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Report

Pacific Horticultural and Agricultural Market Access (PHAMA) Program

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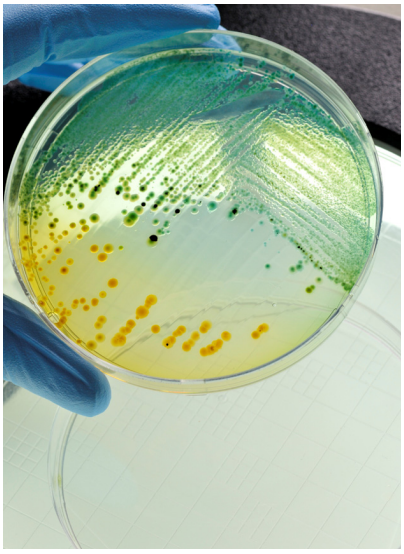
KALANG

SOLS12 (Stage 2): Development of Testing Capacity to Support Fish Exports in Solomon Islands

1 May 2015
42444251 Version 1.0

Prepared for:
Department of Foreign Affairs and Trade

Prepared by URS Australia Pty Ltd



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DOCUMENT PRODUCTION / APPROVAL RECORD				
Issue No.	**Name**	**Signature**	**Date**	**Position Title**
Prepared by	Ron Fyfe, Cawthron Institute		28 April 2015	Short-term Technical Adviser
Checked by	Dale Hamilton		1 May 2015	Long-term Technical Adviser
Approved by	Sarah Nicolson		1 May 2015	Principal-in-Charge

Project:
Pacific Horticultural and Agricultural Market Access (PHAMA) Program

Report Name:
SOLS12 (Stage 2): Development of Testing Capacity to Support Fish Exports in Solomon Islands

DOCUMENT REVISION RECORD		
Issue No.	**Date**	**Details of Revisions**
1.0	1 May 2015	Initial issue

Status:
Final

Client Contact Details:
Department of Foreign Affairs and Trade
R.G. Casey Building
John McEwen Crescent
Barton, ACT 0221
Australia

Issued by:
URS Australia Pty Ltd
Level 27, 91 King William Street
Adelaide, SA 5000
Australia

T: +61 8 8366 1000
F: +61 8 8366 1001

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ABBREVIATIONS

Abbreviation	Description
APC	Aerobic Plate Count
AUD	Australian dollar
CA	Competent Authority
CFU	Colony Forming Unit
EC	*E. coli*
EHD	Environmental Health Division
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FC	Faecal Coliforms
IANZ	International Accreditation New Zealand
IEC	International Electrotechnical Commission
ILCP	Inter Laboratory Comparison Program
ISO	International Organization for Standardization
KGVI	King George VI School
KTP	Key Technical Person
MMGM	Minerals-modified glutamate medium
MPN	Most Probable Number
N/A	Not applicable
NATA	National Association of Testing Authorities (Australia)
NPHL	National Public Health Laboratory
PHAMA	Pacific Horticultural and Agricultural Market Access program
QMS	Quality Management System
SIG	Solomon Islands Government
SIWA	Solomon Islands Water Authority
SOP	Standard Operating Procedures
TC	Total Coliforms
URS	URS Australia Pty Ltd
VRB	Violet Red Bile Agar
WASH	Water, Sanitation and Hygiene
XLD	Xylose lysine deoxycholate

Unless otherwise specified all currency figures are expressed in AUD.

EXECUTIVE SUMMARY

The National Public Health Laboratory (NPHL) was built in 2007 with funding from the Australian Government and the European Union. Its function is to provide testing services to support the public health work of the Ministry of Health and Medical Services, and to support testing requirements for export and domestic food processing industries.

