



Volume 2, Issue 2

June 2007

THE FQS UPDATE



WELCOME TO “THE FQS UPDATE”

In this issue we tackle a subject that seems to cause “high anxiety” among agencies in their quest for ISO 17025 accreditation. I hope that Bill Tilstone’s article on “Uncertainty of Measurement” will help your understanding to go up and your anxiety quotient to go down. We don’t want you to spend your summer worrying.

Pat Wojtowicz, Manager of Accreditations, FQS-I

UNCERTAINTY OF MEASUREMENT

BY WILLIAM J. TILSTONE, PRESIDENT, FQS

Summary. This article describes what ISO 17025 requires testing agencies to do regarding Uncertainty of Measurement, then describes how to measure it, with examples from forensic science. Finally, the article discusses the important issues of when to measure uncertainty of measurement and what to do about reporting and recording it.

ISO 17025 Requirements for Uncertainty of Measurement. The most important requirement is described in Clause 5.4.6.2 which requires that:

... Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement

This means that your Quality Management System (or Management System using the preferred language of ISO/IEC 17025:2005) must include procedures for estimating uncertainty of measurement (UM). Note that (1) when you must apply the procedures is a

little more complex and is covered later, and that (2) the requirements only apply to quantitative data.

There are other specific requirements. For example, in regard to method validation, clause 5.4.1 requires that when validating a method the laboratory shall include, where appropriate, an estimation of the measurement uncertainty, and Clause 5.4.4 requires that when implementing new test methods, procedures should be developed prior to the tests being performed that include information about the uncertainty or the procedure for estimating uncertainty. Most of the time none of this will be bothersome to a forensic science laboratory, since a basic part of the toolkit used in validating methods is to conduct replicate analyses and calculate the mean and standard deviation.. As we shall see later, this gives us a direct measure of UM. **(Continued on Page 2)**

Inside this issue:

FQS-I Top Ten Non-Conformities Part 1	4
Achievements in Accreditation	4
FBI DNA Auditor Training	5
Digital & Multi-media Evidence TAC Update	5
New and Revised FQS-I Documents	5

The FQS Board of Directors Meeting and annual FQS Member’s Meeting will be held in conjunction with the ASCLD meeting in Orlando, Florida on Thursday afternoon, October 4, 2007. All FQS Member representatives will receive information from FQS regarding the meeting by late summer.

UNCERTAINTY OF MEASUREMENT (Cont. from Page 1)

A less direct but very important provision regarding UM is included in the notes to Clause 5.4.5.2, where note 2 states that the techniques used for the determination of the performance of a method should include assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

So far, all the provisions that we have discussed are for testing. There are many stringent provisions regarding UM and calibration. These are described in Clause 5.4.6.1, but the best advice to the forensic testing laboratory is to have all calibrations conducted by an accredited calibration laboratory whenever possible.

ISO 17025 also contains requirements, in Clause 4.13.2.1, covering test records, specifically that:

... The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty ...

There are various clauses in ISO 17025 that deal with measuring UM. For example, Clause 5.4.6.2 states that 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.

However, the most important part of Clause 5.4.6.2 is where it requires that the laboratory:

...shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty.

and that

...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.

Clause 5.4.6.2 ends with notes, namely:

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 customer; the existence of narrow limits on which decisions on conformity 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 ... the laboratory is considered to have satisfied this clause by following the test method

Clause 5.4.6.3 requires that 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. Nearly all cases where UM is required in a forensic science laboratory can be covered by simpler methods, and this clause is cited here more for completeness than for its relevance.

However, the reporting requirements of **Clause 5.10.3.1** are very relevant. The clause requires that test reports shall, where necessary for the interpretation of the test results, include the following:

- c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;

An exact implementation of these requirements could cause problems for laboratories, for example, where there are statutory reporting formats that do not include all of the above. Fortunately, the implementation of ISO 17025 includes scope for interpretative documents describing how clauses may be implemented in specific areas. The International Laboratory Accreditation Cooperation (ILAC) publishes several guidance documents, including one for forensic testing (ILAC Guide 19). The guide states that the reporting requirements of ISO 17025 clause 5.10 can be met by ensuring that the case record relating to a specific investigation contains all the relevant information required by ISO/IEC 17025.

