ISO 17025 Key Elements, Accreditation Strategy, and Gas Chromatography Training for DACA Product Quality and Assessment Directorate

Addis Ababa, Ethiopia
March 5-19, 2010

Trip Report

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

Abstract

The PQM team traveled to Ethiopia to conduct training on ISO 17025 standards in the Product Quality Assessment Directorate (PQAD) of the Drug Administration and Control Authority (DACA). Prior to the training, a gap analysis for compliance to ISO 17025 was performed and an Assessment Document was developed. The PQM team used the results of the assessment as a guide in training the PQAD staff on key elements of ISO 17025. In addition, the team interacted with PQAD staff and facilitated the implementation of some of the key ISO 17025 elements, including SOPs. Training in Gas Chromatography was provided to the PQAD analysts during this visit as well.

Key Words

ISO 17025, Quality Management System, Standard Operating Procedures, Accreditation, Gas Chromatography, DACA, Product Quality and Assessment Directorate

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ACRONYMS

API	Active Pharmaceutical Ingredient
DACA	Drug Administration and Control Authority of Ethiopia
DQI	Drug Quality and Information program
GC	Gas Chromatography
GLP	Good Laboratory Practices
ISO	International Organization for Standardization
JD	Job Description
MCP	Malaria Control Program
MOH	Ministry of Health
MQM	Medicine Quality Monitoring
NGO	Non-governmental organization
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQAD	Product Quality Assessment Directorate
PQM	The Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
USP	United States Pharmacopeia

Background

In 2010, PQM received funding from the President's Emergency Plan for AIDS Relief (PEPFAR) program through USAID/Ethiopia to strengthen DACA's capacity and an implementation plan listing all activities and deliverables for FY10 was drafted. The activities are divided into three areas: strengthening drug registration practices; training and preparing the QC lab for International Organization for Standardization (ISO) 17025 standards; and creating an accreditation plan for the QC lab to meet ISO 17025 in two years. All three objectives involve purchase, upgrade, or servicing of equipment and supplies.

Purpose of Trip

Members of the PQM team had different objectives for this trip:

Mr. Steven Lane

- Conduct a gap analysis of compliance to ISO 17025-2005 standard
- Meet staff in Drug Control Authority
- Train all staff on an overview of ISO programs and implementation strategy
- Establish ongoing schedule of communication
- Communicate process and timeline for accreditation

Dr. Daniel Bempong

- Provide assistance in addressing Good Laboratory Practices (GLP) gaps identified during previous PQM scientists' visits
- Facilitate implementation of key ISO 17025 requirements
- Provide resources for equipment maintenance and calibration
- Interact with analysts in their normal working environment and facilitate integration of previous trainings into daily activities
- Provide training on the analytical technique Gas Chromatography (GC)

Source of Funding

These activities were funded by USAID/Ethiopia, PEPFAR program

Overview of Activities

PART I: ISO 17025 Key Elements/Accreditation Strategy

Monday, March 8, 2010

A brief meeting was held between the PQM team; the Director of Product Quality Assessment Directorate (PQAD), Mr. Bikila Bayissa; and the Quality Assurance (QA) Manager, Mr. Awot G. Egziaber to discuss the agenda for the week. The group agreed that a gap analysis related to ISO 17025 needed to be done first so as to focus the training on the areas of highest need. After the meeting, the PQM team toured the PQAD laboratory facility, including sample receipt and storage, analytical chemistry, toxicology, and microbiology areas.

Led by Mr. Lane, the PQM team conducted gap analysis and reviewed all systems that are currently in place at PQAD with the QA manager. An ISO 17025 Assessment Document, consisting of questions and answers (*See **Annex 4***), was developed for the lab. The rest of the day was spent with the QA manager discussing ISO requirements and potential systems and methods to meet the requirements.

Tuesday, March 9, 2010

The PQM team met briefly with Mr. Bikila Bayissa to discuss the scope of accreditation for PQAD. The group agreed that the initial scope will cover "analytical testing of medicine products" (or similar) and will include these specifics (these suggestions are not final):

- Spectroscopic Identification
- Chromatography (HPLC, GC, TLC)
- Dissolution
- Loss on Drying (LOD)
- Titrimetry
- Water determination

The Director General of DACA, Mr. Yehelu; his deputy, Mr. Mengistab; and USP Consultant, Dr. Wondemagegenehu visited the lab, and Mr. Lane and Dr. Bempong briefed them on their respective objectives for this visit and also provided an overview of the training. Plans for future PQM trainings were also discussed at this meeting.

Mr. Lane began the training series on ISO 17025 Key Elements and completed the following sessions:

- Introduction and Overview of ISO 17025 requirements
- ISO Compliant Document Management
- ISO compliant Training and Competency Program

All 22 laboratory staff participated in this training. The staff was very engaged and asked many questions.

Wednesday, March 10, 2010

Mr. Lane continued the ISO 17025 Key Elements training and completed the following topics:

- Auditing
- Equipment Management Program (Validation and Calibration)
- Assuring the Quality of Laboratory Test results

The afternoon was dedicated to discussing the questions that an ISO auditor might ask. The ISO 17025 Assessment Document developed for the lab was used as a tool for this presentation.

To facilitate the development of key quality system documents for the lab, Mr. Lane provided copies of the following documents to the QA manager:

- 13 SOP templates for ISO compliant programs
- The ISO 17025-2005 Guide
- The WHO Guide QAS 09.296
- ISO 17025 Audit Checklist
- An integrated ISO 17025/ WHO QAS 09.296 workbook

Based on a request from the Microbiology Team Coordinator, Mr. Lane provided copies of the following microbiology SOP templates to PQAD:

- Preservative Effectiveness Testing
- Microbial Limits Testing
- Non-Sterile Microbial Limits Testing
- Sterility Testing
- Bacterial Endotoxin Analysis

The PQM team held discussions with the PQAD director on the following issues:

- A formal accreditation audit needs to be conducted immediately after relocation to the new building
- Weekly or bi-weekly teleconferences/communication with the QA manager will take place to update progress and modify assignment responsibilities
- Monthly reports on progress of ISO accreditation will be provided to the PQAD director and his two immediate supervisors, at the director's request

Mr. Lane left the following assignments for the QA manager to be completed by March 18, 2010:

- Complete a reconciliation of SOP drafts that were provided by Mr. Lane with drafts that the lab had already written, to assure all requirements are met
- Prepare document history files and assure that all controlled documents have the appropriate records in the files, as the SOP requires
- Prepare training files for all staff and begin to assemble required documents for these files

Thursday & Friday, March 11-12, 2010

Document Management and Control

Dr. Bempong worked with the QA manager to draft the following key ISO 17025 documents, take the documents through the PQAD SOP approval process, and finalize the documents for implementation:

- Document Management SOP
- Document Control Change Request Form
- Document History Form
- Document Change Request Log
- Biennial Review of SOPs Form
- Document History Forms for the 11 SOPs now in use at PQAD

These are required for the control and management of all ISO 17025 related documents.

Personnel Training/Training Files
The existing Training Form was extensively revised. Separate training forms were developed for individual/group training, and creation of individual training files was initiated:

- PQAD Training Form (Individual)
- PQAD Training Form (Group)
- Creation of individual staff Training Files for PQAD staff

Monday, March 15, 2010

Gas Chromatography – Basics, Application in Pharmaceutical Analyses, and Troubleshooting Common Problems

Dr. Bempong taught the GC course, and a total of 14 PQAD analysts took the course, as only 3 analysts from the group have had prior GC experience. A comprehensive training was provided to the group on the following aspects of GC:

- Basic theory, detailed description, and functions of GC system components and instrumentation
- Application of GC in pharmaceutical analyses including determination of Residual Solvents (USP General Chapter <467>)
- Troubleshooting common problems encountered in GC Analyses

Hands-on GC training is planned for the next PQM scientist visit and input was solicited from the analysts regarding hands-on training that will most benefit the group. The analysts suggested hands-on practical training demonstrating how to solve common GC problems.

