

Detektionskapabilitet –

Del 4: Metod för att jämföra minsta detekterbara värde med ett givet värde (ISO 11843-4:2003, IDT)

Capability of detection –

Part 4: Methodology for comparing the minimum detectable value with a given value (ISO 11843-4:2003, IDT)

Den internationella standarden ISO 11843-4:2003 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av ISO 11843-4:2003.

The International Standard ISO 11843-4:2003 has the status of a Swedish Standard. This document contains the official English version of ISO 11843-4:2003.

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Foreword

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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*

SS-ISO 11843-4:2005**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.

Capability of detection —

Part 4:

Methodology for comparing the minimum detectable value with a given value

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)

SS-ISO 11843-4:2005**3 Terms and definitions**

For the purposes of this document, the terms and definitions given in ISO 3534 (all parts), ISO 5479, ISO 5725-2, ISO 11095, ISO 11843-1 and ISO Guide 30 apply.

4 Experimental design**4.1 General**

The measurement method is assumed to be standardized. The same complete method shall be used for all measurements, whether of the reference states or of actual states (test samples).

4.2 Choice of reference states and reference materials

The reference states shall include two values of the net state variable

- the value zero of the net state variable (i.e. in analytical chemistry, a sample of the blank material), and
- a given value, x_g , which will be tested to determine whether it is greater than the minimum detectable value.

The composition of the reference materials representing the reference states should be as close as possible to the composition of the material to be measured in order to satisfy the requirement that reference and test materials behave in the same way in the measuring system.

4.3 Number of replications

It is assumed that the capability of detection is assessed in a separate experiment with the same number of replications for both reference states specified in 4.2. In an application of the method, measurements are performed for the reference material (representing the value zero of the net state variable) and the actual state. The number of replications used in applications of the method are usually smaller than the number of replications used in the assessment of the capability of detection of the method. The following notations are used:

- J is the number of replications of measurements on the reference material representing the value zero of the net state variable (blank sample) in an application of the method;
- K is the number of replications of measurements on the actual state (test sample) in an application of the method.
- N is the number of replications of measurements on each reference material (see 4.2) in assessment of the capability of detection;

The value of N should preferably be at least 5.

NOTE In validation of a method, the capability of detection is usually determined for $J = K = 1$.

5 The criterion for sufficient capability of detection**5.1 Basic assumptions**

Basic assumptions in this part of ISO 11843 are

- the measurements of the response variable of all materials are assumed to be independent and normally distributed, and
- the reference and test materials behave in the same way in the measurement system.