from the airport to a point 5 miles on the 090° bearing from the airport; and that airspace extending upward from 3,500 feet MSL to and including 4,800 feet MSL within a 10-mile radius of the Burbank-Glendale-Pasadena Airport from the 104° bearing clockwise to the 004° bearing from the airport excluding that airspace south of the north boundary of the Los Angeles, CA, Terminal Control Area, and excluding that airspace beyond an 8-mile radius north and east of the 294° bearing, and excluding that airspace beyond 5 miles north and east of a line from a point 8 miles on the 343° bearing from the airport to a point 5 miles on the 004° bearing from the airport.

Issued in Washington, DC, December 3, 1987.

Daniel J. Peterson,

Manager, Airspace-Rules and Aeronautical Information Division.

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Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 333 and 369

Topical Antimicrobial Drug Products for Over-the-counter Human Use; Final Monograph for OTC First Aid Antibiotic Drug Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333 and 369

[Docket No. 76N-0482]

Topical Antimicrobial Drug Products for Over-the-counter Human Use; Final Monograph for OTC First Aid Antibiotic Drug Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) topical first aid antibiotic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on topical first aid antibiotic drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

DATE: December 12, 1988.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 1, 1977 (42 FR 17642), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical antibiotic drug products (21 CFR Part 342), together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial II Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 30, 1977. Reply comments in response to comments filed in the initial comment period could be submitted by August 1, 1977.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed rule, in the form of a tentative final monograph, for OTC first aid antibiotic drug products was published in the **Federal Register** of July 9, 1982 (47 FR 29986). FDA proposed to add a new Subpart B to Part 333 rather than continue the rulemaking under Part 342 as designated in the advance notice of proposed rulemaking for OTC topical antibiotic drug products. The redesignation of parts is discussed further in the tentative final monograph at 47 FR 29986. Interested persons were invited to file by September 7, 1982, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by November 8, 1982. New data could have been submitted until July 11, 1983, and comments on the new data until September 9, 1983. Final agency action occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC first aid antibiotic drug products.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but is using instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).

As discussed in the proposed regulation for OTC topical first aid antibiotic drug products (47 FR 29986), the agency advises that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after December 12, 1988, no OTC drug products that are subject to the monogrpah and that contain nonmonograph conditions, i.e., conditions that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date and, as soon as they comply, a Form 6 (Form FD 356H, formerly Form FD 1675) will no longer be required. (See comment 2 below.)

In response to the proposed rule on OTC topical first aid antibiotic drug products, a bi-state drug information center, a drug manufacturers' association, and three drug manufacturers submitted comments. Copies of the comments and data received are on public display in the Dockets Management Branch. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

In proceeding with this final monograph, the agency has considered all objections and the changes in the procedural regulations.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of September 7, 1973 (38 FR 24391) or to additional information that has come to the agency's attention since publication of the notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comments

A. General Comments on OTC First Aid Antibiotic Drug Products

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464); in paragraph 3 of

the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260); and in paragraph 1 of the preamble to the tentative final monograph in the present proceeding (47 FR 29987). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers v. FDA*, 487 F. Supp. 412 (S.D.N.Y 1980), *aff'd* 637 F.2d 887 (2d Cir. 1981).

2. One comment stated that antibiotic dosage forms that would appear in 21 CFR Part 333 would be, by definition, generally recognized as safe and effective, and that agency approval of a Form 6 should not be required before marketing. The comment pointed out that this approach would be consistent with the requirements for all other OTC drug products that are subjects of OTC drug monographs and that were previously considered new drugs. Therefore, the comment requested that the requirement for a Form 6 be deleted for any antibiotic drug product that is subject to the final monograph on OTC first aid antibiotic drug products. The comment added that if Form 6 requirements are to be retained, then the effective date of the final monograph should be 24 months, rather than 12 months, after publication of the final rule. The comment pointed out that, although 12 months would be reasonable for most other drug products included in the OTC drug review, the Form 6 requirement for antibiotic drug products makes them a special case because FDA preapproval of the Form 6 submissions for manufacturing, control, and labeling changes is a time-consuming process.

The agency agrees that approval of an abbreviated antibiotic application (formerly a Form 6) is not a prerequisite to marketing an antibiotic drug product that meets the requirements of this final monograph. OTC drug products that meet the conditions established in Part 330 and the applicable monograph are generally recognized as safe and effective and not misbranded and may be marketed without an approved application or abbreviated application.

The agency recently revised 21 CFR 433.1 to make clear that an antibiotic drug that meets the general requirements established in 21 CFR 330.1 and the requirements of a final OTC drug monograph is exempt from the batch certification requirements of section 507 of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) even without having an approved antibiotic application (formerly a Form 5) or an abbreviated antibiotic application. This clarification was proposed in the **Federal Register** of July 22, 1985 (50 FR 29702) and made final in the **Federal Register** of July 15, 1986 (51 FR 25523).

Because the final monograph does not become effective until 12 months after its publication, technically an abbreviated application would continue to be required for one year after publication of the final rule. The agency does not believe that this requirement is necessary for first aid antibiotic drug products that comply with the conditions of the final monograph. Therefore, manufacturers may market products that comply with the final monograph without an approved abbreviated application during this period, i.e., between December 11, 1987, and December 12, 1988. Manufacturers currently marketing these products under an approved abbreviated application should notify FDA when the product is being marketed under the final monograph, so that the applicability of the abbreviated application can cease. Eventually, FDA will revoke all applications and abbreviated applications that are in effect for products covered by the final monograph.

The request that FDA give a later effective date to the monograph to allow time for Form 6 approvals is moot because an abbreviated application (Form 6) is not required if the first aid antibiotic product meets the conditions of the final monograph.

3. One comment requested that conflicts between the tentative final monograph for OTC topical antibiotic drug products and the existing antibiotic regulations be resolved by incorporating appropriate sections of the existing antibiotic regulations in Subparts F of Parts 444, 446, and 448 into the OTC first aid antibiotic monograph and by deleting those portions that are so incorporated from the antibiotic regulations. The comment contended that this action would eliminate the confusion caused by conflicting requirements for a single product as well as distinguish clearly between antibiotic products that are generally recognized as safe and effective for OTC use and those that are still subject to prescription dispensing and premarketing approval. The comment stated that if necessary, to ensure a safe and effective product, the detailed standards and testing requirements found in the antibiotic regulations may be retained in the OTC drug monograph.

The agency agrees that appropriate portions of the regulations on dermatologic dosage forms in Parts 444, 446, and 448 should be incorporated into the final monograph for OTC first aid antibiotic drug products. The agency consequently is revising the format proposed in the tentative final monograph. The agency is not grouping and combining antibiotic ingredients on the basis of antibacterial activity, and including a cross-reference to Subpart F of Parts 444, 446, and 448. In this final monograph, FDA is including a complete listing of the antibiotic active ingredients (§ 333.110) and the combinations of those ingredients (§ 333.120) that are generally recognized as safe and effective, as well as the concentrations permitted for each of those ingredients and the appropriate dosage forms for the products. The dosage forms included in the monograph reflect those dosage forms currently identified in Subpart F of the specific antibiotic regulations (Parts 444, 446, and 448) that apply to OTC first aid antibiotics. There is an established testing methodology, derived from approved antibiotic applications, for these first aid antibiotic ingredients and combinations in the antibiotic regulations. The final monograph also includes references to the appropriate tests and methods of assay that are set forth in the existing antibiotic regulations and that are applicable to particular antibiotic ingredients and combinations.

All drug products included in the final monograph for OTC first aid antibiotic drug products are generally recognized as safe and effective and not misbranded. Therefore, they do not need premarket approval and are exempt from batch certification requirements. For both marketing control and agency regulatory purposes, it is necessary that appropriate standards and methodology i.e., tests and methods of assay, be established before a first aid antibiotic drug product can be considered generally recognized as safe and effective for OTC use. Any firm interested in marketing a single monograph ingredient in a dosage form not included in the monograph, or a combination of monograph ingredients not currently included in the monograph, may submit an antibiotic application to FDA for review and evaluation or file a petition (with appropriate supporting data, including proposed standards and methodology) to amend the monograph.

4. One comment disagreed with the agency's tentative decision to transfer products and claims for skin wound protectants that do not contain antimicrobial active ingredients to the rulemaking for OTC skin protectant drug products. The comment argued that, although a skin wound protectant may not contain an antimicrobial ingredient, the indications for use of the product (protect wounds against microbial contamination) place it more appropriately in the rulemaking for OTC topical antimicrobial drug products than in the rulemaking for OTC skin protectant drug products. The comment contended that skin protectants are generally used on intact skin and do not serve the same function as skin *wound* protectants, which are indicated for prevention of wound contamination by providing a physical barrier to the entry of dirt and bacteria. The comment added that if the absence of active [antimicrobial] ingredients prohibits the inclusion of skin wound protectants in the monograph for OTC antimicrobial drug products, then there is justification for classifying skin wound protectants that act only as a physical barrier to contamination as medical devices because skin wound protectants "act simply as a physical barrier to contamination and do not affect the structure or function of the body or exert a microbiocidal effect."

The agency believes that the concerns raised by the comment are rendered moot by FDA's decision not to adopt the Panel's recommendation for separate categories of "skin wound protectants" and "skin wound antibiotics." This rulemaking is intended to address only OTC topical drug products that contain antibiotics. Therefore, as FDA explained in the tentative final rule, only one category is necessary for this rulemaking—"first aid antibiotics."

FDA is placing all products that are considered as "skin wound protectants" and that do not contain an antibiotic in the skin protectant rulemaking for consideration of the skin wound protectant claims. The tentative final monograph for OTC skin protectant drug products, published in the Federal Register of February 15, 1983 (48 FR 6820), includes in proposed § 347.50(b) (1) the indication "For the temporary protection of minor cuts, scrapes, burns, and sunburn." This skin protectant category, which is similar to the skin wound protectant indication recommended by the Antimicrobial II Panel (42 FR 17680), covers the type of product described in the comment.

Because this final monograph applies only to products containing an antibiotic, the agency is not considering in this document the issue of whether skin wound protectants that do not contain antimicrobials should be subject to the skin protectant rulemaking or be considered a medical device. That issue will be discussed in the rulemaking for OTC skin protectant drug products.

B. Comments on Labeling of OTC First Aid Antibiotic Drug Products

5. One comment contended that FDA does not have the statutory authority to prescribe exclusive list of terms from which indications for use of OTC drug products must be drawn and to prohibit labeling terminology which is truthful, accurate, not misleading, and intelligible to the consumer. The comment also expressed its intention to make a more detailed statement on the exclusivity policy at the September 29, 1982 hearing on this issue.

In the Federal Register of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under the final rule, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph where exact language has been established and identified by quotation marks in an applicable monograph or other regulation, e.g., 21 CFR 201.63 or 330.1(g).

In the tentative final monograph (47 FR 29999), supplemental language relating to indications had been proposed and captioned as *Other Allowable Indications* and *Other Allowable Statements*. Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph. However, the agency has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under that monograph. (See part III. paragraph 3. below—SUMMARY OF SIGNIFICANT CHANGES FROM THE PROPOSED RULE.)

6. One comment disagreed with the agency's proposed substitution of the word "doctor" for "physician" in OTC drug labeling. The comment stated that because "physician" is a term that is recognized by people of all ages and social and economic levels, there is no need for the change, which would be costly and provide no benefit. The comment further contended that "physician" is a more accurate term, whereas "doctor" is a broad term that could confuse and mislead the lay person into taking advice on medication from persons other than medical doctors, such as optometrists, podiatrists, and even chiropractors. Another comment favored the use of common, simple, and easily understood language in labeling. This comment noted that both "doctor" and "physician" are equally accurate and meaningful and argued that neither term should be prohibited, but instead flexibility to use either term should be allowed.

In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs, including the one for OTC first aid antibiotic drug products, to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulation will give manufacturers the option of using either the word "physician" or the word "doctor." This final monograph provides that option (see § 333.150(e)).

7. Noting that the Panel defined an antibiotic as an agent that either destroys susceptible bacteria or arrests their development, one comment disagreed with the agency's proposed Category II classification of the claim "Helps kill bacteria." The comment contended that this claim is accurate "in that an antibiotic is capable of either killing bacteria or affecting them so that

they can be eliminated more easily by the body's natural defenses." The comment argued that this claim has been used for decades with no known harm to the consumer due to product misuse and that, because first aid antibiotics are not indicated for treatment of infection, the potential for harm due to misuse is also reduced. According to the comment, the agency's concern is theoretical and not substantiated. The comment requested that the agency allow the phrase "helps kill bacteria" as a Category I claim for OTC first aid antibiotics.

In the tentative final monograph, the agency noted that "according to the definition in section 507(a) of the act (21 U.S.C. 357(a)), antibiotics have the capacity to inhibit or destroy microorganisms." (See comment 12, 47 FR 29991.) However, the agency expressed its belief that "the claim 'helps kill bacteria' is misleading to the average consumer because the word 'kill' implies elimination of all bacteria on the skin when, in fact, topical antibiotics only decrease the number of certain bacteria on the skin." The agency still believes that the claim "helps kill bacteria" could be potentially misleading to the average consumer if directly associated with the term "infection" that is included in the indication. However, the agency acknowledges that this information is familiar to the average consumer and may be useful in describing the product's action or intended effect. Therefore, the agency would allow the claim to be included in labeling provided it is not intermixed with monograph labeling.

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. One aspect of the program is to develop standards for certain parts of the labeling of OTC drug products. FDA has found that it is simply not practical—in terms of time, resources, and other considerations—to set standards for all labeling found on OTC drug products. Accordingly, OTC drug monographs directly address only those labeling items that are related in a significant way to the safe and effective use of covered products by lay persons. These labeling items are the product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

The agency finds that the claim "helps kill bacteria" requested by the comment, while descriptive of the action of first aid antibiotic drug products, does not relate in a significant way to the safe and effective use of these products and, therefore, is outside the scope of the monograph.

However, the OTC drug review is also intended to ensure that OTC drug products are not misbranded. Therefore, the agency evaluates claims made on OTC drug product labels on a product-by-product basis, under section 502 of the act (21 U.S.C. 352), to determine whether those claims are false or misleading. Any claim that is outside the scope of the monograph, even though it is truthful and not misleading, may not appear on any portion of the labeling that is required by the monograph. Such a claim also may not detract from the required information. Therefore, the claim requested by the comment may be included on the labeling of OTC first aid antibiotic drug product provided that it is not intermixed with labeling established by the monograph, and that it is not false or misleading.

C. Comments on Gramicidin

8. One comment objected to the Category III classification of gramicidin for safety, stating that the Antimicrobial II Panel apparently decided that gramicidin should be placed in Category III because it "is a potent hemolytic agent." The comment contended that the data supporting this conclusion appear to be quite sparse and are probably a carry-over from the remote observation by Heilman and Herrell (Ref. 1) in 1941 that tyrothricin, a crude preparation containing tyrocidine and gramicidin, had in vitro hemolytic properties against rabbits' and sheep's erythrocytes. The comment cited the animal study by Robinson and Molitor (Ref. 2) as indicating that relatively large intravenous or intraperitoneal doses of gramicidin suspensions were needed to show toxicity. The comment contended that the doses used in this study should be compared with a daily topical human dosage of 0.0083 milligram per kilogram (mg/kg) (0.25 mg gramicidin per gram (g) of ointment, assuming application of 2 g ointment per day to a 60-kg subject). The comment also cited a report (Ref. 3) in which it was noted that an unpublished study by Leyden reports that gramicidin was not detected in the serum or urine of eight subjects with widespread atopic dermatitis or psoriasis who were treated twice daily for 7 days with 30 g of a cream containing (among other antibiotics) gramicidin 0.25 milligram per gram (mg/g).

The comment further noted that the safety and efficacy of gramicidin have been fully discussed in data submitted to FDA (as part of the drug efficacy study implementation (DESI) program) concerning a certified prescription topical product containing gramicidin, neomycin sulfate, nystatin, and triamcinolone acetonide. The comment concluded that the extensive use of gramicidin for over 20 years in both OTC and prescription topical preparations has not resulted in any reports of adverse effects related to any possibility of gramicidin toxicity.

After reevaluating the information on the safety of gramicidin and considering the data cited by the comment, the agency concludes that gramicidin is not generally recognized as safe for OTC use as a first aid antibiotic. The Panel recommended that the safety of gramicidin be studied to determine both systemic and topical toxicity. The Panel said specifically that the amount of gramicidin absorbed through the skin following topical application and the hemolytic (red blood cell breakdown) potential of gramicidin resulting from absorption through fresh superficial wounds need to be determined (42 FR 17660). This information has not been provided.

The agency disagrees with the comment that evidence of hemolytic activity of gramicidin is sparse and notes that reports of such activity were published after the report cited by the comment (Ref. 1). Although, as the comment stated, Heilman and Herrell (Ref. 1) first reported that crude tyrothricin was hemolytic, they later reported that purified gramicidin was also hemolytic (Ref. 4). Dubos and Hotchkiss (Ref. 5) and Rammelkamp and Weinstein (Refs. 6 and 7) concluded that the hemolytic effect of tyrothricin was primarily the result of the tyrocidine content of tyrothricin, although they noted that gramicidin in high concentrations also exhibited hemolytic and leukocytolytic effects. There have also been some reports in which gramicidin was modified in an attempt to reduce the hemolytic activity (Ref. 8, 9, and 10). Lewis et al. (Ref. 8) found that treatment of gramicidin with formaldehyde lowered the hemolytic activity of gramicidin 80 to 90 percent without decreasing its antibacterial properties. Schales and Mann (Ref. 9), although noting that the hemolytic effect of gramicidin was considerably slower than that of tyrocidine, found that various gramicidin derivatives had hemolytic activity that varied from 2 to 87 percent of that of gramicidin. Rambhav and Ramachandran (Ref. 100) evaluated the hemolytic activity of gramicidin and several modified gramicidins and concluded that the

peptide-bound ethanolamine residue was implicated in the hemolytic activity of gramicidin.

Even though Robinson and Molitor (Ref. 2) reported that gramicidin was not toxic when given orally (at 1,000 mg/kg) or injected subcutaneously or intradermally, gramicidin was highly toxic upon parenteral administration. Acute parenteral dosages of 1.25 mg/kg gramicidin administered intravenously or 10 mg/kg administered intraperitoneally were not lethal in mice. The lethal dose for mice by the intravenous route was 3.75 mg/kg.

In most dogs, daily intravenous dosing of gramicidin at 2 mg/kg was lethal within 2 to 3 days. Robinson and Molitor noted that in the case of tyrothricin, daily blood examinations showed that all dogs receiving 2 to 4 mg/kg tyrothricin developed marked leucocytosis. Dogs tolerating more than 10 consecutive doses of the drug became anemic, the erythrocyte count ranging from 2.06×10^5 to 3.95×10^5 cells per cubic millimeter. One dog with marked leucocytosis and anemia returned to normal after 2 months during which no drug was given. Robinson and Molitor suggested that this finding might indicate that the anemia caused by daily injections of tyrothricin is related to the hemolytic properties, which it can display in vitro. The authors noted that gramicidin had no apparent effect upon the blood picture during the short period that the animal survived. They also suggested that equivalent doses of gramicidin might have a similar effect as tyrothricin if the animal could tolerate a larger number of consecutive doses.

Robinson and Molitor noted that the impossibility of preparing true aqueous solutions of gramicidin made it difficult to interpret the data, particularly the data from the intravenous test groups in which physical factors such as large particle size may influence the results. They suggested that in view of the insolubility of gramicidin, it is possible that the effects observed were not caused by a specific pharmacodynamic action but rather were caused by nonspecific physical or physicochemical properties. Robinson and Molitor concluded that it is doubtful whether the toxicological results they reported of parenteral use in animals would have a direct bearing on the clinical use of gramicidin topically, except that application to deep lacerated wounds might approach the experimental conditions present in intravenous injection. Therefore, they cautioned against use of gramicidin where rapid and direct absorption into the bloodstream is likely to occur. As noted above, the Panel was concerned about the hemolytic potental of gramicidin resulting from absorption through fresh superficial wounds. The agency concurs based on the above discussion.

As the comment noted, Leyden (Ref. 3) reported that no significant blood or urine levels could be detected in human subjects after very extensive topical application of a cream containing 0.25 mg/g gramicidin, neomycin sulfate, and polymyxin B sulfate to atopic dermatitis or psoriasis. However, only eight subjects were studied. A limited report of this type is not adequate to establish general recognition of the safety of this ingredient for OTC first aid use. The report does not indicate whether the drug was applied to intact or broken skin, does not describe the assay method, and does not state how many subjects were treated with the cream that contained gramicidin or how many were treated with an alternate ointment that did not contain gramicidin. The information provided seems, on the whole, rather limited especially when the no-effect toxic dose of gramicidin is unknown.

The comment also referred to a prescription product containing gramicidin in combination with other ingredients that is being evaluated under the agency's DESI program. As discussed in comment 9 below, the agency concluded in a DESI notice published in the **Federal Register** of April 17, 1985 (50 FR 15227) that the combination drug policy is satisfied with respect to nystatin and triamcinolone acetonide, two of the four ingredients in the prescription product, for the treatment of cutaneous candidiasis, and the company has agreed to reformulate the product to delete neomycin and gramicidin, the other two ingredients (Ref. 11).

The agency concludes that sufficient data have not been submitted on the absorption of gramicidin and on the hemolytic potential of gramicidin resulting from absorption through fresh superficial wounds. Accordingly, gramicidin is not being included in this final monograph.

References

(1) Heilman, D., and W.E. Herrell, "Hemolytic Effect of Gramicidin," *Proceedings of the Society for Experimental Biology and Medicine*, 46:182–184, 1941.

(2) Robinson, H.J., and H. Molitor, "Some Toxicological and Pharmacological Properties of Gramicidin, Tyrocidine, and Tyrothricin," *Journal of Pharmacology and Experimental Therapeutics*, 74:75–82, 1942.

(3) Bushby, S.R.M., "Blood Concentrations Following Topical Application," *in* "Over-the-Counter Topical Antibiotic Products: Data on Safety and Efficacy," V. Anderson, editor, *International Journal of Dermatology*, 15 (Supplement): 79–82, 1976.

(4) Herrell, W.E., and D. Heilman, "Experimental and Clinical Studies on Gramicidin," *Journal of Clinical Investigation*, 20:433, 1941.

(5) Dubos, R.J., and R.D. Hotchkiss, "The Production of Bactericidal Substances by Aerobic Sporulating Bacilli," *Journal of Experimental Medicine*, 73:629–640, 1941.

(6) Rammelkamp, C.H., and L. Weinstein, "Hemolytic Effect of Tyrothricin," *Proceedings of the Society for Experimental Biology and Medicine*, 48:211–214, 1941.

(7) Rammelkamp, C.H., and L. Weinstein, "Toxic Effects of Tyrothricin, Gramicidin, and Tyrocidine," *Journal of Infectious Diseases*, 71:166–173, 1942.

(8) Lewis, J.C., et al. "Modification of Gramicidin through Reaction with Formaldehyde," *Science*, 102:274–275, 1945.

(9) Schales, O., and G.E. Mann "Gramicidin Derivatives. I. Preparation; Hemolytic and Bacteriostatic Properties," *Archives of Biochemistry*, 15:357–371, 1947.

(10) Rambhav, S., and L.K. Ramachandran, "The Chemical Modification of Peptide Antibiotics: Part II—The Relative Roles of Ethanolamine and Indole Groupings in the Biological Activity of Gramicidin," *Indian Journal of Biochemistry and Biophysics*, 9:225–229, 1972.

(11) OR 000003, Docket No. 84N–0067, Dockets Management Branch.

9. One comment disagreed with the Category III classification of gramicidin for effectiveness. The comment submitted three studies that it claimed demonstrated the effectiveness of gramicidin (in combination with neomycin) (Refs. 1, 2, and 3) and pointed out that the Panel considered the combination of gramicidin D and neomycin to be rational because it broadens antibacterial coverage against the gram-positive organisms most likely to be found in superficial skin wounds (42 FR 17678).

As additional support for the effectiveness of gramicidin, the comment cited the agency's acceptance of a study by Dillon, Maddox, and Ware (Ref. 4), along with other data, as "sufficient evidence to support the claim 'first aid to help prevent infection in minor cuts, scrapes, and burns' for all topical antibiotics" (47 FR 29992). The comment concluded that "the Panel itself resolved the efficacy issue vis-a-vis gram-positive organisms and the rationality of the combination with neomycin, and the FDA has now ruled in support of the efficacy of all topical antibiotics while simultaneously revising the indication ('first aid to help prevent infection') in a manner that favors use of a potent, anti-gram-positive, non-systemically used antibiotic." The comment further noted that efficacy and safety had been fully discussed in data submitted to FDA

concerning a certified prescription topical product that contains gramicidin, neomycin sulfate, nystatin, and triamcinolone acetonide.

The comment contended that there is adequate support for a Category I designation for gramicidin for use in combination only, as "first aid to help prevent infection in minor cuts, scrapes, and burns." The comment requested that the agency revise § 333.110(c) to include the following: "Gramicidin 0.25 milligrams per gram for use only in combination as provided in section 333.120."

After reevaluating the information on the effectiveness of gramicidin and considering the data cited by the comment, the agency concludes that gramicidin cannot be included in the final monograph as a first aid antibiotic.

One in vivo study cited by the comment (Ref. 1) shows that a combination of neomycin and gramicidin decreases the number of organisms from experimentally induced *Staphylococcus aureus* infections. In the tentative final monograph, the agency cited this study as one of four references to support the conclusion that "reducing the number of bacteria on the skin may help prevent infection in minor skin injuries. It is well documented in the medical literature that applying topical antibiotics to skin wounds reduces the number of bacteria at the site of application and serves as an adjunct to cleansing wounds." (See 47 FR 29991 to 29992.)

Two of the publications cited by the comment reported the same clinical study (Refs. 2 and 3). In this study, conducted over an 18-month period, 204 children who had sustained major thermal burns received a triple antibiotic cream formulation containing gramicidin, neomycin, and polymyxin B. The results from use of the cream were compared with those from an earlier period without topical chemotherapy against wound infection or with only topical nitrofurazone. The improvement in overall results was significant when the triple antibiotic cream formulation containing gramicidin, neomycin, and polymyxin B was applied topically.

The agency notes that in these studies (Refs. 1, 2, and 3) gramicidin was used in combination with other ingredients, and that there is no evidence to demonstrate the specific contribution that gramicidin made to the combination.

The Panel stated that the gramicidin-neomycin combination "* * * is rational since it broadens antibacterial coverage against the gram-positive organisms most likely to be found in superficial skin wounds, and also decreases the likelihood of encountering a bacterial strain resistant to both antibiotics as well as the chance of developing an infection that might be resistant to both antibiotics" (42 FR 17678). Nevertheless, the Panel concluded that "prudent scientific judgment does not permit the conclusion that merely arguing their efficacy by analogy is sufficient" (42 FR 17678).

The study by Dillon, Maddox, and Ware (Ref. 4), which did not involve gramicidin, was cited by the agency to demonstrate that antibiotics that have been shown to inhibit or to reduce the number of bacteria under non-OTC conditions in induced wounds or in major wounds can also be presumed to be effective in helping to prevent infection under OTC conditions in minor cuts, scrapes, and burns. The agency's statement on this study in the preamble to the tentative final monograph was intended to show that a claim of "first aid to help prevent infection" was appropriate for OTC topical antibiotics that have sufficient effectiveness data. However, it was not intended to justify reclassification of gramicidin (or of any other antibiotics for which there are no in vivo data) into Category I (monograph) status.

In addition, the comment referred to a prescription product that contains neomycin and gramicidin in combination with other ingredients and that is being evaluated under the agency's drug efficacy study implementation (DESI) program). Under DESI, the agency concluded in 1972 that this product was possibly effective for all of its labeled indications relating to use in various dermatoses and as an anti-infective agent (37 FR 12856). Subsequently, the agency concluded that the data on this product did not demonstrate that each component made a significant contribution to the claimed effects of the drug. (See the **Federal Register** of September 25, 1981 (46 FR 47408).) On October 20, 1981, the manufacturer of the product (which also submitted the comment at issue) requested a hearing, and on November 24, 1981, it filed data and other information in support of its hearing request.

After the firm submitted this comment to this OTC drug rulemaking, the agency published a DESI notice to grant the firm a hearing on the proposal to withdraw approval of the new drug applications for the prescription product. (See the **Federal Register** of September 17, 1984; 49 FR 36439.) At a prehearing conference held on January 11, 1985, the agency concluded that the combination drug policy is satisfied with respect to nystatin and triamcinolone acetonide, two of the four ingredients in the prescription product, for the treatment of cutaneous candidiasis, and the company agreed to reformulate the product to delete neomycin and gramicidin (Ref. 5). (See the **Federal Register** of April 17, 1985; 50 FR 15227.)

Therefore, the agency concludes that the evidence submitted to date does not demonstrate that gramicidin (alone or in combination) is effective for use as a first aid antibiotic drug product. The agency recommends that a well-designed, double-blinded study be conducted to show in vivo efficacy of gramicidin by itself or as a contributor to a combination.

Accordingly, gramicidin is not being included in this final monograph.

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(5) OR 000003, Docket No. 84N–0067, Dockets Management Branch.

