Uncertainty, Detectability and Conformity in Measurements of Ionizing Radiation

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The problem of uncertainty as a general consequence of incomplete information and the approach to quantify uncertainty in metrology is addressed. Then, the statistical foundation of the concepts of uncertainty in measurements is discussed. The basics of the ISO Guide to the Expression of Uncertainty in Measurement as well as of characteristic limits according to ISO 11929 are described and, finally, the role of measurement uncertainties in the assessment of conformity to requirements is dealt with in detail.

KEY WORDS: Bayesian statistics, measurement uncertainties, decision threshold, detection limit, coverage interval, conformity.

I INTRODUCTION

Statistics plays an essential role when interpreting measurements of ionizing radiation for the purpose of radiological protection. It is needed for the quantification of measurement uncertainties, it provides the tools to decide whether or not the measurement result exceeds the background, it allows to assess whether or not a measurement procedure fulfils sensitivity requirements, and, last not least, to decide whether or not a result conforms to requirements, e.g. from regulations. Due to recent developments in metrology a number of international standards and guides exist by which all these aspects can be treated in a consistent and internationally accepted manner.

The Joint Committee for Guides in Metrology (http://www.bipm.org/en/committees/jc/jcgm/) has issued a number of guides which can be downloaded free of charge under http://www.bipm.org/en/publications/guides/. There is the International Vocabulary in Metrology, VIM for short, which defines the general terminology in order to have an unambiguous language for addressing metrological issues. The Guide to the Expression of Uncertainty in Measurement, GUM for short, and its Supplements 1, GUM S1 for short, and 2, GUM S2 for short, provide the basis for quantification of measurement uncertainties. Finally, the guide “Evaluation of measurement data — The role of measurement uncertainty in conformity assessment” gives guidance for conformity assessments. A methodology for assessing detectability is given in ISO 11929.

The methodology provided by these guides and ISO 11929 has been taken into account also in a number of ISO standards dealing with environmental radiation measurements; see e.g. CALMET7) and CALMET et al.8) for surveys.

This paper summarizes some basics of the underlying methodology and gives some guidance for the practical application. It extends a previous paper on “Measuring, Estimating, and Deciding under Uncertainty”9) with respect to the problem of conformity assessments based on an actual recommendation of the German Commission on Radiological Protection (SSK; www.ssk.de).

II THE STATISTICAL BASIS

There are two basic schools in statistics; that of Bayesian statistics and that of conventional or frequentistic statistics. The two schools are contradictory since the term probability does not have the same meaning, though many but not all results obtained by the two statistics are practically equal.

The conventional or frequentist view is that probability is the stochastic limit of relative frequencies. The Bayesian view is that probability is a measure of the degree of belief an individual has in an uncertain proposition. Due to this fundamental difference the two statistics must not be confused with each other.

Bayesians follow the principle that the mathematical theory of probability is applicable to the degree to which a person believes a proposition. The Bayes Theorem can be used as the basis for a rule for updating beliefs in the light of new information. Such updating is known as Bayesian inference. In his “Essay towards solving a problem in the doctrine of chances,” Thomas Bayes (* 1702, † 1761) invented the “Bayesian inference,” i.e. calculating the probability of the validity of a proposition on the basis of a prior estimate of its probability and new relevant evidence.10) Bayesian
inference is the natural way of human learning: incorporating new experience into the available set of prior assumptions. For a general introduction to Bayesian statistics see e.g. references.\textsuperscript{11–16}

Uncertainty is a general characteristic of human existence. It originates from ignorance. Uncertainties are important characteristics of human reasoning, decision making and action and, in the end, they are a consequence of limited and incomplete information. Humans always have to decide and to act under uncertainty, i.e. on the basis of incomplete information. In the case of ignorance one can only rely on probabilities. Uncertainty can be quantified by probabilities.

Probability theory and probability calculus provide the tools to establish and propagate probabilities. Just a few principles are sufficient for a given problem to be derived from the available information the desired probability density function (PDF). Fundamental is the Principle of Indifference, also called Principle of Insufficient Reason.\textsuperscript{17} Given \( n > 1 \) distinguishable, mutually exclusive and collectively exhaustive events, the Principle of Indifference states that without further information each event should be assigned a probability equal to \( 1/n \). The function is normalized:

\[
\int f_Y(y) \, dy = 1
\]

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\[
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\]

After a decade-long controversy about the value,\textsuperscript{18} any other available information, \( \mathcal{I} \), contains the true value of the measurand with a preselected coverage probability \( (1 – \gamma) \). With the PDF \( f_Y(y|\mathcal{I}) \), the best estimate, \( y \), of the true value, \( y \), of the measurand, \( Y \), is the expectation \( \bar{y} = \mathbb{E}(f_Y(y|\mathcal{I})) = \int y \cdot f_Y(y|\mathcal{I}) \, dy \) and the standard uncertainty, \( u(y) \), associated with the best estimate, \( \bar{y} \), is the square root of the variance \( u^2(\bar{y}) = \text{Var}(f_Y(y|\mathcal{I})) = \int (y – \bar{y})^2 \cdot f_Y(y|\mathcal{I}) \, dy \).

The PDF depends on the available information. The GUM – not so explicitly – and explicitly GUM \textsuperscript{19} make use of the Principle of Maximum Information Entropy (PME)\textsuperscript{20} in order to derive various PDFs depending on the available information. If only the measurement result, \( y \), and its associated standard uncertainty, \( u(y) \), are available as in the GUM, the resulting PDF is a normal (Gaussian) distribution, \( N(y, u(y)) \).

### 3.2 The general approach

The Bayesian theory of measurement uncertainties,\textsuperscript{20} provides a basis of the GUM approach, factorizes the searched PDF \( f_Y(y|\mathcal{I}) \)

\[
f_Y(y|\mathcal{I}) = C \cdot f_Y(y) \cdot f_I(y|\mathcal{I})
\]

(\( C \) being normalization constant) \textsuperscript{(1)}

and derives \( f_Y(y|\mathcal{I}) \) by the PME\textsuperscript{18}

\[
S = -\int f_Y(y) \cdot \ln(f_Y(y)) \, dy = \text{max.}
\]

It is assumed that the only prior information is that the measurand, \( Y \), is non-negative.

