
Capability of detection —

Part 4:

Methodology for comparing the minimum detectable value with a given value

Capacité de détection —

Partie 4: Méthodologie de comparaison de la valeur minimale détectable avec une valeur donnée



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Published in Switzerland

Foreword

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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 11843-4 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

ISO 11843 consists of the following parts, under the general title *Capability of detection*:

- *Part 1: Terms and definitions*
- *Part 2: Methodology in the linear calibration case*
- *Part 3: Methodology for determination of the critical value for the response variable when no calibration data are used*
- *Part 4: Methodology for comparing the minimum detectable value with a given value*

Introduction

An ideal requirement for the capability of detection with respect to a selected state variable would be that the actual state of every observed system can be classified with certainty as either equal to or different from its basic state. However, due to systematic and random variations, this ideal requirement cannot be satisfied for the following reasons.

- a) In reality all reference states, including the basic state, are never known in absolute terms of the state variable. Hence, all states can only be characterized correctly in terms of differences from the basic state, i.e. in terms of the net state variable.
- b) In order to prevent erroneous decisions, it is generally recommended to report differences from the basic state only, i.e. data in terms of the net state variable.

NOTE In ISO Guide 30 and in ISO 11095, no distinction is made between the state variable and the net state variable. As a consequence, in those two documents reference states are — without justification — assumed to be known with respect to the state variable.

- c) Furthermore, the calibration and the processes of sampling and preparation add random variation to the measurement results.

In this part of ISO 11843

- the probability is α of detecting (erroneously) that a system is not in the basic state when it is in the basic state;
- the probability is β of (erroneously) not detecting that a system, for which the value of the net state variable is equal to the minimum detectable value (x_d) is not in the basic state.

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1 Scope

This part of ISO 11843 deals with the assessment of the capability of detection of a measurement method without the assumptions in ISO 11843-2 of a linear calibration curve and certain relationships between the residual standard deviation and the value of the net state variable

NOTE These assumptions are often doubtful for values of the net state variable close to zero.

Instead of estimating the minimum detectable value, this part of ISO 11843 provides

- a criterion for judging whether the minimum detectable value is less than a given level of the net state variable, and
- the basic experimental design for testing the conformity of this criterion.

For assessment of the capability of detection, for instance as part of the validation of a measurement method, it is often sufficient to confirm that the method has a minimum detectable value that is less than a given value.

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: Probability and general statistical terms*

ISO 3534-2:—¹⁾, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 3534-3:1999, *Statistics — Vocabulary and symbols — Part 3: Design of experiments*

ISO 5479:1997, *Statistical interpretation of data — Tests for departure from normal distribution*

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 11095:1996, *Linear calibration using reference materials*

ISO 11843-1:1997, *Capability of detection — Part 1: Terms and definitions*

ISO Guide 30:1992, *Terms and definitions used in connection with reference materials*

1) To be published. (Revision of ISO 3534-2:1993)