



LQAP

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AIHA

March 2007 Issue

Get Ready for 2007 Policy Revisions

By Peter Dragasakis

On Jan. 3, AIHA published the 2007 LQAP Accreditation Policy Revision. As discussed in previous editions of the *LQAP News*, the policy revision will become effective April 1, 2007.

The revised policy modules were published in both clean (.pdf) and “track changes” (.doc) formats. In addition, a cross reference document was published that highlights the changes between the 2004 revision and the 2007 revision. The revisions can be found on the LQAP section of the AIHA website at: <http://www.aiha.org/LQAPdocuments.htm>.

The 2007 AIHA policy revision incorporates the ISO/IEC 17025:2005 revision by reference in Module 2A. On Oct. 3, 2006, an e-mail that included a link to an affidavit package was sent to all laboratories’ primary contacts.

The affidavit, which must be submitted by all accredited laboratories, states that you reviewed the changes and are committed to making the appropriate changes. Please review and submit that affidavit if you have not done so already. The affidavit is available online at: <http://www.aiha.org/LQAP.htm>.

It is important that all members of the laboratory who are responsible for maintaining the quality system review the 2007 changes. Many of the changes in the 2007 policy revision are minor (e.g., changes in grammar, numbering, etc.); however, others are substantive and will affect the laboratory and will be cited as

deficiencies if the laboratory is not in compliance by April 1.

One important note to keep in mind while reviewing the “track changes” documents is that just because a requirement looks as if it was deleted, that does not necessarily mean it is no longer a requirement. It may be a requirement of ISO 17025 that was found to be duplicative to include it as an additional AIHA requirement, or it may have moved to another section of the module. These instances will most often be the case in Policy Module 2A where we are laying additional requirements onto the 17025 requirements.

Some of the changes are discussed below. Please review the “track changes” documents or the cross-reference documents noted above to review all changes.

A Few Changes of Note

Aside from the incorporation of ISO 17025:2005 in Policy Module 2A (“General Quality System Requirements”), several other changes were made to this module. One change involves a clarification of who can perform the data review process required by Policy 2A.5.4.5.

Previously, the policy only stated that “the data review process shall be an independent review, conducted by a qualified individual other than the analyst.” The qualifications are now defined in Module 9 which states: “A qualified individual shall be defined as an individual that, minimally, has the education, experience and technical understanding of the work being reviewed.” This person may be an analyst, or, for example, a QAC that has never received the formal six-month

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AIHA Laboratory Accreditation Course Offered at AIHce Expanded to Two Days

AIHA's Laboratory Quality Assurance Programs is pleased to announce that it will repeat its Laboratory Accreditation Course at the 2007 AIHce Conference and Expo in Philadelphia. This year, however, the course is being expanded to two full: Sunday, June 3 and Monday, June 4.

Participants will get the necessary tools to navigate through both the AIHA laboratory accreditation process (including policy revisions that will go in effect in April 2007) and the new ISO 17025:2005. The course will be conducted by the chief site assessor for LQAP, Ron Peters of Peters Consulting.

Peters has been involved in hundreds of assessments and can help new and currently accredited laboratories learn about the application and assessment processes associated with AIHA accreditation or re-accreditation. By attending this course, labs seeking initial accreditation or re-accreditation will understand how the policy changes and the new ISO 17025:2005 requirements will affect their management systems, operations and documentation processes.

Persons who should attend this course include laboratory personnel responsible for:

- Preparing initial accreditation applications and re-accreditation applications for AIHA accreditation program for industrial hygiene, lead or microbiology
- Managing laboratory quality management systems
- Integrating ISO 17025:2005 with current laboratory quality management systems
- Training on the new ISO 17025:2005 standard

Register today to learn how to avoid the pitfalls associated with accreditation or simply to learn more about the new ISO 17025:2005. The cost for this year's expanded course is \$399 which includes a copy of the standard.

Visit <http://www.aiha.org/Content/CE/aihce/aihce-lb.htm> to register. For more information, please contact Cheryl O. Morton, director, LQAP at cmorton@aiha.org.

Reminder: ISO 17025:2005 Affidavits for Accredited Labs Due Soon

A list of changes between ISO/IEC 17025:1999 and ISO/IEC 17025:2005 was published by AIHA along with an affidavit you need to submit that states your commitment to being compliant with these policy changes. The deadline to submit the affidavit to AIHA is April 2007.

An e-mail was sent to all accredited labs with a link to the document. Hardcopies were sent to labs for which we received a non-delivery notice. If you have not yet received or downloaded the document, please do so. It is available online at www.aiha.org/LQAP.htm. After you download the affidavit, submit it to AIHA by the April 2007 deadline.

For more information on the affidavit, contact Pete Dragasakis, LQAP operations manager, at (703) 846-0799 or pdragasakis@aiha.org.

Get Ready for 2007 Policy Revisions

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training required to be a qualified analyst. This definition is referred to in several other places in the policies.

Other Module 2A changes include:

- External calibration services used by the laboratory must be accredited to 17025 whenever possible (2A.5.5.5).
- Final test reports must include date of sample receipt (2A.5.10.1.c), page numbers on each page, and either "x of y" page numbering or a clear indication of the end of the report to ensure that a customer is looking at a complete report (2A.5.10.1.d). [In addition, for microbiology reports, raw counts (2D.7.1) and analytical sensitivity (2D.7.2) shall be included when the results are quantitative.]

The policy specific modules have also seen numerous changes. For example,

Policy Module 2D covering EMLAP requirements has seen several changes including a new requirement that biological indicators (e.g. spore strips or ampoules) be used with steam sterilizers to document the sterilization process (2D.3.2.2.2), a revision of the equipment policy to cover magnification systems other than a compound optical microscope (2D.3.1.2), and the addition of specific requirements for spore trap round robin programs (6A.3.2 & 2D.6.3.2).

