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HALYARD Knowledge Network*

THE CLINICAL ISSUE

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UNDERSTANDING ACCEPTABLE QUALITY LEVELS (AQLS) FOR GLOVES

WHAT IS MEANT BY ACCEPTABLE QUALITY LEVEL?

Medical gloves are critical to protect both patients and healthcare workers and as such, they must be manufactured to a very high standard at all times. Among the most critical protective features is the absence of defects such as pinholes. The accepted rate of defects allowed to be released after passing though control processes is measured by AQL, the Acceptable Quality Level. This test is one of the most direct indicators of a manufacturer's quality and process standards.

AQL is an industry-wide, international standard. It is a statistical sampling process for evaluating quality. According to the International Standards Organization (ISO) (2859-1: 1999)1), AQL is "the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling". Process average is the typical percentage of defective gloves in the lots/batches sampled. The lower the AQL, the lower the chance of finding a defect such as a pinhole in the batch of gloves and the higher the quality of the product.

Various international standards, as shown in Table 1, determine the AQL that manufacturers must comply with. However, manufacturers can set their own standards—as long as they are stricter than the international standards.†

† HALYARD Surgical Gloves are manufactured to a standard AQL of 0.65, exceeding world standards of 1.0 or 1.5.*

HALYARD Exam gloves are manufactured to an AQL of 1.0, exceeding world standards of 1.5 to 2.5.*

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Table 1 : International Surgical and Examination Glove Standards

Surgical Gloves Standards	Inspection Level	AQL	Examination Gloves Standards	Inspection Level	AQL
AS/NZS 4179: 2014[2] Applicable to Australia/ New Zealand	G1	1.0	AS/NZS 4011: 2014[3] Applicable to Australia/ New Zealand	G1	1.5
ASTM 3577:2009[4] Applicable to US & Canada	G1	1.5	ASTM D3578:2010[5] ASTM D6319:2010[6] ASTM D6977:2010[7] Applicable to US & Canada	G1	1.5
EN 455 Part 1: 2000[8] Applicable to the European Union	G1	1.5	EN 455 Part 1: 2000[8] Applicable to the European Union	G1	2.5
ISO 10282: 2014[9] Adopted by the rest of the World	G1	1.5	ISO 11193-1:2008[10] Adopted by the rest of the World	G1	2.5
JIS T9107: 2005[11] Applicable to Japan	G1	1.5	JIS T9115:2000[12] Applicable to Japan	G1	1.5

HOW ARE AQLS MEASURED?

AQL is a pass/fail where a predetermined sample size of a manufactured lot is tested following the sampling plan and protocols established by the various international standards or more stringent standards set by manufacturers to ensure higher quality is delivered to the customer.

The AQL sampling plan is an inspection procedure that is used to determine acceptance or rejection criteria from an inspection batch or lot. The gloves to be tested are a randomly selected sample from a larger batch. The sample size to be tested is set by:

- The lot or batch size
- The inspection level - determined by region as reflected in Table 1
- AQL level specified in standards for the market or determined by individual manufacturers

GLOVE QUALITY TESTING PROCESS

First the manufacturer will need to know the size of the lot being manufactured; this is the amount of gloves produced without any conditions changing in a single run. Based on the lot size, the standards will determine the sampling inspection, which is the number of gloves to be randomly selected for testing. In accordance with Statistical Quality Control, the gloves to be tested have all been through "identical" processing and are truly representative of the total lot or batch.

In this test, the gloves are filled with 1000 ml (1 liter) of water, bound or sealed at the cuff and hung upside down for two minutes and checked for leaks (pin holes) under sustained pressure. This is the recognized test method for global glove standards.

AQL SAMPLING PLANS

If the manufacturer determines that the lot size is 10,000 and the manufacturer is following an AQL of 0.65 with inspection level 1 (as determined by the standards), a sample of 80 gloves must be tested. (See Table 2.)

The full lot (10,000 gloves) can be released if 1 or fewer defective gloves are found among the 80 gloves inspected; this is equivalent to a maximum of 1.25% defective in the tested gloves. However, if the target AQL is 1.5, as determined in the majority of standards, the full 10,000 glove lot will pass if 3 or fewer defective gloves are found among the 80 inspected, which is equivalent to a maximum of 3.75% defectives in the tested gloves.

This clearly illustrates that a more stringent AQL ensures fewer defects in the overall lot.

If there are more than the allowable number of defective gloves found in the sample size, the full lot will be rejected. The rejected lot will either be discarded or 100% reworked through sorting and then checked again for AQL.

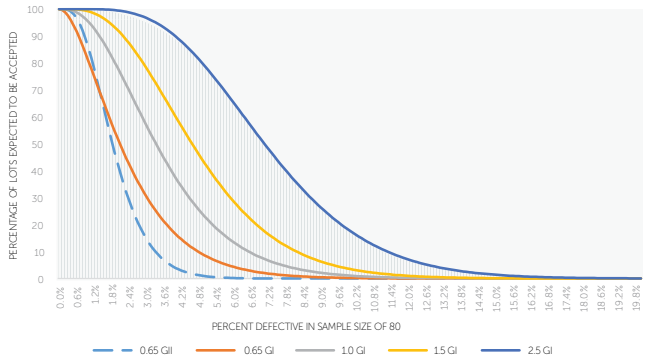
Table 2 : Comparison Table for Selected AQL Sampling Plans

AQL	0.65	1.0	1.5	2.5
Inspection Level (General Level I, GI)	G1	G1	G1	G1
Lot/ Batch Size	10,000	10,000	10,000	10,000
Sample Size	80	80	80	80
Maximum Non-Conformance Number Acceptable	1	2	3	5

In accordance with Statistical Quality Control, only a predetermined sample of gloves are tested, rather than the whole lot/batch. For the example given in this document, out of a 10,000 lot, 9,920 gloves will not be tested and there may be defective gloves among them. In order to demonstrate the likelihood of accepting a lot with a certain percentage of defects in it, each sampling plan has an Operating Characteristic (OC) curve (see Chart 1). The OC curve shows what the sampling plan will do under particular circumstances. More precisely, the OC curve shows the probability of acceptance for lots with assumed values of defective gloves.

The horizontal scale indicates the percentage of defective gloves in our sample size of 80 (for a 10,000 glove lot). The vertical scale indicates the corresponding percent of lots which, on average will be accepted from this process if this sampling plan is applied. In summary, the better the quality level from the production process, the higher the lot acceptance will be.

Chart 1. Operating Characteristic (OC) Curve



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5. ASTM D3578 : 2010 Standard Specification for Rubber Examination Gloves
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