

Summary of the NELAP Accreditation Council Meeting

December 7, 2015

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on Monday, December 7, 2015, for another of its series of assessor conversations. Attendance was not taken, except to note that of the NELAP Accreditation Bodies (ABs), FL, IL, KS, LA DEQ, LA DHH, MN, NH, NJ, NY, OR, PA, TX, UT and VA, plus OK, had representatives present, as well as Analytical Excellence, Dade Moeller, Sims & Associates, Richard Sheibley, Louis Wales and Wade Consulting and Solutions. Representatives from Arizona Department of Health's state certification program joined by invitation, since they were the first to raise the issue of remote data review within the APHL State Assessor Forum.

The AC's Vice Chair, Paul Bergeron of LA DEQ, introduced Ray Frederici of TestAmerica, Inc., for his presentation about remote data review, and then moderated the discussion afterwards. Ray had provided a PowerPoint presentation for participants' use as they listened to his presentation, which was circulated in advance. Larry Penfold of TestAmerica joined Ray in the discussion that followed the presentation.

The Formal Presentation

See the presentation in outline form in Attachment 1, and the PowerPoint file itself which accompanies the email distributing this summary.

Discussion

Since most of the discussion occurred in a Q&A format, that will be how this section is presented.

Q1: How does the lab's internal audit process integrate the offsite reviewers?

A1: They start with raw data and proceed to the finished product (the report.)

Q2: How will TestAmerica make the new corporate SOP regarding offsite data review clear in its quality system documentation?

A2: Not all TestAmerica labs use remote employees, but if they do, they must comply with the corporate SOP. They should mention it in the lab's QA Manual. Also, offsite analysts are so noted in the org chart. If not in current records (from prior assessment), these items will be updated prior to the next site visit.

Q3: How can an AB tell when one lab is using the corporate SOP or a local one?

A3: The corporate SOP is universal and must be used by every TestAmerica lab using offsite data review.

Q4: How can the AB tell whether org charts are up-to-date?

A4: The assessor should inquire for the latest org chart.

Q5: Are ABs being notified at the beginning of the use of remote data review, since there is a

requirement in the standard to notify the AB of any “significant change?”

A5: Remote staff are treated as any other new staff on-site.

Q6: LA DEQ has a requirement that separate locations require separate accreditations.

A6: Remote staff are part of the US fixed base site.

Further Discussion: Define these in the lab’s quality system documentation. Remote staff are not actually running analytical equipment (performing analyses) but are electronically linked to the fixed base site for access to analytical results for review. The data are not physically shipped off-site. This would seem no different than a “work from home” or US-based offsite work station.

Q7: How does TestAmerica quantitate pass/fail for the data review IDOCs? Is that defined in an IDOC SOP?

A7: Any communications, documents and discrepancies are noted before the supervisor signs off on the IDOC. TestAmerica has improved the documentation for this training.

Q8: What provision is made for an annual internal audit of the Thai facility?

A8: The Thai facility is not an individual lab, but rather a location where staff are assigned to use as designated workspace during their affiliation with a fixed base lab in the US. The Thai facility in Bangkok provides training for those remote staff and also the technology to connect to the US. The Operations Director in Bangkok is responsible for the physical facility and maintaining the technology in operational status.

Q9: Is there just the one remote facility in Bangkok?

A9: Yes, except for the occasional (rare) exception where an employee in the US reviews data for a facility different than the facility in which that employee is actually located.

Q10: How many people are involved?

A10: Fourteen labs use this remote option, typically with 1-2 people per lab. There are 40 people total in the Bangkok facility, but some are performing tasks not related to data review.

Q11: When a written document must be reviewed for training, which language is used?

A11: All data and training documents are in English. The Bangkok population is highly English-oriented. However, as with TestAmerica’s US-based labs, there are no hiring requirements based on English proficiency.

Q12: If the quality system requires reviewers to understand, how does TestAmerica verify that the reviewers understood the training?

A12: Successful completion and understanding of training are evaluated based on successful IDOCs, secondary reviews and auditing of the work (supervision.)

Q13: At least one state (PA) has state-specific reporting requirements with stringent time limits, for violations of some parameters. Are remote reviewers made aware of these requirements and how is it verified that reporting is accomplished?

A13: It is the responsibility of the US fixed-base lab to ensure that such reporting is accomplished, so that the Project Manager should be the individual spotting the data flags as

they are noted in the data system. It seems that a violation would be noticed sooner (i.e., overnight) with use of remote reviewers, rather than awaiting the following day for a US-based reviewer to spot it. The lab would need to contact the after-hours emergency number for the lab's client. Ray noted that the TestAmerica lab doing most drinking water analyses does not now use remote data reviewers, but agreed to check this situation out and get back to PA, the AB raising the question.

