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Quality management — Guidance on statistical techniques for ISO 9001:2015

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ii

Contents			Page
For	eword		v
Intr	oductio	on	vi
1	Scor	oe	1
	-		
2		native references	
3	Tern	ns and definitions	1
4	Stati	stical techniques in the implementation of ISO 9001	2
5	Qua	ntitative data and associated statistical techniques in ISO 9001	2
6	App	licability of selected techniques	8
7	Desc	cription of statistical techniques	9
	7.1	Descriptive statistics	9
		7.1.1 General description	9
		7.1.2 Numerical	
		7.1.3 Graphical	
		7.1.4 Benefits	
		7.1.5 Limitations and cautions	
		7.1.6 Examples of applications	
	7.2	Design of experiments	
		7.2.1 General description ARD PREVIEW 7.2.2 Benefits	11
		7.2.2 Benefits AND AND THE VI	12
		7.2.3 Limitations and cautions 1.2.4 Examples of applications	12
		7.2.4 Examples of applications	12
	7.3	Hypothesis testing	13
		Hypothesis testing 7.3.1 General description SO/DIS 10017 7.3.2 https://doi.org/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.1001/10.100	13
		7.3.2 https://doi.org/10.17	13
		7.3.3 Limitations and cautions /iso-dis-10017	
	7.4	7.3.4 Examples of applications	
	7.4	Measurement system analysis	
		7.4.1 General description	
		7.4.2 Benefits	
		7.4.4 Examples of conditions	
	7 5	7.4.4 Examples of applications	
	7.5	Process capability analysis	
		7.5.1 General description 7.5.2 Benefits	
		7.5.2 Benefits 7.5.3 Limitations and cautions	
	7.6	7.5.4 Examples of applications Regression analysis	
	7.0	7.6.1 General description	
		7.6.2 Benefits	
		7.6.3 Limitations and cautions	
		7.6.4 Examples of applications	
	7.7	Reliability analysis	
	, . ,	7.7.1 General description	
		7.7.2 Benefits	
		7.7.3 Limitations and cautions	
		7.7.4 Examples of applications	
	7.8	Sampling	
		7.8.1 General description	
		7.8.2 Benefits	
		7.8.3 Limitations and cautions	
		7.8.4 Examples of applications	21
	7.0	Simulation	21

ISO/DIS 10017:2020(E)

	7.9.1	General description	21
	7.9.2	General description Benefits	21
	7.9.3	Limitations and cautions	21
	7.9.4	Examples of applications	22
7.10	7.9.4 Examples of applications 0 Statistical process control 7.10.1 General description 7.10.2 Benefits		22
	7.10.1	General description	22
	7.10.2	Benefits	23
	7.10.3	Limitations and cautions	23
	7.10.4	Examples of applications	23
7.11	Statistic	cal tolerance	24
	7.11.1	General description	24
	7.11.2	Renefits	24
	7.11.3	Limitations and cautions Examples of applications eries analysis	24
	7.11.4	Examples of applications	25
7.12	Time se	eries analysis	25
	7.12.1	General description	25
	7.12.2	Benefits	26
	7.12.3	Limitations and cautions	26
	7.12.4	Examples of applications	26
Rihliogranhy	v		27

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ISO/DIS 10017 https://standards.iteh.ai/catalog/standards/sist/372cc108-9c2d-4164-9fe9-c0c7e741cb2c/iso-dis-10017

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html. (Standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

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This document cancels and replaces USO/TRb10017/iBjv0decision of ISO/TC 176/SC 3 this work is now revised as a full guidance standard and aligned with ISO 9001:2015.

This ISO standard may be updated to reflect future revisions of ISO 9001. Comments on the contents of this standard may be sent to ISO Central Secretariat for consideration in a future revision. Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Statistical techniques can be employed to benefit a wide spectrum of activities and sectors.

The value of statistical techniques follows from the variability that is inherent in the behaviour and outcome of practically all processes and activities, even under conditions of apparent stability. Such variability can be observed - over the total life cycle - in the quantifiable characteristics of processes and the resulting products and services.

Statistical techniques can help to measure, describe, analyse, interpret and model variability (whether dealing with a relatively limited amount of data or with large data sets). Statistical analysis of data can provide a better understanding of the nature, extent and causes of variability. It can help to solve and even prevent problems and mitigate risks that could stem from such variability.

The analysis of available data using statistical techniques can assist in decision making and thereby help to improve the performance of processes and the resulting products and/or services, to provide benefits in productivity and cost.

The criteria for determining the need for statistical techniques, and the appropriateness of the technique(s) selected, remain the prerogative of the organization.

The purpose of this ISO standard is to assist an organization to identify statistical techniques against the elements of a quality management system as defined by ISO 9001:2015, which may help to improve processes and the resulting products and services.

This document may be also used to support other management systems and supporting standards such as, for example, environmental management system, health/safety management system or other management systems.