In 2012, under activity SOLS12 Stage 1, the Pacific Horticultural and Agricultural Market Access program (PHAMA) conducted an initial assessment of the capacity of NPHL to provide testing services for export industries, particularly the fishing industry. This identified the need for wide-ranging capacity building investment, including on chemical testing, to meet overseas market requirements. The recommended measures were considered unsustainable; as an alternative, PHAMA provided assistance to establish submission of fish product samples to accredited overseas laboratories using a cost recovery system from industry. However, submission of water and product samples for required microbiology testing remains problematic due to transport times. SOLS12 Stage 2 was scoped to revisit the potential for the NPHL to become an ISO 17025 accredited laboratory for microbiological testing.

The activity involved: assessment of NPHL's present position regarding accommodation, equipment, staffing, methodology, and quality management, with a view to determining a practical path towards accreditation for the laboratory to the ISO 17025 standard; attachment training of two NPHL staff in New Zealand for two weeks to provide introduction to an accredited laboratory operation; and a return visit by the consultant to aid with implementation of methods learned, and to design an ongoing program for the laboratory to be in a position to achieve accreditation status.

The assessment findings showed the following key issues and gaps that need to be addressed as prerequisites of any progress towards the accreditation goal:

- Adequate staffing levels. Existing laboratory staff of two are too few and are too inexperienced in running a commercial laboratory to get and maintain the laboratory to the desired ISO 17025 standards.
- Current staff lack adequate technical skills in testing methodologies, operational procedures and laboratory quality management systems.
- NPHL administration structure responsible is too cumbersome and convoluted to be able to assist testing growth at the pace required to attain accreditation within the next two to three years, and to maintain an uninterrupted service.
- The laboratory has insufficient records in all aspects of quality control, quality assurance, calibration and training.
- Staff have little appreciation of the service commitment required to run a commercial laboratory. The vast majority of previous work has been for government agencies, with little private work carried out. Commercial customers will expect a more timely service.
- Ongoing power and water supply problems need to be addressed urgently.
- The system of procurement of consumable supplies and maintenance services is inadequate and requires urgent improvement.
- There is a critical lack of small benchtop equipment such as tubes, racks, pipettes, pipettors and utensils.

- The laboratory processes a very small number of samples per annum for the size of the facility. This means that there is insufficient result data available for any audit assessment.
- An increase in work from commercial customers is crucial if the laboratory wants to achieve accreditation and to generate improved revenues to support operations.

The work identified that, despite these issues, accreditation to ISO 17025 standards for the microbiology laboratory could be achievable within a three-year timeframe, provided that:

- Adequate internal and external resourcing is made available to address the key issues
- Management and staff are committed to embracing the concepts of ISO 17025
- The quality system development and implementation is owned by the staff of the laboratory. Success is unlikely if the systems are developed and imposed by external consultants
- Appropriate technical support and training for laboratory staff is made available for those technicians involved directly in testing and calibration
- There is ongoing commitment from the Solomon Islands Government, and any development partners assisting, to see the project through to the end goal and beyond to ensure continued accreditation.

Recommended capacity building actions include the appointment of a commercially experienced technician who is an International Accreditation New Zealand (IANZ) or National Association of Testing Authorities (NATA) approved signatory to oversee the process toward accreditation, for 6 months in split inputs over the next two years.

A minimum of two new trainee staff need to be employed to help with the day-to-day testing, quality control and quality assurance work.

The estimated cost of providing required appropriate further training and external support based on the recommended option is AUD238,200. Details are provided in Table 8-1. Provision of such support should be made contingent on Solomon Islands Government commitment to addressing the highlighted internal resourcing and staffing issues. Assuming that after 3 years appropriate levels of laboratory operations can be achieved, then an external audit by an accreditation agency such as IANZ would be required to complete the accreditation process. The estimated cost for this is AUD40,000.

1 INTRODUCTION

The Pacific Horticultural and Agricultural Market Access program (PHAMA) has engaged the Cawthron Institute to conduct a Stage 2 of the activity SOLS12.

The objective of the work is to determine appropriate capacity building assistance measures to progress accreditation of the National Public Health Laboratory (NPHL) to ISO 17025 standard for microbiology testing.

