



# THE FQS UPDATE



## Welcome to "THE FQS UPDATE"

Congratulations to all of our readers in northern climes. You've survived another winter! And a very tough one it was, too. At FQS our big news is that we have a new President, and that is definitely "front page worthy" information. Pat Wojtowicz, Manager of Accreditations, FQS-I

## Dr. Sudhir Sinha accepts role as FQS president

**The Board of Directors of Forensic Quality Services is pleased to announce that Sudhir Sinha, PhD, has agreed to serve as the President of FQS.** He fills the position that was previously held by William J. Tilstone, PhD.

Prior to joining FQS as the President, Dr. Sinha was the owner and Laboratory Director of ReliaGene Technologies, an FQS-I-accredited DNA testing laboratory. With over 36 years' experience in chemical and biochemical research and management, Dr. Sinha is well-recognized in the international scientific community, authoring numerous research papers, holding various patents, and having presented his work at many international conferences. For the purposes of expert witness testimony, Dr. Sinha has been qualified as an expert in molecular biology and DNA analysis in twenty-four jurisdictions throughout the United States. His academic background includes a Ph.D. in Chemistry from the Indian Institute of Technology in Kanpur, India, and post-doctorate training at the University of Miami Medical Center, including a position as Research Associate Professor in the Departments of Biochemistry and Medicine at the University of Miami. He is currently a member of Louisiana State University's Center for BioModular Microsystems Industrial Advisory Board, a Fellow of the AAFS, and a member of the AABB Relationship Testing Accreditation Program Unit. Dr. Sinha was instrumental in designing and producing the first commercial Y-STR testing kit for the forensic community and is a member of the Y-STR database consortium established by the National Institute of Justice (NIJ).

The Board of Directors and staff of FQS feel very fortunate to have someone of Dr. Sinha's stature in this important position within FQS. Dr. Sinha will not be working from the FQS office, but can be contacted for FQS business through his e-mail address at [president@forquality.org](mailto:president@forquality.org).

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## additional "ISO Without Tears" workshops in Florida are scheduled

FQS is pleased to announce the schedule for additional "ISO Without Tears" workshop sessions. This workshop was created to be an alternative to our existing customizable workshops that are conducted by FQS at individual agencies.

"ISO Without Tears" includes:

- ◆ Overview of ISO standards and accreditation
- ◆ Review of general and technical requirements of ISO 17025
- ◆ Discussion of agency preparation for ISO 17025 accreditation, including principles of internal auditing and quality manual preparation
- ◆ Review of forensic testing-specific aspects of ISO 17025 and supplements

*The content is generic and relevant to preparation for ISO 17025 accreditation from any accrediting body.*

"ISO Without Tears" has been very well received by those who have attended. Here are some representative comments taken from workshop evaluations completed by our attendees:

- "Good quality information . . . ."
- "Very informative. Good, useful information"
- "The size of the group was great."
- "I went from not understanding ISO whatsoever, to having a clear understanding what to expect."

The workshops will be held at the Summit Executive Center, 13575 58th St. N., Clearwater, FL. 33760, on the following dates:

- ◆ June 9-11, 2008
- ◆ October 27-29, 2008

Because FQS believes that smaller class sizes facilitate discussion and enhance the

learning experience, attendance will be capped at **10** for each session.

The registration fee is \$275. See the FQS web site ([www.forquality.org](http://www.forquality.org)) for up-to-date information on the workshop, including registration instructions and housing options.

FQS can also bring "ISO Without Tears" on-site to an individual agency. Please contact **Katy Savage** for further information at [kas@forquality.org](mailto:kas@forquality.org)



### FQS-Interpretation: "Predetermined schedule"

The use of a "predetermined schedule" is mandated in ISO 17025 for both Internal Audits (Section 4.14) and Management Review (Section 4.15). The question has been raised as to whether a statement in the Quality Manual (or procedures) such as "internal audits will be conducted annually" constitute a "predetermined schedule" or whether something more is needed.