If only \( y \) and \( u(y) \) are known, they are the best estimate and the associated standard uncertainty of \( f_Y(y|\mathcal{I}) \). Thus, they give for the application of the PME the constraints, \( y = \mathbb{E}(f_Y(y|\mathcal{I})) \) and \( u^2(y) = \text{Var}(f_Y(y|\mathcal{I})) \). The PME leads with these constraints to the searched PDF \( f_Y(y|\mathcal{I}) \), by means of

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**Fig. 1** Schematic of a PDF, \( f_Y(y|\mathcal{I}) \), and of the limits of a coverage interval, \([y^a, y^b] \), in red.
variational methods and Lagrangian multipliers and yields the solution \( f(y|y) = \exp\left(-\frac{(y - \bar{y})^2}{2 \cdot \sigma^2}\right) \) and thus:

\[
    f_y(y|y) = C \cdot f_y(y|y) \cdot \exp\left(-\frac{(y - \bar{y})^2}{2 \cdot \sigma^2}\right).
\]  

(3)

The Gaussian distribution in equation 3 is neither an approximation nor a probability distribution from repeated or counting measurements.

If by turning the argument one assumes that only a true value, \( y \), and its associated standard uncertainty, \( u(y) \), are known one obtains the constraints \( y = E(f_y(y|y)) \) and \( u^2(y) = \text{Var}(f_y(y|y)) \) which yield with the PME, \( S = - \int f_y(y|y) \cdot \ln(f_y(y|y)) \, dy = \max \), the solution

\[
    f_y(y|y) = \exp\left(-\frac{(y - \bar{y})^2}{2 \cdot \sigma^2}\right).
\]  

(4)

Again, this is neither an approximation nor a probability distribution from repeated or counting measurements.

The GUM and ISO 11929 are minimalistic for the purpose of general applicability and therefore assume that only \( y \) and \( u(y) \) are known. This leads to the Gaussian PDF, \( f_y(y|y) \), in equation 3. The PDF describing the prior knowledge is also minimalistic, namely it is only assumed that the measurand is non-negative. The knowledge \( y \geq 0 \) is then taken into account by a Heaviside function, \( H(y) \), as PDF

\[
    f_y(y|y) = H(y) = \begin{cases} 
    1 & (y \geq 0) \\
    0 & (y < 0)
    \end{cases}
\]  

(5)

The user is free to take it into account more information, if it is available. Then, the user has to follow the GUM Suppl. 1 approach and to use the tools provided by the PME, the Product Rule, and the Bayes Theorem for establishing, updating and propagating distributions.

3.3 The GUM approach

The GUM distinguishes two ways by which measurement uncertainties can be derived: denoted as type A and type B. Type A uncertainties are derived from repeated or counting measurements. If there are repeated measurements \( (x_i; k = 1, ..., n) \) of a quantity, \( X \), with a standard deviation \( s = \frac{1}{\sqrt{n-1}} \sum \left(x_i - \bar{x}\right)^2 \), the standard uncertainty associated with the mean, \( \bar{x} = \frac{1}{n} \sum x_i \), is according to the GUM S1

\[
    \sigma(\bar{x}) = \frac{s}{\sqrt{n}}.
\]

In measurements where events are counted from a Poisson process the standard uncertainty of \( n \) counts is \( \sigma^2(n) = n \).

Type B uncertainties result from other sources. They result from earlier measured data or from experience or general knowledge about the behavior and characteristics of materials, phenomena and instruments. They are obtained from specifications of a manufacturer, from calibration or certification documents or from handbooks and compilations.

For short we call these uncertainties type A and type B uncertainties. But they are equivalent and the “types” distinguish only the ways the uncertainties are obtained. With respect to the applicable statistics it is important to note that frequentistic statistics cannot take into account type B uncertainties. Further, it only allows establishing the conditional probability \( f_y(y|y) \) but not \( f_y(y|y) \). Only by Bayes statistics type B uncertainties can be accounted for and the desired PDF \( f_y(y|y) \) can be derived.

It is essential that the first step of a measurement and its evaluation is the setting up of the model of evaluation, \( G \), which connects the measurand, \( Y \), as an output quantity with all the input quantities, \( X \):

\[
    Y = G(X; i = 1, ..., n)
\]  

(6)

The model of evaluation, \( G \), may be a simple function or a set of functions or mathematical relationships or also a computer program.

Given a model of evaluation, \( Y = G(X; i = 1, ..., n) \), an estimate \( y \) of the output quantity, \( Y \), is calculated by \( y = G(x; i = 1, ..., n) \). From the estimates, \( x_i \), of the input quantities, \( X_i \) and their associated standard uncertainties, \( u(x_i) \), the standard uncertainty, \( u(y) \), associated with the, \( y \), is calculated using the covariances, \( u(x_i, x_j) \)

\[
    u^2(y) = \sum_{i=1}^{n} \frac{\partial G}{\partial x_i} \frac{\partial G}{\partial x_j} \cdot u(x_i, x_j),
\]  

(7)

which in the case of independent input quantities, \( X_i \), yields the well-known formula

\[
    u^2(y) = \sum_{i=1}^{n} c_i^2 \cdot u^2(x_i) \quad \text{with} \quad c_i = \frac{\partial G}{\partial X_i}.
\]  

(8)

In spite of its widespread and increasing use, the applicability of the GUM is limited. It is an approximation. The standard uncertainties are the result of a Taylor expansion truncated after the linear term. In principle, it should only be applied to models \( G \) which are linear or which at least can be sufficiently linearized. If the GUM approximation is not sufficient for the model of evaluation the GUM offers a second order approximation which, however, is extremely unhandy and moreover has its own limitations. In this case, the approach of the GUM S1 helps to solve the problem in general. The GUM2 is actually a special case contained in the more general approach of the GUM S1 which widely extends the applicability of the GUM methodology.

IV DETECTABILITY AND ISO 11929

4.1 Characteristic limits

In nuclear radiation measurements, the radiation of a sample of radioactive material has to be measured in the presence of a natural background radiation. The same problem is faced in trace element analysis, where the concentration of an element, a compound or a radionuclide has to be determined in the presence of an analytical blank. As a consequence of the natural background radiation, of analytical blanks and of measurement uncertainties the detection capability of a measurement is downward limited.