Scope of works to be conducted:

(i) Assess the microbiological testing capacity of NPHL in terms of equipment, staff competencies and methodology with respect to meeting export testing requirements for product and water, and identify any gaps.
(ii) Assess the laboratory facilities, quality manual and training competencies with respect to ISO/IEC 17025 accreditation for microbiology, and identify any gaps. Assessment to include opportunities for development of private/public partnership on microbiology testing between NPHL and private laboratories such as those operated by Soltuna and Solomon Islands Water Authority (SIWA).
(iii) Assist NPHL in developing a detailed procurement plan for consumables necessary to support microbiology testing. Any such plan will need to be supported by the appropriate Ministry of Health manager responsible for procurement of goods and services.
(iv) Develop and deliver a structured training program on microbiology testing methodologies and provide an introduction to the principles of the ISO quality management system (QMS).
(v) Provide advice to NPHL on fees and charges with reference to consumables and operational costs for service delivery.
(vi) Evaluate training outcomes and provide recommendations on any additional training inputs required.
(vii) Develop a structured specific action plan of recommended steps to ISO 17025 accreditation in microbiology.
(viii) Provide logistical support to NPHL trainees during New Zealand-based training period.
(ix) Provide remote mentoring and technical support to NPHL staff on microbiology testing and QMS.

Outcomes of this Stage 2 will inform scoping of potential need to provide further technical inputs and mentoring to progress towards accreditation. Any future support would be dependent on demonstrated results in terms of training outcomes being maintained, and ongoing provision of adequate operational resourcing for NPHL by Solomon Islands Government (SIG). Any further support is intended to be implemented in collaboration with the Food and Agriculture Organization of the United Nations (FAO).

2 BACKGROUND

The export of whole and processed tuna represents the second-largest export industry in Solomon Islands. The fishing industry as a whole employs 3,000 people, representing a large proportion of registered workers. Processed fish is exported to a number of markets, including the European Union (EU), as frozen cuts and canned fish. Exports to the EU are subject to rigorous food safety testing for parameters such as microbiology, heavy metals and specific chemicals such as histamines. Management of these food safety monitoring programs is the responsibility of the Competent Authority (CA), which is required to conduct such testing through accredited testing laboratories. Countries exporting fish to the EU are subject to regular audit to ensure compliance with testing requirements.

In Solomon Islands, the CA is the Environmental Health Division (EHD), with testing conducted by the NPHL. The laboratory is not accredited for tests required to support market access such as chemical, microbiology and heavy metal testing. Although there is strong demand for NPHL testing services, issues over fee structures and budget allocation affect its ability to provide and maintain adequate services.

In 2012, as Stage 1 of SOLS12, PHAMA conducted an assessment of NPHL to determine potential for capacity building assistance. Stage 1 findings (see PHAMA Technical Report 39) recommended a broad range of capacity building measures be undertaken in a Stage 2 to develop NPHL testing and organisational capacity and obtain laboratory accreditation (ISO 17025). Consultation with stakeholders over the findings showed levels of concern over the sustainability and cost benefit of all the recommended actions.

In February 2013, arrangements were made for sampling and testing of required product and water samples in overseas laboratories to meet EU fish export requirements; sample submission pathways were confirmed; and funding support was provided for freight, consumables and testing fees for initial batches of samples. In April 2013, via the Seafood Industry Working Group established under SOLS11, agreement was reached between the CA and Industry for establishment of a cost recovery fund account to pay for costs of chemical and contaminant sample submission and testing to overseas laboratories. From June 2013, this fund was operational to support testing overseas. However, microbiological testing of water and product remains problematic due to logistics and time limits on sample submission to overseas laboratories. The main fish processing company (Soltuna) has some in-house microbiology testing capacity and there may be opportunity for a degree of public-private partnership on testing for product and water, in terms of testing capacity building, developing and maintaining staff competencies, and procurement of consumables.