Tuesday, March 16, 2010

Dr. Bempong interacted with several of the PQAD analysts during normal work day conditions. The goal was to understand better the workflow process in the lab, talk to analysts to determine how well previous trainings in GLP have been incorporated into daily routines, and provide practical recommendations based on these interactions. The following recommendations were provided to the PQAD director and the QA manager:

- Analysts should be required to have a written and approved testing plan/protocol before beginning sample testing. This would ensure the required tests are performed and are performed in the correct manner. A Plan Writing SOP was drafted and provided to the QA manager.
- Analysts need to perform concurrent determination of water content of samples used as reference material during assay and related analysis.
- Team coordinators need to check that lab notebooks are properly completed, as part of testing data review process
- Spreadsheets that are used to calculate testing data need to be validated. A Spreadsheet Validation SOP was drafted, discussed with the QA manager, and is ready for approval.

Wednesday, March 17, 2010

PQAD Chemical Inventory Database

An action item from the previous PQM scientist visit was for PQM to provide PQAD with a Microsoft Access database to strengthen the chemical inventory system. PQM scientists completed the database containing information on the approximately 1,000 chemicals available at PQAD. Dr. Bempong provided training on the use of the database to the QA Manager and the Chemical Store Manager/Sample Officer. The Store Manager, with assistance from the QA Manager, is to name the various sections of the PQAD chemical storage rooms. After the sections have been clearly identified, the Store Manager will update the database with location information for all chemicals. The Store Manager and QA Manager will then train all analysts on the use of this database.

Laboratory Safety

A Laboratory Safety Team tasked with overseeing all aspects of safety in PQAD was created. Dr. Bempong trained the team on laboratory safety and good laboratory housekeeping practices. Dr. Bempong drafted three laboratory safety SOPs and trained the Safety Team on them. The Team is tasked with providing training for their peers and ensuring these safety SOPs are effectively implemented in the lab. The three SOPs are:

- Lab Protective Clothing and Hygiene Practices
- Eye Protection Policy
- Chemical Waste Disposal Policy

Meeting with PEPFAR

Dr. Bempong met with Ms. Elina Sverdlova, PEPFAR logistics advisor, and gave a short overview of the training the PQM team is providing during this visit. Ms. Sverdlova asked if trainings provided during previous visits have made recognizable differences in the way things are done at PQAD and also if the lab is ready to analyze antiretrovirals. Dr. Bempong briefed her on the strengths of the lab, emphasizing that the trainings are making significant difference in the lab, but that there are still things that need to be in place before the lab can formally seek ISO17025 accreditation.

Thursday, March 18, 2010

Equipment Maintenance

Dr. Bempong demonstrated how to access videos that provide step-by-step procedures for performing preventive maintenance from the websites of HPLC equipment manufacturers. Information was provided to the Equipment Maintenance Team on how to access these videos for Shimadzu and Agilent HPLC systems. The Team was also provided with a schedule for performing preventive maintenance on these systems.

Dr. Bempong met with the with the physico-chemical unit team coordinator to discuss the coordinator's role in implementing recommendations for ensuring testing data reliability and other recommendations outlined in this report. As the person with responsibility for most of the analysts and most of the testing performed in the lab, the team coordinator's role in ensuring the analysts incorporate GLP in their daily activities is very important. Specific recommendations regarding data review, proper use of notebooks, and notebook checks were also discussed.

Friday, March 19, 2010

Equipment Calibration

Dr. Bempong trained a member of the Equipment Maintenance Team on how to perform validation of automatic titrator burettes. He provided a draft SOP and the required Form (worksheet) for the procedure and asked the Team to adapt the draft SOP to PQAD conditions. The analyst should perform a yearly validation of the burettes in the lab following instructions in the SOP.

Action Items from Previous PQM Scientist Visit

The following supplies/materials identified from the previous PQM scientists visit were delivered to PQAD during this visit:

- Laboratory equipment logbooks and blank labels
- Microsoft Access database to strengthen PQAD's chemical inventory system
- Supplies to strengthen PQAD's lab cleaning program
- Safety signs and supplies

Dr. Bempong met with the PQAD Director and outlined what was accomplished during this visit and plans for the next visit. An interim report summarizing accomplishments and recommendations was provided to the Director.

Next Steps

The main issues discovered during this visit will form a priority list of things to work on during the next visit:

- According to ISO, the lab needs a protocol or SOP for selecting suppliers. Being a government lab, they actually have no control over the purchasing and selection of vendors as this is done by a different agency within the government. Plan to discuss with ACLASS.
- There appear to be several technical issues that need resolving prior to formalizing method SOPs. Examples were, the acceptable %RSD for replicate injections on HPLC, consistency in application of response factors, injection sequences for chromatography, and proper "check weighing" for balances.
- Reference materials seem also to be an issue. The current practice is to receive the active pharmaceutical ingredient (API) from the sponsor of the medicine product and use it, without any further characterization, to analyze the medicine. It is possible that the same API is used as both the standard and the active ingredient in the medicine, which everyone agreed is not acceptable practice. We will develop some type of characterization process to verify labeled potency.
- Current practice is to receive methods from a manufacturer and use them without any verification of their performance in the lab. The PQAD Director wishes to change this to requiring method verification prior to use, at a minimum.
- Follow-up training in hands-on GC and Infrared spectrophotometry is needed
- An ongoing schedule of communication with PQAD to provide guidance on implementation of elements of ISO 17025 and GLP needs to be established

Annex 1

List of Participants

Addis Ababa, Ethiopia – March 5-19, 2010

Serial No.	Name of Staff	GC	ISO
1	**Afework Abebe**		√
2	**Asnakeach Alemu**	√	√
3	**Awot G/egziaber**	√	√
4	**Bekele Tefere**	√	√
5	**Beletu Abate**		√
6	**Getachew Genete**	√	√
7	**Getahun Bekele**		√
8	**Girum Habte**	√	√
9	**Habtamu Beyene**	√	√
10	**Habtamu Heailu**	√	√
11	**Henok Alebachew**	√	√
12	**Heran Gerba**	√	√
13	**Kalab Tesfaye**		√
14	**Lantider Kassaye**	√	√
15	**Meaza Kassa**	√	√
16	**Mohammedamin Jemal**	√	√
17	**Nebyou Yigezu**		√
18	**Nigussu Dadi**		√
19	**Seyoum Wolde**	√	√
20	**Tamrat Tesfaye**	√	√
21	**Teferi Mentageftot**	√	√
22	**Tekelegn H/Mariam**	√	√
23	**Yenenesh Kessaye**	√	√

√ = participated

Annex 2

Evaluation by Participants

ISO 17025 Key Elements/Accreditation Strategy Training

Participants will be given evaluation forms at the beginning and asked to rate each module's educational materials and associated activities. Participants will be asked to rate all categories that apply.

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Course objectives were relevant to my needs	14	2	
2. I was able to understand the content of the materials presented	11	5	
3. Overall the course was useful and will help me do my job better	13	3	
4. There were enough practical exercises to facilitate understanding of the course	1	3	7
5. The pacing of sessions was appropriate for my understanding of course materials	7	7	1
6. The instructors were knowledgeable on the subject	13	3	
7. The instructors allowed an appropriate level of participation in the class	12	4	

Any other comments/suggestions:

1. Which topic(s) or aspects of the course should not be included in future workshops?
    - Definition of terms

2. What are your recommendations/suggestions for improvement of the course?
    - Practical exercises
    - Measurement Uncertainty
    - Proficiency Testing
    - Increase the time for the training

The participant evaluations and experience of the facilitators during the course will be used to update the training materials at a later date.