Then there are three questions to be answered:

- Is there a contribution from the sample among the events counted?
- How large is the smallest true value of the measurand
which can be detected with high reliability.
– If a contribution of the sample has been observed, how large is the range of values of the measurand containing the true value with high probability?

The three questions are answered in ISO 119296 by the concept of the characteristic limits:
– The decision threshold decides the question whether there is a contribution from the sample among the counted events.
– The detection limit is the smallest true value of the measurand which can be detected with high reliability.
– The limits of the coverage interval define an interval which contains the true value of the measurand with a pre-selected probability.

Defining a decision threshold is a matter of decision theory21, because one has to decide whether or not there is a contribution of the sample in addition to the background or blank.

According to decision theory, decisions need a loss function. For a given set of information the optimal action to decide between two options $a_0$ and $a_1$ will be to accept option $a_0$ if (and only if) the expected posterior loss of accepting is smaller than the expected posterior loss of rejecting the option $a_0$ and accepting $a_1$. Also the consequences of loss or gain can only be quantified by probabilities. The critical probability for acceptance and rejection has to be chosen by humans weighing the importance of loss or gain. In ISO 119296 a second order loss function is used for defining the decision threshold. In metrology, only second-order loss functions, e.g. used to define uncertainty or in fits including an uncertainty treatment, can meet – at least in a linear model approximation in the data range of interest – the requirement of consistency.22, 23)

Both, the decision threshold and the detection limit, have to be calculated on the basis of the background or blank measurement alone which give the information about $f_Y(y|\bar{y}=0)$. For the decision threshold this is sufficient and no further information is needed. For the calculation of the detection limit some more information is required. For the calculation of $f_Y(y|\bar{y})$ the expected uncertainties, $\hat{u}(y)$, for assumed true values, $\bar{y}$, of the measurand, $Y$, have to be known. The required information regards the standard uncertainty as a function of the true value, $\bar{y}$, of the measurand, $Y$. $\hat{u}(\bar{y}=0)$ can be obtained from $f_Y(y|\bar{y}=0)$ resulting from a background or blank measurement. For another assumed true values, $\bar{y}$, it is possible to experimentally determine the value of this function, e.g. by measurements of reference materials. $\hat{u}(\bar{y})$ can also be approximated by interpolation using the information about $\hat{u}(\bar{y}=0)$ and a measurement result, $y$, and its associated standard uncertainty, $u(y)$. In many cases of counting radiation measurements $u(y)$ can be explicitly calculated (see below).

ISO 119296 provides a basis for the calculation of characteristic limits (decision threshold, detection limit, limits of a coverage interval) for measurements of ionizing radiation and beyond. It is based on the GUM methodology. A detailed description of its foundation and applications may be found elsewhere.9, 24, 25) The standard assumes that only the measurement result $y$ and its associated standard uncertainty $u(y)$ are available and that the measurand is non-negative. With this the respective PDFs, $f_Y(y|\bar{y}=0)$ and $f_Y(y|\bar{y})$, are Gaussians and formulas can be given for the decision threshold and the detection limit. A procedure how to proceed if the GUM S1 is applied can be found elsewhere26 and will be stipulated in an upcoming revision of ISO 11929.

### 4.2 Decisions to be made and the decision threshold

The decision threshold is defined by the basic decision criterion for the presence or absence of a contribution of the sample:

$$P(y > y' | \bar{y} = 0) \int_{y'}^{\infty} f_Y(y | \bar{y} = 0) \, dy = \alpha$$

In words this criterion means that the decision threshold, $y'$, is so defined that the probability, $\alpha$, to obtain a measurement result, $y$, in excess of the decision threshold, $y'$, given that the true value of the measurand, $\bar{y}$, is zero is equal to a preselected probability, $\alpha$.

If the GUM is used for the evaluation of uncertainties the decision threshold is given by:

$$y' = k_{1-\alpha} \cdot \hat{u}(0)$$

with $k_{1-\alpha}$ being the $(1 - \alpha)$-quantile of the standardized Gaussian distribution.

$\alpha$ is a preselected probability for the wrong decision to accept the existence of a contribution from the sample if in reality there is none. If a measured value, $y$, exceeds the decision threshold, $y'$, one decides that a contribution from the sample has been observed.

### 4.3 Characterizing a measurement procedure by the detection limit

The detection limit has to be set sufficiently high above the decision threshold to avoid an unduly high probability for the wrong decision that there is no contribution from the sample if in reality there is one. Given the criterion of the decision threshold, the detection limit is defined by:

$$P(y' < y' | y' = y'^*) = \int_{y'^*}^{\infty} f_Y(y | y'^*) \, dy = \beta$$

In words the criterion for the detection limit means the detection limit, $y'^*$, is so defined that the probability, $\beta$, to obtain a measurement result, $y'$, below the decision threshold, $y'^*$, given that the true value of the measurand, $\bar{y}$, is equal to the detection limit, $y'^*$, is equal to a preselected probability, $\beta$. $\beta$ is thus the probability of the wrong decision to reject a contribution from the sample if in reality there is one.

If the GUM is used for the evaluation of uncertainties the detection limit is given by the implicit equation:

$$y'^* = y'^* + k_{1-\beta} \cdot \hat{u}(y'^*)$$

with $k_{1-\beta}$ being the $(1 - \beta)$-quantile of the standardized Gaussian distribution.

Figure 2 depicts the PDFs involved in the definitions of the decision threshold and detection limit as well as the probabilities for wrong decisions.
4.4 Coverage intervals and the best estimate

The term coverage interval which occasionally also is called credible interval has to be distinguished from the term confidence interval used in frequentistic statistics since the meanings of the two terms are different. The coverage interval contains the true value, \( \hat{y} \), of the measurand, \( Y \), with a pre-selected probability, \( (1 - \gamma) \). The confidence interval is an interval in which the result of a new experiment is expected with the probability, \( (1 - \gamma) \), given a true value, \( \hat{y} \), of the measurand, \( Y \). These two definitions make quite some difference.