In May 2013, a reduction of the potential SOLS12 stage 2 scope was agreed with NPHL and EHD, to be limited to microbiology capacity building only, focused on product and water testing, with a staged approach to progressing towards accreditation depending on resourcing availability and demonstrated commitment by SIG to addressing any organisational and resourcing needs of NPHL identified in this assessment.

Any future external support would be dependent on demonstrated results in terms of training outcomes being maintained, and ongoing provision of adequate operational resourcing for NPHL by SIG. It is currently envisaged that any such support would be implemented in collaboration with FAO.

3 INPUT 1 – INITIAL ASSESSMENT

A two-week visit was conducted in April 2014 for an initial assessment by the consultant of the laboratory's accommodation, staffing, methodology, quality assurance and workload in relation to microbiological testing.

During this initial visit to the NPHL, it was noted that the number of employed staff is still the same as five years ago. One of them, the chemistry analyst, is absent on study leave in Australia until late 2015. Dickson Manongi is still the Laboratory Director, and Kim Irofulifuli is still the microbiology analyst. There are also two other employees. One is the laboratory cleaner and glassware wash-up person, while the other is an odd-job man, driver and gardener.

As far as accommodation is concerned, the laboratory is still in very good order. It is spacious, well lit, fully air-conditioned, and clean and tidy. It is well appointed with equipment, although some pieces are not functioning and have not been repaired.

It was noted that there is an extreme shortage of bench equipment and instruments needed to carry out routine microbiological techniques. Items such as pipettes, pipette aids, pipettors and tips, test tubes and caps, racks and bottles, forceps and scissors are in very short supply or non-existent. This makes it difficult to perform testing on any more than a few samples at one time.

The main testing carried out is on drinking water for SIWA. The laboratory staff collect their own samples of water for testing on behalf of the EHD, with some assistance from health protection officers. There are occasional tests carried out on food samples for E.coli and Aerobic Plate Counts (APC).

Little progress has been made in the past five years towards the further development of quality systems. The Quality Manual is still in draft form and needs significant work. Methods and standard operating procedures (SOPs) are cumbersome and not of sufficient quality to be acceptable for accreditation to ISO 17025 standard. There are no calibration records for any equipment, and no records of routine quality control. The laboratory has no control cultures for any tests that it performs.

To address these fundamental gaps in laboratory quality assurance, several things were introduced immediately.

- Thermometers, each with an identification number, were placed in all incubators and fridges. Charts were attached to each unit and twice daily readings of temperatures were taken and recorded. These thermometers, however, will need to be replaced, as they are not accurate enough to read down to anything less than ± 0.5 of a degree.
- Daily calibration of the pH meter using standard buffers was introduced and results recorded.
- Daily weight checks were started on the two balances and results recorded.
- A plan was created for weekly environmental testing for aerial contamination of various sites throughout the laboratory. This was initiated immediately.
- Positive and negative control cultures were isolated from water samples and were put into use on a daily basis.

- A simpler rapid chromogenic substrate method for coliforms and E.coli in water was introduced.
- EU-approved methods for APC and E.coli testing in food samples were introduced.
- Worksheets for these tests were printed and were used as a permanent record of the testing results.

The layout of the laboratory was changed to separate the media making and the sterilisation of media and glassware from the main laboratory. The laboratory was rearranged into areas for sample preparation, method performance and results reading and confirmation testing. These changes were implemented to help with the workflow in the laboratory. These changes were not intended to be permanent and should be reviewed every few months to see if further modifications would improve efficiency and workflow.

During the visit period, 12 samples of food were tested, which gave both staff members the chance to get hands-on experience of the new tests. This was, however, a tedious and cumbersome exercise due to the lack of equipment necessary to do the testing in an efficient manner. While both staff demonstrated their ability to perform the tests adequately, their task would be a lot easier and more efficient given the proper tools with which to work.

For most of the past year, the laboratory has had the assistance of an overseas volunteer, who has been helping with standardising and streamlining methods. Although this has helped, there are still many methods that need updating. This will be an ongoing task for the laboratory over the next year or so.

