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CITAC

Co-Operation on International Traceability in Analytical Chemistry

EURACHEM / CITAC Guide

Use of uncertainty information in compliance assessment

First Edition 2007

Eurachem CITAC Co-Operation on International Traceability in Analytical Chemistry

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Use of uncertainty information in compliance assessment

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CONTENTS

Use of uncertainty information in compliance assessment

1. Introduction

In order to utilise a result to decide whether it indicates compliance or non-compliance with a specification, it is necessary to take into account the measurement uncertainty. Figure 1 shows typical scenarios arising when measurement results, for example on the concentration of analyte, are used to assess compliance with an upper specification limit. The vertical lines show the expanded uncertainty $\pm U$ on each result and the associated curve indicates the inferred probability density function for the value of the measurand, showing that there is a larger probability of the value of the measurand lying near the centre of the expanded uncertainty interval than near the ends. Cases i) and iv) are reasonably clear; the measurement results and their uncertainties provide good evidence that the value of the measurand is well above or well below the limit, respectively. In case (ii), however, there is a high probability that the value of the measurand is above the limit, but the limit is nonetheless within the expanded uncertainty interval. Depending on the circumstances, and particularly on the risks associated with making a wrong decision, the probability of an incorrect decision may be or may not be sufficiently small to justify a decision of non-compliance. Similarly, in case (iii) the probability that the value of the measurand is below the limit may or may not be sufficient to take the result to justify compliance. Without further information, which has to be based on the risks associated with making a wrong decision, it is not possible to use these two results to make a decision on compliance.

Some guidance is already available on such issues, but it is usually limited to advice to consult with the client and/or regulator as to the appropriate action to take in cases such as ii) and iii). This document provides additional guidance on setting appropriate criteria for unambiguous decisions on compliance given results with associated uncertainty information. Since a great deal of work on compliance assessment has been carried out in other areas, particularly for the testing of electrical and mechanical products, this document follows the principles outlined in existing guidance for electronics and engineering measurement, particularly that set out in ASME B89.7.3.1-2001[1].

2. Scope

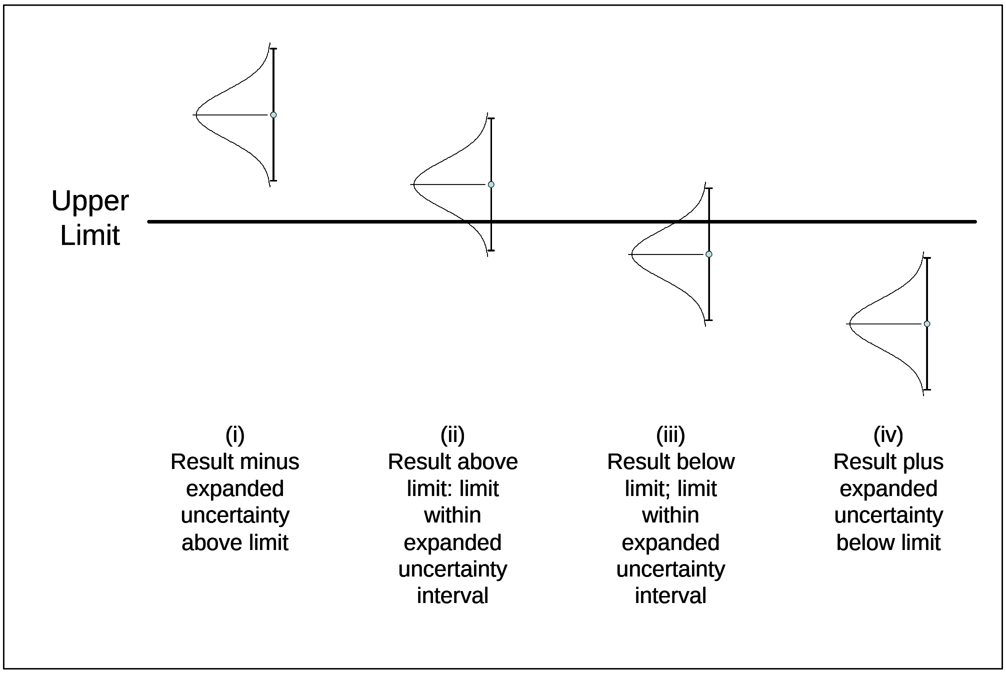
This guide is applicable to decisions on compliance with regulatory or manufacturing limits where a decision is made on the basis of a measurement result accompanied by information on the uncertainty associated with the result. It covers cases where the uncertainty does not depend on the value of the measurand, and cases where the uncertainty is proportional to the value of the measurand.

This guide assumes that the uncertainty has been evaluated by an appropriate method that takes all relevant contributions into account. Guidance on appropriate methods of evaluating uncertainty is provided by the Eurachem[2] and ISO[3] guides on the subject.

