



LQAP

# NEWS

## AIHA

March/April 2006 Issue

## Understanding the New Requirements of ISO 17025:2005

By Steve Lermam

In July, 2005, the International Standards Organization (ISO) revised the ISO/IEC 17025:1999 Standard with the principle objective being to align it closer with ISO 9001:2000. Three underlying principles of ISO 9001:2000 were, in the opinion of the ISO Task Groups, not present in ISO/IEC 17025:1999. These were:

1. Continuous improvement
2. Process definition and mapping
3. Process metrics

There were those who felt that process definition and mapping was reflected in all of section 5 of ISO/IEC 17025:1999, and that process metrics was reflected in section 5.9. These two items are still open today and hopefully will be addressed in the 2010 revision of the ISO/IEC 17025:2010 standard.

Continuous improvement is the topic largely reflected in the additions to ISO/IEC 17025:2005. These additions add major emphasis to the requirements for preventive action, which under the 1999 standard were treated as minor elements by most laboratories and even by many assessors.

This article will discuss the more significant changes to the ISO/IEC 17025:2005 standard and their implications to the laboratory and to the assessment.

### Documentation and Record-Keeping

Surprisingly, none of the additions to the ISO/IEC 17025:2005 standard will require additional documentation, and most additions do not require additional

records—facts that will likely please most laboratories. Most of the new clauses focus on the labs' effective implementation of core quality elements (audits, management review, corrective and preventive action, customer feedback) geared toward continuously improving their facilities' operations.

### New Terminology

There is some new terminology in the ISO/IEC 17025:2005 standard which reflects the shift in thinking in ISO 9001:2000. These are:

- Quality system → Management system
- Client → Customer
- Non-conformance → Non-conformity

These changes reflect the current thinking in quality standards. None of these changes impact anything operationally.

### New Requirements

The following are highlights of new requirements. Underlined italics are used to show new language in existing clauses. **Bold** is used to emphasize key terms in new clauses.

#### 4.1.5 The Laboratory shall:

- a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system.
- k) ensure that its personnel are aware of the **relevance and importance of their activities** and how they contribute to the achievement of the objectives of the management system.

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## Understanding the New Requirements of ISO 17025:2005

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Labs may want to modify job descriptions to comply with 4.1.5a. Assessors may rely on employee interviews to verify 4.1.5k, or the lab may add it to employee orientation training.

4.1.6 Top management shall ensure that **appropriate communication processes** are established within the laboratory and that **communication takes place** regarding the effectiveness of the management system.

All labs have communication processes, which include meetings, memos, e-mails, and postings. Any and all of these will satisfy 4.1.6.

4.2.2 The Quality Policy statement ... shall include at least the following:

- c) The **purpose** of the management system related to quality.
- e) The Laboratory Management's commitment to ... **continually improve the effectiveness** of Management System.

These can go directly into the lab's quality policy.

4.2.3 Top management shall provide **evidence of commitment** to the development and implementation of the management system and continually improving its effectiveness.

4.10 Improvement

The Laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

These last two clauses are very similar, and require no separate actions. Labs can demonstrate compliance by showing evidence of implementing the core quality elements of the ISO/IEC 17025:2005 standard and showing that this has resulted in improvement. Records for the core quality elements will satisfy any records requirements for these clauses.

4.2.7 Top management shall ensure the integrity of the management system is maintained when **changes** to the management system are planned and implemented.

Management of change has always been an important part of ISO 9001. A lab that shows no breakdown of quality over time as they have implemented change would be complying with this clause. Generally the assessor would have to show such a breakdown in order to cite a deficiency against this clause.

4.7.2 The Laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.

This is the only new clause that requires specific new action on the part of the lab. Labs must pro-actively seek feedback from their customers via phone calls, bounce-back cards, e-mail, or any other method that they choose. They must retain these records, and take action, via complaint response, corrective action, or preventive action, whenever the customer's response calls for such action. Many laboratories are already doing this, and these labs are already in compliance with this clause.

4.12 Preventive Action

*When improvement opportunities are identified or* if preventive action is required, action plans shall be developed, implemented and monitored...

The new language in this clause serves to emphasize and clarify that improvements as well as potential non-conformance are both covered under preventive action. This new language, along with the added emphasis on continuous improvement (a synonym for preventive action?) in the rest of the ISO/IEC 17025:2005 standard, raises the bar on preventive action for both labs and assessors.

5.2.2 The effectiveness of the training actions taken shall be evaluated.

Most labs already follow this requirement. Any viable action taken to verify training effectiveness is acceptable. This can include running a reference material, running a sample already run by a trained analyst, or the trainer's observing the trainee's running of the test. The trainer's signature on the training record serves as the record of evaluating the effectiveness, as does the records of running any reference samples.

5.9.2 Quality Control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported.

This was implied, but never explicit, in the ISO/IEC 17025:1999 standard. Labs must now pro-actively review all quality control data to determine outliers and take action when they find any. AIHA has always necessitated this in its LQAP requirements, and now the ISO/IEC 17025:2005 standard does the same.

