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EA Guidelines on the Expression of Uncertainty in Quantitative Testing

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EA guidelines on the expression of uncertainty in quantitative testing

PURPOSE

The purpose of this document is to harmonise the evaluation of uncertainties associated with measurement and test results within EA. To achieve this, recommendations and advice are given for the evaluation of those uncertainties.

Authorship

The EA Expert group on uncertainty of measurement prepared this document on behalf of the EA Laboratory Committee.

Official Language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Further information

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CONTENTS

1 INTRODUCTION

The Guide to the Expression of Uncertainty in Measurement (GUM) [1] is recognised by EA as the master document on measurement uncertainty. Therefore, consistency with the GUM is generally required for specific guidance or recommendations for the evaluation of measurement uncertainty in any field of application associated with EA activity.

In general, the GUM is also applicable in testing, although there are decisive differences between measurement and testing procedures. The very nature of some testing procedures may make it difficult to apply the GUM strictly. Section 6 provides guidance on how to proceed in such cases.

Wherever possible accredited testing laboratories are required, when reporting the uncertainties associated with quantitative results, to do so in accordance with the GUM. A basic requirement of the GUM is the use of a model for the evaluation of uncertainty. The model should include all quantities that can contribute significantly to the uncertainty associated with the test result. There are circumstances, however, where the effort required developing a detailed model is unnecessary. In such a case other identified guidance should be adopted, and other methods based, for example on validation and method performance data be used.

To ensure that clients benefit fully from laboratories' services, accredited testing laboratories have developed appropriate principles for their collaboration with clients. Clients have the right to expect that the test reports are factually correct, useful and comprehensive. Depending on the situation, clients are also interested in quality features, especially

- the reliability of the results and a quantitative statement on this reliability, i.e. uncertainty
- the level of confidence of a conformity statement about the product that can be inferred from the testing result and the associated expanded uncertainty.

Other quality features such as repeatability, intermediate precision reproducibility, trueness, robustness and selectivity are also important for the characterisation of the quality of a test method.

This document does not deal with the use of uncertainty in conformity assessment. In general, the quality of a test result does not reflect the best achievable or the smallest uncertainty. Section 2 defines the scope of application of this guide and Section 3 presents a policy statement jointly made by EUROLAB, EURACHEM and EA. Sections 4, 5 and 6 are tutorial. Section 4 provides a brief summary of the GUM. Section 5 summarises the existing requirements according to ISO/IEC 17025 [7] and the strategy for the implementation of uncertainty evaluation. It also addresses some difficulties associated with uncertainty evaluation in testing. Section 6 explains the use of validation and method performance data for evaluating uncertainty in testing. EA requirements on reporting the result of a measurement are given in Section 7. Guidance on a stepwise implementation of uncertainty in testing is provided in Section 8. The benefits of elaborating the uncertainty associated with the values obtained in quantitative testing are indicated in Section 9.

2 SCOPE OF APPLICATION

This document is intended to provide guidance for the evaluation[1] of uncertainty in quantitative testing. Any test involving the determination of a numerical value of a measurand or a characteristic is called quantitative testing. For the evaluation of uncertainty in calibration, EA–4/02 [11] should be consulted.

3 POLICY STATEMENT

Extract from ILAC-G17:2002 “Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025” [15] :

1. The statement of uncertainty of measurement should contain sufficient information for comparative purposes;

2. The GUM and ISO/IEC 17025 form the basic documents but sector specific interpretations may be needed;

3. Only uncertainty of measurement in quantitative testing is considered for the time being. A strategy on handling results from qualitative testing has to be developed by the scientific community;

4. The basic requirement should be either an estimation of the overall uncertainty, or identification of the major components followed by an attempt to estimate their size and the size of the combined uncertainty;

5. The basis for the estimation of uncertainty of measurement is to use existing experimental data should be used (quality control charts, validation, round robin tests, PT, CRM, handbooks etc.);

6. When using a standard test method there are three cases:

- *when using a standardised test method, which contains guidance to the uncertainty evaluation, testing laboratories are not expected to do more than to follow the uncertainty evaluation procedure as given in the standard[2];*
- *if a standard gives a typical uncertainty of measurement for test results, laboratories are allowed to quote this figure if they can demonstrate full compliance with the test method;*
- *if a standard implicitly includes the uncertainty of measurement in the test results there is no further action necessary[2].*

Testing laboratories should not be expected to do more than take notice of, and apply the uncertainty-related information given in the standard, i.e. quote the applicable figure, or perform the applicable procedure for uncertainty estimation. Standards specifying test methods should be reviewed concerning estimation and statement of uncertainty of test results, and revised accordingly by the standards organisation.

7. The required depth of the uncertainty estimations may be different in different technical fields. Factors to be taken into account include:

- *common sense;*
- *influence of the uncertainty of measurement on the result (appropriateness of the determination);*

[1] The term *evaluation* has been used in preference to the term *estimation*. The former term is more general and is applicable to different approaches for uncertainty. This choice is also made to be consistent with the vocabulary used in GUM.

[2] The laboratories have to demonstrate full compliance with the test methods.

- *appropriateness;*
- *classification of the degree of rigour in the determination of uncertainty of measurement.*

8. In certain cases it can be sufficient to report only the reproducibility;
9. When the estimation of the uncertainty of measurement is limited any report of the uncertainty should make this clear;
10. There should be no development of new guides where usable guides already exist.

4 BRIEF SUMMARY OF THE GUM

The GUM is based on sound theory and provides a consistent and transferable evaluation of measurement uncertainty and supports metrological traceability. The following paragraphs provide a brief interpretation of the basic ideas and concepts.

Three levels in the GUM can be identified. These are basic concepts, recommendations and evaluation procedures. Consistency requires the basic concepts to be accepted and the recommendations to be followed. The basic evaluation procedure presented in the GUM, the law of propagation of uncertainty, applies to linear or linearised models (see below). It should be applied whenever appropriate, since it is straightforward and easy to implement. However, for some cases more advanced methods such as the use of higher-order expansion of the model or the propagation of probability distributions may be required.