When the decision on compliance is applied to all the tested lot or batch of a substance or material, the contribution to measurement uncertainty arising from the sampling could be important. This guide assumes that where the measurand implies a sampling requirement, the uncertainty includes components arising from sampling. Further guidance on uncertainty in sampling is given in a related Guide.[4]

This document does not consider cases involving decisions based on multiple measurands.

Figure 1 Assessment of Compliance with an Upper Limit



3. Definitions

Terms used in this guide generally follow those of the International Vocabulary of Basic and General Terms in Metrology[5] ("the VIM") and the ISO/IEC Guide to the Expression of Uncertainty in Measurement[3] ("the GUM"). Additional terms are taken from ASME B89.7.3.1-2001.[1] A summary of the most important definitions used in this document is provided in Appendix C.

4. Decision rules and Acceptance zones

The key to the assessment of compliance is the concept of "Decision rules". These rules give a prescription for the acceptance or rejection of a product based on the measurement result, its uncertainty and the specification limit or limits, taking into account the acceptable level of the probability of making a wrong decision. On the basis of the Decision rules, an "Acceptance zone" and a "Rejection zone" are determined, such that if the measurement result lies in the acceptance zone the product is declared compliant and if in the rejection zone it is declared non-compliant.

A decision rule that is currently widely used is that a result implies non compliance with an upper limit if the measured value exceeds the limit by the expanded uncertainty. With this decision rule, then only case (i) in figure 1 would imply non compliance.

Another very simple decision rule is that a result equal to or above the upper limit implies non-compliance and a result below the limit implies compliance, provided that uncertainty is below a specified value. This is normally used where the uncertainty is so small compared with the limit that the risk of making a wrong decision is acceptable. To use such a rule without specifying the maximum permitted value of the uncertainty would mean that the probability of making a wrong decision would not be known.

In general the decision rules may be more complicated. They may include, for example, that for cases (ii) and (iii) in Figure 1, additional measurement(s) should be made, or that manufactured product be compared with an alternative specification to decide on possible sale at a different price. The basic requirements for deciding whether or not to accept the test item are the same, that is:

1. A specification giving upper and/or lower permitted limits of the characteristics (measurands) being controlled.
2. A decision rule that describes how the measurement uncertainty will be taken into account with regard to accepting or rejecting a product according to its specification and the result of a measurement.
3. The limit(s) of the acceptance or rejection zone (i.e. the range of results), derived from the decision rule, which leads to acceptance or rejection when the measurement result is within the appropriate zone.

The relevant product specification or regulation should ideally contain the decision rules. Where this is not the case then they should be drawn up as part of the definition of the analytical requirement (i.e. during contract review). When reporting on compliance, the decision rules that were used should always be made clear.

A decision rule should have a well documented method of determining the location of acceptance and rejection zones, ideally including the minimum acceptable level of the probability that the value of the measurand lies within the specification limits. The rule may also give the procedure for dealing with repeated measurements and outliers. The determination of the acceptance/rejection zone will normally be carried by the laboratory based on the decision rule and the information available about the uncertainty in their own measurement result.

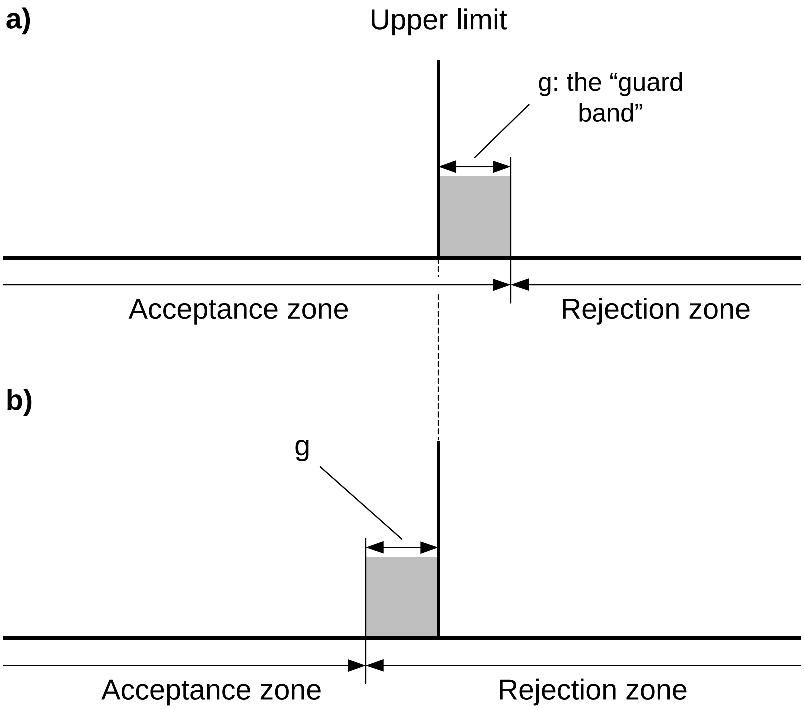
An example of such a decision rule is that given for implementing Directive 96/23/EC,[6] viz.