Implementing the Uncertainty of Measurement Requirements. Uncertainty of Measurement can be defined as:

A parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

It is a measure of the spread of results that would be obtained on replicate measurement; it is not a measure of the accuracy of the results. We know from basic analytical chemistry that the usual measure of dispersion is standard deviation (SD), and that is also the usual way to express UM.

There are three ways that we can estimate UM: Direct measurement, indirect measurement, and uncertainty budgets.

(Continued on Page 3)

UNCERTAINTY OF MEASUREMENT (Cont. from Page 2)

Direct Measurement. This is obtained by calculating the SD of results from replicate measurements on a typical sample. There are various factors that can affect the SD, including concentration range, the influence of different operators, day-to-day (and longer time period) influences, and matrix effects where there is not a completely homogeneous sample presentation.

A less common, but probably better approach, is the use of Shewhart control charts. Here the results of check samples processed with each batch are plotted and the long-term results give an excellent picture of variability that takes account of pretty much all factors.

In all of the above, we calculate standard deviation using equations (for example in an Excel spreadsheet) that assume a normal distribution of results. This direct measurement is known as a Type A estimate of UM.

Indirect Measurement. Here we use professional judgment to derive an acceptable estimate of SD. The first step is to set a reasonable total range of values around the mean. This is termed the expanded uncertainty, U . We then set the acceptable degree of latitude around the mean, or the spread of results that we will accept. This is the coverage factor, k .

In a type A estimate we were able to reasonably assume that we had a normal distribution of value around the mean. In this indirect, or Type B, estimate, we need to define the nature of the distribution before we can calculate the standard deviation.

If we do not know how the results are distributed around the mean and have no reason to assume any bias such as a clustering of values around the mean, then we can conservatively assume a rectangular distribution where every value within the expanded uncertainty range has an equal probability of occurring. In that case, the measurement dispersion (standard deviation) to be used is:

$$SD = \text{Half width interval} / \sqrt{3}$$

If we can reasonably assume that there is a clustering around the mean, then we can conservatively use a triangular distribution with a height equal to the mean and upper and lower boundaries defined by U . In this case the measurement dispersion (standard deviation) to be used is:

$$SD = \text{Half-width interval} / \sqrt{6}$$

Type A Example

Thirty replicate alcohol analyses of a blood sample gave a standard deviation of 0.0018 g/dl.

This establishes the UM for that test as 0.0018. For $k = 99.5\%$ we use three times the standard deviation. Therefore 99.5% of values for repeated assays would lie in the range mean \pm 0.0054 g/dl. Note that the 0.5% not included is made up of 0.25% above the [mean + 3 SD] and 0.25% below the [mean - 3 SD].

Type B example

A firearms examiner conducts a distance estimation by measuring the diameter of residue deposition, and concludes that "the gun was fired from 18 inches give or take 6 inches either way". This translates as a mean of 18 inches and a half width interval of 6 inches.

Measurement dispersion (standard deviation) is 6 divided by the square root of 6 if we assume results are clustered around the mean or $6/\sqrt{3}$ if we assume a rectangular distribution.

That is, for an assumed rectangular distribution, the SD is $6/\sqrt{3}$ or 3.47. For an assumed triangular distribution the SD is $6/\sqrt{6}$ or 2.45. We can now apply k the same way that we do with a Type A estimate of UM.

Uncertainty budget. This is not an issue in forensic laboratories. However, for completeness, estimation of UM from an uncertainty budget involves identifying all the contributing factors, calculating the variance (the square of the SD) for each, adding the variances, and then taking the square root of the sum of squares as an estimate of UM.

