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Guidelines for implementation of statistical process control (SPC) —

Part 2: Catalogue of tools and techniques

Lignes directrices pour la mise en œuvre de la maîtrise statistique des processus (MSP) —

Partie 2: Catalogue d'outils et de techniques



Reference number ISO 11462-2:2010(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11462-2 was prepared by Technical Committee ISO/TC 69, Applications of statistical methods, Subcommittee SC 4, Applications of statistical methods in process management.

ISO 11462 consists of the following parts, under the general title *Guidelines for implementation of statistical process control (SPC)*:

- Part 1: Elements of SPC
- Part 2: Catalogue of tools and techniques

Guidelines for implementation of statistical process control (SPC) —

Part 2:

Catalogue of tools and techniques

1 Scope

This part of ISO 11462 provides a catalogue of tools and techniques to help an organization in planning, implementation and evaluation of an effective statistical process control (SPC) system. This catalogue gives tools and techniques that are essential for the successful realization of the SPC elements specified in ISO 11462-1.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-1, Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability

ISO 3534-2, Statistics — Vocabulary and symbols — Part 2: Applied statistics

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1 and ISO 3534-2 apply.

4 Symbols and abbreviated terms

ANOM analysis of means

ANOVA analysis of variance

c chart count control chart

CDF cumulative distribution function

 C_{p} process capability index

 C_{pk} minimum process capability index

CTQ critical to quality

EWMA exponentially weighted moving average

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EWMA chart control chart using the exponentially weighted moving average

FMEA failure modes effect analysis

FMECA failure modes effect and criticality analysis

FTA fault tree analysis

Me chart control chart using the sample median Me

MR chart control chart using the moving range MR

np chart number of categorized units control chart

proportion categorized units control chart p chart

P chart percent categorized units control chart

machine performance capability index P_{m}

 P_{mk} minimum machine performance capability

process potential index P_{p}

process performance index P_{pk}

PDPC process decision program chart

QC quality control

QFD quality function deployment

R chart control chart using the sample range R

standard deviation, realized value

s chart control chart using the standard deviation, realized value

SPC statistical process control

u chart count per unit control chart

Xindividual measured value

 \bar{X} (Xbar) subgroup average

 \overline{X} chart control chart using the sample average \bar{X}

5 Purpose of the catalogue

This catalogue is intended to be used as a guideline in the quality planning, process control and continual improvement phases, to assist in problem identification and solving in operational activities with the use of statistical process control (SPC) methods.

The techniques listed in this part of ISO 11462 enable an organization to bring their processes under statistical control and, in the state of prediction, conduct a process capability assessment against technical requirements, and determine the inherent process capability and reliability. It provides a means for management to effectively increase the knowledge of processes producing critical to quality (CTQ) product or process parameters. This process capability knowledge may be used to assist in specifying tolerances or to assess feasibility.

Statistical process control is often called the voice of the customer because it signals when a process has gone out of control, enabling the process operator/owner to investigate the cause and correct the process to bring it back into control. By reducing the special causes of the out-of-control state, it enables management to take improvement actions to reduce common cause variation.

Processes that are reliable, predictable and capable provide the organization with more efficient, effective and economic performance, and enhanced customer satisfaction.

The catalogue in this part of ISO 11462 gives guidelines for organizations to use in the planning, development, execution and evaluation of a statistical process control system. In practice, the seven QC tools are used on a continual basis and cover the majority of problems and tasks. However, there are occasions when the full range of tools listed in the catalogue has applications. This catalogue is intended to be helpful in finding the applicable standard.

6 Classification of quality tools and techniques

See Table 1.

Table 1 — Classification of quality tools and techniques

	Element	Statistical tool and technique	Reference
6.1	Demerit control chart	Audit tools	
6.2	p control chart	Control charts for attributes data	ISO 7870-1 ISO 8258 ^a
6.3	np control chart	Control charts for attributes data	ISO 7870-1 ISO 8258 ^a
6.4	c control chart	Control charts for attributes data	ISO 7870-1 ISO 8258 ^a
6.5	u control chart	Control charts for attributes data	ISO 7870-1 ISO 8258 ^a
6.6	\overline{X} (Xbar) and s control chart	Control charts for variables data (often used in mechanized devices)	ISO 7870-1 ISO 8258 ^a
6.7	Control chart, multiple-attribute/demerit/weighted	Control charts for attributes data	ISO 7870-1 Future ISO 7870-5 ^c
6.8	Pareto control chart	Analysis of criticality and significance	ISO 8258 ^a
6.9	Group short-run moving average (or median) and moving range	Control charts for small sample data	Future ISO 7870-5 ^c
6.10	Acceptance control chart	As in ISO 8258 ^a and ISO 7966 ^b	ISO 8258 ^a ISO 7966 ^b

