Icelandic Internation	al Developing Agency
(ICEIDA) Mozambiq	ue

Status Evaluation of the project "Assistance to the Fisheries Laboratories in Maputo, Beira and Quelimane concerning quality assurance and accreditation"

Sigurdur G. Bogason MarkMar ehf December 2007

Table of contents

Executive Summary	3
Introduction	4
Status Evaluation Process	5
Results and Conclusions	6
Project Status Evaluation and progress from initiation	6
Advice to the project implementation group on how to reach the project	
objectives	7
Estimation for the project to be finished in July 2008 - realities	
Recommendations	9
Annexes	10
Appendix I: Memorandum from 27.11.07	

Executive Summary

This report describes the results from the project Status Evaluation conducted in November 2007 carried out by Sigurdur Bogason from MarkMar ehf, for ICEIDA. The laboratories in Beira and Maputo were visited to evaluate the status and readiness of the fishery quality assurance laboratories in Mozambique for accreditation to the ISO/IEC 17025: 2005 standard.

The emphasis was placed on evaluating the overall status of the fishery laboratory project supported by ICEIDA for several years, and assesses actual progress status from the beginning with the aim of advising on how to reach the project objectives.

The dedication of the Top Management at INIP to the Project was highlighted as being the most significant ingredient still needing attention, and this was highlighted in the Memorandum dated 27.11.07, and was discussed with the INIP Director on two occasions during the visit. Related to this is the need to establish the organizational relationships within the competent authority in such a manner that the independence of the laboratories and operational capabilities are meeting the standard requirements.

The laboratory facilities and installed equipment was found to be appropriate to the services to be provided to the competent authority and the needs of the industry. The staff was committed to the work and appreciative of the requirements arising from an ISO/IEC 17025: 2005 based system, although further level of staff training would be advised to strengthen the quality system foundations. Partially this would come as part and parcel of the pending system implementation as the Head of Department LIP is qualified in the field and can give internal training workshops as needed. Further training by external advisors should also be further considered and planned.

A commitment from all responsible parties was gained during the status evaluation visit to start implementing the quality assurance system in January 2008. This would be necessary to test the robustness of the existing documented quality procedures, work instructions and the Quality Manual itself. Guidance was given regarding how to expedite the drafting process and move it to the formal issuing stage and become an operating and implemented system. To support this activity, a scheme for setting up an ongoing action plan with dates and responsibilities was agreed to facilitate the work ahead

A pre-audit of the system would be advisable prior to the visit from the selected accreditation body, and this event should be scheduled as a key milestone in the project time plan for 2008. The pre-audit would therefore act as dedicated pressure point on the personnel involved with the project execution, and create a fully dedicated implementation environment with set goals to be achieved.

Introduction

This report describes the outcome of the Status Evaluation visit carried out by Dr. Sigurdur G. Bogason, MarkMar ehf, in November 2007. This work was carried out for ICEIDA to evaluate the project status and give advice regarding how the project could best be completed. The following objectives for the work were listed in the Terms of Reference for the evaluation:

- a. To evaluate the status of the project,
- b. To evaluate the progress of the project from the beginning,
- c. To advice the implementation group on how to reach the project objectives,
- d. To evaluate if the estimate for the project to be finished in July 2008 is realistic.

The reference to the PROJECT here above is the ongoing work to establish independent national quality system and supporting accredited laboratories for fishery and seafood products in Mozambique. The objectives of this "long term" project funded by ICEIDA are listed in the *Addendum to the "Project Document for ICEIDA support to the Official Fish Inspection System in Mozambique" Concerning assistance to the Fisheries Laboratories*, dated November 2005.

The project immediate objectives

- To establish functional service laboratories in Maputo, Beira and Quelimane with sufficiently trained and qualified personnel, operating in accordance to a Quality Manual based on ISO/IEC 17025: 2005 standard, and able to seek accreditation if desired. The immediate objectives listed are:
 - 1. Determine the scope of the accreditation for the individual laboratories,
 - 2. Make a work and time plan for the implementation of quality control systems in the laboratories based on the ISO/IEC 17025: 2005 standard,
 - 3. Make sure that the laboratories have facilities, environmental conditions, equipments and other necessary materials that are needed for implementation and running of the quality control system,
 - 4. Training of laboratory personnel in quality control procedures and documentation of the quality control system,
 - 5. Organize the structure of the quality system and work routines in the laboratories so that the quality control procedures can be written and implemented with the involvement of all general staff of the laboratories,
 - 6. Determine the future organization, financing and technical and quality management for the laboratories that must be compliance with the requirements of the ISO/IEC 17025: 2005 standard.

