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AQL – a guarantee for quality

The AQL value is one of the most important measures for quality in mass production. But what does it mean exactly? SEMPERMED provides you with this information.

The increasing demand for products in daily use and the invention of the steam engine formed the basis of the Industrial Age at the beginning of the 19th Century. Traditional manual labour was replaced gradually by mass production. This was the beginning of a development both in Europe and the USA, the consequences of which are still determining our working life today.

Mass production methods enabled a variety of products to be manufactured at lower prices, which meant that they could be obtained by a wider circle of people. Falling prices increased demand and therefore the need to increase production. However, mass production had its disadvantages.

In addition to the social problems the new industrial era brought, new measures had to be found in order to bring the quality of mass products to a required standard.

Controlled quality

Technical progress and the application of new, innovative technologies, such as electronics, help ensure a consistently high quality level.

Nevertheless, each production process has it's share of faults, however these are extremely rare.

No manufacturers can guarantee 100% fault-free goods. One only has to remember the large, media-supported recall action of the various car manufacturers. With the knowledge of these problems, all production processes are stringently controlled.

It starts with the raw materials and extends through the various stages until the end product is complete.

Testing the test bench

Not every individual product can be checked as to it's functionality, as many test methods destroy the products when applied. Such test procedures are called destructive test methods, and can be applied to only a small, but representative part of the production. For example, consider the production of an ammunition manufacturer. If such a company was to test its entire

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production, there would be no ammunition left for sale. The US-army therefore developed a system prior to the second World War which would guarantee consistently high quality for those products which can only be tested by a destructive test method: the Military Standard 105-D.
Today's AQL has developed over the years, from this test method.

Already in use during the second World War: the US - Military Standard 105-D

AQL– Quality on highest level

With AQL– Acceptable Quality Level – a certain quantity from the batch of manufactured products is removed for random testing in accordance with an accurately defined procedure. These random samples are then tested in accordance with legally stipulated Standards and Specifications. From the results, an assessment as to the quality of the entire batch can be made. The higher the requirements on a product, the more stringent the prescribed guide-lines are. The AQL is therefore a statistical procedure for determining quality.

Determination of AQL value

1. Coding

Initially the overall quantity of all goods produced is determined, i.e. the batch size (vertical line in Table I). This must be determined by the manufacturer and usually depends on the batch volume.

The next step is to determine the test level. Here a differentiation is made between the "special test level" and the "general test level". Each one of these levels is again subdivided into various sub-categories (horizontal line in Table I). As a result of this (intersection in table 1) the coding letter (A- R) is obtained.

Example:

The manufacturer fixes his batch at 5,000 items, as this is a reasonable volume within the manufacturing process. He will then select the test level (e.g. "general test level III") in accordance with the Standards applicable to his production. The intersection between batch volume and test level is the code letter, in this case M.

2. The AQL-Value

From the ascertained code letter the volume of the partial quantity to be tested (random test) can be read from a further table (the vertical line in Table II-A). Following the example above, this would be a random test of 315 items. During a further step the "acceptable quality limit" can be ascertained – the AQL value (horizontal line in Table II-A).
This is in most areas fixed by legislation on Standards. If an AQL value of 1,0 was fixed for the above example, the intersection of the code letter M and AQL– 1,0 shows

Lot or batch size	Special Inspection levels				General Inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10000	C	D	F	G	J	L	M
10001 to 35000	C	D	F	H	K	M	N
35001 to 150000	D	E	G	J	L	N	P
150001 to 500000	D	E	G	J	M	P	Q
500001 and over	D	E	H	K	N	Q	R

Table 1: Sample size code letters (DINISO 2859 Part 1)

