

ISO/TR 18532:2009-04 (E)

Guidance on the application of statistical methods to quality and to industrial standardization

Contents		Page
Foreword		ix
Introduction		x
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Illustration of value and role of statistical method through examples	1
4.1	Statistical method	1
4.2	Example 1: Strength of wire	2
4.2.1	General	2
4.2.2	Overall test results and lower specification limit	2
4.2.3	Initial analysis	3
4.2.4	Preliminary investigation	3
4.2.5	General discussion on findings	6
4.2.6	Explanation of statistical terms and tools used in this example	6
4.3	Example 2: Mass of fabric	7
4.3.1	General	7
4.3.2	Test results and specification limits	7
4.3.3	Discussion of specific results	10
4.3.4	Discussion on general findings	11
4.4	Example 3: Mass fraction of ash (in %) in a cargo of coal	11
4.4.1	General	11
4.4.2	Test results (reference ISO 11648-1: Statistical aspects of sampling from bulk materials)	12
4.4.3	Initial graphical analysis of specific results	12
4.4.4	Benefits of a statistically sound sampling plan	14
4.4.5	General conclusions	16
5	Introduction to basic statistical tools	16
5.1	General	16
5.2	Basic statistical terms and measures	16
5.3	Presentation of data	19
5.3.1	Dot or line plot	19
5.3.2	Tally chart	19
5.3.3	Stem and leaf plot	19
5.3.4	Box plot	20
5.3.5	Multi-vari chart	22
5.3.6	Position-Dimension (P-D) diagram	23
5.3.7	Graphical portrayal of frequency distributions	25
5.3.8	The normal distribution	31
5.3.9	The Weibull distribution	35
5.3.10	Graphs	41
5.3.11	Scatter diagram and regression	41
5.3.12	Pareto (or Lorenz) diagram	43
5.3.13	Cause and effect diagram	44
6	Variation and sampling considerations	45
6.1	Statistical control and process capability	45

6.1.1	Statistical control	45
6.1.2	Erratic variation	47
6.1.3	Systematic variation	47
6.1.4	Systematic changes with time	48
6.1.5	Statistical indeterminacy	49
6.1.6	Non-normal variation	49
6.1.7	Quality level and process capability	49
6.2	Sampling considerations	50
7	Methods of conformity assessment	54
7.1	The statistical concept of a population	54
7.2	The basis of securing conformity to specification	55
7.2.1	The two principal methods	55
7.2.2	Considerations of importance to the customer	56
7.2.3	Considerations of importance to the supplier	56
8	The statistical relationship between sample and population	57
8.1	The variation of the mean and the standard deviation in samples	57
8.1.1	General	57
8.1.2	Variation of means	58
8.1.3	Variation of standard deviations	60
8.2	The reliability of a mean estimated from stratified and duplicate sampling	64
8.2.1	Stratified sampling	64
8.2.2	Duplicate sampling	66
8.3	Illustration of the use of the mean mass, and the lowest mass, in a sample of prescribed size of specimens of fabric	67
8.4	Tests and confidence intervals for means and standard deviations	69
8.4.1	Confidence intervals for means and standard deviations	69
8.4.2	Tests for means and standard deviations	71
8.4.3	Equivalence of methods of testing hypotheses	77
8.5	Simultaneous variation in the sample mean and in the sample standard deviation	77
8.6	Tests and confidence intervals for proportions	80
8.6.1	Attributes	80
8.6.2	Estimating a proportion	80
8.6.3	Confidence intervals for a proportion	81
8.6.4	Comparison of a proportion with a given value	82
8.6.5	Comparison of two proportions	82
8.6.6	Sample size determination	83
8.7	Prediction intervals	84
8.7.1	One-sided prediction interval for the next m observations	84
8.7.2	Two-sided prediction interval for the next m observations	85
8.7.3	One and two-sided prediction intervals for the mean of the next m observations	85
8.8	Statistical tolerance intervals	86
8.8.1	Statistical tolerance intervals for normal populations	86
8.8.2	Statistical tolerance intervals for populations of an unknown distributional type	87
8.8.3	Tables for statistical tolerance intervals	87
8.9	Estimation and confidence intervals for the Weibull distribution	87
8.9.1	The Weibull distribution	87
8.10	Distribution-free methods: estimation and confidence intervals for a median	88
9	Acceptance sampling	89
9.1	Methodology	89
9.2	Rationale	90
9.3	Some terminology of acceptance sampling	91
9.3.1	Acceptance quality limit (AQL)	91
9.3.2	Limiting quality (LQ)	91
9.3.3	Classical versus economic methods	92
9.3.4	Inspection levels	92
9.3.5	Inspection severity and switching rules	92
9.3.6	Use of "non-accepted" versus "rejected"	93
9.4	Acceptance sampling by attributes	93
9.4.1	General	93