The fact that there are only two technical members of staff to try to run the laboratory operations has made it difficult to address the large numbers of issues facing the laboratory.

The initial assessment concluded that although the facility is adequate for the purposes of microbiological testing, there are substantial capacity gaps in terms of staffing, operational resourcing levels, testing and quality assurance procedures, and training levels of staff. These will all need to be addressed as part of a comprehensive plan if the stated aim of accreditation for microbiological testing is to be considered achievable.

4 INPUT 2 – TRAINING OF NHPL STAFF AT CAWTHRON LABORATORY IN NELSON, NEW ZEALAND

NPHL staff require training in an accredited laboratory to see how things could and should be done, as well as gaining more knowledge and confidence in methodology and bench techniques.

The original intention was for the two technicians to visit the Cawthron Institute in Nelson, New Zealand, for three weeks' training in June 2014 to provide them with initial grounding in methodologies and QMSs. The training had to be shortened to two weeks because of time and funding constraints. The result of this was that training had to be curtailed in some areas and concentrated on the basic quality, methodology and calibration needs to meet ISO 17025.

This training was not in the form of a formal course, but was a hands-on experience in an accredited microbiology laboratory. Topics covered are tabulated below.

Table 4-1 Training topics at Cawthron Laboratory

Topics week one
Use of pipettors and tips
Membrane filtration of waters for faecal coliforms/E.coli and enterococci
Use of rapid chromogenic substrate method for drinking water testing
Testing and result reading of samples put up with Petrifilm, including APC, Staphylococcus and E.coli
Staphylococcus testing using a spread plate technique
Most Probable Number (MPN) testing by tube methods and the IDDEX Enterolert and Colilert systems
Preparation of fish samples for testing
Confirmation tests for faecal coliforms and E.coli using ECMug broth
Confirmation test for Staphylococcus by coagulase
Use of control cultures, including hands-on experience of the three tier method
Enumeration of bacteria in environmental swabs by APC
Instruction in glassware washing, preparation and sterilisation
Reading and interpretation of the results of all samples tested by trainees
Topics week two
Performing tests of food samples for E.coli and APC
Instruction on how to calibrate pipettors, balances and thermometers
Introduction to Salmonella testing using the ISO method
Introduction to Listeria testing, including performing environmental swab testing by a rapid screen method
Quality assurance instruction, including use of complaints and non-conforming work files

A variety of water testing methods were covered and both technicians were given time to perform membrane filtration, MPN and rapid methods for various water source types on a number of routine samples.

Food sample preparation and testing was also included in the first week. The technicians had to weigh out and appropriately dilute a selection of different food samples. Training was restricted to testing that would be relevant in the NPHL. This included APC, Yeasts and Moulds, E.coli, Enterobacteriaceae and Staphylococcus aureus.

The three tier system for the use of daily control cultures was explained and expected reactions of positive and negative cultures were demonstrated.

The process of glassware washing and checking for cleanliness was covered, as well as the preparation of sterile instruments and pipettes for routine use. Detergent residue and water toxicity testing was discussed but not performed due to time restraints. These quality control procedures are a requirement for accreditation. Media making, sterilisation and validation were demonstrated. The different means of sterilisation by hot air, steam and filtration were discussed for the relevant types of media used at the NPHL.

Calibration of laboratory equipment was covered and the timeframe and methodology for each piece of equipment was explained. This included pipettors, balances, pH meters, incubators and fridges.

Copies of each of these methods were supplied so that there was minimal adjustment needed to put them into the NPHL format.

The Cawthron Institute's quality manager spent time with both technicians in the area of quality assurance. This covered the various aspects of quality assurance as laid out in the quality manual that the laboratory would be expected to comply with for accreditation. This included the use of complaints and non-conformance work files. It also covered the place of customer service in a commercial laboratory and the need for accurate and timely reporting of work.