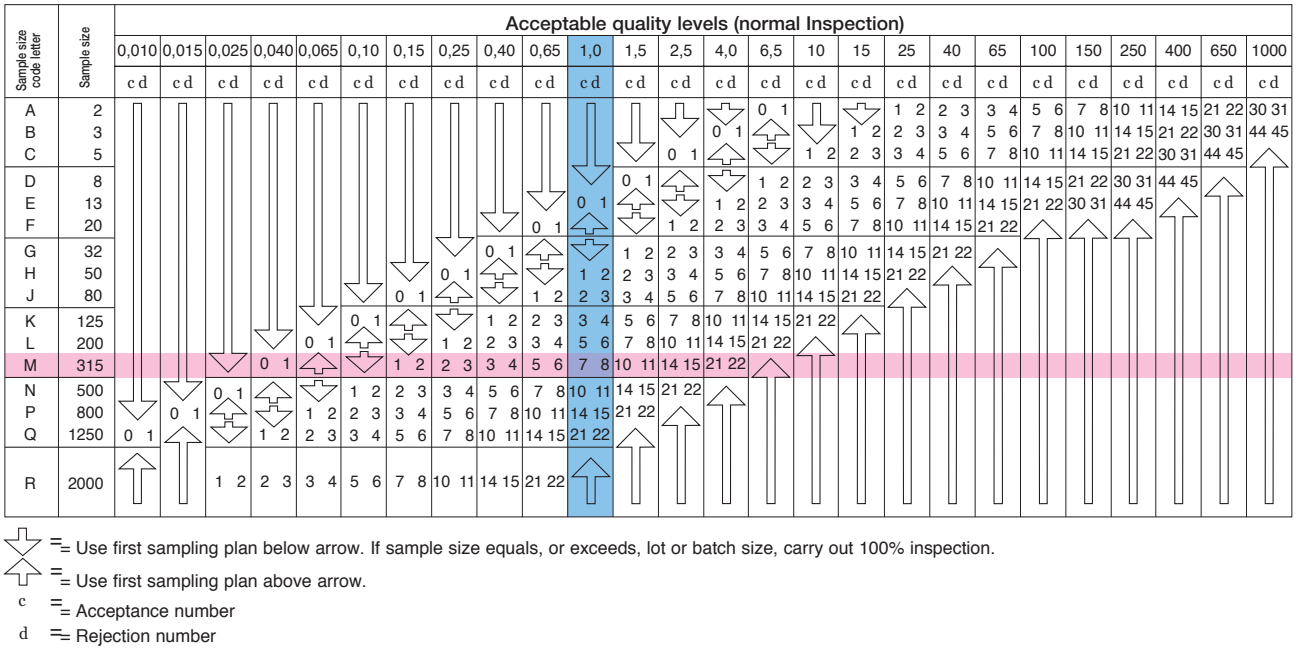

Table 2:
Single sampling plans for normal Inspection (Master table) (DIN ISO 2859 Part 1)

figures 7 and 8. This is the “Acceptance and Rejection figure”. With this example, the batch is accepted if 7 faulty products are found, but rejected at 8 faults, because the overall quantity does not correspond with the prescribed quality criteria.

Looking at the example again, this means that out of a total quantity of 5,000 items, 315 random samples have to be tested. If only 7 faulty products are found in these random samples, the total quantity will comply with the required quality criteria.

If 8 faulty items are found amongst these random samples, the total quantity will have to be rejected and deemed not fit for sale.

3. Confidence interval

If only a partial quantity is tested from a batch, no assumption can be made as to the quality of the total batch.Statistical procedures and experience however allow precise conclusions as to the quality level.