9.4.2	Single sampling	94
9.4.3	Double sampling	96
9.4.4	Multiple sampling	96
9.4.5	Sequential sampling	99
9.4.6	Continuous sampling	100
9.4.7	Skip-lot sampling	101
9.4.8	Audit sampling	102
9.4.9	Sampling for parts per million	102
9.4.10	Isolated lots	103
9.4.11	Accept-zero plans	103
9.5	Acceptance sampling by variables -- Single quality characteristic	104
9.5.1	General	104
9.5.2	Single sampling plans by variables for known process standard deviation -- The "" method	105
9.5.3	Single sampling plans by variables for unknown process standard deviation -- The "s" method	106
9.5.4	Double sampling plans by variables	109
9.5.5	Sequential sampling plans by variables for known process standard deviation	110
9.5.6	Accept-zero plans by variables	110
9.6	Multiple quality characteristics	111
9.6.1	Classification of quality characteristics	111
9.6.2	Unifying theme	111
9.6.3	Inspection by attributes for nonconforming items	111
9.6.4	Inspection by attributes for nonconformities	112
9.6.5	Independent variables	113
9.6.6	Dependent variables	113
9.6.7	Attributes and variables	113
10	Statistical process control (SPC)	113
10.1	Process focus	113
10.2	Essence of SPC	116
10.3	Statistical process control or statistical product control?	117
10.4	Over-control, under-control and control of processes	118
10.4.1	General	118
10.4.2	Scenario 1: Operator reacts to each individual sample giving rise to process over-control	119
10.4.3	Scenario 2: Operator monitors a process using a run chart giving rise to haphazard control	120
10.4.4	Scenario 3: Monitoring using SPC chart with a potential for effective control	121
10.5	Key statistical steps in establishing a standard performance-based control chart	122
10.5.1	General	122
10.5.2	Monitoring strategy	122
10.5.3	Construction of a standard control chart	125
10.6	Interpretation of standard Shewhart-type control charts	127
10.7	Selection of an appropriate control chart for a particular use	128
10.7.1	Overview	128
10.7.2	Shewhart-type control charts	129
10.7.3	Cumulative sum (cusum) charts	129
11	Process capability	130
11.1	Overview	130
11.2	Process performance versus process capability	131
11.3	Process capability for measured (i.e. variables) data	132
11.3.1	General	132
11.3.2	Estimation of process capability (normally distributed data)	132
11.3.3	Estimation of process capability (non-normally distributed data)	133
11.4	Process capability indices	138
11.4.1	General	138
11.4.2	The Cp index	138
11.4.3	The Cpk family of indices	139
11.4.4	The Cpm index	142
11.5	Process capability for attribute data	145
12	Statistical experimentation and standards	148

