FINAL DRAFT

INTERNATIONAL STANDARD

ISO/FDIS 11929-4

ISO/TC 85/SC 2

Secretariat: **AFNOR**

Voting begins on: **2022-04-19**

Voting terminates on: **2022-06-14**

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

Part 4: Guidelines to applications

Détermination des limites caractéristiques (seuil de décision, limite de détection et limites de l'intervalle élargi) pour le mesurage des rayonnements ionisants — Principes fondamentaux et applications —

Partie 4: Lignes directrices relatives aux applications

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Reference number ISO/FDIS 11929-4:2022(E)

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ISO/FDIS 11929-4

https://standards.iteh.ai/catalog/standards/sist/6b0aac6c-9e4f-4cea-9f54-32b6a6ec7714/iso-fdis-11929-4



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Published in Switzerland

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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.

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 www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This third edition of ISO 11929-4 cancels and replaces the second edition (ISO 11929-4:2020), of which it constitutes a minor revision.

The main changes are as follows:

- Editorial changes were done in text and formulae

A list of all parts of ISO 11929 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 <u>www.iso.org/members.html</u>.

Introduction

Measurement uncertainties and characteristic values, i.e. characteristic limits 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.

NOTE 1 Conformity with regulatory limits, constraints or reference values can only be demonstrated taking into account and quantifying all sources of uncertainty. Characteristic limits provide – in the end – the basis for deciding accepting results under uncertainty.

ISO 11929 (all parts) provides characteristic values of a non-negative measurand of ionizing radiation. It is applicable for a wide range of measuring methods extending beyond measurements of ionizing radiation.

The limits to be provided according to ISO 11929 (all parts) 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 and allows for 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 "characteristic limits".

NOTE 2 According to ISO/IEC Guide 99 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 Guide 98-3 as well as on the ISO/IEC Guide 98-3:2008/Suppl.1 and ISO/IEC Guide 98-3:2008/Suppl.2. 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 role in all parts of 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; see also References [21] to [25]. 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. ISO 11929 (all parts) makes use of a theory of uncertainty in measurement^{[26] to [28]} based on Bayesian statistics (e.g. References [29] to [36]) in order to allow taking into account also 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 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^[21], the standard proposal^[22], and the introducing article^[23]. 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. Some

explanatory material about the basics of ISO 11929 (all parts), in general, and its application in has been published elsewhere^{[42][43]}.

Since the ISO/IEC Guide 98-3:2008/Suppl.1 has been published, the Monte Carlo method has been used to deal comprehensively with a more general treatment of measurement uncertainty in complex measurement evaluations. This development provided an incentive for writing a corresponding Monte Carlo supplement^[24] to ISO 11929:2010. The revised ISO 11929 (all parts) is also essentially founded on Bayesian statistics and can serve as a bridge between documents ISO 11929:2010 and the ISO/IEC Guide 98-3:2008/Suppl.1. 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 (all parts), moreover, is more explicit on the calculation of the characteristic values. Reference [25] gives a survey on the basis of the revision. Further, 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 98-3:2008/Suppl.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 "standard uncertainty") derived according to the ISO/IEC Guide 98-3 as well as via probability density functions (PDFs) of the measurand derived on the basis of the ISO/IEC Guide 98-3:2008/Suppl.1. 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.

ISO/FDIS 11929-4

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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 4: Guidelines to applications

1 Scope

This document 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 ISO 11929-1, advanced applications on the basis of the ISO/IEC Guide 98-3:2008/Suppl.1 in ISO 11929-2, applications to unfolding methods in ISO 11929-3, and guidance to the application in ISO 11929-4.

ISO 11929-1 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 ISO 11929-1:2019, Annex A the special case of repeated counting measurements with random influences and in ISO 11929-1:2019, Annex B, measurements with linear analogous ratemeters are covered.

ISO 11929-2 extends ISO 11929-1 to the evaluation of measurement uncertainties according to the ISO/IEC Guide 98-3:2008/Suppl.1. ISO 11929-2 also presents some explanatory notes regarding general aspects of counting measurements and 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, alpha- and gamma-spectrometric measurements. Further, it provides some advice how to deal with correlations and covariances.

ISO 11929-4 gives guidance to the application of ISO 11929 (all parts), summarizing shortly the general procedure and then presenting a wide range of numerical examples. The examples cover elementary applications according to ISO 11929-1 and ISO 11929-2.

The ISO 11929 (all parts) also applies analogously to other measurements of any kind if a similar model of the evaluation is involved. Further practical examples can be found in other International Standards, for example, see References [1 to 20].

