changed to "manufacturer of bulk active ingredient."

FDA agrees with the comment's noted discrepancy; however, no revision of the final rule is necessary.

35. Two comments addressed the proposed amendment to § 314.71(b), which would require the submission of an additional copy of those supplements described in § 314.70(b)(1) or (b)(2). One comment noted that there are numerous grounds for filing supplements and a range of different regulatory questions triggered by these supplements, and questioned what the inspection process is designed to find, for example, in a supplement to add a new packaging component or to change the ink in the printing on a drug product. Both comments suggested that FDA either request certain data and conduct inspections as needed when supplements are submitted or enumerate in the rule the types of supplements which FDA believes raise questions sufficient to warrant application of this rule.

As with an NDA and an ANDA, before approval of a supplemental application, FDA must determine that the facilities involved in the manufacturing, testing, or other manipulation of the applicant's approved drug product have been inspected and are in compliance with CGMP. This is so whether the supplemental application provides for a change that requires preapproval under § 314.70 (b)(1) and (b)(2), a change that may be made before FDA approval under § 314.70(c), or whether the supplement provides for a change of the type that would trigger a preapproval inspection. Therefore, FDA concludes that its investigators must have a copy of all supplements providing for changes to the chemistry section of an NDA and ANDA. This would not include supplements providing for labeling changes. Therefore, on its own initiative, FDA is revising § 314.71 to require an applicant to submit a certified copy of all supplements (field copy) providing for changes to the chemistry section of its NDA described under § 314.70 (b)(1), (b)(2), and (c). Section 314.97 applies this requirement to ANDA's by reference to § 314.71. As with the field copy of original submissions, a U.S. applicant would provide these supplements to its home FDA district office at the same time the supplements are submitted to FDA headquarters and would include in its submission to FDA headquarters a statement certifying that the applicant has provided to its home FDA district office the required information. Foreign applicants would provide the field copy of these supplements to FDA headquarters at the same time the archival and review copies of the supplements are submitted to FDA.

The agency notes that the regulations at § 314.70(d) and § 314.97 by reference provide that certain types of changes in the conditions in an approved NDA and ANDA may be described only in an annual report. FDA's investigators currently review, as necessary, the applicant's copy of its annual reports. FDA intends to continue this practice and not require an applicant to submit to its home FDA district office an additional copy of each annual report. If, based on FDA's inspectional experience, the agency believes additional requirements are necessary to ensure the integrity of the data submitted in an annual report, it will propose appropriate revisions to this rule.

IV. Economic Impact

FDA has examined the economic effects of this final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). This final rule significantly reduces the amount of information that an applicant would submit for a preapproval inspection. Unlike the proposed rule, the final rule does not require the submission of an additional copy of the biopharmaceutics section of an NDA and an ANDA and of the applicant's draft labeling. The final rule also more clearly defines the types of bioavailability, bioequivalence, and stability studies to which the rule applies. The types of studies perceived by some comments as being within the scope of the proposed rule have been greatly reduced in this final rule.

The final rule, however, expands the proposed provision concerning supplemental applications by requiring an applicant to submit an additional copy of all chemistry supplements. This revision should have a minimal impact on the firms involved.

FDA estimates the nationwide annual copying cost of this regulation to be $93,660 for all of the applicants submitting NDA's and ANDA's. The 90 applicants submitting ANDA's would be expected to incur $33,960 in costs for an average annual cost per firm of $380. The 80 applicants submitting NDA's would be expected to incur $59,700 in costs for an average annual cost per firm of $750. These costs should have a negligible impact on the applicants involved.

These new requirements are intended to benefit preapproval inspections and should not themselves delay application approvals, as suggested by one comment. The purpose of this rule is to provide to FDA's district offices information they need in advance of a preapproval inspection thereby facilitating the inspection process. Compliance with this rule should result in more efficient and effective inspections.

Accordingly, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291, and certifies that the final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

VI. Paperwork Reduction Act of 1980

The information requirements contained in this final rule will collect information from persons who must obtain FDA approval prior to marketing a new drug. These persons must submit certain manufacturing and controls information and information about the batches of a drug product used to conduct bioavailability, bioequivalence, and stability studies. FDA will use the information during a preapproval inspection to audit application commitments and statements against actual manufacturing practices.

This final rule amends 21 CFR part 314, which pertains to applications for FDA approval to market a new drug. The information collection requirements of the regulations in part 314 are subject to a separate Office of Management and Budget (OMB) approval request (OMB No. 0910–0001). This OMB approval request is currently being revised. FDA will include these amendments to part 314 in its revision of that information collection approval request.

Therefore, the estimated annual reporting and recordkeeping burden for this final rule that was published as a proposal in the **Federal Register** of January 28, 1991 (56 FR 3180 at 3182), is withdrawn.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

efore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 376).

2. Section 314.50 is amended by revising the introductory text; by redesignating existing paragraph (d)(1)(ii) as paragraph (d)(1)(ii)(*a*); by adding new paragraphs (d)(1)(ii)(*b*), (d)(1)(ii)(*c*), and (d)(1)(v); by revising paragraph (h)(2); and by adding new paragraphs (h)(3) and (h)(4) to read as follows:

§ 314.50 Content and format of an application.

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Three copies of the application are required: An archival copy, a review copy, and a field copy. An application for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling. Other applications will generally contain only some of those items, and information will be limited to that needed to support the particular submission. These include an application of the type described in section 505(b)(2) of the act, an amendment, and a supplement. The application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source. FDA will maintain guidelines on the format and content of applications to assist applicants in their preparation.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(*b*) Unless provided by paragraph (d)(1)(ii)(*a*) of this section, for each batch of the drug product used to conduct a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter or used to conduct a primary stability study: The batch production record; the specifications and test procedures for each component and for the drug product; the names and addresses of the sources of the active and noncompendial inactive components and of the container and closure system for the drug product; the name and address of each contract facility involved in the manufacture, processing, packaging, or testing of the drug product and identification of the operation performed by each contract facility; and the results of any test performed on the components used in the manufacture of the drug product as required by § 211.84(d) of this chapter and on the drug product as required by § 211.165 of this chapter.

(*c*) The proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product or a comparably detailed description of the production process for a representative batch of the drug product.

* * * * *

(v) Except for a foreign applicant, the applicant shall include a statement certifying that the field copy of the application has been provided to the applicant's home FDA district office.

* * * * *

(h) * * *

(2) The applicant shall submit a review copy of the application. Each of the technical sections, described in paragraphs (d)(1) through (d)(6) of this section, in the review copy is required to be separately bound with a copy of the application form required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section.

(3) The applicant shall submit a field copy of the application that contains the technical section described in paragraph (d)(1) of this section, a copy of the application form required under paragraph (a) of this section, a copy of the summary required under paragraph (c) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (d)(1) of this section contained in the archival and review copies of the application.

(4) The applicant may obtain from FDA sufficient folders to bind the archival, the review, and the field copies of the application.

* * * * *

3. Section 314.54 is amended by revising paragraphs (a)(1)(i) and the first sentence of paragraph (a)(2) and by adding new paragraph (a)(4) to read as follows:

§ 314.54 Procedure for submission of an application requiring investigations for approval of a new indication for, or other change from, a listed drug.

(a) * * *

(1) * * *

(i) The information required under § 314.50(a), (b), (c), (d)(1), (d)(3), (e), and (g), except that § 314.50(d)(1)(ii)(*c*) shall contain the proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product.

* * * * *

(2) The applicant shall submit a review copy that contains the technical sections described in § 314.50(d)(1), except that § 314.50(d)(1)(ii)(*c*) shall contain the proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product, and paragraph (d)(3), and the technical sections described in paragraphs (d)(2), (d)(4), (d)(5), (d)(6), and (f) when needed to support the modification. * * *

(3) * * *

(4) The applicant shall submit a field copy of the application that contains the technical section described in § 314.50(d)(1), a copy of the information required under § 314.50(a) and (c), and certification that the field copy is a true copy of the technical section described in § 314.50(d)(1) contained in the archival and review copies of the application.

* * * * *

4. Section 314.60 is amended by adding new paragraph (c) to read as follows:

§ 314.60 Amendments to an unapproved application.

* * * * *

(c) The applicant shall submit a field copy of each amendment to § 314.50(d)(1). The applicant, other than a foreign applicant, shall include in its submission of each such amendment to FDA a statement certifying that a field copy of the amendment has been sent to the applicant's home FDA district office.

5. Section 314.70 is amended by revising paragraph (a) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

(a) *Changes to an approved application.* The applicant shall notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant shall notify FDA about it in a supplemental application under paragraph (b) or (c) of this section or by inclusion of the information in the annual report to the application under paragraph (d) of this section. Notwithstanding the requirements of paragraphs (b) and (c) of this section, an applicant shall make a change provided for in those paragraphs (for example, the deletion of an ingredient common to many drug products) in accordance with a guideline, notice, or regulation published in the **Federal Register** that provides for a less burdensome notification of the change (for example, by notification at the time a supplement is submitted or in the next annual report). Except for a supplemental application providing for a change in the labeling, the applicant, other than a foreign applicant, shall include in each supplemental application providing for a change under paragraph (b) or (c) of this section a statement certifying that a field copy of the supplement has been provided to the applicant's home FDA district office.

* * * * *

6. Section 314.71 is amended by revising paragraph (b) to read as follows:

§ 314.71 Procedures for submission of a supplement to an approved application.

* * * * *

(b) All procedures and actions that apply to an application under § 314.50 also apply to supplements, except that the information required in the supplement is limited to that needed to support the change. A supplement is required to contain an archival copy and a review copy that include an application form and appropriate technical sections, samples, and labeling; except that a supplement for a change other than a change in labeling is required also to contain a field copy.

* * * * *

7. Section 314.94 is amended by revising the first two sentences of the introductory text and paragraphs (a)(9)(i) and (d)(4) and by adding new paragraph (d)(5) to read as follows:

§ 314.94 Content and format of an abbreviated application.

Abbreviated applications are required to be submitted in the form and contain the information required under this section. Three copies of the application are required, an archival copy, a review copy, and a field copy. * * *

(a) * * *

(9) *Chemistry, manufacturing, and controls.* (i) The information required under § 314.50(d)(1), except that § 314.50(d)(1)(ii)(*c*) shall contain the proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product.

* * * * *

(d) * * *

(4) The applicant may obtain from FDA sufficient folders to bind the archival, the review, and the field copies of the abbreviated application.

(5) The applicant shall submit a field copy of the abbreviated application that contains the technical section described in paragraph (a)(9) of this section, a copy of the application form required under paragraph (a)(1) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (a)(9) of this section contained in the archival and review copies of the abbreviated application.

8. Section 314.96 is amended by redesignating existing paragraph (b) as paragraph (c) and by adding new paragraph (b) to read as follows:

§ 314.96 Amendments to an unapproved abbreviated application.

* * * * *

(b) The applicant shall submit a field copy of each amendment to § 314.94(a)(9). The applicant, other than a foreign applicant, shall include in its submission of each such amendment to FDA a statement certifying that a field copy of the amendment has been sent to the applicant's home FDA district office.

* * * * *

9. Section 314.440 is amended by revising the first two sentences in paragraph (a)(1) and the first sentence in paragraph (a)(2) and by adding new paragraph (a)(4) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) * * *

(1) Except as provided in paragraph (a)(4) of this section, an application under § 314.50 or § 314.54 submitted for filing should be directed to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20852. Applicants may obtain folders for binding applications from the Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785. * * *

(2) Except as provided in paragraph (a)(4) of this section, an abbreviated application under § 314.94, and amendments, supplements, and resubmissions should be directed to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. * * *

* * * * *

(4) The field copy of an application, an abbreviated application, amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application and an abbreviated application shall be sent to the applicant's home FDA district office, except that a foreign applicant shall send the field copy to the appropriate address identified in paragraphs (a)(1) and (a)(2) of this section.

* * * * *

Dated: March 30, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–21798 Filed 9–7–93; 8:45 am]

BILLING CODE 4160–01–P

federal register

Wednesday
September 8, 1993

Part V

Department of the Interior

Bureau of Land Management

43 CFR Part 3160
Onshore Oil and Gas Operations; Federal and Indian Oil Gas Leases; Onshore Oil and Gas Order No. 7: Disposal of Produced Water; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

RIN 1004–AA66

[WO–610–4111–02–24 1A; Circular No. 2650]

Onshore Oil and Gas Operations; Federal and Indian Oil and Gas Leases; Onshore Oil and Gas Order No. 7: Disposal of Produced Water

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This final rule issues Onshore Oil and Gas Order No. 7 (the Order) in accordance with 43 CFR 3164.1. This Order supersedes the Notice to Lessees and Operators of Federal and Indian (except Osage Tribe) Oil and Gas Leases (NTL) 2B, Disposal of Produced Water. This Order addresses the uniform national standards of the Bureau of Land Management (BLM) for the minimum level of performance expected from lessees and operators in the disposal of produced water associated with the oil and gas operations. The Order also details enforcement actions and prescribes the manner in which variances from specific standards may be obtained.