> 1. The result of an analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded.
> 2. If a permitted limit has been established for a substance, the decision limit is the concentration above which it can be decided with a statistical certainty of $1 - \alpha$ that the permitted limit has been truly exceeded.
> 3. If no permitted limit has been established for a substance, the decision limit is the lowest concentration level at which a method can discriminate with a statistical certainty of $1 - \alpha$ that the particular analyte is present.
> 4. For substances listed in Group A of Annex I to Directive 96/23/EC, the α error shall be 1 % or lower. For all other substances, the α error shall be 5 % or lower.

This is a decision rule for non-compliance or rejection with low probability of false rejection (high confidence of correct rejection). From this decision rule a rejection zone can be defined as shown in Figure 2a). The start of the rejection zone is at the specification limit *L* plus an amount *g* (called the Guard band*). The value of *g* in Figure 2a) is chosen so that for a measurement result greater than or equal to $L+g$ the probability of false rejection is less than or equal to α; that is, if the result is in the rejection zone, the rule gives a low probability that the permitted limit has not actually been exceeded. In Figure 2b), *g* has been chosen to provide low risk of false acceptance.

In general, *g* will be a multiple of the standard uncertainty *u*. For the case where the distribution of the likely values of the measurand is approximately normal, a value of 1.64*u* will give a probability of α of 5% and a value of 2.33*u* implies a probability α of 1%. An example from analytical measurements is the use of CCα as described in Commission Decision 2002/657/EC.[7] CCα is the lowest *measured* concentration at which it is certain, with a given probability, that the *true* concentration is above the permitted level. Thus CCα is a *decision limit* and the risk that the true value is below the permitted limit is characterised by α. A typical value for α is 5 % indicating that the probability of a false rejection is 5 %. CCα is equivalent to $L+g$.

Figure 2: Acceptance and Rejection zones for an Upper Limit

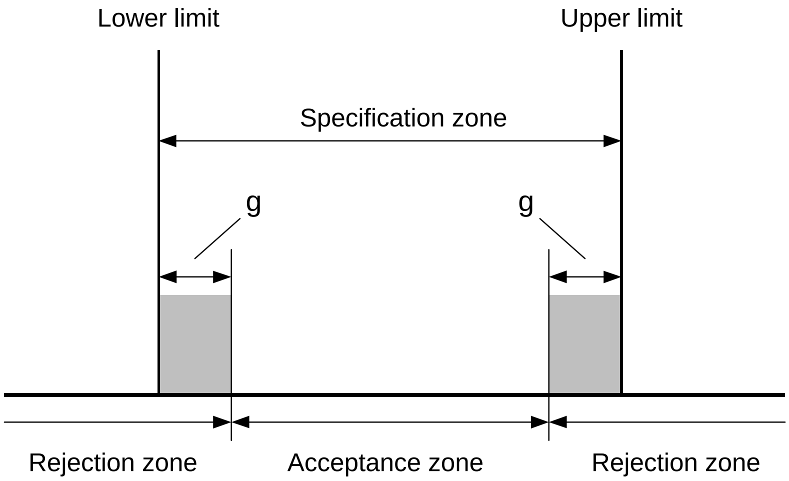


The figure shows the relative positions of the acceptance and rejection zones for a) high confidence of correct rejection; b) high confidence of correct acceptance. The distance g is often called the 'guard band'.

* There is a large amount of literature on compliance assessment, mainly on electrical and mechanical products, which uses the concept of guard bands. See reference 1 for information about some of this literature

In some cases a specification sets upper and lower limits, for example to control the composition. Figure 3 shows the acceptance and rejection zones for such a case, where the guard bands have been chosen so that for a sample that is in compliance there is a high probability that the measurand is within the specification limits.

Figure 3: Acceptance and rejection zones for simultaneous Upper and Lower Limits



The figure shows the relative positions of the specified limits and of the acceptance and rejection zones for low risk of false acceptance.

