

Substances	Limitations
<p style="text-align: center;">* * * * *</p> <p>3,9-Bis[2-{3-(3-<i>tert</i>-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane (CAS Reg. No. 90498-90-1).</p> <p style="text-align: center;">* * * * *</p>	<p>For use only:</p> <ol style="list-style-type: none"> At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520(c), item 1.1 of this chapter. The finished polymer is to be used in contact with food only under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter. At levels not to exceed 0.3 percent by weight of polyethylene complying with § 177.1520(c) of this chapter, item 2.1, provided that the polymer has a minimum density of 0.94 grams per cubic centimeter and is used in contact with food only under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter. <p style="text-align: center;">* * * * *</p>

Dated: June 15, 1995.

Janice F. Oliver,
*Deputy Director for Systems and Support,
 Center for Food Safety and Applied Nutrition.*
 [FR Doc. 95-15922 Filed 6-28-95; 8:45 am]
 BILLING CODE 4160-01-F

21 CFR Part 442

[Docket No. 94N-0132]

Antibiotic Drugs; Cefotetan and Cefotetan Disodium Injection; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is technically amending a final rule that appeared in the **Federal Register** of May 25, 1994 (59 FR 26939). The document amended the antibiotic drug regulations to provide for the inclusion of accepted standards for a new bulk form of cefotetan. The agency received a comment on the final rule that pointed out, among other things, that the correct name of the antibiotic is cefotetan disodium. This document corrects those errors.

EFFECTIVE DATE: June 29, 1995.

FOR FURTHER INFORMATION CONTACT: James M. Timper, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6714.

SUPPLEMENTARY INFORMATION: As published, the final regulation contains errors that may prove to be misleading

and are in need of clarification. The name of the antibiotic is "cefotetan disodium" not "cefotetan sodium." The calculation for determining cefotetan concentration in the finished dosage form was published incorrectly, and an additional sample preparation, potassium bromide discs, can be used also. Accordingly the agency is amending 21 CFR 442.52 to correct those errors.

List of Subjects in 21 CFR Part 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 442 is amended as follows:

PART 442—CEPHA ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. Section 442.52 is amended by revising paragraphs (b)(1)(iv) and (b)(3) to read as follows:

§ 442.52 Cefotetan.

(b) * * *

(1) * * *

(iv) *Calculation.* Calculate the micrograms of cefotetan per milligram of sample as follows:

$$\text{Micrograms of cefotetan per milligram} = \frac{A_U \times P_S \times V_f \times 1,000}{A_S \times V_s}$$

where:

A_U = Area of the cefotetan peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefotetan peak in the chromatogram of the cefotetan working standard;

P_S = Cefotetan activity in the cefotetan working standard solution in micrograms per milliliter;

V_f = Volume of flask used to dilute standard; and

V_s = Volume of sample diluted.

* * * * *

(3) *Identity.* Proceed as directed in § 436.211 of this chapter using the potassium bromide discs prepared as described in § 436.211(b)(1) of this chapter or the mineral oil mull prepared as described in § 436.211(b)(2) of this chapter.

Dated: May 9, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95-15923 Filed 6-28-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 637

[FHWA Docket No. 94-13]

RIN 2125-AD35

Quality Assurance Procedures for Construction

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is revising its regulations that establish general

requirements for quality assurance procedures for construction on Federal-aid highway projects. The rule provides more flexibility than the existing regulation. The rule allows the use of contractor test results in making the acceptance decision and allows the use of consultants in the independent assurance program and verification sampling and testing. The regulation requires testers and laboratories to be qualified. However, it gives the States the flexibility to establish those qualifications. The revisions will clarify existing policy and procedures and provide additional guidance on the use of contractor-supplied test results in acceptance plans.

EFFECTIVE DATE: July 31, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Rafalowski, Office of Engineering, HNG-23, 202-366-1571; or Mr. Wilbert Baccus, Office of the Chief Counsel, HCC-32, 202-366-0780; Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are 7:45 a.m. to 4:15 p.m., e.t., Monday Through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

The current regulations on sampling and testing of materials and construction appear in 23 CFR Part 637, Construction Inspection and Approval. These regulations were last revised in January 1987. The regulations were written using the concept of the State performing all the sampling and testing, which had been the traditional approach to sampling and testing. The regulations do not address the use of contractor testing. As a result, a number of questions arose in those States which were using contractor testing in their quality control/quality assurance (QC/QA) programs.

The existing regulations do not recognize the use of contractor testing results in an acceptance program. An acceptance program is the process of determining whether the materials and workmanship are in reasonably close conformity with the requirements of the approved plans and specifications. In 1992, the FHWA studied the ramifications of using contractor-performed sampling and testing results. The results of its study are reported in "Limits of Use of Contractor Performed Sampling and Testing," dated July 1, 1993. (A copy of the report is available in the docket for inspection and copying.) One of the report's recommendations was that contractor sampling and testing may be used in acceptance programs, provided

adequate checks and balances are in place to protect the public investment. The revisions to part 637 made in this final rule would implement the committee's recommendation.