The basic concepts in uncertainty evaluation are

- the knowledge about any quantity that influences the measurand is in principle incomplete and can be expressed by a probability density function (PDF) for the values attributable to the quantity based on that knowledge
- the expectation value of that PDF is taken as the best estimate of the value of the quantity
- the standard deviation of that PDF is taken as the standard uncertainty associated with that estimate
- the PDF is based on knowledge about a quantity that may by inferred from
  - repeated measurements—Type A evaluation
  - scientific judgement based on all the available information on the possible variability of the quantity—Type B evaluation.

This document interprets the GUM as based on

- a model formulated to account for the interrelation of the input quantities that influence the measurand
- corrections included in the model to account for systematic effects; such corrections are essential for achieving traceability to stated references (e.g. CRMs, reference measurement procedures, SI units).
- the reporting of the result of a measurement that specifies the value and a quantitative indication of the quality of that result
- the provision, when required, of an interval about the result of a measurement that may be expected to encompass a large fraction of the values that could reasonably be attributed to the measurand. This interval, often expressed in terms of an expanded uncertainty, is a very suitable quantitative indication of the quality of the result. The expanded uncertainty is often expressed as a multiple of the standard uncertainty. The multiplying factor is termed the coverage factor k (see Section 7).

The evaluation procedure comprises four parts:

- Derivation of the model of the measurement. Because in general this is the most difficult part of the evaluation, the use of a cause-effect-relationship linking the input quantities to the measurand is recommended
- The provision of probability density functions (PDFs) for the input quantities to the model, given information about these quantities. In many cases in practice, it is necessary to specify only the expectation value and standard deviation of each PDF, i.e. the best estimate of each quantity and the standard uncertainty associated with that estimate
- Propagation of uncertainty. The basic procedure (the law of propagation of uncertainty) can be applied to linear or linearised models, but is subject to some restrictions. A working group of the Joint Committee for Guides in Metrology (JCGM) is preparing guidance for a more general method (the propagation of PDFs) that includes the law of propagation of uncertainty as a special case
- Stating the complete result of a measurement by providing the best estimate of the value of the measurand, the combined standard uncertainty associated with that estimate and an expanded uncertainty (Section 7).

The GUM [1] provides guidance on stating a complete result of a measurement in its section 7, titled "Reporting uncertainty". Section 7 in this document follows the recommendations of the GUM and provides some more detailed guidance. Note that the GUM permits the use of either the combined standard uncertainty $u_c(y)$ or the expanded uncertainty $U(y)$, *i.e.* the half width of an interval having a stated level of confidence, as a measure of uncertainty. However, if the expanded uncertainty is used, one must state the coverage factor k, which is equal to the value of $U(y)/u_c(y)$.
For the evaluation of the uncertainty associated with the measurand Y one needs only to know

- the model, $Y = f(X_1,..., X_N)$,
- the best estimates x_i of all input quantities X_i and
- the uncertainties $u(x_i)$ and the correlation coefficients $r(x_i,x_j)$ associated with x_i and with x_i and x_j.

The best estimate x_i is the expected value of the PDF for X_i, $u(x_i)$ is the standard deviation of that PDF and $r(x_i,x_j)$ is the ratio of the covariance between x_i and x_j and the product of the standard deviations.
To state the combined standard uncertainty $u_c(y)$ associated with the measurement result y, no further knowledge of the PDF is required. To state the half width of an interval having a stated level of confidence, i.e. an expanded uncertainty, it is necessary to know the PDF. This requires more knowledge since the two parameters, expectation value and standard deviation, do not fully specify a PDF unless it is known to be Gaussian.

Section 7 provides guidance on obtaining the expanded uncertainty in those cases where a Gaussian PDF is not assumed for the measurand Y.

5 TUTORIAL ON MEASUREMENT AND QUANTITATIVE TESTING

5.1 Requirements

In principle, the standard ISO/IEC 17025 does not include new requirements concerning measurement uncertainty but it deals with this subject in more detail than the previous version of this standard:

"5.4.6 Estimation of uncertainty of measurement

5.4.6.1 *A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.*

5.4.6.2 *Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.*

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- *the requirements of the test method ;*
- *the requirements of the client ;*
- *the existence of narrow limits on which decisions on conformance to a specification are based.*

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

5.4.6.3 *When estimating the uncertainty of measurement, all uncertainty components, which are of importance in the given situation shall be taken into account using appropriate methods of analysis.*

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and conditions of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see bibliography)".

5.2 Specific difficulties of uncertainty evaluation in testing

The terms "test result" and "measurement result" correspond to two well-defined concepts. In metrology the word "measurand" as defined in VIM [2, clause 2.6] is used and in testing the word "characteristic" as defined in ISO 3534-2 [6] is preferred.

Measurand (VIM 2.6) Particular quantity subject to measurement **(measurable) quantity** (VIM 1.1) attribute of a phenomenon, body or a substance that may be distinguished qualitatively and determined quantitatively	**Characteristic** (ISO 3534) A property which helps to differentiate between items of a given population

The difference between the terminology used in "measurement" and "testing" activities will be more clearly seen upon comparing the definitions of the two operations:

Measurement (VIM 2.1) Set of operations having the object of determining a value of a quantity	**Test** (ISO/IEC Guide 2 [3]) Technical operation that consist of the determination of one or more characteristics of a given product, process or service according to a specified procedure

A measurand as defined by the VIM is therefore a particular case of a characteristic as defined by ISO 3535, in the sense that a well-defined characteristic can be regarded as a measurand. In particular, a quantitative characteristic is a 'quantity' in the VIM definition, and in the course of a test the value of that quantity will be determined by measurement. It follows that the properties of measurement results and quantitative test results can be expected to be identical. Further, in both cases an appropriate definition of the measurand or of the characteristic is essential. Here, "appropriate" means sufficiently detailed and related to the process of measuring or testing and sometimes also related to the further use of the result.

