

International Statistical Standards: A Guide for the Uninitiated

by Mark E. Johnson, Dept. of Statistics, Univ. of Central Florida
mejhnso@mail.ucf.edu

Background on International Statistical Standards

The International Standards Organization has its headquarters in Geneva, Switzerland and consists of many diverse Technical Committees, one of which is ISO TC69 "Application of Statistical Methods." The scope of TC69 is "standardization in the application of statistical methods, including generation, collection (planning and design), analysis, presentation and interpretation of data." France, under the auspices of the Association française de normalization (AFNOR) is the Secretariat and is responsible for overseeing the business of the technical committee. Twenty-four countries pay in order to be participating members (i.e., have voting privileges on documents). Besides France, the participating countries and their national standards bodies are, as follows:

Argentina (IRAM)	India (BIS)	Russian Federation (GOST R)
Bulgaria (BDS)	Iran (ISIRI)	Slovakia (SUTN)
Canada (SCC)	Italy (UNI)	South Africa (SABS)
China (SAC)	Japan (JISC)	Sri Lanka (SLSI)
Czech Republic (UNMZ)	Korea, Republic of (KATS)	Sweden (SIS)
Denmark (DS)	Malaysia (DSM)	USA (ANSI)
Finland (SFS)	Mexico (DGN)	United Kingdom (BSI)
Germany (DIN)	Poland (PKN)	

An additional twenty-nine countries are observer nations who may provide comments on documents but cannot vote. Ultimately, a document is published by ISO with the consent and contributions of AFNOR, as all standards are published in both French and English. In view of the large number of reviewers from many countries, final published documents will have survived an extensive review process, leading to documents that are very clearly written and likely to be free of any errors.

Each document emanates from a project at the working group level within the subcommittees of TC69 or TC69 itself. These subcommittees provide a natural organization to the published documents. Presently, there are six active subcommittees within ISO TC 69, as follows:

TC 69/SC 1	Terminology and symbols
TC 69/SC 4	Applications of statistical methods in process management
TC 69/SC 5	Acceptance sampling
TC 69/SC 6	Measurement methods and results
TC 69/SC 7	Applications of statistical and related techniques for the implementation of Six Sigma
TC 69/SC 8	Application of statistical and related methodology for new technology and product development

Documents have been produced through the former subcommittees SC2 (Applications of statistical methods) and SC3 (Bulk sampling) and are now under the aegis of TC69. Subcommittee SC 7 has been in existence for only three years and was created at the request of the Six Sigma community to address some of their specific needs regarding statistical methods. SC 7 has produced two published documents to date. Likewise, SC 8 has recently been created to address perceived needs in the product development area such as robust design methods and quality function deployment but have not yet generated a published document.

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How Standards are Used

Before describing the collection of international statistical standards, some examples of their use in business and governmental applications are noted. These examples are intended to demonstrate the utility of these standards and thus, to make a case for their inclusion in the toolbox of practicing statisticians. International standards having gone through world-wide expert review achieve ready acceptance in the marketplace and with government agencies.

An area of current topical interest involves contaminants (biological as in the 2010 chicken egg recall for salmonella or oil from the Deep Horizon spill). In these situations, some samples may contain a small level of a dangerous or toxic substance that is barely discernible by available measurement devices. Capability of detection is a topic covered by the ISO 11843 series produced by SC6 and is not covered in statistical textbooks or monographs. Wilrich (2002) cites ISO 11843 in the context of safety regulations for food and pharmaceuticals.

Interlaboratory testing is another important area for which the ISO statistical standards play a paramount role. In particular, the ISO 5725 series documents the methodologies used for this purpose. Statisticians at the US National Institute of Standards and Technology have contributed extensively to producing these documents. The importance of interlaboratory testing has been recognized by the American Statistical Association with the establishment in 1985 of the WJ Youden Award in Interlaboratory Testing to "to recognize the authors of publications that make outstanding contributions to the design and/or analysis of interlaboratory tests or describe ingenious approaches to the planning and evaluation of data from such tests." ISO 5725 is the international source document for interlaboratory testing which focuses on the comparison of results across laboratories and the attainment of consensus rather than on statistical research aspects associated with the WJ Youden Award (Feinberg, 1995). Additional recent usages of ISO 5725 can be found in Deuwer et al. (2009) and Voulgaropoulos (2007). Thousands more instances can be located using the key words "interlaboratory testing ISO 5725" with standard internet search engines.

Acceptance sampling problems have motivated many of the published ISO statistical standards (ISO 2859 series) and continue to be relevant in applications (Neubauer, 2010). Edward Schilling, author of the classic text on Acceptance Sampling (1982), actively participated in SC5 standards developments over the years, adapting material from various military standards into the international arena. David Baillie of the United Kingdom likewise has been instrumental in the British effort involving acceptance sampling standards with particular emphasis on military applications. For this work he was awarded the Order of the British Empire (OBE). The sampling inspection methods embodied in the ISO SC5 standards are recognized nationally and internationally. As a specific example, the National Marine Fisheries Services' Voluntary Seafood Inspection Program relies upon ISO 2859-1.