Time was also spent on the reading and interpretation of test results. Troubleshooting of issues such as contamination, equipment failure and technical error were discussed. The use of confirmation tests was demonstrated and calculations of Colony Forming Unit (CFU) and MPN results explained.

An introduction to pathogen testing was all that the attachment period permitted. Standard tests for Listeria and Salmonella were demonstrated but could not be covered in detail.

It was an intense two weeks for both technicians, who had to take on board a lot of information and then try to implement as much as possible on their return to the NPHL.

The training conducted in this input represents only an initial exposure to the correct testing methodologies and quality assurance practices. Substantial sustained further training and mentoring by experienced laboratory staff will be required to progress capacity building to levels required to achieve accreditation.

5 INPUT 3 – SUPPORT FOR TRAINING OUTCOMES

A second two-week visit by the consultant started a week after the two technicians had returned to the NPHL. Unfortunately, the timing of this visit (due to time constraints for activity implementation) did not really give them much time to digest all their recently gained knowledge and implement any changes in the laboratory.

Procedures introduced during the first visit (i.e. temperature checks, balance checks) had still been mostly carried out by the volunteer and two university interns during the absence of the two technicians.

It was immediately planned to make media and to generate some work so that the recently learned methods could become routine. It was also a good way to introduce the trainee interns to the common food and water testing techniques.

This plan was delayed by lengthy power outages on the first three days, and the laboratory running out of water at approximately 2.30 pm every afternoon. The laboratory has an electricity generator but the battery used to start it was dead. This required a request to the Health Department stores for replacement. It had not arrived by the end of the consultant's visit. Unfortunately, it is clear that these types of issues characterise the limitations placed on what staff can do in terms of performing regular consistent testing.

Most of the first week was taken up with training the two interns in basic microbiology. Mr. Manongi was mostly committed to administrative duties and Miss Iro to trying to catch up on the issuing of reports. The latter was no easy task as the system used and the inadequacy of the computer available made producing each report a very slow process.

Some time was spent ensuring that the day-to-day quality control jobs were being performed and results recorded. These tasks were being carried out by the interns. Empirical technical procedures were taught, such as Gram staining, wet preparations, plating and media making.

PowerPoint presentations on a variety of microbiological topics were also used to provide some basic instruction to the interns. This was all in an attempt to get them to a point where they would be useful in the laboratory and able to perform most of the basic procedures with minimal supervision.

The interns were supervised putting up water tests and preparing and testing a small number of food samples for E.coli and APC.

The second week was shortened as the Monday was a public holiday. Emphasis this week was on testing a number of fish product, food samples, and ice creams, as well as drinking waters and some swimming pool waters.

Miss Iro did much of this work along with the interns. This was once again a slow process as the laboratory has not enough bench tools (pipettes, pipettors, tubes, racks) to do any more than a few samples at a time.

Attempts were made to meet with people from the Health Department central stores and finance sections to discuss potential improvements in procurement practices. However, meetings were not able to be conducted due to staff in those departments having competing commitments.

6 NHPL FEES AND OPERATIONAL COSTS FOR SERVICE DELIVERY

The fees for the provision of testing services for the NPHL are set in the Pure Food (Food Control) Regulation 2010 (twentieth schedule, regulation 65(4)). It is not clear how the fees for each test have been determined, nor is it clear which of the tests detailed are actually expected to be performed in-house and which are subcontracted to overseas laboratories (in which case the fees may be based on the costs charged by these laboratories – this seems to be the case for more complex tests).

In general, the fees for more routine basic tests listed in the regulation are significantly higher (by 3–10 times) than those charged in overseas laboratories such as in Australia and New Zealand.

Before establishing an appropriate testing cost that will be charged to customers, agreement needs to be had on what the actual purpose of the NPHL is, and how it is financially structured.