EFFECTIVE DATE: October 8, 1993.

ADDRESSES: Suggestions or inquiries should be sent to: Director (610), Bureau of Land Management, room 601, Premier Building, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sie Ling Chiang, (202) 653–6610.

SUPPLEMENTARY INFORMATION: Section 3164.1 of title 43 of the Code of Federal Regulations provides for the issuance of Onshore Oil and Gas Orders when needed to implement and supplement the regulations in part 3160. All orders are promulgated through the rulemaking process and, when issued in final form, apply nationwide. This final rule, Onshore Oil and Gas Order No. 7, supersedes the Notice to Lessees and Operators of Federal and Indian (except Osage Tribe) Oil and Gas Leases (NTL)–2B, Disposal of Produced Water.

This Order specifies: (1) Procedural requirements for the submission of, and the information to be contained in, an application for approval of a proposed disposal of produced water; (2) the design, construction, and maintenance requirements for an acceptable disposal facility; (3) the minimum standards necessary to satisfy those requirements; and (4) the procedures for requesting variances from the minimum standards. The Order also identifies violations, corrective actions, normal abatement periods, and those enforcement actions that would result when violations of requirements are not abated in a timely manner. This Order should be followed in conjunction with Onshore Oil and Gas Order No. 1 for approval of operations and Order No. 2 for drilling of an injection well.

The BLM published the rule proposing Onshore Oil and Gas Order No. 7 in the **Federal Register** on January 19, 1990 (55 FR 1837), requesting comments on the proposed rule by March 20, 1990. During the 60-day comment period, comments were received from 25 sources: 12 from business entities, 7 from Federal agencies, 4 from State agencies, and 2 from individuals. The comments are discussed in the same sequence as the sections of the proposed Order. Many of the suggestions were adopted and are reflected in the final rule.

General Comments

Two comments questioned the basis for issuing the Order and argued that the rule is unnecessary. The primary basis for the issuance of this Order, and its predecessor NTL–2B, is the Mineral Leasing Act, not the Federal Oil and Gas Royalty Management Act (FOGRMA) as one of the comments stated. The NTL–2B was issued before FOGRMA. The implementing regulations at 43 CFR 3164.1 further authorize the Director, BLM, to issue Onshore Oil and Gas Orders when necessary to implement or supplement the operating regulations. There is a solid basis for the issuance of this Order. The Order is needed to protect surface and subsurface resources from contamination.

Several respondents expressed their concern over the jurisdictional overlap of multiple regulatory agencies involved, especially between the Environmental Protection Agency (EPA) or the primacy State and BLM. They are concerned that this rule would establish another layer of bureaucracy and create conflicts among agencies involved. They urged BLM to establish procedural memoranda of understanding (MOU) with other agencies to streamline the permit process and to resolve conflicts. The roles and responsibilities of EPA and BLM in administering the disposal of produced water on Federal and Indian lands are mutually complementary rather than overlapping. In approving an injection well proposal, the EPA or the primacy State exercises authority granted under the Clean Water Act to protect ground water through issuing an underground injection control (UIC) permit, while BLM's approval focuses on downhole integrity, protection of other mineral resources and protection of surface resources. In issuing a National Pollution Discharge Elimination System (NPDES) permit to allow surface discharge, the EPA or the primacy State ensures that the water quality at the discharge point meets the standards, while BLM ensures that the treatment facilities upstream from that discharge point are satisfactory. Thus, it is unavoidable that both agencies are involved in the approval of a given application. Both agencies will keep the paperwork to a minimum. A few BLM State Offices have existing MOU's with the EPA and/or State to facilitate coordination and cooperation between the agencies in this regard.

One comment was concerned that the EPA, the Interstate Oil Compact Commission (IOCC), and the BLM may establish separate regulations to be imposed on industry. The EPA reviewed the proposed rule and did not raise the issue of possible separate sets of regulations. On the contrary, the EPA stated that Order No. 7 as proposed "has the potential to ensure that disposal of produced water from onshore oil and gas operations for Federal and Indian oil and gas leases does not degrade water quality." The IOCC consists of members representing all oil producing States that may have established standards and requirements of their own. The policy of the Department of the Interior (the Department) has been that, wherever BLM standards differ from those of the States, the operator is required to comply with whichever standards are more stringent. There have been no unresolvable conflicts in this practice.

Another comment contended that BLM should convert to consolidated regulations for onshore Federal/Indian lands similar to those of the Minerals Management Service for oil and gas operations in the Outer Continental Shelf (OCS). The recent consolidation of OCS Orders into the regulations resulted in a more comprehensive but also more voluminous set of regulations. The BLM chooses to continue to use Orders under the authority of the regulations to supplement or implement the regulations, which remain simple and general. There are pros and cons for each approach. The BLM system has been working well.

Although one respondent argued that the proposed rule will have substantial economic impacts on independent operators, another comment stated that the proposed Order will have no adverse economic impacts if timely and reasonable approval is given to disposal requests. In the interest of timely

processing of the application, this Order imposes a new requirement for the BLM to respond to a request within 30 days.

Authority

One comment stated that this Order is a regulation that will "show how the Federal government will implement the National Environmental Protection (sic) Act of 1969, plus many other acts." It went on to argue that the Order should be limited to specific direction related to oil and gas, that the National Environmental Policy Act of 1969 (NEPA) should be administered only by the EPA, and, similarly, that only the resource management agency, as opposed to the EPA, should manage the resource itself. However, NEPA establishes environmental policies to be applied by all Federal agencies. Hence, all Federal agencies are required to incorporate the policy and objectives of NEPA in their regulations. This Order is intended to provide specific standards and requirements for disposal of produced water relative to the BLM's authority under various mineral laws and must also meet the objectives of several environmental laws including NEPA. The comment also stated that specific design details for such features as pits and fences should be left either for the agency directives or plans of operations. However, one objective of the Order is to provide specific design standards and establish uniform application of the Order throughout BLM. These comments were not adopted in the final rule.

Scope

Several comments requested clarification of the second sentence under "Scope," which states that the Order does not apply to disposal facilities on non-Federal leases committed to communitized or unitized areas. The BLM agrees that this seems confusing and has changed the language to clarify the scope.

Some of the same comments also requested that an exemption for secondary and tertiary recovery operations be added to the paragraph. However, because of the complexity of enhanced recovery projects and the varying situations that could occur, an exemption is not feasible. A separate approval under this Order is not required if the method of disposal has been approved as part of the enhanced recovery approved by the authorized officer.

Definitions

Two comments addressed the requirement for a leak detection system for lined pits in the definition of that term, and recommended that it be dropped from the definition. The leak detection system is only required for lined pits used in association with long-term use for disposal of produced water. It is therefore retained as part of the definition.

Several comments were received on the definition of "free-board". The comments have been adopted and the definition is revised to read as follows: "Free-board" means the vertical distances from the top of the fluid surface to the lowest point on the top of the dike surrounding the pit.

One comment suggested that the definition for Produced Water be clarified as follows: "Water containing dissolved and free hydrocarbons produced in conjunction with oil and gas production." This comment is not adopted because it was felt that the present definition is clear enough. The suggested definition would also be too restrictive: contaminants other than dissolved and free hydrocarbons may also be present and require control.

One comment suggested that the definition for lined pit be modified to state that the materials used in the construction of pit "substantially limit seepage." This comment has not been adopted because the intent of the Order is to prevent all leaks and seepage.

One comment requested that a definition for "fresh water" and "usable water" be added to the Order. Since these terms were not used in the Order, there is no reason to define them.

Several comments suggested that the definition for unlined pits be clarified. These comments have been adopted and the last sentence in the definition has been rewritten as follows: Any pit that is lined but does not have a leak detection system is still defined as an unlined pit.

One comment requested that a list of toxic substances, or a reference to where such a list can be found, be added as an appendix to the Order. Such listing can be found at 40 CFR part 116. The subject listing of toxic constituents is very comprehensive. It is not the intent of this Order to have the oil and gas operator test all the produced water for all of these constituents. The intent of the Order is to have the produced water tested only if the authorized officer has reason to believe a toxic constituent exists in a certain area.

One comment suggested that the word "waste" in the definition of "Underground Injection Control" be removed from the definition, because the word was thought to have a negative connotation. In cases where the water is used for enhanced recovery or beneficial use, the produced water is not considered waste water. We have therefore adopted this suggestion and have removed the word "waste" from the definition.

III.A. General Requirements

Several comments suggested that surface discharge under NPDES permit be added to this paragraph as a fourth method of disposal of produced water. This method of disposal was included in the proposed rule and Order under Section III.G. as one of the other disposal methods. In response to these comments, it was decided to identify NPDES disposal methods specifically under the third category, methods approved by the authorized officer, and provide more detailed guidance under Section III.G.

Several comments received suggested the statement "Injection is the preferred method of disposal" should be removed from the Order. However, in most instances, water disposal into a suitable formation is environmentally acceptable and preferred to surface disposal methods. Therefore, the wording will be changed to read "Injection is generally the preferred method of disposal."

With respect to the statement "Applications filed pursuant to NTL–2B and still pending approval shall be supplemented or resubmitted if they do not meet the requirements and standards of this Order", and the statement "However, upon written justification, the authorized officer may impose additional conditions * * *", some comments expressed concern that when the Order becomes effective the authorized officer might require changes to existing disposal operations approved under NTL–2B. Existing approvals will not be altered unless it is discovered that there is, or could be, environmental damage taking place and that without change the problem may worsen. This provision was always in place even under NTL–2B and this Order does not change that procedure. Applications still pending approval will require a supplement or resubmission only if they do not conform to the requirements of this Order. Most pending applications should already comply and resubmittal rates should be low. This provision of the proposed Order is not changed in the final rule.

One comment objected to the wording "or that an unlined pit should be lined," given as an example of a condition that could be imposed by the authorized officer. It is not the BLM's intent that unlined pits be routinely required to be lined. This is only an example of possible corrective measures that might be required should obvious environmental damage be taking place.

Other examples might include requiring protective flagging and/or netting for waterfowl protection, installation of skimmer pits or other similar equipment or other alterations necessary to protect the environment. Language has been added in the final rule that limits the application of such conditions to situations where changes in water quality or other environmental parameters warrant it.

Some respondents commented that the disposal method does not require applications for approval but is only a notification procedure. This is not correct. The authorized officer is responsible for ensuring proper disposal of produced water from oil and gas operations within his/her authority. The comment is not adopted in the final rule.

One comment stated that the 30-day processing time for the BLM was unreasonable because operators would have to shut in newly completed wells until such time as an application is approved. One comment suggested that the application turn-around time should be 2 days. However, the Order is clear that the operator has 90 days for temporary disposal into reserve pits if the pit was approved as part of an application for permit to drill. Extensions of disposal into reserve pits past 90 days may be granted by the authorized officer. No producing well will be shut in while the water disposal application is being processed. The comment is not adopted in the final rule.

For clarification, the following language has been added to General Requirements, at the end of III.A.: "If the approval for a disposal facility, e.g., commercial pit or class II injection well, is revoked or suspended by the permitting agency (EPA or a primary state), BLM's water disposal approval is immediately terminated and the operator shall propose an alternative disposal method."

III.B. Application and Approval Authority

Several comments addressed the structure of III.B. The comments stated that the structure in the proposed Order is confusing. Several formats were suggested. One format included a section for Natural Gas Dehydration Pits. The BLM agrees that the structure of the subsection is confusing and has reorganized it as shown below. However, the BLM believes that it is important to differentiate clearly between on-lease disposal and off-lease disposal on leased and unleased Federal/Indian Lands, because on-lease disposal is permitted as a lease right and off-lease disposal on other leased and unleased Federal/Indian lands is required to be approved through right-of-way authorizations. Third party ownership of facilities such as natural gas dehydration pits is considered by BLM as a right-of-way issue beyond the scope of this Order. The modified organizational structure is shown below:

B. Application and Approval Authority
1. On-lease Disposal
a. Disposal of Water in Injection Wells
b. Disposal of Water in Pits
2. Off-lease Disposal
a. Disposal of Water on leased or unleased Federal/Indian Lands
i. Disposal of Water in Injection Wells
ii. Disposal of Water in Pits
iii. Right-Of-Way Procedures
b. Disposal of Water on State and Privately-Owned Lands
i. Disposal of Water in Injection Wells
ii. Disposal of Water in Pits
iii. Right-of-Way Procedures

Several comments recommended that this subsection include specific approval procedures for surface discharge authorized by NPDES permits. This Order has been modified to include more specific procedures for such disposal methods in III.G. Other Disposal Methods.