D. Comments on Combination Drug Products

10. One comment requested that FDA expand the proposed allowable concentrations for bacitracin, bacitracin zinc, and neomycin sulfate to include the concentrations of these ingredients in all combinations currently approved for OTC use in the antibiotic regulations. The comment pointed out that § 448.510e permits a bacitracin concentration of 400 units per g for a combination bacitracin-neomycin sulfate-polymyxin B sulfate ointment, and that § 448.513c permits a bacitracin zinc concentration of 400 units per g and a neomycin sulfate concentration equivalent to 3 mg neomycin for a combination bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment. The comment stated that it is not clear why these concentrations were omitted from the tentative final monograph. The

comment added that to resolve these conflicts between the OTC topical antibiotic tentative final monograph and the antibiotic regulations, the tentative final monograph should be revised so that bacitracin and bacitracin zinc concentration could be 400 or 500 units per g, and the allowable concentration for neomycin sulfate could be the equivalent of 3 or 3.5 mg neomycin.

As discussed in comment 3 above, the agency is revising the format for listing monograph antibiotic ingredients from that used in the tentative final monograph. In this final monograph, the agency is listing each generally recognized as safe and effective ingredient and the dosage forms of that ingredient that have been specified in the antibiotic regulations. The agency is also revising the combinations of first aid antibiotic drug products to specify the particular antibiotic ingredients, the concentrations permitted for each of these ingredients, and the dosage forms currently identified in the specific monographs in the antibiotic regulations that apply to OTC drug monograph first aid antibiotics. These revisions correct the conflicts in FDA's proposed regulations that the comment pointed out.

11. Two comments disagreed with the agency's decision not to include antibiotic-anesthetic combinations in the tentative final monograph until data were submitted to show that the population that would use these combinations on skin wounds would not be at risk and until information is submitted to show that the combinations meet the criteria in 21 CFR 330.10(a)(4)(iv) (47 FR 29996).

One of the comments stated that, except for a possible safety issue, sufficient information to meet all the remaining criteria of 21 CFR 330.10(a)(4)(iv) is presently in the record. Both comments pointed out that combinations of certain antibiotics and anesthetics are allowed under the antibiotic certification regulations (§§ 444.542a [neomycin sulfate ointment with 200 milligrams benzocaine per gram of ointment]; 444.542j [neomycin sulfate-polymyxin B sulfate-gramicidin ointment with 10 milligrams benzocaine per gram of ointment]; 448.510a [bacitracin ointment with a suitable local anesthetic]; and 448.510e [bacitracin-neomycin sulfate-polymyxin B sulfate ointment with a suitable local anesthetic]), and that Form 6's for products containing these combinations have been approved by FDA for OTC use. One comment also noted that the Topical Analgesic Panel's recommended monograph for OTC external analgesic drug products (44 FR 69768, 69864; December 4, 1979) provides for combinations of many Category I analgesics, anesthetics, or antipruritics with single Category I topical antimicrobial active ingredients or combinations of Category I topical antimicrobial active ingredients.

The comments contended that the agency's concern that the presence of an anesthetic will mask symptoms of infection is unfounded because OTC antibiotics are indicated for "first aid" use and not for the treatment of existing infections. One comment argued that the absence of a safety issue with OTC use of such combinations is demonstrated by the lack of a single adverse reaction report for such products in the records of FDA's Division of Drug Experience. The comment added that 21 CFR 310.300 and 310.301 require that the holder of an approved antibiotic application report adverse reactions to FDA. The comment requested that the agency include any reports of adverse reactions that are in its files in the administrative record of this proceeding as new data for use in determining whether there is any risk to the population in approving OTC antibiotic-analgesic combinations. The comment stated that the absence of adverse reaction reports in FDA's files constitutes data supporting both the general safety of such OTC combination products and the conclusion that masking of infection should not be a concern. The other comment added that the action of the anesthetic ingredient does not persist for the entire 8- to 24-hour period between applications of the product. Thus, the comment argued, it is hardly conceivable that inclusion of the anesthetic could mask symptoms of a worsening infection and present a hazard to consumers.

Concerning the requirements of 21 CFR 330.10(a)(4)(iv), one comment pointed out that only Category I ingredients would be allowed in these combinations, and that the label claim for the product would be to help prevent infection and to provide relief of pain associated with minor wounds. The comment added that the contribution of the respective ingredients to these claimed effects is known, that the combination does not decrease safety or effectiveness, and that such combination therapy would be rational because it is common knowledge that pain usually accompanies minor wounds.

One comment concluded that the antibiotic-anesthetic combinations permitted under the existing antibiotic certification regulations should also be permitted in the OTC first aid antibiotic monograph and requested that the agency provide for such combinations in the final monograph. The other comment further requested that all combinations of Category I first aid antibiotics and Category I local anesthetics be approved as Category I combinations.

Based on the points raised by the comments and after further review as discussed below, the agency has reconsidered its decision in the tentative final monograph and now agrees with the comments that certain topical antibiotic-anesthetic combinations are Category I.

The agency acknowledges that in the tentative final monograph it pointed out that no data on such combinations had been reviewed by the Panel or submitted in comments (47 FR 29996). The agency stated, however, that it was conceivable that the combination could provide rational therapy for OTC use.

Upon further review, the agency finds that the combination of a topical antibiotic with a local anesthetic has had a marketing history that predates the OTC drug review. For example, on June 29, 1972 (37 FR 12857), a notice on certain OTC topical antibiotic products under the DESI program deferred action on these products pending the results of the OTC drug review. This DESI notice included products containing topical antibiotics combined with the local anesthetic benzocaine (four products) or with diperodon hydrochloride (one product). These antibiotic-anesthetic drug products currently have first aid labeling claims, such as "to help prevent infection" and "as an aid for the temporary relief of discomfort in minor cuts, burns, and abrasions." Also, as the comments noted, combinations of certain antibiotics and anesthetics for topical use are currently allowed under the antibiotic certification regulations. A review of the FDA adverse drug reaction reports failed to show any adverse reaction reports for these combinations.

Both the advance notice of proposed rulemaking (44 FR 69865) and the tentative final monograph (48 FR 5852, 5868; February 8, 1983) for OTC external analgesic drug products provide for combinations of Category I external analgesic, anesthetic, or antipruritic ingredients with Category I topical antimicrobial active ingredients. The agency notes that no adverse comments about masking infection or other objections have been received from the medical community regarding the combination in that rulemaking.

Although the tentative final monograph for OTC external analgesic drug products provides only for combinations of Category I external

analgesic, anesthetic, or antipruritic ingredients with Category I topical antimicrobial active ingredients identified in Part 333, Subpart A, the agency believes that combinations with first aid antibiotics (Part 333, Subpart B) are also appropriate. The combination of a first aid antibiotic and an external analgesic, anesthetic, or antipruritic is similar in action and intended use to the combination of a topical antimicrobial and an external analgesic, anesthetic, and antipruritic and will be included in this final monograph for first aid antibiotic drug products.

The agency agrees with the comment that OTC first aid antibiotics are not labeled for the treatment of existing infections and are limited to use on minor injuries for not longer than 1 week with warnings to stop use and to consult a doctor if the condition persists or gets worse. Accordingly, the agency concludes that combinations of first aid antibiotic and local anesthetic ingredients provide rational concurrent therapy for a significant proportion of the target population and that the combination is suitable for OTC use under adequate directions for use and warnings against unsafe use, as required under § 330.10(a)(4)(iv).

The agency proposed in § 348.50(b)(2) of the tentative final monograph for OTC external analgesic drug products (48 FR 5868) the following indication for local anesthetics: "For the temporary relief of" (select one of the following: "pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following) "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritation,")). This indication is very similar to the indication for first aid antibiotics in § 333.150(b) of this final monograph, which reads, "First aid to help * * * prevent" (select one of the following: "infection," "bacterial contamination," or "infection or bacterial contamination") "in minor cuts, scrapes, and burns." Therefore, it would be reasonable for an individual with a minor cut, scrape, or burn to apply both a local anesthetic drug product and a first aid antibiotic drug product to the same minor wound.

First aid antibiotics are included in the monograph based on labeling that they be used only on small areas of the body for a minor cut, scrape, or burn, and that they bear a warning that they not be applied over large areas of the body. Accordingly, those proposed Category I claims for external analgesic drug products that refer to conditions other than minor wounds, and particularly conditions likely to involve large areas of the body (e.g., sunburn), would be nonmonograph for the topical antibiotic-anesthetic combination drug product.

The agency acknowledges the Panel's concern that the addition of an anesthetic to a topical antibiotic drug product could pose safety problems by masking signs of infection. However, the agency believes that appropriate labeling can be written to alleviate this concern. In the tentative final monograph, the agency proposed the following warning in § 333.150(c)(2): "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor." The rationale for this warning was discussed in comment 9 of the tentative final monograph (47 FR 29990). The agency believes that this warning adequately informs consumers using these products when to consult a doctor, if necessary, even if the product is an antibiotic-anesthetic combination.

A number of topical antibiotic-anesthetic combinations have been marketed OTC for a number of years under current antibiotic monographs in 21 CFR Parts 444 and 448 (see below). FDA is currently including some of these combinations in this final monograph, as discussed below, so that it conforms to the current antibiotic regulations in the Code of Federal Regulations (CFR).

In conclusion, the agency is including in the final monograph only those topical antibiotic-anesthetic combinations that include Category I ingredients from both the external analgesic and first aid antibiotic rulemakings and that are subject to a current CFR antibiotic monograph with labeling containing adequate directions under which the layman can use the drug safely and efficaciously. The following anesthetic-antibiotic combinations currently have CFR monographs:

Section 444.542a(a)(1)(i)(j)—Neomycin sulfate ointment with benzocaine.

Section 444.542c(a)(1)(i)—Neomycin sulfate lotion with diperodon hydrochloride and aluminum dihydroxyallantoinate.

Section 444.542j—Neomycin sulfate-polymyxin B sulfate-gramicidin-benzocaine ointment.

Section 448.510a—Bacitracin ointment (with a suitable local anesthetic).

Section 448.510e—Bacitracin-neomycin sulfate-polymyxin B sulfate ointment (with a suitable local anesthetic).

Neomycin sulfate lotion combined with the local anesthetic diperodon hydrochloride under § 444.542c is not being included in this final monograph. Diperodon has not been included in the rulemaking for OTC external analgesic drug products. Accordingly, a topical antibiotic-anesthetic combination containing diperodon is not being included in the first aid antibiotic final monograph. Because gramicidin is not included in this final monograph, the combination included in § 444.542j is also not being included in the monograph. Both of these combinations still require a drug application to be marketed.

The agency interprets the term "suitable local anesthetic" as currently specified in § 448.510a and § 448.510e of the antibiotic regulations to mean any of the ingredients identified in § 348.10(a) of the tentative final monograph for OTC external analgesic drug products. These are identified as amine or "caine"-type local anesthetics and include:

(1) Benzocaine 5 to 20 percent.

(2) Butamben picrate 1 percent.

(3) Dibucaine 0.25 to 1 percent.

(4) Dibucaine hydrochloride 0.25 to 1 percent.

(5) Dimethisoquin hydrochloride 0.3 to 0.5 percent.

(6) Dyclonine hydrochloride 0.5 to 1 percent.

(7) Lidocaine 0.5 to 4 percent.

(8) Lidocaine hydrochloride 0.5 to 4 percent.

(9) Pramoxine hydrochloride 0.5 to 1 percent.

(10) Tetracaine 1 to 2 percent.

(11) Tetracaine hydrochloride 1 to 2 percent.

Because the above local anesthetics are not yet subject to a final monograph, FDA cannot refer in this first aid antibiotic final monograph to a final regulation that does not currently exist. Nonetheless, consistent with the approach taken by FDA in the final monograph for OTC antacid drug products (21 CFR 331.15), the agency is listing these combinations in general terms as combinations of drug classes rather than combinations of specific ingredients, because the nonantibiotic ingredients are not yet subject to a final rule. FDA is including the following first aid antibiotic-anesthetic combinations in the final monograph: in § 333.120(b)(1) the combination of bacitracin and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient and in § 333.120(b)(2) two combinations of bacitracin-neomycin sulfate-polymyxin B sulfate and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient.

Until the agency makes a determination on which local anesthetic ingredients to include in the final external analgesic monograph, it will take no regulatory action against such products based solely on the combination of ingredients, provided that the combinations are marketed in accordance with this final monograph, contain a local anesthetic as proposed in § 348.10(a) of the tentative final monograph for OTC external analgesic drug products, and are consistent with an antibiotic monograph in 21 CFR Part 444 or Part 448. Products meeting these conditions may be marketed without a drug application.

At this time, because benzocaine is specifically identified as the local anesthetic in a combination that would otherwise have been included in this final monograph, i.e., neomycin sulfate ointment with benzocaine, the agency is likewise withholding action until the external analgesic monograph, which presently proposes to include benzocaine among specific ingredients, is finalized. In the interim, such a combination can continue to be marketed only under a drug application.

When the final monograph for OTC external analgesic drug products is issued, the agency will amend § 333.120(b) (1) and (2) to include the appropriate cross-reference to the local anesthetics included in that monograph. If benzocaine is included in that final monograph, the agency will also amend Part 333 to provide for the neomycin-benzocaine combination.

II. Agency-initiated Changes

1. In the **Federal Register** of April 17, 1985 (50 FR 15107) FDA announced that, under the agency's DESI program, several topical antibiotic drug products that previously were available by prescription had been reformulated, switched from prescription to OTC status, and labeled as first aid antibiotic drug products. These products are bacitracin zinc-polymyxin B sulfate topical powder (§ 448.513d), bacitracin zinc-polymyxin B sulfate topical aerosol (§ 448.513e), and neomycin sulfate-polymyxin B sulfate cream (§ 444.5421). In the **Federal Register** of October 2, 1986 (51 FR 35211), the agency amended the antibiotic drug regulations to provide for a new OTC dosage form of bacitracin-polymyxin B sulfate topical aerosol (§ 448.510f). Because these products are marketed OTC and contain only monograph ingredients, and because CFR antibiotic regulations have been established for these combinations, the agency is including them in this final monograph for OTC first aid antibiotic drug products. Labeling information for these combinations appears in § 333.160 of this final monograph.

One product, described in § 444.5421, was a reformulation of a cream product that originally contained neomycin sulfate, polymyxin B sulfate, and gramicidin. Gramicidin was not included in the reformulated product because of a lack of sufficient evidence to support its effectiveness, either alone or in combination (50 FR 15108). (See also comments 8 and 9 above.) Two products, a powder and an aerosol, described under § 448.513d and § 448.513e, originally contained neomycin sulfate, polymyxin B sulfate, and bacitracin zinc. Neomycin was removed from these products because of concerns about the safety of applying neomycin in aerosol solution or powder dosage forms over extensive burns or wounds (50 FR 15108). Because of these concerns, the agency has determined that neomycin-containing drug products for OTC use should be limited to ointment and cream topical dosage forms. Therefore, neomycin-containing powders and aerosols are not included in this final monograph for OTC first aid antibiotic drug products. In addition, FDA revoked the antibiotic regulation that allowed OTC labeling for a neomycin aerosol product, described in § 444.542d, because this drug product is no longer manufactured (49 FR 34350; August 30, 1984).

2. The agency notes that the labeling directions recommended by the Panel for all topical antibiotics in the advance notice of proposed rulemaking in § 342.50(c) was intended to limit the area of application, namely: "* * * apply a small amount (an amount equal to the surface area of the tip of a finger) directly to the affected area and cover with sterile gauze if desired. May be applied 1 to 3 times daily." (See 42 FR 17681.) In the tentative final monograph, the agency proposed simpler directions that did not limit the amount of product to be applied to an amount equal to the surface area of the tip of a finger (proposed § 333.150(d); 47 FR 29999).

Based on concerns about neomycin toxicity, as discussed below, and to better inform the consumer of the maximum size of an injury that would be suitable for self-treatment, the agency has reevaluated the directions and has decided to adopt directions for use of ointment and cream products based on the Panel's recommendations. These directions, which are set forth in § 333.150(d)(1), state "* * * Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily * * *."

3. Because powder products and aerosol products are applied in a different manner, the agency has added separate directions for using powders and aerosols in § 333.150(d) (2) and (3).

4. Neomycin sulfate was listed in Category III in the Panel's report because of safety concerns about the potential of this ingredient to cause sensitization or antibiotic-resistant staphylococci (42 FR 17666). Neomycin sulfate was reclassified as a Category I first aid antibiotic in the tentative final monograph. After reviewing the Panel's report and the comments, the agency concluded that the short-term use of neomycin in minor cuts and burns would not present a toxicologic risk. The agency concurred with the Panel's conclusion that no further toxicologic testing is needed for neomycin for OTC topical use (47 FR 29995).

The agency has further reviewed neomycin toxicity, including ototoxicity (having a deleterious effect upon the eighth nerve or upon the organs of hearing and balance), that may result from administration by any route when systemic absorption occurs, including application to extensive wounds or burns. In most reports of ototoxicity occurring after topical application of neomycin, "topical" has been interpreted in the broadest sense. For example, it has been interpreted to include irrigation of wounds with solutions of neomycin or intraperitoneal and intrapleural instillations and inhalations (Ref. 1). Moreover, the quantities applied have been comparable to those used in systemic therapy (Ref. 1).

There have been isolated reports of deafness resulting from local application of neomycin-containing preparations to treat extensive skin damage from burns or other causes (Refs. 2 through 7). In most of these reports, the neomycin was applied in aerosol preparations (Refs. 2 through 5). In all cases, treatment was for severe conditions, not for OTC uses commonly encountered (i.e., minor cuts, scrapes, and burns), and the amount of drug used was greater than that being proposed for OTC use.

The agency believes that application of neomycin in an ointment or cream topical dosage form to small areas of the body (minor cuts, scrapes, and burns) would not result in significant systemic absorption. Panzer and Epstein (Ref. 8) reported that single external exposure of normal human skin of the entire body of 6 adult male subjects, and portions of the body of 9 other subjects, to neomycin sulfate ointment for 6 hours

did not result in any percutaneous absorption of neomycin sulfate that could be detected by the usual bioassay methods. Bushby (Ref. 9) reported that Leyden found that no significant blood or urine levels of neomycin could be detected in 8 human subjects with at least 50 percent involvement of their body with psoriasis or atopic dermatitis who were treated twice daily for 7 days with 30 g of either a petrolatum ointment containing neomycin-polymyxin B-bacitracin zinc or a cream containing neomycin-polymyxin B-gramicidin.

Livingood (Ref. 10) found that systemic absorption through burns is more likely to reach measurable blood levels when neomycin sulfate in aqueous solution is applied locally as a compress than when neomycin sulfate ointment is topically applied. Livingood determined blood serum levels or neomycin in 16 patients after neomycin ointment and/or neomycin in aqueous solution had been applied to extensive denuded skin surfaces for at least 1 week. Evidence of systemic absorption of neomycin was found in only 2 of these patients, and in both patients neomycin compresses had been applied on a denuded surface that resulted from second and third degree burns and covered about 20 percent of the body.

The agency concludes that the labeling in this final monograph, i.e., warnings against prolonged use of first aid antibiotic drug products and against use on deep extensive wounds, is adequate for all the antibiotics included in the final monograph, including neomycin. However, the agency believes that it is prudent to specify the dose more fully. Accordingly, as discussed above, the agency has revised the directions in this final monograph to limit the size of the area to be treated by directing consumers to apply only an amount of the product equal to the surface of the tip of a finger. (See also part III. paragraph 7, below—SUMMARY OF SIGNIFICANT CHANGES FROM THE PROPOSED RULE.) The agency believes that the labeling (indications, warnings, and directions) required for OTC first aid antibiotic drug products is sufficient to provide adequate information for the safe OTC topical use of neomycin-containing and other first aid antibiotic drug products.

References

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III. Summary of Significant Changes From the Proposed Rule

1. OTC first aid antibiotic drug products that conform to this monograph are exempt from the requirements for approved applications or approved abbreviated applications or for antibiotic batch certification. (See comment 2 above.)

2. The agency is modifying the "scope" that was proposed in § 333.101 of the tentative final monograph. The scope in this final monograph does not include the phrase "the exemptions established in § 433.1, and the applicable sections of Subpart F of Parts 444, 446, and 448." (See comment 3 above.)

3. The agency has reviewed the labeling proposed in the tentative final monograph and has concluded that the indication proposed in § 333.150(b)(1), "First aid to help prevent infection in minor cuts, scrapes, and burns," and the other allowable indications proposed in § 333.150(b)(2) are very similar and should be combined to avoid duplicative words in the labeling. The section entitled "other allowable statements," proposed in § 333.150(b)(3), has not been included in the final monograph in accordance with the current exclusivity policy. (See comment 5 above.) The revised indication is as follows: "First aid to help" [select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against"] [select one of the following: "infection," "bacterial contamination," or "skin infection"] "in minor cuts, scrapes, and burns."

4. The agency has revised the format for listing antibiotic ingredients and combinations of those ingredients in the monograph to specify the particular antibiotic ingredients, the concentrations permitted for each of those ingredients, and the dosage forms currently identified in the specific monographs in the antibiotic regulations that apply to OTC Category I first aid antibiotics. First aid antibiotic drug products in this final monograph include only those products that have established testing methodology in 21 CFR Parts 444, 446, and 448. Consequently, the agency has modified the format of the final monograph from that proposed in the tentative final monograph, in which antibiotics were grouped and combined solely on the basis of antibacterial activity, without consideration of testing methodology. (See comments 3 and 10 above.)

5. The following combinations are being included in this final monograph: Bacitracin-polymyxin B sulfate topical aerosol, bacitracin zinc-polymyxin B sulfate topical aerosol, bacitracin zinc-polymyxin B sulfate topical powder, and neomycin sulfate-polymyxin B sulfate cream. (See part II, paragraph 1 above—AGENCY-INITIATED CHANGES.) Further, directions that are consistent with the labeling of currently marketed products are being provided for aerosol and powder dosage forms. Aerosol products will bear the following statements under the heading "Directions": "Clean the affected area. Spray a small amount of this product on the area one to three times daily. May be covered with a sterile bandage." Powder products will bear the following statements under the heading "Directions": "Clean the affected area. Apply a light dusting of the powder on the area one to three times daily. May be covered with a sterile bandage." Cream products will have the same directions as ointment products.

6. The agency is including in the final monograph several combinations of first aid antibiotics and local anesthetics. These specific combinations are currently provided for in the antibiotic regulations. (See comment 11 above.) These antibiotic-anesthetic drug products currently have first aid labeling claims such as "to help prevent infection and as an aid for the temporary relief of

discomfort in minor cuts, burns, and abrasions." In addition to the required indication contained in § 333.150(b), the agency is providing in this final monograph that products containing first aid antibiotic ingredients combined with a local anesthetic ingredient may contain an additional indication as follows: "First aid for the temporary relief of" (select one of the following: "pain," "discomfort," "pain or discomfort," or "pain and itching") "in minor cuts, scrapes, and burns." (See § 333.160(b)(2).) As discussed in comment 11 above, claims for OTC external analgesic drug products that refer to conditions other than minor wounds, particularly conditions likely to involve large areas of the body (e.g., sunburn), are nonmonograph for the antibiotic-anesthetic combination drug product.

7. The agency has revised the directions for using first aid antibiotic drug products to better inform the consumer of the maximum size of an injury that would be suitable for self-treatment: The directions for ointment and cream products read as follows: " * * * Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily * * *." (See Part II, paragraph 2, above—AGENCY-INITIATED CHANGES.) Because powder products and aerosol products are applied in a different manner, the directions instruct the consumer to "apply a light dusting of the powder" or to "spray a small amount of this product."

IV. The Agency's Final Conclusions on OTC First Aid Antibiotic Drug Products

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC first aid antibiotic drug products are generally recognized as safe and effective and not misbranded. Specifically, the following ingredients are included in this final rule for OTC first aid antibiotic use: Bacitracin, bacitracin zinc, chlortetracycline hydrochloride, neomycin sulfate, oxytetracycline hydrochloride (for use in combination only), polymyxin B sulfate (for use in combination only), and tetracycline hydrochloride. FDA has determined that the one other ingredient considered in this rulemaking, gramicidin, is a nonmonograph ingredient. Any drug marketed for use as an OTC first aid antibiotic that is not in conformance with the final monograph (21 CFR Part 333, Subpart B) will be considered a new drug within the meaning of section 210(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)) and may not be marketed for this use unless it is the subject of an approved antibiotic application or abbreviated antibiotic application. Conversely, any drug marketed for use as an OTC first aid antibiotic that is in conformance with the final monograph does not need prior approval for marketing.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (47 FR 29986). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC first aid antibiotic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, the requirement for a Regulatory Flexibility Analysis under the Regulatory Flexibility Act does not apply to this final rule for OTC first aid antibiotic drug products because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

As discussed in the **Federal Register** of July 9, 1982 (47 FR 29998), the agency is removing § 369.6 and portions of §§ 369.20 and 369.21 applicable to OTC first aid antibiotic drug products, because these portions of the regulations are superseded by the requirements of this final monograph (Part 333, Subpart B). The items being removed include the entry for "ANTIBIOTICS FOR EXTERNAL USE FOR PREVENTION OF INFECTION" under § 369.20 and the entries for "ANTIBIOTIC-CONTAINING DRUGS FOR EXTERNAL USE FOR PREVENTION OF INFECTION," "BACITRACIN-CONTAINING OINTMENTS," "BACITRACIN (ZINC BACITRACIN)-POLYMYXIN OINTMENT; BACITRACIN-POLYMYXIN-NEOMYCIN OINTMENT," and "OXYTETRACYCLINE AND POLYMYXIN B SULFATE" under § 369.21. Although other regulations concerning an OTC drug product are usually removed when an applicable final monograph is published, the agency is not removing the sections of the antibiotic regulations in Subpart F of Parts 444, 446, and 448 that apply to the tests and methods of assay for those first aid antibiotics that are contained in the final monograph. Instead, the final OTC drug monograph will cross-reference the tests and methods of assay contained in those parts of the regulations, in compliance with section 507(e) of the act (21 U.S.C. 357(e)). (See comment 3 above.)

List of Subjects

21 CFR Part 333

Labeling, Over-the-counter drugs, First aid antibiotic drug products.

21 CFR Part 369

OTC drugs, Warning and caution statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. Part 333 is added to read as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—[Reserved]

Subpart B—First Aid Antibiotic Drug Products

Sec.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

Subpart A—[Reserved]

Subpart B—First Aid Antibiotic Drug Products

§ 333.101 Scope.

(a) An over-the-counter first aid antibiotic drug product in a form

suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 333.103 Definitions.

As used in this subpart:

(a) *Antibiotic drug.* In accordance with section 507(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357(a)), "any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance)."

(b) *First aid antibiotic.* An antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

§ 333.110 First aid antibiotic active ingredients.

The product consists of any of the following active ingredients within the specified concentration established for each ingredient and in the specified dosage form:

(a) Bacitracin ointment containing, in each gram, 500 units of bacitracin in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 448.510a(b).

(b) Bacitracin zinc ointment containing, in each gram, 500 units of bacitracin zinc in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 448.513f(b).

(c) Chlortetracycline hydrochloride ointment containing, in each gram, 30 milligrams of chlortetracycline hydrochloride in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 446.510(b).

(d) Neomycin sulfate ointment containing, in each gram, 3.5 milligrams of neomycin in a suitable water soluble or oleaginous ointment base: *Provided,* that it meets the tests and methods of assay in § 444.542a(b).

(e) Tetracycline hydrochloride ointment containing, in each gram, 30 milligrams of tetracycline hydrochloride in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 446.581d(b).

§ 333.120 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established concentration and in the specified dosage form, and the product is labeled in accordance with § 333.160.

(a) *Combinations of antibiotic active ingredients.* (1) Bacitracin-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 448.510d(b).

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B;

Provided, that it meets the tests and methods of assay in § 448.510e(b).

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided,* that it meets the tests and methods of assay in § 448.510f(b).

(4) Bacitracin zinc-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 448.513b(b).

(5) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, and 8,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B;

Provided, that it meets the tests and methods of assay in § 448.513c(b).

(6) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable ointment base: *Provided,* that it meets the tests and methods assay in § 448.513a(b).

(7) Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each 90-gram container, 10,000 units of bacitracin and 200,000 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided,* that it meets the tests and methods of assay in § 448.513e(b).

(8) Bacitracin zinc-polymyxin B sulfate topical powder containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable base: *Provided,* that it meets the tests and methods of assay in § 448.513d(b).

(9) Neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, 3.5 milligrams of neomycin and 5,000 units of polymyxin B in a suitable water miscible base: *Provided,* that it meets the tests and methods of assay in § 444.542e(b).

(10) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin and 10,000 units of polymyxin B in a suitable vehicle: *Provided,* that it meets the tests and methods assay in § 444.5421(b).

(11) Oxytetracycline hyrochloride-polymyxin B sulfate ointment containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B in a suitable ointment base: *Provided,* that it meets the tests and methods assay in § 446.567b(b).

(12) Oxytetracycline hydrochloride-polymyxin B sulfate topical powder containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B with a suitable filler: *Provided,* that it meets the tests and methods assay in § 446.567c(b).