### What This Means for Labs

For the most part, the new ISO/IEC 17025:2005 standard should have minimal impact on most laboratories. Labs that have been using the core quality elements of the ISO/IEC 17025:1999 standard as they are meant to be used will feel practically no change. Labs that have been giving perfunctory attention to these areas will have to revisit their quality programs to ensure that they are not doing little more than generating documents for the assessors.

*Lerman is with SIL Consulting Inc, in Plainview, NY and is an AIHA site assessor.*

## **NACLA Evaluation Conducted in March**

AIHA underwent its week-long evaluation by the National Cooperation for Laboratory Accreditation (NACLA) the week of March 6. NACLA recognizes AIHA as an accreditation body and evaluates LQAP against compliance with ISO/IEC 17011 requirements.

A team of NACLA evaluators reviewed records, met with LQAP staff, and traveled to various labs across the country to observe AIHA site assessors as they conducted audits. Now that the evaluation process has been completed, LQAP staff is developing responses to the findings contained in the evaluation team's report.

This summer, NACLA will review these findings along with AIHA's responses and decide whether AIHA should continue to be recognized as an accreditation body. More information about NACLA's deliberations will be included in a future edition of the *LQAP News*.

## **Call for AAB and TAP Applications**

AIHA's Laboratory Quality Assurance Programs are seeking qualified candidates to either run for a position on the Analytical Accreditation Board or to be appointed to the Technical Advisory Panel (TAP). The deadline for applications is May 30.

The Analytical Accreditation Board (AAB) oversees the governance and processes related to LQAP. AAB members are required to attend meetings at least three times annually: once in January/February, once in conjunction with AIHce, and once in conjunction with PCIH. AIHA will cover reasonable customary travel expenses to each of these meetings.

TAP members advise the AAB and thoroughly review accreditation applications to one of AIHA's accreditation programs (IHLAP, ELLAP, and EMLAP). TAP performs a thorough assessment of the accreditation process steps to ensure conformance to the process and to technical requirements. Members are required to attend at least one training meeting annually.

Applications and additional information about both AAB and TAP may be found at [www.aiha.org/Content/LQAP/documents/documents.htm](http://www.aiha.org/Content/LQAP/documents/documents.htm) under "LQAP Governance Documents."

## **Technical Consultants Needed for AAR Program**

The Asbestos Analyst Registry (AAR) program needs volunteers to perform technical reviews of submitted organization applications and NIOSH 582 Equivalency courses. As technical consultants for the AAR, candidates will perform reviews in conjunction with the current Laboratory Quality Assurance Programs (LQAP) of the AIHA. They will be accountable for all responsibilities specified in the current version of AIHA AAR Technical Consultant procedures and documents including the Quality Systems Procedure and Work Instruction for application review, which will be supplied to them upon acceptance as a reviewer. These responsibilities include, but are not limited to:

- Maintaining a current knowledge of the AIHA AAR policy document and the most recent version of the NIOSH 7400 method
- Timely response of the assigned reviews and adherence to all review responsibilities within the timelines specified in the AAR policies
- Abiding by AIHA's policies regarding disclosure of confidential information

As technical consultants, candidates will be asked to review applications on an as-needed basis depending on their availability. They will be contacted for availability when there are applications in need of review and given 30 days to complete the review. Training in the review process will be provided.

Persons interested in volunteering their time and expertise to improving the quality of fiber counting organizations should review the minimum qualifications below and complete the AAR technical consultant application located on the AIHA website at <http://www.aiha.org/Content/LQAP/documents/>. Questions regarding becoming an AAR technical consultant should be directed to AAR Program Specialist, Carter Dezio, at (703) 846-0798 or [cdezio@aiha.org](mailto:cdezio@aiha.org).

Qualifications for an Asbestos Analyst Registry technical consultant are:

- Graduate of an accredited institution of higher education holding a bachelor's degree in industrial hygiene, chemistry, physics, engineering, biology, or other scientific discipline.
- Engaged a majority of his or her time in asbestos analytical activities (analysis and interpretation of quality control data) for at least three years. Some experience with field analysis preferred, but not required.
- Member of the Analytical Accreditation Board (AAB), Technical Advisory Panel (TAP), or the Asbestos Analysis Committee (AAC).

## **Additional Site Assessors Sought**

AIHA employs the services of expert site assessors to visit laboratories and conduct site assessments for LQAP—which is the second step in a lab's path toward AIHA accreditation.

AIHA is seeking applications from those persons with laboratory backgrounds and expertise in industrial hygiene, environmental lead, or environmental microbiology that may be interested in serving as site assessors. All qualified candidates, who ideally should also be experienced or trained in ISO/IEC 17025:1999 (and 17025:2005) and/or quality management systems, will be interviewed by the AIHA executive director and LQAP director.

If selected, all new site assessors will be required to attend a two-day orientation session in February 2007 to learn about the application of AIHA program-specific policies while assessing laboratories. New assessors will also be required to observe at least two AIHA site assessments. A stipend is paid to each site assessor per lab visited.