Several comments expressed concern that the proposed Order would create an unwarranted amount of paperwork by requiring copies of permits and information to support obtaining UIC permits as well as information already furnished in conjunction with Orders No. 1 and 2. The following sentence has been added to III.B.1.a.: "If the authorized officer has on file a copy of the approval for the receiving facilities, he/she may determine that a reference to that document is sufficient." This statement is also found in III.B.2.a. The BLM believes these statements make it clear that if the authorized officer has copies of permits and supporting data, it would not be necessary to require such data to be submitted again.

One comment suggested that a sentence be added to indicate BLM's authority on split-estate lands, i.e., where minerals rights are held by the United States or Indian tribes and the surface is private or State land. The BLM believes that it is clearly understood that the Order is applicable to water produced from Federal/Indian lands, including private/State surface with Federal/Indian Minerals. This comment further points out that "Federal Lands" include private surface/Federal minerals and that no right-of-way can be issued on private surface. This point is clear in the right-of-way regulations; the use of the term "Federal Lands" in the Order should not be misunderstood.

Two comments questioned the approval of surface disturbing activities on National Forest System lands and the effect of the Leasing Reform Act of 1987 on this Order. A MOU will be written specifically to address this question.

One comment suggested that these provisions should provide for notification to the surface managing agency (SMA). Order No. 1 requires that the authorized officer, in consultation with any other involved SMA, may require a field inspection before approving surface disturbing activities subsequent to drilling. Therefore, the requirement does not need to be repeated in this Order.

Two comments questioned why provisions for disposal of produced water from non-Federal or non-Indian leases were not identified. This Order pertains only to water produced from Federal and Indian leases and not water produced on State and private lands and disposed of on Federal/Indian lands. The latter cases are strictly right-of-way issues.

III.B.1. Comments were received concerning the first sentence of this subsection and the reference to "* * * committed leases if in a unit or communitized area, * * *." Subsection I.C. Scope has been modified in this final rule to make it clear that the scope of this Order is disposal of produced water from completed wells of Federal and Indian oil and gas leases. The words "Federal/Indian" will be inserted after "committed" to make this subsection consistent with the defined scope.

B.2. Several comments concerned inconsistencies related to right-of-way and disposal facility authorizations. This subsection has been amended to consolidate and clarify the information concerning procedures for rights-of-way contained in B.2.a.1 and B.2.a.2 of the proposed Order. The revisions are included in subsection B. under B.2.a.iii and B.2.b.iii.

B.2.a.1. and B.2.a.2. Two comments suggested that the phrase in B.2.a.1 and B.2.a.2. "* * * authorization from the Bureau of Land Management for disposing of the water * * *" include the term "right-of-way" before the word "authorization." These sentences refer to Title V of FLPMA and 43 CFR part 2800 which is sufficient to make it clear that the disposals referred to are those made under right-of-way authority. No change is made in the final rule except as noted in the previous paragraph.

B.2.a., B.2.b. and B.3. (renumbered B.2.a., B.2.b., and B.2.b.iii.). One comment pointed out that authorization under a right-of-way could be required

for transportation even if surface disturbance would not occur. The BLM agrees and the references to surface disturbances have been removed.

B.2. and B.3. (renumbered as B.2. and B.2.b.iii.). One comment stated that it should be the responsibility of the operator generating the produced water to obtain necessary road and pipeline right-of-ways. The Order states "* * * or other responsible party." This provides flexibility for several situations.

III.B.2.b.1. and B.2.b.2. (renumbered B.2.b.i. and ii.). Some comments objected to the statement in B.2.b.1. that the permits "will be accepted by the authorized officer and approval will be granted for removal of the produced water unless the authorized officer states in writing that such approval will have adverse effects on the Federal/Indian lands or public health and safety." The authorized officer does have the authority and obligation to deny removal of produced water under such conditions. The key word in this sentence is "removal". The BLM is not suggesting approval/disapproval authority for such facilities but does maintain approval/disapproval authority for removal of produced water. In conjunction with other comments on this section and specifically on the last sentence of B.2.b.2., the sentence is revised to read: "If such a permit is not issued by the State or other regulatory agency, the requested removal of the produced water from leased Federal or Indian lands will be denied."

III.C. Informational Requirements for Injection Wells

One comment recommended that this Order should address the procedures relative to private and State lands. The BLM has issued policy with regard to its authority on wells on communitized or unitized private or State lands (43 CFR part 3161.1). Such authority does not extend to approval of the disposal of produced water.

One comment stated that the Order is unclear as to right-of-way requirements for off-lease disposal wells on public lands and procedures to be followed by third parties operating such facilities. These elements are appropriately addressed in the right-of-way regulations (43 CFR part 2800) and are beyond the scope of this Order.

One comment stated that the Order fails to require certain data on environmental impacts that had been required under NTL–2B, and argued that the BLM therefore cannot properly document its actions under NEPA. Information and data to support EPA or State approval under the UIC program are the responsibility of those agencies, and compliance with NEPA in connection with such approvals is no longer under the BLM's jurisdiction. Portions of the program outside of the scope of the UIC program are analyzed through Order No. 1 and NEPA is applied through that Order for those portions.

III.D. Informational Requirements for Pits

Several comments stated that the sentence concerning water analysis samples being taken at the discharge point was vague because the proposed discharge point may be different from the existing discharge point at the time an application was being considered. Since this is a point source sampling procedure, the word "current" was added before "discharge point."

Several respondents argued that it is unnecessary to include a reclamation plan at the time of application for a permit to dispose of produced water. Reclamation plans are more appropriate when a location or pit is being abandoned. The requirement was changed to require reclamation plans to be submitted prior to pit abandonment.

Another comment suggested that the reclamation plan should include plans for disposal of any precipitated or collected solids. As noted above, the requirement that a reclamation plan be submitted was changed to "prior to pit abandonment." If, at that time, precipitated or collected solids are a problem, the authorized officer may require them to be disposed of properly.

One respondent stated that this section was unclear as to who would take water samples, when, and how often. Normally only one sampling is required unless there is an indication of a major change in water quality over time. Where approval is based on a NPDES permit, the sampling schedule is determined by and under the jurisdiction of the EPA or State having primacy. Sampling procedures will also be covered for BLM field personnel in the Manual.

One comment recommended that anticipated emergency situations should be identified with the required content of a contingency plan. These types of conditions are site specific and will be prescribed by the authorized officer when a contingency plan is required.

Under III D.1. Lined Pits, one comment stated that reference to a topographic map would result in too small a scale to show the necessary information. The BLM agrees and has removed the word "topographic."

One comment stated that the informational requirements should apply to pits located off a Federal/Indian lease but on BLM-administered Federal surface. It is BLM policy to accept the requirements established in Onshore Order No. 7 for rights-of-way administration of such pits.

One comment stated that, at a minimum, tests should be carried out for toxic constituents as defined on page 1840 of the proposed rule. This has been addressed in the discussion under "Definitions."

Another comment stated that the authorized officer should receive copies of all other applicable permits including those for disposal of hazardous solid waste. As stated under the section on "Scope," this Order is limited to disposal of produced water from Federal and Indian oil and gas wells. Hazardous solid waste is outside the scope of this Order.

III. D.2. Several respondents urged that NPDES permits should be included in this section. Others stated that pits for NPDES permits should be under the permit authority of the EPA or the primacy State. Section III.G. has been expanded to clarify requirements relative to NPDES permits.

III.D.2.a.(i). Two comments stated that disposal of produced water into unlined pits could, in some circumstances, violate Section 101(a) of the Clean Water Act. They stated that the water going into these pits should be tested for toxic constituents as well as dissolved solids. The criteria applied to unlined pits have been designed to address this type of problem. If the authorized officer has reason to believe that toxic constituents exist in produced water to be disposed of in any pit, a water analysis for those constituents can be required. It is not economically feasible to require expensive analysis for the entire range of toxic chemicals if the authorized officer has no reasonable basis for expecting the presence of these toxins. Protection of surface and groundwater is the primary purpose of this Order. Disposal in unlined pits is only allowed in certain circumstances. The sections on disposal in unlined pits should be read in their entirety for a full understanding of the requirements. Each method of disposal is required to meet all other Federal and State standards. Guidance will be provided for BLM field personnel in the Manual for this Order. This will include the determination of the need for water analysis.

III.D.2.a.ii. Several comments expressed concerns about the term "beneficial use." Some felt it meant the same as beneficial use as identified in

State water quality standards. It does not. The water described as intended for beneficial use is not discharged into a stream. It should not be confused with the requirements of a NPDES permit. One purpose of the standards of the Order is to prevent degradation of existing fresh and usable aquifers and surface water from historical water quality standards (where this information is available), in compliance with the intent of Section 101(a) of the Clean Water Act.

Two comments stated that paragraph III.D.2.a.iii. was confusing and unclear. This part addresses the non-degradation of surface or subsurface waters in the area. It has been reorganized without changing its substance in order to clarify the meaning.

One comment outlined conditions under which paragraph III.D.2.a.iv., which would allow discharge of less than five barrels per day into an unlined pit, would not be acceptable, given the need to protect aquifers. The BLM agrees with the concerns expressed. Where shallow fresh water aquifers exist, they should be protected. A lined pit may be necessary in this type of situation. The authorized officer should consider existing conditions and act accordingly.

Paragraph III.D.2.b.i.(B) requires information on the daily quantity of water to be disposed of and a water analysis. One comment suggested that this should be required of facilities applying under paragraph III.D.2.a.iv. that do not exceed an average production of five barrels of produced water per day on a monthly basis. This suggestion was not adopted in the final rule and Order. The Order does not prohibit a water analysis, and the authorized officer can request one for this type of facility if it is necessary.

One comment recommended a change in the second sentence of paragraph III.D.2.b.i.(D), to clarify the term "certifiable percolation test". The BLM agrees that the language in the proposed rule was confusing, and the sentence has been changed to read, "In some cases the authorized officer may require percolation tests using accepted test procedures."

Another clarification recommended and accepted was in paragraph III.D.2.b.i.(E) of the proposed Order. The word "known" was added between "shallowest" and "aquifer" in order to enhance practicability. Order No. 1 requires the testing of all fresh water zones encountered while drilling, which will provide the information necessary for this requirement.

Paragraphs III.D.2.b.iii. (A) and (B) both address requirements in terms of a 2-mile radius. Several comments stated that this was an excessive distance. The requirements in Onshore Oil and Gas Order No. 1 call for a 1-mile radius. The distance requirements for this Order have been changed to 1 mile for consistency with Order No. 1.

One comment stated that paragraph III.D.2.b.iii.(C) was overly vague. The intent of the requirements of this standard is to leave the burden of proof up to the operator to show there will be no adverse effects on existing water quality. There is no need to change this provision for clarity.

Several comments were received seeking clarification as to the scope of section III.D.3. The section was restructured and limited to emergency pits for overall clarification. The temporary use of reserve pits has been moved to the Section III.A. General Requirements.

A suggestion to add the words "and fluids" after "produced water" in the second sentence of section III.D.3, which discusses reserve pits, was considered but rejected. This Order is concerned only with produced water. Other fluids are addressed in Orders Nos. 1 and 2 regarding drilling operations.

One comment stated that the Order should require any disposal of produced water into a reserve pit to be covered by a contingency plan. Order No. 1 does not require a contingency plan for construction and use of a reserve pit. If extenuating circumstances call for a contingency plan, the authorized officer can require one under 43 CFR 3162.5. The need for a contingency plan would be dependent on whether or not there were any surface or subsurface waters or other resources to be protected.

Another general comment concerned the use of bentonite or clay as liners for disposal pits. The experiences of the correspondent with bentonite-lined pits were described as unsatisfactory. We agree with the view that bentonite is unsatisfactory when the produced water contains high salt content. It is well known that potassium chloride is added to drilling fluid to prevent swelling when drilling through bentonite. Bentonite liners are effective under certain conditions other than those with high salt content.