Evaluation by Participants

Gas Chromatography Training - Lecture

Participants will be given evaluation forms at the beginning and asked to rate each module's educational materials and associated activities. Participants will be asked to rate all categories that apply.

Indicator	Strongly Agree	Agree	Disagree Somewhat
8. Course objectives were relevant to my needs	11	2	1
9. I was able to understand the content of the materials presented	9	5	
10. Overall the course was useful and will help me do my job better	12	2	
11. There were enough practical exercises to facilitate understanding of the course		3	7
12. The pacing of sessions was appropriate for my understanding of course materials	9	4	
13. The instructors were knowledgeable on the subject	10	4	
14. The instructors allowed an appropriate level of participation in the class	12	2	

Any other comments/suggestions:

3. Which topic(s) or aspects of the course should not be included in future workshops?
    - None, all topics important

4. What are your recommendations/suggestions for improvement of the course?
    - Practical, hands-on application
    - Common problems encountered

The participant evaluations and experience of the facilitators during the course will be used to update the training materials at a later date.

Annex 3

List of Supplies Sent to DACA Product Quality and Assessment Directorate

UNITS	COUNTRY OF MFG	DESCRIPTION OF GOODS	UNIT VALUE	SUB TOTAL
6	USA	BRUSHES, DISHWASHING	$8.50	$51.00
16	USA	PENS	$0.50	$16.00
6	USA	DISSOLUTION VESSELS, 1 LITER	$80.50	$483.00
3	USA	PIPET BULB FILLER	$11.37	$34.11
12	USA	PIPET, 0.5 ML	$6.61	$79.32
12	USA	PIPET, 1 ML	$7.10	$82.50
12	USA	PIPET, 2 ML	$7.17	$86.04
12	USA	PIPET, 5 ML	$7.17	$82.20
12	USA	PIPET, 10 ML	$7.72	$92.64
30	USA	TRAINING MANUALS	$2.00	$60.00
1	USA	BLANK NOTEBOOK	$1.00	$1.00
4	USA	NOTE PAPER	$0.25	$1.00
1	USA	PENS, MARKING	1.00	$1.00
50	USA	LAB SAFETY SIGN LABELS	$0.25	$30.00
20	USA	LOG BOOKS	$5.13	$102.60
12	USA	BRUSHES	$5.25	$63.00
19	USA	SAFETY GLASSES	$7.53	$150.60
2	USA	GAS CYLINDER MOUNTING BRACKET	$43.78	$87.56
12	USA	FLASK, 5 ML	$13.97	$167.64
12	USA	FLASK, 10 ML	$13.85	$166.20
12	USA	FLASK, 50 ML	$27.83	$333.96
12	USA	FLASK, 100 ML	$28.66	$343.92
12	USA	FLASK, 250 ML	$36.32	$435.84
12	USA	FLACK, 500 ML	$52.83	$633.96
12	USA	FLASK, 1000 ML	$63.37	$760.44
6	USA	PIPET, 0.5 ML	$6.61	$39.66
6	USA	PIPET, 1 ML	$7.10	$42.60
6	USA	PIPET, 2 ML	$7.17	$43.02
6	USA	PIPET, 5 ML	$7.10	$42.60
6	USA	PIPET, 10 ML	$7.72	$46.32
12	USA	PIPET, 15 ML	$9.63	$115.56
12	USA	PIPET, 25 ML	$10.90	$130.80
12	USA	PIPET, 50 ML	$19.30	$231.60
3	USA	PIPET FILLER BULB	$11.37	$34.11
1	USA	PIPET WASHER	$474.45	$474.45
60	USA	LAB SAFETY SIGN LABELS	$0.60	$30.00
12	USA	LOG BOOKS	$5.13	$61.56

Annex 4

ISO 17025 Assessment

4. Organization/Management

4.1.1

Is the laboratory/parent organization an entity that can be held legally responsible?

Yes, find legislation or government requirement for the lab.

4.1.2

Is the laboratory carrying out testing/calibration activities to meet the requirements of the International Standard and satisfying the needs of customers, regulatory authorities, or organizations providing recognition?

For now, all work is done at this location

4.1.3

Does the laboratory's management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary/mobile facilities?

Yes, only this site is included as not work is outsourced at this time

4.1.4

If the laboratory is part of an organization performing activities other than testing or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on testing or calibration activities defined in order to identify potential conflicts of interest?

This is not applicable to this laboratory; no other functions are carried out.

4.1.5

Does the laboratory:

(i) 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, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures?

Yes, see organizational chart and job descriptions

(ii) have arrangements to ensure management and personnel are free from any undue internal/external commercial, financial and other pressures and influences that may adversely affect the quality of their work?

Need policy and records for conflict disclosures.

(iii) have policies and procedures to ensure protection of customers' confidential information and proprietary rights, including procedures for protecting electronic storage and transmission of results?

In practice but need written policy

(iv) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity?

Need "Whistleblower policy" as well as conflict disclosure policy

(v) define the organization and management structure of the laboratory, its place in any parent organization, and relationships among quality management, technical operations, and support services?

Need to work on org. chart - both within government and within lab.

(vi) specify the responsibility, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the quality of tests/calibrations?

- provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each test and/or calibration, and with the assessment of the test or calibration results?

These will be in the job descriptions (JD). Current JD are not in English, need to translate.

(vii) have technical management which has overall responsibility for technical operations and the provision of the resources needed to ensure the required quality of laboratory operations?
Yes, described in job descriptions. Provision of resources will tie in the annual planning and quarterly review of budget processes

(viii) have a member of staff who is appointed as quality manager (however named) who, irrespective of other duties and responsibilities, has the defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times;
A Quality Manager has been designated. Ensure that all requirements are met in his JD.

(ix) does the quality manager have direct access to the highest level of management at which decisions are made on laboratory policy or resources?
Yes, this will be demonstrated by the organizational chart.

(x) have deputies appointed for key managerial personnel?
Similar to signature authority or letter of delegation.

(xi) 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?
This will be done through training with staff on how everyone contributes

4.1.Z1
Does the laboratory have a member of staff who is appointed as technical manager who has overall responsibility for the technical operations?
Team coordinator, job descriptions must include this. Lab has a team coordinator for each of the 3 units - Physico-chemical, Toxicology, and Microbiology.

4.1.6
Does top management ensure that appropriate communication processes are established in the laboratory and that communication occurs regarding the effectiveness of the management system?
Management reviews and quarterly reviews

4.2 Management System
4.2.1
(i) Has the laboratory established, implemented, and maintained a management system appropriate to the scope of its activities?
Yes, established through SOPs, implemented and managed through audits and management reviews

(ii) Has the lab documented its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the test/calibration results?
Yes, see SOP master index

(iii) Is the system's documentation communicated to, understood by, available to, and implemented by appropriate personnel?
Yes, refer to training program and personnel training files

4.2.2
(i) Are the laboratory's management system policies defined in a quality manual (however named), including a quality policy statement?
Yes, ensure quality policy statement is included in the quality manual

(ii) Are overall objectives established in the management system and reviewed during management review?
We need some work on developing and communicating performance objectives

(iii) Is the quality policy statement issued under the authority of top management?
Verify that the quality policy statement exists in the QM. Yes, through the Quality Manual which is approved by the top management.

(iv) Does the quality policy statement include at least the following:
laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers?
- management's statement of the laboratory's standard of service?
- the purpose of the management system related to quality?
- a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work?
- laboratory management's commitment to comply with the International Standard and to continually improve the effectiveness of the management system?
We need some work here to meet all these requirements

4.2.3
Does evidence exist showing top management is committed to the development and implementation of the management system and to continually improving its effectiveness?
We will develop a "Quality Charter" to demonstrate this commitment.