12.1	Basic concepts	148
12.1.1	What is involved in experimentation?	148
12.1.2	Why experiment?	148
12.1.3	Where does statistics come in?	149
12.1.4	What types of standard experimental designs are there and how does one make a choice of which to use?	149
13	Measuring systems	164
13.1	Measurements and standards	164
13.2	Measurements, result quality and statistics	165
13.3	Examples of statistical methods to ensure quality of measured data	166
13.3.1	Example 1: Resolution	166
13.3.2	Example 2: Bias and precision	169
13.3.3	Precision -- Repeatability	171
13.3.4	Precision -- Reproducibility	172
Annex A (informative) Measured data control charts: Formulae and constants		177
Bibliography		181
Index		188
Figure 1 -- Dot plot of breaking strength of 64 test specimens		2
Figure 2 -- Basic cause and effect diagram for variation in wire strength (due to possible changes of material and process parameters within specified tolerances)		3
Figure 3 -- Line plots showing patterns of results after division into rational groups		4
Figure 4 -- Diagram indicating the effect of the interrelationship between oil quench temperature and steel temperature on wire strength		5
Figure 5 -- Means of masses plotted against sample number (illustrating decreasing variation in the mean with the sample size increase)		9
Figure 6 -- Ranges of masses within each sample vs sample number [illustrating increasing (range) variation within a sample with sample size increase]		9
Figure 7 -- Averages of mass fraction of ash (in %) of coal by lot from cargo		13
Figure 8 -- Progressive averages of mass fraction of ash (in %) in terms of lot		13
Figure 9 -- Schematic diagram showing plan for sampling percentage ash from cargo of ship		14
Figure 10 -- Mass fraction of ash (in %) plotted against test number for lots 19 and 20 (illustrating relative consistency of percentage ash within each of these lots)		15
Figure 11 -- Mass fraction of ash (in %) plotted against test number for lots 9 and 10 (illustrating rogue pairs in both lots)		15
Figure 12 -- Line plot of breaking strength of wire (Table 1 data)		19
Figure 13 -- Typical tally charts		19
Figure 14 -- Stem and leaf plot for data		20
Figure 15 -- Box plot		21
Figure 16 -- Box plot for Delta E panel shade variation between supply sources		21
Figure 17 -- Multi-vari chart as a tool for process variation analysis		23
Figure 18 -- Measurements on cylinder to determine nominal size, ovality and taper		23

Figure 19 -- Measurement on cylinder -- P-D diagrams showing ideal diameter values, pure taper and pure ovality	24
Figure 20 -- Measurement on cylinder -- P-D diagrams indicating progressive decrease of mean and increase in geometric form variation and the beneficial effects of overhaul	25
Figure 21 -- Frequency histogram for immersion times in Table 6	27
Figure 22 -- Percentage frequency histogram for immersion times in Table 6	27
Figure 23 -- Cumulative percentage frequency histogram for immersion times in Table 6	28
Figure 24 -- Cumulative percentage frequency diagram for immersion times in Table 6	29
Figure 25 -- Normal curve overlaid on the immersion time histogram (mean = 6,79; standard deviation = 1,08)	30
Figure 26 -- Straight line plot on normal probability paper indicating normality of data in Table 6	31
Figure 27 -- Percentages of normal distribution in relation to distances from the mean in terms of standard deviations	32
Figure 28 -- Standard normal probability density with indications of percentage expected beyond a value, U or L, that is z standard deviation units from the mean	33
Figure 29 -- Comparison with Weibull distributions, all with $\beta = 1$	37
Figure 30 -- Q-Q plot to assess the fit of days between accidents (data in column one of Table 8) to a Weibull distribution	39
Figure 31 -- Weibull probability plot of days between accidents (data in column one of Table 8)	40
Figure 32 -- Scatter diagrams of four data sets that all have the same correlation coefficients (r) and fitted regression lines	43
Figure 33 -- Relative contribution of different types of in-process paint faults	44
Figure 34 -- Process cause and effect diagram for cracks in a casting	45
Figure 35 -- Diagram indicating types of variation in samples	47
Figure 36 -- Contrast of the capabilities of two filling machines	50
Figure 37 -- Illustration of one-sided test	73
Figure 38 -- Scatter chart for sample means and standard deviations in canned tomatoes data	78
Figure 39 -- Standardized control chart for mean and standard deviation	79
Figure 40 -- Type A and B OC curves for $n = 32$, $A_c = 2$, $N = 100$	94
Figure 41 -- Type B OC curves for $A_c = 0, 1/3, 1/2$ and 1	95
Figure 42 -- OC curves for single, double and multiple sampling size code letter L and AQL 2,5 % ...	97
Figure 43 -- Average sample size (ASSI) curves for single, double and multiple sampling plans for sample size code letter L and AQL 2,5 %	98
Figure 44 -- Curves for the double and multiple sampling plans for sample size code letter L and AQL 2,5 % showing the probability of needing to inspect significantly more sample items than under single sampling	99