Table 1 (continued)

	Element	Statistical tool and technique	Reference
6.11	Slant control chart	Group charts for variables data	Future ISO 7870-5 ^c
6.12	Probability chart, non-normally distributed control chart	Determination of distribution for given data and assessment of short-term capability	ISO 22514-3 ISO/TR 22514-4
6-13	Probability control chart	Determination of distribution for given data and assessment of short-term capability	ISO 22514-3 ISO/TR 22514-4
6.14	Individual X with moving range (non-normal)	Control charts for variables data	ISO 7870-1 ISO 8258 ^a
6.15	Individual X with moving range (normal)	Control charts for variables data	ISO 7870-1 ISO 8258 ^a
6.16	Median control charts	Group charts for variables data	ISO 7870-1 ISO 8258 ^a
6.17	Modified control chart	Chart for allowance of process drift	Future ISO 7870-5 ^c
6.18	Moving average control chart	Charts for observing trends	Future ISO 7870-5 ^c
6.19	Moving range control chart	Charts for observing trends	Future ISO 7870-5 ^c
6.20	Pre-control control chart (not preferred)	Chart for individuals using tolerance	
6.21	Runs test	Test for trend data analysis	ISO 7870-1
6.22	Standardized control charts (Z chart)	Short-run chart group charts for variables data	Future ISO 7870-5 ^c
6.23	Normalized (or nominal) control charts	Short-run chart group charts for variables data	Future ISO 7870-5 ^c
6.24	$ar{X}$ (Xbar) control chart, constant subgroup	Group charts for variables data	ISO 8258 ^a
6.25	\overline{X} (Xbar) control chart, non-constant subgroup	Group charts for variables data	ISO 8258 ^a
6.26	Group control chart	To track large number of locations or process streams	ISO 7870 (all parts)
6.27	Multi-variable control chart	Monitor several characteristics	ISO 7870-1
6.28	CUSUM control chart	Control charts advanced for variables data	ISO/TR 7871
6.29	EWMA control chart	Control charts advanced for variables data	ISO 8258 ^a
6.30	Manhattan diagram (control chart)	Early response chart	ISO/TR 18532
6.31	Adaptive control chart	Control charts time series for variables data	ISO 8258 ^a
6.32	Bar control chart	Descriptive statistics	ISO 7870 (all parts)
6.33	Coefficient of variation	Descriptive statistics	
6.34	$C_{\rm p}, C_{\rm pk}$ measured against specification limits	Measurement of process capability statistics	ISO 22514 (all parts)
6.35	Histogram (frequency distribution)	Descriptive statistics	ISO 7870 (all parts)
6.36	Normality tests	Descriptive statistics	ISO 5479
6.37	Pie control charts (frequency distribution)	Descriptive statistics	ISO 7870 (all parts)

Table 1 (continued)

	Element	Statistical tool and technique	Reference
6.38	$P_{\rm m.}P_{\rm mk}$ for machine (or any other single factor of production)	Descriptive statistics	ISO 22514-3
6.39	$p_{m}.p_{mk}$ for process	Descriptive statistics	ISO/TR 22514-4
6.40	Quantile plots or graph	Descriptive statistics	ISO 7870 (all parts)
6.41	Significance testing	Inference	ISO 2854
6.42	Analysis of variance, covariance and ANOVA	Experimental design tools	
6.43	Analysis of means (ANOM)	Experimental design tools	
6.44	Cause and effect diagram	Investigation tool	
6.45	Experimental designs	Experimental design tools	ISO/TR 29901
6.46	Evolutionary operation	Experimental technique	
6.47	Shainin: components search, variables search, product-process search, paired comparison, B vs. C. Multi vary analysis.	Experimental design tools shainin	
6.48	Box-and whiskers plot	Exploratory data analysis	
6.49	Check sheet	Exploratory data analysis	
6.50	Density trace (measles chart)	Exploratory data analysis	
6.51	Dot plot	Exploratory data analysis	
6.52	Scatter plot	Exploratory data analysis	
6.53	Stem-and-leaf plot	Exploratory data analysis	
6.54	Hypothesis testing	Inference	ISO 2854
6.55	Outlier tests (various)	Inference	
6.56	Repeatability and reproducibility analysis	Measurement system analysis	ISO 5725-1 ISO 5725-2
6.57	Calibration analysis	Wear trend analysis	
6.58	Discrimination analysis	Measurement system analysis	
6.59	Intermediate prediction analysis	Measurement system analysis	
6.60	Linearity analysis	Measurement system analysis	
6.61	Stability analysis	Measurement system analysis	
6.62	Cluster analysis	Multivariate analysis	
6.63	Discriminate analysis	Multivariate analysis	
6.64	Hotelling's T-squared chart	Multivariate analysis	
6.65	Principal component analysis	Multivariate analysis	
6.66	Regression analysis	Regression diagnostics	
6.67	Systems, design and process FMEA and FMECA	Root cause analysis	
6.68	Fault tree analysis (FTA)	Root cause analysis	
6.69	Five why's analysis	Root cause analysis	
6.70	Affinity diagram	Relational tools	
6.71	Control plan worksheet	Relational tools	
6.72	Cross-functional process mapping	Relational tools	