4.2.4
Does top management communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements?
Annual planning and notification to all staff. Quarterly implementation of annual plan reporting to all staff

4.2.Z.2
(i) Does the quality manual or related documentation contain a description of the organization and management structure of the laboratory, its place in any parent organization, and related organization charts?
This will be included or referenced in the quality manual

(ii) Does the quality manual or related documentation identify the laboratory's approved signatories (where this concept is appropriate)?
Yes, there is a list of approved signatories for the quality manual

4.2.5
(i) Does the quality manual include or make reference to supporting procedures including technical procedures?
We will reference internal procedures for technical requirements as they are available or drafted.

(ii) Does the quality manual outline the structure of documentation used in the management system?
Yes, currently according to the ISO 17025 guide itself. We need to add reference to our internal SOPS.

4.2.6
Are the roles/responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the International Standard, defined in the quality manual?
Not yet, we can either reference these job descriptions, or describe them in the quality manual. I prefer referencing so we won't have 2 documents to update should there be changes.

4.2.7
Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?
Yes, through extensive review of changes through the document change SOP as well as routine auditing of the program through the auditing SOP. These will be reviewed at management reviews

4.2 A.1
Does the quality manual cover field (on-site) operations, where applicable?
Not applicable

4.2 A.2
Has the laboratory identified the specific calibration(s) and/or test(s) conducted in the field (on-site) and/or at satellite sites? This information is needed for the scope of accreditation.
Not applicable

4.2 A.3
Is the quality manual available to personnel at the satellite site(s) and does it include details of how the quality system is applied to satellite site(s)? These details shall include at a minimum:

- Arrangements for supervision of the satellite site(s) where the site(s) is not controlled by the corporate organization
- Organizational chart of the corporate organization showing lines of responsibility and authority of the satellite sites.

Not applicable

4.2 A.4
For organizations performing field (on-site) calibrations or maintaining satellite site(s), are the calibration and/or test reports/certificates issued from the corporate site?
Not applicable

4.3 Document Control
4.3.1 General
Does the laboratory establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test/calibration methods, as well as drawings, software, specifications, instructions, and manuals?
Do have draft. Need to review.

4.3.2 Document Approval/Issue
4.3.2.1
Are all documents issued to personnel in the lab as part of the management system reviewed and approved for use by authorized personnel prior to issue?
Is a master list or an equivalent document control procedure identifying current revision status and distribution of documents in the management system established and readily available to preclude use of invalid and/or obsolete documents?
Have electronic copy. Need to reconcile with SL's Documents needed list and add other items such as JDs.

4.3.2.2 Will the procedure(s) adopted ensure that:

- authorized editions of appropriate documents are available at all locations where operations essential to effective functioning of the laboratory are performed?
- documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements?
- invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?

Need to ensure that all these bullets are included in the document management SOP.

4.3.2.3
(i) Are management system documents generated by the lab uniquely identified?
Yes, each is given a unique document number.

(ii) Does such identification include the date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority?
Date of issue is included in the header, pages are numbered, need to add total number of pages.
Need to formally identify "Effective Date"

4.3.3 Document Changes
4.3.3.1
Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise?
Do designated personnel have access to pertinent background information upon which to base their review and approval?
Need definition of who has to approve each SOP as a minimum, to be added to the document management SOP

4.3.3.2
Is the altered or new text identified in the document or appropriate attachments?
When a document is being revised, the approval packet will show changes.
We need to work on this to make sure it is clear. This can either be handwritten corrections or "track changes" in MS Word.

4.3.3.3
If the lab's documentation control system allows for amendment of documents by hand pending re-issue of documents, are procedures and authorities for such amendments defined?
This will not be applicable as it isn't allowed. Immediate changes may be done through the deviation program. Need to reconcile this with the non-conformity SOP.

Are amendments clearly marked, initialed, and dated?
Is a revised document formally re-issued as soon as practicable?
Yes, amendments will be clearly communicated, trained on, and re-issued as soon as practicable.

4.3.3.4
Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?
Need to define what the "Official" documents are. Are they the paper or electronic copies?

4.4 Review of Requests/Tenders/Contracts
4.4.1

Does the laboratory establish and maintain procedures for review of requests, tenders, and contracts? Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that:
- requirements, including methods to be used, are adequately defined, documented, and understood (see 5.4.2)?
- the laboratory has the capability and resources to meet the requirements?
- the appropriate test and/or calibration method is selected and capable of meeting customers' requirements (see 5.4.2)?
- Are any differences between the request or tender and the contract resolved before any work commences? Is each contract acceptable to both the laboratory and the customer?

4.4.2
Are records of review, including any significant changes, maintained?
Are records maintained of pertinent discussions with a customer relating to the customer's requirements or results of the work during the period of execution of the contract?

4.4.3
Does the review also cover any work that is subcontracted by the lab?
Not applicable, the lab doesn't subcontract work.

4.4.4
Is the customer informed of any deviation from the contract?

4.4.5
If a contract needs to be amended after work has commenced, is the same contract review process repeated and are any amendments communicated to all affected personnel?
There seems to be an informal process for review of requests, tenders, contracts. We will need to formalize and document the review and assign responsibility.

4.5 Subcontracting of Tests/Calibrations

4.5.1
When a laboratory subcontracts work whether because of unforeseen reasons or on a continuing basis is work placed with a competent subcontractor?

4.5.2
Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer?

4.5.3
Is the laboratory responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used?

4.5.4
Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of evidence of compliance with the International Standard for the work in question?
At this time there is no testing that this lab sub-contracts. We can revisit this later as needed.

4.6 Purchasing Services/Supplies

4.6.1
Does the laboratory have a policy and procedure for the selection and purchasing of services and supplies it uses that affect the quality of tests and/or calibrations?
Do procedures exist for purchase, reception, and storage of reagents and laboratory consumable materials relevant for tests and calibrations?
Yes, there is a process in place for determining purchasing specifications, after that, the request to purchase is turned over to the government purchasing agency and all requests must receive multiple bids.

Only bids that meet the specifications determined by the laboratory will be elected. We cannot change this process, we will have to think about how to answer these questions.

4.6.2
Does the laboratory ensure purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for test and/or calibrations concerned?
The C/A for supplies that are received will be reviewed by the committee that set the purchasing specification for conformance. This check is documented and records are available.

Do services and supplies used comply with specified requirements?
Yes, according to the procedure for verifying certificates of analysis, they must comply.

Are records of actions taken to check compliance maintained?
Yes. Need to verify files for reviews such as this.

4.6.3
Do purchasing documents for items affecting the quality of laboratory output contain data describing services and supplies ordered?
Are these purchasing documents reviewed and approved for technical content prior to release?
Yes, when items are needed, the services are described in a purchasing specification and that specification is reviewed and approved by an internal technical committee.

4.6.4
Does the laboratory evaluate suppliers of critical consumables, supplies, and services which affect the quality of testing and calibration, and maintain records of these evaluations and a list of those approved?
The laboratory must use the government purchasing procedures. Specifications are developed for each item/ order needed. The lab will maintain a list of "Approved Suppliers" whom we have used in the past. An SOP for special testing or review may be appropriate if a new vendor is used.

4.7 Service to the Customer
4.7.1
Is the laboratory willing to cooperate with customers or their representatives in clarifying the customer's request to monitor the laboratory's performance in relation to work performed, provided the laboratory ensures confidentiality to other customers?