There are, however, important differences in the practice of measurement (as seen in calibration and in testing), and these affect the practice of uncertainty evaluation:

A *measurement process* typically yields a result that in principle is independent of the measurement method apart from different uncertainties associated with different methods. For example, temperature values indicated by a mercury thermometer and a platinum resistance thermometer can be expected to be similar (to an extent dictated by their associated uncertainties), but the uncertainty associated with the former value will be much larger than that associated with the latter.

A *test result* typically depends on the method and on the specific procedure used to determine the characteristic, sometimes strongly. In general, different test methods may yield different results, because a characteristic is not necessarily a well-defined measurand.

In *measurement procedures*, environmental and operational conditions will either be maintained at standardised values or be measured in order to apply correction factors and to express the result in terms of standardised conditions. For example, in dimensional measurements the temperatures of workpieces will be measured in order to correct the result for the effects of thermal expansion, and in gas flow measurement pressure and temperature will either be maintained at specified values or measured and used as a basis for correction.

Test methods are often determined by conventions. These conventions reflect different concerns or aims:

- the test must be representative of the real conditions of use of the product
- the test conditions are often a compromise between extreme conditions of use
- the test conditions must be easily reproducible in a laboratory
- individual test conditions should control the variability in the test result.

To achieve the last aim, a nominal value and a tolerance for the relevant conditions are defined. The test temperature is often specified, e.g. 38.0 °C ± 0.5 °C. However, not all conditions can be controlled. This lack of knowledge introduces variability to the results. A desirable feature of a test method is to control such variability.

For tests, an indicator (such as a physical quantity) is used to express the test results. For instance, the ignition time is often used as an indicator for a burning test. The uncertainty associated with the measurement of the ignition time adds variability to the test results. However, this contribution to the variability is generally dwarfed by contributions inherent in the test method and uncontrolled conditions, although this aspect should be confirmed.

Testing laboratories should scrutinise all elements of the test method and the conditions prevailing during its application in order to evaluate the uncertainty associated with a test result.

In principle, the mathematical model describing the test procedure can be established as proposed in the GUM. However, the derivation of the model may be infeasible for economic or other reasons. In such cases alternative approaches may be used. In particular, the major sources of variability can often be assessed by interlaboratory studies as stated in ISO 5725 [8], which provides estimates of repeatability, reproducibility and (sometimes) trueness of the method.

Despite the differences in terminology above, for the purposes of this document, a quantitative test result is considered to be a measurement result in the sense used in the GUM. The important distinction is that a comprehensive mathematical model, which describes all the effects on the measurand, is less likely to be available in testing. The evaluation of uncertainty in testing may therefore require the use of validation and method performance studies as described in section 6.

6 USE OF VALIDATION AND METHOD PERFORMANCE DATA FOR UNCERTAINTY EVALUATION

6.1 Sources of method performance and validation data

The observed performance characteristics of test methods are often essential in evaluating the uncertainty associated with the results (Section 4). This is particularly true where the results are subject to important and unpredictable effects, which can best be considered as random effects, or where the development of a comprehensive mathematical model is impractical. Method performance data also very frequently includes the effect of several sources of uncertainty simultaneously and its use may accordingly simplify considerably the process of uncertainty evaluation. Information on test method performance is typically obtained from

- data accumulated during validation and verification of a test method prior to its application in the testing environment
- interlaboratory studies according to ISO 5725
- accumulated quality control (that is, check sample) data
- proficiency testing schemes as described in EA-3/04 [10].

This section provides general guidance on the application of data from each of these sources.

6.2 Data accumulated during validation and verification of a test method prior to application in the testing environment

6.2.1 In practice, the fitness for purpose of test methods applied for routine testing is frequently checked through method validation and verification studies. The data so accumulated can inform the evaluation of uncertainty for test methods. Validation studies for quantitative test methods typically determine some or all of the following parameters:

Precision. Studies within a laboratory will obtain precision under repeatability conditions and intermediate conditions, ideally over time and across different operators and types of test item. The observed precision of a testing procedure is an essential component of overall uncertainty, whether determined by a combination of individual variances or by a study of the complete method in operation.

Bias. The bias of a test method is usually determined by studying relevant reference materials or test samples. The aim is typically to identify and eliminate significant bias. In general, the uncertainty associated with the determination of the bias is an important component of overall uncertainty.

Linearity. Linearity is an important property of methods used to make measurements over a range of values. Correction for significant non-linearity is often accomplished by the use of non-linear calibration functions. Alternatively, the effect is avoided by the choice of a restricted operating range. Any remaining deviations from linearity are normally sufficiently accounted for by the use of overall precision data. If these deviations are negligible compared with the uncertainties associated with calibration, additional uncertainty evaluation is not required.

Capability of detection. The lower limit of operability of a test method may be established. The value obtained is not directly relevant to the evaluation of uncertainty. The uncertainty in the region at or near this lower limit is likely to be significant compared with the value of the result, leading to practical difficulties in assessing and reporting uncertainty. Reference to appropriate documentation on the treatment and reporting of results in this region is accordingly recommended [13].

Selectivity and specificity. These terms relate to the ability of a test method to respond to the appropriate measurand in the presence of interfering influences, and are particularly important in chemical testing. They are, however, qualitative concepts and do not directly provide uncertainty information, though the influence of interfering effects may in principle be used in uncertainty evaluation [12].

Robustness or ruggedness. Many method development or validation protocols require that the sensitivity to particular parameters be investigated directly. Ruggedness data can therefore provide information on the effect of important parameters, and is particularly important in establishing whether a given effect is significant [13].

6.2.2 **Experimental studies of method performance should be carried out carefully. In particular:**

- *Representativeness* is essential: as far as possible, studies should be conducted to provide a realistic survey of the number and range of effects operating during normal use of the method, as well as covering the range of values and sample types within the scope of the method. Estimates of precision covering a wide variety of sources of variation are particularly appropriate in this respect.
- Where factors are suspected to interact, the effect of interaction should be taken into account. This may be achieved either by ensuring random selection from different levels of interacting parameters, or by careful systematic design to obtain both variance and covariance information.
- In carrying out studies of overall bias, it is important that the reference materials and values are relevant to the materials under routine test.