NOTE A code system, named UncertRadio, is available allowing for calculations according to ISO 11929-1 to ISO 11929-3. UncertRadio^{[40][41]} can be downloaded for free from https://www.thuenen.de/en/fi/fields-of -activity/marine-environment/coordination-centre-of-radioactivity/uncertradio/. The download contains a setup installation file that copies all files and folders into a folder specified by the user. After installation ender 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. Another tool is the package 'metRology'^[44] which is available for programming in R. It contains the two R functions 'uncert' and 'uncertMC' which perform the GUM-conform uncertainty propagation, either analytically or by the Monte Carlo method, respectively. Covariances/correlations of input quantities are included. Applying these two functions within iterations for decision threshold and the detection limit calculations simplifies the programming effort significantly. It is also possible to implement this document in a spreadsheet containing a Monte Carlo add-in or into other commercial mathematics software.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11929-1, 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

ISO 11929-2, Determination of the characteristic limits (decision threshold, detection limit and limits of the coverage interval) for measurements of ionizing radiation — Fundamentals and application — Part 2: Advanced applications

ISO 80000-1, Quantities and units — Part 1: General

ISO 80000-10, Quantities and units — Part 10: Atomic and nuclear physics

ISO/IEC Guide 98-3, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

ISO/IEC Guide 98-3:2008/Suppl.1, Evaluation of measurement data — Supplement 1 to the "Guide to the expression of uncertainty in measurement" — a Propagation of distributions using a Monte Carlo method, JCGM 101:2008

ISO/IEC Guide 98-3:2008/Suppl.2, Evaluation of measurement data — Supplement 2 to the "Guide to the expression of uncertainty in measurement" — Extension to any number of output quantities, JCGM 102:2011

ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

IEC/TR 62461, Radiation protection instrumentation — Determination of uncertainty in measurement, Ed. 2.0, IEC 23.1.2015

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 80000-1, ISO 80000-10, ISO/IEC Guide 98-3, ISO/IEC Guide 98-3:2008/Suppl.1, ISO/IEC Guide 98-3:2008/Suppl.2, ISO/IEC Guide 99, ISO 3534-1, ISO 11929-1, and ISO 11929-2 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform available at https://www.iso.org/obp
- IEC Electropedia available at <u>https://www.electropedia.org/</u>

4 Quantities and symbols

The quantities and symbols below are used throughout this document. Additional quantities and symbols are listed – if necessary – in the respective examples.

т	number of input quantities, also used for the mass of the test sample
n _M	number of Monte Carlo trials performed
X _i	input quantity $(i = 1,, m)$
Y	measurand, quantity of interest
G	model of evaluation connecting the input quantities with the measurand: $Y = G(X_1,, X_m)$
x _i	measured value of the input quantity X_i , estimate of the true value \tilde{x}_i of X_i
<i>x</i> _i	possible or assumed true values of the input quantity X_i
$u(x_i)$	standard uncertainty of the input quantity X_i associated with the estimate X_i
Δx_i	width of the region of the possible values of the input quantity X_i
$u_{\rm rel}(w)$	relative standard uncertainty of a quantity W associated with the estimate w
ỹ https://standards.i	possible or assumed true values of the measurand; if the physical effect of interest is not present, then $\tilde{y} = 0$ otherwise, $\tilde{y} > 0$ -4 cea-9154-32b6a6ec7714/iso-fdis-
у	determined value of the measurand <i>Y</i> , estimate of the measurand, primary measure- ment result of the measurand
У _j	values y from different measurements ($j = 0,1,2,$)
u(y)	standard uncertainty of the measurand associated with the primary measurement result \boldsymbol{y}
$\tilde{u}(\tilde{y})$	standard uncertainty of an estimator of the measurand Y as a function of an assumed true value \tilde{y} of the measurand
ŷ	best estimate of the measurand
$u(\hat{y})$	standard uncertainty of the measurand associated with the best estimate \hat{y}
<i>y</i> *	decision threshold of the measurand
<i>y</i> [#]	detection limit of the measurand
<i>y</i> _r	guideline value of the measurand
$y^{\triangleleft}, y^{\triangleright}$	lower and upper limit of the symmetric coverage interval, respectively, of the measurand
$y^{\triangleleft}, y^{\triangleright}$ $y^{<}, y^{>}$	lower and upper limit of the shortest coverage interval, respectively, of the measurand