4.7.2
Does evidence exist that the laboratory encourages feedback, both positive and negative, from customers or other parties? Is the feedback used to improve the management system, testing/calibration activities, and customer service?
We will need to develop a procedure for obtaining customer feedback. This may come in the form of a survey that is sent every month or quarter or so with a lab report.

4.8 Complaints
Does the laboratory have a policy and procedure for resolution of complaints received from customers or other parties?
Are records maintained of all complaints and of investigations and corrective actions taken by the laboratory?
There is a procedure in place, need to review for adequacy.

4.9 Control of Nonconforming Testing/Calibration Work
4.9.1

Does the laboratory have a policies and procedure that shall be implemented when any aspect of its testing/calibration work, or results of this work, do not conform to its own procedures or the agreed requirements of the customer? Do the policies/procedures ensure that:
- responsibilities and authorities for management of nonconforming work are designated and actions (including halting of work and withholding of test reports/calibration certificates, as necessary) are defined and taken when nonconforming work is discovered?
- an evaluation of the significance of nonconforming work is made?
- corrective actions are taken immediately, together with any decision about the acceptability of nonconforming work?
- where necessary, the customer is notified and work is recalled?
- the responsibility for authorizing resumption of work is defined?

There is a "Control of Non-conforming work" SOP in draft. We will need to include definitions in the SOP (e.g. what exactly is "non-conforming work"). We will also need a thorough review to assure that all these requirements are met.

4.9.2
Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are corrective action procedures given in 4.11 promptly followed?
Need to ensure that this is stated in the SOP QCT/ GEN/ 014.

4.10 Improvement
Does the lab continually improve the effectiveness of its management system through the use of:

- the quality policy
- quality objectives
- audit results
- analysis of data
- corrective/preventive actions
- management review

Yes, all these tools will be used to continuously improve the quality of the QMS.

4.11 Corrective Action
4.11.1 General
Has the laboratory established a policy and a procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified?
Yes, this is described in SOP QCT/ GEN/ 014. The authority is given to the director of the lab. We will want to make sure everything in the SOP is implemented. It contains a good framework for the process.

4.11.2 Cause Analysis
Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?
Yes, refer to SOP mentioned above (QCT/ GEN/ 014)

4.11.3 Selection/Implementation of Corrective Actions
Where corrective action is needed, does the laboratory identify potential corrective actions? Does it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?
Need to add section to SOP QCT-014 that stated that based on our best scientific judgment, the corrective actions will be selected based on their ability to eliminate the root cause.

Are corrective actions to a degree appropriate to the magnitude and risk of the problem?

Does the laboratory document and implement any required changes resulting from corrective action investigations?
Yes, will be documented on the C/A form. This form will need to be created with all these requirements included.

4.11.4 Monitoring of Corrective Actions
Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?
Corrective actions will be an item on the agenda for management reviews.
They will also be required to e reviewed prior to internal audits and the solutions will be followed up on during the audit to determine effectiveness.

4.11.5 Additional Audits
Where identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies and procedures or on its compliance with the International Standard, does the lab ensure the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?
Need to add this option to SOP QCT-014. "At the discretion of the Director (or QA Manager), additional audits may be requested.

4.12 Preventive Action
4.12.1
Are needed improvements and potential sources of non-conformances, either technical or concerning the management system, identified?
If preventive action is required, are action plans developed, implemented, and monitored to reduce the likelihood of occurrence of such non-conformances and to take advantage of opportunities for improvement?

4.12.2
Do procedures for preventive actions include initiation of such actions and application of controls to ensure that they are effective?
Need a mechanism to capture preventive actions. Suggestion box? This is always a struggle.

4.13 Control of Records
4.13.1 General
4.13.1.1
Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records?
Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?

4.13.1.2
Are all records legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?

Are retention times of records established?

4.13.1.3
Are all records held secure and in confidence?

4.13.1.4
Does the laboratory have procedures to protect/back-up records stored electronically and to prevent unauthorized access to or amendment of these records?

4.13.2 Technical Records

4.13.2.1
- Does the laboratory retain records of original observations, derived data, and sufficient information to establish an audit trail, calibration records, staff records, and a copy of each test report/calibration certificate issued, for a defined period?
- Do records for each test/calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test/calibration to be repeated under conditions as close as possible to the original?
- Do records include the identity of personnel responsible for the performance of the sampling, test/calibration and checking of results?
Need to identify a records management SOP. There is a current practice in place, we will just need to formalize it into an SOP.

4.13.2.2
Are observations, data, and calculations recorded at the time they are made and identifiable to the specific task?

4.13.2.3
When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered alongside?
Are all such alterations to records signed or initialed by the person making the correction?
There is not an existing SOP for this now. We will develop a "Good documentation Practices" SOP that will include all the requirements in 4.13.2.2 and 4.13.2.3.

In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data?
Are any records stored electronically? If so, we will need a backup policy. I think at this point, all records are hard-copy. Need to verify. When the lab moves into the new building, there will be a network, this may become applicable at that time.

4.13 A.5 -
Are procedures in place for recording and reporting all results obtained in the field (on-site)? These procedures shall ensure confidentiality and integrity of data obtained in the field (on-site).
All recording and reporting of results are conducted on site. This section is not applicable.

4.13 A.6
For satellite sites, are these procedures defined and coordinated with the procedures of the corporate site in order to assure integrity and confidentiality of all data and records?
Not applicable.

4.14 Internal Audits
4.14.1
- Does the lab periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with requirements of the management system and the International Standard?
- Does the internal audit program address all elements of the management system, including the testing/calibration activities? It is the responsibility of the quality manager to plan/organize audits as required by the schedule and requested by management.
- Are such audits carried out by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited?
Couple of items here. Need to make sure we have documentation in training files of our "qualified auditors". We will need to develop an audit schedule (QA) that is approved by top management (the director) and will include all the elements of the management system.

4.14.2
If audit findings cast doubt on the effectiveness of operations or on the correctness or validity of the laboratory's test/calibration results, does the laboratory take timely corrective action and notify customers in writing if investigations show that the lab results may have been affected?
We will include this requirement in the audit SOP. There will have to be a customer notification section, most likely in our non-conformance SOP.

4.14.3
Are the areas of activity audited, the audit findings, and corrective actions that arise from them recorded?

4.14.4
Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?
These requirements will need to be in our audit SOP.

4.14 A.7
Does the corporate site include the satellite site in its internal audit? This internal audit shall be carried out according to the procedures of the corporate site including visiting the satellite site(s) by the designated internal auditor.
Not applicable, there are no satellite sites.

4.15 Management reviews
4.15.1
In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing/calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements? Does the review take account of:

- the suitability of policies and procedures?
- reports from managerial and supervisory personnel?
- the outcome of recent internal audits?
- corrective and preventive actions?
- assessments by external bodies?
- the results of inter-laboratory comparisons/ proficiency tests?
- changes in volume and type of work?
- customer feedback?
- complaints?
- recommendations for improvement?

other relevant factors, such as quality control activities, resources, and staff training?

4.15.2
Are findings from management reviews and actions that arise from them recorded?
Does management ensure that those actions are carried out within an appropriate/agreed timescale?

4.15 A.8
Do records indicate management reviews have taken into account the satellite site activities?
There is an existing draft procedure for management reviews. Need to ensure that all these requirements are met. In addition, there needs to be direction on how to record minutes from the management review meetings and a "vote" on whether the QMS maintains its effectiveness.

5. Technical requirements
5.1 General
5.1.1

Many factors contribute to the correctness and reliability of the tests/calibrations performed by a lab. These factors include:

- human factors (5.2)
- accommodation and environmental conditions (5.3)
- test/calibration methods and method validation (5.4)
- equipment (5.5)
- measurement traceability (5.6)
- sampling (5.7)
- the handling of test/calibration items (5.8)

5.1.2
The extent to which factors contribute to the total uncertainty of measurement differs considerably between types of tests/calibrations. Does the laboratory take into account these factors in developing test/calibration methods and procedures, in training and qualification of personnel, and in selection and calibration of the equipment it uses?
Need to work on these, what type of objective evidence can we provide to prove we are compliant with these?