This final rule provides more flexibility to the States in designing their acceptance programs than currently exists. Acceptance of materials and construction will not be based solely on any one set of information. Each State's verification sampling and testing will be used to ensure the quality of the product. In addition, the rule will permit the use of data from the contractors' quality control sampling and testing programs in acceptance programs if the results from the States' verification sampling and testing programs confirm the quality of the material. The verification sampling and testing must be performed on independent samples obtained by the State or designated agent to verify the quality of the material. If the results of a State's verification sampling and testing program do not confirm the quality of the product, a dispute resolution system must be used to determine payment to the contractor.

The requirement for an independent assurance (IA) program will remain in place. The rule will provide the States more flexibility in designing their IA program. The IA program will allow the use of witnessing, split samples, proficiency samples, and equipment calibration as an independent check of the field sampling and testing procedures and equipment to assure that the testing is being performed properly by both the State and the contractor personnel.

Comments to the Docket

A notice of proposed rulemaking (NPRM) was published in the **Federal Register** on July 12, 1994 (59 FR 35493), in which the FHWA proposed to revise 23 CFR Part 637, Construction Inspection and Approval. A total of 50 commenters responded to the NPRM as follows: 35 State highway agencies, 1 local agency, 1 toll authority, 10 construction industry associations and contractors, and 3 Subcommittees of the American Association of State Highway and Transportation Officials (AASHTO). The major comments and the FHWA's response thereto are summarized as follows.

Supportive of Change

Twenty-six commenters expressed their support for the revisions to the regulation. Fifteen commenters provided comments without indicating support or opposition to the NPRM. The

remaining nine commenters were generally opposed to the proposed rule.

Use of Contractor Test Results

Commenters expressed three related concerns over the required system of checks and balances employed when contractor test results are used in the acceptance decision: (1) Requiring the use of independent samples instead of allowing either independent samples or split samples; (2) requiring the use of the F-test and the t-test (which are standard statistical tests for comparing the variances and means of two sets of data) because of the complexity of using the statistical tests; and (3) the perceived duplication of effort between the verification sampling and testing and the testing required by covering the contractor sampling and testing program in the IA program.

The overall intent of the program is to provide adequate assurance that the public is receiving the desired quality in the product produced by the contractor. The first level of assurance is provided by qualifying laboratories and testing personnel. This assures that the equipment and personnel *are capable* of performing the tests properly. The second level of assurance is provided by the IA program. This level assures that the testers and equipment *remain capable* of performing the tests properly. The third level of assurance is provided by verification sampling and testing. This level assures the *quality of the product*.

There appears to have been some misunderstanding of the total level of effort required. The rule as adopted gives the States wide latitude in designing the acceptance program. The system approach to IA assures the capabilities of all equipment and testers regardless of the number of projects or material quantities involved. A broad interpretation of the existing regulations would allow the system approach to IA. However, the final rule explicitly allows the system approach to IA. In those States that are performing a significant amount of testing on split samples and no testing on independent samples, testing on split samples would remain as IA sampling and testing; however, some verification testing on independent samples would be required to confirm the quality of the product. In addition, the verification of the *quality* of the material can be performed on a mix design or grading of material from a given source and is not limited to project-specific data.

Eleven commenters expressed concern over requiring the use of independent samples for the verification sampling and testing program. The

commenters recommended that the use of split samples be permitted for the verification sampling and testing program. The commenters are concerned about the potential problems that may arise with differences in testing results caused by sampling errors.

There are three sources of differences between two test results, differences in the material, differences in test procedures and differences in sampling procedures. Split samples will only address the differences in test procedures and will only provide assurance that the contractor is performing the tests properly. In a balanced system it is also necessary to assure that sampling of materials is performed properly. It is our intent that the verification sampling and testing program be used to independently validate the quality of the material. Using independent samples will insure that all sources of differences are measured. The FHWA recognizes the need to ensure that each contractor performs the tests correctly; that is the reason for extending laboratory and testing personnel qualification requirements and IA program requirements to the contractor if the contractor's test results are to be used in the acceptance decision. The FHWA expects the testing variability between the contractor and the State to be held to a minimum by requiring the contractor's testing program to be covered by an IA program and requiring the testing personnel and laboratories to be qualified. The FHWA has changed the definition of "verification sampling and testing" and § 637.207(a)(1)(ii)(B) to clarify the fact that the verification sampling and testing program is being used to validate the quality of the material.

