

about one-third of the 140 annual occupational transmissions of HBV infections (approximately 40 cases) may potentially be associated with the current quality level of medical gloves. If only 6 percent of these cases develop chronic conditions, then an average of 2.4 annual cases of chronic HBV are associated with defective medical gloves.

HBV currently infects 3.9 million persons (Ref. 3). Over 2.7 million patients have reported chronic conditions. More than 40,000 new cases were reported during 1999. The risk of exposure to health care workers, however, appears to be extremely low. In fact, according to the CDC, for other than needle stick punctures, no transmission of HCV for health care personnel has been documented from intact or no intact skin exposures to blood or other fluids or tissues (Ref. 4). Thus, there is little evidence that glove defects are associated with HCV exposures.

As a result, FDA estimates the overall annual transmission of blood-borne pathogens due to defects in glove barrier protection in health care settings to include 2.4 cases of HIV infection and 2.4 cases of HBV infection. Increasing the AQL of gloves by lowering the rate of acceptable defects would reduce the transmission rates of these pathogens.

#### *D. Baseline Conditions*

The current AQL for medical gloves allows a defect rate of 4.0 percent (0.04) for patient examination gloves and 2.5 percent (0.025) for surgeons' gloves. The AQL represents the proportion of sampled gloves from a given lot that may include defects such as leaks or foreign material and still be accepted for entry into the marketplace. Currently, if more than 4 percent of the sampled patient examination gloves exhibit defects, the entire lot of gloves may not be sold as medical devices. Surgeons' gloves are sampled to a higher quality level (the lower AQL requires a higher proportion of nondefective gloves in order to pass inspection), because these products have a higher likelihood of contact with bodily fluids. Of course, medical glove lots that fail to meet the AQL may be marketed as household or other products. If a sample of gloves fails to meet the AQL, the marketer may petition for resampling of the lot. The required resampling plan for a lot originally found to be out of compliance is more intensive than the original sampling plan for a randomly selected lot. Lots initially found to be out of compliance are either resampled and subsequently offered as medical gloves after meeting the current AQL, offered

as nonmedical gloves, or sold in foreign markets.

Approximately 30.8 billion medical gloves were sold in the United States during the year 2000 (Ref. 6). According to FDA records, there are 417 manufacturers of medical gloves. Of these, only six are domestic firms. Malaysian manufacturers supply almost 44 percent of the medical gloves in the United States (Ref. 7). Only 250 million surgical gloves are imported each year (0.8 percent of the medical glove market) and the impact on this sector is negligibly different from overall patient examination gloves. Therefore, this analysis focuses exclusively on patient examination gloves.

FDA expects the demand for medical gloves to increase by the same rate as employment in the medical services industry. The Bureau of Labor Statistics (BLS) projects annual employment growth of 2.6 percent for this industry (NAICS 6200) (Ref. 8), which implies an annual demand for almost 40 billion medical gloves within 10 years. (A 2.6 percent annual growth rate results in an expected increase of 29.3 percent in 10 years).

Medical glove lot sizes may vary from as few as 25 gloves to as many as 500,000. According to discussions with manufacturers (Eastern Research Group, Inc. (ERG); 2001), a typical production or import lot from a foreign manufacturer contains an average of 325,000 gloves (either patient examination or surgeons'). This implies that the U.S. medical glove market currently imports about 95,000 lots of gloves per year. FDA currently samples only about 1.5 percent (0.015) of all glove lots, or 1,400 lots per year. Within 10 years, FDA expects the number of lots offered for import to increase to 122,500 per year. If the compliance sampling rate remains constant, FDA would sample 1,850 lots during that year.

FDA's Winchester Engineering and Analysis Center (WEAC) analyzed results from samples collected from 2000 and 2001. These samples represent approximately one-third of FDA's total sampling effort for that period. A total of 98,067 gloves were tested from 942 separate lots. Of these gloves, 2,354 (0.024) were defective, which implies that 2.4 percent of marketed gloves are likely to be defective. If so, then approximately 740 million defective medical gloves are currently marketed (30.8 billion gloves  $\times$  0.024). At the current AQL of 4.0 percent, 28 lots failed (0.0297) the WEAC analysis. Consequently, approximately 42 of the annually sampled lots are defective (1,400  $\times$  0.0297). By the 10th year, in the

absence of the proposed regulation, 955 million defective gloves would be marketed and 55 percent of the sampled lots would fail to meet the AQL.

FDA allows glove lots that fail to meet the AQL to be resampled. Sponsors usually attempt to resample the glove lot rather than divert the entire lot to alternative markets. According to discussions with industry sources and testing laboratories, the cost of domestic lot resembling and retesting for leakage and tensile strength equals approximately \$1,400. The current annual industry cost of resampling glove lot failures with the current AQL, therefore, is approximately \$59,000 (42 lots  $\times$  \$1,400 per lot). This resampling and retesting cost would equal \$77,000 within 10 years.

#### *E. Costs of the Proposed Regulation*

FDA expects that the proposed regulation would result in changed shipping practices by medical glove manufacturers. Currently, manufacturers use the target AQLs as a guide for releasing production lots of gloves for export to the United States because the release criteria are lower in the United States. Manufacturers attempt to avoid having three lot inspection failures within a 24-month period, because this results in rejection of future imports under FDA's current recidivist policy. Thus, to maintain an uninterrupted supply of gloves to customers, and to guard brand loyalty while avoiding the recidivist list, manufacturers would be expected to raise their level of quality control to at least maintain the current average lot rejection rate of 2.97 percent. FDA also expects the regulation to increase the costs of sampling by requiring larger and more detailed sampling plans to assure that the lower AQL is met for each inspected glove lot. FDA does not envision increased regulatory oversight costs because the number of inspections is not expected to change.

##### *1. Costs of Quality Control*

Manufacturers currently conduct quality control tests on glove lots prior to release. These tests include water-tight leak and tensile strength assays. According to interviews with glove manufacturers, the current cost of conducting these tests at the manufacturing site is approximately \$310 per lot, whereas more stringent quality control testing may cost an additional \$45 per lot. The additional cost is for increased inventory and larger sample sizes to ensure more precise measurements at the lower AQL. Because approximately 95,000 lots of medical gloves are imported per year,