The status evaluation work was carried out based on the TOR for the project status evaluation visit in November, and in consideration of the above listed core objectives of the "Project".

In preparation for the status evaluation, meetings were held with the responsible persons at ICEIDA and laboratory management. Also available reports¹ on the project and relevant sections from the report² from Dóróthea Jóhannsdóttir were used to generate important background information.

Status Evaluation Process

The evaluation visit to Mozambique was conducted from 18 – 29 November 2007, and began by preparatory work at the ICEIDA offices. Available reports and project relevant documents were reviewed, and meetings held with Gudmundur Valur Stefánsson and Jóhann Þorsteinsson, who is currently acting as a seconded Quality Manager within the laboratories, to establish necessary background to the evaluation work. On Tuesday 20.11.07 the laboratory in Maputo was visited and facilities inspected and laboratory staff introduced. The laboratory manager was away on a inspection tour, and it was decided to travel to Beira on Wednesday to visit the laboratory there and link up with Maria Luiz Fernades Head of Laboratory Department at INIP, who also is the Maputo laboratory manager. An early morning flight to Beria was taken by myself and Jóhann Þorsteinsson, and on arrival we were met by Carlos Morais, the laboratory manager in Beira. After visiting the laboratory facilities and meeting the staff a meeting was held with Carlos to review progress within the laboratory quality system implementation. In the evening a further meeting was held with Maria Luiz who had arrived in Beira.

On Thursday morning a meeting was held with Maria Luiz, Carlos, and Jóhann Porsteinsson to discuss status of the quality system documentation and procedure implementation. Later we were joined by the head of the INIP provincial office in Beira Mr. Carlos Horario Herminio to discuss the problems of daily operational funding mechanisms, and general administrative issues concerning the provincial laboratories.

A late Thursday evening flight was taken from Beria to Maputo, and Friday used for follow up evaluations in the Maputo laboratory. On Friday afternoon a very constructive meeting was held with Ana Paula Baloi the Directoresa of INIP to discuss organizational issues relating to the laboratories, as well as the pending accreditation and its importance for Fish Inspection Services in Mozambique in relation to export markets. At the meeting it was decided that initial reporting from the evaluation mission would take place at the INIP offices on Tuesday 27.11.07 at 16:00.

¹ Snorri Þórisson, 2005, Evaluation of the quality system in Fish Inspection laboratories in Maputo and Beira, Mozambique.

Hjörleifur Einarsson, 2004, Project Evaluation: Upgrading of Laboratory facilities in Maputo and Inhambande.

² Dóróthea Jóhannsdóttir 2006, INIP, the Fish Inspection Institution, Assistance in structuring the administration and financial activities

The weekend was used to draft a Memorandum³ addressed to Ana Paula Baoli in preparation for the briefing meeting on Tuesday. Monday and first part of Tuesday were used to review status of the existing quality system documentation and discuss scenarios with Maria Luiz Fernandes and Jóhann Þorsteinsson. On Wednesday the evaluation mission work was wrapped up at the Maputo laboratory and at the ICEIDA office.

Results and Conclusions

Project Status Evaluation and progress from initiation

The status evaluation of the laboratories and the review of the quality system gave an overall positive impression and it was concluded that most critical elements were already in place. The available and to often existing draft versions of documents needed to be tied together into a more organized structured Quality Assurance System. The facilities and laboratory equipment in Maputo and Beira was found to be suitable and in good progress of a sustainable operational performance.