(b) *Combinations of first aid antibiotic active ingredients and local anesthetic active ingredients.*

(1) Bacitracin ointment containing, in each gram, 500 units of bacitracin and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base: *Provided,* that it meets the tests and methods of assay in § 448.510a(b).

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient.

Provided, that it meets the tests and methods of assay in § 448.510e(b).

§ 333.150 Labeling of first aid antibiotic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "first aid antibiotic."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "First aid to help" [select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against"] [select one of the following: "infection," "bacterial contamination," or "skin infection"] "in minor cuts, scrapes, and burns." Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor."

(2) "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by doctor."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions": (1) *For ointment and cream products.* "Clean the affected area. Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with a sterile bandage."

(2) *For powder products.* "Clean the affected area. Apply a light dusting of the powder on the area 1 to 3 times daily. May be covered with a sterile bandage."

(3) *For aerosol products.* "Clean the affected area. Spray a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage."

(e) The word "doctor" may be substituted for the word "physician" in any of the labeling statements in this subpart.

§ 333.160 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the "Indications" sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations identified in § 333.120(a).* The indications in § 333.150 should be used.

(2) *For permitted combinations identified in § 333.120(b).* In addition to the required indication identified in § 333.150, the labeling of the product may state, under the heading "Indications," the following additional indication: "First aid for the temporary relief of" (select one of the following: "pain," "discomfort," "pain or discomfort" or "pain and itching") "in minor cuts, scrapes, and burns."

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs. When the time intervals or age limitations for administrations of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

2. The authority citation for 21 CFR Part 369 is revised to read as follows:

Authority: Secs. 502, 503, 506, 507, 701, 52 Stat. 1050–1052 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 352, 353, 356, 357, 371); 21 CFR 5.10 and 5.11.

§ 369.6 [Removed]

3. By removing § 369.6, *Warnings required on certifiable antibiotic exempted from prescription-dispensing requirements.*

§ 369.20 [Amended]

4. In § 369.20 *Drugs; recommended warning and caution statements,* by removing the entry for "ANTIBIOTICS FOR EXTERNAL USE FOR PREVENTION OF INFECTION."

§ 369.21 [Amended]

5. In § 369.21 *Drugs; warning and caution statements required by regulations,* by removing the entries for "ANTIBOTIC-CONTAINING DRUGS FOR EXTERNAL USE FOR PREVENTION OF INFECTION," "BACITRACIN-CONTAINING OINTMENTS," "BACITRACIN (ZINC BACITRACIN)-POLYMYXIN OINTMENT; BACITRACIN-POLYMYXIN-NEOMYCIN OINTMENT," and "OXYTETRACYCLINE AND POLYMYXIN B SULFATE."

Dated: July 31, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87–28422 Filed 12–10–87; 8:45 am]

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Friday
December 11, 1987

Part VII

Department of Transportation

Federal Highway Administration

49 CFR Part 383

Commercial Driver Testing and Licensing Standards; Notice of Proposed Rulemaking and Public Forums

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 383

[FHWA Docket No. MC-87-18]

Commercial Driver Testing and Licensing Standards

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking and public forums.

SUMMARY: The FHWA proposes to amend Part 383 of the Federal Motor Carrier Safety Regulations (FMCSRs) to establish minimum standards for State testing and licensing of commercial motor vehicle (CMV) drivers. This document contains alternative proposals for establishing standards which include commercial driver licensing and testing procedures to be used by the States; knowledge, skills, and abilities which drivers of different types of CMVs must possess; and the information to be contained on the commercial driver's license (CDL) issued by the States. The standards also would require that CMV drivers take and pass the appropriate knowledge and skills tests by April 1, 1992, in order to be qualified and licensed to operate a CMV. Under the Commercial Motor Vehicle Safety Act of 1986 (the Act), the standards must be established by July 15, 1988. The FHWA has proposed three alternative approaches for the States to meet the testing and licensing standards. The first alternative requires each State to submit to FHWA a plan for its testing and licensing program that demonstrates that the State is complying with the Act. In the second alternative, the FHWA has proposed specific testing and licensing standards which the State could use as the minimum standards. The first alternative would maximize flexibility to the States to meet the Act by describing State requirements in terms of general performance standards. The second alternative would reduce flexibility in return for a greater degree of national uniformity in commercial driver testing. The third alternative would allow each State a choice between either of the two main alternatives. The FHWA will hold several forums on these proposals to explain the alternatives and obtain comments on them from the public.

DATE: Comments must be received on or before February 9, 1988. Public forums will be held on the dates and places as follows:

Washington, DC—January 19, 1988. The forum will be held in the Federal Aviation Administration Auditorium, 800 Independence Avenue, SW., Washington, DC 20591; Atlanta, Georgia—January 21, 1988; St. Louis, Missouri—January 26, 1988; and Los Angeles, California—January 28, 1988.

All forums will be held 1:00 p.m.—5:00 p.m., local time and will be open to the public. Sites for the forums in Atlanta, St. Louis, and Los Angeles, will be announced locally and in the **Federal Register.**

Individuals who may be interested in participating at any of the forums should express their desire to do so in writing, at least 2 weeks in advance of the forum they will attend, to: Mr. Stanley Hamilton, Office of Motor Carriers, 400 Seventh Street, SW., Washington, DC 20590.

The forums will be chaired by a panel composed of representatives of the FHWA, States, and industry. Speakers are invited to make a short presentation, approximately 5 minutes, which will be followed by an opportunity for questions and comments from the panel. Written information and comments will also be accepted for inclusion in the docket at these forums and may be submitted (preferably in triplicate) to the FHWA representative at the forum.

Additional information on any of these forums is available from Mr. Stanley Hamilton, (202) 366–0665.

ADDRESS: All written comments must be signed and should refer to the docket number that appears at the top of this document and should be submitted (preferably in triplicate) to Room 4205, HCC–10, 400 Seventh Street, SW., Washington, DC 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., ET, Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Jill L. Hochman, Office of Motor Carrier Standards, (202) 366–4009, or Mr. Thomas P. Holian, Office of the Chief Counsel, (202) 366–1350, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

Currently, only 32 States issue some form of a classified driver's license (i.e., a license which makes a distinction between types of vehicles the holder may operate). Of these, only 12 require State-conducted, behind-the-wheel testing of all applicants in a vehicle which represents the type which the driver operates or expects to operate. The other 20 States waive testing if the applicants meet certain conditions, such as certification of training and testing by their employer, and two States recognize training schools. The remaining 18 States and the District of Columbia do not require applicants to demonstrate their driving skills in the types of vehicles they drive or intend to drive. Drivers in these States who may be qualified to drive only a passenger car may also drive an 18-wheeler to a three-axle intercity bus.

The Congress enacted the Commercial Motor Vehicle Safety Act of 1986 (Title XII of Pub. L. 99–570) to address these problems. Section 12005 of the Act directs the issuance of minimum testing standards to ensure the fitness of drivers of CMVs. In general, the standards must include written and driving tests. The written tests must cover the driver's knowledge of Federal regulations related to the safe operation of CMVs contained in Title 49 of the FMCSRs (49 CFR Chapter III) and knowledge of the vehicle's safety systems. The skills tests must be taken in a vehicle representative of the type of vehicle that each person operates or expects to operate. Also, the standards must ensure that persons are qualified to operate a CMV according to regulations published in the FMCSRs, to the extent that these regulations are applicable to such persons. In addition, the standards must ensure that drivers of CMVs which contain hazardous materials are qualified to operate such vehicles and have a working knowledge of the hazardous materials regulations. Finally, minimum scores for passing the tests must be established.

Section 12006 requires establishment of minimum uniform standards for issuance of CDLs by States. At a minimum, each person to whom a CDL is issued must pass written and driving tests that meet the established standards. Also, CDL documents must contain certain information and be tamperproof.

Section 12009 delineates requirements with which States must comply in order to avoid having Federal-aid highway funds withheld. Some of these requirements are related to issuance of a CDL and must be addressed in the proposed driver licensing procedures. Generally, these requirements define the conditions which must be met for a State to issue a CDL, the information a State must provide to the Commercial Driver's License Information System (CDLIS) about its CDL holders, and the checks a State must make of each applicant's driving record before issuing the CDL.

Throughout implementation of the Act, the FHWA has solicited comment from the States, industry, and the general public. These cooperative efforts help to ensure the commercial driver's licensing program is effective and practical. The FHWA used information and recommendations from several sources in developing the alternative approaches in this proposed rule.

In August 1986, the FHWA published an advance notice of proposed rulemaking (ANPRM) at 51 FR 27567 on the feasibility, scope and practical implementation of a single and classified licensing system. The FHWA received 107 comments to Docket MC–125, Notice No. 86–9, by the November 5, 1986, closing date. Additional comments were received after that date and were also considered in developing this document.

The FHWA also received views and comments during two workshops. The first was funded by the FHWA and sponsored by the American Association of Motor Vehicle Administrators (AAMVA) and Highway Users Federation for Safety and Mobility (HUFSAM) on January 22 and 23, 1987, for State, industry, and driver groups. The second was funded and sponsored by the FHWA on July 14 and 15, 1987, for State, industry and driver groups with an interest in the clearinghouse and related licensing issues. In addition, the FHWA considered advice received from the National Motor Carrier Advisory Committee (NMCAC) which conducted two meetings, announced in the **Federal Register** (51 FR 45981 and 52 FR 2814) and open to the public, on January 12–13 and February 4, 1987. The transcripts or recommendations from the workshop and the NMCAC meetings have been included as part of Docket MC–125.

The final rule and request for comments on the Commercial Driver Licensing Standards; Requirements and Penalties published in the **Federal Register** on June 1, 1987, implements provisions of the Act required to be effective July 1, 1987. The FHWA requested comments on several issues in that publication. These comments were considered in developing this proposal. Comments received before and after that final rule are also included in Docket MC–125. Relevant comments and suggestions are addressed as appropriate, in the section discussions which follow.

The final rule issued on June 1, 1987, discussed several question areas, including the definition of a commercial motor vehicle and what types of vehicles should be subject to the requirements of Part 383. For example, this question area considered issues such as the minimum gross vehicle weight rating for which Part 383 would apply, as well as whether and to what degree the requirements should be extended to cover vehicles carrying hazardous materials that are not required to be placarded. Comments have been received on these issues and are being evaluated. The FHWA intends to issue a separate notice of proposed rulemaking to address these concerns.

This document sets forth three alternatives to the standards required by the Act for States to use to test and license CMV operators. Alternative 1 intends to grant maximum latitude and discretion to the States in establishing their CDL program. Alternative 2 is more detailed and specific regarding the design and operation of a State's CDL program. Alternative 3 would provide States a choice of submitting a State plan (Alternative 1) or comply with the detailed and specific regulation (Alternative 2).

The FHWA also seeks comments on the desirability of different levels of CDL program discretion in the final standards than those reflected in the three regulatory alternatives included in this document. Additional suggestions regarding the form and content of the final standards are encouraged. Public comment is also requested on any scientific research or accident data related to driving and testing programs.

Regardless of the regulatory approach finally chosen, it is intended that the issued standards be minimum standards. States would have full discretion to impose additional or more stringent requirements in their CDL program.

Alternative Approaches

The Act was passed because of the public attention and concern for improving safety on the Nation's highways. As a result of these concerns, the Congress reviewed truck safety practices and concluded that standards used by many States to test and license heavy truck and bus drivers are inadequate and nonuniform. To remedy these concerns and assure the public that all CMV operators possess at least the minimum knowledge and skills necessary to safely operate their vehicles, the Act directs the Secretary to develop minimum test and licensing standards which all States must meet.

In response to this mandate, the FHWA considered whether to propose very specific and detailed standards or more general standards that would give the States greater discretion in implementing the testing and licensing programs mandated by the Act. The FHWA has decided to propose two principal alternatives for consideration by the States and other interested parties, and a third alternative that would allow States to use either of the two main alternatives.

The FHWA did not have sufficient information to justify the rejection of either approach to writing minimum standards. Thus, two principal alternatives are included in this proposal for comment and consideration. Under Alternative 1, the States would have maximum flexibility to develop and implement a commercial motor vehicle driver licensing program which meets the requirements of the Act. Each State would be required to submit its plan to the FHWA explaining how its licensing program meets the requirements in the Act. The FHWA would then review each plan to determine whether it is likely to be effective in determining whether a person is qualified to operate a CMV.

Under Alternative 2, the FHWA would issue a relatively detailed level of standards, especially with regard to the content of basic tests, number and type of vehicle classifications, method of testing, and license document information. States would have to meet those specific testing and licensing standards in order to satisfy the requirements of the Act.

The FHWA requests comments on the desirability of each of the two main alternatives. The FHWA also seeks comment on a third alternative—whether the States should have a choice to meet the requirements of the Act using either of the two principal alternatives.

The FHWA believes that all three alternatives meet the requirement in the Act for the establishment of standards for the testing and licensing of CMV operators. The first and third alternatives emphasize the Administration's goal of encouraging the States to develop their own policies to achieve program objectives. They provide States with the maximum administrative discretion possible. To ensure that the mandate of the Act is met, the FHWA will review State plans under Alternative 1 or Alternative 3 if the State chooses to submit a plan. These approaches avoid overly intrusive Federal oversight, and at the same time establish the Federal role to ensure that the State programs meet the intent of the Act. A State program based on the standards presented in Alternative 2 (or if a State chooses to follow the detailed requirements option of Alternative 3) also would meet the requirements of the Act. Even under Alternatives 2 and 3, the States are not restricted to the

standards contained in Alternative 2; States may develop more comprehensive testing and licensing processes which achieve the goals and objectives of the Act. This provision also gives States flexibility in achieving their program objectives.

While maximum latitude and discretion for the States resides with Alternative 1, Alternative 2 would provide the States with some flexibility to improve upon or add to the proposed standards. The FHWA also invites public comment on modifications to Alternative 2 to accomplish the intent of the Act and provide the States with greater flexibility to implement the Act's goals for minimum and uniform testing and licensing procedures. Additional alternatives within the general framework of Alternative 2 could deal with parts of the proposed rule or could propose an entirely different method. For example, a commenter could reflect an alternative for Subpart H—Tests that would give a State complete flexibility on procedures to administer licensing tests. Or, a commenter could propose that standards for Subpart G—Required Driver Knowledge and Skills only contain the broad categories of knowledge and skills, and the details contained in the proposed rule would be provided as a guideline rather than as a mandatory requirement. A commenter could also propose that the testing and licensing standards deal with the initial licensing of a CMV driver and that States have complete flexibility on whether or not, or on what basis to test drivers who apply for license renewals, upgrades, or transfers from another State. These are meant to be examples of suggestions that commenters may wish to make; any other suggestions are also welcome.

Section 12011 of the Act requires that Federal-aid highway funds be withheld from States which do not substantially comply with any requirements of this rule, beginning in FY 1994. Thus, the level of detail contained in the proposed Alternative 2 may influence decisions on the adequacy of State programs. The FHWA requests comments from all States on this issue; those which currently have classified licensing and testing programs, as well as those which do not.

Alternative 3: Narrative Description

The FHWA also requests comment on a third alternative under which each State would decide whether to comply with all of Alternative 1 or all of Alternative 2. The FHWA would stipulate that each State must advise the FHWA on which Alternative it would comply with for testing and licensing persons to drive commercial motor vehicles.

Alternative 3 provides the States flexibility in deciding how to carry out its testing and licensing responsibilities while meeting the minimum Federal standards. Under Alternative 3, each State would have the prerogative to determine which regulatory alternative provides an appropriate framework for managing its activities in a way that best suits the States's own needs.

Commenters should address whether the FHWA should adopt Alternative 3 if the States and other docket commenters are divided in their preference for Alternative 1 or 2. Alternative 3 embodies an implicit trade-off between providing flexibility to the States and achieving uniformity in the licensing and testing of drivers of commercial motor vehicles. In light of these considerations, commenters should address whether they believe Alternative 3 is a desirable or superior alternative and explain why.

Paperwork

While developing the proposed testing and licensing standards, the FHWA recognized that the proposal could impose a major paperwork burden on States and drivers. The FHWA attempted, to the extent practical, to design the three alternatives to make them compatible with testing and licensing procedures now used by the States and to minimize the burden increase. The FHWA, however, believes that an increase in these burdens may be necessary to accomplish the goals and objectives of the Act. The FHWA invites comments on these alternatives, as well as other approaches commenters may suggest, which would reduce the burden without compromising safety. The FHWA is particularly interested in ways to simplify the procedures, minimize the potential expense of licensing CMV drivers, and allow States sufficient latitude to be innovative in the testing of CMV drivers.

The rest of this supplementary section contains a summary of the requirements of the Act addressed by this proposal and a section-by-section analysis of the two alternative approaches.

Section-by-Section Analysis

Two Section-by-Section analyses are included in this proposed notice: Alternative 1 and Alternative 2. Regulatory language for each alternative follows the Section-by-Section analysis.

Alternative 1: Section-by-Section Analysis

Subpart B—License Requirements

This subpart sets forth general requirements that drivers be tested and licensed in accordance with the Act. This proposed subpart is the same in both Alternatives 1 and 2. A full discussion of these general requirements is contained in the Section-by-Section analysis accompanying Alternative 2 below.

Subpart E—State Testing and Licensing Plans

Section 383.71 Formulation of testing and licensing plan.

The FHWA recognizes that the States and their licensing agencies have the capability to develop and implement programs to ensure the fitness of CMV operators consistent with the goals of the Act. Many States are already developing programs which may already comply with the Act and effectively establish that CMV operators have the skills and knowledge necessary to safely operate such vehicles.

Since the Act directs the FHWA to establish minimum standards to ensure the commercial motor vehicles are qualified, the FHWA would require States to develop commercial driver's license plans that meet the Act's objectives.

Each State would be required to submit to the FHWA a plan for its testing and licensing programs. The State's programs would have to meet the driver licensing and testing requirements of sections 12005(a)(1) through 12005(a)(8) of the Act, the licensing requirements of section 12006 of the Act, and the requirements of section 12009.

State plans would show how commercial motor vehicle operators would be required to take and pass written and driving tests and to take their driving tests in a vehicle that is representative of the class or type which they operate. Written tests would need to be designed to test the drivers' knowledge of safe vehicle operations, vehicle safety systems, safe operating procedures for various traffic and weather conditions and relation of cargo to vehicle control at a working level. The written tests must also be designed so that they ensure that drivers of commercial motor vehicles carrying hazardous materials have the appropriate working knowledge of regulations, handling procedures, emergency equipment and response

procedures for hazardous materials transportation.

Section 12005(a)(7) of the Act states that regulations for testing of CMV operators shall ensure that each person taking such test is qualified to operate commercial motor vehicles under regulations issued by the Secretary and contained in Title 49 of the CFR, "to the extent such regulations are applicable to such person." These requirements, found in Part 391 of the FMCSRs, apply to drivers of motor vehicles engaged in interstate commerce. In response to section 12005(a)(7), the proposed rule would require that States demonstrate in their plans the means to ensure that applicants meet the applicable Federal driver qualification requirements if the applicant operates or expects to operate in interstate commerce. States would continue to have the responsibility to establish intrastate driver qualification standards and to determine the applicant's compliance with these standards.

Enforcement of driver compliance with the driver qualifications requirements would continue under current practice of roadside inspections, carrier audits, and other State and Federal enforcement avenues. The driver license agencies would also play a related enforcement role by obtaining required certifications, maintaining commercial driver records, completing required checks of these records, and making appropriate notifications to the CDLIS. States would also have the option to have their driver license agencies assume greater review of driver medical and other qualifications during the licensing process.

Section 383.21 currently requires that persons who operate CMVs shall have only one driver's license. Also, section 12009 of the Act requires that a State not issue a CDL to an individual whose license is suspended, revoked, or canceled or who is disqualified from operating a CMV. To ensure these requirements are met by drivers applying for a CDL, the FHWA proposes that States would include in their plans methods to check and consider information in the CDLIS and the National Drivers Register (NDR) about such drivers before issuing a CDL to determine if the driver is licensed elsewhere and to provide information to the CDLIS as required by the Act.

Section 383.73 Approval of Plan.

States would be required to submit their commercial driver's license program plans to the FHWA no later than July 15, 1989, and within 30 days following any significant change in such plan The FHWA would approve State plans, provided the FHWA determines that these plans are likely to result in an effective program that ensures that only qualified driver applicants are licensed.

The proposed rule also encourages, but does not require, States to periodically review and evaluate their programs. In addition, the FHWA would be able to withdraw its approval in cases where the FHWA determines that the State program is no longer effective, after the State has an opportunity for comment.

Section 383. 75 Third party testing.

Section 12005(c)(3) of the Act allows for third parties to administer driving tests. The FHWA proposes that States may use a third party to administer driving skills tests. According to the Act, a third party may be a person (including a department, agency, or instrumentality of a local government). The FHWA proposal would allow a broad interpretation of this provision to include another State or public or private organizations with which the State has an agreement.

The State would submit to the FHWA its agreements for having a third party administer tests along with its commercial driver's license plans. When the FHWA approves the State's commercial driver's license plan, the third party testing agreements would also be approved.

Section 383.77 Substitute for driving skills test.

This section provides an option to the State to grandfather certain current CMV operators from the driving test. The FHWA proposes the same procedure for Alternatives 1 and 2. A full discussion of the substitute test procedure is contained in § 383.77 of the Alternative 2 Section-by-Section Analysis.

Subpart F—Motor Vehicle Groups and Endorsements

As part of its commercial driver's license program plans, each State would require driver applicants to demonstrate knowledge and driving skills for the category of vehicle for which the applicant requests a license. The FHWA proposes the same vehicle groups and endorsements for Alternatives 1 and 2. A full discussion of the vehicle groups and endorsements is contained in the Alternative 2 Section-By-Section Analysis.

Subpart G—Required Knowledge and Skills

This subpart would require that for a person to be issued a CDL, he/she must be familiar with the FMCSRs and any safety system of the vehicle he/she intends to drive. This subpart also would require all operators of vehicles carrying hazardous materials to have a working knowledge of the hazardous materials regulations issued by the Department. These drivers would also be required to know how to handle hazardous materials, operate emergency equipment, and follow appropriate emergency response procedures. The FHWA requests public comment on whether the hazardous materials knowledge requirements should apply only to drivers of commercial motor vehicles which are placarded.

Subpart H—Tests

This subpart would establish the minimum passing scores for the various tests which States would administer. The minimum passing scores would be the same in both Alternatives 1 or 2. The Subpart H section in the Alternative 2 Section-by-Section Analysis contains a full discussion on minimum scores.

Subpart I—[Reserved]

Subpart J—Commercial Driver's License Document

This subpart includes the standards for CDL documents. The FHWA proposes the same document requirements for Alternatives 1 and 2. Subpart J in the Alternative 2 Section-by-Section includes a full discussion on the document to be issued.

Alternative 2: Section-by-Section Analysis

This section-by-section analysis includes a discussion of each Subpart in Part 383 which is modified by this proposal. Subpart B is modified to require that CMV drivers be tested and licensed in accordance with the Act. Subparts E through J are proposed sections pertaining to testing and licensing procedures, vehicle categories, required knowledge and skills, test giving, and the license document. Subpart I is reserved for the future specifications of the CDLIS. Each of these subparts, beginning with the changes to Subpart B, is discussed below:

Subpart B—License Requirements

Section 383.23 Commercial driver's license.

According to the requirements which became effective on July 1, 1987, drivers of CMVs can have only a single license. This section proposes additional requirements for persons who operate CMVs. After April 1, 1992, all operators of CMVs shall take and pass written

and driving tests that meet the minimum standards promulgated by FHWA. Operators of CMVs with special handling characteristics such as a double trailer combination, or a vehicle required to be placarded for hazardous materials, would also be required to take and pass additional tests to obtain an endorsement to the CDL authorizing him/her to operate such a vehicle. This proposal would also require CMV drivers to posses a CDL while operating a CMV. The CDL would be issued by States only to drivers who pass both the written and driving tests.

To allow novice drivers to obtain the necessary training in a CMV, the FHWA would allow States, if they so choose, to issue limited learner's permits. The issuance of a learner's permit would not be a precondition to issuing a CDL. However, States may choose to make learner's permits available for limited time periods to first-time applicants for use in behind-the-wheel training on public roads or highways and/or taking the required skills tests in traffic. States which issue learner's permits for CMV drivers would do so as a continuation of their existing learner's permit programs and may also require applicants to pass test(s) prior to issuance of the learner's permit for the specific vehicle groups or endorsement desired. Conditions for issuance of a learner's permit and circumstances under which such permits may be used would be determined by the State of issuance.

Subpart E—Testing and Licensing Procedures

This section contains the testing and licensing procedures for CDLs. The proposed tests would be for each vehicle group in which the applicant operates or wishes to operate, and would be at least cover the knowledge and skills described in Subpart G. Knowledge tests could be given in written, oral, and/or automated format. Skills tests would have to be given in a vehicle that is representative of the group of vehicle which the applicant operates or expects to operate.

Verification of Driver Qualifications. Section 12005(a)(7) of the Act states that regulations for testing of CMV operators shall ensure that each person taking such tests is qualified to operate commercial motor vehicles under regulations issued by the Secretary and contained in Title 49 of the CFR, "to the extent such regulations are applicable to such person." These requirements, found in Part 391 to the FMCSRs, apply to drivers of motor vehicles engaged in the interstate commerce. In response to section 12005(a)(7), the proposed rule would require that States include in the commercial driver license application process, a means for applicants to certify that they meet the applicable Federal driver qualification requirements if the applicant operates or expects to operate in interstate commerce. States would continue to have the responsibility to establish intrastate driver qualification standards and to determine the applicant's compliance with these standards.

Enforcement of driver compliance with the driver qualifications requirements would continue under current practice of roadside inspections, carrier audits, and other State and Federal enforcement avenues. The driver license agencies would also play a related enforcement role by obtaining required certifications, maintaining commercial driver records, completing required checks of these records, and making appropriate notifications to the CDLIS. States would also have the option to have their driver license agencies assume greater review of driver medical and other qualifications during the licensing process.

Section 383.71 Driver application procedures.

In general, a CMV operator would obtain his/her license in the State in which he/she is domiciled. The FHWA proposes that every CDL applicant complete the following process to obtain his/her CDL for the first time (other than renewals or transfers):

(a) An applicant subject to 49 CFR Part 391 would certify that he/she meets the driver qualification requirements of Part 391 as a condition to taking the tests;

(b) Pass a knowledge test to demonstrate that he/she is familiar with the regulations designed to ensure the public safety and with the skills needed to safely operate the type of vehicle that he/she operates or expects to operate;

(c) Certify that the vehicle in which he/she will take the driving skills tests is representative of the type of vehicle he/she operates or expects to operate;

(d) Pass the necessary driving skills tests; and

(e) Provide all information required by the standard.

If he/she satisfies all of the requirements described above, surrenders his/her existing noncommercial license and is not disqualified according to Subpart D, then the State may issue the applicant a CDL.

The FHWA proposes that any driver who applies for a renewal of his/her CDL would make the certification of driver qualification, and provide an update of required information. In addition, holders of the hazardous materials endorsement (§ 383.123) would be further tested and must pass the hazardous materials test to retain that endorsement. The hazardous materials endorsement retest would help keep drivers of such vehicles current on changes in the hazardous materials regulations and safety related procedures.

For those commercial drivers who wish to drive a vehicle in a different vehicle group, the FHWA proposes that the driver would make the certification of driver qualification, certify that the vehicle in which he/she takes the driving skills tests is representative of the type of vehicle he/she operates or expects to operate, and pass the tests related to the upgraded vehicle group or endorsement.

Any driver who moves (i.e., changes his/her domicile) from another State or jurisdiction would be required to apply for a new CDL within 30 days of moving and to surrender his/her current CDL as a condition of receiving a new CDL. Such a driver would make the certification of driver qualification and provide any new or updated information. The new State may require that the driver be retested.

Section 383.73 State procedures.

This section outlines the procedures which a State would follow, as a minimum, for the issuance of a CDL which meets the requirements of the Act.

Driver Manual—The FHWA proposes that States would make available to all CDL applicants information on the licensing procedures, qualifications, and tests required by the State and the knowledge and skills each driver applicant must possess. The knowledge and skill requirements are described in Subpart G.

Initial CDL—Prior to the first-time issuance of a CDL to a person, the State would:

(a) Adopt a program for testing and ensuring the fitness of persons to operate CMVs in accordance with the standards;

(b) Ensure that persons choosing to operate in interstate commerce and subject to Part 391 of the FMCSRs make the appropriate certifications regarding their qualifications prior to being issued a CDL;

(c) Issue CDLs only to persons who pass written and driving tests for the operation of a CMV which comply with these standards;

(d) Issue CDLs which contain information and other specifications included in the standard;

(e) For persons moving from another State or jurisdiction, request and consider the applicant's driving record from the prior State of issuance before issuing an initial CDL and require the applicant to surrender his/her noncommercial license;

(f) Not issue a CDL to a person who is disqualified from operating a CMV, or whose driver's license is suspended, revoked, or canceled;

(g) Issue CDLs only to persons domiciled in the State; except persons domiciled in a foreign jurisdiction that does not test and issue licenses meeting the standards may be issued a commercial driver certificate;

(h) Notify the CDLIS of the issuance of a CDL and provide the CDLIS with information on that driver. (The required information will be discussed in a separate rulemaking or other action on the CDLIS.)

