

● Guidance on statistical techniques for ISO 9001:1994

1 Scope

This Technical Report provides guidance on the selection of appropriate statistical techniques that may be useful to an organization in developing, implementing or maintaining a quality system in compliance with ISO 9001. This is done by examining the requirements of ISO 9001 that involve the use of quantitative data, and then identifying and describing those statistical techniques that may be useful when applied to such data.

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

This Technical Report is not intended for contractual, regulatory or certification purposes. It is not intended to be used as a mandatory checklist for compliance with ISO 9001:1994 requirements. The justification for using statistical techniques is that their application would help to improve the effectiveness of the quality system.

2 Terms and definitions

For the purposes of this Technical Report, the terms and definitions given in ISO 8402, ISO 3534 (all parts) and IEC 60050 apply.

References in this Technical Report to "product" are applicable to the generic product categories of service, hardware, processed materials, software or a combination thereof, in accordance with Notes 1 and 2 accompanying the definition of "product" in ISO 8402.

3 Identification of potential needs for statistical techniques

The need for quantitative data that may reasonably be associated with the implementation of the clauses and sub-clauses of ISO 9001 is identified in Table 1. Listed against the need for quantitative data thus identified are one or more appropriate statistical techniques that potentially may be applied to such data, and whose application would benefit the organization.

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

Discretion has been exercised in citing only those techniques that are well known and have been used in a wide range of applications, with recognized benefits to users.

Each of the statistical techniques noted below is described briefly in clause 4, to assist the organization to assess the relevance and value of the statistical techniques cited, and to help determine whether or not to use them in a specific context.

Table 1 — Needs involving quantitative data, and supporting statistical technique(s)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.1 Management responsibility 4.1.1 Quality policy	Need to assess the extent to which the quality policy is implemented in the organization	Sampling
4.1.2 Organization 4.1.2.1 Responsibility and authority	None identified	
4.1.2.2 Resources	None identified	
4.1.2.3 Management representative	None identified	
4.1.3 Management review	Need for quantitative assessment of the organization's performance against its quality objectives	Descriptive statistics; Sampling; SPC charts; Time series analysis
4.2 Quality system 4.2.1 General	None identified	
4.2.2 Quality system procedures	None identified	
4.2.3 Quality planning	None identified	
4.3 Contract review 4.3.1 General	None identified	
4.3.2 Review 4.3.2.a Review	None identified	
4.3.2.b Review	None identified	
4.3.2.c Review	Need to analyse tender, contract or order and to ensure that the supplier has the capability to meet requirements	Measurement analysis; Process capability analysis; Reliability analysis; Sampling
4.3.3 Amendment to a contract	None identified	
4.3.4 Records	None identified	
4.4 Design control 4.4.1 General	None identified	
4.4.2 Design and development planning	None identified	
4.4.3 Organizational and technical interfaces	None identified	
4.4.4 Design input	Need to identify and review input requirements for adequacy, and resolve differences	Measurement analysis; Process capability analysis; Reliability analysis; Statistical tolerancing
4.4.5.a Design output	Need to assess that design outputs satisfy input requirements	Descriptive statistics; Hypothesis testing; Measurement analysis; Process capability analysis; Reliability analysis; Sampling; Statistical tolerancing
4.4.5.b Design output	None identified	
4.4.5.c Design output	Need to identify critical design characteristics	Regression analysis; Reliability analysis; Simulation
4.4.6 Design review	None identified	

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Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.4.7 Design verification	Need to ensure that design meets stated requirements	Design of experiments; Hypothesis testing; Measurement analysis; Regression analysis; Reliability analysis; Sampling; Simulation
4.4.8 Design validation	Need to ensure that product conforms to defined user needs and/or requirements	Hypothesis testing; Regression analysis; Reliability analysis; Sampling; Simulation
4.4.9 Design changes	None identified	
4.5 Document and data control		
4.5.1 General	None identified	
4.5.2 Document and data approval and issue	None identified	
4.5.3 Document and data changes	None identified	
4.6 Purchasing		
4.6.1 General	None identified	
4.6.2.a Evaluation of subcontractors	Need to evaluate subcontractors on the basis of their ability to meet requirements	Descriptive statistics; Hypothesis testing; Process capability analysis; Sampling
4.6.2.b Evaluation of subcontractors	None identified	
4.6.2.c Evaluation of subcontractors	Need to describe and summarise performance of sub-contractors	Descriptive statistics
4.6.3 Purchasing data	None identified	
4.6.4 Verification of purchased product		
4.6.4.1 Supplier verification at subcontractor's premises	None identified	
4.6.4.2 Customer verification of subcontracted product	None identified	
4.7 Control of customer-supplied product	None identified	
4.8 Product identification and traceability	None identified	
4.9 Process control		
4.9.a Process control	None identified	
4.9.b Process control	Need to ensure the suitability of equipment	Descriptive statistics; Measurement analysis; Process capability analysis
4.9.c Process control	None identified	
4.9.d Process control	Need to monitor and control suitable process parameters and product characteristics	Descriptive statistics; Design of experiments; Regression analysis; Sampling; SPC charts; Time series analysis
4.9.e Process control	Need to approve processes and equipment	Descriptive statistics; Measurement analysis; Process capability analysis
4.9.f Process control	None identified	
4.9.g Process control	Need for suitable maintenance of equipment to ensure continuing process capability	Descriptive statistics; Process capability analysis; Reliability analysis; Simulation

Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.10 Inspection and testing 4.10.1 General	Need to specify inspection and test activities to verify that product requirements are met	Hypothesis testing; Reliability analysis; Sampling
4.10.2 Receiving inspection and testing 4.10.2.1 Receiving inspection and testing	Need to verify that incoming product conforms to specified requirements	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling
4.10.2.2 Receiving inspection and testing	None identified	
4.10.2.3 Receiving inspection and testing	None identified	
4.10.3.a In-process inspection and testing	Need to inspect and test product as required	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling
4.10.3.b In-process inspection and testing		
4.10.4 Final inspection and testing	Need to verify that finished product conforms to specified requirements	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling
4.10.5 Inspection and test records	None identified	
4.11 Control of inspection, measuring and test equipment 4.11.1 General	None identified	
4.11.2.a Control procedure	Need to assess the capability of inspection, measurement and test equipment	Descriptive statistics; Measurement analysis; Process capability analysis; SPC charts
4.11.2.b Control procedure	None identified	
4.11.2.c Control procedure	Need to define process for calibration of inspection, measurement and test equipment	Descriptive statistics; Measurement analysis; Process capability analysis; SPC charts
4.11.2.d Control procedure	None identified	
4.11.2.e Control procedure	None identified	
4.11.2.f Control procedure	Need to assess validity of previous inspection and test results.	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling; SPC charts
4.11.2.g Control procedure	None identified	
4.11.2.h Control procedure	None identified	
4.11.2.i Control procedure	None identified	
4.12 Inspection and test status	None identified	
4.13 Control of nonconforming product 4.13.1 General	None identified	
4.13.2.a Review and disposition of nonconforming product	None identified	
4.13.2.b Review and disposition of nonconforming product	None identified	

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Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.13.2.c Review and disposition of nonconforming product	None identified	
4.13.2.d Review and disposition of nonconforming product	None identified	
4.14 Corrective and preventive action		
4.14.1 General	None identified	
4.14.2.a Corrective action	Need to assess effectiveness of process for handling customer complaints and reports of product nonconformities.	Descriptive statistics; Sampling
4.14.2.b Corrective action	Need to analyse the cause of non-conformities relating to product, process or quality system	Descriptive statistics; Design of experiments; Measurement analysis; Process capability analysis; Regression analysis; Reliability analysis; Sampling; Simulation; SPC charts; Statistical tolerancing; Time series analysis
4.14.2.c Corrective action	None identified	
4.14.2.d Corrective action	Need to evaluate the effectiveness of corrective action	Descriptive statistics; Hypothesis testing; Regression analysis; Sampling; SPC charts; Time series analysis
4.14.3.a Preventive action	Need to summarise and analyse product or process data related to actual or potential non-conformities	Descriptive statistics; Regression analysis; Time series analysis
4.14.3.b Preventive action	None identified	
4.14.3.c Preventive action	Need to ensure the effectiveness of preventive action	Descriptive statistics; Hypothesis testing; Regression analysis; Sampling; SPC charts; Time series analysis
4.14.3.d Preventive action	None identified	
4.15 Handling, storage, packaging, preservation and delivery		
4.15.1 General	None identified	
4.15.2 Handling	None identified	
4.15.3 Storage	Need to assess deterioration of product in stock, and to determine appropriate interval between assessments	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling; Time series analysis
4.15.4 Packaging	Need to assess conformance of packing, packaging and marking processes to specified requirements	Descriptive statistics; Process capability analysis; Sampling; SPC charts;
4.15.5 Preservation	Need to assess the adequacy of preservation and segregation of product under supplier's control	Descriptive statistics; Hypothesis testing; Sampling; Time series analysis
4.15.6 Delivery	Need to assess adequacy of protection of product quality after final inspection and test	Descriptive statistics; Sampling
4.16 Control of quality records	None identified	

Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.17 Internal quality audits	Potential need for sampling in planning and conducting internal audits; and need for summarising data from audits and verifying effectiveness	Descriptive statistics; Sampling
4.18 Training	None identified	
4.19 Servicing	Need to verify that servicing meets specified requirements	Descriptive statistics; Sampling
4.20 Statistical techniques		
4.20.1 Identification of need	This clause calls for the identification of the need for statistical techniques.	Suitable statistical techniques identified for consideration.
4.20.2 Procedures	None identified	

The findings of Table 1 are summarized in annex A, which presents an overview of the range of statistical techniques and the extent to which they could be used to support the implementation of ISO 9001.

4 Descriptions of statistical techniques identified

4.1 General

The following statistical techniques, or families of techniques, that might help an organization to meet its needs, are identified in clause 3:

- descriptive statistics
- design of experiments
- hypothesis testing
- measurement analysis
- process capability analysis
- regression
- reliability analysis
- sampling
- simulation
- Statistical Process Control charts
- statistical tolerancing
- time series analysis

As stated earlier, the criteria used in selecting the techniques gathered above are that the techniques are well known and widely used, and their application has resulted in benefit to users.

The choice of technique and the manner of its application will depend on the circumstances and purpose of the exercise, which will differ from case to case.

A brief description of each statistical technique, or family of techniques, listed above is provided in 4.2 to 4.13. The descriptions are intended to assist a lay reader to assess the potential applicability and benefit of using the statistical techniques in implementing the requirements of a quality system. However, the actual application of statistical techniques cited here will require more guidance and expertise than is provided by this Technical Report.