Table 1 (continued)

	Element	Statistical tool and technique	Reference
6.73	Matrix diagram	Relational tools	
6.74	Poka yoke (mistake-proofing)	Prevention tool	
6.75	Process decision program chart (PDCP diagram)	Relational tools	
6.76	Process flow diagram	Relational tools	
6.77	Quality function deployment (QFD)	Quality planning tool	
6.78	Relation diagram	Rational subgrouping	
6.79	Stratification	Relational tools	
6.80	Tree diagram	Relational tools	
6.81	Reliability analysis: hazard function plot (generalized Weibull, distribution unknown); reliability growth analysis; reliability prediction; survival prediction; survival analysis, log-rank trace, survival distributions; survivorship distributions estimates, survivor percentiles, Weibull plot/lognormal plot/exponential plot (distribution known)	Reliability/survival analysis	
6.82	Sampling: sample size estimation; sample size confidence level estimation; sample size precision estimation, randomization	Sampling	Reference [20]
6.83	Statistical tolerancing	Tolerance analysis	
6.84	Variational simulation	Tolerance analysis	

a It is intended to replace ISO 8258 with future ISO 7870-2 when it is revised.

7 Categories of SPC tools and techniques

The categories of SPC tools and techniques enable the user to find the appropriate method for the analysis and solution of a quality problem using a proven method (see Table 2).

8 Description of the recommended significant tools and techniques, application and range

See Table 2.

It is intended to replace ISO 7966 with future ISO 7870-3 when it is revised.

^c Future development for ISO 7870 (all parts) includes future ISO 7870-5 (specialized control charts) and future ISO 7870-6 (guidance to the application of statistical control charts).

Table 2 — Recommended significant tools and techniques, application and range

Title	Range	Application	Description	Reference
p control chart	Quality planning, control and improvement	When collecting attribute data from a process, understanding process capability where sample sizes may vary. Typically used for assembly line data. There are many non-manufacture applications such as banking errors, housekeeping audits and delivery performance.	The p chart is an attribute chart used to study the percentage of nonconforming products. Often, data are collected on multiple characteristics.	ISO 7870-1 ISO 8258 ^a
np control chart	Quality planning, control and improvement	Similar to p charts but where the sample size for convenience is fixed, e.g. the number of nonconforming units from a fixed random sample size of 30 parts.	The np chart is used in a similar manner to the p chart, but when there is a fixed sample size.	ISO 7870-1 ISO 8258 ^a
c control chart	Quality planning, control and improvement	Using the same chart, but with different control limits, i.e. the nonconformities found on one sheet of gasket material.	The c chart is an attribute chart that is used to analyse the inherent number incidents, nonconformities in one unit, i.e. the defects found on one sheet of gasket material.	ISO 7870-1 ISO 8258 ^a
u control chart	Quality planning, control and improvement	A multiple characteristic chart is often used for data collection, enabling maximum use of information available, i.e. the number of nonconformities per 100 engines as a ratio.	The u chart is an attribute chart used for collecting data from the proportion of nonconformities per fixed number of units, when the number of nonconformities can vary from one batch to the next.	ISO 7870-1 ISO 8258 ^a
\overline{X} (Xbar) and R control chart	Quality planning, control and improvement	Used to analyse a process for statistical control, process capability and control purposes to replace 100 % inspection for economic reasons.	The \overline{X} (Xbar) and R chart is also called the average and range; it consists of two charts: the first is the measuring central tendency Xbar and the second is the range, R . Data are subgrouped, plotted on the separate charts and statistical control limits applied.	b

Table 2 (continued)