5. Choosing Acceptance and Rejection Zone limits

The size of the guard band *g* depends upon the value of the uncertainty and is chosen to meet the requirements of the decision rule. For example if the decision rule states that for non-compliance, the observed value should be greater than the limit plus $2u$, then the size of the guard band is $2u$. If the decision rule states that for non-compliance that the probability *P* that the value of the measurand is greater than the limit L, should be at least 95%, then *g* is chosen so that for an observed value of $L+g$, the probability that the value of the measurand lies above the limit L is 95%. Similarly, if the decision rule is that there should be at be least a 95% probability that the value of the measurand is less than *L*, then *g* is chosen, so that for an observed value of $L-g$, the probability that the value of the measurand lies below the limit is 95%. In general the value of *g* will be a function of or a simple a multiple of *u* where *u* is the standard uncertainty. In some cases the decision rule may state the value of the multiple to be used. In others the guard band will depend upon the value of *P* required and the knowledge about the distribution of the likely values of the measurand. Some typical cases are described in Appendix A

6. Specifying an acceptable value for *u*

The larger the value of *u* the larger is the proportion of the samples that will be judged incorrectly. The smaller the value of *u*, in general, the higher will be the cost of analysis. Thus, ideally *u* should be chosen to minimise the costs of analysis plus the costs of the decisions. However the information needed to do this is very rarely available. In some cases, where the specification sets upper and lower limits, the maximum permissible size of *u* is given as a fraction of the difference between these limits. For example, one such specification states that the expanded uncertainty should be no greater than one eighth of this difference.[1] A common approach is to carry out screening measurements using a relatively cheap method with a comparatively large uncertainty and follow this using a method with a small uncertainty for those samples for which the screening result does not lead to a clear decision. In all cases the maximum permissible size of the uncertainty should form part of the definition of the analytical requirement.

7. Recommendations

1 In order to decide whether or not to accept/reject a product, given a result and its uncertainty, there should be

   a) a specification giving the upper and/or lower permitted limits of the characteristics (measurands) being controlled

   and

   b) a decision rule that describes how the measurement uncertainty will be taken into account with regard to accepting or rejecting a product according to its specification and the result of a measurement.

2 The decision rule should have a well-documented method of unambiguously determining the location of the acceptance and rejection zones, ideally stating or using the minimum acceptable level of the probability that the measurand lies within the specification limits. It should also give the procedure for dealing with repeated measurements and outliers.

3 Utilising the decision rule the size of the acceptance or rejection zone may be determined by means of appropriate guard bands. The size of the guard band is calculated from the value of the measurement uncertainty and the minimum acceptable level of the probability that the measurand lies within the specification limits, as described in Section 5

4 In addition, a reference to the decision rules used should be included when reporting on compliance.

8. References

1 ASME B89.7.3.1-2001 “Guidelines for Decision Rules: considering Measurement Uncertainty in Determining Conformance with Specifications”

2 EURACHEM/CITAC Guide “Quantifying Uncertainty in Analytical Measurement” Second edition (2000). A Williams, S L R Ellison, M Roesslein (eds.) ISBN 0 948926 15 5. Available from the Eurachem Secretariat (see http://www.eurachem.org/)

3 ISO/IEC Guide to the Expression of Uncertainty in Measurement, ISO, Geneva, 1993

4 EURACHEM/EUROLAB/CITAC/NORDTEST Guide “Estimation of Measurement Uncertainty arising from Sampling”. (2007) Available from the Eurachem Secretariat (see http://www.eurachem.org/)

5 International Vocabulary of Basic and General Terms in Metrology, ISO, Geneva (1993)

6 COMMISSION DECISION of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (2002/657/EC) Article 6

7 Annex II.5: Concept Set by Commission Decision 2002/657/Ec Implementing Council Directive 96/23/Ec Concerning the Performance of Analytical Methods and the Interpretation of Results

Appendix A. Determining the size of the Guard Band

The size of the guard band *g* is chosen to meet the requirements of the decision rule. It depends upon the value of the uncertainty, the minimum acceptable level of the probability *P* that the measurand lies within the specification limits, and the knowledge available about the distribution of the likely values of the measurand. Where there is little detailed knowledge about this distribution the value of *g* will be just *ku,* as in Cases 1, 2, and 3 below. In other cases the value of *g* can be determined from the shape of the distribution and the desired value of *P,* as in Cases 3 and 4.

Case 1a: Only standard uncertainty available.

In this case, the size of the guard band will be *ku* and the value of *k* will either be specified in the decision rule or will be derived from the probability distribution of the values attributed to the measurand, which is usually assumed to be normal. The basis for making this assumption and the conditions under which it might be appropriate are given in Annex G of the GUM. The assumption is based on the use of the Central Limit Theorem and GUM section G 2.3 points out that "…. if the combined standard uncertainty *u* is not dominated by a standard uncertainty component obtained from Type A evaluation based on just a few observations, or by a standard uncertainty component obtained from a Type B evaluation based on a rectangular distribution, a reasonable first approximation to calculating the expanded uncertainty *U* that provides an interval with a level of confidence *P* is to use for *k* the value from the normal distribution"

In many cases, current practice is to use $k = 2$. On the assumption that the distribution is approximately normal, this gives the level of confidence of approximately 95% that, for an observed value *x*, the value of the measurand lies in the interval $x \pm 2u$. On this basis the probability that the value of the measurand is less than $x + 2u$ is approximately 97.5%.