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Quality management — Guidance on statistical techniques for ISO 9001:2015

1 Scope

This document provides guidance on the selection of appropriate statistical techniques that may be useful to an organization, irrespective of size or complexity, in developing, implementing, maintaining and improving a quality management system in compliance with ISO 9001:2015.

Note 1 This standard is not intended for contractual, regulatory or certification/registration purposes. It is not intended to be used as a mandatory checklist for compliance with ISO 9001:2015 requirements.

Note 2 This standard does not provide guidance on how to use the statistical techniques.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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: Probability and general statistical terms

ISO 3534-2, Statistics — Vocabulary and symbols Spart 2. Statistical quality control

ISO 3534-3, Statistics — Vocabulary and symbols — Part 3: Design of experiments

ISO 3534-4, Statistics — Vocabulary and symbols — Part 4: Survey sampling

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9001:2015, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534, Parts 1, 2, 3 and 4 and in ISO 9000:2015, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

statistical technique

methodology for the analysis of quantitative data (ISO 9000:2015, 3.8.1) associated with variation in products, processes, services and phenomena under study to provide information (ISO 9000:2015, 3.8.2) on the object of the study.

Note 1 to entry: Statistical techniques are equally applicable to qualitative (non-numeric) data if such data can be converted to quantitative (numeric) data

Note 2 to entry: For the purposes of this document, the term "statistical techniques" are interchangeable with "statistical methods"

4 Statistical techniques in the implementation of ISO 9001

The justification for using statistical techniques is that their application could help to improve the effectiveness of the quality management system.

Statistical techniques, or families of techniques, that find useful and ready application in the implementation of ISO 9001 are listed below (in alphabetical order)

- descriptive statistics;
- design of experiments;
- hypothesis testing;
- measurement system analysis;
- process capability analysis;
- regression analysis;
- reliability analysis;
- sampling;
- simulation;
- statistical process control:
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- statistical tolerance;

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time series analysis.

Many of these techniques are used in conjunction with other techniques or as sub-sets of other statistical techniques.

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The list of statistical techniques cited in this standard is neither complete nor exhaustive and does not preclude the use of any other techniques (statistical or otherwise) that are deemed to be beneficial to the organization. Furthermore, this standard does not attempt to prescribe which statistical technique(s) are to be used; nor does it attempt to advise on how the technique(s) are to be implemented.

5 Quantitative data and associated statistical techniques in ISO 9001

Quantitative data that may be reasonably encountered in activities associated with the clauses and sub-clauses of ISO 9001:2015 is noted in <u>Table 1</u>. Listed against the quantitative data identified are statistical techniques that could be of potential benefit to the organization when applied to such data.

Where no need for quantitative data could be readily associated with a clause or sub-clause of ISO 9001, no statistical technique is identified.

The statistical techniques cited in this guidance standard are limited to those that are well known. A brief description of each of these statistical techniques is given in <u>Clause 7</u>.

The organization can assess the relevance and value of each statistical technique listed in <u>Table 1</u> and determine whether it may be useful in the context of that clause.

Table 1 — Quantitative data and possible statistical technique(s)

Clause/sub-clause of ISO 9001:2015	Quantitative data involved	Statistical technique(s)
1 Scope	Not applicable	
2 Normative references	Not applicable	

 Table 1 (continued)

Clause/sub-clause of ISO 9001:2015	Quantitative data involved	Statistical technique(s)
3 Terms and definitions	Not applicable	
4. Context of the organization	_	
4.1 Understanding the organization and its context	Data regarding internal and external issues, for example:	Descriptive statistics Statistical process control
	Financial	Sampling
	Market research	Time series analysis
	• Sales	Time series unaryons
	Product and service performance	
	Competition / benchmarking	
4.2 Understanding the	Subjective and objective data regarding	Descriptive statistics
needs and expectations of	expectations of interested parties (e.g. market research)	Sampling
Interested parties	inarketresearch	Time series analysis
4.3 Determining the scope of the quality management system	None identified	
4.4 Quality management system and its processes	n STANDARD PREV	IEW
4.4.1	Nonéidentifiedards iteh ai)	
4.4.2	None identified	
5. Leadership	<u>ISO/DIS</u> 10017	
5.1 Leadership and comstand mitment	ards.iteh.ai/catalog/stan da rds/sist/372cc108-9c2 c0c7e741cb2c/iso-dis-10017	d-4164-9fe9-
5.1.1 General	None Identified	
5.1.2 Customer focus	None identified	
5.2 Policy	_	
5.2.1 Establishing the quality policy	None identified	
5.2.2 Communicating the quality policy	Data to determine extent to which policy is understood	Descriptive statistics Sampling
5.3 Organizational roles, responsibilities and authorities	None identified	
6 Planning	_	
6.1 Actions to address risks and opportunities	_	
6.1.1	Business data to assess risks	Descriptive statistics
6.1.2	Business data to assess effectiveness of actions	Descriptive statistics
6.2 Quality objectives and planning to achieve them	_	
6.2.1	None identified	
6.2.2	None identified	
6.3 Planning of changes	None identified	
7 Support	_	
7.1 Resources	_	