Careful experimental design is accordingly invaluable in ensuring that all relevant factors are duly considered and properly evaluated.

6.2.3 The general principles of applying validation and performance data to uncertainty evaluation are similar to those applicable to the use of performance data (above). However, it is likely that the performance data available will adequately cover fewer contributions. Correspondingly further supplementary estimates will be required. A typical procedure is:

- Compile a list of relevant sources of uncertainty. It is usually convenient to include any measured quantities held constant during a test, and to incorporate appropriate precision terms to account for the variability of individual measurements or the test method as a whole. A cause and effect diagram [13] is a very convenient way to summarise the uncertainty sources, showing how they relate to each other and indicating their influence on the uncertainty associated with the result
- Assemble the available method performance and calibration data
- Check to see which sources of uncertainty are adequately accounted for by the available data. It is not generally necessary to obtain separately the effects of all contributions; where several effects contribute to an overall performance figure, all

such effects may be considered to be accounted for. Precision data covering a wide variety of sources of variation are therefore particularly useful as they will often encompass many effects simultaneously (but note that in general precision data alone are insufficient unless all other factors are assessed and shown to be negligible)

- For any sources of uncertainty not adequately covered by existing data, either seek additional information from the literature or existing data (certificates, equipment specifications, etc.) or, plan experiments to obtain the required additional data.

6.3 Interlaboratory study of test methods performance according to ISO 5725 or equivalent

6.3.1 Interlaboratory studies according to ISO 5725 typically provide the repeatability standard deviation s_r and reproducibility standard deviation s_R (both as defined in ISO 3534-1 [5]) and may also provide an estimate of trueness (measured as bias with respect to a known reference value). The application of these data to the evaluation of uncertainty in testing is discussed in detail in ISO TS 21748 [9]. The general principles are:

i) Establishing the relevance of method performance data to measurement results from a particular measurement process. Section 6.2 of this document provides details of the measures required.
ii) Establishing the relevance of method performance data to the test item by identifying differences in sample treatment, sampling, or expected level of response between the laboratory's test item and those test items examined in a collaborative study. An adjustment of the reproducibility standard deviation to take account of, for example, changes in precision with level of response may be necessary.
iii) Identifying and evaluating the additional uncertainties associated with factors not adequately covered by the interlaboratory study (see 6.3.2).
iv) Using the principles of the GUM to combine all the significant contributions to uncertainty, including the reproducibility standard deviation (adjusted if necessary), any uncertainty associated with the laboratory component of bias for the test method, and uncertainties arising from additional effects identified in iii).

These principles are applicable to test methods that have been subjected to interlaboratory study. For these cases, reference to ISO TS 21748 is recommended for details of the relevant procedure. The EURACHEM/CITAC guide [12] also gives guidance on the application of interlaboratory study data in chemical testing.

6.3.2 The additional sources (6.3.1 iii)) that may need particular consideration are:

- Sampling. Collaborative studies rarely include a sampling step. If the method used in-house involves sub-sampling, or the measurand is a bulk property of a small sample, the effects of sampling should be investigated and their effects included
- Pre-treatment. In most studies, samples are homogenised, and may additionally be stabilised, before distribution. It may be necessary to investigate and add the effects of the particular pre-treatment procedures applied in-house
- Method bias. Method bias is often examined prior to or during interlaboratory study, where possible by comparison with reference methods or materials. Where the bias itself, the standard uncertainties associated with the reference values used, and the standard uncertainty associated with the estimated bias are all small

compared with the reproducibility standard deviation, no additional allowance need be made for the uncertainty associated with method bias. Otherwise, it will be necessary to make such allowance.

- Variation in conditions. Laboratories participating in a study may tend to steer their results towards the means of the ranges of the experimental conditions, resulting in underestimates of the ranges of results possible within the method definition. Where such effects have been investigated and shown to be insignificant across their full permitted range, however, no further allowance is required.
- Changes in sample type. The uncertainty arising from samples with properties outside the range covered by the study will need to be considered.

6.4 Test or measurement process quality control data

6.4.1 Many test or measurement processes are subject to control checks based on periodic measurement of a stable, but otherwise typical, test item to identify significant deviations from normal operation. Data obtained in this way over a long period of time provide a valuable source of data for uncertainty evaluation. The standard deviation of such a data set provides a combined estimate of variability arising from many potential sources of variation. It follows that if applied in the same way as method performance data (above), the standard deviation provides the basis for an uncertainty evaluation that immediately accounts for the majority of the variability that would otherwise require evaluation from separate effects.

6.4.2 Quality control (QC) data of this kind will not generally include sub-sampling, the effect of differences between test items, the effects of changes in the level of response, or inhomogeneity in test items. QC data should accordingly be applied with caution to similar materials, and with due allowance for additional effects that may reasonably apply.

6.4.3 Data points from QC data that gave rise to rejection of measurement and test results and to corrective action should normally be eliminated from the data set before calculating the standard deviation.

6.5 Proficiency testing data

6.5.1 Proficiency tests are intended to check periodically the overall performance of a laboratory, and are best used for that purpose (EA-3/04 [10] and references cited therein). A laboratory's results from its participation in proficiency tests can accordingly be used to check the evaluated uncertainty, since that uncertainty should be compatible with the spread of results obtained by that laboratory over a number of proficiency test rounds.

6.5.2 In general, proficiency tests are not carried out sufficiently frequently to provide good estimates of the performance of an individual laboratory's implementation of a test method. Additionally, the nature of the test items circulated will typically vary, as will the expected result. It is thus difficult to accumulate representative data for well-characterised test items. Furthermore, many schemes use consensus values to assess laboratory performance, which occasionally lead to apparently anomalous results for individual laboratories. Their use for the evaluation of uncertainty is accordingly limited. However, in the special case where

- the types of test items used in the scheme are appropriate to the types tested routinely

- the assigned values in each round are traceable to appropriate reference values, and
- the uncertainty associated with the assigned value is small compared with the observed spread of results,

the dispersion of the differences between the reported values and the assigned values obtained in repeated rounds provides a basis for an evaluation of the uncertainty arising from those parts of the measurement procedure within the scope of the scheme.