"Conducted annually" may be used as a policy statement to establish an audit or management review cycle length; however, **it is FQS-interpretation that a "predetermined schedule" must include more specificity.**

A "schedule", to quote Webster, is "a procedural plan that indicates the time and sequence of each operation". Therefore, a "predetermined schedule" will describe a timetable for the audit or management review activities that will be conducted within the established cycle.

It is not necessary in this context for the schedule to specify exact days, but there must be evidence of advance planning, such as monthly or quarterly targets for conducting activities. This will help to ensure that all elements are covered as required by ISO 17025 and any applicable supplemental requirements.

For example, the target time periods might be described in the procedures, or a schedule for audit activities might be prepared by the Quality Manager prior to the start of a particular audit cycle.

## Internal Auditor Training Dr. Katy Savage

FQS has several options available for training. The most popular option is our internal auditor training class and its associated variations. Typically, FQS identifies an experienced instructor to send to an agency to conduct the training. The basic options for this class are as follows:

<i>Workshop</i>	<i>Duration</i>
<i>Understanding ISO 17025</i>	<i>1 day</i>
<i>Understanding and Applying ISO 17025</i>	<i>3 days</i>
<i>Understanding and applying ISO 17025, and post-audit management</i>	<i>5 days</i>

We customize our training for each client so that the outcomes of the training meet individual requirements. The most popular is the 3-day training. We normally spend the first day talking to the agency staff about the ISO 17025 standard and helping them understand what the requirements mean, and more importantly, what they mean to the individual agency. The second day and part of the third is spent assisting the staff to conduct a GAP audit of a section of their own agency. This guided hands-on method has proven to be very successful, and all the agencies who have done this report increased staff buy-in to the ISO 17025 accreditation process. The training closes out with a written and verbal report to management based on the audit findings. The 5-day workshop also includes post-audit management, including how to address non-conformances.

For further information about Internal Auditor training please contact Dr Katy Savage at [kas@forquality.org](mailto:kas@forquality.org)

## Documenting the management system: policy vs. procedure

by Pat Wojtowicz, FQS-I Manager of Accreditations

A critical element of documenting and implementing a management system that is conformant with the requirements of ISO 17025 is, of course, understanding the requirements. This includes an appreciation for the terms used in the International Standard.

Experience in FQS-I assessments and FQS training courses indicates that the terms **policy** and **procedure** are not always well understood and/or correctly applied.

ISO 17025 and supplemental requirements have numerous clauses that require an agency to have a **policy**, a **procedure**, or **both**, to describe their practices with regard to various elements.

A **policy** is a governing principle pertaining to goals, objectives, and/or activities. It is a statement of the overall direction of an organization with respect to the subject activity.

A **procedure** is a "specified way to carry out an activity or a process," (from ISO 17000) generally in support of implementing a policy. A procedure defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsi-

bility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work.

The policies related to quality must be in the quality manual. The quality manual can satisfy both the policy and procedure elements if a procedure is included in the quality manual as well, or the procedures may be found in other documents as long as they are referenced from the quality manual (per clause 4.2.5).

FQS-I assessors have seen on more than one occasion that agencies have interpreted and applied "policy" and "procedure" as though they are interchangeable. For example, an agency will write policy statements in its quality manual and say that these constitute their procedures. Unfortunately, these statements do not generally contain enough operational detail (what, who, when, where, how, etc.) to be considered procedures.

This happens most often in documenting the Section 4 management requirements (complaints, internal audits, etc.). It is not encountered as often with technical requirements, as it seems that most established testing agencies are accustomed to

writing relatively detailed technical procedures.

Less often, FQS-I assessors have reviewed documents that the agency calls "policies", but that have sufficient detail to fully meet the ISO definition of "procedures".

