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ACCEPTABLE QUALITY LEVEL (AQL)

What is Acceptable Quality Level?

AQL is an industry 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.

What are the required AQLs?

Various international standards, as shown in Table 1, determine the AQL that manufacturers must comply to. However, manufacturers can set their own standards as long as they are stricter than the international standards. This is the case of Ansell, which has the following AQL Standards:

- Surgical gloves are 0. 65 (natural rubber latex and non-latex), exceeding world standards of 1.0 or 1.5.
- Examination gloves are 1.5, meeting or exceeding world standards of 1.5-2.5

The lower the AQL, the lower the chance of finding a defect in the batch of gloves and the higher the quality of the product.

Technical data sheets, containing the AQL for each specific glove, are available upon request.

How is AQL determined and measured for gloves?

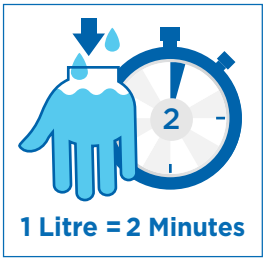
AQL is a pass/fail where a predetermined sample size of a manufactured lot is tested following the sampling plan and protocols established by the various international standards or more stringent standards set by manufacturers to ensure stricter and higher quality is delivered to the customer.

The sampling plan is an inspection procedure of a sample size (which are gloves that are randomly selected from a batch of gloves) that is used to determine acceptance or rejection criteria from an inspection batch or lot. 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

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



1 Litre = 2 Minutes

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 randomly selected to be tested. The gloves tested, according with Statistical Quality Control, 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 litre) 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 recognised test method for global glove standards.

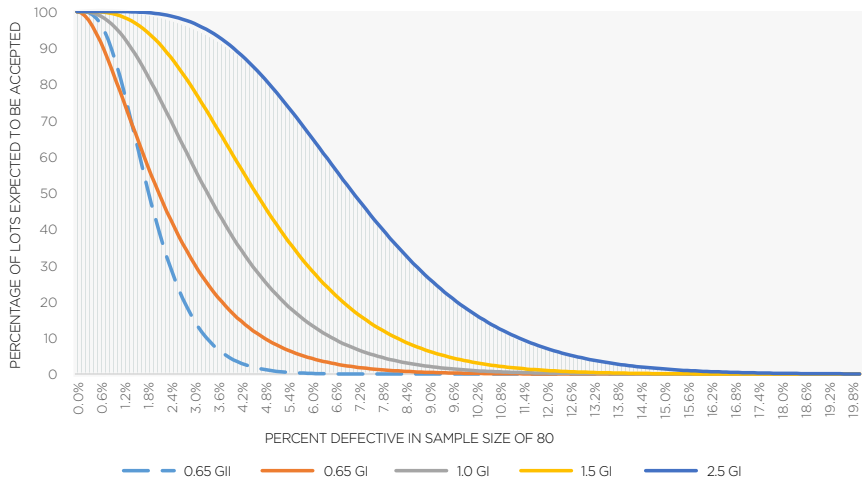
In Table 2, if the lot size is 10,000 (this is determined by the manufacturer) and they are following an AQL of 0.65 with inspection level 1 (determined by the standards), you will need to select a sample test of 80 gloves. The full lot (10,000 gloves) can be released if you find 1 or less defective gloves in the 80 gloves inspected; that is equivalent to a maximum of 1.25% defective in the tested gloves. However, if your AQL is 1.5, as determined in the majority of standards, your full 10,000 gloves lot will pass if you find 3 or less defective gloves in 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 ensure less defects in the overall lot.

If there are more than the allowable number of defective gloves in the sample size the 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

Chart 1. Operating Characteristic (OC) Curve



Operating Characteristic (OC) Curve

According 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, 9920 gloves will not be tested and there may be defective gloves amongst 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.

Ansell's Acceptable Quality Level, a guarantee for higher quality and protection.

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. Amongst the most critical protective features are the absence of pinholes. The accepted rate of defects allowable to be released after passing though control processes is measured by AQL, and therefore this test is one of the most direct indicators of manufacturers' quality and process standards.

References:

1. *ISO 2859-1:1999 Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*
2. *AS/NZS 4179:2014 Single-use sterile rubber surgical gloves*
3. *AS/NZS 4011.1:2014 Single-use medical examination gloves*
4. *ASTM 3577:2009 Standard Specification for Rubber Surgical Gloves*
5. *ASTM D3578 : 2010 Standard Specification for Rubber Examination Gloves*
6. *ASTM D6319 - 10 Standard Specification for Nitrile Examination Gloves for Medical Application*
7. *ASTM D6977 - 04 Standard Specification for Polychloroprene Examination Gloves for Medical Application*
8. *EN 455 Part 1: 2000 Medical Gloves for single use*
9. *ISO 10282:2014 Single-use sterile rubber surgical gloves*
10. *ISO 11193-1:2020 Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution*
11. *JIS T 9107:2005 Single-use Sterile Surgical Rubber Gloves*
12. *JIS T 9115:2018 Single-use Rubber Examination Gloves*

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