

payments were due until the date MMS receives them.

§ 204.213 May I obtain relief for a property that benefits from other Federal or State incentive programs?

You may obtain accounting and auditing relief for your marginal property under this subpart even if the property benefits from other Federal or State production incentive programs.

§ 204.214 Are the information collection requirements in this subpart approved by the Office of Management and Budget?

The information collection requirements contained in this subpart have been approved by OMB under 44 U.S.C. 3501 *et seq.* and assigned OMB control number 1010-____. See part 210 of this chapter for details concerning your estimated reporting burden and how you may comment on the accuracy of the burden estimate.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 800

[Docket No. 03N-0056]

Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the sampling plans, test method, and acceptable quality levels (AQLs) for medical gloves contained in its medical device regulations. As prescribed by its regulation, FDA samples patient examination and surgeons' gloves and examines them for visual defects and water leaks. Glove lots are considered adulterated if they do not meet the specified quality levels. The objective of the proposed regulation is to improve the barrier quality of medical gloves on the U.S. market. The updated regulation would accomplish this by reducing the acceptable level of defects observed during FDA testing of medical gloves. By reducing the AQLs for medical gloves, FDA would also harmonize the level with consensus standards developed by the International Organization for Standardization (ISO) and the American Society for Testing Materials (ASTM).

DATES: Submit written or electronic comments by June 30, 2003. See section VII of this document for the proposed effective date of a final rule based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Office of Compliance, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4692.

SUPPLEMENTARY INFORMATION:

I. Background

With the advent of the human immunodeficiency virus (HIV) infections and the progression of infections into acquired immune deficiency syndrome (AIDS), scientists and medical and public health experts developed risk reduction strategies, including protective and preventive strategies for health care workers. These strategies were based on the etiology, and mechanisms and routes of transmission, of HIV infections.

A. Routes and Mechanisms of HIV Transmission

HIV is transmitted primarily through sexual contact. However, nonsexual transmission occurred in health care settings as a result of contact with infected blood. HIV was also isolated from other body fluids. The prevalence of HIV infections in health care settings and the risk of clinical transmission of other infections increased the importance of using effective procedures and barriers. The potential for infection heightened the importance of the quality of the barriers selected for protection.

B. The Need for Precautions in Health Care Settings

On August 21, 1987, the Centers For Disease Control (CDC) published a report emphasizing the need for all health care workers to routinely use appropriate universal precautions when they expect to come into contact with blood or other body fluids of any patient (Ref. 1). This report recommended that health care workers wear medical gloves when: (1) Touching blood or other body fluids, mucous membranes, or non-intact skin of patients; (2) handling items or surfaces soiled with blood or other bodily fluids; and (3) performing venipuncture and other vascular access

procedures. The collective term, medical gloves, includes patient examination and surgeons' gloves (see 21 CFR 880.6250 and 878.4460).

C. The Need for Testing

After the publication of the CDC's recommendations, and the rise in HIV infections, health care workers increasingly relied on surgeons' gloves and patient examination gloves as a barrier to the transmission of HIV and other blood- and fluid-borne infectious agents. The CDC's recommendations clearly recognized that defects in medical gloves had the potential of resulting in transmission of HIV between patients and health care workers.

Consequently, FDA reviewed and evaluated the quality control procedures that manufacturers used in making medical gloves. FDA concluded that manufacturers could only meet reasonable expectations of barrier protection by establishing adequate specifications for medical gloves, and adequate test procedures to detect defects in gloves. Glove defects include rips, tears, embedded foreign objects in the glove that may cause the glove to rip or tear upon stretching, or holes that allow the passage of fluids and fluid-borne microorganisms. Each of these defects compromises the glove barrier integrity and may expose health care workers and patients to infectious agents. Articles written by health care professionals who studied glove quality and the use of gloves as a barrier to infectious agents noted that gloves with defects may not provide this protection (Refs. 2 through 6). In 1989, when FDA proposed § 800.20 (21 CFR 800.20), FDA's position was that existing consensus standards did not establish adequate test methods and acceptance criteria for patient examination or surgeons' gloves (54 FR 48218, November 21, 1989). Therefore, the agency concluded that it needed to communicate clearly the test procedures and the acceptance levels it would use to determine whether medical gloves were adulterated.

D. The Setting of Adulteration Levels

In the **Federal Register** of December 12, 1990 (55 FR 51254), FDA issued a final rule that identified minimum AQLs for both patient examination and surgeons' gloves, and established the sample plans and test method for determining whether a lot of gloves were acceptable. This rule defined defects as "leaks, tears, mold, embedded foreign objects, etc." The definitions, sampling plans, test methods, and adulteration levels identified in the