The FHWA expects most or all States to develop a licensing program consistent with the Act's requirements. However, if the Administrator determines that a State will not adopt and implement a program to test and license CMV drivers according to standards included in this part by April 1, 1992, FHWA proposes to allow drivers from such States to obtain a commercial driver's certification (CDC) from a State which does conform to the testing standards. The FHWA believes that issuance of a CDC rather than a CDL from another State is the best way to ensure that these drivers do not violate the single license-single record requirement.

Drivers from nonconforming States would be prohibited from obtaining a CDC until October 1, 1991. This period (October 1, 1991, to April 1, 1992) will allow drivers sufficient time to go to another State to apply for a CDC and be tested. The CDCs would be issued according to the standards described in § 383.73 and would be considered a valid CDL only when used in conjunction with the driver's State-issued license.

Multiple License and Driver's Record Check—Section 383.21 currently requires that persons who operate CMVs shall have only one driver's license. Also, section 12009 of the Act requires that a State not issue a CDL to an individual whose license is suspended, revoked, or canceled or who is disqualified from operating a CMV. To ensure these requirements are met by drivers applying for a CDL, the FHWA proposes that States check and consider information in the CDLIS and the National Drivers Register (NDR) about such drivers before issuing a CDL to determine if the driver is licensed elsewhere.

Prior to April 1, 1992, a check of only the CDLIS and the NDR may not yield complete information about the driver because he/she does not yet have a CDL and would not be reflected in the CDLIS. To eliminate this problem, the FHWA proposes that States check with all other States to determine if the driver is licensed elsewhere. By April 1, 1992, all operators of CMVs must be tested and licensed based on the Federal standards. Once licensed, information on all CMV drivers will be contained in the CDLIS and the State can check solely with the CDLIS and the NDR for the license status of the applicant.

Before April 1, 1992, the FHWA proposes that States have the option to perform the check either prior to issuing a CDL or to verify the information for each driver applicant within 60 days after issuing a CDL. This proposal would allow States to complete the necessary checks before the time when the CDLIS is operational. The check may occur by any means, including mail or electronic checks.

During the period before April 1, 1992, a State may determine that a driver to whom it has issued a CDL has a valid license from another State or has a suspended, revoked or canceled license, or has been convicted of or charged with a disqualifying offense from another State. In this case, the State that issued the CDL would suspend or revoke the driver's CDL within 30 days. However, the FHWA believes that after April 1, 1992, and when the CDLIS is fully operational, this provision would no longer be necessary because the States would determine the driver's status before issuing the CDL.

Although the States would not be required by this rule to check the NDR until it is determined to be operational by the National Highway Traffic Safety Administrator, it is recognized that the States are exploring the development of systems which would enable them to access both CDLIS and the NDR prior to that time. Because States are authorized to access the NDR under separate legislation, efforts in this regard are encouraged.

Transfers—The FHWA proposal includes requirements for a person who has a CDL and then changes his/her State of domicile and applies for a CDL from his/her new State. For these cases, the State would have the option to accept the credentials of that driver or to require that the driver be further tested according to its own testing and licensing procedures. At a minimum, the new State of domicile would be required to obtain the certification of driver qualification, information updates and complete the driver record checks that would be required for issuance of an initial CDL. The State would also be required to retest those drivers who wish to retain his/her hazardous materials endorsement. The FHWA believes this proposal would ensure that such drivers continue to be knowledgeable about the safe operations and requirements related to hazardous materials.

Renewals—Under the proposal, State procedures for renewing a CDL would include the certification of driver qualification, updates of information that would be required to be included on the CDL and completion of a check of the driver's record. As mentioned in the earlier section, a driver who desires to retain his/her hazardous materials endorsement would be required to successfully complete the test being given by the State for the hazardous materials endorsement to ensure he/she continues to be knowledgeable about hazardous materials regulations and safety procedures.

Upgrades—The FHWA proposes that the State follow a combination of procedures whenever a driver changes the vehicle group in which he/she is currently licensed to operate. The driver applicant would have to provide the certification of driver qualification and information specified under the renewal section, and would be tested for the different portion(s) of the CDL as if he/she were making an initial application.

License Issuance and Notification—This paragraph in the proposed rule specifies that if the driver applicant has successfully met the requirements for a CDL, he/she can be issued a CDL or CDC. Once the document is issued, the State would inform the CDLIS and provide it with the appropriate information.

Certification of Fitness. Section 12005(a)(8) of the Act allows the Secretary to consider a requirement that States issue certificates of fitness to operate a CWV to each person who passes the required tests. Such a requirement would accommodate drivers whose States do not participate in the commercial driver licensing program and drivers from contiguous foreign countries whose licensing standards do not meet the Federal standards and would ensure that such drivers do not violate the single license requirement. The FHWA proposes that States issue CDCs only to such drivers. Drivers from a State which does not comply would be able to obtain a CDC only after October 1, 1991. Foreign drivers would be able to obtain a CDC

after FHWA determines that their countries or political subdivisions do not test and license consistent with the standard.

A CDC would not be valid as a stand alone document. The CDC would be issued under the same requirements as a CDL and would only be valid in combination with a valid license issued by the drivers' State of domicile or country of residence. The CDC would only be issued after the driver takes and passes tests which meet the Federal standard.

Drivers with these certificates would continue to notify their State of licensure or country of domicile of any violation as described in § 383.31 and of any suspensions, revocations, and cancellations as specified in § 383.33. In addition to notifying the State of licensure, the FHWA proposes that drivers with these certificates would notify the State which issued the CDC of any violation or license suspension, cancellation, or revocations as described in §§ 383.31 and 383.33. This action would ensure that each CMV operator has a driver's record consistent with the goals of the Act in both States. Also, it would ensure that appropriate information about the driver is included in the CDLIS and would ensure that these records can be appropriately monitored by States

CDL Revocation—This paragraph proposes minimum revocation requirements for persons who falsify the information or certification required to be provided by CDL applicants. If a State determines that a person falsified the information, the State would revoke the license within 30 days.

Reciprocity—Section 12009(a)(14) of the Act requires that States allow any person who has a valid CDL and who is not disqualified from operating a CMV, to operate a CMV in the State. The FHWA proposes to include this requirement in § 383.73 as a condition for States to issue a CDL which meets the standards.

Section 383.75 Third party testing.

Section 12005(c)(3) of the Act allows for third parties to administer driving tests. The FHWA proposes that States may use a third party to administer driving skills tests. According to the Act, a third party may be a person (including a department, agency, or instrumentality of a local government). The FHWA proposal would allow a broad interpretation of this provision to include another State or public or private organizations with which the State has an agreement. Because of concerns that third party testers may compromise standards adopted by the States, agreements between States and third parties would need to include the provisions required by the Act as well as additional provisions that would establish mechanisms to ensure that people who pass the tests given by third parties would have passed tests had they taken them from the State. Under the FHWA proposal, third parties may give driving tests if the following conditions are met:

(a) Tests given by the third party are the same as those which the State would give;

(b) The State's agreement with the testing party allows the FHWA or its representative and the State to conduct random examinations, inspections, and audits without prior notice;

(c) The State agrees to conduct on-site inspections at least annually;

(d) All third party examiners meet the same qualification and training standards as State examiners; and

(e) State employees periodically "check-ride" with examiners on actual tests, or States periodically test a sample of drivers who were examined by third parties to compare pass/fail results.

Section 383.77 Substitute for driving skills test.

The FHWA recognizes that CMV drivers are professionals who are, as a group, highly experienced in the skills needed to operate such vehicles. In response to the overwhelming number of comments from the States and the motor carrier industry in this regard, the FHWA proposal provides States an option to allow certain drivers to substitute a good driving record and experience for the driving skills test. States would be able to exercise this option only for the basic skills tests. The provision would not be used for the knowledge tests or the tests related to the proposed endorsements, except for the driving skills test required for the air brake endorsement. The option would apply to drivers of commercial motor vehicles who were licensed before July 15, 1988, and who either (1) have a good driving record and have previously passed an acceptable skills test or (2) have a good driving record in combination with certain driving experience. The FHWA believes that for many current drivers, their experience is an appropriate indication that the individual has the minimum driving skills to operate a commercial motor vehicle. Accordingly, the FHWA believes that this provision would not diminish public safety or overall safe operation of commercial vehicles.

A State which chooses to exercise this option would have to adopt criteria to eliminate certain applicants from consideration under this provision. As a minimum, an applicant must be licensed before July 15, 1988, and must:

(1) Certify that he/she has not committed certain offenses; and

(2) Certify that he/she has previously passed an acceptable skills test or has certain experience driving a commercial motor vehicle.

The FHWA looked at the practices used by several States to determine whether applicants who are transferring their licenses from another State need to take driving tests. Based on these current practices, the FHWA proposes that an applicant would first have to certify that he/she has not violated the single license or disqualification provisions in Part 383. In addition, an applicant could not have a violation of State or local law relating to motor vehicle traffic control (other than a parking violation) arising in connection with any traffic accident or a record of an accident where he/she was at fault, during the 2 years immediately preceding application for a CDL. Second, the applicant would have passed an acceptable skills test—i.e., one which was given by a State with a classified licensing and testing system, and which was taken by the driver behind-the-wheel in a vehicle representative of the type or classification which the applicant operates or expects to operate. In lieu of an acceptable skills test, the applicant may qualify for an exception to the driving skills test that is based on prior experience. In this case, an applicant would be required to have 2 years experience of driving a vehicle that is representative of the type or class of vehicle for which he/she wishes to obtain a CDL. A State would need to ensure that the applicant has this experience through mechanisms such as requiring the employer to provide certification.

Question Area: Licensing Procedures

Comments are specifically requested on:

(1) What proof of domicile, if any, school an applicant be required to provide to the State for initial licensing renewals, upgrades, and transfers? Should applicants be required to provide a specific mailing address rather than a post office box?

(2) The FHWA has proposed that States continue their existing learner's permit programs for CMV drivers. Should there be any Federal standard for learner's permits? What time period, if any, should be included if such a standard were adopted?

(3) When the CDLIS is operational, the statute provides a maximum period of 60 days for States to check the driver's record any up to a 30-day period for States to notify the CDLIS of the issuance of a CDL or CDC. This may be excessive. Should the FHWA shorten these time periods? If so, what would be the appropriate future maximum time periods for the record check and for the notification?

(4) Is it appropriate for the testing and licensing standards to require a CDL holder to retake the complete set of tests, after he/she has had his/her CDL for a certain period of time? For example, should the complete set of tests be required 1 year prior to renewal or 10 years after the applicant first receives a CDL? What timeframes would be appropriate for these cases?

(5) What additional conditions and standards should be contained in the standards for the State agreements for third party testers to limit potential for abuse and conflicts of interest? Would it be appropriate to strengthen or eliminate requirements for such provisions? Should the third party be required to provide evidence to the State when an applicant successfully passes a test?

(6) Should the States be given the option of accepting another State's hazardous materials endorsement instead of retesting the driver when he/she transfer his/her CDL from another State? Also, is it appropriate to require periodic retesting for any driver to retain his/her hazardous materials endorsement as the FHWA has proposed? If so, what timeframe should be required?

(7) The FHWA's proposal requires drivers from States which do not comply with the standard to obtain a CDC. An alternative would be to require such drivers to get a CDL from a State of their choice. In this case, the FHWA's standard could preempt any State residency laws which require individuals who reside in the State to be licensed in that State. What would be the benefits and costs of this alternative as it compares to the FHWA proposal? How could the related legal problems with respect to preemption of State laws be resolved?

(8) In addition to notifying their State of licensure, drivers who obtain a CDC according to the proposal would also need to notify the State which issued the CDC of any violation or license cancellation, revocation, or suspension. These notifications would help ensure that the driver's CDC is invalidated by the State which issued it when and if the driver is disqualified. What methods can be used to ensure that these drivers are notifying both States of the proper information? Are there ways, such as requiring these drivers to get a CDL as suggested in Question 7 above, which can reduce the potential complexity of enforcing these requirements? If so, what are they and how would they be enforced?

Subpart F—Vehicle Groups, Representative Vehicles, and Endorsements.

In accordance with section 12005 of the Act, any applicant for a CDL must demonstrate driving skills in a vehicle which is representative of the type of vehicle such person operates or expects to operate. Four broad vehicle groups are proposed by FHWA to help define the types of vehicles which would be considered acceptable representative vehicles. These groups reflect different vehicle handling characteristics under different traffic conditions and situations. Thus, separate skills and in some cases, knowledge tests are required for each group. These tests are described in Subpart G.

Section 383.91 Vehicle groups.

The four vehicle groups proposed by FHWA are:

"Combination Vehicle"—any combination of vehicles with a Gross Combination Weight Rating (GCWR) of 26,001 pounds or more provided the vehicle or trailer being pulled is at least 10,001 pounds Gross Vehicle Weight Rating (GVWR). Drivers who successfully complete the test requirements for this group may also operate vehicles in the Heavy Straight Truck and Small Vehicle groups without passing additional tests.

"Bus"—any vehicle designed to carry more than 15 passengers, including the driver. Drivers who successfully complete the test requirements for this group may also operate vehicles in the Small Vehicle group without further tests (except for any endorsements required). (An alternative approach to defining the bus vehicle group is discussed at length under the question areas included later in the Preamble for this section of the proposed rule.)

"Heavy Straight Truck"—any vehicle with a Gross Vehicle Weight Rating of 26,001 pounds or more, or any combination of vehicles with a GCWR of 26,001 pounds or more provided the trailer or vehicle being pulled is not greater than 10,000 pounds GVWR. Drivers who successfully complete the test requirements for this group may also operate vehicles in the Small Vehicle group without further tests.

"Small Vehicle"—any vehicle with a GVWR or GCWR of under 26,001 pounds. This group is proposed in order to ensure that operators of vehicles within these weight limits that are required to be placarded for hazardous materials are qualified and have the basic knowledge and skills needed to safely operate such vehicles. (Drivers of vehicles which carry hazardous materials would also be required to obtain a separate endorsement.) Also, individual State licensing requirements for vehicles in these weight limits which would not otherwise be subject to Part 383 could be covered by this proposed group.

Section 383.93 Endorsements.

The FHWA is proposing endorsements to the CDL designed to ensure that the operators of CMVs with specialized handling characteristics possess specialized knowledge and skills related to those vehicles. Drivers of such equipment must demonstrate these knowledge and skills, in addition to the knowledge and skills required for the basic vehicle group. Endorsements are proposed for: (1) Air brakes for any vehicle so equipped which would not be included in the Combination Vehicle Group, (2) double/triple trailers, (3) articulated buses, (4) cargo tanks, and (5) vehicles that carry hazardous materials in quantities sufficient to be placarded. For the air brake and cargo tank endorsements, the driver must pass knowledge and skills tests. For the other endorsements, the driver will be required to pass a knowledge test.

Vehicle Groups—Responses received by FHWA to Docket MC–125 supported classification of vehicles according to weight and number of articulation points. The AAMVA, the American Automobile Association (AAA), the American Trucking Association (ATA), the HUFSAM, and the NMCAC suggested specific vehicle classifications to FHWA. The vehicle groups included in this proposal generally follow the recommendations by AAMVA, ATA, and HUFSAM. The exception is the separate group for buses which follows the NMCAC recommendation. Because of the critical passenger safety-related factors associated with the transportation of passengers, a separate test for buses is proposed. The AAA recommended a separate vehicle class for tandem tractor-trailers; the proposed endorsements recognized the additional operational consideration of these types of vehicles.

Endorsements—Accident analyses indicate that the driver's actions and reactions are the principal causal factors in the majority of accidents involving motor carriers. The operation of certain

heavy trucks and buses also requires specific skills and knowledge unique to their configuration, and loading and handling characteristics. Of particular concern are vehicles that have increased articulation points, vehicles which carry cargoes that change the handling and operating characteristics of the vehicle, or vehicles which require unique knowledge to operator safely. Therefore, FHWA proposes that operators of such vehicles have knowledge about the safe operation of these vehicles in addition to the knowledge related to the vehicle groups.

The FHWA's data on accidents related to equipment failure consistently show brake defects as the most frequently reported cause of accidents related to mechanical defects. Thus, the FHWA would include knowledge and skills related to air brakes as part of the basic requirements for the Combination Vehicle Group since the majority of vehicles in this group are so equipped. Safe operation of other CMVs that may be equipped with air brakes requires such drivers to have additional knowledge and skills and the FHWA's proposed standard would require operators of such other CMVs to have an air brake endorsement.

According to data in the National Highway Traffic Safety Administration's (NHTSA's) Fatal Accident Reporting System,[1] the number of multitrailer combination vehicles involved in fatal accidents as a percent of the number of all fatal accidents involving all combination vehicles increased from 4.1 percent in 1975 to 4.8 percent in 1985. While this increase may not be significant, the relative incidence of accidents involving operation of doubles or triples compared to tractor-semitrailer operation continue to be subject to much debate and study. The results of these debates and research efforts yield no conclusive results; except that it is clear that there are differences in the operation of double or triple trailers compared to the operation of tractor-semitrailers. For example, offtracking of "twins" at low speeds has been shown to be significantly less than that which occurs at low speeds for a tractor semitrailer. On the other hand, a vehicle with shorter wheelbases, such as those typically used with twins, may be more difficult to control when turns are entered at high speed. Therefore, FHWA proposes that drivers who operate or expect to operate doubles or triples be required to have an endorsement to their CDL in order to operate those vehicles.

For reasons similar to those described above, FHWA's proposed standard also includes a requirement that operators of articulated buses possess an endorsement. Research done by the Urban Mass Transportation Administration (UMTA) and reported in its November 1984 "Planning Handbook for Articulated Buses," page 39, found that most metropolitan transportation agencies "have reported somewhat worse accident experience with artics (articulated buses) than with standard buses." The articulated bus endorsement would be separate from the double/triple trailers endorsement because the requirements for carrying passengers are different from other operations, and the safety systems of buses are different from other CMVs.

The FHWA recognizes that cargo tank operations present special concerns. For example, in 1986, there were 818 accidents reported to the FHWA involving cargo tank trucks transporting hazardous materials resulting in 136 fatalities, 761 injuries, and over $17 million in property damage. In the same year there were 1,276 accidents reported by nonhazardous materials cargo tank carriers, resulting in 142 fatalities, 1,177 injuries and over $17 million property damage. The most important operating difference between driving a cargo tank motor vehicle and a standard dry freight truck is liquid product surge which may be the most significant condition that a cargo tank driver must be able to mitigate. Other factors that may threaten vehicle stability, therefore presenting a safety risk, include: Sloshing liquids in various cargo tank designs; various loading conditions; and the impact of liquids on driving maneuvers such as braking, backing, turning, and combined braking/steering maneuvers. It is important that the drivers of these vehicles be given special emphasis during the licensing process, and FHWA's standard includes a requirement that drivers of cargo tanks have an endorsement.

Section 12005(a)(5) of the Act requires that drivers of vehicles that carry hazardous materials demonstrate a knowledge of hazardous materials regulations and emergency procedures. The FHWA proposes to implement this provision of the Act by including a special hazardous materials endorsement in the standard. Also, drivers of cargo tanks transporting hazardous materials would obtain an endorsement both for cargo tanks and hazardous materials.

Representative Vehicles—Section 12005(a)(2) of the Act requires that the skills test be taken in a vehicle representative of the type which the person operates or expects to operate. While there were no specific questions in Docket MC–125 on the types of vehicles in which applicants for a CDL should be required to demonstrate their driving skills, several commenters addressed the concern in their responses to questions about the requirements of an operator test. Generally, the commenters leaned toward testing in the type of vehicle the driver intends to drive. The National Transportation Safety Board (NTSB) recommended that applicants be tested in the largest vehicle allowable in a given class. Such a requirement could place an unreasonable burden on a driver applicant to obtain for test purposes only, a vehicle other than one he/she typically operates or expects to operate. Alternatively, it would place a burden on States to acquire or to have available such vehicles for applicants to use for the tests. Comments are invited on whether this burden on States would be reasonable.

The FHWA proposes, however, that applicants be required to take their skills test in a representative vehicle—one that meets the definition of the vehicle group in which they drive or intend to drive—and to certify such to their State. The FHWA believes that the driving tests will adequately determine the ability of the driver to operate any CMV within that group. The FHWA proposes that the applicant certify to the licensing authority at the time of the test that the vehicle that he/she uses for the skills tests is a representative vehicle. The FHWA believes that the States should have flexibility in allowing drivers to use vehicles other than the exact vehicle or type of vehicle which the driver operates or expects to operate. States would also have the option of providing the representative vehicle for any vehicle group. This flexibility could resolve problems associated with bringing unique vehicles, such as fire trucks and specialized auto transporters, to the skills test location while allowing States to require testing with such vehicles where appropriate. As specified in § 383.75, States would also have the option of allowing other persons or employers to administer the skills tests.

Question Area: Vehicle Groups and Endorsements

The FHWA requests comment on the following specific issues:

[1] Transportation Research Board, National Research Council, "Twin Trailer Trucks, Effects on Highways and Highway Safety," Special Report 211, 1986.

(1) *All Groups*—Except for the bus group, the vehicle groups proposed by FHWA are distinguished by two factors: the weight rating of the vehicle and the weight rating of the trailer being pulled. Public comment is sought on whether the groups of vehicles should be separated only by the combined weight rating regardless of the size of the vehicle being towed.

(2) *Small Vehicle Group*—The principal reason this group is proposed is to provide a category of licenses for operators of vehicles which are under 26,001 pounds CVWR but which carry hazardous materials. The proposed rule also requires the driver to certify that the vehicle used in the skills test represents the type of vehicle used by the driver. Is such certification by the driver sufficient given the various types of vehicles which fall into this category which are placarded for hazardous materials? Public comment is also requested on whether the group should be split to include vehicles up to 10,000 pounds GVWR or GCWR and vehicles between 10,001 and 26,000 pounds GVWR or GCWR. Also, public comment is requested on whether the driving skills within these two potential groups can be differentiated in an on-road test.

(3) *Bus Group*—Because buses vary considerably by length of wheelbase and by height and weight, the knowledge and skills which a driver of a large transit bus would possess may be significantly different from those of a driver of a large van, a small school bus, or a large intercity bus. Canada's national safety code separates buses by the number of passengers carried. For example, a typical Canadian Class 2 provincial license permits operation of any bus of any seating capacity, and the Class 4 provincial license permits operation of buses with seating capacity of not more than 24 passengers. The FHWA, therefore, is considering an alternative which would use a 24 person threshold to separate the bus vehicle group into two groups; Large Bus and Small Bus. Under this scheme the air brake knowledge and skills could be part of the mandated test for the Large Bus Group. What would be the costs and benefits related to this alternative approach? Can the skills between these groups be differentiated in a test? Would requiring drivers of all Large Buses to demonstrate skills with an air brake equipped vehicle pose problems for drivers of large school buses (greater than 24 passengers) which may not be so equipped? What other ways could this group be subdivided?

(4) *Double/Triple Trailers and Articulated Buses*—Operators of both double/triple and articulated buses would be required to obtain endorsements based on separate but similar knowledge tests. Since the required knowledge for these endorsements is similar (see discussion under Subpart G), the FHWA is considering an alternative which would combine the two into one endorsement: Articulated Vehicles. This approach would result in fewer types of endorsements and therefore, fewer different pieces of information to be recorded on a CDL and in the driver's record. What would be the costs and benefits of this approach? Are the knowledge requirements for operators of Double/Triple and Articulated Buses similar enough to be combined into one endorsement?

(5) *Air Brake*—The FHWA has proposed that operators of all CMVs in the Combination Vehicle Group have knowledge and skills related to air brakes as part of the basic test standards. The air brake endorsement is included in the FHWA proposal so that drivers of CMVs which may fall into the other vehicle groups, but which are equipped with air brakes, have the necessary knowledge and skills related to the safe operation of such braking systems. The FHWA has proposed this knowledge and skill test to be included by States within the basic exam for the Combination Vehicle Group. The majority of vehicles included in this group are equipped with air brake systems. In cases where a driver operates a vehicle in the Combination Vehicle Group which is not equipped with air brakes, a State could restrict to non-air brake-equipped vehicles the license of such drivers, rather than requiring such drivers to take tests which cover air brakes. How many restrictions would be likely to result? An alternative approach would be to require a separate air brake endorsement for drivers of any vehicle so equipped (e.g., Combination Vehicles and Large Buses). The FHWA requests comment on this alternative approach.

Subpart G—Required Driver Knowledge and Skills

This section describes the knowledge and skills which CMV operators would be required to have and demonstrate for each vehicle group and endorsement. Information about these skills and knowledge areas would be included in drivers' manuals available to driver applicants. States may also require knowledge of and include questions related to any unique or special traffic laws and regulations within their jurisdictions.

Section 383.111 Required knowledge.

A primary cause of accidents is improper vehicle control in adverse environmental conditions and/or emergency traffic situations. More than 20 percent of the preventable accidents involving CMVs are attributable to this cause. Other primary causes of accidents include: Following too closely; failure to maintain control, improper/erratic lane change; improper turning; starting and braking improperly; and failure to yield right-of-way. To ensure that all CMV drivers are at least aware of these dangers and the correct driving responses, an appropriate number of these areas must be covered in questions on the knowledge examinations.

Safe Operation Regulations. Section 12005(a)(4)(A) of the Act requires that tests ensure that drivers have working knowledge of regulations pertaining to safe operation of commercial vehicles issued under Title 49, CFR. To meet this requirement, the FHWA proposes that applicants be provided with information about the regulations contained in Parts 391 through 397 and that applicants be tested on this information.

Commercial Motor Vehicle Safety Systems. Section 12005(a)(4)(B) requires that drivers have a working knowledge of the proper use of the safety systems of commercial vehicles. The FHWA proposes that tests to ensure drivers have this "working knowledge" cover such items as proper use of lights, horns, side and rear-view mirrors, proper mirror adjustments, fire extinguishers, symptoms of improper operation revealed through instruments, vehicle operation characteristics, diagnosing malfunctions, and proper use of these safety systems during emergencies.

Safe Vehicle Control. Section 12005(a)(1) requires each CMV operator take written knowledge tests. The FHWA proposes that such tests cover the CMV operator's knowledge of the procedures used to safely operate the vehicles under various traffic and road conditions, and under various weather and lighting conditions.

Relationship of Cargo to Vehicle Control. The FHWA is also proposing that drivers have general knowledge about cargo placement, balance, securement and its relationship to safe vehicle operations for the particular vehicle group.

Vehicle Pre-Trip, Post-Trip, and Other Inspections. Pre-trip inspections as well as periodic inspections and repair are important actions which help prevent breakdowns and improve safety. Therefore, the FHWA's proposal

includes a requirement that CMV drivers must know and understand the various inspection procedures.

Combination Vehicle and Bus Knowledge. The FHWA is proposing that an operator of a motor vehicle which falls into the Combination Vehicle or the Bus Group be tested on additional information as part of the basic knowledge requirements. The information is delineated in § 383.111 and for Combination Vehicles addressed knowledge and skills related to air brakes and for Bus Vehicle covers procedures related to passengers.

Section 383.113 Required drivers skills tests.

Section 12005(a) of the Act requires that each driver applicant demonstrate his/her ability to safely operate a vehicle that is representative of the class of type of vehicle he/she operates or expects to operate. The FHWA proposes that each driver applicant be required to demonstrate the basic skills included in this proposal; the State would also test any other skills it deems appropriate and necessary. The skills tests would be conducted entirely in actual road conditions or in a combination of road and off street conditions. The decision as to where the skills test will be conducted would remain at the discretion of the States. However, regardless of where the skills test is conducted, an applicant for a CDL would have to demonstrate that he/she is capable of operating the CMV safely.

Applicants for each vehicle group would be required to successfully demonstrate the basic vehicle control skills as well as safe driving skills. The specific skills which would be required are contained in § 383.113 (a) and (b).

Section 383.115–123 Endorsement tests.

The FHWA proposes that an operator of special types of CMVs obtain an endorsement to his/her CDL because of the knowledge and skills needed, in addition to the knowledge and skills contained in §§ 383.111 and 383.113, to safely operate such vehicles. Endorsements to the CDL would be required to operate vehicles equipped with air brakes, double/triple trailers; articulated buses; cargo tankers; or vehicles involved in transportation in hazardous materials. Each of the endorsements would require additional knowledge tests. The air brake and cargo tank endorsements would also require each driver to take and pass a skills test in a representative vehicle. Information on these knowledge areas and skills would be included in the drivers' manuals. The FHWA's specific proposals for each endorsement standard are contained in Subpart G and are summarized below:

Section 383.115 Air brake endorsement

To obtain an air brake endorsement for vehicles which are not included as part of the Combination Vehicle Group, driver applicants would demonstrate knowledge of the operation of air brakes; pre-trip inspection requirements; proper use of fail-safe devices, monitoring devices and alarms; inspection procedures; and ways to determine that a system's component is in need of repair. Drivers of vehicles equipped with air brakes would also need to pass a driving test on a vehicle equipped with air brakes and on the skills which make up a pre-trip inspection

Section 383.117 Double/triple trailers endorsement.

Increased length, larger freight capacity and greater number of articulation points lead to differences in handling and performance characteristics of double/triple trailers. Each applicant would demonstrate his/her knowledge in a test of unit assembly and hookup, trailer placement, handling and stability characteristics, and potential problems of such vehicles in traffic. Skills test(s) are not proposed for this endorsement because of the lack of evidence as to the specific skills which a driver can be tested on which would be different from the skills required in the basic test(s). Comments are invited on this issue.