Coverage intervals are frequently used in metrology. The limits of a coverage interval, \( y^* \), \( y^\# \), define an interval, \( [y^*, y^\#] \), which contains the true value, \( \hat{y} \), of the measurand, \( Y \), with a pre-selected probability, \( (1 - \gamma) \).

\[
P(y^* < \hat{y} < y^\# | Y, \Xi) = \int_{y^*}^{y^\#} f_Y(y | \hat{y}, \Xi) \, dy = 1 - \gamma \quad (13)
\]

Note that the definition of a coverage interval is not unique and that different types of coverage interval can be defined for the same probability, \( (1 - \gamma) \). For example, the shortest coverage interval, \( [y^*, y^\#] \), can be used alternatively

\[
P(y^* < \hat{y} < y^\# | Y) \leq \int_{y^*}^{y^\#} f_Y(y | \hat{y}, \Xi) \, dy = 1 - \gamma \text{ with } y^\# - y^* = \min. \quad (14)
\]

In the following, only the probabilistically symmetric coverage interval will be used. In ISO 11929 (ISO 2010) it is calculated from a Gaussian truncated by the Heaviside step function, \( H(\cdot) \).

\[
f_Y(y | \hat{y}, \Xi) = C \cdot H(\hat{y}) \cdot \exp \left( -\frac{(y - \hat{y})^2}{2 \cdot u^2(\hat{y})} \right) \quad (15)
\]

The probabilistically symmetric coverage interval is calculated with the additional conditions

\[
P(y < y^* | Y, \Xi) = \int_{-\infty}^{y^*} f_Y(y | \hat{y}, \Xi) \, dy = \gamma / 2.
\]

\[
P(y > y^\# | Y, \Xi) = \int_{y^\#}^{\infty} f_Y(y | \hat{y}, \Xi) \, dy = \gamma / 2
\]

If the GUM is used for the evaluation of the uncertainties the limits of the probabilistically symmetric coverage interval are calculated with the auxiliary quantity,

\[
\omega = \frac{1}{2\pi} \int_{-\infty}^{\infty} \exp \left( -\frac{y^2}{2} \right) \, dy = \Phi(y/u(y)),
\]

and

\[
y^* = y - k_p \cdot u(y) \text{ with } p = \omega \cdot (1 - \gamma / 2) \quad (17)
\]

with \( k_p, k_q \) being the quantiles of the standardized normal distribution for the probabilities, \( p \) and \( q \). Values of the quantiles are tabulated, e.g. in ISO 11929.\(^6\)

If the relative uncertainty, \( u_r(y) = u(y)/y \), associated with \( y \) does not exceed 25\%, the limits of the probabilistically symmetric coverage interval are given by

\[
y^* \leq y + k_{1 - \gamma / 2} \cdot u(y) \quad (18)
\]

Figure 3 gives an example of a probabilistically symmetric coverage interval where the relative uncertainty, \( u_r(y) \), exceeds 25\%. In such a case the limits of the coverage interval, \( y^* \) and \( y^\# \), do not lie symmetrically relative to the measurement result, \( y \), as it is the case in equation 18.

If the measurement result, \( y \), exceeds the decision threshold, \( y^* \), also the best estimate, \( \hat{y} \), and its associated uncertainty, \( u(\hat{y}) \), can be calculated as the expectation respectively the square root of the variance of the PDF \( f_Y(\hat{y} | y, \Xi) \). In contrast to the primary measurement result, \( y \), and its associated uncertainty, \( u(y) \), the best estimate, \( \hat{y} \), and its associated uncertainty, \( u(\hat{y}) \),
take into account the information, $\mathcal{X}$, that the measurand is non-negative.

If the GUM is used for the evaluation of the uncertainties, the best estimate and its associated uncertainty are calculated with the auxiliary quantity, $y_0 = \Phi(y/u(y))$, by

$$
\hat{y} = y + \frac{u(y) \exp\left|-\frac{1}{2} \left\{2u(y)\right\}^2\right|}{\alpha/\sqrt{2\pi}}
$$

and $u(\hat{y}) = \sqrt{u^2(\hat{y}) - (\hat{y} - y)y'}$.

If the relative uncertainty, $u_\text{m}(y) = u(y)/y$, associated with $y$ does not exceed 25%, the approximations $\hat{y} = y$; $u(\hat{y}) = u(y)$ are sufficient and a separate calculation of the best estimate, $\hat{y}$, and its associated uncertainty, $u(\hat{y})$, is not necessary.

### 4.5 A simple model of evaluation

In counting measurements of ionizing radiation the situation is somewhat special. It will be explained here for a simple, but frequently model of evaluation. See ISO 11929$^{60}$ for more and other models of evaluation.

$$
y = (r_g - r_b) \cdot w = r_g \cdot w = (n_g/t_g - n_b/t_b) \cdot w.
$$

The model of equation 20 describes counting measurements in which the measurand is a net quantity resulting from the difference of the count rates, $(r_g - r_b)$, of a gross and a background measurement with measurement times of $t_g$ and $t_b$, respectively. The net counting rate is multiplied by a calibration factor $w$ which was independently determined together with its associated standard uncertainty, $u(w)$, beforehand.

Knowing that the counts $n_g$ and $n_b$ obtained from the gross and background measurements are obtained from a Poisson process allows quantifying the uncertainty as $u^2(n_g) = n_g/t_g$ and $u^2(n_b) = r_b/t_b$, respectively. Thus, one obtains the standard uncertainty

$$
\hat{u}(\hat{y}) = \sqrt{\frac{w^2}{(r_g/t_g + r_b/t_b)} + \hat{y}^2 u^2_m(w)}
$$

with $u^2_m(w) = \sum r_i^2/\hat{w}_i^2$ being the relative uncertainty of the calibration factor, $w$.