Q14: When will labs be contacting the AB (La DEQ) regarding adjustment of records about equipment? LA DEQ requires notification of purchase and use of any new equipment, not just analytical equipment.

A14: The TestAmerica presenters were surprised since the remote data reviewers are not using any special equipment or technology.

Other points made included:

For Individual Demonstration of Competency for remote reviewers, unlike with analysts running equipment, the data reviewer does not perform four LCS runs but rather four complete data package reviews. The IDOC data packages provided to the reviewers may be "rigged" by the lab QA Manager, with alterations to ensure that the reviewers can identify abnormalities in the data.

At least one assessor encountered language difficulties in interviewing a remote reviewer. TestAmerica relies on the Operations Director who is fluent in both English and the language of Thailand, and/or one of several Thai staff who are fluent in English as a second language, to assist, but admittedly there are challenges when interviewing a remote reviewer directly. Writing good English is not the same as speaking it, particularly in a highly technical conversation, but TestAmerica staff don't seem to encounter problems when using the available personnel to assist with translations.

There was some confusion about whether IDOCs are performed and maintained in the LIMS system of TestAmerica or on a separate SharePoint system.

A suggestion was offered that, even though remote data reviewers are "just lab staff," some labs have a variety of languages used by employees, and that offering training materials in the native language of the employee could reasonably be provided.

Paul thanked the TestAmerica presenters and indicated that if any others had questions, they should contact the Program Administrator, Lynn Bradley.

Next Meeting

The date for the next Assessor Call has not been set, but will likely be the first Monday in either March, April or May, depending on who volunteers to present for that program.

The next NELAP AC meeting will be Monday January 4, 2016, at 1:30 pm Eastern, and then again at conference in Tulsa during the last week of January 2016. As usual, an agenda and

teleconference information will be sent the week before the meeting.

Attachment 1 -- Accompanying PowerPoint presentation

Offsite Business Applications

Sawatdee (Hello)

"The World is Flat" (by Thomas L. Friedman)

The New Age of Connectivity (the rise of the Web)

This event "enabled more people to communicate and interact with more other people anywhere on the planet than ever before."

Work Flow Software

This force "enabled more people in more places to design, display, manage, and collaborate on business data previously handled manually," resulting in more work to be able to flow "between companies and continents faster than ever."

A flat world has enabled businesses to take specific, but limited, functions they are doing in-house and use offsite staff to perform those functions and integrate the work into the overall operation.

Offsite Staffing

Company employees, not contractors!

Essentially any business process that can be connected through the company's secure intranet site could be supported by staff working offsite, for example:

Data review/processing

Information Technology and Programming

Accounting/invoicing

Login and project setup review

Report assembly

Electronic data auditing

Quality Systems record keeping

There is no difference between staff located across the hall in the same building, in a separate building, in a different location in the U.S. or in a different country working offsite.

Offsite Data Processing (ODP)

ODP Principles

Company employees, not contractors!

Connected via secure network access to the same IT and analytical applications that the company uses in the U.S.

Offsite staff can only access these systems once they have been trained, granted authorization and when provided appropriate user permissions.

Software is web enabled, hosted by the company in the U.S. and does not reside on any offsite computer.

Security, user access and permission, as well as electronic data storage are maintained and controlled by the company's Information Technology (IT) staff in U.S. facilities.

When the offsite staff work on any business system, they are deployed as a member of that business unit or laboratory organization

For example, an offsite data reviewer processing organics data receives basic training from staff at the offsite facility and then receives additional laboratory specific training in procedures, policies and client programs specific to the base lab.

The offsite reviewer's training is documented by the base laboratory facility and when qualified, reports to the laboratory and is listed on the laboratory's organization chart.

Instructions, work critique, auditing and demonstration of competency/capability are performed as a data reviewer of the U.S. facility.

Employing ODP staff

Offsite Operations Director, U.S. citizen

76% B.S. degrees

24% M.S. degrees
80% B.S. or M.S. in Chemistry
20% Other related BS or MS science degrees
Microbiology, Biology or Food/Agricultural Sciences (with >20 semester hrs of chemistry course work)
All have GCMS, GC, LC/MS/MS or HPLC experience and are experts in data review
Offsite analysts are dedicated to data review

ODP Benefit

Proven to improve the quality of laboratory reports
Improved analysis turn around time
Improved client satisfaction
Provides an expanded human resource talent pool
Minimizes limitations of geographic resource shortages
Maximizes the number of data reviewers working during a 24 hour period