To provide a guide on revenues, some assumptions can be made based on the experience of the consultant from working with a number of laboratories in the Pacific. In general terms, in order to break even, without any additional funding or financial support, a laboratory in a Pacific Island country, with limited access to suppliers, and exposed to higher consumable costs than an equivalent laboratory in Australia or New Zealand, needs revenue that is around three times its labour cost. For the NPHL, this would amount to approximately AUD70,000. This is based on one technician (AUD8400), one assistant (AUD7400) and 50% of a lab manager (AUD7500).

In the past 12 months, the laboratory processed 456 samples, although none of these were actually charged out as they were all for internal Health Department purposes. Charged at the prices proposed in Appendix D, this would have generated a revenue of AUD17,865.

The minimum staffing level for any laboratory is three full-time equivalent staff, plus some admin support (cover for sick leave, annual leave, etc.). This will allow for the routine provision of basic microbiological and chemical testing services. It will benefit from regular support from experienced laboratory people.

The total revenue requirement to support effective operations is determined by two factors: price and volume. Within the economy of Solomon Islands, it is highly unlikely that the testing requirements from commercial customers will be sufficient in volume to generate the revenue levels required for the lab to break even, should tests be charged at fee rates comparable to overseas laboratories. However, charging high fees that would reflect the underlying test capacity costs will likely provide little incentive for commercial operators to use the services of the NPHL.

It would appear that to generate the sample volume required to generate the testing throughput to achieve and maintain accreditation for microbiology testing, the pricing of the testing services needs to be close to that of overseas laboratories, unless there is another compelling reason to use the NPHL (for example, turnaround time).

In reality, NPHL will, as is the case for most laboratories in the Pacific Island region, need ongoing financial support for the foreseeable future in order to provide testing services to government and industry at competitive rates. This could come directly from additional Government budget support, or through cost recovery from industry. As an example, Solomon

Island Government could make testing by the NPHL compulsory for export product at a cost recovery rate that reflects the costs of providing the service, or at least a significant proportion thereof. However, consideration will need to be given to what burden this may place on industry and whether they will receive a credible service.

It is important to note that sample volumes from domestic industry testing could provide an additional revenue source / means of covering labour cost for the NPHL staff. This could include providing sampling services to Ministry of Health, providing training programs to businesses regarding food safety risks, and providing testing services to domestic food and water suppliers.

It is clear that the current volume of work carried out by the laboratory is insufficient to achieve accreditation at ISO Standard level. This needs to be addressed by NPHL and EHD to substantially increase the sampling and testing volumes for both domestic and export products.

It is possible that relationship building with other laboratories in Solomon Islands (Soltuna and SIWA) could result in the use of the same methods for water and food testing, making comparison of results useful to all concerned. It is also possible that exchange of staff for training and work experience could be helpful to all three laboratories.

The option of a public-private partnership may also be an option. This was not investigated fully, due to limited access to the parties involved during the consultancy period. However, it is worth noting that there are obviously potential benefits of collaboration between Soltuna and NPHL in terms of ensuring similar training, qualifications and competency development for staff through combined training inputs. There may also be opportunities to reduce costs by collaborating on procurement for equipment and consumables. This will require further discussion between stakeholders.

7 RECOMMENDATIONS

The NPHL is an excellent facility that has been, and still is, underutilised.

The aim of accreditation for microbiology testing to an internationally acceptable level is an admirable one and is one that is ultimately achievable.

However, significant effort is still required to achieve this goal. The following issues will need to be addressed utilising either Solomon Island Government (SIG) resources internally or external support from development partners. Those issues that are considered a high priority and that require internal resourcing should be considered as prerequisites before further progress can be made. Any realistic progress toward the goal of accreditation will be contingent on these issues being addressed. NPHL and EHD management will need to take responsibility for resolving the staffing, procurement and maintenance issues identified. If the necessary commitment is shown by SIG, and staff from NPHL and EHD, then development partners such as PHAMA and FAO can have confidence in being able to provide the additional capacity building assistance identified to progress towards accreditation.