6.5.3 Systematic deviation from traceable assigned values and any other sources of uncertainty (such as those noted in connection with the use of interlaboratory study data obtained in accordance with ISO 5725) must also be taken into account.

6.5.4 It is recognised that the above approach is relatively restricted. Recent guidance from EUROLAB [14] suggests that proficiency testing data may have wider applicability in providing a preliminary estimate of uncertainty in some circumstances.

6.6 Significance of uncertainty contributions

6.6.1 Not all the uncertainty sources identified during an uncertainty evaluation will make a significant contribution to the combined uncertainty; indeed, in practice it is likely that only a small number will. Those few clearly need careful study to obtain reliable estimates of their contributions. A preliminary estimate of the contribution of each component or combination of components to the uncertainty should therefore be made, by judgement if necessary, and attention paid to those that are most significant.

6.6.2 In deciding whether an uncertainty contribution can be neglected, it is important to consider

- The relative sizes of the largest and the smaller contributions. For example, a contribution that is one fifth of the largest contribution will contribute at most 2% of the combined standard uncertainty
- The effect on the reported uncertainty. It is imprudent to make approximations that materially affect the reported uncertainty or the interpretation of the result
- The degree of rigour justified for the uncertainty evaluation, taking into account the client and regulatory and other external requirements identified, for example, during contract review.

6.7 Use of prior study data

In order to use the results of prior studies of the method to evaluate the uncertainty, it is necessary to demonstrate the validity of applying prior study results. Typically, this will consist of:

- Demonstration that a precision comparable to that obtained previously can be achieved
- Demonstration that the use of the bias data obtained previously is justified, typically through the determination of bias on relevant reference materials (see, for example, ISO Guide 33 [4]), by satisfactory performance on relevant proficiency schemes, or other interlaboratory comparisons
- Continued performance within statistical control as shown by regular QC sample results and the implementation of effective analytical quality assurance procedures.

Where the conditions above are met, and the method is operated within its scope and field of application, it is normally acceptable to apply the data from prior studies (including validation studies) directly to uncertainty evaluations in the laboratory in question.

For methods operating within their defined scope, when the reconciliation stage shows that all the identified sources have been included in the validation study or when the contributions from any remaining sources have been shown to be negligible, the reproducibility standard deviation s_R may be used as the combined standard uncertainty.

If there are any significant sources of uncertainty that are not included in the validation study their contribution is evaluated separately and combined with s_R to obtain the overall uncertainty.

7 REPORTING RESULTS OF A QUANTITATIVE TEST

A quantitative test always yields a value, which should preferably be expressed in SI units. The guidance in this section should be followed if an associated uncertainty is also to be reported (see ISO/IEC 17025 [7]).

7.1 Once the expanded uncertainty has been calculated for a specified level of confidence (typically 95%), the test result y and the expanded uncertainty U should be reported as $y \pm U$ and accompanied by a statement of confidence. This statement will depend on the nature of the probability distribution; some examples are presented below.

All clauses below that relate to a 95% level of confidence require modification if a different level of confidence is required.

7.1.1 Normal distribution

It is generally safe to assume a normal distribution from the viewpoint of providing a coverage interval at the 95% level of confidence when the model is linear in the input quantities *and* one of the following three possibilities applies:

1. There is a single, dominant contribution to the uncertainty, which arises from a normal distribution, and the corresponding degrees of freedom exceed 30.
2. The three largest uncertainty contributions are of comparable size.
3. The three largest contributions are of comparable size, <u>*and*</u> the effective degrees of freedom[3] exceed 30.

Under these circumstances the following statement can be made:

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2, which for a normal distribution provides a level of confidence of approximately 95%.

Note: Normality should NOT be assumed if the measurement model is significantly non-linear in the region of interest, particularly if uncertainties in input values are large

[3] The effective degree of freedom can be estimated by one of the following:
- taking the effective degree of freedom for a single, dominant contribution
- using the Welch-Satterthwaite formula given in the GUM and EA-4/02
- (approximately) by taking the number of degrees of freedom for the largest contribution.

compared with the input values themselves. Under these circumstances, reference to more advanced texts, e.g. the GUM, is necessary.

7.1.2 *t*-distribution

The *t*-distribution may be assumed if the conditions for normality (above) apply but the degrees of freedom is less than 30. Under these circumstances the following statement (in which the appropriate numerical values are substituted for *XX* and *YY*) can be made:

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = XX, which for a t-distribution with ν_{eff} *= YY effective degrees of freedom provides a level of confidence of approximately 95%.*

7.1.3 Dominant (non-normal) contributions in a Type B evaluation of uncertainty

If the uncertainty associated with the measurement result is dominated by a contribution resulting from an input quantity that is non-normal and that contribution is so large that a normal or t-distribution is not obtained when the quantity is convolved with the remaining input quantities, special consideration should be given to obtaining a coverage factor that will provide a level of confidence of approximately 95%. For an additive model, i.e. when the measurand can be expressed as a linear combination of the input quantities, the PDF for the measurand can be obtained by convolving, i.e propagating, the PDFs for the input quantities. Even in this case, and almost always when the model is non-linear, the mathematics required can, however, be difficult. A practical approach is to make the assumption that the resulting distribution will be little different in form from that of the dominant component.

In many cases a rectangular distribution will be assigned to a dominant non-normal input quantity. In such a case a rectangular distribution can then be assigned to the measurand. An expanded uncertainty at the 95% level of confidence can be obtained by multiplying the combined uncertainty by $0.95\sqrt{3} = 1.65$. Under these circumstances the following statement can be made:

The reported expanded uncertainty is dominated by a single component of uncertainty for which a rectangular probability distribution has been assumed. A coverage factor of 1.65 (= $0.95\sqrt{3}$) has therefore been used in order to provide a level of confidence of approximately 95%.