Section 383.119 Articulated bus endorsement.

Each applicant for an articulated bus endorsement would demonstrate his/her knowledge in a test on the same types of information specified for the double/triple trailers endorsement test, except for those items related to coupling and uncoupling of the vehicle. These applicants would also demonstrate knowledge of rules pertaining to operation of passenger transport vehicles and proper braking and emergency procedures.

Section 383.121 Cargo tank endorsement.

Each applicant for a cargo tank endorsement would demonstrate his/her knowledge in areas such as vehicle operations under different loadings, product density, cargo tank type and construction. The driver would also have knowledge of and be tested on the causes and prevention of cargo surge, and the likelihood of rollover due to improper control of cargo surge.

Each driver who wishes to obtain a cargo tank endorsement to his/her CDL would also demonstrate his/her skills by taking a skills test in a partially loaded cargo tank (between 30 and 60 percent full in each compartment). As proposed in § 383.121(b), each driver would demonstrate, among other things, the ability to put the vehicle in motion smoothly, to stop the vehicle smoothly, negotiate turns and lane changes, and select and change to proper gear without clashing.

The FHWA fully expects that States would make agreements with employers to allow the employer to administer the cargo tank skills test as a third party. Such agreements would reduce the potential costs and liabilities which may occur because of the requirement that the skills test for a cargo tank endorsement be taken with a partially loaded cargo tank.

Section 383.123 Hazardous materials endorsement.

Section 12005(a)(5) of the Act requires that an individual who will operate vehicles carrying hazardous materials shall be qualified to operate a CMV in accordance with all regulations pertaining to the transportation of hazardous materials issued under the Hazardous Materials Transportation Act.

The FHWA proposes that such operators would demonstrate his/her knowledge of these areas to obtain an endorsement to his/her CDL as follows:

(a) *Hazardous material regulations*—would include the Hazardous Material Table, shipping paper requirements, hazardous material packaging, marking, labeling, and placarding requirements;

(b) *Hazardous material handling*—would include the different procedures to be utilized for different kinds of hazardous materials, loading and unloading of materials, cargo segregation, and regulations regarding the routing of materials (in tunnels, on highways etc.), attendance of vehicles, parking, fueling, and vehicle repair;

(c) *Operation of emergency equipment*—would include knowledge of when and how such equipment is to be used and any other precautions that the vehicle operator must implement to protect the public; and

(d) *Emergency response procedures*—would include general knowledge of appropriate and necessary actions for all types of hazardous materials and specific knowledge for any type of freight that person expects to transport.

Question Area: Required Knowledge and Endorsements

The FHWA requests input from the public on these endorsement tests. Specific areas where public comment is requested are:

(1) Whether or not skills tests should be included as part of the standard for all endorsements? If so, under what conditions would it be appropriate to allow States the option to recognize employer certification of training and testing in lieu of endorsement skills tests and/or knowledge tests?

(2) What would be the impact on safety of the proposals described in Question 1?

(3) If a State accepts employer certification as a substitute for the skills test, what, if any, requirements for such certification should be indicated in the Federal standards?

(4) Knowledge of Parts 398 (Migrant Workers) and 399 (Employee Health and Safety) is excluded from the test standard. Should knowledge of these requirements be included in the standard for the knowledge tests for the CDL?

(5) The FHWA is aware of the possibility of using simulators for skills testing. For what portions of the skills tests would the use of a simulator be appropriate? What are the advantages and disadvantages associated with the use of a simulator? Which, if any, skills can and cannot be evaluated given current technological constraints of simulators?

(6) Is there some basic knowledge of hazardous materials which all CMV operators, even those who do not need a hazardous materials endorsement, should be required to demonstrate prior to receiving a CDL?

Subpart H—Tests

To ensure that all drivers have the knowledge and skills to safely operate a CMV on the public roadways, every CDL applicant must pass tests which demonstrate the person's knowledge or skills described in Subpart G and H. To the extent practicable, the tests should have similar content, similar test administration procedures, and similar scoring procedures to establish uniform testing of CMV operators anywhere in the country. This section contains the test administration methods and standards for minimum passing scores which the FHWA is proposing for the knowledge and skills tests.

Section 383.131 Procedures.

Because licensing examinations within a State are given to different applicants, at different times, in different locations, and by different examiners, it is critical to minimize any impact of these differences. The FHWA proposes that test procedures and methods be standardized and documented by the State and provided to its licensing examiners.

The FHWA proposes that States develop procedural information for the test applicant and for the test examiner. The directions for the test applicant would expalin, as clearly and simply as possible, what he/she must do to take the test. These directions would be given by the license test examiner and/or would be a part of the test (content information would be made available to the applicant through a driver manual). For the knowledge and skills tests, the directions given to the driver applicant would cover the purpose of the test, how to choose a response, how to make a response, any time limits, and any other special procedures determined by the State. Directions for taking knowledge tests would differ depending on the particular testing format used by the States (e.g., paper, oral or automated equipment for knowledge tests). All information provided to the applicant would be at or below the sixth grade reading level. The FHWA understands that this level of reading competency would be sufficient to fully test driver's knowledge without discriminating based on literacy.

Directions for the examiner would include the information the examiner must give to the applicant, information about how to conduct the tests, how to score, and for the skill tests, specific testing information, e.g., what is being tested, how it would be tested, how it would be scored. In addition, directions to the examiner would list the skills to be tested (from Subpart G); identify where and how the skills would be tested; and how the performance of the skills would be scored. As part of the scoring, the correct response and how to determine that it is a correct response would also be provided to the examiner. Standardized scoring sheets for the skill tests would be provided, as well as standardized driving instructions for the applicant.

Section 383.133 Test methods.

The States would be required to establish specific testing and scoring procedures and the associated administrative procedures that meet the standards. Testing procedures would, however, be standardized within the State and meet the testing requirements as stipulated in this rule. In other words, the knowledge and skills tests would uniformly assess the performance of applicants regardless of the location of the test.

To assure that the knowledge and skill tests can accurately determine the proficiency of CDL license applicants, the tests would be required to be reliable. Accordingly, the FHWA proposes that the "knowledge" tests contain a minimum of at least 30 items per test which cover all of the knowledge areas described in Subpart G for that vehicle group and that the tests have a reliability coefficient of at least $r=0.90$. This proposed requirement is based on commonly accepted testing principles to assure reliability and validity of any knowledge test. A State would have flexibility to choose a specific method for giving the knowledge test as long as the tests meet the standards. For example, the knowledge tests could be administered by paper and pencil, orally or given on automated equipment. States may also arrange for tests to be given with an oral interpreter as appropriate. (This would *not* relieve the interstate driver of the language requirements contained in § 393.41.) To assure that the "skill" tests are reliable, it would be required that the reliability coefficient between any two examiners be at least $r=0.80$. This coefficient has been established as a minimum in the TORQUE Tests developed by the National Highway Traffic Safety Administration.

Specific methods for skill testing and scoring would be determined by the State. For example, the States may use a single score for a right hand turn starting with the initiation of the right turn signal and ending following the turn and cancellation of the turn signal, or they may use several scores for the turn comprised of the different performances involved in a right hand turn—initiates the turn signal, uses appropriate lanes, uses the right side mirror(s), blocks inside traffic, stays in roadway, cancels turn signal—or they may use some combination of the two approaches. The latter approach being a "disaggregate" or "elements" test approach which is used in the TORQUE tests.

The FHWA proposes that the CDL examiners would be required to be qualified to administer the tests. A qualified examiner would have to demonstrate the ability to use the standardized procedures as stipulated in this section.

Section 383.135 Minimum passing scores.

For the knowledge tests, the FHWA proposes that the driver applicant would correctly answer at least 80 percent of the questions to pass. For the skills

tests, all skills identified as being required for the standard tests would be performed by all applicants. The passing score depends on how a State administers the tests. For example, if a State tests the applicant on successful completion of general skills, such as completion of a right turn, the passing score must be 100 percent. If the State uses a "disaggregated" or "elements" test approach, the driver would need to demonstrate all the required skills, but the lowest acceptable passing score would be 80 percent. The State would automatically fail any driver applicant who does not obey traffic laws or causes an accident during the test.

The State would determine the appropriate amount of time an applicant must wait in order to retake any test which he/she fails. The State would also determine the maximum number of times a person may take and fail any test before he/she may be prohibited by the State from obtaining a CDL. The FHWA invites comment on the appropriateness of requiring, through regulation, minimum time periods (such as 1 week) between taking tests to give the applicant time to study and become prepared to successfully complete the test.

Subpart I—[Reserved]

Subpart J—Commercial Driver's License Document

This section includes standards for CDLs that are required by section 12006 of the Act. Generally, these State-issued documents would be, to the maximum extent practicable, tamperproof, and would include information as described below. The FHWA has also included in the proposal a sample set of uniform CDL document specifications which may be used by States.

Section 383.153 Information on the document.

The information that would be required to be included on all CDLs issued by the States is that which is delineated in section 12006 of the Act. This section requires the CDL document to include the social security number or other information appropriate to identify the driver. Although the FHWA is aware of "state-of-the-art" technologies that may be available to help identify the driver, such as retinal imaging, digital dental records, and thumbprints, their use is not required as part of the standard because of concerns about their costs and benefits. Therefore, the FHWA proposes to require the driver's social security number, along with a color photograph of the driver and his/her date of birth, sex, weight, height, hair color, and eye color to help identify the CDL holder. The FHWA proposal does not mandate a specific requirement in order to give States flexibility to use current identification methods. As technology evolves and better, more cost-effective identification means become available, States would be free to impose such methods.

The FHWA's proposal would also require the CDL to contain the statement that the license is a "Commercial Driver's License," the driver's signature, and endorsements. The FHWA proposes that uniform codes for vehicle groups and endorsements be used. The proposed codes are intended to provide uniformity for enforcement purposes. Eventually, the codes would make the CMV driver documentation easily recognizable to enforcement officials. For example, a CDL with A–HM would be recognized by enforcement officials across the country to mean the driver is authorized to drive a combination vehicle and has a hazardous materials endorsement.

Section 383.155 Tamperproofing requirements.

Section 12006 of the Act requires that the CDL document be tamperproof to the maximum extent practicable. A tamperproof license is one which is designed, manufactured and/or processed to protect against counterfeiting, forgery, and alteration, i.e., it would be beyond the capabilities of the general public to reproduce or change the document. All State licensing authorities would be required to use license materials and procedures to reasonably assure that their licenses are tamperproof. At a minimum, each State would continue to use the same tamperproof method it currently uses for noncommercial licenses. The FHWA has provided the States flexibility to use current technologies to make the CDL tamperproof. However, as the technology is improved and new methods become cost-effective, the States would be free to improve tamperproof methods.

Section 383.157 Commercial driver's certificate document.

Under FHWA's proposal, a CDC issued by a State would contain the same information, except for the statement that the document is a "Commerical Driver's Certificate," rather than a CDL.

Section 383.159 Document specification.

The FHWA has proposed an optional set of specifications for CDL and CDC documents which can be used by the States which desire to issue and achieve a uniform CDL document. A State that chooses to follow these sample specifications would issue a CDL or CDC card which would not exceed 2⅛ inches high and 3⅜ inches wide—ANSI standards for financial records. The information described in § 383.153 as contained on the card would be placed as shown in Illustrations A and B at the end of Subpart J.

Question Area: CDL Documentation

(1) Can the information proposed to be included on the CDL be readily placed on existing documents? What, if any, additional information is required? What would be the benefits and costs of requiring, in the standard, that the drivers' fingerprints be included?

(2) Should the sample specifications for a CDL be included in the standard; i.e., mandated for all States? If so, what information should be added or deleted? Should the driver's fingerprints be included?

(3) The FHWA recognizes that technologies are emerging, such as "smart cards" or magnetic strips, which would allow States to cost-effectively store/retrieve biometric data in conjunction with issuing a CDL. Should the FHWA require the use of such automated data-encoding technologies and if so, what would be the appropriate phase-in time period?

(4) Although FHWA's proposal uses the social security number as the number to identify CMV operators, FHWA recognizes that there are several new and developing technologies that could be used to uniquely identify each CMV operator. These technologies include retinal imaging, digital dental records, and thumbprints, among others. Should any of these technologies be required as part of the standard? What would be the related costs and benefits of these technologies? The FHWA seeks information and recommendations on timing and methods for development, demonstration, and implementation of these technologies.

(5) The FHWA is also aware of developing technologies to make a document tamperproof, beyond most methods currently used by States for driver license documents. Such new methods include use of holograms, fine line patterns, use of light refracting seals, use of magnetic strips, etc. The FHWA requests comments on the suitability of such technologies for the CDL documentation.

(6) For commercial driver certificates that would be issued to foreign drivers, what would be the appropriate

identification number to use in lieu of the social security number?

Question Area: State Compliance

The Act requires that the Secretary withhold Federal-aid highway funds from those States who do not comply. The FHWA requests guidance from the States on the criteria and procedures to be used by the Administrator to determine whether the States have implemented CDL tests and testing procedures that meet the requirements of this Section. Is it appropriate for the Governor to certify that the State is in compliance? Should the FHWA monitor the licensing procedures and, if so, on what basis? What is the most practical and cost effective method that can be used to certify that the States are in compliance? Should the FHWA approve each of the States' programs? If so, how often should the FHWA review these determinations?

Regulatory Impact

The FHWA has determined that this action does not constitute a major rule under Executive Order 12291. The proposed rule is not expected to result in an annual effect on the economy of $100 million or more, or lead to a major increase in costs or prices, or have significant adverse effects on the United States economy. However, because of the public interest in the issue of commercial motor vehicle safety and the expected benefit in transportation, this proposed rule is considered significant under the regulatory policies and procedures of the DOT. For this reason and pursuant to Executive Order 12498, this rulemaking action has been included on the Regulatory Program for significant rulemaking actions.

The economic impacts of this rulemaking that will occur are primarily mandated by the statutory provisions themselves. Since an analysis of impacts, including economic factors, is necessarily involved in the preparation of related motor vehicle safety regulations, an overall regulatory evaluation has been prepared for the various rulemaking actions that will be issued to implement the Act. This evaluation, which addresses some of the provisions contained in the final rule issued on June 1, 1987, and this proposed rule, has been placed in the public docket and is available for inspection in the Headquarters office of the FHWA, 400 Seventh Street, SW., Washington, DC 20590. A regulatory evaluation addressing the specific impacts associated with this NPRM is currently being prepared.

A significant part of the motor carrier industry and other employers covered by the Act are made up of small firms, from one-person, one-truck operations of some owner-operators, to the thousands of small fleet operators throughout the country. For this reason, the benefit and cost considerations described in the preliminary regulatory evalution/initial regulatory flexibility analysis as applicable to employers and the motor carrier industry in general, are equally applicable to the small entity component of the industry. Small entities have been represented at public meetings held to discuss the Act and small entities have had the opportunity to submit comments to the public docket established in conjunction with FHWA's August 1, 1986, ANPRM (49 CFR Part 391). The FHWA is fully committed to doing all that it can to ensure that no undue burdens are placed on small entities as a result of this proposal.

List of Subjects in 49 CFR Part 383

Commercial driver's license documents, Commercial motor vehicles, Highways and roads, Motor carriers licensing and testing procedures, Motor vehicle safety.

(Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety)

Issued on December 8, 1987.

R.A. Barnhart,

Federal Highway Administrator, Federal Highway Administration.

In consideration of the foregoing, the FHWA hereby proposes to amend Title 49, Code of Federal Regulations, Chapter III, Subchapter B, as set forth below.

Alternative 1

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES—[AMENDED]

1. The authority citation for 49 CFR Part 383 continues to read as follows:

Authority: Title XII of Pub. L. 99-570, 100 Stat. 3207-170; 49 U.S.C. 3102; 49 U.S.C. App. 2505; 49 CFR 1.48.

2. The table of sections to Part 383 is amended as follows:

* * * * *

Subpart B—License Requirements

Sec.

* * * * *

383.23 Commercial driver's license.

* * * * *

Subpart E—Testing and Licensing Plans

383.71 Formulation of testing and licensing plan.
383.73 Approval of plan.
383.75 Third party testing.
383.77 Substitute for driving skills tests.

Subpart F—Motor Vehicle Groups and Endorsements

383.91 Motor vehicle groups.
383.93 Endorsements.

Subpart G—Required Knowledge and Skills

383.110 General requirement.
383.111 Hazardous materials requirement.

Subpart H—Tests

383.131 Minimum passing scores.

Subpart I—[Reserved]

Subpart J—Commercial Driver's License Document

383.151 General.
383.153 Information on the document.
383.155 Tamperproofing requirements.
383.157 Commercial driver's certificate document.

3. Section 383.1 is amended by removing the word "and" from the end of paragraph (b)(4), substituting a semicolon for the period at the end of paragraph (b)(5) and adding paragraphs (b)(6) through (b)(11) to read as follows:

§ 383.1 Purpose and scope.

* * * * *

(b) * * *

(6) Establishes testing and licensing requirements for commercial motor vehicle operators;

(7) Requires States to give knowledge and skills tests to all qualified applicants for commercial driver's licenses or certificates which meet the Federal standard;

(8) Sets forth commercial motor vehicle groups and endorsements;

(9) Sets forth the knowledge and skills test requirements for the motor vehicle groups and endorsements.

(10) Sets forth the Federal standards for procedures, methods, and minimum passing scores for States and others to use in testing and licensing commercial motor vehicle operators; and

(11) Establishes requirements for the State issued commercial license documentation.

4. Section 383.5 is amended by adding eight definitions and revising the two definitions entitled "Commercial driver's license" and "Commercial motor vehicle", placing them in alphabetical order as follows:

§ 383.5 Definitions.

* * * * *

"*Commercial driver's certificate (CDC)*" means a certificate issued by a State to an individual. Such certificate authorizes the individual to operate a class of a commercial motor vehicle and is considered as a valid CDL only when used with the individual's driver license issued by the individual's State of domicile or country.

"Commercial driver's license (CDL)" means a license issued by a State or jurisdiction, in accordance with the standards contained in 49 CFR Part 383, to an individual which authorizes the individual to operate a class of a commercial motor vehicle. A CDC accompanied by a valid driver's license shall be considered a valid CDL.

"Commercial driver's license information system (CDLIS)" means the CDLIS established by FHWA pursuant to section 12007 of the Commercial Motor Vehicle Safety Act of 1986.

"Commercial motor vehicle (CMV)" means a motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the motor vehicle—

(a) Has a gross vehicle weight rating or gross combination weight rating of 26,001 or more pounds;

(b) Is designed to transport more than 15 passengers, including the driver; or

(c) Is of any size and is used in the transportation of materials found to be hazardous for the purposes of the Hazardous Materials Transportation Act and which require the motor vehicle to be placarded.

* * * * *

"Driver applicant" means an individual who applies to a State to obtain, transfer, upgrade, or renew a CDL or CDC.

* * * * *

"Endorsement" means an authorization to an individual's CDL or CDC required to permit the individual to operate certain types of commercial motor vehicles.

* * * * *

"Representative vehicle" means a motor vehicle which represents the type of motor vehicle that a driver applicant operates or expects to operate.

* * * * *

"State of domicile" means that State where a person has his/her true, fixed, and permanent home and principal residence and to which he/she has the intention of returning whenever he/she is absent.

* * * * *

"Vehicle" means a motor vehicle unless otherwise specified.

"Vehicle group" means a class or type of vehicle with certain operating characteristics.

5. Part 383, Subpart B is revised by adding a new § 383.23 to read as follows:

Subpart B—License Requirements

* * * * *

§ 383.23 Commercial driver's license.

(a) *General rule.* (1) Effective April 1, 1992, no person shall operate a commercial motor vehicle unless such person has taken and passed written and driving tests which meet the Federal standards contained in Subparts F, G, and H of this part for the commercial motor vehicle that person operates or expects to operate.

(2) Effective April 1, 1992, except as provided in paragraph (b) of this section, no person shall operate a commercial motor vehicle unless such person possesses a CDL which meets the standards contained in Subpart J of this part, issued by his/her State or jurisdiction of domicile.

(b) *Exceptions.* (1) If, after October 1, 1991, a commercial motor vehicle operator is domiciled in a State which does not test drivers and issue a CDL in accordance with the Federal standards contained in Subparts F, G, and H of this part, the person shall obtain a CDC from a State which does comply with the testing and licensing standards contained in such Subparts F, G, and H.

(2) If a commercial motor vehicle operator is domiciled in a foreign jurisdiction which, as determined by the Administrator, does not test drivers and issue a CDL in accordance with, or similar to, the standards contained in Subparts F, G, and H of this part, the person shall obtain a CDC from a State which does comply with the testing and licensing standards contained in such Subpart F, G, and H.

(c) *Learner's permit.* State learner's permits, issued for limited time periods according to State requirements, shall be considered valid commercial driver's licenses for purposes of behind-the-wheel training on public roads or highways and for taking required driving tests, which a State may give in traffic.

6. Part 383 is amended by adding Subparts E, F, G, H, I, and J to read as follows:

Subpart E—Testing and Licensing Plans

§ 383.71 Formulation of testing and licensing plan.

(a) Each State shall develop a plan for testing and licensing persons who operate or expect to operate a commercial motor vehicle. The plan shall describe the procedures, resources and facilities which the State intends to devote to the commercial driver's license propram activities. Each plan must be approved by the FHWA as demonstrating that the State:

(1) Requires a person to pass written and driving tests to operate a commercial motor vehicle;

(2) Requires a person to pass a driving test in a commercial motor vehicle which is representative of the type of vehicle such person operates or expects to operate;

(3) Has in effect and enforces a law which provides that any person with a blood alcohol concentration level at or above the level established by the Secretary when operating a commercial motor vehicle is deemed to be operating under the influence of alcohol;

(4) Administers different tests for each different class of commercial motor vehicle described in Subpart F;

(5) Authorizes a person to operate a commercial motor vehicle only by issuance of a commercial driver's license which contains the information described in Subpart J;

(6) For commercial driver's licenses issued prior to April 1, 1992, checks with every other State to determine whether the person has a valid driver's license in another State;

(7) Checks with the CDLIS, when it is determined to be operational by the Administrator, to determine whether the driver applicant already has a CDL, whether the applicant's license has been suspended, revoked, or canceled, or if the driver applicant has been disqualified from operating a commercial motor vehicle;

(8) Checks with the National Driver Register (NDR), when it is determined to be operational by the National Highway Traffic Safety Administrator, to determine whether the driver applicant has:

(i) Been disqualified from operating a motor vehicle (other than a commercial motor);

(ii) Had a license (other than a CDL or CDC) suspended, revoked or canceled for cause in the 3-year period ending on the date of application; or

(iii) Been convicted of any offenses contained in section 205(a)(3) of the National Driver Register Act of 1982 (23 U.S.C. 401 note);

(9) Before issuance of a CDL, requests from any other State which has issued a CDL to such person all information pertaining to the driving record of such person;

(10) Notifies the CDLIS within 30 days after the issuance of a CDL;

(11) Within 10 days of the disqualification of the holder of the CDL or any suspension, revocation or cancellation (of 60 days or more), notifies the CDLIS and the State which issued the license;

(12) Within 10 days of conviction of a CDL holder for a violation of a State or local law relating to motor vehicle traffic control occurring within its boundaries, notifies the State which issued the license;

(13) Does not issue a CDL to person during a period in which such person is disqualified from operating a

commercial motor vehicle or the driver's license of such person is suspended, revoked, or canceled;

(14) Does not issue a CDL to person who has a CDL issued by any other State unless such person first returns the driver's license issued by the other State;

(15) Only issues a CDL to persons domiciled in the State, except that a State may issue a CDC to a person domiciled in another State or foreign jurisdiction if the Administrator has determined that the commercial motor vehicle testing and licensing standards in the State or foreign jurisdiction do not meet the standards contained in this Part. A State shall issue a CDC in the same manner as it issues CDLs;

(16) Imposes a penalty for operating a commercial motor vehicle while not having a CDL, while having a driver's license suspended, revoked, or canceled, or while being disqualified from operating a commercial motor vehicle;

(17) Allows any person to operate a commercial motor vehicle within its boundaries if such person is not disqualified from operating a commercial motor vehicle and has a CDL:

(i) Which is issued by any other State in accordance with the minimum Federal standards for the issuance of a CDL, and

(ii) Which is not suspended, revoked, or canceled.

(18) Has in effect and enforces minimum Federal disqualifications and penalties under Subpart D or comparable provisions.

(b) Each State should submit the plan to the FHWA no later than July 15, 1989, and within 30 days following significant changes in its commercial driver's license program. The plan should demonstrate that the proposed State CDL program is likely to be effective in ensuring that the State only issues a CDL to a person qualified to drive a CMV.

§ 383.73 Approval of plan.

(a) Within 90 days following its receipt, the FHWA shall review the plan and notify the State of its acceptability in demonstrating that the State complies with the requirements of this Part.

(b) The state should evaluate its CDL program periodically to ensure its effectiveness in ensuring that the State only issues a CDL to persons qualified to drive a commercial motor vehicle.

(c) The FHWA may withdraw approval of any State plan. Prior to withdrawal of any approval of a State plan for lack of effectiveness, a State shall have an opportunity to demonstrate that its CDL program is effective and meets the requirements of this Part.

§ 383.75 Third party testing.

(a) *Third party tests.* A State may allow a person (including another State, an employer, a private driver training facility or other private institution, or a department, agency or instrumentality of a local government) to administer the skills tests as specified in Subpart G and H of this part, if the following conditions are met:

(1) The tests given by the third party are the same as those which would otherwise be given by the State; and

(2) The third party has an agreement with the State with at least the following provisions:

(i) Allow the FHWA, or its representative, and the State to conduct random examinations, inspections and audits without prior notice;

(ii) Require the State to conduct on-site inspections at least annually;

(iii) Require all third party examiners meet the same qualification and training as State examiners; and

(iv) Require that State employees periodically take the tests actually administered by the third party as if the State employee were a test applicant, or that States periodically test a sample of drivers who were examined by the third party to compare pass/fail results.

(b) *Proof of testing by a third party.* Driver applicants who take and pass driving tests administered by a third party shall provide evidence to the State licensing agency that he/she has successfully passed the driving tests administered by the third party.

(c) The State shall submit to the FHWA any agreement for third party testing with the State's testing and licensing plan. The FHWA's approval of the plan shall also constitute approval of the agreement.

§ 383.77 Substitute for driving skills tests.

At the discretion of a State, the driving skill tests may be waived for drivers licensed before July 15, 1988, and substituted with either an applicant's driving record and previous passage of an acceptable skills test, or an applicant's driving record in combination with certain driving experience. The State shall impose conditions and limitations to restrict the applicants from which a State may accept alternative requirements for the skills test. Such conditions must require at least the following:

(a) An applicant must certify that he/she:

(1) Has not had more than one license since July 1, 1987;

(2) Has not had any license suspended, revoked, or canceled since July 1, 1987;

(3) Has not has any convictions for any type of motor vehicle for the disqualification offenses contained in § 383.51 since July 1, 1987; and

(4) Has not had any violation of State or local law relating to motor vehicle traffic control (other than a parking violation) arising in connection with any traffic accident or has no record of an accident where he/she was at fault, during the 2 years immediately preceding application for a CDL; and

(b) An applicant must provide evidence and certify that:

(1) He/she has previously taken a skills test given by a State with a classified licensing and testing system, and that the test was behind-the-wheel in a representative vehicle for that applicant's driver's license classification; or

(2) He/she has operated, for at least 2 years, immediately preceding application for a CDL, a vehicle representative of the commercial motor vehicle the driver applicant operates or expects to operate.

Subpart F—Motor Vehicle Groups and Endorsements

§ 383.91 Motor vehicle groups.

(a) *Vehicle group descriptions.* Each driver applicant must possess and be tested on his/her knowledge and skills, described in Subpart G of this part, for the vehicle group(s) for which he/she desires a CDL. The vehicle groups are as follows:

(1) *Combination vehicle*—any combination of motor vehicles with a Gross Combination Weight Rating (GCWR) of over 26,001 pounds or more provided the motor vehicle or trailers being pulled have a Gross Vehicle Weight Rating (GVWR) of over 10,000 pounds.

(2) *Bus*—any vehicle designed to carry more than 15 passengers, including the driver.

(3) *Heavy straight truck*—any vehicle with a GVWR of 26,001 pounds or more, or any combination of motor vehicles with a GCWR of 26,001 pounds or more provided the vehicle or trailers being pulled have a GVWR of not more than 10,000 pounds.

(4) *Small Vehicle*—any motor vehicle with a GVWR or GCWR of under 26,001 pounds.

(b) *Representative vehicle.* For purposes of taking the driving test, a representative vehicle is any motor vehicle which meets the definition of that vehicle group.

(c) *Relation between vehicle groups.* Each driver applicant who desires to operate in a different vehicle group from the one which his/her DCL or CDC authorizes shall be required to retake and pass all related tests, except the following:

(1) Drivers who have passed the knowledge and skills test for a combination vehicle may operate a heavy straight truck or a small vehicle;

(2) Drivers who have passed the knowledge and skills test for a bus may operate a small vehicle; and

(3) Drivers who have passed the knowledge and tests for a heavy straight truck may operate any small vehicle.