In order to obtain $\hat{y}(\hat{y})$ one assumes a true value, $\hat{y}$, and calculates from equation 20 the then expected gross counts

$$
n_g = (y/w + r_b)/t_g \text{ with } u^2(n_g) = n_g.
$$

Inserting $n_g$ from equation 22 into equation 21 yields

$$
\hat{u}(\hat{y}) = w \cdot \left(\frac{y}{w + r_b}/t_g + r_b/t_b\right) + \hat{y}^2 u^2_m(w).
$$

with this one obtains the decision threshold

$$
y' = k_{1 - a} \cdot \hat{u}(0) = k_{1 - a} \cdot w \cdot \sqrt{(n_g/t_g)/t_g + n_b/t_b}
$$

and the detection limit

$$
y'' = y' + k_{1 - a} \cdot \hat{u}(y') = y' + k_{1 - a} \cdot \sqrt{w^2 \cdot \left((y'/w + n_g/t_g)/t_g + n_b/t_b\right) + \hat{y}^2 u^2_m(w)}
$$

For $\alpha = \beta$ this implicit equation has the solution

$$
y'' = \left[2 \cdot y' + (k_{1 - a} \cdot w) / t_g \right] / \left[1 - k_{1 - a}^2 \cdot u^2_m(w)\right]
$$

Equation 25 only has a solution if $1 - k_{1 - a}^2 \cdot u^2_m(w) > 0$. This has been criticized, but the explanation is simple. For large relative uncertainties the GUM approximations do not work and one has to apply the methods stipulated in GUM S11. This will be considered during an ongoing revision of ISO 11929.

For the calculation of the coverage interval and the best estimate and its associated standard uncertainty equations 16–19 in Clause 4.4 hold and shall not be repeated here.

### V Conformity with requirements

#### 5.1 Tolerance intervals and acceptance intervals

The JCGM also made recommendations for assessments conformity with requirements taking into account measurement uncertainties (JCGM 2012b). The German Commission on Radiological Protection (SSK) has used the JCGM 106 (JCGM 2012b) recommendation to give explicit advice how to assess conformity with requirements in ionizing radiation measurements for the purpose of radiological protection.$^{27}$

Requirements for technical testing result from safety regulations according to the state of science and technology and from legal limits. Such requirements can be can be defined for various parameters (measurands) in form of single- or double-sided limited tolerance intervals, $[T_L, T_U]$ (Fig. 4).

For ease of practical application also a acceptance interval, $[A_L, A_U]$, may be defined in a way that one decides in favor of conformity with the requirement set by $[T_L, T_U]$ independent of the measurement uncertainty if the measured value lies within the acceptance interval, $[A_L, A_U]$. Consequently, the acceptance interval lies inside the tolerance interval and is smaller than the former and will be located asymmetric relative to the tolerance interval (Fig. 4). Setting of the limits of an acceptance interval needs the knowledge of the standard uncertainty associated

[Fig. 4 Double-sided tolerance interval, $[T_L, T_U]$, for the true value of the measurand $y$ and acceptance interval, $[A_L, A_U]$, for measurement results, $y$.]
with a measurement result as a function of the measurement result; see Clause 5.5. Fig. 4 gives a graphical representation of the concepts of the tolerance and acceptance intervals taking a two-sided tolerance interval as an example.

A proof of conformity is then based on measurements, the results of which have uncertainties associated with them and which have to be taken into account in the assessment. The uncertainties referred to are understood as standard uncertainties, \( u(y) \), according to the GUMS\(^2\) or GUM S1\(^3\) associated with the measurement result, \( y \). A decision in favor of conformity with the requirement is made if the true value of the measurand lies within the tolerance interval with a preselected probability. With the concept of measurement uncertainties according to the GUM and GUM S1 decision rules can be derived by means of the limits of the probabilistically symmetric coverage interval of the PDF \( f_y(y) \).

A requirement is fulfilled, i.e. the measurement result conforms to the requirement,

1. If – in case of a one-sided downward tolerance interval, \( [T_L, \infty] \), the lower limit \( y' \) of the probabilistically symmetric coverage interval, \( [y', y'] \), for the coverage probability 90% is larger than the limit of the tolerance interval, \( T_L \);
2. if – in case of a one-sided upward limited tolerance interval, \( [0, T_U] \), the upper limit \( y' \) of the probabilistically symmetric coverage interval, \( [y', y'] \), for the coverage probability 90% is smaller than the limit of the tolerance interval, \( T_U \);
3. if – in case of a two-sided tolerance interval, \( [T_L, T_U] \), the probabilistically symmetric coverage interval, \( [y', y'] \), for the coverage probability 95% lies within the tolerance interval, \( [T_L, T_U] \).

If the GUM is used for the quantification of measurement uncertainties, the calculation of the limits of the coverage interval can be calculated by means of the standard measurement uncertainties and quantiles of the standardized normal distribution as stipulated in ISO 11929 (ISO 2010) and described in Clause 4.4. If the GUM S1 is applied, numerical procedures are needed for the calculation of the limits of the coverage interval.\(^{28}\) The decision rules 1–3 given above are substantiated in detail in Clauses 5.2 and 5.3.

5.2 The probability of wrong decisions in favor of conformity

If requirements are stipulated by definition of a single- or two-sided tolerance interval, it is demanded that the true value of the measurand lies in the tolerance interval. Since the true value of the measurand is unknown and unknowable only probability statements can be made about it taking into account the measurement uncertainty.

Since only probability statements can be made about the true value of a measurand, there is the possibility to wrongly decide on the conformity with requirements. While the scientific judgement about a measurement objective can only give boundary conditions about an acceptable or tolerable probability for a wrong decision, the setting of this probability can only be performed by the regulator. It is the result of societal agreement.

The German Commission on Radiological Protection (SSK), which is consulting the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, recommended setting the probability for a correct decision in favor of conformity with requirements to 95%. Consequently, the probability for a wrong decision in favor of conformity with a requirement is 5%. The latter value of 5% is frequently cited in international standards. Given the limited possibility to calculate reliably very small percentiles of an estimated PDF, the setting of 5% for a wrong decision appears to be meaningful and justified.

5.3 Conformity with one-sided tolerance intervals

If the requirement is specified by a one-sided upward limited tolerance interval \( [0, T_U] \) with an upper limit, \( T_U \), below which the true value of the measurand shall lie with a high probability, one shall decide in favor of conformity if the upper limit of the probabilistically symmetric coverage interval for the coverage probability of 90% is smaller than the limit \( T_U \):

\[
P(y > T_U | y, u(y)) < 0.05. \tag{27}
\]

If the GUM (JCGM 2008a) is used for quantifying the measurement uncertainty and if the relative measurement uncertainty is smaller than 25% the condition for conformity reads:

\[
y + 1.65 \cdot u(y) \leq T_U. \tag{28}
\]

For larger relative measurement uncertainties the limits of the coverage interval shall be calculated according to ISO 11929\(^{29}\) as described in equation 17 because the coverage interval is no longer symmetric around \( y \).