Eight commenters objected to requiring the use of the F-test and t-test for verifying a contractor's test data. The commenters were concerned about the complexity of the F-test and t-test which would have to be used by field personnel and the lack of flexibility in allowing other comparison systems. The commenters requested that the regulation be revised to allow other types of comparison systems. The FHWA agrees with the concerns and has removed the requirement for a specific comparison procedure. Each State will have the latitude to develop its own verification system.

Three commenters—two State Highway Agencies and one local highway agency—objected to including contractors' testers in States' IA programs. The commenters are concerned over the additional resources

involved in extending the IA program to contractor testing.

If a contractor's test results are to be used in the acceptance decision, assurance must be provided that the contractor's testers and equipment remain capable of performing the tests properly. Some States are currently performing split sampling and testing on project sites to validate the contractor's test results. This split sampling and testing would meet the requirements for an IA program on contractor testing. This proposed requirement has been retained in the final rule.

Qualified Sampling and Testing Personnel

Four commenters specifically supported the concept of certifying testing personnel.

Two commenters wanted to change the term certified personnel to qualified personnel. The FHWA agrees with the comments since the goal of the FHWA is to have qualified personnel perform the testing. The term "certified" was deleted from the definition of qualified testing personnel.

Sixteen commenters expressed concern about the cost, specific requirements, and/or two-year implementation period for establishing qualification programs for testing personnel. To allow adequate time to develop qualification programs, we have extended the implementation time from two years to five years. If a State chooses to use a certification program as its qualification program, the FHWA is developing training material that can be modified for State use. The FHWA will also assist the States in adapting the material for their use.

Independent Assurance Program

Thirteen commenters objected to the proposal to remove the requirement that State highway agency (SHA) personnel perform IA testing. The States wanted to continue to perform IA testing as a means to maintain expertise in the materials sampling and testing area and maintain the credibility of their materials programs. Since materials sampling and testing are an essential part of determining the quality of the product that is obtained from the use of Federal-aid funds, the FHWA has an interest in maintaining the States' expertise and credibility. However, in cases where States are using contractor test results in acceptance decisions, the FHWA believes it is important that the States have the option of using consultants to perform IA testing. It is important to note that the final rule does not require a SHA to use consultants in

the IA program, but simply gives SHAs the option to do so. The FHWA has added § 637.205(b) which requires States to maintain an adequate, qualified staff with the capability of overseeing the entire quality assurance program and specifically requires the States to maintain a central laboratory. This requirement is consistent with 23 U.S.C. 302 which requires each State to maintain an adequate highway department.

Three commenters requested further clarification on the use of the system approach in performing an IA program. The intent of the system approach to the IA program is to concentrate on assuring that the testing personnel and equipment remain capable of performing the tests properly, regardless of the location or number of projects covered by the equipment and tester. The system approach will permit an SHA to fulfill the requirement for an IA program by implementing a schedule of activities to cover equipment operations and tester competence. The activities may include calibration checks, split samples, proficiency samples, and observations. The schedules and type of activity would be based on the test procedure. In the system approach, the frequency of IA may be independent of the number of tests performed or the quantity of material tested. It is envisioned that the system approach will be especially useful in cases where one tester performs testing for more than one project during a construction season. The previous requirement for IA entailed sampling and testing frequencies based on individual project production. In addition, a State may choose to use the information developed from the IA program in the qualification programs for testers and laboratories. One commenter asked if the NPRM would allow a State to use a hybrid approach, which would include some frequencies based on project quantities and frequencies based on the overall system. This rule as written would allow that approach. It should be noted that the rule does not require a State to use this approach.

One commenter wanted the requirements for the IA program to be less stringent. The requirements in the final rule for IA have been made less prescriptive than the current regulations and give a State more latitude in designing its IA system. The existing regulation requires State personnel to perform the IA sampling and testing. The final rule would allow: (1) The use of accredited consultant laboratories in executing an IA program, (2) a system approach instead of a project approach, (3) proficiency samples instead of split

samples, and (4) equipment calibration to cover the testing equipment.

Laboratory Qualification

Four commenters supported the proposed requirements for laboratory qualifications.

Eight commenters expressed concerns about the requirements for laboratory qualifications. The NPRM proposed to include by reference two paragraphs from the "Standard Recommended Practice for Establishing and Implementing a Quality System for Construction Testing Laboratories" (R-18) published by the AASHTO in the "Standard Specifications for Transportation Materials and Methods of Sampling and Testing." The commenters believed that R-18 was not appropriate for field laboratories. It was not the FHWA's intent that the entire R-18 standard be used for the qualification of field laboratories. Due to the confusion caused by specifying only a part of R-18, the rule has been revised to specifically list the minimum requirements for field laboratories and delete the reference to R-18.