When to report UM. You MUST have a record of UM for every quantitative measurement that you will report and that is either required by the customer or where a decision on conformity will be made based on your reported measurements.

... Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement

The issue then comes down to what is a measurement. The practical answer to that is to refer back to **Clauses 5.4.6.2 and 5.10.3.1**. Every time that you report a measurement, you must know the associated UM to a degree of precision that provides objective information that the dispersion of results is small enough not to bear on the interpretations or conformity decisions that will be made from your results.

FQS-I “TOP TEN” NON-CONFORMITIES—PART 1

Pat Wojtowicz, Manager of Accreditations, FQS-I

An article in the last FQS Newsletter dealt in a general way with “FQS-I Assessment Non-conformities”. In this issue, we provide some specific information with regard to the most often-seen non-conformities in recent accreditation assessments.

Of the “top ten” non-conformities, numbers six through ten are listed below. The top five will appear in the next FQS Newsletter. The non-conformities are grouped within major clauses of ISO 17025 (and the forensic supplemental requirements FRA-1).

#10. 5.6 Measurement Traceability. The non-conformities were spread throughout the section. There were some citations for missing procedures and some citations for lack of documented traceability (to national standards) of reference standards used by the laboratories. There were also situations where laboratories were using non-ISO 17025 accredited calibration laboratories for calibration of critical measuring equipment, and the competence of these providers had not been otherwise established.

#9 4.6 Purchasing Services and Supplies. At least half of the non-conformities were clustered in clause 4.6.1 and were due to incomplete procedures that did not contain all required elements. For example, a laboratory might have had a procedure that covered the purchase of critical supplies, but did not address the purchase of critical services, such as calibration..

#8 4.15 Management Review Non-conformities were evenly distributed between the two sub-clauses. Prob-

lems with 4.15.1 were incomplete procedures (all required elements not addressed) and the lack of predetermined schedules for conducting management review. In 4.15.2, many laboratories failed to record “actions arising” from Management Review and/or did not establish timescales for dealing with the “actions arising” from the review.

#7 4.14 Internal Audits. Most non-conformities were clustered in sub-clause 4.14.1. These included: no predetermined schedule and/or audit procedures that did not address all elements of the management system. (Note to DNA labs: an audit with the FBI OAS will not address all elements of the ISO 17025 standard. Note to all agencies: Don't forget to audit the internal audit program.) The biggest issue in the remaining sub-clauses of 4.14 dealt with appropriate follow-up on problems that were identified during internal audits.

#6 5.2 Personnel. Non-conformities were evenly distributed between sub-clauses 5.2.1, 5.2.2, and 5.2.5. The lack of appropriate records—for training and educational background (5.2.1) and for competency testing and authorization to perform work (5.2.5)—were cited as non-conformities. Under 5.2.2, non-conformities were (1) lack of training plans for areas of testing performed in the agency and (2) training/education/skills goals that either were not documented or were too narrow in scope to effectively anticipate future needs.

Next Time: The “top five” non-conformities, as well as a few other “problem areas” that are worth a mention.

ACHIEVEMENTS IN ACCREDITATION

Congratulations to the following agencies that achieved FQS-I ISO 17025 accreditation, reaccreditation, or expansion of scope of accreditation in the 2nd quarter of 2007:

Rhode Island State Crime Laboratory
(initial accreditation)

Denver Police Department
(reaccreditation)

Paternity Testing Corporation
(reaccreditation)

DDC/DNA Diagnostics Center (expansion
of scope)



NEW AND REVISED FQS-I DOCUMENTS

The following is a list of new and revised documents recently authorized for use by FQS-I. FRA-6 contains the only new requirements. The revisions in the remaining FRA's were made for clarification and do not substantively change requirements that were in place in the previous versions of the documents. The documents are posted on the FQS web site at www.forquality.org

FRA-1: revised Replaced "should" in most contexts with "shall" (to reflect that ILAC G19 was adopted as forensic standards and to reduce confusion regarding intent); preamble deleted; for clarity, deleted references and bibliography that are available in the ILAC G19:2002 source document.