Another example of an important substantive change comes in Module 6B which covers proficiency testing requirements for industrial hygiene laboratories. Section 6B.3.3, which describes how an internal QC program can be developed as a demonstration of competency for fields of testing not covered by AIHA PT programs, is now more rigorous so that

this option is more analogous to participating in a third party proficiency testing program or round robin program. In addition, 6B.3.2 now requires that round robin programs used as a demonstration of competency meet certain requirements.

Policy Module 7, covering AIHA's requirements for laboratory advertising in reference to their types of accreditation, was almost entirely rewritten in order to eliminate some of the common advertising complaints that are received by AIHA.

These are not the only important changes in the 2007 policy revision. Please ensure that you review the changes, noting that they become effective on April 1. Should you have any questions, please send an e-mail to Pete Dragasakis, LQAP operations manager at pdragasakis@aiha.org.

LQAP Staffing Changes

AIHA welcomes two new Laboratory Quality Assurance Programs (LQAP) staff members and announces one position change:

- **Alex Reeder** joined the LQAP staff on Jan. 2 as laboratory accreditation specialist filling the position vacated by Chris Denhardt who resigned at the end of 2006. Reeder has a clinical laboratory background having received a B.S. medical technology from the University of Washington. She has worked as both a medical technologist and laboratory technician in several hospital laboratories. Reeder's laboratory experience and knowledge of microbiology and chemistry make her an outstanding addition to our staff and we expect to continue to make significant progress on our accreditation applications with her help.
- On Jan. 23, **Pete Dragasakis**, who was quality systems manager for the past 15 months, assumed the position of operations manager, LQAP. In taking on this newly-created position, Dragasakis will have an opportunity to fine-tune his already exceptional skills in operations-related work and better serve our laboratory customers. Dragasakis will also continue to support the quality systems efforts in LQAP.
- **Scott Goeringer, Ph.D.** joined the LQAP staff on Feb. 5 to take on the position of quality systems manager that was previously held by Dragasakis. Goeringer earned bachelors in chemistry and mathematics and both a masters in chemistry and a Ph.D. in analytical chemistry from the University of North Texas. He has considerable laboratory, auditing and quality systems experience and will be working to ensure that AIHA's quality management system complies with all applicable international standards by which AIHA is evaluated. Goeringer will also be available to address technical questions our laboratory customers.

We hope that our laboratory customers can see that AIHA is focusing on building staff capacity with these most recent hires and Dragasakis's new role. More information about how the staff will be organized and functioning will appear in a future edition of *LQAP News*.

For questions and/or additional information, please call LQAP Director Cheryl O. Morton at (703) 846-0789.

AIHA Recognition

The National Cooperation for Laboratory Accreditation Acceptance Panel met on Nov. 1, 2006 to deliberate on AIHA's status as a recognized accreditation body. Following formal interviews with Laboratory Quality Assurance Programs staff and a review of the NACLA Evaluation Team's report from AIHA's full evaluation (conducted in March 2006), the panel voted unanimously to continue to recognize AIHA's laboratory accreditation programs under NACLA.

LQAP staff will meet with NACLA officials again during the first quarter of 2007 to follow up on some non-conformances identified during the March 2006 evaluation. For more information about NACLA recognition, please contact LQAP Director Cheryl O. Morton at (703) 846-0789 or cmorton@aiha.org.

LQAP Undergoes Annual Internal Audit

In an effort to ensure its continued compliance with ISO requirements, AIHA's Laboratory Quality Assurance Programs annual internal audit was conducted. Chief Site Assessor Ron Peters (who was the Audit Team Leader), Analytical Accreditation Board Chair Jim Kenny and Site Assessor Fred Grunder made up the audit team. The audit was conducted against ISO/IEC 17011.

The limited number of non-conformances, concerns and comments that were identified are currently being addressing by LQAP staff. For more information on the internal audit, please contact Pete Dragasakis, operations manager at (703) 846-0799 or pdragasakis@aiha.org.

Mark Your Calendars

Please keep these dates that each PT kit ships on your calendar and notify AIHA if you do not receive your samples. Enrollment deadlines can be located in the 2007 LQAP Fee Schedule.

Industrial Hygiene Proficiency Analytical Testing Program (IHPAT)

168*	January 1, 2007
169	April 1, 2007
170*	July 1, 2007
171	October 1, 2007

* Includes Diffusive Samplers

Environmental Lead Proficiency Analytical Testing Program (ELPAT) (Air)

58	January 1, 2007
59	April 1, 2007
60	July 1, 2007
61	October 1, 2007

Environmental Lead Proficiency Analytical Testing Program (ELPAT) (Paint, Soil, Dust)

58	February 1, 2007
59	May 1, 2007
60	August 1, 2007
61	November 1, 2007

Bulk Asbestos Proficiency Analytical Testing Program (BAPAT)

70	February 15, 2007
71	May 15, 2007
72	August 15, 2007
73	November 15, 2007

Beryllium Proficiency Analytical Testing Program (BePAT)

13	March 1, 2007
14	July 2, 2007
15	November 1, 2007

Environmental Microbiology Proficiency Analytical Testing Program (EMPAT) (Culturable)

32	February 5, 2007
33	June 4, 2007
34	October 1, 2007

Environmental Microbiology Proficiency Analytical Testing Program (EMPAT) (Direct Exam)

9	January 8, 2007
10	April 9, 2007
11	July 9, 2007
12	October 8, 2007

Asbestos Analytical Testing (AAT)

81	March 1, 2007
82	June 1, 2007
83	September 1, 2007
84	December 1, 2007