Procedures can take a variety of forms—from flow charts, to forms, to documents that contain several pages of text. Admittedly, writing procedures can be a "fine art" and a constant search for striking the right balance between too much detail and too little detail. While the level of detail may change from procedure to procedure, there must always be *sufficient* information to ensure that a particular process is conducted in the desired way so that the desired outcome is attained.

All accredited agencies and those working to become accredited are encouraged to take a fresh look at their management system documents. Make sure that the "policies" are policies and that the "procedures" are truly procedures. Not only will this help agency staff to know what it is they're supposed to be doing and how, it will help an agency to avoid assessment non-conformities related to insufficiency of procedures.

### FQS calendar of activities

**March 12, 2008: "ISO 17025 Accreditation for DNA Laboratories"**, presented by FQS-I Mgr. of Accreditations Pat Wojtowicz at the Bode DNA West Coast Workshop in San Diego, CA

**April 1-2, 2008: National Cooperation for Laboratory Accreditation (NACLA) Annual Forum and Board Mtg.**, to be attended by FQS-I Mgr. of Accreditations and NACLA Board Member Pat Wojtowicz; Columbia, MD

**April 7-9, 2008: "ISO Without Tears"**, FQS Workshop, Clearwater, FL

**May 21, 2008: "ISO 17025 Accreditation for DNA Laboratories"**, to be presented by FQS-I Mgr. of Accreditations Pat Wojtowicz at the Bode DNA East Coast Workshop in Captiva Island, FL

**June 9-11, 2008: "ISO Without Tears"**, FQS Workshop, Clearwater, FL

**July 2008: "ISO Without Tears"** mini-workshop, to be presented by FQS-I Mgr. of Accreditations Pat Wojtowicz, IAFS Meeting, New Orleans, LA

**October 27-29, 2008: "ISO Without Tears"**, FQS Workshop, Clearwater, FL

### FQS-I Accreditation program pricing changes

The FQS Board of Directors announces the following changes in FQS-I Accreditation Program pricing, effective April 1, 2008.

- 1) **Office surveillance:** The cost for single-site agencies with more than 15 technical staff increases from \$500 to \$750. The price remains \$500 for (a) single-site agencies with 15 or less technical staff and (b) all sites within a multi-site system operating under a centralized management system, regardless of staff size at the individual sites.
- 2) **Annual fee:** FQS-I will implement a modest annual fee for its accredited agencies. There will be no annual fee for the first year of an accreditation cycle, but a fee will be assessed on the accreditation anniversary date during each subsequent year of an agency's accreditation cycle. The fee will apply to a variety of general operational costs associated with the ongoing delivery of accreditation services. The minimum fee will be \$500/site and the maximum fee will be \$1000/site. The annual fee will be included on the invoice with the applicable fees for that year's surveillance activities.

The implementation of the fee changes at individual agencies will depend upon existing written contracts between FQS-I and the agencies. See the "**FQS-I ISO Accreditation Pricing Guidelines**" posted on the FQS web site for full details.

# FORENSIC QUALITY SERVICES

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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).**

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## Achievements in accreditation

**Congratulations to the following agencies that achieved FQS-I ISO 17025 accreditation, reaccreditation, or expansion of scope of accreditation in the 1st quarter of 2008:**

EPA Region 4, Science and Ecosystem Support Division (initial accreditation)

Forensic Analytical Sciences (initial accreditation)

Independent Forensics (reaccreditation)

Marshall University Forensic Science Center (reaccreditation)

Strand Analytical Laboratories (reaccreditation)



## Submit an article to "the fqs update"

"The FQS Update" is published quarterly in March, June, September, and December by Forensic Quality Services.

**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](mailto:pcw@forquality.org)

### Rates for ad space are as follows:

One-eighth page: \$75/issue, \$200/yr (4 issues)

One-quarter page: \$100/issue, \$300/yr (4 issues)

One-half page: \$125/issue, \$400/yr (4 issues)

Ads should be in an electronic format such as jpeg. Color or black-and-white are acceptable.

Submissions should be sent to [pcw@forquality.org](mailto:pcw@forquality.org)