Eight commenters wanted clarification of the requirements for accreditation of the SHA central laboratory. It is the intent of the FHWA that the accreditation program must meet the guidelines in ASTM E-994. In addition to the guidelines in ASTM E-994, we have two additional concerns: First, regarding the acceptability of the assessors; and second, concerning the scope of the on-site assessment. For an accreditation program to be acceptable to the FHWA, the assessor must be employees of the accrediting body and not employed by a laboratory which may compete for work with the laboratory being assessed. This would avoid any potential conflicts of interest. In addition, the on-site assessment must include a detailed review of the test procedures in which the laboratory is being accredited. The FHWA believes that only one laboratory accreditation program currently meets the above concerns, and that is the AASHTO Accreditation Program. As we understand the operating procedures of other accreditation programs, they allow reviewers to be employees of other testing laboratories and do not require the laboratory to demonstrate all the tests in which the laboratory is being accredited. If other accreditation programs can satisfy our concerns, we will approve them. Any inquiries or requests for approval should be directed to the FHWA's Office of Engineering.

Six commenters expressed concern about the cost and implementation time necessary for accrediting an SHA central

laboratory. The commenters believe that two years is too short a time in which to become accredited. At this time 30 SHAs are accredited by the AASHTO Accreditation Program (AAP). The FHWA contacted the AAP to obtain data on the average length of time required by the AAP to accredit a SHA laboratory after receipt of an application for accreditation. Based on the information supplied by AAP, the FHWA believes that two years is an adequate lead time for obtaining accreditation. The requirement for accreditation replaces the inspections by the National Reference Laboratories which are required by § 637.205 of the current regulation. The actual cost of accreditation to the SHA is the same as the cost of inspection program that it replaces. However, there will be some costs associated with developing the quality system for the initial accreditation for the SHAs. The rule provides flexibility to the SHAs to designate private laboratories to perform independent assurance tests and dispute resolution testing. Since the SHAs must review the qualifications of designated laboratories, the SHAs need to be qualified at the highest level, which is accreditation. Therefore, this final rule maintains the laboratory accreditation requirements as originally proposed.

Definitions

Four commenters suggested changes to the definition of quality control. The definition of quality control was adapted from the definition in ANSI 90 and ISO 9000 which are the industry consensus standards for quality assurance. Therefore, the FHWA is retaining the definition as proposed.

Two commenters wanted to delete the word "accredited" from the definition of "qualified laboratories". There appears to be confusion over the use of the term "accreditation" since the NPRM used the word to describe two different levels of qualifications. The FHWA agrees with the comment because of the apparent confusion. The word "accredited" has been removed from the definition of "qualified laboratories".

Two commenters wanted clarification of the term "vendor." A definition of "vendor" has been added to insure that it includes suppliers of project-produced materials. It was the FHWA's intent that the rule cover only project-produced materials and not manufactured materials.

One commenter suggested changes to the definition of "quality assurance". The definition of "quality assurance" was adapted from the definitions in the ANSI 90 and ISO 9000 standards which

are the industry consensus standards for quality assurance. Therefore, the FHWA has retained this definition as proposed in the NPRM.

One commenter suggested requiring random sampling. The FHWA agrees with the comment. In order for test data used in the acceptance decision to be properly analyzed, samples must be obtained on a random basis. Section 637.205(e) has been added to require random sampling.

One commenter was concerned with the wording of the definition for IA, which the commenter interpreted as requiring the IA to be performed by a consultant. As stated earlier, it is the FHWA's intent that the States have the option to perform IA sampling and testing themselves or have a qualified designated agent perform the testing. The definition in the final rule has been revised to reflect our intent.

Miscellany

Eight commenters requested a delay in issuing a final rule. Their major concern was over potential conflicts between this final rule and AASHTO's effort to develop guide specifications for Quality Assurance. The AASHTO effort is related to this rulemaking. However, the "AASHTO Quality Assurance Guide Specification" and the "AASHTO Implementation Manual for Quality Assurance" are in the draft stage and are still being reviewed. It may be some time before these documents receive full endorsement by AASHTO. Since the current regulations do not address the practice of using contractor testing in making acceptance decisions, the FHWA believes that it is necessary to proceed with the final rule. The commenters were also concerned that the SHAs did not have adequate time to comment on the regulation. The NPRM provided a 60 day comment period. All comments that were received by the FHWA, including the eleven received after the closing of the comment period, were considered and included in the analysis. In addition, the FHWA received comments from 35 of the 52 SHAs. Therefore, the FHWA believes that adequate time was provided.

Five commenters provided comments on the dispute resolution system. There were comments on both sides of the issue of whether the dispute resolution system should allow third party involvement. Three commenters were in favor of keeping the system in the State; two were in favor of using third parties. In the NPRM the FHWA proposed to permit the SHAs to determine how they wanted to set up the dispute resolution system. The FHWA is aware of cases where a dispute resolution system has

worked well in both cases, so this proposal has been retained in the final rule.

