

the expected costs are \$4.3 million (95,000 lots x \$45 per lot). Due to the expected increase in the demand for medical gloves by the 10th evaluation year, the compliance cost of meeting this increased quality level will equal \$5.5 million. Over the 10-year period, the average annualized cost of this increased level of testing (at a 7 percent discount rate) is \$4.9 million.

## 2. Increased Sampling Costs

A lower AQL would result in increased sampling costs for imported glove lots. The increased sampling costs would result from the need to test greater quantities of gloves to ensure sufficient statistical power. Based on reported costs from U.S. testing laboratories, ERG, an independent economic contractor, estimated that increased testing would add approximately \$200 to the current costs of \$1,400 per sample. (The difference between this increased cost and the \$310 increased import sampling cost is attributable to lower costs in the foreign countries that produce medical gloves.) FDA currently samples about 1.5 percent of the 95,000 annual imported lots, or 1,400 samples. Thus, the increased sampling costs due to the proposal are \$0.3 million (\$1,400 x \$200). Within 10 years, this increased cost will equal \$0.4 million (due to expected increases in the number of inspected glove lots) and the average annualized sampling cost (at a 7 percent discount rate) increase is \$0.3 million.

## 3. Withheld Lots

In addition, the proposed AQL is likely to result in an increase in the number of lots of medical gloves that are not released for shipment to the U.S. medical market. For example, manufacturers may attempt to maintain a target compliance level in order to avoid FDA's recidivist listing. FDA's WEAC research laboratory sampled 942 lots and discovered that 28 failed using the current AQL while 79 lots failed using the proposed AQL. To maintain the original 0.0297 (28/942) lot failure rate, the 53 lots with the highest defect rate would have to be held back by the affected manufacturers (.056)<sup>1</sup>. Therefore, FDA expects, that under the proposed AQL, approximately 5,500 lots would be held back by manufacturers. In order to meet the expected demand in 10 years, 7,000 lots would be held

back. FDA believes that glove lots that fail to meet the proposed AQL medical quality standards would most likely be sold as nonmedical gloves.

Manufacturers and distributors would experience some loss of revenue from this shift, because of the price premium commanded by medical gloves. FDA believes this loss would be inconsequential.

## 4. Costs of FDA Inspections

FDA does not envision increased inspection costs due to the proposed regulation. The rate of sampled glove lots is not expected to change and FDA resources are not expected to increase over the evaluation period.

## 5. Total Costs

In sum, therefore, FDA estimates that the proposed regulation would have an average annualized cost of about \$5.2 million.

## F. Benefits of the Proposed Regulation

The proposed regulation would result in public health gains by reducing the frequency of blood-borne pathogen transmissions due to defects in the barrier protection provided by medical gloves. Based on an implied societal willingness to pay (WTP), an annualized monetary benefit of \$12.3 million would be saved due to fewer pathogen transmissions and unnecessary blood screens. Moreover, fewer glove defects would reduce the number of, and, therefore, the cost and anxiety associated with, unnecessary blood screens (i.e., those that yield negative results for health care personnel).

## 1. Reductions in Marketed Defective Gloves

As noted in the previous paragraphs, FDA finds that approximately 740 million defective gloves are marketed each year in the United States, or 2.4 percent of all medical gloves. In the absence of this regulation, FDA expects that the number of defective medical gloves marketed in the United States each year would increase to 955 million gloves within 10 years. The proposed regulation would substantially reduce this figure.

WEAC's analysis of 98,067 medical gloves from 942 sampled lots collected in 2000 and 2001 resulted in approximately 3 percent lot failures under the current AQL of 4 percent (28 failed lots). This lot failure rate was associated with 2,356 defective gloves, or 2.4 percent of the total number of sampled gloves. Under the proposed AQL of 2.5 percent, the WEAC analysis concluded that 51 additional lots would fail (a total of 79 failed lots), increasing

the lot failure rate from 2.97 percent to 8.39 percent.

As discussed earlier, FDA maintains a recidivist policy under which manufacturers are denied import entry if three lots fail statistical sampling within a 24-month period. To avoid the denial of entry, manufacturers may be expected to hold a sufficient number of defective lots from shipment in order to maintain the same target lot failure rate (approximately 3 percent) with a new AQL. For example, removing the 53 most defective lots in the testing sample would result in 26 lot failures from 889 total lots, thereby maintaining the original 2.92 percent lot failure rate. This scenario leaves 85,172 total gloves in the sample, of which 1,512 gloves were defective, resulting in a glove defect rate of 1.78 percent. The proposed regulation, therefore, could reduce the proportion of marketed defective medical gloves from 2.4 percent of all marketed gloves to 1.78 percent of all marketed gloves.

The implications of this expected reduction in defective gloves are significant. The current AQL is associated with 740 million glove defects in the present year and within 10 years would result in 955 million annually marketed defective medical gloves. If the proposed AQL were in place, the current annual number of defective gloves would approximate 548 million and within 10 years would reach 709 million. The number of defective gloves, therefore, would be reduced by more than 25 percent due to the new AQL.

## 2. Reductions in Blood-Borne Pathogens

FDA has estimated that, on average, there are potentially 4.8 annual transmissions of blood-borne pathogens associated with medical glove defects (section IV.C of this document). These transmissions include 2.4 cases of HIV and 2.4 cases of chronic HBV. Because there are currently no documented cases of cutaneous transmission of HCV that would be affected by improving glove quality levels, this analysis does not consider potential HCV cases.

a. *Reductions in HIV transmission.* While the direct relationship between defective medical gloves and HIV is unknown, FDA believes it is reasonable to apply the proportional reduction in the number of defective gloves due to the proposed regulation (about 25 percent) to the annual transmission rate of the HIV pathogen to health care personnel. In the absence of this regulation, the current expectation of 2.4 annual cases of HIV transmission to health care personnel would likely increase to 3.1 annual cases within 10

<sup>1</sup> The current lot failure rate (28/942=0.0297) is reached by removing 53 defective lots from the sample. If only the 51 additional failing lots are removed, the overall failure rate is 0.0314 (28/891). The expected future failure rate is 0.0292 (26/889). FDA expects the withheld lots to include those with the highest defect rates.