Another comment urged that neither lined nor unlined pits should be allowed for temporary or emergency use. The correspondent wanted such uses restricted to metal containers. In some circumstances the use of tanks may be necessary or even preferred. However, the Order should remain sufficiently flexible to permit the use of pits in circumstances where they would be appropriate. The comment is not adopted in the final rule.

Two comments argued that reference to NTL–3A was inappropriate. They wanted the BLM to require a 48-hour notification on emergency pit use and to allow up to 7 days for disposal of the contents. The comment was not adopted in the final rule. The reference to NTL–3A is merely to provide guidance on how to report undesirable events. It requires an oral notification of major undesirable events within 24 hours, followed by a full written report within 15 days. The notice also provides for tracking volumes lost and recovered. We believe that 48 hours is a reasonable time within which to empty pits upon conclusion of an emergency. However, under this section the authorized officer can extend the 48 hours based on field conditions, if requested.

One comment asked why emergency pits were a part of Order No. 7, and stated that they could be authorized under the Application for Permit to Drill (APD) process. If the type of pit for disposal of produced water is known or anticipated, the construction of such pits can be requested in the APD. The requirements for construction and use of those pits remain in Onshore Order No. 7.

Two comments stated that there was some confusion as to the process of permitting a pit under the emergency use category and the use of the pit without some other approval. The suggestion was to change the wording to make it clearer. The suggestion was accepted and the first sentence now begins: "Application for a permanent pit (lined or unlined) to be used for anticipated emergency purposes * * *."

Another comment stated that construction of an emergency pit normally would have to be done instantly in order to contain a sudden fluid flow, and suggested that the Order should provide for verbal approval to be given. The suggestion is not adopted in the final rule. As stated above, an emergency pit is a permanent pit to be used for anticipated emergency purposes. This would not be the same as necessary stop-gap construction measures to prevent or limit damage from an accident. Such temporary measures as were described in the comment would require immediate restoration as determined by the authorized officer.

One comment said the last sentence in the first paragraph should have the word "written" added between "requires" and "approval." Any extension of time, even if verbal, must

be documented, and the Order has been amended to make this clear.

One comment stated that blow-down/flare pits should have been covered under section III.D.3. Routine or regular use of a pit does not qualify for use as an emergency pit. Such use may qualify under the category of unlined pit for operations producing water at a rate of no more than five barrels per day per disposal facility.

Section E Design Requirements

General Comments

There were two comments suggesting that the design requirements of this section should not apply to drilling and workover pits. This is true. Any requirements for pits approved in conjunction with drilling or workover of wells will be addressed at the time of approval of these types of operations.

One comment requested that pits approved under a NPDES permit be exempt from paragraphs III.E.1.d. and e., as are pits approved under criterion III.D.2.a.iv Another comment argued that no pits should be exempt from any of the design requirements set forth in this section, and a third comment suggested that emergency pits be exempt from all of the design requirements. None of these suggestions has been adopted in the final rule for the following reasons:

1. Pits used in conjunction with NPDES permitted discharges are used to skim the oil off the water in order to condition the water for discharge in accordance with the approved NPDES permit. Generally, these types of pits are of large size and handle a large volume of liquids. For these reasons, the pits should be constructed to meet all the design standards in order to prevent spills due to erosion or any other type of pit failure.

2. Pits approved under criterion III.D.2.a.iv. are exempt from the requirements of paragraphs III.E.1.d. and e., because the volume of water that goes into these types of pits is so small that, in the majority of cases, there is no accumulation of fluid in the pit due to evaporation or percolation. Also the authorized officer may, when circumstances require, modify or condition the approval of these types of pits to include any other requirements or stipulations, under section A. General Requirements.

3. Emergency pits cannot be exempt from the requirement of section E. These pits are constructed to contain all liquids, whether oil or water, during emergency situations involving, in some cases, large volumes. Therefore, these pits have to be constructed to the design standards for safe containment of these liquids.

III.E.1.b. Two comments suggested that this subsection should not apply to pits approved under criterion III.D.2.a.iv. Although the volume of water going into pits approved under criterion III.D.2.a.iv. is small, and in most cases there is no accumulation of fluids in the pits, there are periods when evaporation rates are low and precipitation is high. The pits need to be designed using this standard to prevent overflow during these periods.

Several comments discussed the requirement that the pit be equipped to deter entry by birds. The comments suggested that the standard was too vague and requested that it specify a minimum pit size to require such deterrence. This suggestion is not adopted because there are different types of devices now in use to deter entry by birds, two examples of which are netting material and flags. No minimum size is specified: birds may be attracted by any body of water, regardless of the size of the pit containing it, and be killed or injured by contaminants. The only requirement the BLM will impose is that whatever material or device is used, it must serve its intended purpose.

One comment suggested that the fencing requirement be limited to the use of stock tight fence. The fencing requirements vary throughout the country, depending on the kind of livestock or wildlife deterrence to be accomplished. Accordingly, the requirement is best left to the operator and the authorized officer to work out at the time the application for pit approval is received. The comment is not adopted.

One comment suggested that emergency pits should be exempt from this subsection. Although emergency pits have to be emptied within 48 hours following their use, the deterrence of entry by birds, livestock, and wildlife during the emergency is still necessary; therefore, this suggestion is not adopted.

III.E.1.d. A comment concerning the slope of the pits suggested showing the ratios as the vertical rise to the horizontal distance, thus describing the inside grade of the levee as no steeper than 1:2 and the outside grade no steeper than 1:3. This suggestion is adopted, and the Order reflects the change.

One comment requested that the pit wall and levee grade requirements be relaxed to allow the use of levees at the natural angle of repose. The construction of levees at the natural angle of repose can be approved by requesting a variance from the authorized officer if the operator can furnish soil test information that would justify the use of steeper grades without compromising the integrity of the pit.

III.E.1.e. There were two comments concerning the levee width at the top. One suggested that the top width be limited to 6 inches, while the other wanted the top to be no less than 10 feet wide. Neither of the comments was accepted because the BLM considers 18 inches to be the minimum top width necessary to enable a person to safely stand on the levee and take a sample of the fluid, if needed, and yet sufficient to prevent failure as long as the pit is maintained to the design standards.

III.E.2. Several comments were received on this section concerning the types of materials used in the construction of lined pits. The comments requested that the Order specify the minimum thickness, burst, break, or tear strength, in pounds per square inch, of the materials to be used in the construction of the pits. It is not the intent of this Order to specify the type of liner or set the minimum strength for the materials used. The requirement imposed by the final Order remains that the installation be done according to the manufacturer's specifications. In all cases, the BLM will require that lined pits contain leak detection systems. If a pit fails and leaks are detected, the pit will be required to be emptied of its contents and repaired prior to any further use.

III.F. Construction and Maintenance

One comment expressed a concern that the title "Construction and Maintenance" was inappropriate and should be changed to "Incidences of Noncompliance." Although this section does address violations, corrective actions, and abatement periods, it is primarily a compilation of the BLM's standards for construction and maintenance of pits. The suggestion was rejected.

F.1. One comment requested that the language in III F.1. "whether existing prior to or after the effective date of this Order" be stricken from the Order as unnecessary. This suggestion was adopted and the phrase has been deleted accordingly.

F.3. One respondent suggested that, if a liner is installed and then covered with material (i.e., sand, gravel, etc.) to protect the liner, the authorized officer should be notified prior to the covering. It is not necessary to address this matter in the final Order, because its occurrence would be rare. It will be handled in the Manual Handbook and can be considered as a condition of approval when needed.

One comment stated that failure to notify under section III.F.3. should be a major violation. Another comment stated that section III.F.3. should apply only to lined pits. The intent of this standard is to apply to both lined and unlined pits. The purpose of the requirement is to verify whether pits were constructed in accordance with the approved plan. As the consequence of failure to notify is determined by the degree of failure to comply with the approved plan, the violation for failure to notify the authorized officer is considered minor. However, the violation for failure to comply with the approved plan may be minor or major. If, as a result of substandard construction, the pit is causing or threatening immediate, substantial, and adverse impacts on public health, safety, or the environment, then the violation would be major by definition. The violation, corrective action, and abatement period provisions of section III.F.3. for failure to construct in accordance with the approved plan have been rewritten to clarify the matter.

F.5. One comment suggested that requirement III.F.5. appears contradictory in stating that a pit should be designed to prevent entrance of surface water by providing surface drainage. The requirement has been rewritten for clarification as follows. "The pit shall be maintained as designed to prevent entrance of surface water by providing adequate surface drainage away from the pit."

F.8. Many comments stated that the requirement in III.F.8. "that the pit shall be kept reasonably free from surface accumulations of liquid hydrocarbons" was ambiguous and in need of clarification. It is extremely difficult to specify that a pit must be kept free of hydrocarbons over a certain percent of the surface, during a particular season, or that the oil may be allowed to accumulate to a certain thickness. As is the practice under NTL–2B, the authorized officer must use experience and judgment to determine whether the amount of oil in a pit is out of compliance. He or she will weigh the requirement against the intent of the approval, the nature and type of pit, seasonal factors, and environmental sensitivity.

F.9. Several respondents stated that the 30-day operator self-inspection requirement in III.F.9. was too frequent. Other respondents stated it was too infrequent and suggested 7 days. The requirement remains as written. The 30-day period was chosen because it is within the range of inspection requirements imposed by other Orders and is a reasonable period of time.

III.G. Other Disposal Methods

One comment stated that the authorized officer may allow surface discharges in violation of effluent guidelines. Any surface discharge would either be under a NPDES permit or otherwise meet the requirements of State and Federal laws and regulations. Coordination with the EPA or the primacy State would be necessary.

In response to several comments on the 3 methods of disposal mentioned in III.A., and one comment urging the BLM to allow use of new technology, final III.G. now contains 3 subcategories. Additional guidance has been provided as to disposal under an NPDES permit.

One respondent asked whether a buried tank should meet all the requirements applied to a lined pit. A buried tank used in lieu of a lined pit is considered a lined pit and therefore should meet all applicable standards of this Order. The leak detection requirements for buried tanks could be met by a monitoring well system depending on an analysis of the subsurface conditions by the authorized officer.

III.H. Reporting Requirements for Disposal Facilities

One comment suggested that the annual report for well and/or surface water facilities should be required to track water quantity and quality. Such reports were required under NTL–2B but have been deleted from this Order because they created burdensome paperwork that was of limited usefulness to the authorized officer. The BLM now places the responsibility on the operator to amend the pit design when changes in quantity and/or quality of water cause the pit no longer to meet the unlined pit criteria.

IV. Variances From Requirements or Minimum Standards

One comment stated that Indian Tribes may obtain primacy for UIC programs, and therefore that Tribal authority should be included in the last sentence. The comment was correct and a reference to the Tribal authority has been made in the final Order.

Comments were received from two entities stating that the Order should allow the authorized officer orally to approve variances from minimum standards under unusual or emergency situations. The intent of this section of the Order is to accommodate special situations where an alternative means may meet or exceed the objectives. Temporary deviation from standards under an emergency situation may be granted orally by the authorized officer followed by written confirmation. Such temporary deviation is not considered as a variance under this section. Any variance must be pre-approved in writing.

Two comments expressed concern that the authorized officer has too much latitude in granting variances and suggested developing criteria or guidance for the authorized officer. A Manual and Handbook will be prepared for this Order to provide such guidance. One example of such criteria would be that if an applicant proposes to use a 1:2.5 slope for the levee, soil test data supporting the proposed slope shall be presented for approval. The authorized officer will take into account a proper factor of safety in addition to the test data.

Attachments

Two comments recommended that the words "minimum standards" be removed from the titles of Figures 1 through 3. The recommendation was adopted, because the figures were presented as examples of what could be acceptable under the standards established in this Order.

With respect to Figures 4 and 5, one respondent expressed a preference for the vertical riser over the sloped riser and the location of the riser to be on the transverse centerline of the pit, rather than at the end of the pit as indicated. The BLM agrees with the view expressed and affirms that the suggested location of the riser is equally acceptable.

In response to a comment that a low riser shown in Figure 5 may cause surface discharge if leakage occurs, the example now shows the riser to be even with the top of the levee.

Editorial corrections have been made as necessary.

The principal authors of this final rule are Sie Ling Chiang, Chief, Division of Minerals Policy Analysis and Economic Evaluation, Washington Office, Jamie Sparger, Vernal District Office, Utah; Armando Lopez, Roswell District Office, New Mexico; T.R. Beaven, Wyoming State Office; and Bob Schooler, Jackson District Office, Mississippi, assisted by the staff of the Division of Legislation and Regulatory Management, BLM.

