

## FINAL DRAFT International Standard

Determination of the characteristic limits (decision threshold, detection limit and limits of the coverage interval) for measurements of ionizing radiation — Fundamentals and application — https://standards.

## Part 1: **Do Elementary applications**

ISO/FDIS 11929-1

Détermination des limites caractéristiques (seuil de décision, 5-5d) limite de détection et extrémités de l'intervalle élargi) pour mesurages de rayonnements ionisants — Principes fondamentaux et applications —

Partie 1: Applications élémentaires

## ISO/FDIS 11929-1

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#### Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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This document was prepared by ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 430, *Nuclear energy, nuclear technologies, and radiological protection*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11929-1:2019), of which it constitutes a minor revision. and ards iteh al/catalog/standards/iso/24b94065-5d1c-4fa3-b283-cc91fed34565/iso-fdis-11929-1

The main changes are as follows:

- correction of the internal references within the text;
- correction of <u>Formulae (3)</u>, (A.5) and (B.3);
- correction of the definitions of decision threshold (3.12) and the detection limit (3.13);
- introduction of NOTE 3 in <u>5.8</u>, for clarity;
- complement of the NOTE in <u>9.1</u>;
- correction of the 1<sup>rst</sup> paragraph and NOTE 2 in <u>Clause 10</u>;
- correction of the 8<sup>th</sup> paragraph in <u>Annex B</u>.

A list of all the parts in the ISO 11929 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

#### Introduction

Measurement uncertainties and characteristic values, such as the decision threshold, the detection limit and limits of the coverage interval for measurements, as well as the best estimate and its associated standard measurement uncertainty, are of importance in metrology in general and for radiological protection in particular. The quantification of the uncertainty associated with a measurement result provides a basis for the trust an individual can have in a measurement result. Conformity with regulatory limits, constraints or reference values can only be demonstrated by taking into account and quantifying all sources of uncertainty. Characteristic limits provide, at the end, the basis for deciding if uncertainties have to be taken into account.

This standard provides characteristic values of a non-negative measurand of ionizing radiation. It is also applicable for a wide range of measuring methods extending beyond measurements of ionizing radiation.

The limits to be provided according to ISO 11929 series for specified probabilities of wrong decisions allow detection possibilities to be assessed for a measurand and for the physical effect quantified by this measurand as follows:

- the "decision threshold" allows a decision to be made on whether or not the physical effect quantified by the measurand is present;
- the "detection limit" indicates the smallest true quantity value of the measurand that can still be detected with the applied measurement procedure; this gives a decision on whether or not the measurement procedure satisfies the requirements and is therefore suitable for the intended measurement purpose;
- the "limits of the coverage interval" enclose, in the case of the physical effect recognized as present, a coverage interval containing the true quantity value of the measurand with a specified probability.

Hereinafter, the limits mentioned are jointly called the "characteristic limits".

NOTE According to ISO/IEC Guide 99:2007 updated by JCGM 200:2012 the term "coverage interval" is used here instead of "confidence interval" in order to distinguish the wording of Bayesian terminology from that of conventional statistics.

All the characteristic values are based on Bayesian statistics and on the ISO/IEC 98-3 as well as on the ISO/IEC Guide 98-3:2008/Suppl 1:2008 and ISO/IEC Guide 98-3:2008/Suppl 2:2011. As explained in detail in ISO 11929-2, the characteristic values are mathematically defined by means of moments and quantiles of probability distributions of the possible measurand values.

Since measurement uncertainty plays an important part in ISO 11929, the evaluation of measurements and the treatment of measurement uncertainties are carried out by means of the general procedures according to the ISO/IEC Guide 98-3 and to the ISO/IEC Guide 98-3:2008/Suppl 1:2008; see also References [13] to [17]. This enables the strict separation of the evaluation of the measurements, on the one hand, and the provision and calculation of the characteristic values, on the other hand. The ISO 11929 series makes use of a theory of uncertainty in measurement [18] to [20] based on Bayesian statistics (e.g. see References [21] to [26]) in order to take into account those uncertainties that cannot be derived from repeated or counting measurements. The latter uncertainties cannot be handled by frequentist statistics.

Because of developments in metrology concerning measurement uncertainty laid down in the ISO/IEC Guide 98-3, ISO 11929:2010 was drawn up on the basis of the ISO/IEC Guide 98-3, but using Bayesian statistics and the Bayesian theory of measurement uncertainty. This theory provides a Bayesian foundation for the ISO/IEC Guide 98-3. Moreover, ISO 11929:2010 was based on the definitions of the characteristic values, [13] the standard proposal, [14] and the explanatory article. [15] It unified and replaced all earlier parts of ISO 11929 and was applicable not only to a large variety of particular measurements of ionizing radiation but also, in analogy, to other measurement procedures.