5.2 Personnel
5.2.1
Does management ensure the competence of all who operate specific equipment, perform tests/calibrations, evaluate results, and sign test reports/calibration certificates?
Yes, job descriptions describe the minimum requirements for each job. Work assignment may need to be formalized a bit more to assure we meet this requirement.

When using staff who are undergoing training, is appropriate supervision provided?
Need to check training SOP here. Is there an interim period where the person being trained does not generate reportable results?

Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience, and/or demonstrated skills, as required?
Yes, job descriptions, Resume's or CVs and training files. We need to work on training files for each staff but when completed, they will answer this question.

5.2.2
Does management formulate goals with respect to the education, training, and skills of laboratory personnel?
Yes, they are described in the job descriptions.

Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?
Are training programs relevant to the present and anticipated tasks of the lab?
Need to make sure this is covered in the training SOP.

Is the effectiveness of the training actions taken evaluated?
Performance reviews of staff?

5.2.3
Does the laboratory use personnel who are employed by, or under contract to, the lab?
Yes, both full time and contracted employees are used

Where contracted and additional technical and key support personnel are used, does the laboratory ensure such personnel are supervised and competent and that they work in accordance with the laboratory's management system?
Need to make sure that this is included in the scope of our training SOP. This procedure is applicable to all staff (permanent and contract) that generate reportable data)

5.2.4
Does the laboratory maintain current job descriptions for managerial, technical, and key support personnel involved in tests/calibrations?
Yes, need translation into English.

5.2.5
- Does management authorize specific personnel to perform particular types of sampling, tests/calibrations, to issue test reports/calibration certificates, to give opinions and interpretations, and to operate particular types of equipment?
- Does the laboratory maintain records of relevant authorizations, competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel?
- Is this information readily available and does it include the date on which authorization and/or competence is confirmed?
We discussed this briefly. We will need to generate some type of record of this "authorization". The authorization is done at this time, however, it is informal and not documented.

5.2 A.9
Does the laboratory ensure personnel indirectly affiliated or subcontracted with the laboratory seeking accreditation do not perform field (on-site) or satellite site tests and/or calibrations unless they meet all training requirements and are supervised by staff of the accreditation-seeking laboratory?
Not applicable to this laboratory

5.2 A.10 -
Do procedures exist at the corporate site to ensure personnel at the satellite site(s) are technically competent and trained? Training records shall be available for the satellite personnel.
Not applicable to this laboratory.

5.3 Accommodation/Environmental Conditions
5.3.1
- Do laboratory facilities for testing/calibration (including but not limited to energy sources, lighting, and environmental conditions), facilitate correct performance of tests/calibrations?
- Does the laboratory ensure environmental conditions do not invalidate results or adversely affect the required quality of any measurement?
- Is particular care taken when tests/calibrations are undertaken at sites other than a permanent lab facility?
- Are the technical requirements for accommodation and environmental conditions that can affect the results of tests/calibrations documented?
We will need to do some work here. There are no "other sites" so there is nothing to do with that requirement. However, we will need to document the technical requirements that we will require for analysis.

5.3.2
- Does the laboratory monitor, control, and record environmental conditions as required by relevant specifications, methods, and procedures or where they influence the quality of the results?
Not at this time. Again, humidity, temperature, lighting, etc. may be important environmental factors in analysis. Need to evaluate and document these.

- Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned?
- Are tests/calibrations stopped when the environmental conditions jeopardize the results of the tests/calibrations?

Can probably answer all these with an SOP on environmental conditions of testing. Need to be careful that the SOP can be met.

5.3.3

- Is there effective separation between neighboring areas in which there are incompatible activities?
- Are measures taken to prevent cross-contamination?

No incompatible activities between the individual groups. There are requirements for microbiology work that is separated. This will have to be answered with a lab tour for the auditor.

5.3.4

- Is access to and use of areas affecting the quality of the tests/calibrations controlled?
- Does the lab determine the extent of control based on its particular circumstances?

We will need to document access areas. As example, who has access to the sample room and the document archival room.

5.3.5

- Are measures taken to ensure good housekeeping in the lab?
- Are special procedures prepared where necessary?

Is there a "good housekeeping practices" SOP? We have seen a lot of staff cleaning and sweeping and mopping, are there SOPs regarding these activities? Also trash removal?

5.3 A.11 -

Procedures shall be in place for each site to monitor environmental conditions which may affect instrumentation and test and/or calibration results. Monitoring records shall be maintained.

Need to define and document monitoring requirements (e.g. temperature/ humidity)

5.4 Test/Calibration Methods and Method Validation

5.4.1

Does the laboratory use appropriate methods and procedures for all tests/calibrations within its scope?

Do these include handling, transport, storage, and preparation of items to be tested/calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test/calibration data?

Does the laboratory have instructions on use and operation of all relevant equipment, and on handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests/calibrations?

Are all instructions, standards, manuals, and reference data relevant to the work of the lab kept up to date and made readily available to personnel?

Do deviations from test/calibration methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?

5.4.2 Selection of Methods

Does the laboratory use test/calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests/calibrations it undertakes?

Are the preferred methods published in international, regional, or national standards used?

Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so?

When necessary, is the standard supplemented with additional details to ensure consistent application?

When the customer does not specify the method to be used, does the laboratory select appropriate methods that have been published either in international, regional, or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment? Lab-developed methods or methods adopted by the lab may also be used if they are appropriate for the intended use and if they are validated.

Is the customer informed as to the method chosen?

Does the laboratory confirm it can properly operate standard methods before introducing the tests/calibrations?

If the standard method changes, is the confirmation repeated?
Does the laboratory inform the customer when the method proposed by the customer is considered to be inappropriate or out of date?
5.4.3 Laboratory-Developed Methods
Is introduction of test/calibration methods developed by lab for its own use a planned activity and assigned to qualified personnel equipped with adequate resources?

Are plans updated as development proceeds and is effective communication among all personnel involved ensured?

5.4.4 Non-Standard Methods
When it is necessary to use methods not covered by standard methods, are these subject to agreement with the customer and do they include a clear specification of the customer's requirements and the purpose of the test/calibration?

Is the method developed validated appropriately before use?
5.4.5 Validation of Methods
5.4.5.1
Validation is confirmation by examination and the provision of objective evidence that particular requirements for a specific intended use are fulfilled.

5.4.5.2
Does the laboratory validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use?

Is validation as extensive as is necessary to meet the needs of the given application or field of application?

Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?

5.4.5.3
Are the range and accuracy of the values obtainable from validated methods as assessed for the intended use, relevant to the customers' needs?

5.4.Z.3
Do the procedures contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified? Do they contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances, or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards? Are they consistent with the accuracy required and with any standard specifications relevant?

METHODS:
All methods that are used by the laboratory are "Standard" methods and all are "Validated" prior to receipt. There are a couple of sources: first, compendial methods may be used, secondly, sponsor supplied methods are used. Sponsors of application for drug registration are required as a pre-requisite of submission to submit validation data for all analytical methods. Compendial methods are also considered "validated"
The lab will develop a procedure for "verification" of methods on site prior to initiating reportable result.

5.4.6 Estimation of Uncertainty of Measurement
Work has not started for this section yet. We will plan on developing an SOP and appropriate training presentations for the May visit.

5.4.6.1
Does the calibration laboratory or a testing laboratory performing its own calibrations, have and apply a procedure to estimate the uncertainty of measurement for all calibrations/types of calibrations?