Title	Range	Application	Description	Reference
$ar{X}$ (Xbar) and s control chart	Quality planning, control and improvement	\overline{X} (Xbar) and s charts are extensively used for in-line automated process controls with autocorrection based on statistical signals.	\overline{X} (Xbar) and s chart is used where the means of data collection are mechanized and calculations are automated.	b
R control chart	Quality planning, control and improvement	Used where variable data are available, but limited, i.e. destructive testing or slowly changing processes.	The group short-run moving average (or median) and moving range consists of the two charts measuring the mean and the moving range. Data are not subgrouped, and the difference between the subsequent readings and the moving ranges, are plotted on the <i>R</i> chart.	b
Individual X	Quality planning, control and improvement	The chart is used to analyse variable data that are not generated frequently enough for an \overline{X} (Xbar) and r chart.	The individual X with moving range (normal) consists of two charts. Data are not subgrouped, individual data results are plotted on the X chart and the difference between sequential results and the moving ranges are plotted on the moving range chart.	b
Pareto analysis control chart	Quality planning, control and improvement		Pareto analysis chart	b
Group control chart	Quality control and improvement	Group control charts are used for multistation processes, such as multispindle lathes, multiple cavity casting or plastic moulding and many other applications where the economic cost and time factors of sampling would be expensive and time consuming. Analysis is carried out to find the greatest source of data and any unusual patterns of variability.	Group control charts are an adaptation of the multi-variable chart where samples are taken from all stations to a sampling plan plotted on a standard chart. The results are plotted directly on to the chart and a line drawn between the highest and lowest reading. The mean is calculated and plotted. The means of the successive samples are connected up. Control limits are calculated based on the upper and lower means.	b

Title	Range	Application	Description	Reference
Cause and effect diagram	Quality planning, control and improvement	The cause and effect diagram, sometimes called the Ishikawa or fishbone diagram, is used for further analysis of the special causes of a process problem.	The cause and effect diagram is a fishbone-like diagram with five arms typically listed as the five Ms (Men, Methods, Materials, Machines, Measurement/ environment) and a problem statement listed in a box to the right of the diagram.	b
The process capability index	Quality planning, control and improvement	The process capability index enables management to see the "voice of process" in terms of performance on all new products and services. It is now common practice to specify capability indices as quality objectives for a new programme.	Capability indices, $C_{\rm p}$, $C_{\rm pk}$, measure the process capability against specification limits for performance indicators once the process is under statistical control.	ISO 22514 (all parts)
	Quality planning, control and improvement	The histogram is commonly used to show frequency distributions. They include stem and leaf plots, polygon charts, point graphs and CDF charts.	The histogram (frequency distribution) is a univariate frequency diagram in which rectangles proportional in area to the class frequencies are erected on sections of the horizontal axis, the width of each section representing the corresponding class interval of the variable.	b
Checklist and check sheets	Quality planning, control and improvement		Checklist and check sheets. A checklist is a predetermined list of characteristics for inspection or consideration for process control purposes. A check sheet is a structure, prepared form or template for collecting and analysing data.	b

Table 2 (continued)

Title	Range	Application	Description	Reference
Scatter diagram	Quality planning, control and improvement	A scatter diagram is used to look for relationships between variables.	Scatter diagram reveals relationships and verifies that they are independent by plotting numerical data, one variable on each axis to look for a relationship. When they are correlated, the plots fall along a line or curve. The better the corelationship, the tighter the spread to the line.	b
Stratification	Quality control and improvement	The process of stratification may be divided up on a geographical basis by dividing up the sample area in to sub areas on a graph. Use distinguishing colour or coding to show the stratified effect.	Stratification is the division of a population in to parts, known as strata, especially for the purposes of drawing a sample, an assigned proportion of the sample being selected from each stratum.	b
Sampling	Quality control and improvement	Sampling is used to make decisions on a large batch of material or parts, when it would be costly and time consuming to test or inspect the whole quantity. Rational subgrouping is essential to maximize the value of SPC in detecting the maximum variability in the sample taken.	Sampling is the evaluation of the quality of material or units of a product by the inspection of a part of the process or batch, rather than 100 % inspection, using a recognized statistical sampling plan or rational subgrouping in process control.	b
P_{m}, P_{mk}	Quality planning, control and improvement	Can be used to verify or assess the potential machine capability using a probability technique.	$P_{ m m.}$ $P_{ m mk}$ for machine (or any other single factor of production). Similar to $C_{ m pk}$ but from a probability distribution and not time-based or known statistical control.	ISO 22514-3
CUSUM control charts	Quality planning, control and improvement		Cusum control chart	ISO/TR 7871

Continual improvement

The catalogue may be used as the generic quality tool box on an enterprise's continual improvement programme and referred to in the enterprise's quality management system.

ISO/TC 69 SPC International Standards not yet developed for these parameters.

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