In the commonly encountered case of requiring proof of compliance with an upper limit, as shown in Figure 2a,) taking $k = 2$ and requiring proof of clear non-compliance (case i) in Figure 1) is equivalent to setting a guard band $g = +2u$. If the observed value exceeds the limit by more than *g* then the value of the measurand is above the limit with at least 97.5% confidence. This will therefore result in fewer false non-compliance decisions than decisions based on one-tailed significance tests at 95% confidence (i.e. with k=1.65).

If it is important to implement decisions at other levels of confidence, or with modest degrees of freedom, then a value of *k* may be obtained from tables for the normal or (for modest degrees of freedom) *t* distributions at the appropriate level of confidence.

However in the GUM, section G 1.2, it is pointed out that since the value of *U* is at best only approximate, it is normally unwise to try to distinguish between closely similar levels of confidence (say a 94% and a 96% level of confidence). In addition, the GUM indicates that obtaining intervals with levels of confidence of 99% or greater is especially difficult.

Case 1b: Only expanded uncertainty available, with a stated coverage factor k.

Divide *U* by the given value of *k* and determine the value of the guard band using the revised value of *k* appropriate to the application as in case 1a.

Case 2: Standard uncertainty available together with effective degrees of freedom (ν_{eff})

In this case it is accepted practice to assume that the values that could be attributed to the measurand follow the "*t*" distribution with ν_{eff} degrees of freedom and use t_{95} or $t(P)$ as the value of *k*. This is discussed in more detail in GUM, sections G3 & G4.

Note: An alternative approach, which avoids the problems with the use of effective number of degrees of freedom, has been proposed by Williams[1] and by Kacker and Jones[2] .

Case 3: Individual components and distributions available

This case is dealt with in GUM Section G 1.4. This states that if the probability distributions of the input variables are known and the value of the measurand is linearly related to these input quantities, then the probability distribution of the values attributed to the measurand can be calculated by convolution of these distributions.

The size of the guard band can then be calculated directly from distribution of the values attributed to the measurand.

Note: The GUM also states that such an approach is rarely if ever implemented. Since the publication of the GUM, however, substantial work has been done on combination of uncertainties using simulation (Monte Carlo methods).[3] These methods are intended to provide a direct estimate of the probability distribution of the values attributable to the measurand, which can be used to implement the decision rule. It is widely accepted that, properly implemented, these methods provide viable alternatives to rigorous application of the law of propagation of uncertainty

Case 4: Asymmetric distributions

The case where an input quantity is distributed asymmetrically is covered in general terms in section G 5.3 of GUM. It points out that "this does not affect the calculation of *u* but may affect the calculation of *U*".

In more general terms, there are three important situations where asymmetric confidence intervals are necessary for decision taking:

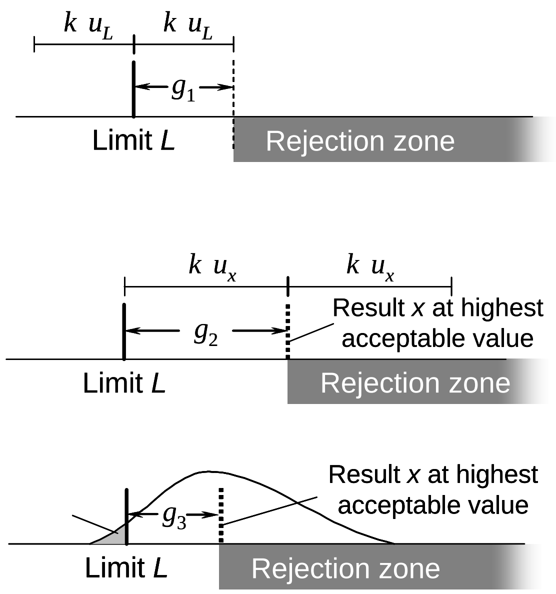
1. When the (assumed) distribution of the measurand *x* is inherently asymmetric (such as the Poisson distribution with low degrees of freedom).
2. When the measured response *x* is close to a physical constraint (e.g. observed concentrations close to zero).
3. When the uncertainty associated with the result depends strongly upon the value of the measurand.

