BSI Standards Publication

Capability of detection

Part 5: Methodology in the linear and non-linear calibration cases

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National foreword

This British Standard is the UK implementation of
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The start and finish of text introduced or altered by amendment is
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Capability of detection —

Part 5:
Methodology in the linear and non-linear calibration cases

Capacité de détection —

Partie 5: Méthodologie des étalonnages linéaire et non linéaire

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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 11843-5 was prepared by Technical Committee ISO/TC 69, *Application 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*

— *Part 5: Methodology in the linear and non-linear calibration cases*

Introduction

Both linear and non-linear calibration functions are encountered in practice. This part of ISO 11843 treats both cases equally in the context of the capability of detection, by paying attention to the probability distributions of the net state variable (measurand), rather than the calibration functions themselves.

The basic concepts of ISO 11843-2 including the probability requirements, α and β, and the linear calibration cases are retained by this part of ISO 11843. In the interval of values between the basic state and minimum detectable value, a linear calibration function may be applied. In this manner, compatibility with ISO 11843-2 is assured.

In the case that an analytical method characterized with a linear calibration function is compared with a method with a non-linear calibration function, this part of ISO 11843 is recommended. In a linear calibration case, ISO 11843-2 and this part of ISO 11843 are both available. ISO 11843-2 which uses the precision profile for the response variable alone will give the same result as this part of ISO 11843 which requires the precision profiles for both the response variable and net state variable, since the precision profile for the response variable is the same as that for the net state variable in the linear case.

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Capability of detection —

Part 5:
Methodology in the linear and non-linear calibration cases

1 Scope

This part of ISO 11843 is concerned with calibration functions that are either linear or non-linear.

It specifies basic methods to

— construct a precision profile for the response variable, namely a description of the standard deviation (SD) or coefficient of variation (CV) of the response variable as a function of the net state variable,

— transform this precision profile into a precision profile for the net state variable in conjunction with the calibration function, and

— use the latter precision profile to estimate the critical value and minimum detectable value of the net state variable.

The methods described in this part of ISO 11843 are useful for checking the detection of a certain substance by various types of measurement equipment to which ISO 11843-2 cannot be applied. Included are assays of persistent organic pollutants (POPs) in the environment, such as dioxins, pesticides and hormone-like chemicals, by competitive ELISA (enzyme-linked immunosorbent assay), and tests of bacterial endotoxins that induce hyperthermia in humans.

The definition and applicability of the critical value and minimum detectable value of the net state variable are described in ISO 11843-1 and ISO 11843-2. This part of ISO 11843 extends the concepts in ISO 11843-2 to the cases of non-linear calibration.

The critical value, x_c, and minimum detectable value, x_d, are both given in the units of the net state variable. If x_c and x_d are defined based on the distribution for the response variable, the definition should include the calibration function to transform the response variable to the net state variable. This part of ISO 11843 defines x_c and x_d based on the distribution for the net state variable independently of the form of the calibration function. Consequently, the definition is available irrespective of the form of this function, whether it is linear or non-linear.

The calibration function should be continuous, differentiable, and monotonically increasing or decreasing.

A further method is described for the cases where the SD or CV is known only in the neighbourhood of the minimum detectable value.

Examples are provided.

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: General statistical terms and terms used in probability*

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