5.4.6.2
Do testing labs have and apply procedures for estimating uncertainty of measurement? In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement.

In these cases, does the lab at least attempt to identify all the components of uncertainty and make a reasonable estimation, and ensure that the form of reporting of the result does not give a wrong impression of the uncertainty?

Is the reasonable estimation based on knowledge of the performance of the method and on the measurement scope and does it make use of, for example, previous experience and validation data?

5.4.6.3
When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis?

5.4. Z.4
Does the laboratory ensure that the calibrations uncertainties are sufficiently small so that the adequacy of the measurement is not affected?

5.4.7 Control of Data
5.4.7.1
Are calculations and data transfers subject to appropriate checks in a systematic manner?
Team coordinators are responsible for checking data prior to issuance of reports. Not sure if there is a procedure requiring this, but this is the existing practice. May need to put this requirement in the reporting SOP as a pre-requisite.

5.4.7.2

When computers or automated equipment are used for acquisition, processing, recording, reporting, storage, or retrieval of test/calibration data, does the laboratory ensure that:

- computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use?
- procedures are established and implemented for protecting the data?
- such procedures include, as a minimum, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing?

- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test/calibration data?

Need to develop a mechanism for control of spreadsheets used in the lab for calculations. Also need to develop "validation of spreadsheets" SOP.

5.4 A.12 -
Does the laboratory ensure that field (on-site) and satellite site environmental conditions, when relevant, are taken into consideration when calculating measurement uncertainty?
Not applicable to this laboratory

5.5 Equipment
5.5.1
Is the laboratory furnished with all items of measurement and test equipment required for the correct performance of the tests/calibrations (including sampling, preparation of test/calibration items and processing and analysis of test/calibration data)?
In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of the International Standard are met?

5.5.2
Is equipment/software used for testing, calibration, and sampling capable of achieving the accuracy required and does it comply with the specifications relevant to tests/calibrations concerned?

Are calibration programs established for key quantities or values of the instruments where these properties have a significant effect on the results?

Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications? Is it checked or calibrated before use?

5.5.3
Is equipment operated by authorized personnel? Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate lab personnel?

5.5.4
Is each item of equipment and its software used for testing/calibration and significant to the result, when practicable, uniquely identified?

5.5.5
Are records maintained of each item of equipment and its software significant to the tests/calibrations performed? Do the records include at least the:
identity of the item of equipment and its software?-
manufacturer's name, type identification, and serial number or other unique identification?

checks that equipment complies with the specification?
current location, where appropriate?
manufacturer's instructions, if available, or reference to their location?
dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?
maintenance plan, where appropriate, and maintenance carried out to date?
damage, malfunction, modification, or repair to the equipment?

5.5.Z.5
Do equipment records include the measured value observed for each parameter found to be out of tolerance during calibration /verification?

5.5.6
Does the laboratory have procedures for safe handling, transport, storage, use, and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration?

5.5.7
Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service?

Is it isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration/test to perform correctly?

Does the laboratory examine the effect of the defect or departure from specified limits on previous tests/calibrations and institute the "Control of nonconforming work" procedure?

5.5.8
Whenever practicable, is all equipment under the control of the lab and requiring calibration labeled, coded, or otherwise identified to indicate the status of calibration, including the date of the last calibration and the date or expiration criteria when re-calibration is due?

5.5.Z.6
Does the laboratory have a procedure stating its policy for establishing and changing calibration intervals for equipment that it controls?

5.5.9
When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?

5.5.10
When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined procedure?

5.5.11
Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer software) are correctly updated?

5.5.12
Is test/calibration equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test/calibration results?

5.5.Z.7

Are tamper-resistant seals affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, would invalidate the calibration?

Does the laboratory's calibration system provide instructions for the use of tamper-resistant seals and for the disposition of equipment with damaged or broken seals?

5.5 A.13
If field (on-site) or satellite personnel use equipment not owned by the corporate site, does the provider of such equipment meet the requirements of sections 5.5 and 5.6 of ISO/IEC 17025?
EQUIPMENT VALIDATION/ CALIBRATION
Our program will consist of SOPs for:
Validation Policy
Validation Master Planning
IQ, OQ, and PQ SOPs
Change Control for equipment SOP
Preventive Maintenance SOP
Calibration Program SOP

5.6 Measurement Traceability
5.6.1
Is all equipment used for test/calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling, calibrated before being put into service?

Does the laboratory have an established program and procedure for the calibration of its equipment?
Yes, in practice, equipment is validated and calibrated. Need to review log books and develop procedures to assure that best practices are in place.

5.6.Z.8
Does the laboratory document any and all exemptions from periodic calibration or verification of its equipment?
Not sure if there is a current practice for this. Would need to document exceptions in the equipment notebooks as well as a deviation program.

5.6.2 Specific Requirements
5.6.2.1 Calibration
5.6.2.1.1
For calibration laboratories, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the lab are traceable to the International System of Units (SI)?

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI standards which are standards calibrated by another national metrology institute. See Below

When using external calibration services, is traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability, and traceability?

Do the calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification? (See also 5.10.4.2).

5.6.2.1.2
There are certain calibrations that currently cannot be strictly made in SI units. In these cases does the laboratory provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of material?
- the use of specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned?
- participation in a suitable program of inter-laboratory comparisons where possible?

5.6.2.2 Testing
5.6.2.2.1
For testing laboratories, requirements given in 5.6.2.1 apply for measuring/test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.

When this situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?
5.6.2.2.2
When traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration labs (see 5.6.2.1.2).
5.6.3 Reference Standards and Reference Materials
5.6.3.1 Reference Standards
Does the laboratory have a program and procedure for the calibration of its reference standards?

Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1?

Are such reference standards of measurement held by the lab used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated?

Are reference standards calibrated before and after any adjustment?

5.6.3.2 Reference materials
Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?

Are internal reference materials checked as far as is technically and economically practicable?

5.6.3.3 Intermediate Checks
Are checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference materials carried out according to defined procedures and schedules?

5.6.3.4 Transport and Storage
Does the laboratory have procedures for safe handling, transport, storage, and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity?

5.6 A.14
Does the corporate site ensure the traceability of all reference standards and equipment used by field (on-site) and satellite site personnel?

5.7 Sampling
5.7.1
Does the lab have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing/calibration?

Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken?

Are sampling plans, whenever reasonable, based on appropriate statistical methods?

Does the sampling process address the factors to be controlled to ensure the validity of the test and calibration results?

5.7.2
Where the customer requires deviations from, additions to, or exclusions from the documented sampling procedure, are these recorded in detail with the appropriate sampling data, included in all documents containing test/calibration results, and communicated to the appropriate personnel?

5.7.3
Does the laboratory have procedures for recording relevant data and operations relating to sampling that forms part of the testing/calibration that is undertaken?

Do these records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon?

5.8 Handling of Testing and Calibration Items
5.8.1
Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of test/calibration items, including all provisions necessary to protect the integrity of the test/calibration item, and to protect the interests of the laboratory and the customer?

5.8.2
Does the laboratory have a system for identifying test/calibration items?

Is the identification retained throughout the life of the item in the laboratory?

Is the system designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents?

Does the system, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory?

5.8.3
Upon receipt of the test/calibration items, are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded?

When there is doubt as to the suitability of an item for test/calibration, or when an item does not conform to the description provided, or the test/calibration required is not specified in sufficient detail,

does the laboratory consult the customer for further instructions before proceeding and is the discussion recorded?

5.8.4
Does the laboratory have procedures and appropriate facilities for avoiding deterioration, loss, or damage to the test/calibration item during storage, handling, and preparation?

Are handling instructions provided with the item followed?