§ 383.93 Endorsements.

(a) *General.* In addition to taking and passing the knowledge and skills tests described in Subpart G of this part, all persons who operate or expects to operate the type(s) of motor vehicle described in paragraph (b) of this section shall take and pass specialized tests to obtain each endorsement. The State shall issue CDL endorsements only to drivers who successfully complete the tests.

(b) *Endorsement descriptions.* Operators must obtain State-issued endorsements to his/her CDL or CDC to operate commercial motor vehicles which are:

(1) Equipped with air brakes;

(2) Required to be placarded for hazardous materials;

(3) Cargo tanks;

(4) Double/triple trailers; or

(5) Articulated buses.

(c) *Endorsement testing requirements.* The following tests are required for the endorsements contained in paragraph (b) of this section:

(1) *Air Brakes*—a knowledge and skills test. The skills test must be taken in a motor vehicle equipped with air brakes;

(2) *Hazardous Materials*—a knowledge test;

(3) *Cargo Tank*—a knowledge and skills test;

(4) *Double/Triple Trailers*—a knowledge test; and

(4) *Articulated Bus*—a knowledge test.

Subpart G—Required Knowledge and Skills

§ 383.110 General requirements.

All persons who pass tests for the issuance of a CDL shall have knowledge of regulations pertaining to safe operation of a commercial motor vehicle issued by the Secretary and contained in title 49 of the Code of Federal Regulations, and any safety system of such vehicle he/she is authorized to drive with the issuance of a CDL.

§ 383.111 Hazardous materials requirement.

In the case of a person who operates or expects to operate a commercial motor vehicle carrying a hazardous material, such person:

(a) Shall be qualified to operate a commercial motor vehicle in accordance with all regulations pertaining to motor vehicle transportation of hazardous materials issued by the Secretary under the Hazardous Materials Transportation Act; and

(b) Shall have a working knowledge of—

(1) Such regulations,

(2) Handling such material,

(3) The operation of emergency equipment used in response to emergencies arising out of the transportation of such material, and

(4) Appropriate response procedures to be followed in such emergencies.

Subpart H—Tests

§ 383.131 Minimum passing scores.

(a) The driver applicant must correctly answer at least 80 percent of the questions on the knowledge test in order to achieve a passing score on such knowledge test.

(b) The passing scores for the skills test shall depend on the way the test is administered. If a disaggregated or elements test approach is used, the lowest acceptable passing score shall be 80 percent. If the test requires successful completion of general skills, the passing score must be 100 percent.

(c) If the driver applicant does not obey traffic laws, or causes an accident during the test, he/she shall automatically fail the test.

Subpart I—[Reserved]

Subpart J—Commercial Driver's License Document

§ 383.151 General.

The CDL shall be a document that is easy to recognize as a CDL. At a minimum, the document shall contain information specified in § 383.153.

§ 383.153 Information on the document.

All CDLs shall contain the following information:

(a) The statement that the license is a "Commercial Driver's License."

(b) The full name, signature, and mailing address of the person to whom such license is issued;

(c) Physical and other information to identify and describe such person including date of birth (month, day, and year), sex, weight, height, eye color, and hair color;

(d) Color photograph of the driver;

(e) The driver's social security number;

(f) The name of State which issued the license;

(g) The date of issuance and the date of expiration of the license;

(h) The group or groups of commercial motor vehicle(s) that the driver is authorized to operate, indicated as follows:

(1) A for Combination Vehicle;

(2) B for Bus;

(3) C for Heavy Straight Truck; and

(4) D for Small Vehicle;

(i) The endorsement for which the driver has qualified, indicated as follows:

(1) AR for air brakes;

(2) TT for double/triple trailers;

(3) AB for articulated bus;

(4) CT for cargo tank; and

(5) HM for hazardous materials.

§ 383.155 Tamperproofing requirements.

States shall make the CDL or CDC tamperproof to the maximum extent practicable. At a minimum, a State shall use the same tamperproof method used for noncommercial drivers' licenses.

§ 383.157 Commercial Driver's Certification (CDC) document.

Each CDC shall contain the same information as contained in § 383.153 except the CDC shall contain the State "Commercial Driver's Certificate" or "CDC" in lieu of "Commercial Driver's License" or "CDL."

Alternative 2

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES—[AMENDED]

1. The authority citation for 49 CFR Part 383 continues to read as follows:

Authority: Title XII of Pub. L. 99-570, 100 Stat. 3207-170; 49 U.S.C. 3102; 49 U.S.C. App. 2505; 49 CFR 1.48.

2. The table of sections to Part 383 is amended as follows:

* * * * *

Subpart B—License Requirements

Sec.

* * * * *

383.23 Commercial driver's license.

* * * * *

Subpart E—Testing and Licensing Procedures

383.71 Driver application procedures.
383.73 State procedures.
383.75 Third party testing.
383.77 Substitute for driving skills tests.

3. Section 383.1 is amended by removing the word "and" from the end of paragraph (b)(4), substituting a semicolon for the period at the end of paragraph (b)(5) and adding paragraphs (b)(6) through (b)(11) to read as follows:

§ 383.1 Purpose and scope.

* * * * *

(b) * * *

(6) Establishes testing and licensing requirements for commercial motor vehicle operators;

(7) Requires States to give knowledge and skills tests to all qualified applicants for commercial drivers' licenses or certificates which meet the Federal standard;

(8) Sets forth commercial motor vehicle groups and endorsements;

(9) Sets forth the knowledge and skills test requirements for the motor vehicle groups and endorsements.

(10) Sets forth the Federal standards for procedures, methods, and minimum passing scores for States and others to use in testing and licensing commercial motor vehicle operators; and

(11) Establishes requirements for the State issued commercial license documentation.

4. Section 383.5 is amended by adding eight definitions and revising the two definitions entitled "Commercial drivers license" and "Commercial motor vehicle", placing them in alphabetical order as follows:

§ 383.5 Definitions.

* * * * *

"Commercial driver's certificate (CDC)" means a certificate issued by a State to an individual. Such certificate authorizes the individual to operate a class of a commercial motor vehicle and is considered as a valid CDL only when used with the individual's driver license issued by the individual's State of domicile or country.

"Commercial driver's license (CDL)" means a license issued by a State or jurisdiction, in accordance with the standards contained in 49 CFR Part 383, to an individual which authorizes the individual to operate a class of a commercial motor vehicle. A CDC accompanied by a valid driver's license shall be considered a valid CDL.

"Commercial driver's license information system (CDLIS)" means the CDLIS established by FHWA pursuant to Section 12007 of the Commercial Motor Vehicle Safety Act of 1986.

"Commercial motor vehicle (CMV)" means a motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the motor vehicle—

(a) Has a gross vehicle weight rating or gross combination weight rating of 26,001 or more pounds;

(b) Is designed to transport more than 15 passengers, including the driver; or

(c) Is of any size and is used in the transportation of materials found to be hazardous for the purposes of the Hazardous Materials Transportation Act and which require the motor vehicle to be placarded.

* * * * *

"Driver applicant" means an individual who applies to a State to obtain, transfer, upgrade, or renew a CDL or CDC.

* * * * *

Endorsement" means an authorization to an individual's CDL or CDC required to permit the individual to operate certain types of commercial motor vehicles.

* * * * *

"Representative vehicle" means a motor vehicle which represents the type of motor vehicle that a driver applicant operates or expects to operate.

* * * * *

"State of domicile" means that State where a person has his/her true, fixed, and permanent home and principal residence and to which he/she has the intention of returning whenever he/she is absent.

* * * * *

"Vehicle" means a motor vehicle unless otherwise specified.

"Vehicle group" means a class or type of vehicle with certain operating characteristics.

5. Part 383, Subpart B is revised by adding a new § 383.23 to read as follows:

Subpart B—License Requirements

* * * * *

§ 383.23 Commercial driver's license.

(a) *General rule.* (1) Effective April 1, 1992, no person shall operate a commercial motor vehicle unless such person has taken and passed written and driving tests which meet the Federal standards contained in Subparts F, G, and H of this part for the commercial motor vehicle that person operates or expects to operate.

(2) Effective April 1, 1992, except as provided in paragraph (b) of this section, no person shall operate a commercial motor vehicle unless such person possesses a CDL which meets the standards contained in Subpart J of this part, issued by his/her State or jurisdiction of domicile.

(b) *Exceptions.* (1) If, after October 1, 1991, a commercial motor vehicle operator is domiciled in a State which does not test drivers and issue a CDL in accordance with the Federal standards contained in Subparts F, G, and H of this part, the person shall obtain a CDC from a State which does comply with the testing and licensing standards contained in such Subparts F, G, and H.

(2) If a commercial motor vehicle operator is domiciled in a foreign jurisdiction which, as determined by the Administrator, does not test drivers and issue a CDL in accordance with, or similar to, the standards contained in Subparts F, G, and H of this part, the person shall obtain a CDC from a State which does comply with the testing and licensing standards contained in such Subpart F, G, and H.

(c) *Learner's permit.* State learner's permits, issued for limited time periods according to State requirements, shall be considered valid commercial drivers' licenses for purposes of behind-the-wheel training on public roads or highways and for taking required driving tests, which a State may give in traffic.

6. Part 383 is amended by adding Subparts E, F, G, H, I, and J to read as follows:

Subpart E—Testing and Licensing Procedures

§ 383.71 Driver application procedures.

(a) *Initial Commercial Driver's License.* Prior to obtaining a CDL or CDC, a person must meet the following requirements:

(1) A person who operates or expects to operate in interstate or foreign commerce, or is otherwise subject to Part 391 of this title, shall certify that he/she meets the qualification requirements contained in Part 391 of this title. A person who operates or expects to operate in intrastate commerce which is not subject to Part 391, is subject to State driver qualification requirements and must certify that he/she is not subject to Part 391;

(2) Pass a knowledge test in accordance with the standards contained in Subparts G and H of this part for the type of motor vehicle the person operates or expects to operate;

(3) Pass a driving or skills test in accordance with the standards contained in Subpart G and H of this part taken in a motor vehicle which is representative of the type of motor vehicle the person operates or expects to operate or provide evidence that he/she has successfully passed a driving test administered by a third party;

(4) Certify that the motor vehicle in which the person takes the driving skills test is representative of the type of motor vehicle that person operates or expects to operate;

(5) Provide to the State of issuance the information required to be included on the CDL or CDC as specified in Subpart J of this part; and

(6) The applicant shall surrender his/her (noncommercial) driver's license to the State.

(b) *License transfer.* When applying to transfer a CDL, applicants shall apply for a CDL from the new State of domicile within 30 days.

(1) If the transfer of a CDL is from one State of domicile to a new State of domicile, all applicants shall:

(i) Provide certification contained in § 383.71(a)(1);

(ii) Provide updated information as specified in Subpart J of this part;

(iii) If a person wishes to retain a hazardous materials endorsements, pass the test for such endorsement as specified in § 383.123; and

(iv) Surrender the CDL from the old State of domicile to the new State of domicile.

(2) If a commercial motor vehicle operator with a CDC issued by a State changes his/her State of domicile to a State which tests and licenses according to Subparts G and H of this part, such person shall complete the requirements included in paragraph (b)(1) of this section; and

(3) If a commercial motor vehicle operator with a CDL issued by a State changes his/her domicile to a State which does not test and license in accordance with Subparts G and H of this part, such person shall surrender his/her CDL to the State that issued such license and obtain a CDC.

(c) *License renewal.* When applying for a renewal of a CDL, all applicants shall:

(1) Provide certification contained in § 383.71(a)(1); (2) Provide updated information as specified in Subpart J of this part; and

(3) If a person wishes to retain a hazardous materials endorsements, pass the test for such endorsement as specified in § 383.123.

(d) *License upgrades.* When applying to operate a commercial motor vehicle in a different group from the group in which the applicant already has a CDL, all persons shall:

(1) Provide the certifications as specified in § 383.71(a) (1) and (4); and

(2) Pass all tests specified in § 383.71(a) (2) and (3) for the new vehicle group and/or different endorsements.

(e) *Commercial Driver's Certificate for domestic drivers.* When an applicant is domiciled in a State which, as determined by the Administrator, does not test and license in conformance with the standard contained in Subparts G and H of this part, such applicant shall, no earlier than October 1, 1991, obtain a CDC from a State which does test and license in conformance with the standards. Such applicant shall:

(1) Complete the requirement to obtain a CDL as contained in § 383.71(a) by April 1, 1992;

(2) Notify the State which issued the CDC of any conviction as required in § 383.31(a); and

(3) Notify the State which issued the CDC of any license suspension, revocation or cancellation or if he/she is disqualified from operating a commercial motor vehicle. The notification must be made in accordance with the time periods specified in § 383.33.

(f) *Commercial Driver's Certificates for foreign drivers.* When an applicant is domiciled in a foreign jurisdiction where the commercial motor vehicle operator testing and licensing standards do not meet the standards contained in Subparts G and H of this part, as determined by the Administrator, such applicant shall obtain a CDC from a State which meets such standards. Such applicant shall:

(1) Complete the requirements to obtain a CDL contained in § 383.71(a);

(2) Show proof that he/she has a current license from a foreign jurisdiction; and

(3) Notify the State which issued the CDC of any license suspension or revocation, of if he/she is disqualified from operating a commercial motor vehicle. The notification shall be made within the time periods specified in § 383.33.

§ 383.73 State procedures.

(a) *Initial licensure.* Prior to issuing a CDL or CDC to a person, a State shall:

(1) Require the driver applicant to certify, pass tests, and provide information as described in § 383.71(a)(1) through (5);

(2) Check that the vehicle in which the applicant takes his/her test is representative of the vehicle group the applicant has certified that he/she operates or expects to operate.

(3) Initiate and complete a check within 60 days after issuance of the CDL of the applicant's driving record to ensure that the person is not subject to any disqualification, suspensions, revocations, or cancellations as contained in § 383.51 or that the person does not have a driver's license from more than one State. The record check shall include the following:

(i) For commercial drivers' licenses issued prior to April 1, 1992, a check with every other State to determine whether the person has a valid driver's license in another State. If the person is licensed in another State, the State making the check shall request information pertaining to the applicant's driving record from the other State.

(ii) A check with the CDLIS, when it is determined to be operational by the Administrator, to determine whether the driver applicant already has a CDL, whether the applicant's license has been suspended, revoked, or canceled, or if the applicant has been disqualified from operating a commercial motor vehicle; and

(iii) A check with the National Driver Register (NDR), when it is determined to be operational by the National Highway Traffic Safety Administrator, to determine whether the driver applicant has:

(A) Been disqualified from operating a motor vehicle (other than the commercial motor vehicle);

(B) Had a license (other than CDL or CDC) suspended, revoked, or canceled for cause in the 3-year period ending on the date of application; or

(C) Been convicted of any offenses contained in section 205(a)(3) of the National Drivers Register Act of 1982 (23 U.S.C. 401 note).

(4) Require the driver applicant, if he/she has moved from another State, to surrender his/her driver's license issued by another State

(5) Provide notification of the proposed issuance and the driver applicant's social security number and other required information to the operator of the CDLIS within 60 days of issuing a CDL or CDC.

(b) *License transfers.* Prior to issuing a CDL or CDC to a person who has a CDL or CDC from another State, a State shall:

(1) Require the driver applicant to make the certification contained in § 383.71(a);

(2) Complete a check of the driver applicant's record as contained in paragraph (a)(3) of this section;

(3) Request and receive updates of information specified in Subpart J of this part;

(4) If such applicant wishes to retain a hazardous material endorsement, require the driver to pass the tests for such endorsement specified in § 383.123; and

(5) Obtain the CDL issued by the applicant's previous State of domicile.

(c) *License renewals.* Prior to renewing an CDL or CDC a State shall:

(1) Require the driver applicant to make the certifications contained in §383.71(a);

(2) Complete a check of the driver applicant's record as contained in paragraph (a)(3) of this section;

(3) Request and receive updates of information specified in Subpart J of this part; and

(4) If such applicant wishes to retain a hazardous materials endorsement, require the driver to pass the test for such endorsement specified in § 383.123.

(d) *License upgrades.* Prior to issuing an upgrade of a CDL or CDC, a State shall:

(1) Require such driver applicant to certify and pass tests as described in § 383.71(c); and

(2) Complete a check of the driver applicants record as described in § 383.73(a)(3).

(e) *License issuance.* After the State has completed the procedures described in § 383.73 (a), (b), (c), or (d) and issued a CDL or CDC, the State shall notify the operator of the CDLIS of such the issuance, renewal or upgrade within the period of time specified by the operator of the CDLIS but no later than 30 days.

(f) *Commercial Driver's Certificates.* A State may issue a CDC to a person domiciled in another State or foreign justification if the Administrator has determined that the commercial motor vehicle testing and licensing standards in that State or foreign jurisdiction do not meet the standards contained in this Part. Issuance of a CDC shall be based on the following provisions:

(1) A State shall not issue a CDC to a person domiciled in another State earlier than October 1, 1991, and shall:

(i) Require the applicant to certify, pass tests, and provide information as described in § 373.71(a);

(ii) Require the applicant to show proof that he/she has a current license from a State;

(iii) Complete a check of the applicant's record as described in § 383.73(a)(3); and

(iv) Provide the clearinghouse with information on such driver.

(2) A State may issue a CDC to a person domiciled in a foreign jurisdiction, provided the State:

(i) Requires the applicant to certify, pass tests and provide information as described in § 383.71(a);

(ii) Requires the applicant to show proof that he/she has a current license from a foreign jurisdiction;

(iii) Completes a check of the applicant's record as described in § 383.73(a)(3) of this section; and

(iv) Provides the clearinghouse with information on such driver.

(g) *Revocation.* If a State determines, in its check of an applicant's prior license status and record, that the applicant has falsified information contained in Subpart J of this part or the certification required in § 383.71(a), the State shall revoke the applicant's CDL within 30 days.

(h) *Reciprocity.* A State shall allow any person who has a valid CDL which is not suspended, revoked, or canceled, and who is not disqualified from operating a commercial motor vehicle, to operate a commercial motor vehicle in the State.

§ 383.75 Third party testing.

(a) *Third party tests.* A State may allow a person (including another State, an employer, a private driver training facility or other private institution, or a department, agency or instrumentality of a local government) to administer the skills tests as specified in Subpart G and H of this part, if the following conditions are met:

(1) The tests given by the third party are the same as those which would otherwise be given by the State; and

(2) The third party has an agreement with the State with at least the following provisions:

(i) Allow the FHWA, or its representative, and the State to conduct random examinations, inspections and audits without prior notice;

(ii) Require the State to conduct on-site inspections at least annually;

(iii) Require all third party examiners meet the same qualification and training as State examiners; and

(iv) Require that State employees periodically take the tests actually administered by the third party as if the State employee were a test applicant, or that States periodically test a sample of drivers who were examined by the third party to compare pass/fail results.

(b) *Proof of testing by a third party.* Driver applicants who take and pass driving tests administered by a third party shall provide evidence to the State licensing agency that he/she has successfully passed the driving tests administered by the third party.

§ 383.77 Substitute for driving skills tests.

At the discretion of a State, the driving skill tests as specified in § 383.113 may be waived for drivers licensed before July 15, 1988, and substituted with either an applicant's driving record and previous passage of an acceptable skills test, or an applicant's driving record in combination with certain driving experience. The State shall impose conditions and limitations to restrict the applicants from which a State may accept alternative requirements for the skills test described in § 383.113. Such conditions must require at least the following:

(a) An applicant must certify that he/she:

(1) Has not had more than one license since July 1, 1987;

(2) Has not had any license suspended, revoked, or canceled since July 1, 1987;

(3) Has not had any convictions for any type of motor vehicle for the disqualification offenses contained in § 383.51 since July 1, 1987; and

(4) Has not had any violation of State or local law relating to motor vehicle traffic control (other than a parking violation) arising in connection with any traffic accident or has no record of an accident where he/she was at fault, during the 2 years immediately preceding application for a CDL; and

(b) An applicant must provide evidence and certify that:

(1) He/she has previously taken a skills test given by a State with a classified licensing and testing system, and that the test was behind-the-wheel in a representative vehicle for that applicant's driver's license classification; or

(2) He/she has operated, for at least 2 years, immediately preceding application for a CDL, a vehicle representative of the commercial motor vehicle the driver applicant operates or expects to operate.

Subpart F—Motor Vehicle Groups and Endorsements

§ 383.91 Motor vehicle groups.

(a) *Vehicle group descriptions.* Each driver applicant must possess and be tested on his/her knowledge and skills, described in Subpart G of this part, for the vehicle group(s) for which he/she desires a CDL. The vehicle groups are as follows:

(1) *Combination vehicle.* Any combination of motor vehicles with a Gross Combination Weight Rating (GCWR) of over 26,001 pounds or more provided the motor vehicle or trailers being pulled have a Gross Vehicle Weight Rating (GVWR) of over 10,000 pounds.

(2) *Bus.* Any vehicle designed to carry more than 15 passengers, including the driver.

(3) *Heavy straight truck.* Any vehicle with a GVWR of 26,001 pounds or more, or any combination of motor vehicles with a GCWR of 26,001 pounds or more provided the vehicle or trailers being pulled have a GVWR of not more than 10,000 pounds.

(4) *Small Vehicle.* Any motor vehicle with a GVWR or GCWR of under 26,001 pounds.

(b) *Representative vehicle.* For purposes of taking the driving test in accordance with § 383.113, a representative vehicle for the vehicle groups contained in § 383.91(a), is any motor vehicle which meets the definition of that vehicle group.

(c) *Relation between vehicle groups.* Each driver applicant who desires to operate in a different vehicle group from the one which his/her CDL or CDC authorizes shall be required to retake and pass all related tests, except the following:

(1) Drivers who have passed the knowledge and skills tests for a combination vehicle may operate a heavy straight truck or a small vehicle;

(2) Drivers who have passed the knowledge and skills tests for a bus may operate a small vehicle; and

(3) Drivers who have passed the knowledge and tests for a heavy straight truck may operate any small vehicle.

§ 383.93 Endorsements.

(a) *General.* In addition to taking and passing the knowledge and skills tests described in Subpart G of this part, all persons who operate or expects to operate the type(s) of motor vehicle described in paragraph (b) of this section shall take and pass specialized tests to obtain each endorsement. The State shall issue CDL endorsements only to drivers who successfully complete the tests.

(b) *Endorsement descriptions.* Operators must obtain State-issued endorsements to his/her CDL or CDC to operate commercial motor vehicles which are:

(1) Equipped with air brakes;

(2) Required to be placarded for hazardous materials;

(3) Cargo tanks;

(4) Double/triple trailers; or

(5) Articulated buses.

(c) *Endorsement testing requirements.* The following tests are required for the endorsements contained in paragraph (b) of this section:

(1) *Air Brakes*—a knowledge and skills test. The skills test must be taken in a motor vehicle equipped with air brakes;

(2) *Hazardous Materials*—a knowledge test;

(3) *Cargo Tank*—a knowledge and skills test;

(4) *Double/Triple Trailers*—a knowledge test; and

5) *Articulated Bus*—a knowledge test.

Subpart G—Required Knowledge and Skills

§ 383.110 General requirement.

All drivers of commercial motor vehicles shall have knowledge and skills necessary to operate a commercial motor vehicle safely as contained in this Subpart.

§ 383.111 Required knowledge.

All commercial motor vehicle operators must have knowledge of the following:

(a) *Safe operations regulations.* (1) Motor vehicle inspection, repair, and maintenance requirements as contained in Parts 393 and 396 of this title;

(2) Procedures for safe vehicle operations as contained in Part 392 of this title;

(3) The effects of alcohol, drugs, fatigue, poor vision, hearing, and general health upon safe commercial motor vehicle operation as contained in Parts 391 and 395 of this title; and

(4) The types of motor vehicles and cargoes subject to the requirements contained in Part 397 of this title.

(b) *Commercial motor vehicle safety control systems.* Proper use of the motor vehicle's safety system, including lights, horns, side and rear-view mirrors, proper mirror adjustments, fire extinguishers, symptoms of improper operation revealed through instruments, motor vehicle operation characteristics, and diagnosing malfunctions. Commercial motor vehicle drivers shall have knowledge on the correct procedures needed to use these safety systems in an emergency situation, e.g., skids and loss of brakes.

(c) *Safe vehicle control.* (1) The relationship of wheel base length, articulation, and number of axles to path of a turn;

(2) the proper position from which to begin a turn and how to "set up," execute and recover from a turn;

(3) Shifting procedures and selection of proper gear;

(4) Common shifting errors and their consequences;

(5) The procedures for backing and parking;

(6) The hazards of attempting to operate a commercial motor vehicle when the driver is not qualified;

(7) The relationship between speed and sight distance;

(8) Search patterns appropriate for straight driving, changing speed or direction, and entering or crossing traffic;

(9) When to actuate turn signals to provide adequate warning without creating confusion;

(10) Importance of signaling to the prevention of accidents;

(11) The relationship of speed to stopping distance, needed sight distance, hydroplaning, crash severity, and ability to maneuver;

(12) Causes and procedures to avoid overturning including safe speed and turning maneuvers, and safely negotiating ramps;

(13) The amount of separation which should be maintained from other motor vehicles to ensure room to maneuver in response to driver errors;

(14) Affects of intensity of illumination on ability to see under nighttime conditions;

(15) The symptoms and danger of fatigue in relationship to night driving;

(16) The general factors affecting night vision including interior illumination and use of sunglasses during daytime;

(17) The effects of rain, snow, and ice upon the ability to maneuver and stop the motor vehicle;

(18) Causes and procedures for avoiding skis and/or jackknifing;

(19) The effect of ice, snow, water, mud, and debris on operation of the brakes;

(20) Procedures for hot weather driving;

(21) The effect of motor vehicle weight and speed upon braking and shifting ability for uphill and downhill driving;

(22) The meaning and use of percent of grade signs (mountain driving);

(23) Activities of other road users that provide clues to potential danger and conflict situations including head and body movement (hazard perception);

(24) Appropriate ways to handle an impending head-on collision (emergency maneuver);

(25) Procedures for handling brake failure and blowouts (emergency maneuver); and

(26) Rules of the road.

(d) *Relationship of cargo to vehicle control.* (1) Procedures for securing cargo, including methods of blocking, bracing, packing, stacking, and use of straps, rope, cable, chains, and chain binders for tie down to prevent damage and accidents;

(2) Categories of hazardous materials, the need for specialized training to handle hazardous materials, and correct placarding;

(3) Regulations on loading, weight limits, and distribution of cargo; and

(4) The consequences of improper loading and unloading, overloading, and improper weight distribution.

(e) *Vehicle pre-trip, post-trip, and other inspections.* (1) Procedures for performing inspections;

(2) The importance of periodic inspection and repair to prevention of enroute breakdowns, longevity of parts, safety, and economy of operation;

(3) The name, location, function, and acceptable reading range of the various instruments required to monitor motor vehicle and engine speed as well as status of fuel, oil, air, cooling, exhaust, and electrical systems; and

(4) The effect of undiscovered malfunction upon safety.

(f) *Operators for the combination vehicle group shall also have knowledge of:* (1) Proper procedures for coupling and uncoupling;

(2) Components of pre-trip inspections and indications of problems; and

(3) Proper operation of air brakes as required in § 383.115(a).

(g) *Operators for the bus vehicle group shall also have knowledge of:* (1) Proper procedures for loading/unloading passengers;

(2) Proper use of emergency exits, including push-out windows; and

(3) Proper procedures at railroad crossings;

§ 383.113 Required skills.

(a) *Basic vehicle control skills.* All applicants for a CDL or CDC must possess and demonstrate the following basic motor vehicle control skills for each vehicle group which the driver operates or expects to operate. These skills shall include:

(1) Ability to start, warm-up, and shut down the engine, according to the manufacturer's specifications;

(2) Ability to put the motor vehicle in motion and accelerate smoothly, forward and backward;

(3) Ability to bring the motor vehicle to a smooth stop;

(4) Ability to back the motor vehicle in a straight line, and check path and clearance while backing;

(5) Ability to position the motor vehicle for a turn and negotiate turns of diffeent degrees;

(6) Ability to shift as required and select appropriate gear;

(7) Ability to parallel park; and

(8) Ability to observe road and behavior of other motor vehicles, particularly before changing speed and direction.

(b) *Safe driving skills.* All applicants for a CDL or CDC must possess and demonstrate the following safe driving skills for any vehicle group. These skills shall include:

(1) Ability to ascertain that brakes are functioning properly;

(2) Ability to signal appropriately;

(3) Ability to adjust speed to the configuration and condition of the roadway, weather and visibility conditions, traffic conditions, and motor vehicle, cargo and driver conditions;

(4) Ability to change lanes;

(5) Ability to position the motor vehicle appropriately in initiating and completing a turn to prevent other motor vehicles from passing on the wrong side and to minimize encroachment on other lanes;

(6) Ability to maintain a following distance appropriate to traffic, road surface, visibility, and motor vehicle weight; and

(7) Ability to adjust operation of the motor vehicle to adverse weather conditions including speed selection, braking, direction changes and following distance to maintain control and avoid jackknifing.

(c) *Test area.* Skills tests shall be conducted in on-street conditions or under a combination of on-street and off-street conditions.

