
Capability of detection —

Part 3:

**Methodology for determination of the
critical value for the response variable
when no calibration data are used**

Capacité de détection —

*Partie 3: Méthodologie pour déterminer la valeur critique d'une variable
de réponse lorsque aucun étalonnage n'est utilisé*



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

This document is a preview generated by EVS

© ISO 2003

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Experimental design	2
5 Computation of the critical value of the response variable y_c	3
Annex A (normative) Symbols used in this part of ISO 11843	6
Annex B (informative) Examples	7

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 11843-3 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 because:

- 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.

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.

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

In this part of ISO 11843, the symbol α is used for the probability of detecting (erroneously) that a system is not in the basic state when it is in the basic state.

This document is a preview generated by EVS

Capability of detection —

Part 3:

Methodology for determination of the critical value for the response variable when no calibration data are used

1 Scope

This part of ISO 11843 gives a method of estimating the critical value of the response variable from the mean and standard deviation of repeated measurements of the reference state in certain situations (see 5.1) in which the value of the net state variable is zero, for all reasonable and foreseeable purposes. Hence, it can be decided whether values of the response variable in an actual state (or test sample) are above the range of values attributable to the reference state.

General procedures for determination of critical values of the response variable and the net state variable and of the minimum detectable value have been given in ISO 11843-2. Those procedures are applicable in situations in which there is relevant straight-line calibration and the residual standard deviation of the measured responses is either constant or is a linear function of the net state variable. The procedure given in this part of ISO 11843 for the determination of the critical value of the response variable only is recommended for situations in which no calibration data are used. The distribution of data is assumed to be normal or near-normal.

The procedure given in this part of ISO 11843 is recommended for situations in which it is difficult to obtain a large amount of the actual states although a large amount of the basic state can be prepared.

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, *Statistics — Vocabulary and symbols — Part 2: Statistical quality control*

ISO 3534-3, *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 11843-2:2000, *Capability of detection — Part 2: Methodology in the linear calibration case*

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