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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 33260.5-2018

**Capability of detection -- Part 5: Methodology in the linear and
nonlinear calibration cases**

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Table of Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

Foreword

GB/T 33260 "Detection Capability" is currently divided into the following sections.

--- Part 1. Terminology and definitions;

--- Part 2. Determination of the detection limit of linear calibration cases;

--- Part 3. Method for determining the critical value of the response variable without calibration data;

--- Part 4. Comparison of the minimum detectable value and the given value;

--- Part 5. Determination of the detection limit of nonlinear calibration cases.

This part is the fifth part of GB/T 33260.

This part is drafted in accordance with the rules given in GB/T 1.1-2009.

This section uses the redrafting method to modify the use of ISO 11843-5:2008 "detection capability part 5. non-linear calibration situation detection limit

Determination method. Compared with ISO 11843-5:2008, the main technical changes are as follows.

---About the normative reference documents, this part has made technical adjustments to apply to China's technical conditions, adjustments

The situation is reflected in Chapter 2, "Regulatory References", and the specific adjustments are as follows.

* Replace ISO 3534-1 with GB/T 3358.1-2009 equivalent to international documents;

* Replace ISO 3534-2 with GB/T 3358.2-2009 equivalent to international documents;

* Replace ISO 3534-3 with GB/T 3358.3-2009 equivalent to international documents;

* Replace ISO 5725-1 with GB/T 6379.1-2004 equivalent to international documents;

* Replaced ISO 11843-1:1997 with GB/T 33260.1-2016 modified with international documents;

* Replace ISO 11843-2:2000 with GB/T 33260.2-2018 modified with international documents.

This part is proposed and managed by the National Statistical Method Application Standardization Technical Committee (SAC/TC21).

This section was drafted by: China National Institute of Standardization, Beijing University of Technology, Xiamen Optimization Technology Co., Ltd., Central University of Finance and Economics, China

Liaoning Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China, Tianjin University, Tsinghua University, and CITIC Daika Co., Ltd.

Introduction

Both linear and nonlinear calibration functions will appear in the real world. This part of GB/T 33260 has two types in the scope of detection capability.

The situation is handled uniformly by the probability distribution of the net state variables rather than by the calibration function itself.

This section follows the basic concepts of GB/T 33260.2-2018, including the probability of making mistakes α and β , and linear calibration. in case

The linear calibration function can be used in the value range of the base state value and the minimum detectable value, and is in combination with GB/T 33260.2-2018.

Tolerance.

When comparing an analytical method based on a linear calibration function with a method based on a nonlinear calibration function, it is recommended to use the method in this section.

law. In the case of linear calibration, GB/T 33260.2-2018 and this part can be used. GB/T 33260.2-2018 only uses the response

The precision profile function of the variable can be used to draw the same conclusions as this part, and this part requires both the response variable and the net state variable.

The density profile function because the precision profile function of the response variable is the same as the precision profile function of the net state variable in the linear case.

Detection capability part 5.

Method for determining the detection limit of nonlinear calibration

1 Scope

This part of GB/T 33260 is mainly applicable to the case where the calibration function is non-linear and can also be used for linear cases.

The basic methods given in this section are used to.

--- Construct a precision profile function of the response variable, a function of the net state variable, using the standard deviation (SD) or variation of the response variable

Different coefficient (CV) representation;

--- Using the calibration function, the precision profile function of the response variable is transformed into the precision profile function of the net state variable;

--- Use the precision profile function of the net state variable to estimate the critical value and the minimum detectable value of the net state variable.

When the method given in GB/T 33260.2-2018 is not effective for the detection of various types of measurement methods (measurement equipment)

The methods presented in this section are very useful when evaluating. This includes measuring the loop by competitive ELISA (enzyme-linked immunosorbent assay)

Persistent organic pollutants (POPs, such as dioxin, pesticides and hormonal chemicals) and bacterial toxins that cause high fever.

GB/T 33260.1-2016 and GB/T 33260.2-2018 describe the threshold value of the net state variable and the minimum detectable value

Righteousness and applicability. This section extends the concept in GB/T 33260.2 to a non-linear calibration scenario.

Both the critical value x_c and the minimum detectable value x_d are given in units of net state variables. If x_c and x are defined based on the distribution of response variables

x_d , then this definition should include a calibration function that transforms the response variable into a net state variable. The x_c and x_d defined in this section are based on the net shape

The distribution of state variables is independent of the form of the calibration function. Therefore, this definition applies regardless of whether the function form is linear or non-linear.

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

This section further gives a description of how SD or CV is known only in the neighborhood of the smallest detectable value.

Some examples are given in Chapter 6.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only dated versions apply.

This document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 3358.1-2009 Statistical vocabulary and symbols - Part 1. General statistical terms and terms for probabilities

(ISO 3534-1:2006, IDT)

GB/T 3358.2-2009 Statistical vocabulary and symbols - Part 2. Application statistics (ISO 3534-2:2006, IDT)

GB/T 3358.3-2009 Statistical vocabulary and symbols - Part 3. Experimental design (ISO 3534-3:1999, IDT)

GB/T 6379.1-2004 Accuracy of measurement methods and results (accuracy and precision) Part 1. General and definition

(ISO 5725-1:1994, IDT)

GB/T 33260.1-2016 Detection capability Part 1. Terms and definitions (ISO 11843-1:1997, MOD)

GB/T 33260.2-2018 Detection capability Part 2. Methods for determining the ability to detect linear calibrations (ISO 11843-2:

2000, MOD)

3 Terms and definitions

GB/T 3358.1-2009, GB/T 3358.2-2009, GB/T 3358.3-2009, GB/T 6379.1-2004,