It is hereby determined that this proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment, and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)) is required. The BLM has determined that this proposed rule is categorically excluded from further environmental

review pursuant to 516 Departmental Manual (DM), Chapter 2, Appendix 1, Item 1.10, and that the proposal would not significantly affect the 10 criteria for exceptions listed in 516 DM 2, Appendix 2. Pursuant to the Council on Environmental Quality regulations (40 CFR 1508.4) and environmental policies and procedures of the Department of the Interior, "categorical exclusions" means a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency and for which neither an environmental assessment nor an environmental impact statement is required.

The Department of the Interior has determined under Executive Order 12291 that this document is not a major rule. A major rule is any regulation that is likely to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This order does not establish new requirements and therefore will not cause an increase in costs or prices. Reporting requirements have been reduced, which will ease the burden on industry. Further, for the same reasons, the Department has determined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that it will not have a significant economic impact on a substantial number of small entities.

The Department certifies that this proposed rule does not represent a governmental action capable of interference with constitutionally protected property rights. No private property would be taken as a result of this rule, and no lawful activity would be impaired on private property. Therefore, as required by Executive Order 12630, the Department of the Interior has determined that the rule would not cause a taking of private property.

The information collection requirements contained in this rule have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1004–0135.

List of Subjects in 43 CFR Part 3160

Government contracts, Indian lands-mineral resources, Mineral royalties, Oil and gas exploration, Penalties, Public lands-mineral resources, Reporting and recordkeeping requirements.

For the reasons cited in the Preamble, and under the authorities cited below, part 3160, group 3100, subchapter C, chapter II of title 43 of the Code of Federal Regulations is amended as set forth below:

Dated: July 16, 1993.

Bob Armstrong,

Assistant Secretary of the Interior.

PART 3160—[AMENDED]

1. The authority citation for part 3160 is revised to read:

Authority: 43 U.S.C. 1733; 30 U.S.C. 181 *et seq.*; 30 U.S.C. 351–359; 30 U.S.C. 301–306; 25 U.S.C. 396; 25 U.S.C. 396a-396q, 397, 398, 398a-398e, 399; 43 U.S.C. 1457; see also 40 Op. Atty. Gen. 41; 40 U.S.C. 471 *et seq.*; 42 U.S.C. 4321 *et seq.*; 43 U.S.C. 6508; 30 U.S.C. 1701 *et seq.*; and 25 U.S.C. 2101 *et seq.*

2. Section 3164.1(b) is amended by revising the table to read as follows:

§ 3164.1 Onshore Oil and Gas Orders.

* * * * *

(b) * * *

Order No.	Subject	Effective date	FEDERAL REGISTER reference	Supersedes
1.	Approval of operations	Nov. 21, 1983	48 FR 48916 and 48 FR 56226.	NTL–6.
2.	Drilling	Dec. 19, 1988	53 FR 46790	None.
3.	Site security	Mar. 27, 1989	54 FR 8056	NTL–7.
4.	Measurement of oil	Aug. 23, 1989	54 FR 8086	None.
5.	Measurement of gas	Mar. 27, 1989, new facilities greater than 200 MCF production; Aug. 23, 1989, existing facility greater than 200 MCF production; Feb. 26, 1990, existing facility less than 200 MCF production.	54 FR 8100	None.
6.	Hydrogen sulfide operations	Jan. 22, 1991	56 FR 48968	None.
7.	Disposal of produced water	October 8, 1993	NTL–2B.	

Note: Numbers to be assigned sequentially by the Washington Office as proposed Orders are prepared for publication.

The Appendix—Text of Oil and Gas Order reads as follows:

Appendix—Text of Oil and Gas Order

Note: This appendix will not appear in the Code of Federal Regulations.

Onshore Oil and Gas Order No. 7

Disposal of Produced Water

I. Introduction.
A. Authority.
B. Purpose.
C. Scope.
II. Definitions.
III. Requirements.
A. General Requirements.
B. Application and Approval Authority.
C. Informational Requirements for Injection Wells.
D. Informational Requirements for Pits.
E. Design Requirements for Pits.
F. Construction and Maintenance Requirements for Pits.
G. Other Disposal Methods.
H. Reporting Requirements for Disposal Facilities.
IV. Variances from Requirements or Minimum Standards.
Attachment.
I. Figures.

Onshore Oil and Gas Order No. 7

Disposal of Produced Water

I. Introduction

A. *Authority.* This Order is established pursuant to the authority granted to the Secretary of the Interior by various Federal and Indian mineral leasing statutes and the Federal Oil and Gas Royalty Management Act of 1982. Said authority has been delegated to the Bureau of Land Management and is implemented by the onshore oil and gas operating regulations contained in 43 CFR part 3160. Section 3164.1 thereof specifically authorizes the Director to issue Onshore Oil and Gas Orders when necessary to implement or supplement the operating regulations and provides that all such Orders shall be binding on the operators of Federal and restricted Indian oil and gas leases which have been, or may hereafter, be issued.

As directed by the Federal Onshore Oil and Gas Leasing Reform Act of 1987, for National Forest lands the Secretary of Agriculture shall regulate all surface-disturbing activities and shall determine reclamation and other

actions required in the interest of conservation of surface resources. Specific authority for the provisions contained in this Order is found at section 3162.3, Conduct of Operations; section 3162.5, Environment and Safety; and Subpart 3163, Noncompliance and Assessments.

B. *Purpose.* This Order supersedes Notice to Lessees and Operators of Federal and Indian Oil and Gas Leases (NTL–2B), Disposal of Produced Water. The purpose of this Order is to specify informational and procedural requirements for submittal of an application for the disposal of produced water, and the design, construction and maintenance requirements for pits as well as the minimum standards necessary to satisfy the requirements and procedures for seeking a variance from the minimum standards. Also set forth in this Order are certain specific acts of noncompliance, corrective actions required and the abatement period allowed for correction.

C. *Scope.* This Order is applicable to disposal of produced water from completed wells on Federal and Indian (except Osage) oil and gas leases. It does not apply to approval of disposal facilities on non-Federal leases. Separate approval under this Order is not required if the method of disposal has been covered under an enhanced recovery project approved by the authorized officer.

II. Definitions

The following definitions are used in conjunction with the issuance of this Order.

A. *Authorized officer* means any employee of the Bureau of Land Management authorized to perform duties described in 43 CFR Groups 3000 and 3100.

B. *Federal lands* means all lands and interests in lands owned by the United States which are subject to the mineral leasing laws, including mineral resources or mineral estates reserved to the United States in the conveyance of a surface or nonmineral estate.

C. *Free-board* means the vertical distance from the top of the fluid surface to the lowest point on the top of the dike surrounding the pit.

D. *Injection well* means a well used for the disposal of produced water or for enhanced recovery operations.

E. *Lease* means any contract, profit share arrangement, joint venture, or other agreement issued or approved by the United States under a mineral leasing law that authorized exploration for, extraction of, or removal of oil or gas (see 43 CFR 3160.0–5).

F. *Lessee* means a person or entity holding record title in a lease issued by the United States (see 43 CFR 3160.0–5).

G. *Lined pit* means an excavated and/or bermed area that is required to be lined with natural or manmade material that will prevent seepage. Such pit shall also include a leak detection system.

H. *Unlined pit* means an excavated and/or bermed area that is not required to be lined, or any pit that is lined but does not contain a leak detection system.

I. *Major violation* means noncompliance that causes or threatens immediate, substantial, and adverse impacts on public health and safety, the environment, production accountability, or royalty income (see 43 CFR 3160.0–5).

J. *Minor violation* means noncompliance that does not rise to the level of a "major violation" (see 43 CFR 3160.0–5).

K. *National Pollutant Discharge Elimination System (NPDES)* means a program administered by the Environmental Protection Agency or primacy State that requires permits for the discharge of pollutants from any point source into navigable waters of the United States.

L. *Operator* means any person or entity, including but not limited to the lessee or operating rights owner, who has stated in writing to the authorized officer that it is responsible under the terms and conditions of the lease for the operations conducted on the leased lands or a portion thereof (see 43 CFR 3610.0–5).

M. *Produced water* means water produced in conjunction with oil and gas production.

N. *Toxic constituents* means substances in produced water that when found in toxic concentration have harmful effects in plant or animal life. These substances include but are not limited to arsenic (As), barium (Ba), cadmium (Cd), hexavalent chromium (hCr), total chromium (tCr), lead (Pb), mercury (Hg), zinc (Zn), selenium (Se), benzene, toluene, ethylbenzene, and xylenes, as defined in 40 CFR 116.

O. *Underground Injection Control (UIC)* program means a program administered by the EPA, primacy State, or Indian Tribe under the Safe Drinking Water Act to ensure that subsurface waste injection does not endanger underground sources of drinking water.

III. Requirements

A. *General Requirements*

Operators of onshore Federal and Indian oil and gas leases shall comply with the requirements and standards of this Order for the protection of surface and subsurface resources. Except as provided under section III.D.3 of this Order, the operator may not dispose of produced water unless and until approval is obtained from the authorized officer. All produced water from Federal/Indian leases must be disposed of by (1) injection into the subsurface; (2) discharging into pits; or (3) other acceptable methods approved by the authorized officer, including surface discharge under NPDES permit. Injection is generally the preferred method of disposal. Operators are encouraged to contact the appropriate authorized officer before filing an application for disposal of produced water so that the operator may be apprised of any existing agreements outlining cooperative procedures between the Bureau of Land Management and either the State/Indian Tribe or the Environmental Protection Agency concerning Underground Injection Control permits for injection wells, and of any potentially significant adverse effects on surface and/or subsurface resources. The approval of the Environmental Protection Agency or a State/Tribe shall not be considered as granting approval to dispose of produced water from leased Federal or Indian lands until and unless BLM approval is obtained. Applications filed pursuant to NTL–2B and still pending approval shall be supplemented or resubmitted if they do not meet the requirements and standards of this Order. The disposal methods shall be approved in writing by the authorized officer regardless of the physical location of the disposal facility. Existing NTL–2B approvals will remain valid. However, upon written justification, the authorized officer may impose additional conditions or revoke any previously approved disposal permit, if the authorized officer, for example, finds that an existing facility is creating environmental problems, or that an unlined pit should be lined, because the quality of the produced water has changed so that it no longer meets the standards for unlined pits.

Unless prohibited by the authorized officer, produced water from newly completed wells may be temporarily disposed of into reserve pits for a period of up to 90 days, if the use of the pit was approved as a part of an application for permit to drill. Any extension of time beyond this period requires documented approval by the authorized officer.

Upon receipt of a completed application the authorized officer shall take one of the following actions within 30 days: (1) Approve the application as submitted or with appropriate modification or conditions; (2) return the application and advise the applicant in writing of the reasons for disapproval; or (3) advise the applicant in writing of the reasons for delay and the expected final action date.

If the approval for a disposal facility, e.g., commercial pit or Class II injection well, is revoked or suspended by the permitting agencies such as the Environmental Protection Agency or the primacy State, the BLM water disposal approval is immediately terminated and the operator is required to propose an alternative disposal method.

B. *Application and Approval Authority*

1. *On-lease Disposal.* For water produced from a Federal/Indian lease and disposed of on the same Federal/Indian lease, or on other committed Federal/Indian leases if in a unit or communitized area, the approval of the disposal method is usually granted in conjunction with the approval for the disposal facilities. An example would be the approval of a proposal to drill an injection well to be used for the disposal of produced water from a well or wells on the same lease.

a. *Disposal of water in injection wells.* When approval is requested for onlease disposal of produced water into an injection well, the operator shall submit a Sundry Notice, Form 3160–5. Information submitted in support of obtaining the Underground Injection Control permit shall be accepted by the authorized officer in approving the disposal method, provided the information submitted in support of obtaining such a permit satisfies all applicable Bureau of Land Management statutory responsibilities (including but not limited to drilling safety, down hole integrity, and protection of mineral and surface resources) and requirements. If the authorized officer has on file a copy of the approval for the receiving facilities, he/she may determine that a reference to that document is sufficient.

b. *Disposal of water in pits.* When approval is requested for disposal of produced water in a lined or unlined pit, the operator shall submit a Sundry Notice, Form 3160–5. The

operator shall comply with all the applicable Bureau of Land Management requirements and standards for pits established in this Order. On National Forest lands, where the proposed pit location creates new surface disturbance, the authorized officer shall not approve the proposal without Forest Service concurrence.