7.2 For the purposes of this document the term *approximately* is interpreted as meaning *effectively* or *for most practical purposes*.

7.3 Reference should also be made to the method by which the uncertainties have been evaluated.

7.4 In some testing situations it may not be possible to evaluate a metrologically sound numerical values for each component of uncertainty; in such circumstances the means of reporting should be such that this is clear. For example, if the uncertainty is based only on repeatability without consideration being made to other factors then this should be stated.

7.5 Unless sampling uncertainty has been fully taken into account, it should also be made clear that the result and the associated uncertainty apply to the tested sample only and do not apply to any batch from which the sample may have been taken.

7.6 The number of decimal digits in a reported uncertainty should always reflect practical measurement capability. In view of the process for evaluating uncertainties, it is rarely justified to report more than two significant digits. Often a single significant digit is appropriate. Similarly, the numerical value of the result should be rounded so that the last decimal digit corresponds to the last digit of the uncertainty. The normal rules of rounding can be applied in both cases.

For example, if a result of 123.456 units is obtained, and an uncertainty of 2.27 units has resulted from the evaluation, the use of two significant decimal digits would give the rounded values 123.5 units ± 2.3 units.

7.7 The test result can usually be expressed as $y \pm U$. However there may be situations where the upper and lower bounds are different; for example if cosine errors are involved. If such differences are small then the most practical approach is to report the expanded uncertainty as ± the larger of the two. However, if there is a significant difference between the upper and lower values they should be evaluated and reported separately. This may be achieved, for example, by determining the shortest coverage interval at the desired level of confidence in the PDF for the measurand.

For example, for an uncertainty of +6.5 units and –6.7 units, for practical purposes ± 6.7 units could simply be stated. However, if the values were +6.5 units and –9.8 units they should be separated, e.g. +6.5 units; –9.8 units.

8 STEPWISE IMPLEMENTATION OF THE UNCERTAINTY CONCEPT

It is recognised that the knowledge of mathematical modelling and the determination of the various influence factors is generally different in different testing fields.

This aspect has to be taken into account when implementing ISO/IEC 17025. Laboratories cannot in general be expected to initiate scientific research to assess the uncertainties associated with their measurements and tests. The respective requirements of the accreditation bodies should be adapted according to the current state of knowledge in the respective testing field.

If a mathematical model as a basis for the evaluation of measurement uncertainty is not available, laboratories can

- list those quantities and parameters that are expected to have a significant influence on the uncertainty and estimate their contribution to the overall uncertainty
- use data concerning repeatability or reproducibility that might be available from validation, internal quality assurance or interlaboratory comparisons
- refer to data or procedures given in the relevant testing standards
- combine the approaches mentioned above.

Laboratories should strive to refine their uncertainty evaluations, where appropriate, taking into account for instance

- recent data from internal quality assurance in order to broaden the statistical basis for the uncertainty evaluation
- new data from the participation in interlaboratory comparisons or proficiency tests
- revisions of the relevant standards
- specific guidance documents for the respective testing field.

Consequently, accreditation bodies will be able to redefine their requirements concerning measurement uncertainty according to the development of knowledge in the field. In the long term differences in the requirements for different sectors on the manner in which measurement uncertainty is evaluated will diminish. Laboratories should, however, select the most suitable approach for their area and evaluate measurement uncertainty to the extent appropriate to the intended use.

9 ADVANTAGES OF UNCERTAINTY EVALUATION FOR TESTING LABORATORIES

There are several advantages linked with the evaluation of measurement uncertainty in testing, although the task can be time-consuming.

- Measurement uncertainty assists in a quantitative manner in important issues such as risk control and the credibility of test results

- A statement of measurement uncertainty can represent a direct competitive advantage by adding value and meaning to the result

- The knowledge of quantitative effects of single quantities on the test result improves the reliability of the test procedure. Corrective measures may be implemented more efficiently and hence become more cost-effective

- The evaluation of measurement uncertainty provides starting points for optimising the test procedures through a better understanding of the test process

- Clients such as product certification bodies need information on the uncertainty associated with results when stating compliance with specifications

- Calibration costs can be reduced if it can be shown from the evaluation that particular influence quantities do not substantially contribute to the uncertainty.

10 REFERENCES

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[4] ISO Guide 33:2000, Uses of certified reference materials

[5] ISO/IEC 3534-1:1994, Statistics - Vocabulary and symbols Part 1: Probability and general statistical terms

[6] ISO/IEC 3534-2:1994, Statistics - Vocabulary and symbols Part 2: Statistical quality control

[7] ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories

[8] ISO/IEC 5725: 1994, Accuracy (trueness and precision) of measurement methods and results

[9] ISO/TS 21748: 2002, - Guide to the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation

[10] EA-3/04, Use of Proficiency Testing as a Tool for Accreditation in Testing (with EUROLAB and EURACHEM) Aug 2001

[11] EA-4/02 Expression of the Uncertainty of Measurements in Calibration (including supplements 1 and 2 to EA-4/02) *(previously EAL-R2),* Dec 1999

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[13] EURACHEM, The Fitness for Purpose of Analytical Methods (ISBN 0- 948926-12-0) 1998

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[15] ILAC G17:2002, Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025, November 2002

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12 APPENDIX

Inventory of documents (normative and non normative, existing or in the process of drafting) on measurement uncertainty (Document established by the CEN / WG 122 and the EA group « uncertainty ») synthesis prepared by Bernd Siebert.