When items have to be stored under specified environmental conditions, are these conditions maintained, monitored, and recorded?

Where a test/calibration item or a portion of an item is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned?

5.9 Assuring the Quality of Test/Calibration Results
5.9.1
Does the laboratory have quality control procedures for monitoring the validity of tests/calibrations undertaken?

Is the resulting data recorded in such a way that trends are detectable and, where practicable, are statistical techniques applied to the reviewing of the results?

Is the monitoring planned/reviewed, and does it include (not to be limited to) some/all of the following:

- regular use of certified reference materials and/or internal quality control using secondary reference materials?
- participation in inter-laboratory comparison or proficiency-testing programs?
- replicating tests/calibrations using the same or different methods?
- retesting or recalibration of retained items?
- correlation of results for different characteristics of an item?

5.9.2
Is quality control data analyzed?

If the data analyzed is found outside pre-defined criteria, is planned action taken to correct the problem and to prevent incorrect results from being reported?

5.9.A.15
Does the PT/ILC Provider adhere to ISO Guide 43?
If No:

- Do the reference values and associated uncertainties comply with ’ traceability policy (see Document Number 3) (i.e. are they supported by accredited calibrations)?
- Are the final results (e.g. En values) meaningful metrics for the test?
- Are the calculations involved correct?

Is the laboratory’s uncertainty claim for the test in accordance with the laboratory’s normal procedure for estimating uncertainty for accredited calibrations/tests of this type?
Are all results acceptable?
If No:

- Has the laboratory initiated corrective actions in accordance with its corrective action procedures?

- Do the results support continued accreditation without altering the laboratory's current scope of accreditation?
- Has the laboratory participated in a minimum of one PT/ILC each calendar year?

Has the laboratory participated in PT/ILC for each major sub-area of its scope in the last four years? If the laboratory has less than four years' history of participation, the assessor shall review the laboratory's plan for participation.

Does the laboratory ensure it includes PT/ILC for the higher accuracy parameters or standards used for a large proportion of calibrations (example: gage blocks, multifunction calibrators, high frequency RF, S-1 weights)?

5.9 A.16
Does each satellite site participate in PT/ILC as appropriate to its scope of accreditation?

5.10 Reporting the Results
5.10.1 General
Are results of each test/calibration (or series of tests/calibrations carried out by the lab) reported accurately, clearly, unambiguously, objectively, and in accordance with any specific instructions in the test/calibration methods?

Are the results reported, usually in a test report/calibration certificate (see note 1), and do they include all the information requested by the customer and necessary for the interpretation of the test/calibration results and all information required by the method used? This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4. In case of tests/calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way.

If any information listed in 5.10.2 to 5.10.4 is not reported to the customer, is it readily available in the laboratory which carried out the tests/calibrations?

5.10.2 Test Reports/Calibration Certificates
Does each test report/calibration certificate include at least the following information, unless the lab has valid reasons for not doing so (See WHO Guidance):

a title (e.g. "Test Report" or "Calibration Certificate")?

- the name and address of the lab, and the location where the tests/calibrations were carried out, if different from the address of the lab?

- unique identification of the test report/calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report/calibration certificate, and a clear identification of the end of the test report or calibration certificate?

the name and address of the customer?
identification of the method used?

- a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?

- the date of receipt of the test/calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration?

- reference to the sampling plan and procedures used by the lab or other bodies where these are relevant to the validity or application of the results?

the test/calibration results with, where appropriate, the units of measurement?

the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate?

Where relevant, a statement to the effect that the results relate only to the items tested or calibrated. (Required for Z540-1)

5.10.3 Test Reports
5.10.3.1
In addition to the requirements listed in 5.10.2, do test reports, where necessary for the interpretation of the test results, include the following:

deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions?

where relevant, a statement of compliance/non-compliance with requirements and/or specifications?

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?

where appropriate and needed, opinions and interpretations (see 5.10.5)?

additional information which may be required by specific methods, customers, or groups of customers?

5.10.3.2
In addition to the requirements listed in 5.10.2 and 5.10.3.1, do test reports containing the results of sampling include the following, where necessary for the interpretation of test results:

the date of sampling

unambiguous identification of substance, material or product sampled (including the name of the manufacturer, the model or type of designation, and serial numbers as appropriate)

the location of sampling, including any diagrams, sketches or photographs

a reference to the sampling plan and procedures used

details of any environmental conditions during sampling that may affect the interpretation of the test results

any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned

5.10.4 Calibration Certificates
5.10.4.1
In addition to the requirements listed in 5.10.2, do calibration certificates include the following, where necessary for the interpretation of calibration results: See below

the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?

the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof?
evidence that the measurements are traceable? (see note in 5.6.2.1.1)
5.10.4.2
Does the calibration certificate relate only to quantities and results of functional tests?

If a statement of compliance with a specification is made, does it identify which clauses of the specification are met or not met?
When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, does the laboratory record those results and maintain them for possible future reference?

When statements of compliance are made, is the uncertainty of measurement taken into account

5.10.4.3
When an instrument for calibration has been adjusted or repaired, are the calibration results before and after adjustment or repair (if available) reported?

5.10.Z.9
Do certificates or reports designate any special limitations of use?

5.10.4.4
Does the laboratory ensure its calibration certificate (or calibration label) contains no recommendation on the calibration interval except where this has been agreed with the customer? This requirement may be superseded by legal regulations.

5.10.5 Opinions/Interpretations

When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made?

Are opinions and interpretations clearly marked as such in a test report?

5.10.6 Testing and Calibration Results Obtained from Subcontractors

When the test report contains results of tests performed by subcontractors, are these results clearly identified?

Does the subcontractor report the results in writing or electronically?

When a calibration has been subcontracted, does the laboratory performing the work issue the calibration certificate to the contracting lab?

5.10.7 Electronic Transmission of Results
In the case of transmission of test/calibration results by telephone, telex, facsimile, or other electronic or electromagnetic means, are the requirements of the International Standard met? (see also 5.4.7).

5.10.8 Format of Reports/Certificates
Is the format designed to accommodate each type of test/calibration carried out and to minimize the possibility of misunderstanding or misuse?

5.10.9 Amendments to Test Reports/Calibration Certificates
Are material amendments to a test report/calibration certificate after issue made only in the form of a further document, or data transfer, which includes the statement: “Supplement to Test Report (or Calibration Certificate), serial number...(or as otherwise identified)”, or an equivalent form of wording?

Do such amendments meet all requirements of the International Standard?

When it is necessary to issue a complete new test report or calibration certificate, is it uniquely identified and does it contain a reference to the original that it replaces?

5.10.Z.10 -
If any event, such as the identification of defective laboratory calibration equipment, casts doubt on the validity of results given in any prior calibration report or certificate or amendment to a report or certificate, does the calibration laboratory notify the customer promptly in writing?

Does such notification quantify the magnitude of error created in the calibration results?

Is the customer promptly notified when any customer's measuring and test equipment is found significantly out of tolerance during the calibration/verification process? Is measurement data reported so that appropriate action can be taken?

5.11.A.17
Is the symbol being used properly (if being used) when making reference to the laboratory’s accreditation in communication media such as the internet, documents, brochures, or advertising?
Does the laboratory use the symbol only within its scope of accreditation?
Does the laboratory ensure it does not make any misleading or unauthorized statements regarding its accreditation?
Does the laboratory ensure that reports or certificates containing the symbol are not used in a misleading manner?
Does the laboratory ensure it does not use its accreditation to imply that a product, process, system, or person is approved by?
If the laboratory uses the ILAC mark, do they ensure they use it only in conjunction with the symbol?
If the ILAC mark is used, does the laboratory have on file a signed sub-licensing agreement?