2. *Off-lease Disposal*

a. *On leased or unleased Federal/Indian lands.* The purpose of the off-lease disposal approval process is to ensure that the removal of the produced water from a Federal or Indian oil and gas lease is proper and that the water is disposed of in an authorized facility. Therefore, the operator shall submit a Sundry Notice, Form 3160–5, for removal of the water together with a copy of the authorization for the disposal facility. If the authorized officer has a copy of the approval for the receiving facilities on file, he/she may determine that a reference to that document is sufficient. Where an associated right-of-way authorization is required, the information for the right-of-way authorization may be incorporated in the Sundry Notice, and the Bureau of Land Management will process both authorizations simultaneously for Bureau lands.

i. *Disposal of water in injection wells.* When approval is requested for removing water that is produced from wells on leased Federal or Indian lands and that is to be injected into a well located on another lease or unleased Federal lands, the operator shall submit to the authorized officer a Sundry Notice, Form 3160–5. along with a copy of the Underground Injection Control permit issued to the operator of the injection well, unless the well is authorized by rule under 40 CFR part 144.

ii. *Disposal of water in pits.* When approval is requested for removing water that is produced from wells on leased Federal or Indian lands and is to be disposed of into a lined or unlined pit located on another lease or unleased Federal lands, the operator shall submit to the authorized officer a Sundry Notice, Form 3160–5.

iii. *Right-of-way procedures.* The operator of the injection well or pit is required to have an authorization from the Bureau of Land Management for disposing of the water into the pit or well, under Title V of FLPMA and 43 CFR Part 2800, or a similar authorization from the responsible surface management agency. In transporting the produced water from the lease to the pit or injection well, e.g., building a road or laying a pipeline, a right-of-way authorization under Title V of FLPMA and 43 CFR Part 2800 from the Bureau of Land Management or a similar permit from the responsible surface management agency also shall be obtained by the operator of the pit or any injection well or other responsible party.

b. *Disposal of water on State and privately-owned lands.*

i. *Disposal of water in injection wells.* When approval is requested for removing water that is produced from wells on leased Federal or Indian lands and that is to be injected into a well located on State or privately-owned lands, the operator shall submit to the authorized officer, in addition to a Sundry Notice, Form 3160–5, a copy of the Underground Injection Control permit issued for the injection well by the Environmental Protection Agency or the State where the State has achieved primacy. Submittal of the Underground Injection Control permit will be accepted by the authorized officer and approval will be granted for the removal of the produced water unless the authorized officer states in writing that such approval will have adverse effects on the Federal/Indian lands or public health and safety.

ii. *Disposal of water in pits.* When approval is requested for removing water that is produced from wells on leased Federal and/or Indian lands and is to be disposed of into a pit located on State or privately-owned lands, the operator shall submit to the authorized officer, in addition to a Sundry Notice, Form 3160–5, a copy of the permit issued for the pit by the State or any other regulatory agency, if required, for disposal in such pit. Submittal of the permit will be accepted by the authorized officer and approval will be granted for removal of the produced water unless the authorized officer states in writing that such approval will have adverse effects on the Federal/Indian lands or public health and safety. If such a permit is not issued by the State or other regulatory agency, the requested removal of the produced water from leased Federal or Indian lands will be denied.

iii. *Right-of-way procedures.* If the water produced from wells on leased Federal and/or Indian lands, and to be disposed of at a location on State or privately-owned lands, will be transported over off-lease Federal or Indian lands, the operator of the disposal facility or other responsible party shall have an authorization from the Bureau of Land Management under Title V of FLPMA and 43 CFR part 2800, or a similar authorization from the responsible surface management agency.

C. *Informational requirements for injection wells.*

For an injection well proposed on Federal or Indian leases, the operator shall obtain an Underground Injection Control (UIC) permit pursuant to 40 CFR parts 144 and 146 from the Environmental Protection Agency or the State/Tribe where the State/Tribe has achieved primacy. The operator shall also comply with the pertinent procedural and informational requirements for Application for Permit to Drill or Sundry Notice as set forth in Onshore Oil and Gas Order No. 1. The injection well shall be designed and drilled or conditioned in accordance with the requirements and standards described in Order No. 2 and pertinent NTLs, as well as the Underground Injection Control permit.

D. *Informational requirements for pits.*

Operators who request approval for disposal of produced water into a lined or unlined pit shall file an application on a Sundry Notice, Form 3160–5, and identify the operator's field representative by name, address and telephone number, and the source of the produced water. Sources of produced water shall be identified by facility, lease number, well number and name, and legal description of well location. A reclamation plan should be included as appropriate. If requested, a contingency plan as prescribed by the authorized officer shall be provided. All samples for water analysis shall be taken at the current discharge point. A reclamation plan detailing the procedures expected to be followed for closure of the pit and the contouring and revegetating of the site shall be submitted prior to pit abandonment. If requested by the authorized officer, a contingency plan to deal with specific anticipated emergency situations shall be submitted as provided for in 43 CFR 3162.5–1(d).

1. *Lined pits.* The authorized officer shall not consider for approval an application for disposal into lined pits on Federal/Indian leases unless the operator also provides the following information:

a. A map and drawings of the site on a suitable scale that show the pit dimension, cross section, side slopes, leak detection system, and location relative to other site facilities.

b. The daily quantity of water to be disposed of (maximum daily quantity shall be cited if major fluctuations are anticipated) and a water analysis (unless waived by the authorized officer as unnecessary) that includes the concentrations of chlorides, sulfates, pH, Total Dissolved Solids (TDS), and toxic constituents that the authorized officer reasonably believes to be present.

c. Criteria used to determine the pit size, which includes a minimum of 2 feet of freeboard.

d. The average monthly evaporation and the average monthly precipitation for the area.

e. The method and schedule for periodic disposal of precipitated solids.

f. The type, thickness, and life span of material to be used for lining the pit and the method of installation. The manufacturer's guidebook and information for the product shall be included, if available.

2. *Unlined pits.*

Application for disposal into unlined pits may be considered for approval by the authorized officer where the application of the operator shows that such disposal meets one or more of the following criteria:

i. The water to be disposed of has an annual average TDS concentration equal to or less than that of the existing water to be protected, provided that the level of any toxic constituents in the produced water does not exceed established State or Federal standards for protection of surface and/or ground water.

ii. All, or a substantial part, of the produced water is being used for beneficial purposes and meets minimum water quality standards for such uses. For example, usage of produced water for purposes such as irrigation and livestock or wildlife watering shall be considered as beneficial.

iii. (A) The water to be disposed of will not degrade the quality of surface or subsurface waters in the area;

(B) The surface and subsurface waters contain TDS above 10,000 ppm, or toxic constituents in high concentrations; or

(C) The surface and subsurface waters are of such poor quality or small quantity as to eliminate any practical use thereof.

iv. That the volume of water to be disposed of per disposal facility does not exceed an

average of 5 barrels per day on a monthly basis.

b. Operators applying for disposal into an unlined pit shall also submit the following information, as appropriate:

(i) Applications for disposal into unlined pits that meet the criteria in a., above, shall include:

(A) A map and drawings of the site on a suitable scale that show the pit dimension, cross section, side slopes, size, and location relative to other site facilities.

(B) The daily quantity of water to be disposed of and a water analysis that includes Total Dissolved Solids (in ppm), pH, oil and grease content, the concentrations of chlorides and sulfates, and other parameters or constituents toxic to animal or plant life as reasonably prescribed by the authorized officer. The applicant should also indicate any effect or interaction of produced water with any water resources present at or near the surface and other known mineral deposits. For applications submitted under criterion a.iv., above, the water quality analysis is not needed unless requested by the authorized officer.

(C) The average monthly evaporation and the average monthly precipitation for the area. For applications submitted under criterion a.iv., average annual data will be acceptable.

(D) The estimated percolation rate based on soil characteristics under and adjacent to the pit. In some cases the authorized officer may require percolation tests using accepted test procedures.

(E) Estimated depth and areal extent of the shallowest known aquifer with TDS less than 10,000 ppm, and the depth and extent of any known mineral deposits in the area.

ii. Where beneficial use (criterion a.ii., above) is the basis for the application, the justification submitted shall also contain written confirmation from the user(s).

iii. If the application is made on the basis that surface and subsurface waters will not be adversely affected by disposal in an unlined pit (criterion a.iii., above), the justification shall also include the following additional information:

(A) Map of the site showing the location of surface waters, water wells, and existing water disposal facilities within 1 mile of the proposed disposal facility.

(B) Average concentration of TDS (in ppm) of all surface and subsurface waters within the 1-mile radius that might be affected by the proposed disposal.

(C) Reasonable geologic and hydrologic evidence that shows the proposed disposal method will not adversely affect existing water quality or major uses of such waters, and identifies the presence of any impermeable barrier(s), as necessary.

(D) A copy of any State order or other authorization granted as a result of a public hearing that is pertinent to the authorized officer's consideration of the application.

3. *Emergency pits*

Application for a permanent pit (lined or unlined) to be used for anticipated emergency purposes shall be submitted by the operator on a Sundry Notice, Form 3160–5, for approval by the authorized officer, unless it has been approved in conjunction with a previously approved operational activity. Design criteria for an emergency pit will be established by the authorized officer on a case by case basis. Any emergency use of such pits shall be reported in accordance with NTL–3A or subsequent replacement Order procedures, and the pit shall be emptied and the liquids disposed of in accordance with applicable State and/or Federal regulations within 48 hours following its use, unless such time is extended by the authorized officer.

E. *Design requirements for pits*

1. Pits shall be designed to meet the following requirements and minimum standards. For unlined pits approved under criterion D.2.a.iv., requirements d. and e., below, do not apply.

a. As much as practical, the pit shall be located on level ground and away from established drainage patterns, including intermittent/ephemeral drainage ways, and unstable ground or depressions in the area.

b. The pit shall have adequate storage capacity for safe containment of all produced water, even in those periods when evaporation rates are at a minimum. The design shall provide for a minimum of 2 feet of free-board.

c. The pit shall be fenced or enclosed to prevent access by livestock, wildlife, and unauthorized personnel. If necessary, the pit shall be equipped to deter entry by birds. Fences shall not be constructed on the levees. Figure 1 shows an example of an acceptable fence design.

d. The pit levees are to be constructed so that the inside grade of the levee is no steeper than 1 (vertical):2 (horizontal), and the outside grade no steeper than 1:3.

e. The top of the levees shall be level and at least 18 inches wide.

f. The pit location shall be reclaimed pursuant to the requirements and standards of the surface management agency. On a split estate (private surface, Federal mineral) a surface owner's release statement or form is acceptable.

2. Lined pits shall be designed to meet the following requirements and minimum standards in addition to those specified above:

a. The material used in lining pits shall be impervious. It shall be resistant to weather, sunlight, hydrocarbons, aqueous acids, alkalies, salt, fungi, or other substances likely to be contained in the produced water.

b. If rigid materials are used, leak-proof expansion joints shall be provided, or the material shall be of sufficient thickness and strength to withstand expansion without cracking, contraction, and settling movements in the underlying earth. Semi-rigid liners such as compacted bentonite or clay may also be used provided that, considering the thickness of the lining material chosen and its degree of permeability, the liner is impervious for the expected period of use. Figure 2 shows examples of acceptable standards for concrete, asphalt, and bentonite/clay liners.

c. If flexible membrane materials are used, they shall have adequate resistance to tears or punctures. Figure 3 gives an example of acceptable standards for installation of the flexible membrane.

d. Lined pits shall have an underlying gravel-filled sump and lateral system or other suitable devices for the detection of leaks. Examples of the acceptable design of the leak detection system are shown in Figure 4 and Figure 5.

3. Failure to design the pit to meet the above requirements and minimum standards will result in disapproval of the proposal or a requirement that it be modified unless a request for variance is approved by the authorized officer.

F. *Construction and maintenance requirements for pits*

Inspections will be conducted according to the following requirements and minimum standards during the construction and operation of the pit. Failure to meet the requirements and standards may result in issuance of an Incident of Noncompliance (INC) for the violation. The gravity of the violation, corrective actions, and the normal abatement period allowed are specified for each of the requirements/standards.

1. Any disposal method that has not been approved shall be considered an incident of noncompliance and may result in the issuance of a shut-in order or assessment of penalties pursuant to 43 CFR part 3163 until an acceptable disposal method is provided and approved by the authorized officer.

Violation: Minor: If it causes no significant environmental damages or effects.