In 2008 the ISO/IEC Guide 98-3:2008/Suppl 1:2008 has been published, dealing comprehensively with a more general treatment of measurement uncertainty using the Monte Carlo method in complex measurement evaluations. This provided an incentive for writing a corresponding Monte Carlo supplement [16] to ISO 11929:2010 and to revise ISO 11929:2010. The revised ISO 11929 is also essentially founded on Bayesian statistics and can serve as a bridge between ISO 11929:2010 and the ISO/IEC Guide 98-3:2008/Suppl 1:2008. Moreover, more general definitions of the characteristic values (ISO 11929-2) and the Monte

Carlo computation of the characteristic values make it possible to go a step beyond the present state of standardization laid down in ISO 11929:2010 since probability distributions rather than uncertainties can be propagated. It is thus more comprehensive and extending the range of applications.

The revised ISO 11929, moreover, is more explicit on the calculation of the characteristic values. It corrects also a problem in ISO 11929:2010 regarding uncertain quantities and influences, which do not behave randomly in measurements repeated several times. Reference [17] gives a survey on the basis of the revision. Furthermore, in ISO 11929-3, it gives detailed advice how to calculate characteristic values in the case of multivariate measurements using unfolding methods. For such measurements, the ISO/IEC Guide 3-2 provides the basis of the uncertainty evaluation.

Formulae are provided for the calculation of the characteristic values of an ionizing radiation measurand via the "standard measurement uncertainty" of the measurand (hereinafter the "standard uncertainty") derived according to the ISO/IEC Guide 98-3 as well as via probability density functions (PDFs) of the measurand derived in accordance with the ISO/IEC Guide 98-3:2008/Suppl 1:2008. The standard uncertainties or probability density functions take into account the uncertainties of the actual measurement as well as those of sample treatment, calibration of the measuring system and other influences. The latter uncertainties are assumed to be known from previous investigations.

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# Determination of the characteristic limits (decision threshold, detection limit and limits of the coverage interval) for measurements of ionizing radiation — Fundamentals and application —

#### Part 1:

### **Elementary applications**

#### 1 Scope

The ISO 11929 series specifies a procedure, in the field of ionizing radiation metrology, for the calculation of the "decision threshold", the "detection limit" and the "limits of the coverage interval" for a non-negative ionizing radiation measurand when counting measurements with preselection of time or counts are carried out. The measurand results from a gross count rate and a background count rate as well as from further quantities on the basis of a model of the evaluation. In particular, the measurand can be the net count rate as the difference of the gross count rate and the background count rate, or the net activity of a sample. It can also be influenced by calibration of the measuring system, by sample treatment and by other factors.

ISO 11929 has been divided into four parts covering elementary applications in this document, advanced applications on the basis of the ISO/IEC Guide 3-1 in ISO 11929-2, applications to unfolding methods in ISO 11929-3, and guidance to the application in ISO 11929-4.

This document covers basic applications of counting measurements frequently used in the field of ionizing radiation metrology. It is restricted to applications for which the uncertainties can be evaluated on the basis of the ISO/IEC Guide 98-3 (JCGM 2008). In <u>Annex A</u>, the special case of repeated counting measurements with random influences is covered, while measurements with linear analogous ratemeters are covered in <u>Annex B</u>.

ISO 11929-2 extends the former ISO 11929:2010 to the evaluation of measurement uncertainties according to the ISO/IEC Guide 98-3:2008/Suppl 1:2008. ISO 11929-2 also presents some explanatory notes regarding general aspects of counting measurements and on Bayesian statistics in measurements.

ISO 11929-3 deals with the evaluation of measurements using unfolding methods and counting spectrometric multi-channel measurements if evaluated by unfolding methods, in particular, for alpha- and gamma-spectrometric measurements. Further, it provides some advice on how to deal with correlations and covariances.

ISO 11929-4 gives guidance to the application of the ISO 11929 series, summarizes shortly the general procedure and then presents a wide range of numerical examples. Information on the statistical roots of ISO 11929 and on its current development may be found elsewhere [33][34].

The ISO 11929 series also applies analogously to other measurements of any kind especially if a similar model of the evaluation is involved. Further practical examples can be found, for example, in ISO 18589, [ $^{1}$ ] ISO 9696, [ $^{2}$ ] ISO 9697, [ $^{3}$ ] ISO 9698, [ $^{4}$ ] ISO 10703, [ $^{5}$ ] ISO 7503, [ $^{6}$ ] ISO 28218, [ $^{7}$ ] and ISO 11665 [ $^{8}$ ].

NOTE A code system, named UncertRadio, is available for calculations according to ISO 11929-1 to ISO 11929-3. UncertRadio[31][32] can be downloaded for free from <a href="https://www.thuenen.de/en/institutes/fisheries-ecology/fields-of-activity/marine-environment/coordination-centre-of-radioactivity/uncertradio">https://www.thuenen.de/en/institutes/fisheries-ecology/fields-of-activity/marine-environment/coordination-centre-of-radioactivity/uncertradio</a>. The download contains a setup installation file which copies all files and folders into a folder specified by the user. After installation one has to add information to the PATH of Windows as indicated by a pop-up window during installation. English language can be chosen and extensive "help" information is available.