The statistical probability that the result of the random sample will also be valid for the entire batch is designated as confidence interval and can be ascertained with the

	x	Sample size (n)= 19		20		32		50		80		125		200		315	
Fault proportion	0	0,000	0,177	0,000	0,169	0,000	0,109	0,000	0,071	0,000	0,045	0,000	0,029	0,000	0,018	0,000	0,012
	1	0,001	0,260	0,001	0,249	0,001	0,162	0,000	0,107	0,000	0,068	0,000	0,044	0,000	0,028	0,000	0,018
	2	0,013	0,331	0,012	0,317	0,008	0,208	0,005	0,137	0,003	0,088	0,002	0,057	0,001	0,036	0,001	0,023
	3	0,034	0,396	0,032	0,379	0,020	0,250	0,013	0,166	0,008	0,106	0,005	0,069	0,003	0,043	0,002	0,028
	4	0,061	0,456	0,057	0,437	0,035	0,290	0,022	0,192	0,014	0,124	0,009	0,080	0,005	0,050	0,003	0,032
	5	0,091	0,512	0,087	0,491	0,053	0,328	0,033	0,218	0,021	0,141	0,013	0,091	0,008	0,058	0,005	0,037
	6	0,126	0,566	0,119	0,543	0,072	0,364	0,045	0,243	0,028	0,157	0,015	0,102	0,011	0,065	0,007	0,041
	7	0,163	0,617	0,154	0,592	0,093	0,400	0,058	0,267	0,036	0,173	0,023	0,112	0,014	0,071	0,009	0,045
	8	0,203	0,665	0,191	0,640	0,115	0,434	0,072	0,292	0,044	0,189	0,028	0,121	0,017	0,078	0,011	0,050
	9	0,245	0,711	0,231	0,685	0,137	0,468	0,086	0,314	0,053	0,204	0,033	0,132	0,021	0,084	0,013	0,054
	10	0,289	0,756	0,272	0,728	0,161	0,501	0,100	0,337	0,061	0,219	0,039	0,143	0,024	0,090	0,015	0,058

Table 3:
Confidence Interval for the number of defective units in the Binomial Distribution, P=0,95
(Source: DGQ e.V.,Frankfurt/Main)

aid of calculations and tables. The result is given in percentage figures. For the chosen example, 315 random samples out of a total lot of 5,000 were tested at an assumed AQL value of 1,0, which showed up, e.g. to 6 faults. This means that the fault proportion from this random test amounted to 1,9%. From a further table (Table 3) it follows that at a random sample volume of 315 items and 6 faults, the confidence range lies between 0,7 and 4,1%, which means that within the total batch the proportion of faults lies between 0,7 and 4,1% (at a statistical probability of 95%). The above mentioned limiting data are of course extreme values which are not achieved on average.

Water retention test

AQL for medical gloves

For medical gloves, the European Standard DIN/EN 455 Part 1 fixes the "General Test Level I" and AQL of 1,5 as quality criteria. This applies to leak-proof tests for medical gloves.

The test procedure is that for water retention or any other test procedure recognised for water retention testing. The prescribed water-retention test is a destructive test procedure. The glove is filled with 1,000 ml water and must remain completely leak-proof over an accurately defined period of time.

Air testing, another test during which the glove is blown up at a defined pressure and checked for perforation is however a non-destructive test procedure and can therefore be used for the entire production quantity. It must however be borne in mind that additional stress and further handling of gloves may result in damage or contamination of the latex films. Experience has shown that if complete quality control is carried out manually a certain percentage of faults must be accepted.

Even complete testing of all gloves with the aid of electronic sensors cannot guarantee a complete absence of perforations. Particularly perforations between the fingers, which may not be discovered when the test equipment passes over the area, as these parts are not exposed. As always, avoiding faults during the production process is still the best guarantee for constant product quality - testing.

Air test

SEMPERMED – the European experts for medical gloves

SEMPERMED specialists are experts in the art of latex immersion. We have been manufacturing medical gloves for more than 80 years. As the caoutchouc pioneers of Europe, we have more than 175 years experience in processing this natural raw material. The vast experience and knowledge we have gained over this period, are a constant guarantee for high quality.

Additionally, our gloves are tested far beyond the legally prescribed AQL value of 1,5.

Our continuous quality control in respect of perforations achieves internally an AQL of 0,4.

SEMPERMED gloves are regarded as one of the best quality products on the market.

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