The first situation is known from, for example, radioactivity measurements with a small number of detected events. The second situation is known from measurements close to a limit of detection or determination, or when the definition of a variable is limited to a specific interval; here, symmetric intervals may imply unfeasible values of the measurand, dictating alternative expression of uncertainty.[4] Examples of such variables are mass and amount–of–substance fractions. The third commonly occurs when the uncertainty is proportional to the analyte concentration. This can lead to considerable asymmetry in the distribution of values attributable to the measurand if the uncertainty is large compared to the value of the measurand (i.e. to the analyte concentration).

Considerable care is needed in designing the decision rule when the uncertainty u is proportional to the value of the measurand, as consideration of the following three decision rules and schematic illustrations will show.

Figure A-1: Different decision rules with uncertainty dependent on the value of the measurand

1. The result will be taken as indicating non-compliance if the measured value x is greater than the limit value L by more than $k_a.u_L$ where u_L is the value of the uncertainty at the limit. This gives a guard band g_1 of $L.k_a.u_{rel}$ where u_{rel} is the relative uncertainty.
2. The result will be taken as indicating non-compliance if the measured value x is greater than the limit value L by more than $k_a.ux$ where u_x is the value of the uncertainty at the measured value. This gives a guard band g_2 of $L.k_a.u_{\mathrm{rel}}/(1 - k_a.u_{\mathrm{rel}})$ [Note 1]
3. The result will be taken as indicating non-compliance if, for a measured value x, the probability of the value of the measurand being less than the limit is less than a. [Note 2]



Note 1: The "Result x" for rules 2 and 3 is shown at the highest acceptable value deduced by applying the particular decision rule.

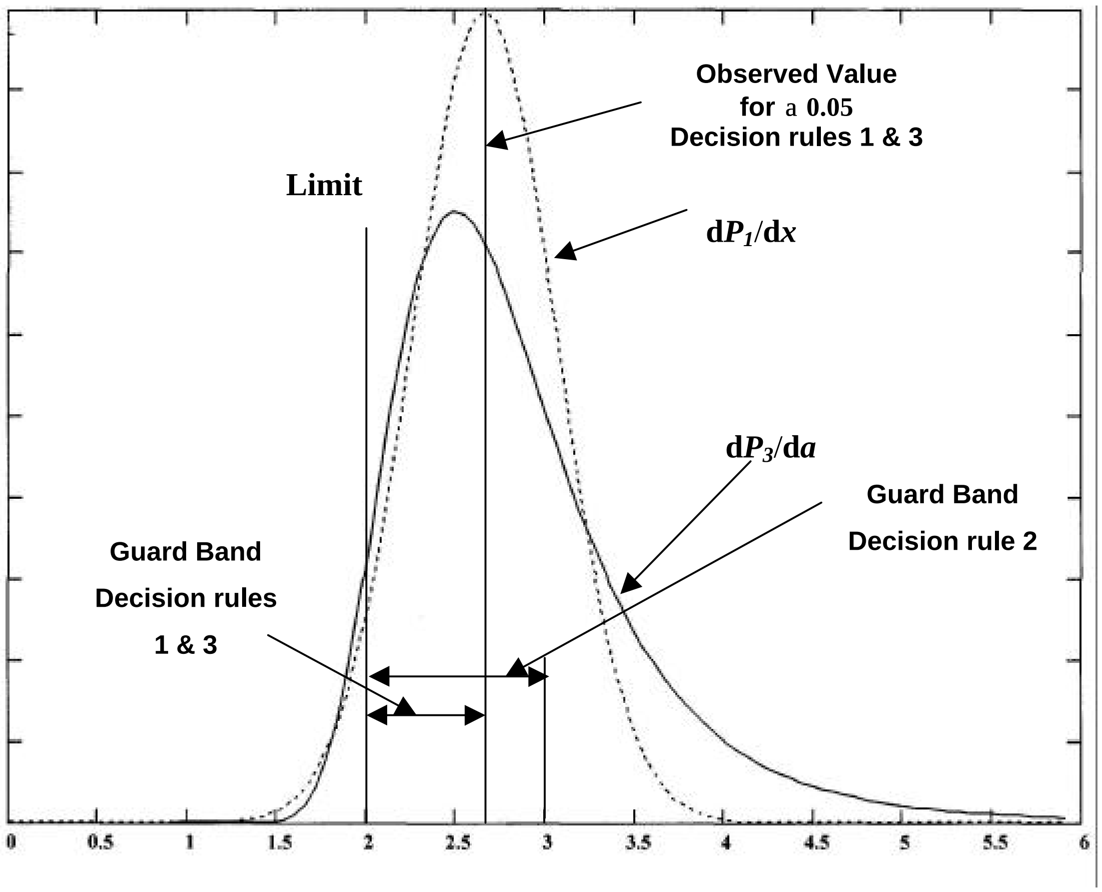
Note 2: The distribution shown is the probability density function for the values attributable to the measurand on the basis of the observed value x.