Major: If it causes or threatens immediate, substantial and adverse impacts on public health and safety, the environment, production accountability, or royalty income.

Corrective action: Minor: Submit acceptable application.

Major: Shut-in, take corrective action to repair or replace damages according to instructions of authorized officer.

Abatement periods: Minor: 1 to 20 days or as directed by authorized officer.

Major: Within 10 days.

2. The operator shall notify the authorized officer to inspect the leak detection system at least 2 business days prior to the installation of the pit liner.

Violation: Minor.

Corrective action: Require verification of its installation.

Abatement period: Prior to use of pit.

3. At least 2 business days prior to its use, the operator shall notify the authorized officer of completion of the pit construction, so that the authorized officer may verify that the pit has been constructed in accordance with the approved plan.

For failure to notify:

Violation: Minor.

Corrective action: Not applicable.

For failure to construct in accordance with the approved plan:

Violation: Minor, unless Major by definition.

Corrective action: The authorized officer may shut-in operations and require corrections to comply with the plan or require amendment of the plan.

Abatement period: 1 to 20 days depending on the severity of the violation and the degree of difficulty to correct, if the pit is in use.

4. Lined pit shall be maintained and operated to prevent unauthorized subsurface discharge of water.

Violation: Usually Minor, unless Major as result of discharge.

Corrective action: Repair/replace liner and possibly shut in operations.

Abatement period: 1 to 20 days depending on the onsite situation.

5. The pit shall be maintained as designed to prevent entrance of surface water by providing adequate surface drainage away from the pit.

Violation: Minor.

Corrective action: Provide surface drainage.

Abatement period: Within 20 days.

6. The pit shall be maintained and operated to prevent unauthorized surface discharge of water.

Violation: Usually Minor, unless discharge results in Major.

Corrective action: Clean up if spill occurs, and reduce the water level to maintain the 2 feet of free-board; shut-in operations, if required by authorized officer.

Abatement period: 1 to 20 days depending upon the onsite situation.

7. The outside walls of the pit levee shall be maintained as designed to minimize erosion.

Violation: Minor.

Corrective action: Necessary repair.

Abatement period: Within 20 days.

8. The pit shall be kept reasonably free from surface accumulation of liquid hydrocarbons that would retard evaporation.

Violation: Minor.

Corrective action: Clean-up, and may require skimmer pits, settling tanks, or other suitable equipment.

Abatement period: Within 20 days.

9. The operator shall inspect the leak detection system at least once a month. The record of inspection shall describe the result of the inspection by date and shall be kept and made available to the authorized officer upon request.

Violation: Minor.

Corrective action: Commence the required routine inspection and recordkeeping.

Abatement period: Within 30 days.

10. Prior to pit abandonment and reclamation, the operator shall submit a Sundry Notice for approval by the authorized officer, if not previously approved.

Violation: Minor.

Corrective action: Cease operations and file an application.

Abatement period: Within 10 days.

11. When change in the quantity and/or quality of the water disposed into an unlined pit causes the pit no longer to meet the unlined pit criteria listed under section D.2.a., the operator shall submit a Sundry Notice amending the pit design for approval by the authorized officer.

Violation: Minor unless the resulting damage is Major.

Corrective action: Submit the required amendment; shut-in operations if damage is determined by the authorized officer to be Major.

Abatement period: As specified by the authorized officer.

G. *Other disposal methods*

1. Surface discharge under NPDES permit. The person applying to use this disposal method shall furnish a copy of the NPDES permit issued by the EPA or the primacy State, a current water quality analysis and a Sundry Notice, Form 3160–5, describing site facilities (e.g., retention ponds, skimmer pits and equipment, tanks, and any additional surface disturbance). Operations from the point of origin to the point of discharge are under the jurisdiction of the BLM. Operations from the point of discharge downstream are under the jurisdiction of the EPA or the primacy State.

2. Use of existing commercial pits designed for containment of produced water or tanks in lieu of pits.

3. New technology or any other proposal meeting the objective of this Order that the authorized officer deems acceptable and that meets the requirements of State and Federal laws and regulations.

H. *Reporting requirements for disposal facilities*

All unauthorized discharges or spills from disposal facilities on Federal/Indian leases shall be reported to the authorized officer in accordance with the provisions of NTL–3A or subsequent replacement Order.

Violation: Minor unless resulting damage is major.

Corrective action: Submit the required report.

Abatement period: As specified by the authorized officer.

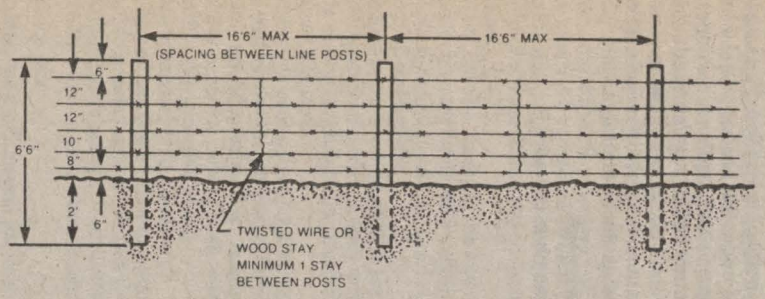
IV. Variances from Requirements or Minimum Standards

An operator may request that the authorized officer approve a variance from any of the requirements or minimum standards prescribed in Section III. of this Order. All such requests shall be submitted in writing to the appropriate authorized officer and provide information as to the circumstances that warrant approval of the variance(s) requested and the proposed alternative means by which the requirements or related minimum standard(s) will be satisfied. The authorized officer, after considering all relevant factors, will approve the requested variance(s) if it is determined that the proposed alternative(s) meet or exceed the objectives of the applicable minimum standard(s); or if the authorized officer determines that the exemption of the requirement is justified. Variances granted by BLM under this section shall be limited to proposals and requirements under BLM statutory and/or regulatory authority only, and shall not be construed as granting variances to regulations under EPA, State, or Tribal or State authority.

Attachments

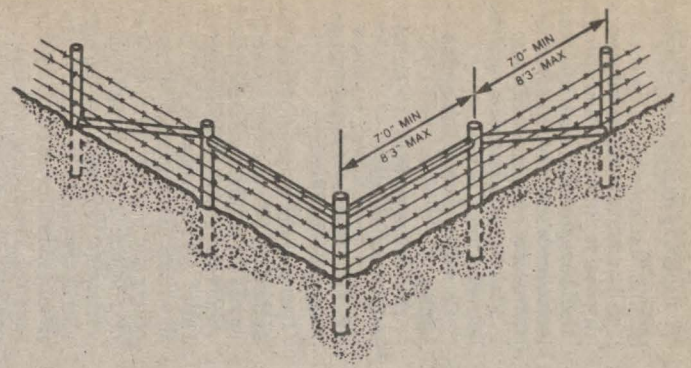
BILLING CODE 4310–84–P

FENCE CONSTRUCTION

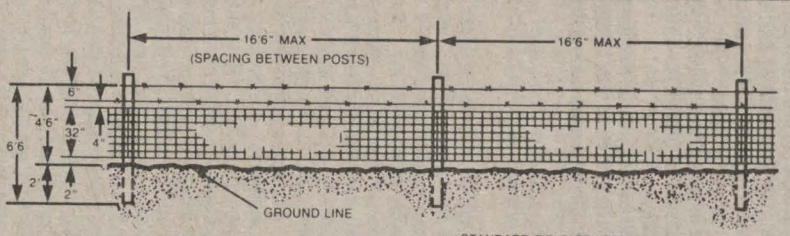


TYPICAL 5-WIRE BARB WIRE FENCE
using wood, pipe or steel "T" type posts

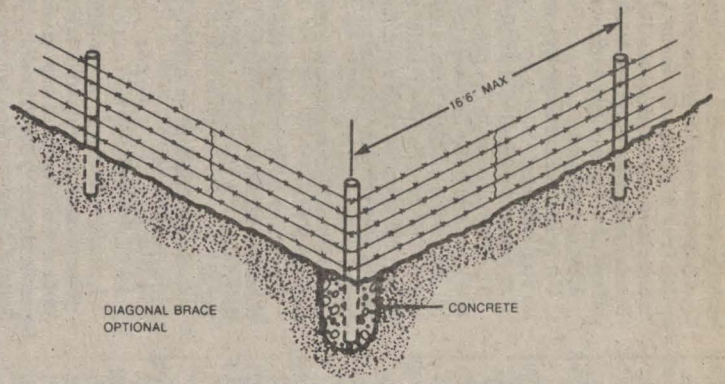
CORNER CONSTRUCTION
(applicable to barbed or net type wire)



TYPICAL CORNER CONSTRUCTION
for buried corner posts



TYPICAL "STOCK TIGHT" FENCE
using wood, pipe or steel "T" type posts



TYPICAL CORNER CONSTRUCTION
for corner post set in concrete

FIGURE 1. EXAMPLES FOR DESIGN AND CONSTRUCTION OF FENCES AND CORNER POSTS.

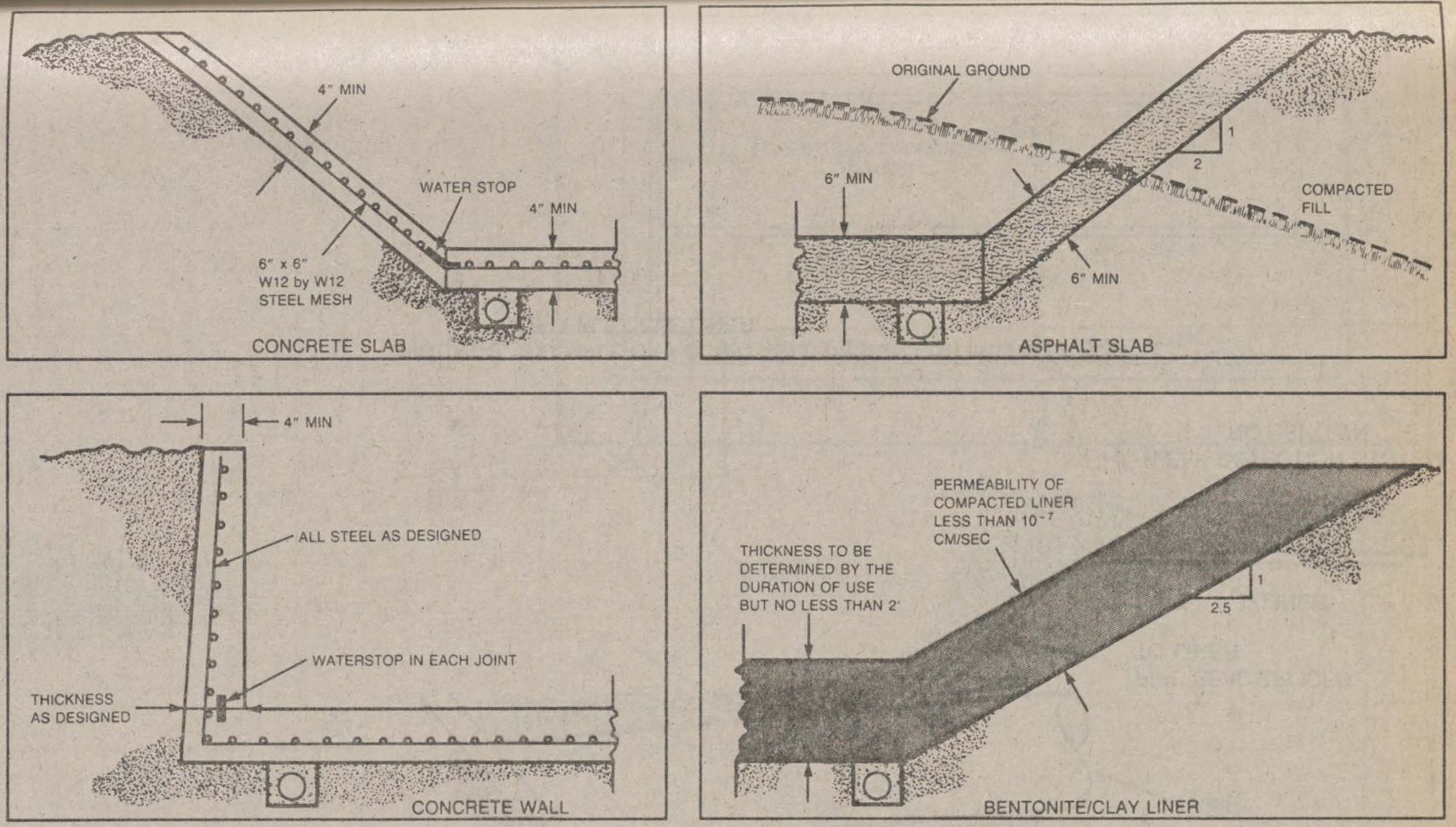


FIGURE 2. EXAMPLE OF ACCEPTABLE DESIGN FOR CONCRETE, ASPHALT AND BENTONITE/CLAY LINERS.