(d) Operators for the combination vehicle group shall also demonstrate the skills required for air brakes contained in § 383.115 (b) and (c).

§ 383.115 Requirements for air brake endorsement.

In order to obtain an air brake endorsement each applicant must pass tests on the following:

(a) *Knowledge of air brakes.* (1) General air brake system nomenclature;

(2) The dangers of contaminated air (dirt, moisture and oil) supply;

(3) Implications of severed or disconnected air lines between the power unit and the trailer(s);

(4) Implications of low air pressure readings;

(5) Procedures to conduct safe and accurate pre-trip inspections, including knowledge about:

(i) Automatic fail-safe devices;

(ii) System monitoring devices; and

(iii) Low pressure warning alarms.

(6) Procedures for conducting enroute and post-trip inspections of air actuated brake systems, including ability to detect defects which may cause the system to fail, including:

(i) Tests which indicate the amount of air loss from the braking system within a specified period, with and without the engine running; and

(ii) Tests which indicate the pressure levels at which the low air pressure warning devices and the tractor protection valve should activate.

(b) *Pre-trip inspections skills.* Applicants shall demonstrate the skills necessary to conduct a pre-trip inspection which includes the ability to:

(1) Locate and verbally identify each of the operating controls and monitoring devices such as gauges and alarms;

(2) Determine the motor vehicle's brake system condition for proper adjustments and that air system connections between motor vehicles have been properly made and secured;

(3) Inspect the low pressure warning devices(s) to ensure that they will activate in emergency situations;

(4) Ascertain, with the engine running, that the system maintains an adequate supply of compressed air;

(5) Determine that required minimum air pressure build up time is within acceptable limits and that required alarms and emergency devices automatically deactivate at the proper pressure level; and

(6) Operationally check the brake system for proper performance.

(c) *Driving skills.* Applicants shall successfully complete the skills tests contained in § 383.113 in a representative vehicle equipped with air brakes.

§ 383.117 Requirements for double/triple trailers endorsement.

In order to obtain a Double/Triple Trailers endorsement each applicant must pass a knowledge test on:

(a) Procedures for assembly and hookup of the units;

(b) Proper placement of heaviest trailer;

(c) Handling and stability characteristics including offtracking, response to steering, sensory feedback, braking, oscillatory sway, rollover in steady turns, yaw stability in steady turns; and

(d) Potential problems in traffic operations, including problems the

motor vehicle creates for other motorists due to slower speeds on steep grades, longer passing times, possibility for blocking entry of other motor vehicle on freeways, splash and spray impacts, aerodynamic buffeting, view blockages, and lateral placement.

§ 383.119 Requirements for articulated bus endorsement.

In order to obtain an Articulated Bus Endorsement each applicant must pass a knowledge test on:

(a) Information as specified in § 383.117 (c) and (d);

(b) Rules pertaining to operation of passenger transport motor vehicles; and

(c) Proper braking and emergency procedure.

§ 383.121 Requirements for cargo tank endorsement.

In order to obtain a Cargo Tank Endorsement, each applicant must pass tests on the following:

(a) *Knowledge of cargo tank safety.* (1) Causes, prevention, and effects of cargo surge on motor vehicle handling;

(2) Proper braking procedures for the motor vehicle when it is empty, full and partially full;

(3) Differences in handling of baffled/compartmental tank interiors versus non-baffled motor vehicles;

(4) Differences in cargo tank type and construction;

(5) Differences in cargo surge for liquids of varying product densities;

(6) Effects of road grade and curvature on motor vehicle handling with filled, half-filled and empty tanks;

(7) Proper use of emergency systems; and

(8) For drivers of DOT specification cargo tanks, retest and marking requirements.

(b) *Driving skills.* Each applicant shall pass a driving skills tests using a motor vehicle with partially loaded (between 30 to 60 percent full in each compartment) cargo tank(s) which includes ability to:

(1) Start, warm up and shut down the engine;

(2) Put the motor vehicle in motion smoothly, both forward and reverse;

(3) Stop the motor vehicle smoothly;

(4) Back the motor vehicle in a straight line while checking clearance,

(5) Negotiate turns and lane changes;

(6) Select and change to proper gear without clashing; and

(7) Park in a jackknife position.

§ 383.123 Requirements for hazardous materials endorsement.

In order to obtain a Hazardous Material Endorsement each applicant must pass a knowledge test from information contained in 40 CFR Parts 171, 172, 173, 177, 178, and 397 on the following:

(a) *Hazardous materials regulations including:* (1) Hazardous materials table;

(2) Shipping paper requirements;

(3) Marking;

(4) Labeling;

(5) Placarding requirements;

(6) Hazardous materials packaging;

(7) Hazardous materials definitions and preparation;

(8) Other regulated material;

(9) Reporting hazardous materials accidents; and

(10) Tunnels and railroad crossings.

(b) *Hazardous materials handling including:* (1) Forbidden Materials and Packages;

(2) Loading and Unloading Materials;

(3) Cargo Segregation;

(4) Passenger Carrying Buses and Hazardous Materials;

(5) Attendance of Motor Vehicles;

(6) Parking;

(7) Routes; and

(8) Cargo Tanks.

(c) *Operation of emergency equipment including:* (1) Use of equipment to protect the public;

(2) Special precautions for equipment to be used in fires;

(3) Special precautions for use of emergency equipment when loading or unloading a hazardous materials laden motor vehicle; and

(4) Use of emergency equipment for cargo tanks.

(d) *Emergency response procedures including:* (1) Special care and precautions for different types of accidents;

(2) Special precautions for driving near a fire and carrying hazardous materials, and smoking and carrying hazardous materials;

(3) Emergency procedures; and

(4) Special driver and carrier requirements for Class A and B explosives.

Subpart H—Tests

§ 383.131 Test procedures.

(a) *Driver information manuals.* Information on how to obtain a CDL and endorsements shall be included in manuals and made available by States to CDL applicants. All information provided to the applicant shall include the following:

(1) Information on the requirements described in § 383.71, State procedures described § 383.73, and other appropriate driver information contained in Subpart E of this part;

(2) Information on vehicle groups and endorsements as specified in Subpart F of this part;

(3) Knowledge and skills which drivers shall have as specified in Subpart G of this part for the different vehicle groups and endorsements;

(4) Details of testing procedures, including the purpose of the tests, how to respond, any time limits for taking the test, and any other special procedures determined by the State of issuance; and

(5) Directions for taking the tests.

(b) *Examiner information manuals.* A State shall provide to test examiners details on testing and any other State imposed requirements in the examiner's manual. States shall provide standardized scoring sheets for the skills tests, as well as standardized driving instructions for the applicants. Such examiners' manuals shall contain the following:

(1) Information on State procedures contained in § 383.71, State procedures described § 383.73, and other appropriate driver information contained in Subpart E of this part;

(2) Details on information which must be given to the applicant;

(3) Details on how to conduct the tests;

(4) Scoring procedures and minimum passing scores;

(5) Information for selecting driving test routes;

(6) List of the skills to be tested;

(7) Instructions on where and how the skills will be tested;

(8) How performance of the skills will be scored; and

(9) Causes for automatic failure of skills tests.

§ 383.133 Test methods.

(a) All tests shall be constructed in such a way to determine if the applicant possesses the required knowledge and skills contained in Subpart G of this part for the type of motor vehicle or endorsement the applicant wishes to obtain.

(b) States shall develop their own specifications for the tests for each vehicle group and endorsement which must be at least as stringent as the Federal standards;

(c) States shall determine specific methods for scoring the knowledge and skills tests;

(d) Passing scores must meet those standards contained in § 383.135.

(e) Knowledge and skills tests shall be based solely on the information contained in the driver manuals referred to in § 383.131(a).

(f) The knowledge test shall contain at least 30 items per test and have established reliability coefficients of at least $r=0.90$.

(g) The skill tests, shall have established administrative procedures

such that interrater reliability of the examiners is at least r=.80.

§ 383.135 Minimum passing scores.

(a) The driver applicant must correctly answer at least 80 percent of the questions on the knowledge test in order to achieve a passing score on such knowledge test.

(b) The passing scores for the skills test shall depend on the way the test is administered. If a disaggregated or elements test approach is used, the lowest acceptable passing score shall be 80 percent. If the test requires successful completion of general skills, the passing score must be 100 percent.

(c) If the driver applicant does not obey traffic laws, or causes an accident during the test, he/she shall automatically fail the test.

Subpart I—[Reserved]

Subpart J—Commercial Driver's e License Document

§ 383.151 General.

The CDRL shall be a document that is easy to recognize as a CDL. At a minimum, the document shall contain information specified in § 383.153. A sample set of specifications for a unique document is contained in § 383.159.

§ 383.153 Information on the document.

All CDLs shall contain the following information:

(a) The statement that the license is a "Commercial Driver's License."

(b) The full name, signature, and mailing address of the person to whom such license is issued;

(c) Physical and other information to identify and describe such person including date of birth (month, day, and year), sex, weight, height, eye color, and hair color;

(d) Color photograph of the driver;

(e) The driver's social security number;

(f) The name of State which issued the license;

(g) The date of issuance and the date of expiration of the license;

(h) The group of groups of commercial motor vehicle(s) that the driver is authorized to operate, indicated as follows:

(1) A for Combination Vehicle;

(2) B for Bus;

(3) C for Heavy Straight Truck; and

(4) D for Small Vehicle;

(i) The endorsements for which the driver has qualified, indicated as follows:

(1) AR for air brakes;

(2) TT for double/triple trailers;

(3) AB for articulated bus;

(4) CT for cargo tank; and

(5) HM for hazardous materials.

§ 383.155 Tamperproofing requirements.

States shall make the CDL or CDC tamperproof to the maximum extent practicable. At a minimum, a State shall use the same tamperproof method used for noncommercial drivers' licenses.

§ 383.157 Commercial Driver's Certificate (CDC) document.

Each CDC shall contain the same information as contained in § 383.153 except the CDC shall contain the State "Commercial Driver's Certificate" or "CDC" in lieu of "Commercial Driver's License" or "CDL."

§ 383.159 Sample specifications for document appearance.

States desiring to achieve an uniform CDL document may use the following specifications.

(a) The CDL and CDC card should not exceed 2⅛ inches high by 3⅜ inches wide and be of white stock;

(b) The front of the CDL document should contain the following, as shown in Illustration A;

(1) Name of the State of issuance;

(2) The words "Commercial Driver's License" or "CDL" in bold print;

(3) The driver's full legal name and signature;

(4) The driver's mailing address;

(5) The driver's social security number;

(6) The dates of issuance and the date of expiration;

(7) The group of motor vehicle the driver is authorized to operate;

(8) The endorsement(s) the driver may have; and

(9) Signature and title of State issuing official.

(c) The reverse side of the CDL should contain the following, as shown in Illustration B;

(1) Driver's date of birth (month, day, and year);

(2) Driver's sex;

(3) Driver's height;

(4) Driver's weight;

(5) Driver's hair color;

(6) Driver's eye color;

(7) Color photograph of the driver; and

(8) Other information the State may desire or space reserved for future storage of information.

(d) Each CDL, issued by a State should indicate the group of motor vehicle the driver is authorized to operate as described in § 383.153(h).

(e) Each CDL issued by a State should indicate the driver's endorsements as described in § 383.153(i).

BILLING CODE 4910-22-M

Illustration A

Front

(Name of Issuing State) COMMERCIAL DRIVER'S LICENSE	
Social Security Number	Group of Vehicle Endorsements
Last Name, First, Middle Mailing Address Date Issued: _____ Date Expires: _____ Applicant's Signature	State Official's Signature State Official's Title

Illustration B

Reverse

(State Information and Future Data Storage)	Sex Height	COLOR PHOTOGRAPH
Date of Birth Hair Color	Weight Eye Color	
(State Information and Future Data Storage)		

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Part VIII

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 779, 780, 783, 784, 816 and 817

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Fish and Wildlife Resources Information; Fish and Wildlife Plan; and Protection of Fish, Wildlife, and Related Environmental Values; Final Rule

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 779, 780, 783, 784, 816, and 817

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Fish and Wildlife Resources Information; Fish and Wildlife Plan; and Protection of Fish, Wildlife, and Related Environmental Values

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) of the U.S. Department of the Interior (DOI) is amending its rules with respect to fish and wildlife resource information and planning requirements, and standards applied to the protection of fish and wildlife values. The amendments are being made to comply with recent court decisions and to revise and clarify the rules. The revised rules amend reinstated fish and wildlife permitting requirements and provide added protection to endangered or threatened species.

EFFECTIVE DATE: January 11, 1988.

ADDRESS: Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Charles H. Wolf, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, Ten Parkway Center, Pittsburgh, Pennsylvania 15220; telephone: 412–937–2897.

SUPPLEMENTARY INFORMATION:

I. Background

The Surface Mining Control and Reclamation Act of 1977, 30 U.S.C. 1201 *et seq.* (the Act) sets forth general requirements governing surface coal mining operations and surface impacts of underground coal mining. Sections 515(b)(24) and 516(b)(11) of the Act, 30 U.S.C. 1265(b)(24) and 1266(b)(11), require that surface coal mining and reclamation operations shall: to the extent possible using the best technology currently available, minimize disturbances and adverse impacts of the operation on fish, wildlife, and related environmental values, and achieve enhancement of such resources where practicable;

In addition, section 515(b)(2) of the Act, 30 U.S.C. 1265(b)(2), requires that the operator, in consideration of public health and safety and proposed land use, restore mined land to a condition capable of supporting the uses which it was capable of supporting prior to any mining or higher or better uses. Section 516(b)(10) imposes that same requirement on underground mines with such modifications as are necessary to accommodate the distinct difference between surface and underground coal mining.

To implement the requirements of these provisions and the provisions of the Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. 1531 *et seq.*), the Bald Eagle Protection Act, as amended (16 U.S.C. 668 *et seq.*), the Fish and Wildlife Coordination Act, as amended (16 U.S.C. 661 *et seq.*) and other statutes protecting fish and wildlife resources, OSMRE promulgated 30 CFR 779.20, 780.16, 783.20, 784.21, 816.97, and 817.97 on March 13, 1979, as a part of the permanent regulatory program (44 FR 15356, 15359, 15364, 15369, 15410, 15437). Sections 779.20, 780.16, 783.20, and 784.21 were remanded by court decision and suspended by OSMRE (45 FR 51547, August 4, 1980).

On June 30, 1983, OSMRE revised §§ 816.97 and 817.97 (48 FR 30312) to clarify the relationship of the Act to the ESA and the Bald Eagle Protection Act. On October 1, 1984, the District Court for the District of Columbia remanded portions of these rules to modify requirements pertaining to endangered or threatened species and the protection of wildlife from toxic ponds. *In re: Permanent Surface Mining Regulation Litigation II*, No. 79–1144 (D.D.C. 1984). The court also ordered that §§ 779.20, 780.16, 783.20, and 784.21 be reinstated pending a new rulemaking. The sections were subsequently reinstated by OSMRE (50 FR 7274, February 21, 1985). Additional information regarding these actions is provided in the **Federal Register** as cited and in the preamble to the proposed fish and wildlife rules (51 FR 19498, May 29, 1986).

On May 29, 1986 (51 FR 19498) OSMRE proposed revisions to the fish and wildlife provisions of §§ 779.20, 780.16, 783.20, 784.21, 816.97, and 817.97. The purpose of the proposed revisions was to comply with the court decision and to revise and clarify the rules. Throughout the development of the final rules, OSMRE solicited public comment and recommendations. A 70-day period for public comment was provided, ending August 7, 1986, and the public was given the opportunity to request public hearings. However, no public hearings were requested and therefore none were held.

II. Final Rule and Response to Public Comments on Proposed Rule

OSMRE received over 200 comments from representatives of industry, environmental groups, State regulatory authorities, Federal and State fish and wildlife agencies and private citizens. OSMRE has reviewed each comment carefully and has considered the commenters' suggestions and remarks in writing these final rules.

The majority of the comments received on the proposed rule were specific in nature and are discussed in the section-by-section analysis portion of the preamble. Several comments were received in direct response to OSMRE's request for guidance on questions raised in the preamble to the proposed rules. These comments and general concerns expressed by commenters are addressed in the section that follows.

Hereinafter, unless otherwise noted, references to §§ 779.20, 780.16, and 816.97 (surface mining rules) also apply to the counterpart underground mining rules at §§ 783.20, 784.21 and 817.97.

General Comments

OSMRE suspended §§ 779.20 and 780.16 on August 4, 1980 (45 FR 51547) and reinstated these same regulations on February 21, 1985 (50 FR 7274). During the period when the Federal rules were suspended State regulatory authorities could omit or, if desired, adopt special permitting rules pertaining to fish and wildlife. In the preamble to the proposed rules (51 FR 19499), OSMRE specifically requested comments on whether the experiences and events of the four and one-half years when the Federal rules were suspended justify Federal regulation requiring either premining resource information or protection and enhancement plans or both. Based upon remarks from commenters and for the reasons discussed below, OSMRE has concluded that such regulations are necessary.

Most commenters indicated that Federal regulation requiring both premining resource information and protection and enhancement plans are necessary for the protection of fish and wildlife resources. One commenter further stated that because OSMRE is the regulatory authority for Indian lands and in Federal program States such as Georgia and Washington, without Federal regulations, the fish and wildlife resources in these States and lands

would not be protected as section 515(b)(24) of SMCRA demands. OSMRE agrees with the commenter that Federal rules are needed in Federal program States and for Indian lands.

Three commenters felt that permitting regulations for fish and wildlife resources information are not justified or needed. Two of these commenters stated that fish and wildlife resources were adequately protected under their approved state programs during the four and one-half year period in which the Federal regulations were suspended. One of the commenters cited as an example a situation where a species currently proposed to be listed as threatened had been protected. Although certain states may be protecting fish and wildlife resources, OSMRE has concluded that these rules are needed to define Federal standards regarding the submission of permit information needed to assure minimum standards of protection.

Another commenter felt that the proposed regulations appeared to be a rekindling of the ongoing efforts of Federal and State fish and wildlife agencies to gain decisionmaking authority in the permitting process. The commenter believed that such authority was not granted by Congress but would be granted by the final regulations. OSMRE considered the role given the Federal and State fish and wildlife agencies by SMCRA and has adopted a final rule that clarifies that the various Federal and State fish and wildlife agencies act in an advisory capacity to the regulatory authorities. Regulatory authorities retain their responsibility for making decisions on the completeness and adequacy of applications for SMCRA permits.

OSMRE also requested comments in the preamble to the proposed rules (51 FR 19499) on whether fish and wildlife information and planning requirements can be addressed effectively under one section as proposed or whether they should remain as separate and distinct sections as in the existing rules under Parts 779 and 780. OSMRE has decided that the fish and wildlife information and planning requirements can be addressed under one section as has been adopted in the final rule.

Several commenters agreed with the proposal that fish and wildlife information and planning requirements be addressed under one section. One commenter who disagreed stated that existing Part 779 requires specific resource information for each component of the premine environment, including wildlife (§ 779.20). Similarly, the commenter stated, Part 780 requires a resource protection plan for each component of the premining environment, including wildlife (§ 780.16). The commenter contended that if fish and wildlife baseline data collection and protection requirements are to be combined as one section under Part 780, then all other environmental resource components should be similarly treated. Otherwise, the combination of the two fish and wildlife requirements may de-emphasize the importance of baseline data collection, since this requirement is being shifted in the final rule to Part 780 which deals with resource protection. The commenter suggested that OSMRE be consistent in its treatment of each resource component.

OSMRE believes that the combining of §§ 779.20 and 780.16 will not result in a loss of importance attached to the collection of fish and wildlife baseline data. Requirements for data collection for certain resources (such as hydrology and geology) are combined with the requirements for protection plans for those resources, while in other cases the requirements for information collection and the plans remain separate (such as soils and land use). It is OSMRE's intent to combine resource information collection and protection plan requirements whenever possible because of the logical link between baseline information pertaining to a resource and the protection and enhancement of that resource.

In the preamble to the proposed rules (51 FR 19499), OSMRE solicited comments on whether or not there are distinct differences between surface and underground mining that would justify differences in the regulations. After considering remarks from commenters, and for the reasons discussed below, OSMRE has determined that the same requirements should apply to both surface and underground mining.

Several commenters indicated that from a fish and wildlife protection and enhancement perspective there are no distinct differences between surface and underground mining that justify differences in the regulations. Three commenters expressed concerns over subsidence-related impacts on fish and wildlife resources. These commenters further suggested that subsidence impacts receive special attention during the permit review and interagency consultation process. OSMRE disagrees with the commenters that the impacts of subsidence on fish and wildlife need special attention because 30 CFR 784.21(b) will cover any problem not covered under OSMRE's regulations at 30 CFR 784.20 which provide for detailed subsidence control plans to protect renewable resource lands. One commenter was concerned that underground mining could temporarily disrupt the flow of alluvial water into a surface drainage and cause adverse impacts to the downstream aquatic ecosystem. OSMRE believes that such concerns are adequately addressed under existing rules concerning hydrology. Studies of the hydrologic regime required under existing 30 CFR 784.14(e) and 784.14(f) would indentify any potential adverse impacts to surface drainage from proposed underground mining. 30 CFR 773.15(c)(5) requires that before a permit application is approved, the regulatory authority must find in writing that the proposed operation has been designed to prevent material damage to the hydrologic balance outside the permit area. Also under 30 CFR 817.57, a buffer zone around streams exists within which most mining disturbances may not occur without a specific finding that environmental resources of such streams will not be adversely affected.

One commenter suggested that the last statement in the Summary of the preamble misleads the public into believing that the proposed rule would provide added protection to endangered or threatened species. The commenter contended that this is not true since the proposed rule does not provide any additional protection, for Federally-listed endangered or threatened species but merely reinstates the original (1979) protection for State-listed species. The commenter is correct in recognizing that the proposed rule would reinstate the protection previously given to State-listed endangered or threatened species in OSMRE's March 13, 1979 rulemaking (44 FR 15410, 15437). However, the proposed rule contains other important provisions that provide added protection. The final rule prohibits surface coal mining operations which are likely to jeopardize the continued existence of endangered or threatened species, not just those operations which are certain to do so, as provided in the existing rules. Also, the final rule clearly establishes the requirement for permit applicants to provide site-specific resource information in their applications when the permit area or adjacent area are likely to include endangered or threatened species.

Two commenters expressed support for the rules as proposed. One commenter stated that the proposed rules contain rather specific requirements on the type of fish, wildlife, and related resource information which must be provided in the permit application by the permit applicant. The commenter further stated

that the regulatory authority in his particular state has established a permit review process whereby the State fish and wildlife agencies themselves, not the applicant, provide this information to the regulatory authority. The commenter sought final rules that would have sufficient flexibility to allow for this means of providing wildlife resource information. Although the final rule adopted today would not preclude such a system, the applicant retains the ultimate responsibility for assuring that all the permit application requirements are met.

One commenter questioned how the proposed rule would address the additional protection standards afforded fish, wildlife, and habitats listed under Tribal statutes. The commenter is reminded that OSMRE is the regulatory authority on Indian lands and that Parts 779, 780, 783, 784, 816, and 817 are included in the Indian lands program (30 CFR Part 750) through cross-referencing. When implementing the Indian lands program, OSMRE will treat species and habitats protected under Tribal statutes in a manner similar to those protected by State statutes.

One commenter stated that OSMRE's draft Environmental Assessment (EA) for this rulemaking should be revised to include additional decision alternatives. This suggestion was taken into consideration in the preparation of the final environmental assessment.

A. Fish and Wildlife Permitting Requirements

Resource Information—30 CFR 780.16(a)/784.21(a).

As proposed, § 780.16(a) provided that each application shall include fish and wildlife resource information for the permit area and adjacent area. Furthermore, it required the scope and level of detail for such information to be determined by the regulatory authority in accordance with any written guidance provided by State and Federal agencies with responsibilities for fish and wildlife. The proposed rule required that the information include, at a minimum, the existence of any threatened or endangered species, eagles, migratory birds or other species requiring special protection, and habitats of unusually high value for fish and wildlife. After considering the commenters' remarks, OSMRE has changed § 780.16(a)(1) in the final rule so that the scope and level of detail for fish and wildlife information will be determined by the regulatory authority in consultation with State and Federal agencies with responsibilities for fish and wildlife. Similarly, a new provision was added to require the information to be sufficient to design the protection and enhancement plan required under paragraph (b). Thus, although the level of detail may vary from permit to permit, the fish and wildlife resource information needed for each permit application will be carefully considered by the regulatory authority and those agencies with expertise in the resource area. This procedure will insure that sufficient information will be included to establish a meaningful protection plan.

Three commenters expressed concern that the proposed rules eliminate the requirement existing in § 779.20(b) for permit applicants to contact the regulatory authority to determine what fish and wildlife information will be necessary. One commenter felt that such contact increased the chances of receiving a complete and accurate application which could be easily reviewed by the regulatory authority. Another commenter was concerned that the proposed deletion will leave applicants with too little direction regarding site-specific data collection requirements. The third commenter believed that consultation early in the permitting process will give the respective agencies more time to determine whether specific studies should be required and will prevent unnecessary expenditures by permit applicants. OSMRE agrees that advance planning and consultation can help to reduce delays in processing permits and to avoid unnecessary expenses. As stated in the preamble to the proposed rule, however, OSMRE does not believe it is necessary to impose a Federal rule requiring all applicants to contact their respective regulatory authorities since some regulatory authorities may find it more appropriate and cost effective to set forth in either rules or guidance documents specific requirements for fish and wildlife information for mining in certain areas. Applicants should contact the regulatory authority early in the permitting process if they are unable to determine what information will be needed to meet regulatory requirements.

Proposed § 780.16(a) provided that the scope and level of detail for resource information be determined by the regulatory authority "in accordance with any written guidance" provided by State and Federal fish and wildlife agencies. OSMRE has deleted this provision in the final rule and replaced it with language requiring the regulatory authority to determine the scope and level of detail of resource information in consultation with State and Federal fish and wildlife agencies. This new language was adopted because several commenters requested that the final rule provide for consultation between the regulatory authority and Federal and State fish and wildlife agencies on what information is needed to permit applications to protect fish and wildlife resources. Some of these commenters felt that early consultation with State and Federal fish and wildlife agencies would be an effective means of cooperatively resolving resource issues while others believed that through consultation available information could be shared and determinations could be made on whether site-specific studies would be necessary. One commenter on this topic expressed concern that by specifying that only written guidance be provided by State and Federal fish and wildlife agencies, there would be less interaction between wildlife management and coal permitting. Although OSMRE does not believe that such a result would necessarily occur, OSMRE has changed the rule to provide for consultation. Consultation may include both oral and written advice, participation by these agencies in the development of technical guidance documents, memoranda of understanding, and other communications necessary to protect fish and wildlife resources.

Many commenters suggested that OSMRE more clearly indicate when site-specific fish and wildlife resource information would be required. Accordingly, OSMRE has added new paragraph (a)(2) in the final rule that will require site-specific resource information when the permit area or adjacent area are likely to include listed or proposed endangered or threatened species of plants or animals or their critical habitats; habitats of unusually high value for fish and wildlife; or other species or habitats identified through agency consultation as requiring special protection. One commenter suggested that when any special resource values in proposed § 780.16(a) (1), (2), or (3) are identified, the regulatory authority should require site-specific, in-depth studies of fish and wildlife and their habitats. OSMRE agrees that site-specific resource information is necessary for such identified species and habitats and has addressed the commenter's concern by the addition of paragraph (a)(2) to the final rule.

One commenter expressed concern over OSMRE's rationale for the substitution of the phrase "resource information" in § 780.16(a) for the term "study" as required under previous § 779.20(a). The term "resource information" is intended to allow for the use of existing fish and wildlife information, in addition to any site-

specific studies authorized under § 780.16(a)(2).

One commenter contended that the deletion of the requirement for site-specific data would have deleterious effects on fish and wildlife and that existing information is often out-of-date, incomplete, or not relevant to the site, and/or otherwise of limited value for determining degree of impact. OSMRE is sensitive to this concern and, as stated above, has added new paragraph (a)(2) to address when site-specific information is required.

Another commenter, who is currently developing a computer-based fish and wildlife data system, stated that its data system may not provide enough site-specific information on all proposed permit areas and therefore believed that the responsibility for providing information on fish and wildlife and their habitats should rest with the applicant. OSMRE agrees. As discussed in the preamble to the proposed rule, the authority to require site-specific studies has been retained but the restriction that a study be the only means to achieve compliance is removed. The need for site-specific studies will be determined by the regulatory authority through the consultation process required in the final rule. Site-specific studies could include aquatic sampling of streams to determine their "importance" as one commenter suggested.

One commenter suggested that "minimum standards" be established in the final rules for those areas that are not designated as critical habitat or that are otherwise sensitive, as outlined in proposed § 780.16(a) (1)–(3). This commenter contended that most mining operations are likely to occur in the "non-critical" fish and wildlife habitats and therefore in the majority of cases, the proposed rules provide no minimum standards to the regulatory authority on what resource information must be part of the permit application. OSMRE has added the requirement in § 780.16(a)(1) that the resource information be sufficient to design the protection and enhancement plan. Because of the diversity and variability of lands between and within regions, OSMRE cannot establish minimum resource information standards in the Federal rules for "non-critical" fish and wildlife habitat. Instead, OSMRE has determined that a more practical and as protective an approach will be for the regulatory authority to make these decisions within the framework of that information needed to assure an appropriate fish and wildlife management plan.