If the requirement is specified by a one-sided downward limited tolerance interval, \( [T_L, \infty] \), with a lower limit, \( T_L \), above which the true value of the measurand shall lie with a high probability, one shall decide in favor of conformity if the lower limit of the probabilistically symmetric coverage interval for the coverage probability of 90% is smaller than the limit \( T_L \):

\[
P(y < T_L | y, u(y)) < 0.05. \tag{29}
\]

If the GUM\(^2\) is used for quantifying the measurement uncertainty and if the relative measurement uncertainty is smaller than 25% the condition for conformity reads:

\[
y - 1.65 \cdot u(y) \geq T_L. \tag{30}
\]

For larger relative measurement uncertainties the limits of the coverage interval shall be calculated according to ISO 11929 as described in equation 17.

As an explanation of the rules given by equations 27–30, Fig. 5 shows the extreme cases by which it is ensured that the coverage probability of 90% fixes the probability of a correct decision in favor of conformity with the requirement at 95% and limits that for a wrong decision at 5%.

The use of a coverage probability of only 90% in the case of a probabilistically symmetric coverage interval results from the
fact that just one side of the distribution has the chance that the true value of the measurand lies above respectively below the limits of the tolerance interval, \( T_L \) respectively \( T_U \). The other side of the distribution covers also outside of the coverage interval true values which conform to the requirement.

If requirements are defined in the regulations via a tolerance interval no further requirements regarding permissible magnitude of the measurement uncertainties is necessary.

5.4 Conformity with two-sided tolerance intervals

If the requirement is specified by a two-sided tolerance interval, \([T_L, T_U]\), in which the true value of the measurand shall lie with a high probability, one shall decide in favor of conformity if the probabilistically symmetric coverage interval for the coverage probability of 95% lies in the tolerance interval:

\[
P(\bar{y} < T_L \lor \bar{y} > T_U | y, u(y)) \leq 0.05. \tag{31}
\]

If the GUM\(^{27}\) is used for quantifying the measurement uncertainty and if the relative measurement uncertainty is smaller than 25% the condition for conformity reads:

\[
y - 1.96 \cdot u(y) \geq T_L \quad \text{and} \quad y + 1.96 \cdot u(y) \leq T_U. \tag{32}
\]

For larger relative measurement uncertainties the limits

---

![Fig. 5](image1.png)

**Fig. 5** Extreme cases of one-sided tolerance intervals. For one-sided tolerance intervals a coverage probability of 90% for the probabilistically symmetric coverage interval is sufficient in order to limit the probability of wrong decisions in favor of conformity with a requirement to 5%.\(^{27}\)

![Fig. 6](image2.png)

**Fig. 6** Extreme case of a two-sided tolerance intervals which makes it obligatory to apply a coverage probability of 95%. In this extreme case, the uncertainty is so large that the probabilistically symmetric coverage interval for the coverage probability of 95% completely fills the coverage interval.\(^{27}\)

![Fig. 7](image3.png)

**Fig. 7** Assessment of conformity to a requirement for a one-sided upwards limited tolerance interval (A), for a one-sided downward limited tolerance interval (B), for a two-sided limited tolerance interval (C). The limits of the tolerance intervals are red lines, the measurement results yellow symbols and the coverage intervals horizontal black lines.
of the coverage interval shall be calculated according to ISO 11929 as described in equation 17.

The setting of a coverage probability of 95% is conservative and limits for any measurement relative uncertainty the probability of a wrong decision in favor of conformity with the requirement to 5%. This is exemplified for a limiting case in Fig. 6, which shows the case of maximal possible standard uncertainty and the therefrom resulting demand for a coverage probability of 95%. A measurement procedure with a larger measurement uncertainty is not suitable to proof the conformity with the requirement.

The rules stated in Clauses 5.1, 5.3 and 5.4 are depicted in Fig. 7.

5.5 Acceptance intervals

The specification of a acceptance interval for a one-sided or two-sided tolerance interval requires the knowledge of the measurement uncertainties. The acceptance interval is then given by the implicit equation:

For a one-sided downward limited tolerance interval, \([T_L, +\infty]\), only the lower limit of the acceptance interval is needed. The acceptance interval, \([A_L, +\infty]\), is then given by the implicit equations:

\[
P(y < T_L | y = A_L, u(y = A_L)) = 0.05.
\] (33)

If the GUM is used for the quantifying the measurement uncertainty and if the relative measurement uncertainty is smaller than 25% the condition for the lower limit of the acceptance interval reads (see Fig. 8):

\[
A_L = T_L + 1.65 \cdot u(y = A_L).
\] (34)

For a one-sided upwards limited tolerance interval, \([0, T_U]\), only the upper limit, \(A_U\), of the acceptance interval is needed. The acceptance interval, \([0, A_U]\), is then given by the implicit equations:
If the GUM is used for the quantifying the measurement uncertainty and if the relative measurement uncertainty is smaller than 25% the condition reads (see Fig. 8):

$$A_u = T_{u} - 1.65 \cdot u(y = A_u).$$

For larger relative measurement uncertainties the limits of the coverage interval shall be calculated according to ISO 11929.

For a two-sided tolerance interval, $[T_{L}, T_{U}]$, both the lower and the upper limit of the acceptance interval are needed. The acceptance interval, $[A_{L}, A_{U}]$, is then given by the implicit equations:

$$P(y < T_{L}|y = A_u, u(y = A_u)) = 0.025$$

and

$$P(y > T_{U}|y = A_u, u(y = A_u)) = 0.025.$$ (37)

If the GUM is used for the quantifying the measurement uncertainty and if the relative measurement uncertainty is smaller than 25% the condition reads (Fig. 9):

$$A_l = T_{l} + 1.66 \cdot u(y = A_l)$$

and

$$A_u = T_{u} - 1.66 \cdot u(y = A_u).$$ (38)

For larger relative measurement uncertainties the limits of the coverage interval shall be calculated according to ISO 11929.