Three commenters requested clarification of the terms "acceptance", "verification", and "assurance". This rule requires an acceptance program which includes the establishment of qualifications of testers and laboratories and inspection of construction operations and testing performed by the SHA or its designated agent. Verification sampling and testing is used to validate the quality of the product. Independent assurance is used specifically to insure that the testing is performed correctly and that the equipment is in calibration.

Two commenters provided comments on the materials certificate. One commenter requested that the wording on the material certificate be revised from requiring the materials and operations to be in "conformity with the approved plans and specifications" to "reasonably close conformity to the approved plans and specification." The commenter was concerned about the added work of adding the individual material exceptions to the project plans and specifications to the materials certificate. The current regulation requires the material certificate to list all materials that do not meet the specifications. The FHWA reserves the right to review the materials certificate to determine if the materials are in conformity with the project plans and specifications. Therefore, the FHWA has retained the wording as proposed in the NPRM. The other commenter wanted to eliminate the requirement for the materials certificate. Section 637.201 limits the rule to projects on the NHS. In addition, § 637.207(a)(3) further limits the requirement for a materials certificate to projects that are subject to FHWA oversight reviews. This will eliminate the requirement for a materials certificate for the vast majority of projects. Since the cost of materials make up a substantial portion of each project and the information supplied by the materials certificate indicates the quality of the material, it is necessary to have the materials certificate in order to make an informed decision on whether to accept those projects for which the FHWA has retained construction oversight. Therefore, the FHWA has retained the proposed requirement for a materials certificate in this final rule.

One commenter indicated that the cost of implementing the regulation was high and a full regulatory review was needed. As noted below the FHWA has determined that this action is not a significant regulatory action under Executive Order 12366, Regulatory

Planning and Review, nor significant under DOT Order 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations, and has concluded that a full regulatory evaluation is not required.

Costs to the States. Currently all States must have approved sampling and testing programs which include an IA program. In addition, all States are required to have their central laboratories inspected by the National Reference Laboratories. As indicated in the fee schedule for the AAP, the actual cost of accreditation itself for the SHAs is the same as the current inspection fees. The additional cost to the States for becoming accredited is in developing the quality assurance manuals which are required by the AAP. The justification for requiring accreditation is stated above. Since the vast majority of States have qualification requirements for their subsidiary laboratories, there would be no additional costs for the States that have these requirements. There would be minimal costs to those States that will have to develop qualification requirements for laboratories. There would be some costs in developing qualifications for testers. One aspect of tester qualifications is attendance at training programs. All States have some training for their technicians, but some of this training may have to be upgraded. However, as stated earlier, the FHWA has a training effort that is available to assist the States in setting up certification programs. The certification programs could be used in the States' establishment of tester qualifications.

Costs to the public. There would be no additional costs to the industry if a State chooses not to incorporate contractor tests into the acceptance system. If a State chooses to use contractor tests in acceptance decisions, contractors would be required to hire employees qualified in the appropriate tests and the State would be required to ensure that the contractors maintain a qualified laboratory or hire a qualified laboratory to perform the testing. When a State uses contractor quality control testing results in the acceptance decision, testing performed by the State is reduced. This reduction in testing by the State reduces the overhead costs in the State. However, any additional cost the contractors incur in performing the testing, including costs of obtaining qualified laboratories and testers, will be passed onto the State through higher bid prices. The cost savings by the State due to the reduction of testing by State personnel would be offset by the increase in bid prices charged by the

contractors. As a result, the FHWA believes that the additional costs of these actions would be minimal.

One commenter was concerned because its Quality Assurance program is located in several documents and it did not want to consolidate the information into one document. The FHWA does not see the need for all the documentation of a State's Quality Assurance program to be in one document.

One commenter interpreted the NPRM to propose a requirement for a central laboratory and the commenter opposed such a requirement. The NPRM did not expressly propose to require a central laboratory; however, the NPRM did propose to require that each State's central laboratory be accredited by the AAP or a comparable program approved by the FHWA. For the reasons stated above, this final rule now requires a central laboratory.

One commenter was concerned about the effect of these QC/QA regulations on small projects. As indicated in the preamble of the NPRM, it is not the intent of the FHWA in this regulation to require the use of contractor testing in the acceptance decision. In addition, the rule expressly covers only projects on the National Highway system (NHS); projects not on the NHS can use other SHA procedures to accept materials. It is anticipated that the majority of small projects will not be on the NHS.

One commenter was against QC/QA procedures. The rule does not require SHAs to use statistical concepts or to use contractor-supplied test results in the acceptance decision. However, the rule does establish minimum requirements if an SHA chooses to use contractor tests results in the acceptance decision.