The inputs and assistance regarding new equipment and equipment maintenance by Porsteinsson the laboratory advisor from ICEIDA, who is currently also acting as the Quality Manager at Fisheries Laboratories (LIP), seemed to be quite critical for the operational effectiveness of the laboratories. This raised the concern that it could lead to dulling of own responsibility from the laboratory managers if maintained at this intensive level for to long. Although recommendable by itself, and at the moment quite necessary to ensure fully operational laboratory environments, it should be considered to be a temporary measure. Steps should be taken to give full handover of responsibilities as soon as the quality system has been implemented and be proven to be effective over a period of 3 to 6 months. This should be aligned with the conclusion of training of a local Quality Manager due to take over responsibility from Mr. Porsteinsson. It is advised that this person needs to be identified soon to facilitate training, and overcome the currently ongoing idea of having the Head of LIP Department and Maputo Laboratory Manager as being also the responsible Quality Manager, which would create potentially critical conflicts of interests. The clear division of roles within the quality assurance system in the accredited laboratories should be set up in the functional organizational structure to be adopted.

This project has been ongoing for number of years and the updated project program was reaffirmed in November 2005 in the *Addendum* document⁴. Since then the project has been progressing well, although some delays in the overall timeline were evident. The deadline of September 2007 initially indicated in the Project Addendum has already passed, and will thus need to be revised. Therefore it is advised that a new realistic end date be set for the project, and if ICEIDA will follow the Project trough up to the actual accreditation, a reasonable date could be by end of September 2008.

⁴ Addendum to the "Project Document for ICEIDA support to the Official Fish Inspection System in Mozambique" Concerning assistance to the Fisheries Laboratories, November 2005.

³ Sigurdur G. Bogason, 27 November 2007, Status Evaluation of the Project: Assistance to the Fisheries Laboratories in Maputo, Beira and Quelimane concerning Quality Assurance and Accreditation. (see attached copy in Annex I to this report)

The main remaining hurdle to be passed is to sign and formally issue the quality system documentations, follow through the actual implementation of the whole system, and then use it to refine procedures as may be needed. To delay this much longer will only result in postponing the overall project. To quote an often stated wisdom relating to this kind of work:

- o Say What you do
- Write it down
- o Do what you say you do
- o Prove it (by your quality Records)

Advice to the project implementation group on how to reach the project objectives

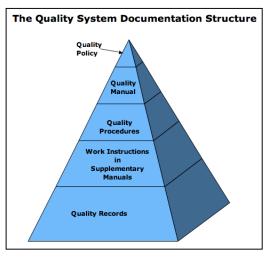
The lack of commitment from the Top management of INIP for establishing a clear independent organizational structure was considered to be a very critical issue for a successful conclusion of the Project. This was discussed with the Director of INIP and recommendations made for possible solution to the situation, although other possible organizational scenarios could also be found to be acceptable. Another linked issue was the problem with ensuring systematic financial administrative service to the laboratory system in particular in the provincial departments. Jóhannsdóttir had also earlier pointed out this matter in the report on administration and financial activities for INIP (ICEIDA Report September 2006).

A Quality Policy needs to be issued as soon as possible, and signed by the Director of INIP, which in turn would signal a commitment from Top Management for the Quality Assurance System and the Accreditation process for the laboratories.

The quality system documentation needs to be collated into one coherent system avoiding lengthy descriptions of unnecessary details in the top-level documents, i.e. the Quality Manual and Quality Procedures. The more detailed descriptions should be given in the applicable Work Descriptions of the Supplementary Manuals used in the various laboratory sections. The two draft versions of the Quality Manual should be combined where practical or adopting more of the "leaner" version being prepared by Porsteinsson. Several Quality Procedures need to be finalized to describe important aspects required for maintaining the overall quality system, e.g. Training and Calibrations to cite two examples.

A pyramid structure for the different levels of documentation in the quality system was presented to Maria Luiz Fernandes, and later incorporated into the Memorandum. This schematic was proposed to ensure that all parties would have a clear grasp of the system structure and its hierarchical responsibilities – starting with the Quality Policy to be issued by Top Management.

The chapter numberings of current documented quality system do not match the current version of the ISO/IEC 17025: 2005, and this should be



corrected to align to the relevant sections in all system documents.

The Quality Manual should be finalized for issuing by the end of this year, and formal implementation started in January 2008. This would be in accordance with the agreed action plan for the Project as was discussed with the LIP Head of Department, and subsequently introduced in the Memorandum to Ana Paula Baloi Directoresa of INIP.

