Bridging the SLIPTA Stars and ISO Accreditation

Lessons Learned from Accredited Labs

Question	TB and Immunology Laboratories, Mozambique	NHLS Tshepong Laboratory, South Africa	National EID laboratory, Cameroon	EDARP Cardinal Otunga Laboratory 2, Kenya
1. What was the hardest thing to do in order to get accredited?	Difficulties to implement the philosophy of quality in daily laboratory activities: resistance from lab staff to change, registration and following the protocols. Difficulties to respond to non-conformances that do not directly depend of laboratory staff but as procurement of laboratory materials….	▪ Accreditation is a team effort and can't be achieved by 1 or 2 people alone. By far the hardest thing for me was to get buy in from all my staff and to get them to understand what the quality management system is about and why it is so important to abide by the rules and for them to accept ownership of the system. To achieve this necessitates a change of mind-set, since human nature is such that we tend to try to get away with the least effort possible when doing things. Education and information were found to be important legs for this step and this task will never be complete. In some instances disciplinary action becomes necessary, which I find very unpleasant. ▪ It is also very hard to implement all the paper work when you start from scratch. ▪ It is difficult to close all the non-conformances in time after audits. ▪ One of the biggest challenges that I encountered, was to get all staff to read and acknowledge the relevant documents, which is a never-ending struggle.	Was to clear the non-conformities after the initial assessment e.g. to maintain the fact that an internal auditor conducted an audit of the laboratory and not an accreditation preparedness expert.	▪ Setting up a quality management system (QMS) which complies to ISO 15189 - Documenting all system and technical procedures for the laboratory which meet requirements of ISO15189 standard. The following documents posed the most challenge: Quality manual (4.2.2.2); Management review (4.15); Validation of examination procedures (5.5.1.3); Measurement of uncertainity (5.5.1.4). ▪ Implementing all QMS documented procedures developed. Corrective Action/Preventive Action*
2. What was the easiest?	To motivate the team. From the beginning, the team was very motivated to be internationally recognized.	The simpler parts of the paperwork, like labelling of instruments and writing of the Books of Life and creating files were the easiest to do.	Writing the SOPs for the procedures in the laboratory since we were well versed in them	Meeting the following requirements of the standard - The following were easiest because they required the least financing to close gaps identified: Personnel (5.1-5.1.9); Accommodation and environmental conditions (5.2 - 5.2.6); Reagent storage and inventory management (5.3.2.2, 5.3.2.4).

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3. What was the most important contributing factor to getting accredited?	The commitment of laboratory staff, the National Institute of Health (INS) Directorate, strong laboratory leadership, mentorship and support from partners.	▪ I found that proper document control was very important, especially compiling a master documents list. After getting this in place, we started to move forward. ▪ It is also very important to hold regular staff meetings for communication with staff members on what needs to be done and why it is important. ▪ The Laboratory Manual is very important, should be detailed and is a living document which needs changes all the time.	Team work. There was great collaboration between the staff, Laboratory management and stakeholders (Partners).	▪ Management support and involvement – Without the involvement of EDARP management it would be very difficult to attain accreditation. Management involvement brought accountability of the process and allocation of resources. ▪ Trainings – SLMTA trainings provided the laboratory team with; o Useful tools e.g. monitoring tools for quality indicators. o Facilitated improvement project reporting, o Understanding of what the standard required and how it was to be implemented. ▪ Mentorship – Having a good mentorship team helped a lot in setting up a working QMS system. Mentorship made it easy to decode the standard and understand what was expected to be done. ▪ Laboratory staff involvement – Accreditation can only be achieved when every person is involved and committed towards its implementation.
4. What paths or major steps did you take to get there? Was there any short-cut?	1. Participating in the SLMTA program. 2. Decision from INS directorate to apply for accreditation 3. Mentorship from an experienced mentor. 4. Application for an accreditation board. 5. Audit.	There are, to my knowledge and experience, no short-cuts to achieve accreditation. 1. Establishing a document control system made a big difference in our laboratory and assisted a lot to achieve accreditation. It took me a long time to grasp what needs to be done in this regard, and I probably will still learn a lot as we go. 2. The Management Review Meeting played a big role in order to identify shortfalls that we needed to concentrate on. 3. "Burning the midnight oil" - the management team had to put in many extra hours to achieve	We had a mentor though not with the accreditation experience, was very helpful and resourceful. Only 2 of the staff had SLMTA training and could coach others. Each staff was assigned duties and responsibilities with another to oversee or assist to see the success of the tasks. I.e. there was cross mentoring and sharing of knowledge. No short-cuts.	The major step we made to attain accreditation was; 1.To unlearn our poor practices and learn best practices prescribed by the standard". This was a trying period because it was a complete overhaul of how laboratory activities were to be conducted. A good example was how quality control was to be implemented, monitored and evaluated. 2.100% implementation of documented procedures by the laboratory team. One of the major challenges we faced was having beautiful documented procedures which were not practical. We reviewed our documents