Several comments were received regarding the qualification requirements of those individuals compiling or reviewing fish and wildlife information. The commenters felt that the required information should be developed and/or reviewed by professional biologists. OSMRE disagrees that there is a need to specify qualifications for the preparers and reviewers of fish and wildlife information. The applicant is responsible for the accuracy and completeness of the submitted information and the regulatory authority is required to consult with agencies which possess the needed resources to competently evaluate the applicant's data.

Proposed rule § 780.16(a)(1) required permit applications to contain information on listed and proposed endangered or threatened species of plants or animals and their critical habitats listed by the Secretary under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and those species and habitats protected by similar State statutes. Commenters generally supported and endorsed this provision of the proposed rule. One commenter felt that listed or proposed endangered or threatened plants should be protected by separate requirements within the vegetation information requirements in existing § 779.19. OSMRE believes it appropriate to address both plants and animals that are afforded special protection under the ESA and similar State statutes under one section for administrative and continuity reasons. Another commenter requested clarification with regard to the reference to "state statutes." This commenter asked if an operation is to be located in a particular state, whether the proposed language would require that the fish and wildlife information address species which are not protected under that state's statute but are protected under the statutes of other states? Section 780.16(a)(2)(i) of the final rule would apply to only those species protected under Federal law and to those species protected under the laws of the state where the particular mining operation is located.

One commenter asked OSMRE to define a "proposed" endangered or threatened species. A "proposed species" as defined under existing 50 CFR 402.02 means any species of fish, wildlife, or plant that is proposed in the **Federal Register** to be listed under section 4 of the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 *et seq.* States with similar statutes may have various definitions for the term "proposed" or may use different terms for species under this classification.

Proposed § 780.16(a)(2) required information about eagles, migratory birds, and other species identified as requiring special protection under State or Federal law. OSMRE has modified this provision and numbered it in the final rule as § 780.16(a)(2)(iii). The final rule requires information on other species or habitats identified through agency consultation as requiring special protection under State or Federal law. OSMRE has deleted the specific reference to eagles and migratory birds. Instead, such species would be included in the general requirement to identify other species requiring special protection under State or Federal law.

Proposed § 780.16(a)(3) required information about habitats of unusually high value for fish and wildlife such as important streams, wetlands, riparian areas, cliffs supporting raptors, areas offering special shelter or protection, migration routes, and reproduction and wintering areas. OSMRE has adopted the proposed rule as final § 780.16(a)(2)(ii). One commenter requested that the term "wetland" be defined using the U.S. Fish and Wildlife Service's (FWS) *Classification of Wetlands and Deepwater Habitats of the United States*, 1979 (FWS/OBS–79–31 December 1979). Under the process outlined in the final rule, OSMRE believes it is unnecessary to define the term "wetland" because definitions in common usage by the appropriate State and Federal agencies are applied.

Three commenters suggested that the list of examples of habitat in proposed § 780.16(a)(3) be expanded to include additional habitat types and areas that they viewed as being of "unusually high value." OSMRE believes that the habitats provided as examples in the final rule are representative and not exclusive of the types that the regulatory authority should consider under this section. One commenter associated the term "migration routes" only with migratory birds and did not consider the term to be a type of habitat. OSMRE included the term "migration routes" under this section because of the different habitat types within migration routes utilized by such species as mule deer and elk in the western states.

Protection and Enhancement Plan—30 CFR 780.16(b)/784.21(b)

As proposed, § 780.16(b) required that each application shall include a description of how, to the extent possible using the best technology currently available, the operator will minimize disturbances and adverse

impacts on fish and wildlife and related environmental values, including compliance with the Endangered Species Act, during surface coal mining and reclamation operations and how enhancement of these resources will be achieved where practicable. After considering remarks from commenters and for the reasons discussed below, OSMRE has adopted § 780.16(b) as proposed.

One commenter suggested that the terminology "protection and enhancement plan" be changed to "mitigation and enhancement plan" and that acceptable definitions of "mitigation" and "enhancement" be provided. OSMRE has retained the terminology "protection and enhancement plan" as proposed. The terms "protection" and "enhancement" are consistent with terminology used in sections 515 and 516 of the Act. OSMRE does not believe that the term "enhancement" requires further definition when it is used in context in § 780.16(b).

Four commenters shared OSMRE's view of that enhancement of fish and wildlife values is practicable for almost all postmining land uses. Other commenters indicated that if a situation arises where fish and wildlife habitat enhancement measures are not practicable, the burden should fall to the applicant to indicate why enhancement is not practicable. OSMRE has reconsidered this provision and agrees that enhancement may not be practicable in *all* situations. Furthermore, the applicant should be afforded the opportunity to state why enhancement is not practicable. OSMRE has therefore modified § 780.16(b)(3)(ii) in the final rule to require that, where enhancement measures are not included in the permit application, the applicant shall provide a statement explaining why such measures are not practicable.

One commenter expressed concern that the proposed regulations requiring a protection and enhancement plan are silent on the enforceability of the plan by the regulatory authority. OSMRE reminds the commenter that the plan is a part of the permit application and thus is enforceable by the regulatory authority when the permit is issued.

Proposed § 780.16(b)(1) required that the description of how the operator will protect and enhance fish and wildlife values be consistent with the requirements of § 816.97. No comments were received regarding this subsection. OSMRE has therefore adopted the proposed rule as final § 780.16(b)(1).

Several commenters expressed concern that the proposed rule did not contain language which explicitly requires the protection and enhancement plan to cover the permit area and adjacent area. Two commenters requested that "adjacent area" be changed to "portions of the adjacent area where effects may reasonably be expected to occur." OSMRE does not agree that any change is necessary since "adjacent area" is already defined in § 701.5 to mean that area outside the permit area where a resource is, or reasonably would be expected to be, adversely impacted by proposed mining operations. Furthermore, § 780.16(b)(2) requires that the protection and enhancement plan apply at a minimum to resource information that is required for both the permit area and adjacent area in § 780.16(a). One commenter was concerned about substituting the terms permit area and adjacent area for mine plan area. OSMRE no longer uses the term mine plan area in the Federal rules. The revision of areal descriptors is discussed in 48 FR 14814. This substitution of terms will provide consistency in the terminology used in the Federal rules without affecting the substantive requirements for fish and wildlife plans required by § 780.16.

Three commenters expressed concern that the language of the proposed rule may leave some ambiguity by the generic reference to paragraph (a) and suggested that the language of § 780.16(b)(2) should read: "Apply, at a minimum, to species and habitats identified under paragraphs (a)(1), (a)(2), and (a)(3) of this section." OSMRE has rejected the commenters suggested language because, to be consistent with sections 515(b)(24) and 516(b)(11) of SMCRA, the protection and enhancement must not be limited to critical species and habitats.

Proposed § 780.16(b)(3)(i) required the protection and enhancement plan to describe the protective measures that will be used during the active mining phase of operation. The proposed rule specified that such measures may include the establishment of buffer zones, the selective location and special design of haul roads and powerlines, and the monitoring of surface water quality and quantity. OSMRE has adopted the proposed rule as final § 780.16(b)(3)(i). One commenter recommended that biological monitoring be added as an example of a protective measure under this section. OSMRE emphasizes that the protective measures provided as examples under this section are not an exclusive list to be considered by the applicant. Other protective measures such as biological monitoring may also be considered.

One commenter argued that the proposed regulations do not establish any minimum protection and enhancement measures. This commenter suggested the proposed rule require that protection and enhancement measures listed as discretionary in proposed § 780.16(b)(3)(i) and § 780.16(b)(3)(ii) be required in the plan when a determination is made by either the regulatory authority or the State or Federal fish and wildlife agency that these measures would improve the overall reclamation of the site for fish and wildlife resources. OSMRE believes the final rule provides the regulatory authority with sufficient guidance in § 780.16 (a) and (b) to determine what measures are necessary for the protection and enhancement of fish and wildlife. Section 515(b)(24) of SMCRA does not require specific protection and enhancement measures but rather requires each operation, to the extent possible using the best technology currently available, to minimize disturbances and achieve enhancement where practicable.

Proposed § 780.16(b)(3)(ii) required the protection and enhancement plan to describe the enhancement measures that will be used during the reclamation and postmining phase of operation to develop aquatic and terrestrial habitat. The proposed rule provided that such measures may include restoration of streams and other wetlands, retention of ponds and impoundments, establishment of vegetation for wildlife food and cover, and the placement of perches and nest boxes. One commenter believed that this section was inaccurate because the commenter did not view the restoration of streams and wetlands as a method of fish and wildlife enhancement. In his opinion, the term "restoration" indicated the return to a previous condition. OSMRE disagrees with the commenter since restored streams and wetlands may contain features that were not present during premining conditions. The addition of pools and riffles to a premine channelized stream is one example. Part of the commenter's concern is semantic. For example, one performance standard which the protection and enhancement plan implements, 30 CFR 816.43(a)(3), illustrates how closely the two concepts are and requires restoration or approximation of premining characteristics to promote the recovery and enhancement of the aquatic habitat.

A commenter stated that the establishment of vegetation for wildlife food and cover may not constitute wildlife enhancement. The commenter believed that a comparison of the

premining vegetation and habitats and the proposed postmining revegetation plan must be made before one can determine if the revegetation plan would enhance wildlife. OSMRE does not agree that such a comparison must be made; however, a comparison of pre- and postmining vegetative conditions may be one approach to reflect that wildlife enhancement has been realized. Enhancement can also be achieved by developing a postmining land use plan that benefits or promotes a selected or featured fish and wildlife species or a diversity of species.

The same commenter agreed that some enhancement measures—such as the creation of impoundments—can be implemented during mining and that proposed § 780.16(b)(3)(ii) stipulates the enhancement measures to be implemented after mining. OSMRE agrees that impoundments are normally created during the active phase of mining and has used the word "retention" in reference to ponds and impoundments in the final rule.

One commenter suggested that this section of the proposed rules be amended to include consultation with the appropriate fish and wildlife agency to ensure that the premining habitat diversity found in the permit area and adjacent areas is protected as much as possible when reclaiming the site to a postmining land use. OSMRE believes that through the consultation process in § 780.16(a)(1) the permit review process required by §§ 773.13 and 773.15, habitat diversity will receive adequate consideration.

Fish and Wildlife Service Review—30 CFR 780.16(c)/784.21(c).

Proposed § 780.16(c) required that upon request, the regulatory authority provide the resource information submitted by permit applicants under paragraph (a) and the protection and enhancement plan submitted under paragraph (b) to the U.S. Department of the Interior, Fish and Wildlife Service (USFWS) Regional or Field Office for their review. The proposed rule required that the information be provided within 10 days of receipt of the request from the Service. After considering remarks from commenters and for the reasons discussed below, OSMRE has adopted paragraph (c) as proposed. Several commenters supported the proposal while others offered suggestions for modifications. One commenter suggested that the final rule be expanded to require other information such as is found in the reclamation, revegetation and hydrologic balance restoration plans be provided to the USFWS if requested. OSMRE and the USFWS have discussed this provision and are in agreement that the resource information required under paragraph (a) and the protection and enhancement plan required under paragraph (b) will in most situations be sufficient for USFWS reviews. In those cases where an inspection of other parts of the permit application is desired, the USFWS can visit the location where the public file copy of the application is kept or make other arrangements with the regulatory authority to obtain the additional information.

Another commenter who acts as a liaison between the USFWS and a regulatory authority requested that the regulatory authority or the State agency charged with the protection of the plant and wildlife resources provide the resource information and the protection and enhancement plan to the USFWS.

OSMRE believes there is sufficient flexibility in the final rule to provide for this transfer as suggested by the commenter. One commenter expressed concern that the implementation of this provision could relegate State fish and wildlife agencies to a role where their comments are solicited but are never implemented. OSMRE does not believe that this will happen. Under § 780.16(a)(1), the regulatory authority is required to consult with both State and Federal agencies in setting information requirements. Regulatory authorities that are provided comments by fish and wildlife agencies must consider all comments in their decisions to issue permits. To be defensible, these decisions must be well-reasoned and consistent with the State regulatory program.

One commenter questioned how many days the Service would have to review and comment on the permit application. Section 773.13(b)(1) requires each regulatory authority to establish a reasonable time for the submittal of written comments or objections on permit applications by State and Federal fish and wildlife agencies and other public entities.

Two commenters opposed § 780.16(c) as proposed and urged deletion of the proposal from the final rule. The commenters contended that there was no basis in the statute for this provision. OSMRE does not agree. Sections 201(c)(2), (6), (12), and (13), 501(b), and 510(b) of the Act provide authority. Moreover, in order for the USFWS to discharge its responsibilities under the Endangered Species Act, Bald Eagle Protection Act and the Fish and Wildlife Coordination Act, and to assure that sections 515(b)(24) and 516(b)(10) of SMCRA are implemented, the USFWS must have access to information supplied under § 780.16.

B. Performance Standards

Sections 816.97(b)/817.97(b)

OSMRE proposed to amend § 816.97(b) to provide for the protection of endangered and threatened species by requiring that no mining activity shall be conducted which is likely to jeopardize the continued existence of endangered or threatened species listed by the Secretary or which is likely to result in the destruction or adverse modification of designated critical habitats of such species in violation of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). The previous rule was more limited in that it prohibited only mining activity which *will* jeopardize the existence of endangered or threatened species or which *will* result in the destruction or adverse modification of designated critical habitats. OSMRE also proposed to require the operator to promptly report to the regulatory authority any State- or Federally-listed endangered or threatened species within the permit area of which the operator becomes aware. The proposed rule added the requirement to report State-listed species to the existing requirement that the operator report Federally-listed species. OSMRE has adopted § 816.97(b) as proposed.

Several commenters expressed support for this proposal. One commenter, however, noted that a number of states do not maintain state endangered species lists and instead classify certain species as "rare." OSMRE is aware that classification or terminology may differ in the various States; however, it is the protection afforded these special species under similar State statutes that is intended. This commenter further stated that it is not necessary or desirable to report immediately every threatened or endangered species observed within the permit area and cited an example of wintering bald eagles foraging over coal permit areas on a daily basis. Sections 515(b)(24) and 516(b)(10) require that disturbances to fish and wildlife and related environmental values be minimized. Accordingly, OSMRE has required, since 1979, that the operator promptly report the presence of certain species in the permit area. In the example provided, the eagles may be nesting or resting off the mine site but could be dependent upon a food source on the mine site and, thus, be adversely impacted by the mining operations. The reporting provision enables the

regulatory authority to ensure compliance with the Endangered Species Act and with the Bald Eagle Protection Act.

One commenter suggested that the reporting requirement be expanded to include not only the permit area but also the adjacent area. The rule is sufficiently flexible to allow the regulatory authority to require reports of sightings on adjacent areas if it wishes to do so. This commenter further suggested that the rule be expanded to mandate consultation when the regulatory authority receives sighting reports from any person, unless the sightings are deemed to be frivolous. While the rule requires the operator to notify the regulatory authority whenever the operator becomes aware of an endangered or threatened species in the permit area, it does not preclude other persons from so notifying the regulatory authority. The regulatory authority would have discretion on whether to initiate the consultation process.

Two commenters objected to the inclusion of the term "any State" in the proposed rule. The commenters further stated that SMCRA does not extend protection to State-listed species. As discussed in the preamble to the proposed rule, OSMRE proposed to amend the existing rule to include "State-listed" species in response to the District Court's decision of October 1, 1984. *In re: Permanent Surface Mining Regulation Litigation II*, No. 79–1144, slip op. at pp. 58–63 (D.D.C. 1984). The deletion of a reference to State-listed species from the previous rule was found by the court to be contrary to section 515(b)(24) of the Act. The commenters objected to the requirement to report the presence of endangered or threatened species within the permit area because they believed it would require duplicative reporting inasmuch as an operator will have already reported in the permit application the existence of any endangered or threatened species. The commenters cited for support the District Court's decision upholding the Secretary's regulation which requires identification of critical habitats in the permit application but not during the mining operation. *In Re: Permanent Surface Mining Regulation Litigation II*, No. 79–1144 (D.D.C. October 1, 1984) Slip op. at 60–1. OSMRE does not agree with the commenter's reasoning that the court's decision regarding critical habitats also applies to the reporting of threatened or endangered species. Unlike critical habitats which are designated by the Secretary after an administrative proceeding, threatened and endangered species are mobile rather than stationary and may enter the permitted area after a permit is approved.

Sections 816.97(e)/817.97(e)

Sections 816.97 (e)(2) and (e)(3) of the existing regulations were republished in the proposed rule solely for editorial reasons to reflect the addition of § 816.97(e)(4) and not to make substantive changes. OSMRE has therefore adopted these proposed rules as final §§ 816.97(e)(2) and 816.97(e)(3).

As proposed, § 816.97(e)(4) required each operator to fence, cover, or use other appropriate methods to exclude wildlife from ponds which contain hazardous concentrations of toxic-forming materials. After considering remarks from commenters and for the reasons discussed below, OSMRE has adopted the proposed rule as final § 816.97(e)(4). One commenter expressed support for the rule as proposed. Five commenters asked for clarification as to what constitutes "hazardous concentrations of toxic-forming materials" and one suggested that OSMRE work with the U.S. Environmental Protection Agency (EPA) to develop a standard definition for this term, consistent with the existing regulations for toxic-forming materials found in EPA's regulations at 40 CFR 261.2 and 40 CFR 261.3. OSMRE does not believe that further regulatory changes are necessary since OSMRE already defines "toxic-forming materials" in 30 CFR 701.5.

The final rules also amend §§ 779.10 and 783.10 which pertain to Federal information collection by deleting references to §§ 779.20 and 783.20 respectively. This amendment was necessary because §§ 779.20 and 783.20 have been deleted in the final rules.

Effect in Federal Program States and on Indian Lands

The final rules apply through cross-referencing in those States with Federal programs. This includes Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington. The Federal programs for these States appear at 30 CFR Parts 910, 912, 921, 922, 933, 937, 939, 941, 942, and 947, respectively. The final rules also apply through cross-referencing to Indian lands under the Federal program for Indian Lands as provided in 30 CFR Part 750.

III. Procedural Matters

Federal Paperwork Reduction Act

The information collection requirements of Parts 780 and 784 have been submitted to the Office of Management and Budget under 44 U.S.C. 3507. The following clearance numbers were assigned: 30 CFR Part 780 (OMB Control No. 1029–0036) and 30 CFR Part 784 (OMB Control No. 1029–0039). The information is needed to meet the requirements of sections 515(b)(24) and 516(b)(11) of Pub. L. 95–87, and will be used by the regulatory authority to assess the impact of proposed mining operations on fish and wildlife resources and the adequacy of proposed protection and enhancement plans. The obligation to respond is mandatory.

Executive Order 12291 and the Regulatory Flexibility Act

The Department of the Interior has determined that this document is not a major rule under E.O. 12291 and certifies that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The rule does not distinguish between small and large entities, and will make no change in the threshold for determining whether to approve permits for surface coal mining operations because of fish and wildlife considerations. No incremental economic effects are anticipated as a result of the rule.

National Environmental Policy Act

OSMRE has prepared an environmental assessment (EA) on the impacts on the human environment of this final rulemaking and has made a finding that the rules would not have a significant impact under section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C). The EA and finding of no significant impact are on file in the OSMRE Administrative Record Room 5131, 1100 L Street NW., Washington, DC.

Author

The author of this rule is Bruce Klein, Office of Surface Mining Reclamation and Enforcement, Knoxville Field Office, Knoxville, Tennessee 37902; telephone 615–673–4330.

List of Subjects

30 CFR Part 779

Coal mining, Environmental protection, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 780

Coal mining, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 783

Coal mining, Environmental protection, Reporting and recordkeeping requirements, Underground mining.

30 CFR Part 784

Coal mining, Reporting and recordkeeping requirements, Underground mining.

30 CFR Part 816

Coal mining, Environmental protection, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 817

Coal mining, Environmental protection, Reporting and recordkeeping requirements, Underground mining.

For the reasons set out in this preamble, 30 CFR Parts 779, 780, 783, 784, 816, and 817 are amended as set forth below.

Dated: April 9, 1987.

J. Steven Griles,

Assistant Secretary for Land and Minerals Management.

Editorial Note: This document was received at the office of the Federal Register December 10, 1987.

PART 779—SURFACE MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR INFORMATION ON ENVIRONMENTAL RESOURCES

1. The authority citation for Part 779 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, sec. 115 of Pub. L. 98–146, (30 U.S.C. 1257), and 16 U.S.C. 470 *et seq.*

§ 779.10 [Amended]

2. Section 779.10 is amended by removing the term "779.20,".

§ 779.19 [Amended]

3. Section 779.19, paragraph (b) is amended by removing the words "30 CFR 779.20" and adding in their place the words "30 CFR 780.16."

§ 779.20 [Removed]

4. Section 779.20 is removed.

PART 780—SURFACE MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR RECLAMATION AND OPERATION PLAN

5. The authority citation for Part 780 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, sec. 115 of Pub. L. 98–146, (30 U.S.C. 1257), and 16 U.S.C. 470 *et seq.*

6. Section 780.16 is revised to read as follows:

§ 780.16 Fish and wildlife information.

(a) *Resource information.* Each application shall include fish and wildlife resource information for the permit area and adjacent area.

(1) The scope and level of detail for such information shall be determined by the regulatory authority in consultation with State and Federal agencies with responsibilities for fish and wildlife and shall be sufficient to design the protection and enhancement plan required under paragraph (b) of this section.

(2) Site-specific resource information necessary to address the respective species or habitats shall be required when the permit area or adjacent area is likely to include:

(i) Listed or proposed endangered or threatened species of plants or animals or their critical habitats listed by the Secretary under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), or those species or habitats protected by similar State statutes;

(ii) Habitats of unusually high value for fish and wildlife such as important streams, wetlands, riparian areas, cliffs supporting raptors, areas offering special shelter or protection, migration routes, or reproduction and wintering areas; or

(iii) Other species or habitats identified through agency consultation as requiring special protection under State or Federal law.

(b) *Protection and enhancement plan.* Each application shall include a description of how, to the extent possible using the best technology currently available, the operator will minimize disturbances and adverse impacts on fish and wildlife and related environmental values, including compliance with the Endangered Species Act, during the surface coal mining and reclamation operations and how enhancement of these resources will be achieved where practicable. This description shall—

(1) Be consistent with the requirements of § 816.97 of this chapter;

(2) Apply, at a minimum, to species and habitats identified under paragraph (a) of this section; and

(3) Include—

(i) Protective measures that will be used during the active mining phase of operation. Such measures may include the establishment of buffer zones, the selective location and special design of haul roads and powerlines, and the monitoring of surface water quality and quantity; and

(ii) Enhancement measures that will be used during the reclamation and postmining phase of operation to develop aquatic and terrestrial habitat. Such measures may include restoration of streams and other wetlands, retention of ponds and impoundments, establishment of vegetation for wildlife food and cover, and the replacement of perches and nest boxes. Where the plan does not include enhancement measures, a statement shall be given explaining why enhancement is not practicable.

(c) *Fish and Wildlife Service review.* Upon request, the regulatory authority shall provide the resource information required under paragraph (a) of this section and the protection and enhancement plan required under paragraph (b) of this section to the U.S. Department of the Interior, Fish and Wildlife Service Regional or Field Office for their review. This information shall be provided within 10 days of receipt of the request from the Service.

PART 783—UNDERGROUND MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR INFORMATION ON ENVIRONMENTAL RESOURCES

7. The authority citation for Part 783 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, sec. 115 of Pub. L. 98–146 (30 U.S.C. 1257), and 16 U.S.C. 470 *et seq.*

§ 783.10 [Amended]

8. Section 783.10 is amended by removing the term "783.20,".

§ 783.19 [Amended]

9. Section 783.19, paragraph (b) is amended by removing the words "30 CFR 779.20" and adding in their place the words "30 CFR 784.21."

§ 783.20 [Removed]

10. Section 783.20 is removed.

PART 784—UNDERGROUND MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR RECLAMATION AND OPERATION PLAN

11. The authority citation for Part 784 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, sec. 115 of Pub. L. 98–146 (30 U.S.C. 1257), and 16 U.S.C. 470 *et seq.*

12. Section 784.21 is revised to read as follows:

§ 784.21 Fish and wildlife information.

(a) *Resource information.* Each application shall include fish and wildlife resource information for the permit area and adjacent area.

(1) The scope and level of detail for such information shall be determined by the regulatory authority in consultation with State and Federal agencies with

responsibilities for fish and wildlife and shall be sufficient to design the protection and enhancement plan required under paragraph (b) of this section.

(2) Site-specific resource information necessary to address the respective species or habitats shall be required when the permit area or adjacent area is likely to include:

(i) Listed or proposed endangered or threatened species of plants or animals or their critical habitats listed by the Secretary under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), or those species or habitats protected by similar State statutes;

(ii) Habitats of unusually high value for fish and wildlife such as important streams, wetlands, riparian areas, cliffs supporting raptors, areas offering special shelter or protection, migration routes, or reproduction and wintering areas; or

(iii) Other species or habitats identified through agency consultation as requiring special protection under State or Federal law.

(b) *Protection and enhancement plan.* Each application shall include a description of how, to the extent possible using the best technology currently available, the operator will minimize disturbances and adverse impacts on fish and wildlife and related environmental values, including compliance with the Endangered Species Act, during the surface coal mining and reclamation operations and how enhancement of these resources will be achieved where practicable. This description shall—

(1) Be consistent with the requirements of § 817.97 of this chapter;

(2) Apply, at a minimum, to species and habitats identified under paragraph (a) of this section; and

(3) Include—

(i) Protective measures that will be used during the active mining phase of operation. Such measures may include the establishment of buffer zones, the selective location and special design of haul roads and powerlines, and the monitoring of surface water quality and quantity; and

(ii) Enchancement measures that will be used during the reclamation and postmining phase of operation to develop aquatic and terrestrial habitat. Such measures may include restoration of streams and other wetlands, retention of ponds and impoundments, establishment of vegetation for wildlife food and cover, and the placement of perches and nest boxes. Where the plan does not include enhancement measures, a statement shall be given explaining why enhancement is not practicable.

(c) *Fish and Wildlife Service Review.* Upon request, the regulatory authority shall provide the resource information required under paragraph (a) of this section and the protection and enhancement plan required under paragraph (b) of this section to the U.S. Department of the Interior, Fish and Wildlife Service Regional or Field Office for their review. This information shall be provided within 10 days of receipt of the request from the Service.

PART 816—PERMANENT PROGRAM PERFORMANCE STANDARDS—SURFACE MINING ACTIVITIES

13. The authority citation for Part 816 is revised to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 *et seq.*), unless otherwise noted.

14. In § 816.97, paragraphs (b), (e)(2), and (e)(3) are revised and paragraph (e)(4) is added to read as follows:

§ 816.97 Protection of fish, wildlife, and related environmental values.

* * * * *

(b) *Endangered and threatened species.* No surface mining activity shall be conducted which is likely to jeopardize the continued existence of endangered or threatened species listed by the Secretary or which is likely to result in the destruction or adverse modification of designated critical habitats of such species in violation of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). The operator shall promptly report to the regulatory authority any State- or federally-listed endangered or threatened species within the permit area of which the operator becomes aware. Upon notification, the regulatory authority shall consult with appropriate State and Federal fish and wildlife agencies and, after consultation, shall identify whether, and under what conditions, the operater may proceed.

* * * * *

(e) * * *

(2) Locate and operate haul and access roads so as to avoid or minimize impacts on important fish and wildlife species or other species protected by State or Federal law;

(3) Design fences, overland conveyors, and other potential barriers to permit passage for large mammals, except where the regulatory authority determines that such requirements are unnecessary; and

(4) Fence, cover, or use other appropriate methods to exclude wildlife from ponds which contain hazardous concentrations of toxic-forming materials.

* * * * *

PART 817—PERMANENT PROGRAM PERFORMANCE STANDARDS—UNDERGROUND MINING ACTIVITIES

15. The authority citation for Part 817 is revised to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 *et seq.*), unless otherwise noted.

16. In § 817.97 paragraphs (b), (e)(2), and (e)(3) are revised and paragraph (e)(4) is added to read as follows:

§ 817.97 Protection of fish, wildlife, and related environmental values.

* * * * *

(b) *Endangered and threatened species.* No underground mining activity shall be conducted which is likely to jeopardize the continued existence of endangered or threatened species listed by the Secretary or which is likely to result in the destruction or adverse modification of designated critical habitats of such species in violation of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). The operator shall promptly report to the regulatory authority any State- or federally-listed endangered or threatened species within the permit area of which the operator becomes aware. Upon notification, the regulatory authority shall consult with appropriate State and Federal fish and wildlife agencies and, after consultation, shall identify whether, and under what conditions, the operator may proceed.

* * * * *

(e) * * *

(2) Locate and operate haul and access roads so as to avoid or minimize impacts on important fish and wildlife species or other species protected by State or Federal law;

(3) Design fences, overland conveyors, and other potential barriers to permit passage for large mammals except where the regulatory authority determines that such requirements are unnecessary; and

(4) Fence, cover, or use other appropriate methods to exclude wildlife from ponds which contain hazardous concentrations of toxic-forming materials.

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