The drafting of several key Quality Procedures, e.g. Training and Calibration, etc. should be finalized no later than by mid January and full implementation be completed by end of February at the latest according to the proposed action plan.

The Work Descriptions / Instructions contained in the Supplementary Manuals need to be formally issued, and as these documents are currently in use at the laboratories, their formal implementation should be straightforward.

The record keeping of the analytical results from received samples of fishery and seafood products has been properly systemized, and the computerized database being set up should be adequate for proper documentation control when completed.

It should be noted here that it would provide fundamental boost to the project progress if Top Management of INIP would become highly visible in the launch activities of formal full system implementation. This could be organized as a scheduled event at the Laboratories with speeches and light refreshments for staff and relevant political figures being present. Such an event should facilitate very much dedication and interest by everyone involved, both at administrative level as the technical and general laboratory staff levels.

Attention should be given to the organizational issues for INIP and the laboratories to ensure that the independence issues are maintained at the forefront of ongoing dialogue within the Project, and that financial and administrative systems are adequate for daily operative security of the laboratories in all provincial districts.

Estimation for the project to be finished in July 2008 - realities

During the status review it became evident that systemic review of the comments raised in the report of Þórisson in 2005 had not been completed, and this review was added to the new proposed action plan. Due to this and above listed key observation it was not warranted to do a formal audit of selected procedures within the Quality System. Rather the attention became focused on the means necessary to move the Project forward to implementation and provide basis for responding to one of the expected outcomes from the Status Evaluation mission's TOR, namely to evaluate if the estimate for the project to be finished in July 2008 could be realistically achieved. It was concluded that this was too optimistic, and a realistic timeline for conclusion of the project could be the following:

- o Pre-audit of the Quality System June to August,
- The end of the ICEIDA supported project should thereby be set for end of September 2008,
- Based on outcome from pre-audit, a date selected, and then scheduled with the selected accreditation body. Date to be targeted could be as late as in November to December 2008,

This timeline would enable the Mozambique authorities to have achieved a traceable history for an operational Quality Assurance System with the necessary quality

records for a few months prior to accreditation. Following a successful accreditation during late 2008, the quality system would also have operated for several more months prior to the visit in 2009 from the European Community inspectors. This proposed timeline would also involve the staged full handover of ownership to the personnel responsible for operating the fisheries laboratories, and the Quality Assurance System.

Audits and training

Training for staff to conduct internal audits during the implementation phase will be an important element for creation of a successful environment for proper quality system maintenance, and improvements. This should be scheduled early on and focus on training one to two persons from each of the laboratories in the beginning. By periodically swapping auditors among the different laboratories more uniform system operation could be ensured, as well as transferring best practices around the LIP organization.

A formal **Pre-Audit** of the quality system and its operational caliber would be advisable and should take place at least 3 months into the full system implementation, and about 4-6 months prior to the actual accreditation visit from the chosen Accreditation Body. This should give time for any necessary quality system improvements needed to ensure a positive evaluation from the accreditation body.

Recommendations

The Top management of INIP needs to take visible ownership of the Project for the laboratories quality system and its subsequent accreditation, see the attached Memorandum for further elaboration of this aspect, and the provision of clear independent organizational structure for the laboratories.

The Project needs to be proactively implemented, as the lengthy incubation period should be over. Enough progress has been made on the most important documentation of the Quality Assurance System for the laboratories. Documents need to be signed off and formally issued and the procedures therein implemented officially. Only by taking this step it will become evident if the procedures are factual and can be reliably followed over a period of time.

It is to be expected that improvement needs will become obvious through internal audits of the procedures and work instructions in the Supplementary Manual covering laboratory methodologies. Actually it will be sign of a viable quality system that some documents have undergone amendments and have been reissued – some even several times during the implementations phase.

Training of staff was identified as an important need for successful implementation and for the future system maintenance under accreditation. Several areas of immediate training needs were listed in the Memorandum on 27 November.

The Quality Manager and the INIP Head of Laboratory Department should update action plans and timeline for the Project on weekly basis. The monthly meetings of the Project Management Committee (PMC) should monitor the overall project

progress as originally planned, which should ensure successful implementation of the quality system and its subsequent accreditation before end of 2008.		

