

1990 **Federal Register** are currently codified in title 21 of the Code of Federal Regulations in § 800.20.

## II. Proposed Changes

### A. Rationale and Summary of Changes

#### 1. Continuing HIV/AIDS Incidence and Need for Protective Measures for Health Care Workers

In a May 1998 report, CDC reaffirmed its expectation that health care workers should use medical gloves as an effective barrier to HIV, hepatitis B virus, and other blood-borne infections, and that these gloves should provide effective protection against exposure to pathogenic microorganisms in blood and other body fluids (Ref. 7).

In the December 10, 1999, *Morbidity and Mortality Weekly Report* (MMWR), CDC estimated that the prevalence of HIV at the end of 1998 ranged from 800,000 to 900,000 infected persons. CDC estimated that, of these 800,000 to 900,000 persons, HIV infection or AIDS was diagnosed in approximately 625,000 of the individuals (Ref. 8). In a fact sheet posted on the Internet in June 1999, CDC reported that 54 documented cases of HIV seroconversion resulted from occupational exposure to HIV (Ref. 9). In April 2002, CDC reported that, as of December 31, 1999, 22,218 out of 437,407 adults reported diagnosed with AIDS were health care workers (Ref. 10). FDA concluded that medical gloves play an important role in the prevention of infectious disease transmission in health care settings, and that lowering the acceptable level of defects is necessary to further reduce the risk of transmission of such diseases and to harmonize the quality of gloves sold in the United States with international consensus standards.

#### 2. Harmonization With Consensus Standards

Following the publication of § 800.20, several consensus standards organizations, such as the ISO and the ASTM, adopted the FDA test methodology and acceptance criteria for patient examination and surgeons' gloves. As glove manufacturing capabilities improved, these consensus standards organizations lowered the minimum acceptance criteria for holes/leaks for these gloves. In 1994, ISO published standards for surgeons' and patient examination gloves with AQLs of 1.5 and 2.5, respectively. ASTM adopted these same acceptance criteria in April 1998, and March 1999, for surgeons' and patient examination gloves, respectively. Because the standards organizations updated their standards to reflect the improvement in

manufacturing technology, the consensus standards currently have lower AQLs for medical gloves than FDA's regulation (§ 800.20).

The consensus standards differ from the current FDA regulation in two other respects: (1) They use metric units for specifying dimensions, and (2) they refer to sampling plans from the ISO's document ISO 2859, "Sampling Procedures for Inspection by Attributes," instead of the MIL-STD-105E sampling plan that is currently referenced in § 800.20.

FDA believes that, whenever feasible, it is important to harmonize its requirements with consensus standards. Harmonization helps ensure an acceptable standard of safety and effectiveness for all manufacturers and allows manufacturers to market their products more efficiently in a global economy. FDA has recognized the ASTM standards for patient examination and surgeons' gloves for the purpose of premarket notification submissions (510(k)s), and believes that it is appropriate to use the same standards for determining the acceptability of lots of medical gloves.

#### 3. Interpretation of Defects

Since issuing § 800.20, FDA has received many questions from FDA field laboratories, glove manufacturers, importers, and private laboratories regarding the definition of defects in the current regulation. Many questions concerned whether lumps of latex material on or beneath the glove surface are considered defects. These questions arise because the definition of defects in § 800.20 refers to "embedded foreign objects," and latex is not "foreign" to a latex glove. Other questions were whether "mold" is an appropriate defect to be included in a sampling plan intended primarily to detect physical defects. FDA believes these questions are valid and has addressed them in the proposed amendments.

#### 4. Tightened Sampling Plans for Reconditioned Gloves

FDA recognizes the difficulty of adequately representing a large lot of gloves with a relatively small sample size. FDA has sometimes allowed manufacturers and importers to segregate and retest portions of the lot(s) or sizes of reconditioned gloves that initially failed FDA or private laboratory analysis to identify those portions of the larger lot(s) or sizes that meet quality requirements. The agency recognizes, however, that passing a retest does not provide the same assurance of quality as when the lot passes the initial analysis. This is due, in part, to the nature of the

standard sampling plans, and in part to the fact that retesting is performed to identify acceptable portions of the larger lot(s) after failing the initial test. Recognized consensus standard sampling plans address the issue of previous test failures by allowing tightened sampling during retesting in order to provide additional assurance to the consumer. FDA proposes to apply this principle to testing of reconditioned lots that have failed an initial analysis.

#### 5. Proposed Reclassification of Medical Gloves

On July 30, 1999, FDA published a proposed rule in the **Federal Register** (64 FR 41710) that addressed several issues pertaining to medical examination gloves, including their reclassification from class I to class II in order to provide reasonable assurance of safety and effectiveness. To provide this assurance, appropriate special controls (applicable to class II medical devices) were also proposed. The proposal to reclassify medical examination gloves reflects the increased importance of these devices in the health care arena and is consistent with the changes FDA is now proposing for § 800.20. However, this proposal to lower the acceptable level of defects in medical gloves is an independent initiative that will go forward as FDA continues to review the comments it received on the reclassification proposal.

Therefore, in summary, FDA is proposing to: (1) Lower the AQL to which the level of defects in lots of gloves is tested, thereby assuring improved quality of gloves; (2) lower the AQLs, convert units of measure to the metric system; eliminate references to obsolete sampling plans, and reference current ISO standards; thereby harmonizing with recognized consensus standards; (3) clarify visual defects and current methodology for conducting water leak testing; and (4) provide tightened sampling plans for testing reconditioned lots of medical gloves that have already failed one analysis.

Specifically, FDA is proposing to lower the AQL for surgeons' gloves from 2.5 to 1.5, and is proposing to base the sampling plans on the tables in the ISO sampling standard, ISO 2859-1995.

FDA is also proposing to lower the AQL for patient examination gloves from 4.0 to 2.5, and is proposing to base the sampling plans on the tables in ISO sampling standard, ISO 2859-1995. Lowering the AQLs for medical gloves will reduce the allowable defect level for patient examination gloves. Further, FDA is proposing to amend the regulation to tighten sampling plans for reconditioned lots of medical gloves