 Table 1 (continued)

Clause/sub-clause of ISO 9001:2015	Quantitative data involved	Statistical technique(s)
7.1.1 General	Summary data on capability	Descriptive statistics
7.1.2 People	None identified	
7.1.3 Infrastructure	Quantitative data related to the per-	Descriptive statistics
	formance and reliability of equipment (hardware and software) and trans-	Process capability analysis
	portation	Reliability analysis
7.1.4 Environment for the	Data on the environment, for example:	Descriptive statistics
operation of processes	Contamination levels	Measurement system analysis
	Antistatic controls	Process capability analysis
	Temperatures (e.g. bacteria con-	Sampling
	trol)	Statistical process control
	Morale (e.g. absenteeism)	Time series analysis
7.1.5 Monitoring and meas-	_	
uring resources		
7.1.5.1 General	Data relating to measurement capability	Descriptive statistics
		Measurement system analysis
	TOL STANDADD DI	Statistical tolerance
7.1.5.2 Measurement	Data relating to stability of measure-	Descriptive statistics
traceability	ment system standards.iteh	Time series analysis
7.1.6 Organizational knowledge	None identified ISO/DIS 10017	
7.2 Competence	Quantitative data on training and ef-72co	Descriptive statistics
- Competence	fectiveness of training41cb2c/iso-dis-1001	7
7.3 Awareness	None identified	
7.4 Communication	None identified	
7.5 Documented Information	_	
7.5.1 General	None identified	
7.5.2 Creating and updating	None identified	
7.5.3 Control of documented information	_	
7.5.3.1	None identified	
7.5.3.2	None identified	
8 Operation		
8.1 Operational planning and control	No specific data identified	
8.2 Requirements for products and services	_	
8.2.1 Customer communications	None identified	

 Table 1 (continued)

Clause/sub-clause of ISO 9001:2015	Quantitative data involved	Statistical technique(s)
8.2.2 Determining the	Data to demonstrate capability and organizational performance	Descriptive statistics
requirements for products and services		Hypothesis testing
and services		Measurement system analysis
		Process capability analysis
		Regression analysis
		Reliability analysis
		Sampling
		Statistical process control
8.2.3 Review of the requirements for products and services	_	
8.2.3.1	Data to demonstrate capability and	Descriptive statistics
	organizational performance	Hypothesis testing
		Measurement system analysis
		Process capability analysis
iTe	h STANDARD PREV	Reliability analysis Statistical process control
8.2.3.2	Nonesdentifiedards.iteh.ai)	
8.2.4 Changes to requirements for products and services https://stanc	None identified ISO/DIS 10017 ards.iteh.ai/catalog/standards/sist/372cc108-9c2	2d-4164-9fe9-
8.3 Design and development of products and services	c0c7e741cb 2c /iso-dis-10017	
8.3.1 General	None identified	
8.3.2 Design and develop- ment planning	None identified	
8.3.3 Design and develop- ment inputs	None identified	
8.3.4 Design and develop-	Verification and validation of design	Descriptive statistics
ment controls	data	Design of experiments
		Hypothesis testing
		Regression analysis
		Sampling
		Simulation
		Statistical tolerance
8.3.5 Design and develop-	Verification of design output data	Descriptive statistics
ment outputs		Hypothesis testing
		Process capability analysis
		Simulation

 Table 1 (continued)

Clause/sub-clause of ISO 9001:2015	Quantitative data involved	Statistical technique(s)
8.3.6 Design and develop-	Data re verification of impact of changes	Descriptive statistics
ment changes		Design of experiments
		Hypothesis testing
		Regression analysis
		Sampling
		Simulation
8.4 Control of externally provided processes, products and services	_	
8.4.1 General	None identified	
8.4.2 Type and extent of	Incoming control data	Descriptive statistics
control		Measurement system analysis
		Regression analysis
		Sampling
		Time series analysis
	Supplier process control data ITEH STANDARD PR	Descriptive statistics Design of experiments
	(standards.iteh	Hypothesis testing
		Measurement system analysis
ht	ISO/DIS 10017 ps://standards.iteh.ai/catalog/standards/sist/372cc c0c7e741cb2c/iso-dis-1001	Process capability analysis 108-9c2d-4164-9fe9- Reliability analysis
		Sampling
		Statistical process control
		Statistical tolerances
		Time series analysis
8.4.3 Information for external providers	None identified	
8.5 Production and service provision	_	
8.5.1 Control of produc-	Production and service data	Descriptive statistics
tion and service provision		Design of experiments
		Hypothesis testing
		Measurement system analysis
		Process capability analysis
		Regression analysis
		Sampling
		Statistical process control
		Time series analysis
8.5.2 Identification and traceability	None identified	