$f(\tilde{y} y)$	posterior probability density function (PDF) for a true value \tilde{y} given the estimate y taking NOT into account the condition that the measurand Y is non-negative
$f\left(\tilde{y} \middle y, Y \ge 0\right)$	posterior probability density function (PDF) for a true value \tilde{y} given the estimate y taking into account the condition that the measurand Y is non-negative
$f(y \tilde{y}=0)$	predictive probability density function (PDF) to obtain a measured value y if a true value $\tilde{y} = 0$ of the measurand Y is assumed
$f(y \tilde{y} = y^{\#})$ Ga($\tilde{r}; n, 1/t$)	predictive probability density function (PDF) to obtain a measured value y if a true value $\tilde{y} = y^{\#}$ of the measurand Y equal to the detection limit $y^{\#}$ is assumed
Ga(r̃;n,1/t)	Gamma distribution as the probability density function (PDF) of the true value \tilde{r} of a count rate R given n counts obtained during a counting time t ; see ISO 11929-2:2019, Annex A, for details.
$N(\tilde{x};x,u(x))$	Normal or Gaussian distribution as the probability density function (PDF) of the true value \tilde{x} of a quantity X given an estimate x with its associated standard uncertainty $u(x)$
$R(\tilde{x}; x_L, x_U)$	Rectangular distribution as the probability density function (PDF) of the true value \tilde{x} of a quantity X given the lower and upper limits $x_{\rm L}$ and $x_{\rm U}$
$T(\tilde{x};a,b)$	Triangular distribution as the probability density function (PDF) of the true value \tilde{x} of a quantity X being the sum of two quantities, A and B being assigned rectangular probability distributions with the lower and upper limits a_L and b_L respectively a_U and b_L and with $a = a_L + b_L$ and $b = a_U + b_U$.
H(x)	Heaviside step function: $H(x) = \begin{cases} 0 & \text{for } \begin{cases} x < 0 \\ 1 & x \end{cases} \begin{cases} x \ge 0 \end{cases}$
<i>r</i> g, <i>r</i> 0 https://stan	estimate of the gross count rate and of the background count rate, respectively $_{ m S}$ -
r _n	estimate of the net count rate
n _i	number of counted pulses obtained from the measurement of the count rate R_i
n _g , n ₀	number of counted pulses of the gross measurement and of the background meas- urement, respectively
t _i	measurement duration of the measurement of the count rate R_i
$t_{ m g}$, t_0	duration of the gross and the background measurement, respectively
r _i	estimate of the count rate <i>R</i> _i
A	activity
а	estimate of the activity A
W	calibration factor
a _m	activity per unit mass
a _s	activity per unit surface
α, β	probability of a false positive and false negative decision, respectively
$1 - \gamma$	probability for the coverage interval of the measurand
q_p	quantile of a distribution for the probability <i>p</i>

$\Phi(x)$ distribution function of the standard normal distribution

 $\omega = \Phi[y/u(y)]$, value of the distribution function of the standard normal distribution at y/u(y)

5 Summary of this document

5.1 Procedures according to ISO 11929 (all parts)

ISO 11929-1 standardizes the evaluation of measurements of ionizing radiation for a wide range of models of evaluation and the calculation of characteristic limits (decision threshold, detection limit and limits of coverage intervals) on the basis of the ISO/IEC Guide 98-3. However, important exceptions exist for which the procedures do not provide reliable results and other procedures need to be applied, such as those described in ISO/IEC Guide 98-3:2008/Suppl.1. Such procedures are dealt with in ISO 11929-2. Both the aspects of the procedure and the tools to ascertain whether ISO 11929-1 or ISO 11929-2 is suitable or not for the specific application are described in ISO 11929-1.

It is a characteristic of measurements of ionizing radiation that they have to be performed in the presence of a radiation background, which has to be subtracted from a gross measurement quantity. However, the procedures described in this document likewise are applicable to any measurements where a background or blank contribution has to be subtracted from a gross quantity.

5.2 Survey on the examples

This document gives numerical examples of elementary applications of ISO 11929-1 and ISO 11929-2. The data in the tables are often given with more digits than are meaningful, so that the calculations can also be reconsidered and verified with higher accuracy, in particular for testing computer programs under development.

ISO/FDIS 11929-4

NOTE 1 The Monte Carlo calculations were performed in this guide with 1 000 000 trials. As a consequence, the results for the characteristic values remain uncertain in the third significant digit. In addition, the user has to be aware that the necessary number of trials depends significantly on the model of evaluation and on the PDFs assigned to the input quantities. In practical applications, a number of 10 000 trials is often sufficient.

A criterion whether ISO 11929-1 or ISO 11929-2 is to be preferred in practice is given in IEC/TR 62461. It recommends "the results of both methods should be given in order to display their difference. When the 95 % coverage intervals of the Monte Carlo method and of the analytical method do not deviate by more than 10 %, then the analytical one may be used for the uncertainty determination in similar cases, i.e. a similar model function and similar or smaller values of the uncertainty of the input quantities". See also ISO 11929-1:2019, 5.3.

The examples, the models, and the data are exemplary and not normative.

In ISO 11929-1, a quite general model is specified as follows:

$$y = (x_1 - x_2 \cdot x_3 - x_4) \cdot \frac{x_6 \cdot x_8 \cdots}{x_5 \cdot x_7 \cdots} = (x_1 - x_2 x_3 - x_4) \cdot w$$
(1)

with

$$w = \frac{x_6 \cdot x_8 \cdots}{x_5 \cdot x_7 \cdots}$$
(2)

where $x_1 = r_g$ is the gross count rate and $x_2 = r_0$ is the background count rate. The other input quantities, x_i , are calibration, correction or influence quantities, or conversion factors, for instance the emission or response probability. In particular, x_3 is a shielding factor and x_4 an additional background