Appendix: Alphabetic list of documents

CEAL	Measurement uncertainty for environmental laboratories
CEN 12282	In vitro diagnostic medical devices- Measurement of quantities in samples of biological origin – Description of reference materials
CEN ISO 18153	In vitro diagnostic medical devices- Measurement of quantities in samples of biological origin – Metrological traceability of values for catalytic concentration of enzymes assigned to calibration and control materials.
CEN/ISO 17511	In vitro diagnostic medical devices- Measurement of quantities in samples of biological origin – Metrological traceability of values assigned to calibration and control materials.
CLAS Reference Document 5	General Guidelines for Evaluating and Expressing the Uncertainty of Accredited laboratories' Measurement Results.
DIN (DRAFT) 32646	Chemische Analyse -Erfassungs- und Bestimmungsgrenze als Verfahrenskenn-größen - Ermittlung in einem Ringversuch unter Vergleichs-bedingungen - Begriffe, Bedeutung, Vorgehensweise
DIN 1319 Teil 3 Teil 4	DIN 1319 Teil 3."Auswertung v. Messungen einer einzelnen Messgrösse, Messunsicherheit"; DIN 1319 Teil 4 "Behandlung von Unsicherheiten bei der Auswertung von Messungen"
DIN 32645	Chemische Analytik -Nachweis-, Erfassungs- und Bestimmungsgrenze - Ermittlung unter Wiederholbedingungen - Begriffe, Verfahren, Auswertung
DIN 51309	Kalibrierung von Drehmomentmessgeräten für statische Drehmomente (Februar 1998)
DIN 58932-3	Haematology- Determination of the concentration of blood corpuscles- Par 3 Determination of the concentration of erythrocytes; Reference method
DIN 58932-4	Haematology- Determination of the concentration of blood corpuscles- Part 4: Determination of leucocytes; reference method
DKD R 7-1	Kalibrierung elektronischer nichtselbsttätiger Waagen
DKD R 7-1 Blatt 1 bis 3	Kalibrierung elektronischer nichtselbsttätiger Waagen
EA-10/03	Calibration of Pressure Balances (July 1997)
EA-10/04	Uncertainty of Calibration Results in Force Measurement (August 1996)
EA-10/14	EA Guidelines on the Calibration of Static Torque Measuring Devices (June 2000)
EA-4/02	Expression of the uncertainty of measurement in Calibration
EA-4/02 / DKD-3, E1	Angabe der Meßunsicherheit bei Kalibrierungen / Expression of the Uncertainty of Measurements in Calibration
EN 13274-1 to -8	Respiratory protective devices – Methods of test – Parts 1 to 8
EN 550(1984), EN 552 (1984), EN 554(1984), EN ISO 14967 (2000) and EN ISO 14160(1998)	Sterilization of medical devices (CEN/TC 204)
EN 875, EN 876, EN 895, EN 910, EN 1043-1, EN 1043-2, EN 1321, EN 1320, PrEN ISO 17641-2, prEN ISO 17641-3	Destructive testing of welds (CEN/TC 121/SC 5)

Appendix: Alphabetic list of documents – continued

EN 970, EN 1290, EN 1435, EN 1713, EN 1714	Non-destructive testing of welds (CEN/TC 121/WG 13)
EN ISO 14253-1	Geometrical product specification (GPS). Inspection by measurement of workpieces and measuring equipments. Part 1 : decision rules for proving conformance or non-conformance with specifications.
EN ISO 4259	Petroleum products - Determination and application of precision data in relation to methods of test
EN 12286	In vitro diagnostic medical devices- Measurement of quantities in samples of biological origin – Presumptions of reference measurement procedures.
EN 24185	Measurement of liquid flow in closed conduits - Weighing method (ISO 4185:1980)
EN 29104	Measurement of fluid flow in closed conduits -- Methods of evaluating the performance of electromagnetic flow-meters for liquids
EN ISO 2922	Acoustics – Measurement of noise emitted by vessels on inland water ways and harbours
EN ISO 4871	Acoustics – Declaration and verification of noise emission values of machinery and equipment
EN ISO 5167	Measurement of fluid flow by means of pressure differential devices - Part 1: Orifice plates, nozzles and Venturi tubes inserted in circular cross-section conduits running full
EN ISO 6817	Measurement of conductive liquid flow in closed conduits - Methods using electromagnetic flow-meters (ISO 6817:1992)
EN ISO 9300	Measurement of gas flow by means of critical flow Venturi nozzles
EN ISO-8316	Measurement of liquid flow in closed conduits - Method by collection of the liquid in a volumetric tank (ISO 8316:1987)
ENV ISO 13530	Water Quality – Guide to analytical quality control for water analysis (ISO/TR 13530:1997)
EURACHEM	Quantifying Uncertainty in Analytical Measurement
EUROLAB	EUROLAB Technical Report "Measurement Uncertainty – a collection for beginners"
FD X 07-021	Fundamental standards - Metrology and statistical applications - Aid in the procedure for estimating and using uncertainty in measurements and test results (AFNOR)
GUM	Guide to the Expression of uncertainty in measurement
Hanser Verlag	Method for the estimation of uncertainty of hardness testing machines; PC file for the determination (NOTE: This is a comprehensive technical book, but not discussed in the context of this inverntory.)
ISO TS 14253-2	GPS - Inspection by measurement of workpieces and measuring equipment -- Part 2: Guide to the estimation of uncertainty in GPS measurement, in calibration equipment and in product verification
ISO 11200-ISO 11205	Acoustics – Determination of emission sound pressure levels of noise sources (series of standards in 6 parts)
ISO 11453	Statistical interpretation of data - Tests and confidence interfals relating to proportions (1996)
ISO 11843-1	Capability of detection - Part 1: Terms and definitions (1997)
ISO 11843-2	Capability of detection - Part 2: Methodology in the linear calibration case (2000)
ISO 13752	Air quality - Assessment of uncertainty of a measurement method under field conditions using a second method as reference (1998)