VI  A NUMERICAL EXAMPLE: MEASUREMENT OF Cs-137 IN A FOODSTUFF

6.1 Definition of the task and presetting

The gamma-spectrometric measurement of Cs-137 in a foodstuff is exemplarily used to demonstrate the entire procedure. Cs-137 is measured via its $661,64 \text{ keV}$ gamma-line.

$$A_{\text{guide}} = 2 \text{ Bq/kg}$$

is assumed in this example. By comparison of the guideline value with the detection limit it shall be decided whether or not the measurement procedure is suited for the measurement purpose.

For foodstuff a legal limit of 100 Bq/kg is assumed in this example. To prove conformity with this requirement, the true value of the specific activity has to lie with a probability of 95% in the single-sided upward limited tolerance interval $[0, T_{u}] = [0, 100 \text{ Bq/kg}]$.

The preselected parameters as well as some parameters calculated in the course of the evaluation are given in Table 1. Note that throughout this example numbers are given with more digits that necessary and meaningful in order to allow easier recalculation. In an official report the results should be rounded appropriately; i.e. according to rules set beforehand by the customer. Universal rules do not exist.

### 6.2 Calibration factor

The measuring system was calibrated by an independent measurement beforehand. The intensity, $I = 0.850$, of the gamma-line was taken from the literature (29) and has a relative standard uncertainty of $u_{rel}(I) = 0.00235$.

The detector efficiency was determined with a calibration source with a certified activity and a relative standard uncertainty of 5%. The measurement yielded $\varepsilon = 0.0109 \text{ s}^{-1}$ Bq and a relative standard uncertainty $u_{rel}(\varepsilon) = 0.0602$.

The mass of the sample $m = 1.08 \text{ kg}$ was determined by a balance which had according to specifications a relative standard uncertainty $u_{rel}(m) = 0.00463$.

With these data, equation 40 yields a calibration factor $w = 99.938 \text{ s Bq kg}^{-1}$. The relative standard uncertainty $u_{rel}(w)$ is calculated by

### Table 1  Presetting and parameters.

| Preselected parameters | Unit   | Calculated parameters |
|-----------------------|--------|-----------------------|
| $\alpha$              | 0.00135| $k_{\alpha \cdot}$   |
| $\beta$               | 0.05   | $k_{\beta \cdot}$    |
| $\gamma$              | 0.10   | $k_{\gamma}$         |
| $A_{\alpha}$          | 1 Bq kg$^{-1}$ | $k_{\alpha}$         |
| $T_{u}$               | 100 Bq kg$^{-1}$ | $k_{\varepsilon}$    |
\[ u_{\text{eval}}(w) = \sqrt{u^2_{u_a}(m) + u^2_{u_c} + u^2_{\text{eval}}(p)} = 0.0602. \]  

### 6.3 Evaluation of the measurement and characteristic limits

The evaluation of the gamma-spectrum measured for a measuring time, \( t_m \), yields the gross counts, \( n_g \), in the peak and the background counts, \( n_b \), under the peak. Since there are various ways to evaluate a gamma-spectrum these are not given here in detail and it is only assumed that \( n_g \) and \( n_b \) were obtained. Both numbers of counts are obtained from a Poisson value of the measurand, \( U_{HVXOWRIWKHVSHFL¿FDFWLYLW\RIWKHVDPSOH} \) and its associated standard uncertainty.

Table 2 summarizes all input data necessary for the evaluation of the measurement. Together with the presetting count rate, \( \bar{n}_0 \), and the background count rate, \( n_b \), \( r_0 = n_b / t_m \), \( r_g = n_g / t_m \), as \( u^2(r_g) = n_g / t_m \) and \( u^2(r_0) = n_b / t_m \), respectively.

Table 2 | Input data and evaluation of the measurement |
|---|---|---|---|---|---|
| Quantity | Symbol | \( x_i \) | \( u(x_i) \) | Unit | Type | \( u_{\text{eval}}(x_i) \) |
| Number of counts in the gross peak | \( n_g \) | 58621 | 242,1 | l | A | 0,06413 |
| Number of counts in the background | \( n_b \) | 1566 | 39,57 | l | A | 0,02527 |
| Gross count rate | \( r_g \) | 0,9455 | 0,003905 | s \(^{-1} \) | A | 0,03106 |
| Background count rate | \( r_b \) | 0,0253 | 0,000638 | s \(^{-1} \) | A | 0,08006 |
| Mass of the sample | \( m_s \) | 1,08 | 0,005 | kg | B | 0,0463 |
| Intensity of the gamma–line | \( I_{\gamma} \) | 0,850 | 0,002 | l | B | 0,00235 |
| Detector efficiency | \( \varepsilon \) | 0,019 | 0,000654 | s \(^{-1} \) Bq \(^{-1} \) | B | 0,0600 |
| Calibration factor | \( w \) | 99,938 | 6,019 | s Bq kg \(^{-1} \) | B | 0,0602 |

### Table 3 Results and characteristic limits.

| Quantity | Symbol | \( x_i \) | \( u(x_i) \) | Unit | Type | \( u_{\text{eval}}(x_i) \) |
|---|---|---|---|---|---|---|
| Specific activity of the sample | \( a_s \) | 91,97 | 5,55 | Bq kg \(^{-1} \) | A | 0,062 |
| Decision threshold | \( a_d^* \) | 0,2706 | – | Bq kg \(^{-1} \) | – |
| Detection limit | \( a_d^* \) | 1,412 | – | Bq kg \(^{-1} \) | – |
| Lower limit of the 90% probabilistically symmetric coverage interval | \( a_s^\text{l} \) | 82,83 | – | Bq kg \(^{-1} \) | – |
| Upper limit of the 90% probabilistically symmetric coverage interval | \( a_s^\text{u} \) | 101,1 | – | Bq kg \(^{-1} \) | – |

The standard uncertainty as a function of an assumed true value of the measurand, \( u(\bar{a}) \), is obtained from equation 23. With this one obtains the decision threshold

\[ a^* = k_{1-\alpha} \cdot u(\bar{a}) = k_{1-\alpha} \cdot w \cdot \sqrt{2 \cdot \frac{r_g}{t_m}} = 0.2706 \text{ Bq/kg} \]  

and the detection limit as the solution of the implicit equation

\[ a^* = a_{\text{d}, \alpha} \cdot u(\bar{a}) \]

Since the measurement result, \( a_s \), exceeds the decision threshold, \( a^* \), the limits of the coverage interval are calculated. With a relative standard uncertainty of the measurement result below 25%, the limits of the probabilistically symmetric coverage interval for a coverage probability of 90% are calculated by:

\[ a_s^\text{u} = a_s - k^* \cdot u(a_s) = 88,83 \text{ Bq/kg} \]  

and

\[ a_s^\text{l} = a_s + k^* \cdot u(a_s) = 101,1 \text{ Bq/kg} \]  

The quantities are \( k^* = 1.645 \), \( k^* = 1.645 \), with the probabilities \( p = \kappa \cdot (1 - \gamma / 2) = 0.950 \) and \( q = 1 - \kappa \cdot \gamma / 2 = 0.950 \) and a value of the standardized normal distribution \( \kappa = \Phi (\kappa/\sqrt{w}) = 1.000 \).