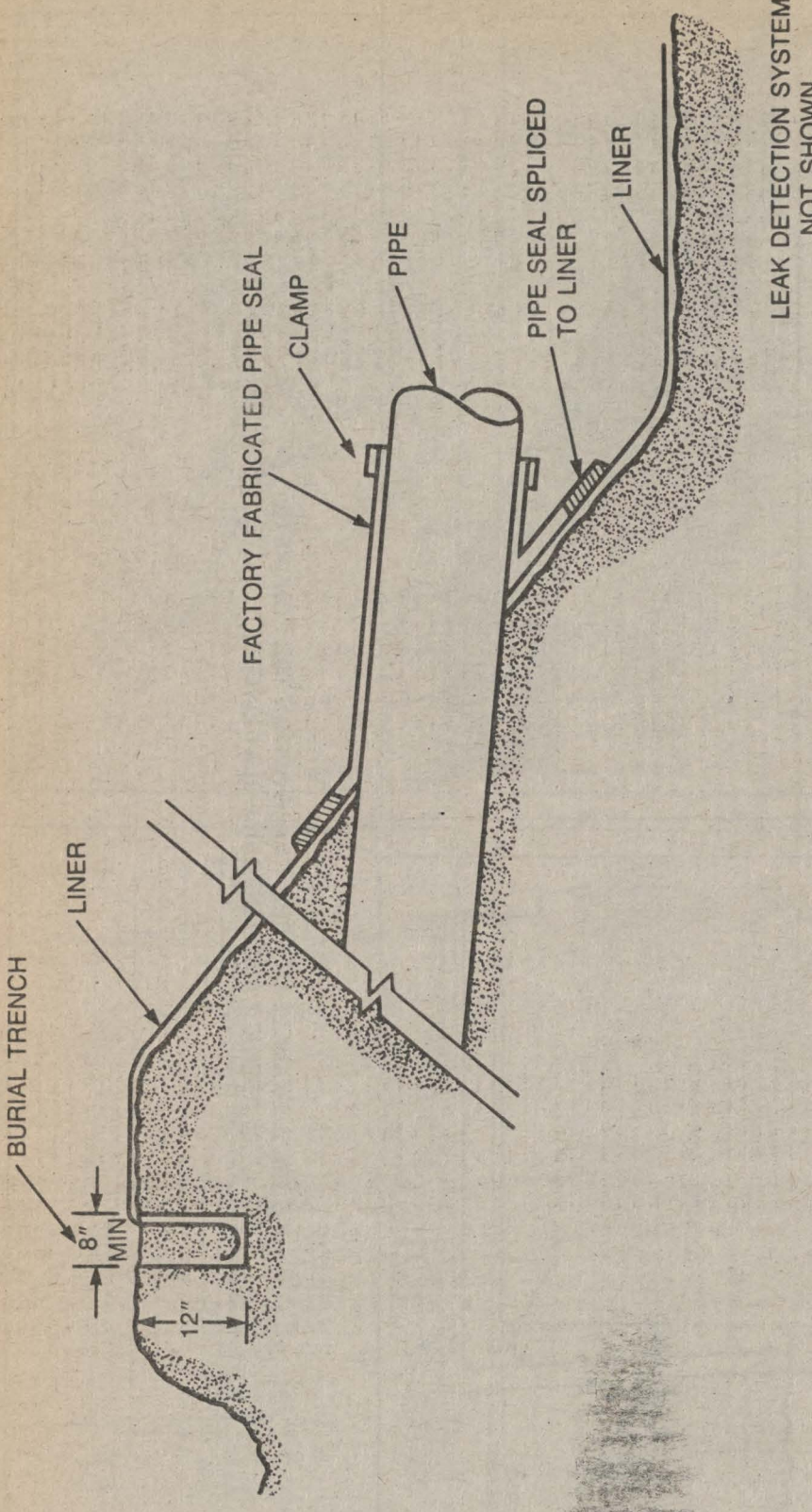


FIGURE 3. EXAMPLE OF ACCEPTABLE DESIGN FOR INSTALLATION OF A FLEXIBLE LINER.

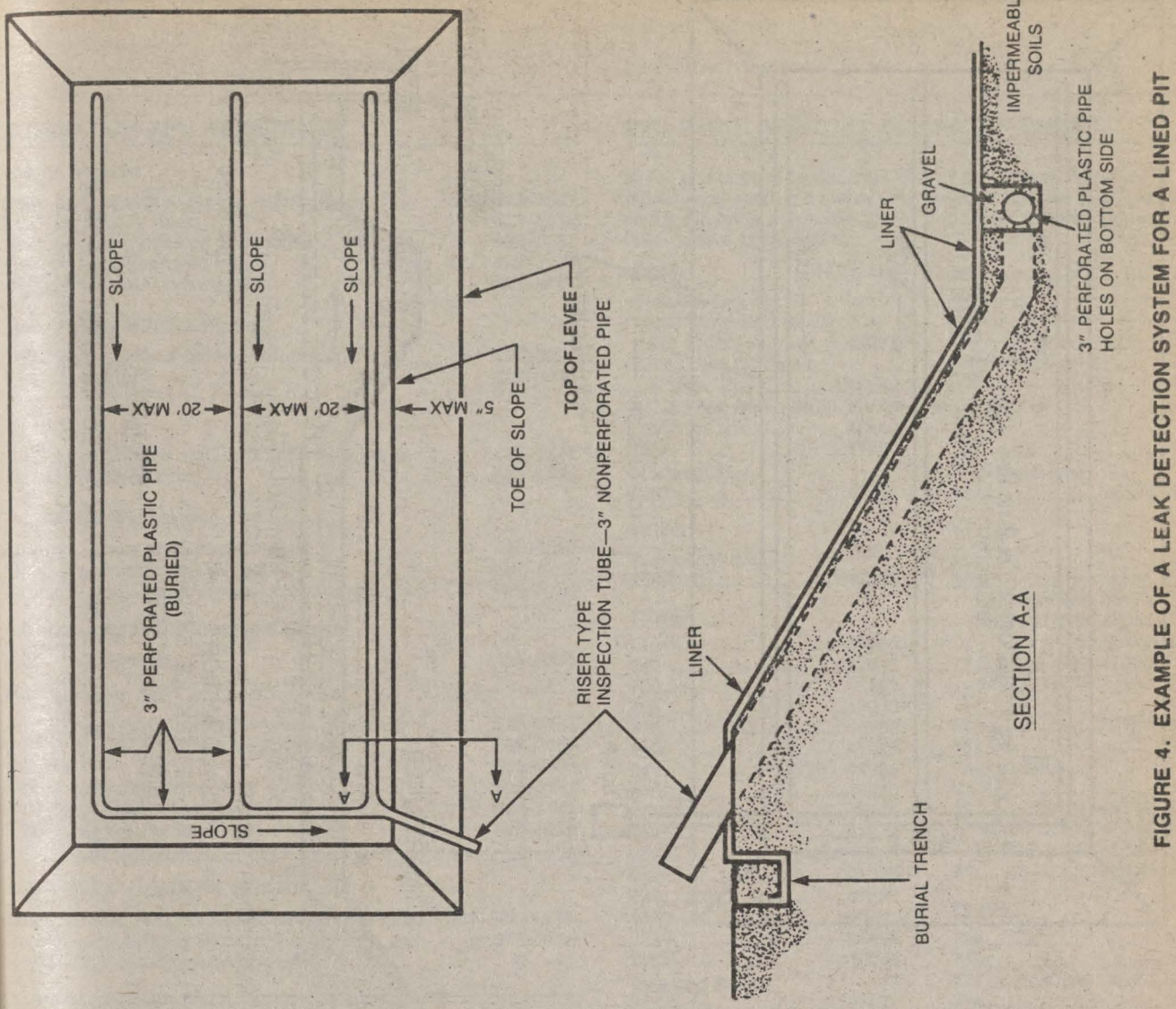


FIGURE 4. EXAMPLE OF A LEAK DETECTION SYSTEM FOR A LINED PIT CONSTRUCTED IN RELATIVELY IMPERMEABLE SOILS.

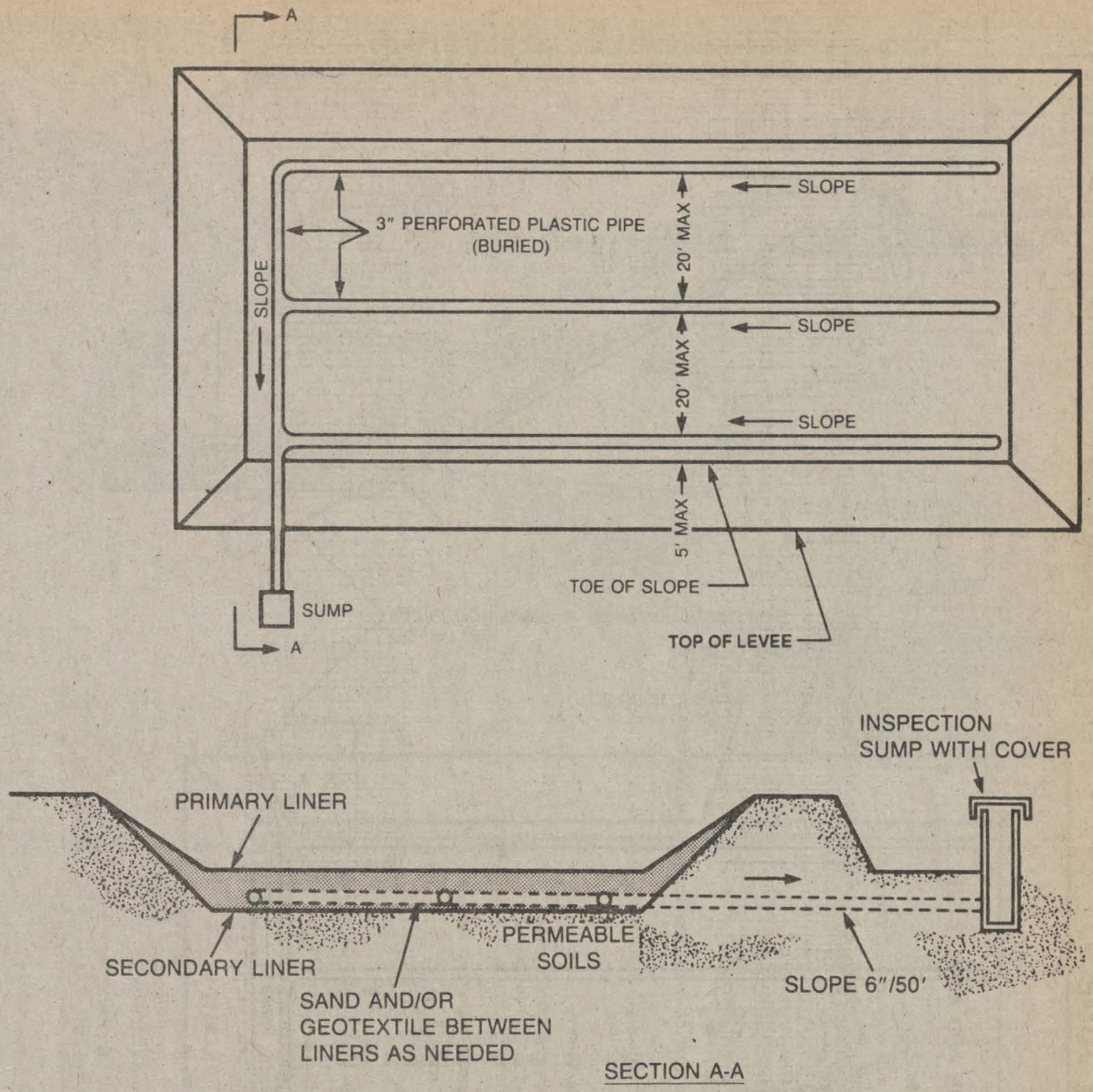


FIGURE 5. EXAMPLE OF A LEAK DETECTION SYSTEM FOR A LINED PIT CONSTRUCTED IN PERMEABLE SOILS.

[FR Doc. 93–21828 Filed 9–7–93; 8:45 am]
BILLING CODE 4310–84–C