Appendix: Alphabetic list of cited documents – continued

ISO 14111	Natural gas - Guidelines for traceability in analysis –
ISO 15195	Clinical Laboratory medicine – Requirements for reference measurement Laboratories
ISO 16269-7	Statistical interpretation of data - Part 7: Median - Estimation and confidence interval (2001)
ISO 3095	Acoustics – Measurement of noise emitted by railbound vehicles.
ISO 3534-1	Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms (1993)
ISO 3534-2	Statistics - Vocabulary and symbols - Part 2: Statistical quality control (1993)
ISO 3534-3	Statistics - Vocabulary and symbols - Part 3: Design of experiments (1999)
ISO 362	Acoustics – Measurement of noise emitted by accelerating road vehicles –Engineering Method
ISO 3740-3747	Acoustics – Determination of sound power levels of noise sources using sound pressure (series of standards in 8 parts).
ISO 5479	Statistical interpretation of data - Tests for departure from the normal distribution (1997)
ISO 5725-1	Accuracy (trueness and precision) of measurement method and results - Part 1: General principles and definitions (1994)
ISO 5725-2	Accuracy (trueness and precision) of measurement method and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method (1994)
ISO 5725-3	Accuracy (trueness and precision) of measurement method and results - Part 3: Intermediate measures of the precision of a standard measurement method (1994)
ISO 5725-4	Accuracy (trueness and precision) of measurement method and results - Part 4: Basic method for the determination of the trueness of a standard measurement method (1994)
ISO 5725-5	Accuracy (trueness and precision) of measurement method and results - Part 5: Alternative methods for the determination of the precision of a standard measurement method (1998)
ISO 5725-6	Accuracy (trueness and precision) of measurement method and results - Part 6: Use in practice of accuracy values (1994)
ISO 6142	Gas analysis - Preparation of calibration gas mixtures - Gravimetric method
ISO 6143	Gas analysis - Comparison method for determining and checking the composition of calibration gas mixtures
ISO 6144, ISO 6145-1, ISO/TR 14167, ISO/DIS 14912, etc.	Gas analysis - Volumetric methods and quality aspects *(several documents)*
ISO 6879	Air quality - Performance characteristics and related concepts for air quality measuring methods (1995)
ISO 6974-1	Natural gas - Determination of composition with defined uncertainty by gas chromatography - Part 1: Guidelines for tailored analysis
ISO 7574-1 to ISO 7574-4	Acoustics – Statistical methods for determining and verifying noise emission values of machinery and equipment (series of standards in 4 parts)……….
ISO 8466-1	Water quality - Calibration and evaluation of analytical methods and estimation of performance characteristics - Part 1: Statistical evaluation of the linear calibration function (1990)
ISO 8466-2	Water quality - Calibration and evaluation of analytical methods and estimation of performance characteristics - Part 2: Calibration strategy for non-linear second order calibration functions(1993)

Appendix: Alphabetic list of cited documents – continued-

ISO 9169	Air quality - Determination of performance characteristics of a measurement method (1996)
ISO 9614-1 to ISO 9614-3	Acoustics – Determination of sound power levels of noise sources using sound intensity (series of standards in 3 parts)..
VIM	International vocabulary of basic and general terms in metrology (1993)
ISO CD 7507-1	Petroleum and liquid petroleum products - Calibration of vertical cylindrical tanks - Part 1: Strapping Method
ISO DIS 11222	Air quality – Determination of the uncertainty of the time average of air quality measurements
ISO DIS 14956	Air quality — Evaluation of the suitability of a measurement procedure by comparison with a required measurement uncertainty
ISO TR 10017	Guidance on statistical techniques for ISO 9001:1994 (1999)
ISO TR 13425	Guide for the selection of statistical methods in standardization and specification (1995)
ISO TR 13530	Water quality - Guide to analytical quality control for water analysis (1997)
ISO TR 13843	Water quality - Guidance on validation of microbiological methods (2000)
ISO TR 20461	Bestimmung der Messunsicherheit von Volumenmessungen nach dem geometrischen Verfahren
ISO/TR 5168	Measurement of fluid flow - Evaluation of uncertainties
ISO/TR 7066-1	Assessment of uncertainty in calibration and use of flow measurement devices - Part 1: Linear calibration relationships
M3003 (UKAS)	The expression of uncertainty and confidence in measurement
NEN 3114	Accuracy of measurements - Terms and definitions (1990)
NEN 6303	Vegetable and animal oils and fats - Determination of repeatability and reproducibility of methods of analysis by interlaboratory tests (1988, in Dutch)
NEN 7777 Draft	Environment - Performance characteristics of measurement methods (2001 in Dutch)
NEN 7778 Draft	Environment - Equivalency of measurement methods(2001in Dutch)
FD V 03-116	Analyse des produits agricoles et alimentaires. Guide d'application des données métrologiques (AFNOR)
NIST Technical Note 1297	Guidelines for evaluating and expressing uncertainty of NIST measurement results
NKO-PR2.8 (EA-4/02 in Dutch)	Uitdrukken van de meetonzekerheid (vertaling van EAL-R2) (translation in Dutch of EAL-R2)
NPR 2813 (NEN, Netherlands)	Uncertainty of length measurment – Terms, definitions and guidelines
NPR 7779 Draft	Environment - Evaluation of the uncertainty of measurement results (2002 in Dutch)
prEN ISO 15011-1, prEN ISO 15011-2, prEN ISO 15011-3, EN ISO 10882-1, EN ISO 10882-2	Health and safety in welding and allied processes (CEN/TC 121/SC 9)
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prISO 11904-1	Acoustics – Determination of sound immissions from sound sources placed close to the ears – Part 1: Technique using microphones in real ears (MIRE-technique)...
SINAL DT-0002	Guida per la valutazione e la espressione dell'incertezza nelle misurazioni –

Appendix: Alphabetic list of cited documents – continued-

SINAL DT-0002/1	Guida per la valutazione e la espressione dell'incertezza nelle misurazioni, esempi applicativi di valutazioni dell'incertezza nelle misurazioni elettriche –
SINAL DT-0002/3	Guida per la valutazione e la espressione dell'incertezza nelle misurazioni, avvertenze per la valutazione dell'incertezza nel campo dell'analisi chimica –
SINAL DT-0002/4	Guida per la valutazione e la espressione dell'incertezza nelle misurazioni, esempi applicativi di valutazione dell'incertezza nelle misurazioni chimiche
SINAL DT-0002/5	Guida per la valutazione e la espressione dell'incertezza nelle misurazioni, esempio applicativo per misurazioni su materiali strutturali
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