Annexes

Memorandum from 27 November 2007 − including:

Annex-1 Quality System Documentation Appendix I

- Annex-2 Organizational overview
- Annex 3 Action List Examples

Appendix - I

Memorandum

Ana Paula Baloi, Directoresa INIP, Ministry of To:

Fisheries, Mozambique

Dr. Sigurdur G. Bogason, CEO From:

Gudmundur Valur Stefánsson, ICEIDA CC:

Maria Luiz Fernandes, Jóhann Þorsteinsson bcc:

27 November 2007 Date:

Status Evaluation of the Project: Assistance

to the Fisheries Laboratories in Maputo,

Re: Beira and Quelimane concerning Quality

Assurance and Accreditation



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This Memo is written to give an overview of findings from the status evaluation visit to Mozambique, including work sessions at the laboratories in Maputo and Beira, that took place from 19-28 November 2007. This Memo gives a short summary of the Status Review results, conclusions and a proposed Action Plans required to get the project to progress more efficiently to meet the project work plans and the ultimate objectives that were set out in the contract.

A status review report will be delivered in December 2007 to give more details on any observed discrepancies from work plans, and advice on how the parties in the collaborative assistance to the fisheries laboratories (LIP) should work jointly to resolve the areas of concern, and to get the work towards accreditation to progress significantly in the coming months.

Summary

The most critical aspects arising from the project status review are listed here below:

- Lack of clear ownership of the project → from the top down perspective
 - Top Management visible ownership of the Quality System is urgently needed.
 - Ensure that conflict of interests for staff is avoided at all levels.
- Previously identified (in report 2005), and considered fundamentally necessary matters not yet implemented, i.e.
 - Clear independent organizational structure for the laboratories,
 - o Financial independence not operational or not implemented,
 - o Number of action points specific to critical sections of the standard not sufficiently addressed to date,

- Action items from Evaluation report 2005 list (pages 7-10) need to brought to the Action Lists, and given a due time and responsible person for each one.
- Training plans should be installed where staff would obtain in-house training on the ISO 17025 based quality system and its daily operation, and e.g. workshops on:
 - Training of auditors for Internal Audits (Section 4.14),
 - Calibration and traceability of measurements (Section 5.6.2),
 - Uncertainty of measurements (Section 5.4.6.2)

Conclusions

The accreditation project has progressed somewhat since the last status review in July 2005, and many of the issues raised as outstanding have been partially accomplished. What remains to be done is to combine the various elements into appropriate levels of documentation, and start implementing the documented quality procedures, standard operation procedures for the laboratory methodologies (currently listed in the Supplementary Manuals). A graphic representation of the overall Quality system is proposed (ISO 17025, 4.2) to ensure that all concerned have a better grasp of the design of the Quality System and the different layers of documentation needed, see Annex-1 attached. This also needs to be described in the Quality Manual

The Quality Policy is available in a draft form, and should be finalized before the upcoming holidays in December. The Quality Policy should be signed by the Director of INIP no later than by 31.12.07, and the quality Assurance Manual itself should be finalized within the next 2-3 weeks and signed by the Head of Laboratory Department for implementation before the end of this year.

It is imperative that work on drafting the documents is given higher priority within the INIP organization to ensure successful conclusion of the project. This would be facilitated by the clearer ownership of the project by you as the Director of INIP. This will reinforce the formal and existing delegation of the work to the team at LIP Headed by Maria Luiz Fernandes and supported by Jóhann Þorsteinsson (ICEIDA), who is the acting Quality Manager during these critical steps ahead.

It became evident in the discussions with Maria Luiz Fernandes that she believed that she could both be the Quality Manager and the Head of Department at the same time, which would not be acceptable due to the conflict of interest issue. It is therefore recommended that a qualified person within LIP will be identified or recruited for this

important role in the quality system operation. Such a staff member would on daily basis be reporting to the LIP Head of Department, and would need to be able to have other duties at LIP as the post of a Quality Manager would not be a full time position when the system has been implemented and is fully operating.

