

ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR PATIENT EXAMINATION GLOVES—Continued

| Lot Size | Sample | Sample Size | Number Examined | Number Defective | |
|------------------|---------------|-------------|-----------------|------------------|--------|
| | | | | Accept | Reject |
| 281 to 500 | Single sample | | 50 | 3 | 4 |
| 501 to 1,200 | Single sample | | 80 | 5 | 6 |
| 1,201 to 3,200 | First | 32 | 32 | 0 | 4 |
| | Second | 32 | 64 | 1 | 6 |
| | Third | 32 | 96 | 3 | 8 |
| | Fourth | 32 | 128 | 5 | 10 |
| | Fifth | 32 | 160 | 7 | 11 |
| | Sixth | 32 | 192 | 10 | 12 |
| | Seventh | 32 | 224 | 13 | 14 |
| 3,201 to 10,000 | First | 50 | 50 | 0 | 5 |
| | Second | 50 | 100 | 3 | 8 |
| | Third | 50 | 150 | 6 | 10 |
| | Fourth | 50 | 200 | 8 | 13 |
| | Fifth | 50 | 250 | 11 | 15 |
| | Sixth | 50 | 300 | 14 | 17 |
| | Seventh | 50 | 350 | 18 | 19 |
| 10,001 to 35,000 | First | 80 | 80 | 1 | 7 |
| | Second | 80 | 160 | 4 | 10 |
| | Third | 80 | 240 | 8 | 13 |
| | Fourth | 80 | 320 | 12 | 17 |
| | Fifth | 80 | 400 | 17 | 20 |
| | Sixth | 80 | 480 | 21 | 23 |
| | Seventh | 80 | 560 | 25 | 26 |
| 35,000 and above | First | 125 | 125 | 2 | 9 |
| | Second | 125 | 250 | 7 | 14 |
| | Third | 125 | 375 | 13 | 19 |
| | Fourth | 125 | 500 | 19 | 25 |
| | Fifth | 125 | 625 | 25 | 29 |
| | Sixth | 125 | 750 | 31 | 33 |
| | Seventh | 125 | 875 | 37 | 38 |

(d) *Compliance.* Lots of gloves that are sampled, tested, and rejected using procedures in paragraphs (b) and (c) of this section, are considered adulterated within the meaning of section 501(c) of the act.

(1) *Detention and seizure.* Lots of gloves that are adulterated under section 501(c) of the act are subject to administrative and judicial action, such as detention of imported products and seizure of domestic products.

(2) *Reconditioning.* FDA may authorize the owner of the product, or the owner's representative, to attempt to recondition, i.e., bring into compliance with the act, a lot or part of a lot of foreign gloves detained at importation, or a lot or part of a lot of seized domestic gloves.

(i) *Modified sampling, inspection, and acceptance.* If FDA authorizes reconditioning of a lot or portion of a lot of adulterated gloves, testing to confirm that the reconditioned gloves meet AQLs must be performed by an independent testing facility. The following tightened sampling plan must be followed, as described in ISO 2859 "Sampling Procedures for Inspection by Attributes:"

(A) General inspection level II,

(B) Single sampling plans for tightened inspection,

(C) 1.5 AQL for surgeons' gloves, and

(D) 2.5 AQL for patient examination gloves.

(ii) *Adulteration levels and acceptance criteria for reconditioned gloves.* (A) FDA considers a lot or part

of a lot of adulterated gloves, that is reconditioned in accordance with paragraph (d)(2)(i) of this section, to be acceptable when the number of defective gloves found in the tested sample does not exceed the acceptance number in the appropriate tables in paragraph (d)(2)(ii)(B) of this section for reconditioned surgeons' gloves or patient examination gloves.

(B) FDA considers a reconditioned lot of medical gloves to be adulterated within the meaning of section 501(c) of the act when the number of defective gloves found in the tested sample meets or exceeds the applicable rejection number in the tables following paragraph (d)(2)(ii)(B) of this section:

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR RECONDITIONED SURGEONS' GLOVES

| Lot Size | Sample | Sample Size | Number Examined | Number Defective | |
|----------|---------------|-------------|-----------------|------------------|--------|
| | | | | Accept | Reject |
| 13 to 90 | Single sample | | 13 | 0 | 1 |