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		deadlines, e.g. I started spending at least 4 hours of every Saturday afternoon in my office, which helped me a lot to catch up on- and to get paperwork done. 4. It further helped to involve other staff members by delegating smaller tasks to them, e.g. the monitoring of maintenance sheets, temperature charts, verifying of pipettes, timers, thermometers.		consistently to make them simple, practical and ensured they met the standards requirement. 3.SLMTA trainings helped in bringing the laboratory team up to speed in understanding ISO15189 standard. They were very practical.
5. What were the biggest mistakes you made that others should avoid?	Lack of awareness of technicians about the importance of a quality management system. More training of lab staff on key quality concepts would have been beneficial. Change of the laboratory quality manager during the process (Laboratory of Cellular immunology).	The biggest mistake was to be too trusting of others and not to check that tasks that were given to other staff members were done and if done, to check for correctness and completeness.	To argue with the assessor instead of working to clear the non-conformities, also to write things in the policy document that were not applicable to our laboratory. Again to neglect correction of a minor con-conformity to become a major one.	Starting the process without proper sensitization of all laboratory and stakeholders on implementation of ISO15189 standard. All key stakeholders need to be sensitized on implementation of the standard. This is a very critical training that made a big difference once it was undertaken. All stakeholders better understood what the standard expected them to do and it enable the implementation team identify gaps and develop action plans to address them.
6. What was the best advice you can give to others? What was the one thing you did that made a difference?	Accreditation is an achievable dream. It requires commitment at all levels, strong laboratory leadership, well-trained and motivated staff to implement Quality Management System, adequate funding and infrastructure; and a robust action plan.	▪ Make full use of opportunities like the SLMTA program by fully implementing the QIP's that are identified – these are important steps in getting things in place. ▪ Appreciate and make full use of the assistance from your mentor, since they have already gone through the whole process. ▪ See every audit as an opportunity to improve your system and fully co-operate with sustaining the corrective actions put in place during the closing of the non-conformances identified. ▪ Never relax and think that you are there. This is a living process never completed.	To work as a team, share challenges in regular meetings and regularly update each other on development within the process. Respect of the time frame to clear off each non-conformity. Accreditation is very possible.	Firm leadership and collective team work: Every person is important in the process and they should work as a team. Laboratory leaders should be 100% committed to the process. Success depends on their leadership and when they are ineffective the entire team will also relax. It will be necessary for us to sacrifice our leisure time to ensure all requirements were met. We had to create extra time to get the work done.

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7. How much did it cost?		Fees to the accrediting body (SANAS) was around R 83 000.00 This does not take into account other costs, like the additional paper needed for all the documentation implemented over the years, accommodation and travel expenses to attend courses and for auditors and mentors to visit the laboratory, etc.		EQA programs*(Two programs) = $6768.34 Licenses Ksh. 68500 ($696.14) Assessment audit fee Ksh.840,000 ($8536.6) Calibration Ksh 200,000 ($2032.52) Trainings Ksh. 400,000 ($4065.04)

Perspectives from Accrediting Bodies

Question	Response
1. How do you determine compliance with measurement of uncertainty? What aspects are you looking for?	KENAS ▪ We expect the lab to estimate the uncertainties for all quantitative methods. In addition we expect the lab to have calibration certificate such as; weighing scales, pipettes, centrifuges bearing the UM associated with the calibration values ▪ We look for a policy or a procedure on how uncertainty is determined ▪ We have a guidance document at KENAS for estimation of UM. We check compliance with this guidance document ▪ The information expected in the uncertainty report includes: o Uncertainty type A from internal QC with data collected over a period of 3-6 months o Uncertainty type B from sources such as EQA, Method validation and calibrator certificates o Combined uncertainty o Expanded uncertainty at 95% confidence level k=2 o Assessment of fitness for purpose for the uncertainty values o We expect the laboratory to publish the uncertainty information and make them available to the users of laboratory services/clinicians
2. How do you ensure competency of your auditors? What measurements are collected and analyzed?	CRESAC The competence of the auditors is managed through the procedures: CRESAC 3-07 «Management of assessors and technical experts» and CRESAC 5-01 «Instructions for the selection of CRESAC Assessors». Surveillance 1. Systematic evaluation after each mission ▪ Review of assessment reports (50 points) ▪ Consideration of complaints or observations related to the assessor's behavior and deemed to be well cohesive (20 points) ▪ Professional and ethical awareness (30 points) 2. Evaluation every 3 years ▪ Participation in capacity building workshops for assessors organized by CRESAC once a year (40 points) ▪ Systematic assessment at each engagement (60 points) 3. Results ▪ Maintenance ≥70%; Warning (between 60 and 70%); Removal from the list <60%

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3. How are challenges handled? What qualifications must the arbitrator have to review and decide these challenges?	All challenges are forwarded to the Accreditation manager either as complaints or disputes to Non conformances to resolve. Depending on the nature of the challenge it can also be referred to the Specialist Technical Committee, which is the technical body comprising of specialists in all disciplines within Medical. The final decision is taken SANAS. SANAS normally uses the Technical Experts in Medical comprising of Assessors and Specialist Technical Committee members, qualified in the relevant scopes
4. What recommendations do you have for laboratories preparing for your on-site visits?	SADCAS ▪ To nominate a quality Manager, who will be responsible and familiar with the laboratory's existing quality system and who will co-ordinate all activities related to seeking accreditation ▪ Contact the SADCAS to understand the accreditation process ▪ To get acquainted with the SADCAS documents and fully understand the assessment Procedure and methodology of making an application ▪ Prepare a Quality manual as recommended in the ISO 15189 standard. ▪ Prepare all standard operating procedures ▪ Ensuring that all competence aspects of the system are in place, which include: o environmental conditions that are effective and are being monitored o Servicing and calibration of equipment as per requirement. o Participation in PT o Conducting IQC o Verification/Validation o Personnel competence ▪ Conduct of at least one Internal Audit and Management Review. ▪ Ensuring proper implementation of all aspects that have been documented in the Quality manual and other documents