The value of k_a for decision rule 1 above depends on the Probability Density Function (PDF) of the observed value x for an assumed value of the measurand, which for the purpose of this discussion will be taken to be normal with a mean value L and a standard deviation u_L. The value of k_a for decision rule 2 depends on the PDF for the value of the measurand for the observed value x. For the purpose of this discussion this will be assumed to be normal with a mean value x and a standard deviation u_x. This corresponds to the usual way in which this decision rule is used. The validity of this assumption is discussed below. To determine the guard band g_3 for decision rule 3 the PDF for the likely values of the measurand needs to be known. This can be derived using Bayes theorem and it can be shown that even for a normal distribution of the observed values of x, the distribution of values attributable to the measurand is asymmetric when the uncertainty depends on the value of the measurand. It can also be shown that decision rules 1 & 3 give essentially the same values for the guard band for values of the relative uncertainty of up to about 0.3 and for values of a of 0.05 & 0.01, whereas decision rule 2 for u_{rel}= 0.3 and a of 0.05 (that is, for k_a =1.65) gives a guard band that is twice that for decision rule 1 and 3.3 times larger for a probability a of 0.01.

A detailed comparison of the result of using these decision rules is shown in Figure A-2 for u_{rel} = 0.2 and a = 0.05. It shows the PDFs for decision rules 1 and 3 for an observed value equal to limit plus the guard band. In order to compare the results for decision rules 1 and 3, the PDF for decision rule 1 (labelled dP_1/dx in the Figure) has been centred on the observed value, using the uncertainty at the limit. The probability that the value of the measurand is below the limit is the same as the probability of observing a value greater than $L + k_a.u_L$, when the value of the measurand is at the limit (that is, as for decision rule 1).

It can be seen that although the distribution of the values attributable to the measurand as calculated for decision rule 3 (shown as dP_3/da in the Figure) is asymmetric, the distributions for decision rules 1 & 3 follow each other closely for values up to the limit. Since decision rule 1 is much simpler, in practice, it would be much more convenient to use decision rule 1. This also has the advantage that this decision rule also applies if the uncertainty does not vary with the concentration. For decision rule 2, with a value of k_a =1.65 and an observed value equal to $L + g_2$, the probability that the value of the measurand is below the limit would be significantly less than 5%. This arises because the assumption that the PDF of the values of the measurand for an observed value x is normal is not valid when the uncertainty depends on the value of the measurand. The distribution is then asymmetric and this asymmetric distribution would have to be used to give the correct value of k_a. However, all of the three decision rules give equal guard bands when the uncertainty does not vary with the concentration.

Figure A-2



To take a particular example, the report “On The Relationship Between Analytical Results, Measurement Uncertainty, Recovery Factors And The Provisions Of EU Food And Feed Legislation, With Particular Reference To Community Legislation Concerning….”[5] recommends that

> “In practice, when considering a maximum value in legislation, the analyst will determine the analytical level and estimate the measurement uncertainty at that level. The value obtained by subtracting the uncertainty from the reported concentration, is used to assess compliance. Only if that value is greater than the maximum level in the legislation is it certain “beyond reasonable doubt” that the sample concentration of the analyte is greater than that required by the legislation.”

This is similar to decision rule 2 above, since it uses the uncertainty at the measured value. The use of these two different rules (1 and 2) has led to much controversy in drug control in sport, where a 30% relative uncertainty is common. With a 30% relative uncertainty, for $\alpha = 0.01$ the guard band for decision rule 2 is 3.3 times the guard band for decision rule 1. Thus although both decision rules are clear and unambiguous, decision rule 2 requires larger observed values for non-compliance than may be appropriate. This is because the distribution of the values attributable to the measurand is asymmetric, with larger values of the measurand being more probable than for the symmetric case. Decision rule 2 does not take this asymmetry into account correctly.

References for Appendix A

1 A Williams. *An alternative to the effective number of degrees of freedom*. Accreditation and Quality Assurance (1999) 4:14 - 17

2 R Kacker and A Jones. *On use of Bayesian statistics to make the Guide to the Expression of Uncertainty in Measurement consistent*. Metrologia (2003) 40:235-248

3 JCGM WG1 GUM, Supplement 1: “Numerical methods for the Propagation of Distributions”.

4 S Cowen, S L R Ellison. *Reporting measurement uncertainty and coverage intervals near natural limits*. Analyst (2006) 131:710–717

5 *Report On The Relationship Between Analytical Results, Measurement Uncertainty, Recovery Factors And The Provisions Of EU Food And Feed Legislation* …… www. europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

Appendix B. Examples

Example 1. Implementation of a decision rule covered by Case 2 in Appendix A.