One commenter suggested a revision to the portion of § 637.207 concerning inspection to reflect the positive as well as the negative aspects of the quality of the product or construction. The section in the NPRM read, "The SHA shall inspect the product or construction or both for attributes that are detrimental to the performance of the finished product." The FHWA agrees with the comment. Section 637.207(a)(1)(i)(C) has been revised to reflect both beneficial and negative aspects of the quality of the finished product.

One commenter indicated that the regulation was too prescriptive. The rule, however, provides more flexibility than the existing regulation. The rule allows the use of contractor test results in making the acceptance decision and allows the use of consultants in the independent assurance program. Neither of these were allowed by the

existing regulations. The regulation requires testers and laboratories to be qualified. However, it gives the States the flexibility to establish those qualifications. In addition, the final rule modified Section 637.207 to remove the requirement for a specific comparison procedure to validate the quality of the material. The rule clarifies existing policy and procedures and provides additional guidance on the use of contractor-supplied test results in acceptance plans.

One commenter questioned the title and purpose of the proposed rule, indicating that the rule covers materials and not construction. Over 50 percent of the cost of construction is the cost of the material. In addition, the rule requires each State to inspect construction to insure that the construction procedures do not adversely affect the properties of the material. Therefore, the title of this rule remains unchanged.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of Department of Transportation's regulatory policies and procedures. The FHWA, at 23 CFR 637, currently has regulations covering sampling and testing. The rule provides the States with additional flexibility in comparison to the current regulations. States will be allowed to use contractor test results in making acceptance decisions and consultants to perform independent assurance testing. Other changes update the current regulations to accommodate contractor-performed sampling and testing and reinforce existing policy. Therefore, it is anticipated that the economic impact of this rulemaking will be minimal and a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), the FHWA has evaluated the effects of this action on small entities. The FHWA concluded that this action may provide some small testing firms with an opportunity to perform more work than was allowed by the previous regulations. Although the regulation will have a positive impact on these testing firms, the number of firms affected will be small and the amount of additional work would be insignificant. Therefore, the FHWA hereby certifies that this rulemaking will not have a

significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The rule provides the States with additional flexibility over the current regulations. States will be allowed to use contractor test results in making acceptance decisions and consultants to perform IA testing. Therefore, it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a separate federalism assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501-3520.

National Environmental Policy Act

This rulemaking does not have any effect on the environment. It does not constitute a major action having a significant effect on the environment, and therefore does not require the preparation of an environmental impact statement pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*)

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 637

Grant programs—transportation, Highways and roads, Quality assurance, Materials sampling and testing.

Issued on: June 22, 1995.

Rodney E. Slater,
Federal Highway Administrator

In consideration of the foregoing, the FHWA is amending title 23, Code of

Federal Regulations, by revising part 637 to read as follows:

PART 637—CONSTRUCTION INSPECTION AND APPROVAL

Subpart A—[Reserved]

Subpart B—Quality Assurance Procedures for Construction

Sec.

- 637.201 Purpose.
- 637.203 Definitions.
- 637.205 Policy.
- 637.207 Quality assurance program.
- 637.209 Laboratory and sampling and testing personnel qualifications.

Appendix A to Subpart B—Guide Letter of Certification by State Engineer

Authority: 23 U.S.C. 109, 114, and 315; 49 CFR 1.48(b).

Subpart A—[Reserved]

Subpart B—Quality Assurance Procedures for Construction

§ 637.201 Purpose.

To prescribe policies, procedures, and guidelines to assure the quality of materials and construction in all Federal-aid highway projects on the National Highway System.

§ 637.203 Definitions.

Acceptance program. All factors that comprise the State highway agency's (SHA) determination of the quality of the product as specified in the contract requirements. These factors include verification sampling, testing, and inspection and may include results of quality control sampling and testing.

Independent assurance program. Activities that are an unbiased and independent evaluation of all the sampling and testing procedures used in the acceptance program. Test procedures used in the acceptance program which are performed in the SHA's central laboratory would not be covered by an independent assurance program.

Proficiency samples. Homogeneous samples that are distributed and tested by two or more laboratories. The test results are compared to assure that the laboratories are obtaining the same results.

Qualified laboratories. Laboratories that are capable as defined by appropriate programs established by each SHA. As a minimum, the qualification program shall include provisions for checking test equipment and the laboratory shall keep records of calibration checks.

Qualified sampling and testing personnel. Personnel who are capable as defined by appropriate programs established by each SHA.

Quality assurance. All those planned and systematic actions necessary to provide confidence that a product or service will satisfy given requirements for quality.

Quality control. All contractor/vendor operational techniques and activities that are performed or conducted to fulfill the contract requirements.

Random sample. A sample drawn from a lot in which each increment in the lot has an equal probability of being chosen.