Figure 45 -- Example of sequential sampling by attributes for percent nonconforming	100
Figure 46 -- Acceptance chart for a lower specification limit	106
Figure 47 -- Acceptance charts for double specification limits with separate control	107
Figure 48 -- Standardized acceptance chart for sample size 18 for double specification limits with combined control at an AQL of 4 % under normal inspection	107
Figure 49 -- Standardized acceptance chart for sample size 18 for double specification limits with combined control at an AQL of 1 % for the upper limit and an AQL of 4 % overall under normal inspection	108
Figure 50 -- ISO 9001:2008 Model of a process-based quality management system	114
Figure 51 -- Control chart for nonconforming underwear	117
Figure 52 -- Outline of process of applying a topcoat to a photographic film	118
Figure 53 -- Probability of setter/operator observing a single mass value when mean = 45	119
Figure 54 -- Example of process run chart with variation, but with no guidance on how to interpret and deal with variation	121
Figure 55 -- Example of process control chart with criteria for "out-of-control" signals	122
Figure 56 -- A two factor nested design is the basis of an X R chart (illustrated with a subgroup size of 3)	123
Figure 57 -- Effect of subgroup size on ability to detect changes in process mean (process nominal = 5,00, process standard deviation = 0,01)	124
Figure 58 -- Mean and range chart for masses of standard specimens of fabric	126
Figure 59 -- Graphical comparison of process capability with specified tolerance	133
Figure 60 -- Illustration of the estimation of capability with a skew distribution (equivalent to a range of ± 3 in a normal distribution)	134
Figure 61 -- Dot plot for percent of silicon data showing overall pattern of variation	135
Figure 62 -- Probability plot for percent of silicon data showing overall pattern of variation	136
Figure 63 -- Probability plot for the logarithm of percent of silicon data showing overall pattern of variation	137
Figure 64 -- Individuals control chart of ln percent of silicon with limits	137
Figure 65 -- Relationship between Cp and CpkU and CpkL for two sets of process variability and locations of specification limits	141
Figure 66 -- Comparison of conformance to toleranced specification with optimal value approach	144
Figure 67 -- Printed circuit board faults SPC chart and cumulative faults per unit (FPU) chart	147
Figure 68 -- Effect of lubrication, speed, surface finish and density on push-off strength	154
Figure 69 -- Interaction between squeegee speed and ink viscosity	155
Figure 70 -- Central composite design of the face-centred cube variety for 3 factors	156

Figure 71 -- Computer-generated contour plot for oxide uniformity in terms of power and pulse of the etching process for gas ratio fixed at its coded level 0	158
Figure 72 -- Illustration of the fundamental difference in designs for two independent factors as compared with a two-component mixture	159
Figure 73 -- Illustration of the fundamental difference in designs for three independent factors as compared with a three-component mixture	160
Figure 74 -- Ten-point augmented simplex centroid three-component design	160
Figure 75 -- Response surface contours for mean burn rate in terms of fuel (X1), oxidize (X2) and binder (X3) blend components	161
Figure 76 -- Response surface contours for standard deviation of burn rate in terms of fuel (X1), oxidize (X2) and binder (X3) blend components	161
Figure 77 -- Factors A and B set at nominal to give a process yield of 68 %	162
Figure 78 -- First stage optimisation using Box EVOP	163
Figure 79 -- First stage Box EVOP as local optimum has been found	163
Figure 80 -- Incomplete 5 stage simplex maximization experiment for two factors in terms of yield .	164
Figure 81 -- Recommended resolution for process control and determination of compliance with specified tolerance	167
Figure 82 -- Range charts showing adequate and inadequate resolutions	168
Figure 83 -- Bias and precision	169
Figure 84 -- Effect of measuring systems uncertainty on compliance decision	170
Figure 85 -- Establishing bias and precision for a pressure gauge	171
Figure 86 -- Individuals and moving range chart for pressure to check for stability of results prior to performing a bias and precision test	172