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

Lignes directrices pour l'application des méthodes statistiques à la qualité et à la normalisation industrielle



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Foreword

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ISO/TR 18532 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*.

Introduction

This Technical Report demonstrates the advantages in the application of statistical methods in as simple and efficient a manner as possible so that they become accessible to the many rather than to the few.

As an introduction to the subject, three examples are given in Clause 4 to focus attention on some of the wider questions at issue. These examples suggest how statistical thinking coupled with the use of simple statistical tools and technical and operational knowledge of the process can help in improving designs, process efficiency and performance and product conformity to specification.

- Example 1, relating to the strength of wire, illustrates the role and value of division of data into so-called rational subgroups coupled with the use of cause and effect diagrams and line plots. It also shows how to exploit interrelationships between process parameters to achieve robust designs. The need is emphasized to treat numerical data not just as a set of figures but as potentially meaningful information on a process. It demonstrates clearly that an enquiring mind and sound judgement, coupled with an understanding of the actual process producing the numerical data, are required as distinct from a mere knowledge of statistical method. This indicates the need for non-statisticians to become more aware of the role of statistical method and to become more involved in their actual application to secure the maximum possible benefits to any organization.
- Example 2, on fabric mass, illustrates key aspects that need to be considered when sampling to establish conformance of an entity to specification. In this example, general conclusions are established by statistical theory and are turned to practical use.
- Example 3 concerns the mass fraction of ash (in %) in coal. Specifically, it demonstrates four principal concepts: how to handle apparent fluctuation of quality within a quantity of material; the need to determine, on a sound basis, the amount of sampling necessary to estimate the quality of a commodity; the necessity to establish, in advance, a well designed sampling procedure; and the value of progressive analysis of results, in a simple graphical manner, as they become available.

More generally, example 3 illustrates the importance of the application of statistical thinking and design method to a numerical study prior to it being undertaken. It also indicates that, to gain full benefit from such a study, persons familiar with the activity under scrutiny should be involved throughout.

Clause 5 introduces basic statistical terms and measures, and a wide range of simpler statistical tools used to present and analyse data. Emphasis has been placed on a pictorial approach that can most readily be communicated to, and understood by, the many.

Clause 6 describes the fundamentals of sampling on a statistical basis and distinguishes between statistical uniformity (stability of a process) and quality level (process capability). Clause 7 introduces sampling with reference to a product requirement. It draws out the two principal methods, *viz.* that of after the event acceptance sampling and that of the ongoing control of inherently capable processes. Clause 8 provides a detailed treatment of the statistical relationship between sample and batch. Clause 9 describes the methodology, terminology and rationale of acceptance sampling. Single, double, multiple, sequential, continuous, skip-lot, audit, parts per million, isolated lot and accept-zero plans for acceptance sampling by attributes are dealt with. Acceptance sampling by variables covers the following plans for individual quality characteristics: single sampling plans for known and for unknown standard deviation; double sampling plans; sequential sampling plans for known standard deviation and accept-zero plans. Multiple-quality characteristic plans are also described.

Clause 10 covers the fundamentals of statistical process control. It distinguishes between statistical process control and the use of statistical process control techniques for statistical product control. Over-control, under-control and control are discussed. The key steps in establishing and interpreting performance-based control charts that are intended primarily to differentiate between special and common causes of variation and

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provide a basis for capability and performance assessment are covered. The principal types of Shewhart-type control charts and the role and application of cumulative sum (CUSUM) charts are dealt with.

Clause 11 deals with performance benchmarking of stable processes under the heading of process capability assessment. Three very pertinent business questions are answered by a control chart: 1) is the process in control?; 2) what is the performance of the process?; and 3) is there evidence of significant improvement in process performance? Clause 11 focuses on answering the second question regarding process capability/performance of both measured data and attribute processes. It introduces the use of the internationally standardized capability indices, C_p , C_{pkL} and C_{pkU} . It also discusses the business implications, in terms of aiming at preferred value and minimizing variation, with the quotation of minimum C_{pm} values, rather than the convention of tolerating maximum use of specified tolerances in determining whether or not an entity conforms to requirements.

Clause 12 begins by illustrating the role and value of simple economic experimental designs where the mathematical content is such that all the necessary calculations can readily be done manually. It then continues to exploit the development of computer software programs in the design and analysis of experiments. Nowadays the need for computational skills has become so minimal that the practitioner can concentrate his attention on choosing the right kind of design for a particular application, how to perform the experiment and how to interpret the computer outputs. In both cases, pictorial outputs are encouraged to facilitate understanding.

Clause 13 deals with the capability of measuring systems. Following a resumé of the basic statistical requisites of a measuring system that ensures the integrity of the data output, examples are given of the application of statistical method to the evaluation of resolution, bias and precision, uncertainty, repeatability and reproducibility.