Vendor. A supplier of project-produced material that is not the contractor.

Verification sampling and testing. Sampling and testing performed to validate the quality of the product.

§ 637.205 Policy.

(a) *Quality assurance program.* Each SHA shall develop a quality assurance program which will assure that the materials and workmanship incorporated into each Federal-aid highway construction project on the NHS are in conformity with the requirements of the approved plans and specifications, including approved changes. The program must meet the criteria in § 637.207 and be approved by the FHWA.

(b) *SHA capabilities.* The SHA shall maintain an adequate, qualified staff to administer its quality assurance program. The State shall also maintain a central laboratory. The State's central laboratory shall meet the requirements in § 637.209(a)(2).

(c) *Independent assurance program.* Independent assurance samples and tests or other procedures shall be performed by qualified sampling and testing personnel employed by the SHA or its designated agent.

(d) *Verification sampling and testing.* The verification sampling and testing are to be performed by qualified testing personnel employed by the SHA or its designated agent, excluding the contractor and vendor.

(e) *Random samples.* All samples used for quality control and verification sampling and testing shall be random samples.

§ 637.207 Quality assurance program.

(a) Each SHA's quality assurance program shall provide for an acceptance program and an independent assurance (IA) program consisting of the following:

(1) Acceptance program.

(i) Each SHA's acceptance program shall consist of the following:

(A) Frequency guide schedules for verification sampling and testing which will give general guidance to personnel responsible for the program and allow adaptation to specific project conditions and needs.

(B) Identification of the specific location in the construction or production operation at which verification sampling and testing is to be accomplished.

(C) Identification of the specific attributes to be inspected which reflect the quality of the finished product.

(ii) Quality control sampling and testing results may be used as part of the acceptance decision provided that:

(A) The sampling and testing has been performed by qualified laboratories and qualified sampling and testing personnel.

(B) The quality of the material has been validated by the verification sampling and testing. The verification testing shall be performed on samples that are taken independently of the quality control samples.

(C) The quality control sampling and testing is evaluated by an IA program.

(iii) If the results from the quality control sampling and testing are used in the acceptance program, the SHA shall establish a dispute resolution system. The dispute resolution system shall address the resolution of discrepancies occurring between the verification sampling and testing and the quality control sampling and testing. The dispute resolution system may be administered entirely within the SHA.

(2) The IA program shall evaluate the qualified sampling and testing personnel and the testing equipment. The program shall cover sampling procedures, testing procedures, and testing equipment. Each IA program shall include a schedule of frequency for IA evaluation. The schedule may be established based on either a project basis or a system basis. The frequency can be based on either a unit of production or on a unit of time.

(i) The testing equipment shall be evaluated by using one or more of the following: Calibration checks, split samples, or proficiency samples.

(ii) Testing personnel shall be evaluated by observations and split samples or proficiency samples.

(iii) A prompt comparison and documentation shall be made of test results obtained by the tester being evaluated and the IA tester. The SHA shall develop guidelines including tolerance limits for the comparison of test results.

(iv) If the SHA uses the system approach to the IA program, the SHA shall provide an annual report to the

FHWA summarizing the results of the IA program.

(3) The preparation of a materials certification, conforming in substance to Appendix A of this subpart, shall be submitted to the FHWA Division Administrator for each construction project which is subject to FHWA construction oversight activities.

(b) [Reserved]

§ 637.209 Laboratory and sampling and testing personnel qualifications.

(a) Laboratories.

(1) After June 29, 2000, all contractor, vendor, and SHA testing used in the acceptance decision shall be performed by qualified laboratories.

(2) After June 30, 1997, each SHA shall have its central laboratory accredited by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by the FHWA.

(3) After June 29, 2000, any non-SHA designated laboratory which performs IA sampling and testing shall be accredited in the testing to be performed by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by the FHWA.

(4) After June 29, 2000, any non-SHA laboratory that is used in dispute resolution sampling and testing shall be accredited in the testing to be performed by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by the FHWA.

(b) Sampling and testing personnel. After June 29, 2000, all sampling and testing data to be used in the acceptance decision or the IA program shall be executed by qualified sampling and testing personnel.

(c) Conflict of interest. In order to avoid an appearance of a conflict of interest, any qualified non-SHA laboratory shall perform only one of the following types of testing on the same project: Verification testing, quality control testing, IA testing, or dispute resolution testing.

Appendix A to Subpart B—Guide Letter of Certification by State Engineer

Date _____
Project No. _____

This is to certify that:

The results of the tests used in the acceptance program indicate that the materials incorporated in the construction work, and the construction operations controlled by sampling and testing, were in conformity with the approved plans and specifications. (The following sentence should be added if the IA testing frequencies are based on project quantities. All independent assurance samples and tests are within tolerance limits of the samples and tests that are used in the acceptance program.)

