following: Use of authentication technologies in products and packaging and labeling, in particular, for drugs most likely to be counterfeited; adoption of secure business practices by stakeholders; adoption of the revised model rules for wholesale distributor licensure by States; stronger criminal penalties and enforcement at the State and national levels; and education and outreach to stakeholders, including greater communication through the counterfeit alert network.

Although FDA is further delaying the effective date of §§ 203.3(u) and 205.30, the agency encourages wholesalers to provide pedigree information that documents the prior history of the product, particularly for most likely to be counterfeited, even when such a pedigree is not required by the act. The suggestion from the comments that there be a one-forward, one-back pedigree for high-risk drugs until an electronic pedigree is uniformly adopted may have some merit. However, FDA believes legislative changes would be needed before it could adopt such a system.

To summarize, FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree. As stated previously, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. Therefore, to allow stakeholders to continue to move toward this goal, FDA has decided to delay the effective date of §§ 203.3(u) and 203.50 until December 1, 2006. Before the effective date, FDA intends to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of PDMA, and determine whether to further delay the effective date of the regulations or take other appropriate regulatory action.

FDA is also further delaying the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. This further delay is necessary to give FDA additional time to address concerns about the requirements raised by affected parties and consider whether regulatory changes are appropriate and, if so, initiate such changes.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry by delaying the effect of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities while FDA works with industry to resolve concerns about these provisions either with the implementation of technological solutions (§§ 203.3(u) and 203.50) or the consideration of possible regulatory changes (§ 203.3(q)). Thus, this action is not a significant action as defined by the Executive order.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. In addition, given the imminence of the current compliance date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the compliance date for the requirements identified below, those companies affected would have to be preparing to comply with the April 1, 2004, compliance date. In accordance with 21 CFR 10.40(c)(1), FDA is also providing an opportunity for comment on whether this delay should be modified or revoked.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: February 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3856 Filed 2–18–04; 4:04 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 75

Self-Contained Self-Rescuers (SCSRs); Updating a Reference for Locating SCSRs More Than 25 Feet From a Miner

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Technical amendment.

SUMMARY: This technical amendment updates the reference in 30 CFR 75.1714–2(e) (Self-rescue devices; use and location requirements) from 30 CFR 75.1101–23 (Program of instruction; location and use of fire fighting equipment; location of escapeways, exits and routes of travel; evacuation procedures; fire drills) to 30 CFR 75.1502 (Mine emergency evacuation and firefighting program of instruction). This action is necessary to amend the outdated reference in § 75.1714–2(e).

DATES: Effective February 23, 2004.

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939, *Nichols.Marvin@dol.gov*, (202) 693–9440 (telephone), or (202) 693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

Background

On September 9, 2003, we published the Emergency Evacuations final rule (68 FR 53037 Sept. 9, 2003). Among other things, the rule removed § 75.1101–23 (Program of instruction; location and use of fire fighting equipment; location of escapeways, exits and routes of travel; evacuation procedures; fire drills) and replaced it with § 75.1502 (Mine emergency evacuation and firefighting program of instruction). The Emergency Evacuations final rule was effective upon publication in the **Federal Register**.

In issuing the Emergency Evacuations rule we inadvertently omitted updating the reference in § 75.1714–2(e). Section 75.1714–2(e) references another section of 30 CFR which provides the mechanism for mine operators to apply to the District Manager for permission to place SCSRs more than 25 feet away from a miner. The reference to § 75.1101–23 in § 75.1714–2(e) should have been renumbered to correspond with the change in the numbering in the Emergency Evacuations rule. This technical amendment updates the

language in § 75.1714–2(e) to refer to the renumbered standard.

Discussion of Change

Section 75.1714–2 (Self-rescue devices; use and location requirements) requires self-rescue devices to be used and located as prescribed in paragraphs (b) through (f) of this section. Paragraph (e) provides the mechanism for a mine operator to allow placement of self-contained self-rescuers (SCSRs) more than 25 feet away when necessary. The mine operator must apply to the District Manager of the Coal Mine Safety and Health district in which the mine is located for permission to place the SCSR more than 25 feet away.

Prior to the promulgation of the Emergency Evacuations rule, the mine operator submitted an application to the District Manager under § 75.1101–23. The promulgation of the Emergency Evacuations rule removed § 75.1101–23 and created § 75.1502 (Mine emergency evacuation and firefighting program of instruction).