Since the relative uncertainty of the measurement result is smaller than 25% the calculation of the best estimate and its associated standard uncertainty can be omitted.

Since the upper limit, \( a_s^{\text{u}} \), of the probabilistically symmetric coverage interval for a coverage probability of 90% exceeds the upper limit, \( T_{\text{UL}} \), of the tolerance interval the measurement result does not conform with the requirements.
VII CONCLUSIONS

With the JCGM series of guides in metrology we have an internationally accepted methodology to deal with uncertainty in measurements. With a Bayesian theory of measurement uncertainty a sound statistical foundation of the GUM standard series exists which has the splendor to reveal the normal methodology of human learning and improving of knowledge. The standard ISO 11929 extends the methodology of the GUM to decision making under uncertainty. Characteristic limits according to ISO 11929 can be calculated for practically every measurement problem. However, as metrology and the GUM are further developing, also ISO 11929 will have to be revised in the future to keep track with the development of metrology. The methodology also is applicable to decide about conformity with requirements. A recent recommendation of the German Commission on Radiological Protection gives explicit guidance for conformity assessments well in line with JCGM guides.

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LIST OF SYMBOLS USED

\begin{align*}
G & \quad \text{model of evaluation; model function} \\
Y & \quad \text{non-negative measurand which quantifies the physical effect of interest; also used as the symbol for a random variable serving as an estimator of the measurand;} \\
\hat{y} & \quad \text{possible or assumed true values of the measurand; if the physical effect of interest is not present, then } \hat{y} = 0; \text{ otherwise, } \hat{y} > 0; \\
y & \quad \text{determined value of the estimator } Y, \text{ estimate of the measurand, primary measurement result of the measurand; } \\
u(y) & \quad \text{standard uncertainty of the measurand associated with the primary measurement result } y \\
\sigma(y) & \quad \text{standard uncertainty of the estimator } Y \text{ as a function of an assumed true value, } \hat{y}, \text{ of the measurand} \\
\hat{y} & \quad \text{best estimate of the measurand} \\
u(\hat{y}) & \quad \text{standard uncertainty of the measurand associated with the best estimate } \hat{y} \\
n & \quad \text{number of input quantities} \\
\chi_i & \quad \text{input quantities; } (i = 1, \ldots, m) \\
\chi_i^* & \quad \text{possible true quantity values of the input quantity } \chi_i \\
x_i & \quad \text{estimate of the input quantity } \chi_i \\
u(x_i) & \quad \text{standard uncertainty of the input quantity } \chi_i \text{ associated with the estimate } x_i \\
u_{st}(x_i) & \quad \text{relative standard uncertainty of the input quantity } \chi_i \text{ associated with the estimate } x_i \\
w & \quad \text{estimate of the calibration factor} \\
u_{st}(w) & \quad \text{relative standard uncertainty associated with the estimate } w \\
y^* & \quad \text{decision threshold of the measurand} \\
y^* & \quad \text{detection limit of the measurand} \\
f_Y(y|\Xi) & \quad \text{conditional probability density function (PDF) for the true value } y, \text{ given a measurement result } y \text{ of the measurand } Y \text{ and any other available information } \Xi \\
f_Y(y|y) & \quad \text{conditional probability density function of the possible true values, } y, \text{ of the measurand, } Y, \text{ given the measured estimate, } y \\
f_Y(y|\hat{y}) & \quad \text{conditional probability density function of estimates, } y, \text{ given an assumed true value, } \hat{y}, \text{ of the measurand, } Y \\
f_Y(y|\Xi) & \quad \text{model prior; it represents all the information } \Xi \text{ about the measurand available before the experiment is performed} \\
E(f_Y(x)) & \quad \text{expectation of } f_Y(x) \\
\text{Var}(f_Y(x)) & \quad \text{variance of } f_Y(x) \\
N(x, u(x)) & \quad \text{Normal or Gaussian distribution with the parameters } x \text{ and } u(x) \\
H(y) & \quad \text{Heaviside step function} \\
T_L, T_U & \quad \text{lower, respectively, upper limit of the tolerance interval} \\
A_L, A_U & \quad \text{lower, respectively, upper limit of the acceptance interval} \\
R_n & \quad \text{count rate of the net effect (net count rate)} \\
R_B & \quad \text{count rate of the gross effect (gross count rate)} \\
R_s & \quad \text{count rate of the background effect (background count rate)} \\
r_n, r_s, r_B & \quad \text{estimate of the net count rate, the gross count rate and of the background count rate, respectively} \\
n_y, n_B & \quad \text{number of counted pulses of the gross effect and of the background effect, respectively} \\
t_n, t_s, t_B & \quad \text{measurement duration of the measurement of the gross effect and of the background effect, respectively} \\
t_m & \quad \text{duration of a measurement (measuring time)} \\
a & \quad \text{activity per unit mass as a measurand} \\
a_s & \quad \text{guideline value of the measurand } a \\
m & \quad \text{mass of the sample} \\
I_\gamma & \quad \text{intensity of a gamma-line} \\
\varepsilon & \quad \text{detecter efficiency} \\
K_p, K_q & \quad \text{quantiles of the standardized normal distribution for the probabilities } p \text{ and } q \text{ e.g. } p = 1 - \alpha, \alpha = 1 - 0.5 \gamma \\
\alpha, \beta & \quad \text{probability of a false positive and false negative decision, respectively} \\
1 - \gamma & \quad \text{probability for the coverage interval of the measurand} \\
\end{align*}

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