Exceptions to the plans and specifications are explained on the back hereof (or on attached sheet).

Director of SHA Laboratory or other appropriate SHA Official.
 [FR Doc. 95-15932 Filed 6-28-95; 8:45 am]
 BILLING CODE 4910-22-P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 3, 7, 15, 18, 23, 32, 33, 36, 40, 43, 45, 48, 56, 57, 70, 71, 75, 77, and 90

Office of Management and Budget Control Numbers Under the Paperwork Reduction Act

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: The Mine Safety and Health Administration (MSHA) is adding a new part to its regulations in order to consolidate the display of Office of Management and Budget (OMB) control numbers approved under the Paperwork Reduction Act. The display references regulations promulgated under the Mine Act containing recordkeeping and reporting requirements. This consolidation will assist the public search for specific information on recordkeeping and reporting requirements approved by OMB and will provide the Agency a format that is simpler to maintain.

EFFECTIVE DATE: June 29, 1995.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, 703-235-1910.

SUPPLEMENTARY INFORMATION: MSHA reviewed its existing regulations requiring collection of information for OMB control number display and accuracy. As part of that review, MSHA is today publishing the control numbers issued by OMB for information collection. The affected regulations are codified in title 30 of the Code of Federal Regulations (30 CFR) parts 7, 15, 18, 19, 20, 21, 22, 23, 26, 27, 28, 29, 32, 33, 35, 36, 40, 41, 43, 44, 45, 48, 49, 50, 56, 57, 70, 71, 75, 77, and 90.

MSHA is presenting the OMB control numbers in a table format to be codified in part 3, subchapter A, chapter I, 30 CFR. This part will fulfill the requirements of 44 U.S.C. 3507(f) of the Paperwork Reduction Act which prohibits an agency from engaging in a collection of information without displaying the control number obtained from OMB. The table lists the part and section numbers with reporting and recordkeeping requirements and the OMB control numbers. MSHA selected the list format to provide ease of referencing paperwork burden hours and to allow consistent updating. As a result of this new format, the parenthetical statements containing OMB control numbers currently found in 30 CFR at the end of individual paragraphs can be removed.

The OMB control numbers listed in this document were approved previously by OMB. This document makes no substantive change to the current OMB information collection budget. When control numbers included on this list are not found in 30 CFR, it is due to their having been inadvertently omitted from publication in the **Federal Register**, even though OMB approval had been obtained. When control numbers in this document differ from those currently listed in 30 CFR, it is due to a correction of errors or an earlier consolidation of control numbers. In other cases, OMB control numbers currently listed at the end of individual paragraphs were removed previously from OMB's List of Active Information Collections Approved Under the Paperwork Reduction Act, but not removed from 30 CFR. OMB removed some of these numbers as a result of a 1990 Supreme Court decision on third-party disclosure rendering some types of regulations no longer applicable for OMB review under the 1980 Paperwork Reduction Act. In some cases, MSHA converted a reporting requirement to certification as provided in 44 U.S.C. 3501-3520.

MSHA has determined that public notice and comment is "unnecessary" in this rulemaking because the reformatting of OMB control numbers from the end of the regulatory information collection sections to a

composite list constitutes a minor technical amendment which contains no new requirements. As a result, MSHA finds that there is "good cause" under 5 U.S.C. 553 (b)(B) of the Administrative Procedure Act (APA) to issue this table without prior public notice and comment. In addition, MSHA has determined that delaying the effective date is "unnecessary" because the technical amendment contains no new requirements for which the public would need time to plan compliance. MSHA finds, therefore, that there is "good cause" to except this action from the 30-day delayed effective date requirement pursuant to 5 U.S.C. 553(d)(3) of the APA.

List of Subjects in 30 CFR Part 3

Reporting and recordkeeping requirements.

Dated: June 23, 1995.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

Accordingly, under the authority of 30 U.S.C. 957, chapter I of title 30, Code of Federal Regulations is amended as set forth below.

1. Subchapter A heading in chapter I is revised to read as follows:

Subchapter A—Official Emblem and OMB Control Numbers for Recordkeeping and Reporting

2. Part 3 is added to subchapter A to read as follows:

PART 3—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Authority: 30 U.S.C. 957; 44 U.S.C. 3501-3520.

§ 3.1 OMB control numbers.

The collection of information requirements in MSHA regulation sections in this chapter have been approved and assigned control numbers by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. Regulation sections in this chapter containing paperwork requirements and their respective OMB control numbers are displayed in the following table:

TABLE 1.—OMB CONTROL NUMBERS

30 CFR citation	OMB control No.
Subchapter B—Testing, Evaluation, and Approval of Mining Products	
7.3	1219-0100
7.4 (a)	1219-0100
7.6 (c)	1219-0100