Contents of the International Standards Toolbox

With respect to the existing published 68 documents (as available on the ISO web site noted earlier as of 17 August 2010, it should be useful to the neophyte to have a list of documents organized by their genesis subcommittee. The following tables provide just such a structure for the published documents. By way of some further explanation, the documents whose number starts with ISO/TR are "technical reports" which have useful information in the form of best practice but do not prescribe statistical methodology. The ending number is, of course, the year of publication. In the event that when a document comes up for periodic review no revision is advocated, then the original publication date is retained.

The documents currently available from ISO reflect the participation over the years of key technical experts who participated actively in ISO TC69 technical activities. Richard Freund, Rudy Kittlitz, Carroll Croarkin, John Mandel, August Mundel, Edward Schilling and Harrison Wadsworth were long term contributors to many of these documents. Other US participants such as Donald Marquardt and Blanton Godfrey were involved in the earlier days of TC69 and then gravitated to TC 176 which produced the well-known ISO 9000 series of documents.

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TABLE 1 TC69 Documents (Originated from former SC2 and SC3)

	Statistical Methodology:
ISO/TR 13425:2006	Guidelines for the selection of statistical methods in standardization and specification
ISO/TR 18532:2009	Guidance on the application of statistical methods to quality and to industrial standardization
ISO 11453:1996	Statistical interpretation of data — Tests and confidence intervals relating to proportions
ISO 5479:1997	Statistical interpretation of data — Tests for departure from the normal distribution
ISO 3494:1976	Statistical interpretation of data — Power of tests relating to means and variances
ISO 3301:1975	Statistical interpretation of data — Comparison of two means in the case of paired observations
ISO 2854:1976	Statistical interpretation of data — Techniques of estimation and tests relating to means and variances
ISO 16269-6:2005	Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals
ISO 16269-7:2001	Statistical interpretation of data — Part 7: Median — Estimation and confidence intervals
ISO 16269-8:2004	Statistical interpretation of data — Part 8: Determination of prediction intervals
ISO 2602:1980	Statistical interpretation of test results — Estimation of the mean — Confidence Interval
ISO 28640:2010	Random variate generation methods
	Bulk Sampling:
ISO 10725:2000	Acceptance sampling plans and procedures for the inspection of bulk materials
ISO 11648-1:2003	Statistical aspects of sampling from bulk materials — Part 1: General principles
ISO 11648-2:2001	Statistical aspects of sampling from bulk materials — Part 2: Sampling of particulate materials

TABLE 2 TC69/SC1 Documents

	Nomenclature and Definitions:
ISO 3534-1:2006	Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability
ISO 3534-2:2006	Statistics — Vocabulary and symbols — Part 2: Applied statistics
ISO 3534-3:1999	Statistics — Vocabulary and symbols — Part 3: Design of experiments

TABLE 3 TC69/SC4 Documents

	Statistical Process Control
ISO 22514-1:2009	Statistical methods in process management — Capability and performance – 1: General principles and concepts
ISO 22514-3:2008	Statistical methods in process management — Capability and performance – Part 3: Machine performance studies for measured data on discrete parts
ISO/TR 22514-4:2007	Statistical methods in process management — Capability and performance – Part 4: Process capability estimates and performance
ISO 21747:2006	Statistical methods — Process performance and capability statistics for measured quality characteristics
ISO 11462-1:2001	Guidelines for implementation of statistical process control (SPC) — Part 1: Elements of SPC
ISO 8258:1991	Shewhart control charts
ISO 7966:1993	Acceptance control charts
ISO 7873:1993	Control charts for arithmetic average with warning limits
ISO/TR 7871:1997	Cumulative sum charts — Guidance on quality control and data analysis using CUSUM techniques
ISO 7870-1:2007	Control charts — Part 1: General guidelines

TABLE 4 TC69/SC5 Documents

	Acceptance Sampling
ISO 24153:2009	Random sampling and randomization procedures
ISO 21247:2005	Combined accept-zero sampling systems and process control procedures for product acceptance
ISO 18414:2006	Acceptance sampling procedures by attributes — Accept-zero sampling system based on credit principle for controlling outgoing quality
ISO 14560:2004	Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million
ISO 13448-1:2005	Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 1: Guidelines for the APP approach
ISO 13448-2:2004	Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 2: Coordinated single sampling plans for acceptance sampling by attributes
ISO/TR 8550-1:2007	Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 1: Acceptance sampling
ISO/TR 8550-2:2007	Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 2: Sampling by attributes
ISO/TR 8550-3:2007	Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 3: Sampling by variables
ISO 8422:2006	Sequential sampling plans for inspection by attributes
ISO 8423:2008	Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)

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ISO 3951-1:2005	Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL
ISO 3951-2:2006	Sampling procedures for inspection by variables — Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics
ISO 3951-3:2007	Sampling procedures for inspection by variables — Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 3951-5:2006	Sampling procedures for inspection by variables — Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)
ISO 2859-1:1999	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 2859-2:1985	Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection
ISO 2859-3:2005	Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures
ISO 2859-4:2002	Sampling procedures for inspection by attributes — Part 4: Procedures for assessment of declared quality levels
ISO 2859-5:2005	Sampling procedures for inspection by attributes — Part 5: System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 2859-10:2006	Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes

TABLE 5 TC69/SC6 Documents

Metrology and Measurement Systems

ISO/TR 22971:2005	Accuracy (trueness and precision) of measurement methods and results – Practical guidance for the use of ISO 5725-2:1994 in designing, implementing and statistically analysing interlaboratory repeatability and reproducibility results
ISO/TS 21749:2005	Measurement uncertainty for metrological applications — Repeated measurements and nested experiments
ISO/TS 21748:2004	Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation
ISO 13528:2005	Statistical methods for use in proficiency testing by interlaboratory comparisons
ISO 11843-1:1997	Capability of detection — Part 1: Terms and definitions
ISO 11843-2:2000	Capability of detection — Part 2: Methodology in the linear calibration case
ISO 11843-3:2003	Capability of detection — Part 3: Methodology for determination of the critical value for the response variable when no calibration data are used
ISO 11843-4:2003	Capability of detection — Part 4: Methodology for comparing the minimum detectable value with a given value
ISO 11843-5:2008	Capability of detection — Part 5: Methodology in the linear and non-linear calibration cases
ISO 11095:1996	Linear calibration using reference materials
ISO 10576-1:2003	Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles
ISO 5725-1:1994	Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions
ISO 5725-2:1994	Accuracy (trueness and precision) of measurement methods and results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method
ISO 5725-3:1994	Accuracy (trueness and precision) of measurement methods and results – Part 3: Intermediate measures of the precision of a standard measurement method
ISO 5725-4:1994	Accuracy (trueness and precision) of measurement methods and results – Part 4: Basic methods for the determination of the trueness of a standard measurement method
ISO 5725-5:1998	Accuracy (trueness and precision) of measurement methods and results – Part 5: Alternative methods for the determination of the precision of a standard measurement method
ISO 5725-6:1994	Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values

TABLE 6 TC69/SC7 Documents

Six Sigma Documents

ISO/TR 29901:2007	Selected illustrations of full factorial experiments with four factors
ISO/TR 12845:2010	Selected illustrations of fractional factorial screening experiments

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Work in Progress—Selected Forthcoming Documents

The documents in Tables 1-6 have withstood the onerous review process and the production of the documents according to the ISO template for documents—the format after all across standards should be standardized! Recognizing the evolution of statistical practice, TC 69 created two new subcommittees (SC 7 and SC 8). The aim of SC7 is to create documents that provide guidance on the application of statistical procedures for the Six Sigma and related communities, both manufacturing and business types, who strive to improve products and processes. Because these communities are characterized by a focus on speed to obtain results, a basic knowledge of statistics, and a propensity to use software applications to guide them through the mathematical challenges of statistical methods, the documents to be developed will have the objective of satisfying these characteristics. To date two documents have been sponsored by TC69/SC7 as given in Table 6 but the following four projects are underway and documents are forthcoming:

ISO/DTR 12888	Selected illustrations of gauge repeatability and reproducibility studies
ISO/DIS 13053-1	Quantitative methods in process improvement — Six Sigma – Part 1: DMAIC methodology
ISO/DIS 13053-2	Quantitative methods in process improvement — Six Sigma – Part 2: Tools and techniques
ISO/PRF TR 14468	Selected illustrations of attribute agreement analysis

Also under early development is a technical guide to response surface methodology. A gap analysis between the Six Sigma body of knowledge (BOK) developed by ASQ and TC69 portfolio of documents was recently conducted jointly by ASQ and TC69 experts and led to the development of a roadmap of SC7 future products.

The other subcommittees have work programs involving revisions to existing documents and in some cases development of new standards. For example, SC1 is developing ISO 3534-4 on statistical sampling. TC 69 also establishes ad hoc committees on occasion to investigate emerging topics or issues for consideration. For example, TC69/WG11 has been pondering issues related to statistical software and standards. Statistical practice requires software but ISO is prohibited from advocating any particular statistical package. This causes a real dilemma for standards developers who want to have standards that contain realistic applications. The two documents published by SC7 on factorial and fractional factorial designs have circumvented the problem by including examples with various statistical commercial software packages (such as JMP and Minitab).

Closing Remarks

International statistical standards have a relatively long and distinguished history and body of work consisting of some excellent documents that have benefited from massive amounts of review and use. Some of the main industries commonly using TC69 documents are: government, manufacturing, laboratories and testing agencies, chemicals and plastics, semi-conductor, certification and auditing, seafood, and pharmaceuticals. Participants in developing such documents end up working closely with experts from other countries and developing long-term friendships and in some cases, external collaborations (Boulanger, et al., 1999). The need for additional experts to contribute to the existing work programs or to define new avenues of development is acute, as the US TAG continues to age. Interested experts should contact ASQ to express interest in working on international statistical standards (Standards@asq.org).

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