For more information on the site assessor application process, site assessor responsibilities, or to receive an application, please contact LQAP Director, Cheryl O. Morton at (703) 846-0789 or via e-mail at [cmorton@aiha.org](mailto:cmorton@aiha.org).

## Advertising 100 Percent Trace Analysis of Spore Trap Samples

Over the past year, AIHA has received an increasing number of complaints regarding laboratories that are advertising that they analyze 100 percent of the trace of spore trap samples.

AIHA has reviewed these complaints along with the advertisements and other vehicles in which these claims are made. AIHA has found that many labs either will analyze 100 percent of the trace up to a certain stopping point, or have procedures in which their slide traverses do not allow for them to analyze the entire trace.

AIHA interprets advertising that states 100 percent of the trace is analyzed as implying that every spore is counted. It is unlikely that each fungal spore is counted and identified in heavily loaded samples. However, the advertising in question does not mention this fact. AIHA believes that this advertising is, therefore, misleading and will be paying special attention to this type of advertising when complaints are received.

In addition, we will be monitoring advertising in the *Synergist* for such claims and contacting laboratories to confirm their procedures before allowing the advertising to be included in the magazine. Please be aware if you advertise analysis of 100 percent of a spore trap sample that you should either indicate that this is being done for every sample or include a disclaimer in the advertising making the exception for heavily loaded traces.

If you have any questions about this information, please contact Pete Dragasakis, quality systems manager, at (703) 846-0799, or [pdragasakis@aiha.org](mailto:pdragasakis@aiha.org).

## LQAP Orientation and Training Held in February

AIHA's Laboratory Quality Assurance Programs (LQAP) held a successful orientation and training meeting in February that included the Analytical Accreditation Board, members of the Technical Advisory Panel, site assessors, and staff. Don Hart, vice president and AAB board coordinator, and Frank Renshaw, AIHA president-elect, were also in attendance. Highlights of the meeting include:

**Training:** All AAB and TAP members participated in a session to review: the LQAP and AIHA structures, policies, governance; the accreditation process; successful TAP reviews and site assessments; and findings from AIHA's PT audits. Participants also learned more about the new version of ISO/IEC 17025:2005. An orientation program for new TAP members provided an opportunity to receive overview training on ISO 1705:2005 and the AIHA accreditation.

**Site Assessment Dialogue:** LQAP site assessors met separately to discuss issues related to conducting site assessments and explore opportunities for improvement.

**NACLA Update:** Attendees were updated on AIHA's role as a recognized accreditation body by the National Cooperation for Laboratory Recognition (NACLA) and the status of AIHA's efforts to attain recognition by the International Laboratory Accreditation Cooperation (ILAC).

**Policy Discussions.** Pending LQAP policy issues were discussed and there was consensus on the next steps regarding policy revisions. A 2006 Policy Task Force will reconvene and use the work from the group discussions to begin revisions of the AIHA Accreditation Policies for 2007.

For more information contact LQAP Director, Cheryl O. Morton at (703) 846-0789 or [cmorton@aiha.org](mailto:cmorton@aiha.org)

### Mark Your Calendars

Keep the following deadlines in mind, and in your calendar, for 2006:

#### Industrial Hygiene Proficiency Analytical Testing Program Enrollment Deadlines

June 1, 2006 (Round 166)  
September 1, 2006 (Round 167)  
December 1, 2006 (Round 168)

#### Bulk Asbestos Proficiency Analytical Testing Program Enrollment Deadlines

April 25, 2006 (Round 67)  
July 25, 2006 (Round 68)  
October 15, 2006 (Round 69)

#### Beryllium Proficiency Analytical Testing Program Enrollment Deadlines

June 1, 2006 (Round 11)  
October 1, 2006 (Round 12)

#### Environmental Lead Proficiency Analytical Testing Program Enrollment Deadlines

April 15, 2006 (Round 55)  
July 15, 2006 (Round 56)  
October 15, 2006 (Round 57)

#### Environmental Lead-Air Proficiency Analytical Testing Program Enrollment Deadlines

June 1, 2006 (Round 56)  
September 1, 2006 (Round 57)  
December 1, 2006 (Round 58)

#### Environmental Microbiology-Culturable Proficiency Analytical Testing Program Enrollment Deadlines

May 15, 2006 (Round 30)  
September 15, 2006 (Round 31)  
January 15, 2007 (Round 32)

#### Environmental Microbiology-Direct Exam Proficiency Analytical Testing Program Enrollment Deadlines

June 15, 2006 (Round 7)  
September 15, 2006 (Round 8)  
December 15, 2006 (Round 9)

#### Environmental Microbiology-Culturable and Direct Exam Combinations Proficiency Analytical Testing Program Enrollment Deadlines

May 15, 2006 (Rounds 30 and 7)  
September 15, 2006 (Rounds 31 and 8)  
December 15, 2006 (Rounds 32 and 9)

#### Asbestos Analysts Registry Enrollment Deadlines

April 18, 2006 (Round 78)  
August 18, 2006 (Round 79)  
November 17, 2006 (Round 80)