Relationship of Offsite Data Review to Base U.S. Labs

Following initial training and implementation, offsite data reviewers are assigned as regular staff members of the U.S. lab they work for
Establishing offsite capability and authorization to begin work is the responsibility of the U.S. lab
Responsibility for maintenance of training records is with the U.S. lab's QA group
The U.S. lab has final responsibility for the data regardless of who performs the data review, whether by their onsite operations group or offsite data reviewers
The responsibility for initiating corrective actions is with the U.S. lab, just as it would for any other department within that laboratory

ODP Extensive One Month Training Plan,

for already highly experienced degreed scientists with analytical experience

Days 1 – 5

Read SOP's and Work Instructions
Corp Ethics, MI and IT training

Day 6 – 10

Sit with trainer and learn LIMS modules
Software and LIMS training

Day 11 – 13

Trainee performs hands on work with direct oversight to demonstrate knowledge of LIMS modules

Reviewer lab and/method transfer

SOPs to be posted to a secure SharePoint site
Read & Understand procedures signed by offsite staff
Base EPA method read
Confirmation of go-ahead by offsite location
Batches sent for IDOCs
Review starts at low volume once IDOCs approved
Feedback process occurs for mentoring the reviewer
U.S. lab supervisor continues oversight of the offsite data reviewer's work product the same as any analysts at the U.S. lab

Offsite Staff SharePoint Site

Offsite staff photos
Data review training documents
Offsite QA documents
Lab specific and client specific SOPs and WIs
Schedule Announcements
Vacations
Holidays

U.S. QA Role

SOPs

Follow company SOP on "Data Processing Using Offsite Analyst"

Post relevant method SOPs to the secure SharePoint site

Post relevant client requirements and Lab specific documents to the secure SharePoint site

LIMS Secure Access

Authorizes offsite data reviewers and sets appropriate permissions in LIMS

Signatures

Posts data reviewer signatures in the LIMS under their user profile for security and protection

Lab Org Chart

Add offsite staff to the laboratory's Organization Chart

Data Review Checklists

Post to Share Point site the updated data review checklists and remove outdated versions

Controlled Locations

SharePoint site added to the U.S. labs document control system to ensure latest document versions are posted at all times

Method Audits

Audits performed on offsite data reviewer and methods the same as any other data reviewer in the U.S. lab

Stop Work Authority

Has full authority to stop work for any methods at any time

Offsite QA Role

Corporate Policy Training

Provides and documents training on:

Ethics and Data Integrity Policy

Manual Integration

IT policies and security

Analyst Assignment

Provide details of reviewer(s) assigned to each lab to the U.S. QA Manager

Maintain Analyst IDOC/CDOC status

Training Records

LIMS authorizations and permissions

Initial Demonstration of Capability (IDOC)

IDOCs are:

To be completed by each offsite reviewer

To be completed for each lab they work for

To be completed per each lab's SOP

Performed on at least 4 batches of data

Final approval of demonstration of capability and authorization to perform work is completed by the U.S. lab

Communication

Communication between offsite data reviewers and U.S. staff is critical for success

The U.S. lab holds primary responsibility for providing routine feedback to offsite data reviewers

The LIMS Non-Conformance Memo (NCM) is utilized to record errors or analytical observations

Email is utilized to provide further training, suggestions, or elaboration of lab and client specific information

Re-training will occur if trends or consistent errors occur

Senior staff will re-train

Screenshots and actual examples are used to assist in the training

Corrective Action Requests (CARs)

QA Managers at the testing lab are responsible for initiating a formal CAR for on-going systematic problems

Process is the same as a CAR process started for any other section of the lab

Enter the issue into the central corrective action tracking system

Generate a CAR report describing the problem with supporting evidence

Like any other operational group in the lab, offsite staff are responsible for adding to the CAR the results of their

investigation and proposed corrective action plan
Final corrective action plan is mutual agreement of all the parties involved
Corporate QA resolves any disagreements

FAQs

Who holds responsibility for the final data?

Final responsibility of the data lies with the U.S. lab, regardless of who performs the data review.
The offsite data reviewers are staff members of the U.S. labs they work for.

Can offsite staff be interviewed?

Yes, just like a second shift analyst at any laboratory
Arrangements can be made to have offsite staff available for interviews. Typically this would occur through a Skype or other similar web communication application.

In Conclusion

Offsite data review is performed by company employees, not contractors!
Offsite reviewers are highly educated degreed scientists and predominantly degreed chemists
Staff with non-chemistry degrees have >20 hrs chemistry course work
Extensive training and competency is demonstrated prior to being certified and authorized to perform work
The U.S. Lab is responsible for the offsite data reviewers work product

In Conclusion

Quality has improved with the increased use of the offsite data review, this includes:

Improved quality of laboratory reports
Improved analysis turn around time
Improved client satisfaction
Minimizes limitations of geographic resource shortages
Maximizes the number of data reviewers working during a 24 hour period

Questions?