This technical amendment updates wording in § 75.1714–2(e) to correctly reference the renumbered § 75.1502 (Mine emergency evacuation and firefighting program of instruction).

List of Subjects in 30 CFR Part 75

Coal mines, Underground coal mining, Fire prevention, Mine safety and health.

Dated: February 13, 2004.

Dave D. Lauriski,

Assistant Secretary of Labor for Mine Safety and Health.

■ Chapter I of title 30, part 75 of the Code of Federal Regulations is amended as follows:

PART 75—[AMENDED]

■ 1. The authority citation for part 75 continues to read as follows:

Authority: 30 U.S.C. 811.

■ 2. Section 75.1714–2 is amended by revising paragraph (e) introductory text to read as follows:

§ 75.1714–2 Self-rescue devices; use and location requirements.

* * * * *

(e) A mine operator may apply to the District Manager under § 75.1502 for permission to place the SCSR more than 25 feet away.

* * * * *

[FR Doc. 04–3771 Filed 2–20–04; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 775

RIN 0703–AA51

Policies and Responsibilities for Implementation of the National Environmental Policy Act Within the Department of the Navy

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DON) is revising portions of its internal regulations that establish the responsibilities and procedures within the DON for complying with the National Environmental Policy Act (NEPA). This revision clarifies when certain DON actions must be studied to determine their effect on the human environment and what types of activities are excluded from the NEPA analysis and documentation requirements.

DATES: Effective February 23, 2004.

ADDRESSES: Interested parties should request copies of the rule from: Mr. Thomas Egeland, Office of the Assistant Secretary of the Navy (Installations and Environment), 1000 Navy Pentagon, Washington, DC 20350–1000.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Egeland, Office of the Assistant Secretary of the Navy (Installations and Environment), 703–614–5913.

SUPPLEMENTARY INFORMATION: The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) establishes national policy and goals for protection of the environment. Section 102(2) of NEPA contains certain procedural requirements directed toward the attainment of such goals. In particular, all Federal agencies are required to give appropriate consideration to the environmental effects of their proposed actions in their decision making and to prepare detailed environmental statements on recommendations or reports significantly affecting the quality of the human environment.

Executive Order 11991 of May 24, 1977, directed the Council on Environmental Quality (CEQ) to issue regulations to implement procedural provisions of NEPA. Accordingly, CEQ issued final NEPA regulations (40 CFR parts 1500–1508) on November 29, 1978, which are binding on all Federal agencies as of July 30, 1979. These regulations require each Federal agency, as necessary, to adopt implementing procedures to supplement the CEQ regulations. Section 1507.3(b) of the CEQ regulations identifies those sections of the regulations that must be addressed in agency procedures.

The final rule revises DON's implementing regulations that were originally published in 55 FR 33898 on August 20, 1990. Significant changes that these amendments bring about include: Revision of and additions to the DON list of approved categories of actions excluded from further analysis and documentation under NEPA; revised criteria for disallowing the application of listed categorical exclusions; and assignment of responsibilities to the Assistant Secretary of the Navy (Research, Development and Acquisition), the General Counsel of the Navy, and the Judge Advocate General of the Navy.

The DON published the proposed rule in 64 FR 37069 on July 9, 1999, and granted a 60-day comment period. DON received comments from one Federal agency, one state agency, one local government agency, and one private party. DON coordinated the proposed rule with Council on Environmental Quality (CEQ). DON carefully considered the comments received. Most comments focused on two general areas: The discussion of policies and responsibilities and the revision of DON categorical exclusions. In response to comments on policies and responsibilities: The rule was modified to more clearly reflect the relationship among internal DON regulations and between the rule and internal Department of Defense directives; the phrase ''environmental analysis'' was substituted for the term ''NEPA document'' where appropriate; and definitions and other discussions perceived as inconsistent with the regulations promulgated by CEQ were deleted.

The discussion of categorical exclusions was also modified in response to comments. Based upon a recommendation from CEQ that routine documentation of categorical exclusions was not necessary, the two-group approach to categorical exclusions contained in the draft rule was eliminated. As a result, the categorical exclusions were placed in a single group and renumbered. The consolidation into a single grouping also reemphasized that, even though a proposed action generally is covered by a listed categorical exclusion, a categorical exclusion will not be used if the proposed action categorical exclusion involved any one of several enumerated conditions.

Several categorical exclusions were modified to reflect that they were