It should be highlighted here that the quality manager appointed would need to have a direct communication channel with the INIP Top Management, Director and/or Deputy Director regarding the system performance. In Annex-2 to this Memorandum two organization overviews are given, proposing how the overall structure of LIP and responsibility lines could meet the requirements for accreditation of the laboratories

Action Plan

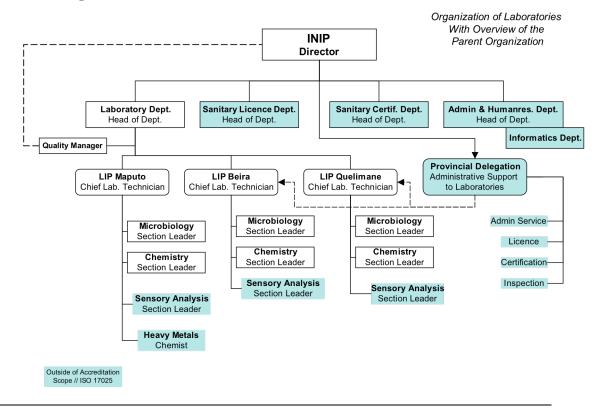
It became evident that a significant and serious effort would have to take place to get the quality system into operation. Therefore priority action plans, see Annex-3 attached, were agreed with the LIP Head of Department and the acting Quality Manager. To get a functioning system into operation and move the project forward it needs to enter into an effective implementing phase.

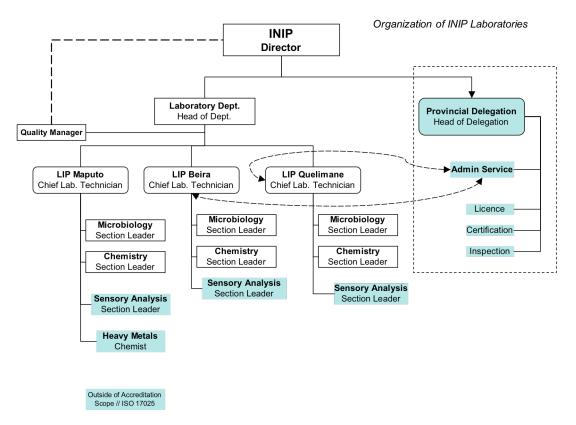
The Top Management at INIP should initiate the commitment by signing of the Quality Policy as soon as possible, and also clarify the independent organizational relationships of LIP within the INIP structure, which was again identified as still being the major obstacle towards meeting basic requirements of the ISO17025 standard. During the coming months you should devote more visible and personal attention to the project and participate in as many of the monthly project management meetings as possible. Later a formal Quality Board for LIP should be installed to follow the Quality System Performance, and replacing the current collaborative meetings between ICEIDA and INIP by scheduled oversight from such a quality board.

STUCTURE OF THE INIP - LIP QUALITY MANAGEMENT SYSTEM



Annex-2 Organizational overview





Annex 3 – Action List Examples

Immediate Actions:

1	Task To Do	Who	Due
	Approve LIP organization within INIP	Ana Paula	27.11.07
	structure	Baloi	
	Add to Action List all outstanding	MLF & JÞ	10.12.07
	documents listed in the 2005 Evaluation		
	Report (S. Þórisson)		
	Approve and signing of Quality Policy, LIP	Ana Paula	31.12.07
		Baloi	
	Quality Manual (QM) issued (version 0.1)	MLF	31.12.07

Pending within 3 months

1	Task To Do	Who	Due
	Work Descriptions / Standard Operation Procedures and analytical methods available in laboratory sections in appropriate Supplementary Manuals in an issued and signed format	JÞ & MLF	15.01.08
	QM Implemented / version 1 signed (by MLF)	MLF	31.01.08
	Compile all Quality Procedures and implement when each is ready and signed by responsible manager	JÞ	latest by 28.02.08
	 QP 5.2.2 Training signed by MLF and implemented 	JÞ & MLF	15.01.08
	 QP 5.4 Calibration signed by MLF and implemented 	JÞ & MLF	15.01.08
	• QP		
	• QP		

Pending within 6 months

1	Task To Do	Who	Due
	Internal Audits of 3-4 critical areas	JÞ (QM)	March 2008
	Pre-audit(s) external	To be decided	March-April 2008
	Apply for Accreditation	APB (INIP)	May-June 2008