FRA-4: revised Changed topic headings to the relevant ISO 17025 clauses; reformatted section 4.13.2.1 b) to more clearly provide equivalence to the three options for providing access to exam quality latent prints.

FRA-5: revised In some statements "should" was changed to "shall" where the original context clearly meant for a practice to be

required. Changed order and format of headings to more clearly align with the ISO 17025 clause numbering system. Added section on ISO 17025 clause 4.13.2.3 to amplify requirements regarding use of non-permanent media in note taking (from FRAP-1 as well as new guidance on erasures in sketches).

FRA-6: new For agencies performing testing in the area of Digital and Multimedia Evidence

Forms:

ISO 17025/FRA-1 checklist: revised Replaced "should" in FRA-1 clauses with "shall" as found in the revised FRA-1.

ISO 17025/FRA-1 checklist for agencies: new A basic checklist as above, but with "agency" substituted for "laboratory". Designed for use when the entity being assessed/evaluated is better described by the more generic term "agency" (police science agencies, environmental field operations, etc.) .

ISO 17025/Supplements checklist: new An all-purpose checklist that incorporates the supplemental requirements most likely to be applicable in conventional crime

laboratories (FRA-1, FRA-4, FRA-5, FRA-6).

ISO 17025/Supplements checklist for agencies: new An all-purpose checklist as above, but with "agency" substituted for "laboratory". Designed for use when the entity being assessed/evaluated is better described by the more generic term "agency" (law enforcement agencies, etc.) .

FOS-I Application for Accreditation: revised Added "expansion of scope of existing accreditation" as a selection for which the application form is to be used.

FOS-I Accreditation Surveillance Report: revised Changed the time frame for submitting materials for "office surveillance review" at FOS-I to tighten the window for submission and modify the time frame that reports are to cover. "...at least 9 and not more than 15 months from the date of the current accreditation certificate" was changed to "...within 30 days (\pm) of your accreditation anniversary date ... covers the period subsequent to your most recent FOS-I on-site assessment (full or surveillance)".

FBI DNA AUDITOR TRAINING IN THE BIG APPLE!

Heather Seubert, FBI Forensic Biology Unit, has informed FQS-I that an FBI DNA Auditor training class will be held in New York City on November 28-29, 2007. There is no charge for the class, but the attendee must cover food, lodging and transportation.

Interested parties should seek further information from:

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DIGITAL & MULTIMEDIA EVIDENCE TECHNICAL ADVISORY COMMITTEE

The FOS-I Technical Advisory Committee (TAC) on Digital and Multimedia Evidence completed its review of the draft supplemental document and **FRA-6: Forensic Requirements for Agencies that Perform Digital and Multimedia Evidence Testing** is now available on the "FOS-I Programs" page on the FQS web site.

FRA-6 includes amplification on ISO 17025 clauses related to subcontracting, personnel, access control/evidence integrity, validation (methods and computer software), equipment, and proficiency testing.

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Forensic Quality Services (FQS) provides a range of organizational assistance and training/education services to support Forensic Science delivery.

Forensic Quality Services-International (FQS-I) is the country's longest established provider of ISO 17025 accreditation to forensic testing agencies in the U.S. It is one of the accrediting bodies recognized by the NDIS Procedures Board and the only one that has successfully completed the rigorous scrutiny of operations required for recognition by the National Cooperation for Laboratory Accreditation (NACLA).



SUBMIT AN ARTICLE TO "THE FQS UPDATE"

FQS welcomes submissions to this newsletter and will evaluate all such submissions with regard to their general interest to the readership. FQS reserves the right to edit submissions for length and editorial correctness. **Deadlines for submissions are March 15, June 15, September 15, and December 15.**

Please send your submissions to pcw@forquality.org