A result of a measurement of the concentration of an analyte gives a result of 205.4 ng/g with a standard uncertainty u=2.2 based on ν =8 effective number degrees of freedom. There is no dominant uncertainty component and it can be assumed that the values attributable to the measurand follow the *t*-distribution. This result is to be used to judge compliance with the following decision rule in the regulation.

The decision rule states that
"The batch will be considered to be non-compliant if the probability of the value of the concentration being greater than 200 ng/g exceeds 95%".

The **single sided** value of *t* for a 95% level of probability and for 8 degrees of freedom is 1.86. Thus this decision rule sets the rejection zone for assessing this result as starting at 200+4.1. The result lies in the rejection zone and hence on the basis of this result the batch would be rejected.

Example 2. Implementation of a decision rule covered by Case 4 in Appendix A.

Case 4 deals with the situation where the uncertainty is proportional to the value of the measurand, for example in the analysis for the control of illegal substances in sport as discussed by Van Eenoo et al [1] and by King[2]. A suitable decision rule would be

"The concentration of the illegal substance will be deemed to be above the limit if on the basis of the analytical result and its uncertainty the probability that concentration is greater than the limit is 99% or greater"

This is the same as the decision rule 3 in Appendix A, Case 4, with α=0.01. As is shown in Case 4, decision rules 1 and 3 are effectively equivalent and thus the appropriate guard band will be $L.k_a.u_{rel.}$

The limit L for 19-norandrosterone (males) is 2ng/ml. In reference 11 it is shown that it reasonable to assume that for analysis of this substance, the relative uncertainty is in the range 23-29%. Taking u_{rel} = 25% and assuming a normal distribution then k_a = 2.33 and the guard band is 1.2ng/ml. Thus a measurement result of greater than 3.2ng/ml would be deemed to be over the limit.

References for Appendix B

1 P Van Eenoo & F T Delbeke. *Reply to "Measurement uncertainty and doping control in sport" by A. van der Veen*, Accred Qual Assur (2003) 8:334–339

2 B King Measurement uncertainty in sports drug testing Accred Qual Assur (2004) 9:369–373

Appendix C: Definitions

The following definitions are taken from the International Vocabulary of Basic and General Terms in Metrology (1993 edition) or the ISO/IEC Guide to the Expression of Uncertainty in Measurement

measurand: particular quantity subject to measurement.

expanded uncertainty: quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand. See GUM, 2.3.5.

The following additional definitions and notes follow those of ASME B89.7.3.1-2001, though cross-references to specific sections of that document have been removed.

decision rule: a documented rule that describes how measurement uncertainty will be allocated with regard to accepting or rejecting a product according to its specification and the result of a measurement.

acceptance zone: the set of values of a characteristic, for a specified measurement process and decision rule, that results in product acceptance when a measurement result is within this zone.

rejection zone: the set of values of a characteristic, for a specified measurement process and decision rule, that results in product rejection when a measurement result is within this zone.[3]

guard band: the magnitude of the offset from the specification limit to the acceptance or rejection zone boundary

Notes:

1) *The specification of a measurand may require statements about such quantities as time, temperature, and pressure.*

2) *When claiming product acceptance, it is important to state the decision rule; e.g., "acceptance using the XX rule."*

3) *When claiming product rejection, it is important to state the decision rule; e.g., "rejection using the XX rule."*

4) *The symbol g is deliberately used for the guard band, instead of the symbol U employed in ISO 14253-1 since U is reserved for the expanded uncertainty which is associated with a measurement result and hence it is confusing to attach U to a specification limit. The evaluation of U is a technical issue, while the evaluation of g is a business decision.*

5) *The guard band is usually expressed as a percentage of the expanded uncertainty, i.e., a 100% guard band has the magnitude of the expanded uncertainty U*

6) *Two-sided guard banding occurs when a guard band is applied to both the upper and lower specification limits. (In some exceptional situations the guard band applied within the specification zone, g_{lu} could be different at the upper specification limit and at the lower specification limit. This would reflect a different risk assessment associated with an upper or lower out-of-specification condition depending on whether the characteristic was larger or smaller than allowed by the specification zone.) If both the upper and lower guard bands are the same size then this is called symmetric two-sided guard banding.*

7) *A guard band is sometimes distinguished as the upper or lower guard band, associated with the upper or lower specification limit. Subscripts are sometimes attached to the guard band notation, g, to provide clarity, e.g.,* g_{up} *and* g_{L0}.

8) *The guard band, g, is always a positive quantity; its location, e.g., inside or outside the specification zone, is determined by the type of acceptance or rejection desired.*

9) *While these guidelines emphasize the use of guard bands, an equivalent methodology is to use gauging limits as in ASME B89.7.2-1999.*