Table 7-1 Issues to be resolved

Issues	Priority	Recommendation for improvement	Source of support
Existing staff are too few in number and are too inexperienced in running a commercial laboratory to get the laboratory to the desired level. Two people with limited quality assurance and testing experience cannot run an accredited laboratory to ISO 17025 standards.	High	Employ two more trained staff, as laboratory assistant / technician. Technicians should ideally be qualified. Assistants should have sufficient laboratory experience.	Internal
Staff currently lack adequate technical skills of testing methodologies, operational procedures and laboratory QMSs.	High	Implement a comprehensive up-skilling training program involving hands-on training and mentoring using experienced laboratory training providers based on a combination of in-country training and additional overseas attachments. Ideally, such training should lead to a recognisable qualification or level of technical competency.	External
The administration structure responsible for the laboratory is too cumbersome and convoluted to be able to assist the laboratory to grow at the pace required to attain accreditation within the next two to three years, and to maintain an un-interrupted service.	High	Agree on delegated authority structure review, combined with an appropriate and adequate operational and capital budget, for a period of at least 6 months, preferably 12 months. Performance against this budget should be regularly monitored (monthly).	Internal
The laboratory has insufficient records in all aspects of quality control, quality assurance, calibration and training to satisfy an auditor.	High	Agree on priority SOPs to develop, if needed with external support. Provide adequate resources to develop record systems.	External

Issues	Priority	Recommendation for improvement	Source of support
The laboratory must demonstrate ongoing satisfactory performance in an Inter-Laboratory Comparison Program (ILCP).	High	Agree on ILCP participation schedule, including costs etc., and implement.	External
Staff have little appreciation of the service commitment required to run a commercial laboratory. The vast majority of previous work has been for government agencies, with little private work carried out. This has led to an institutionalised attitude to sample testing, and delayed reporting of results. Commercial customers will expect a more timely service.	High	Provide staff with exposure to working in a commercial laboratory environment.	External
The power and water supply problems need to be addressed urgently.	High	Agree on plan to mitigate risk, provide business case for management approval and implement.	Internal
The system of procurement of consumable supplies and maintenance services is affecting the laboratory's ability to perform at a satisfactory level. The lack of consumable materials and small benchtop equipment such as tubes, racks, pipettes, pipettors and utensils means that the laboratory can only carry out a very limited amount of testing on a daily basis.	High	Develop a 'procurement' SOP, with details on minimum stock levels and supplier agreements. A list of materials proposed for purchase to allow the laboratory to expand its services is laid out in Appendix A. The ability to order essential items as new work comes on board will help the laboratory immensely.	External
The laboratory processes a very small number of samples per annum for the size of the facility. This means that there is insufficient result data available for any audit assessment. An increase in work from commercial customers is also crucial if the laboratory wants to achieve accreditation in the food testing field. This will allow the laboratory to demonstrate that it is capable to provide an accurate, cost effective and timely service.	High	Arrange for regular samples to be coming in – ideally from paying customers, otherwise from government projects in need of testing (e.g. instigate regular bore water sampling, restaurant kitchen sampling, imported food product sampling). Suggested fees for common tests are proposed in Appendix B. Seek direct contact with potential external and internal (government) customers, to create awareness of the testing capability.	Internal/ external

Assuming the underlying key capacity issues are resolved as a prerequisite, a summary of key technical elements of capacity and systems which will then be required before accreditation itself could be achieved are:

1. Receipt of Supplies – method outlining checks for acceptance.
2. Media Validation – methods for media validations of all media made on site and of ready to use media and kits.

3. Media Making – recipes, dates, weights, volumes, batch numbers of ingredients, pH checks, analyst names, sterility checks and volume checks where appropriate.
4. Autoclaving – load validations need to be performed. Records for each load of time, temperature and load content need to be kept.
5. Tests – records need to be kept showing analyst(s') name(s), dates and times in and out of incubators, batch numbers of media used, results of control culture(s), confirmation test and calculations. Evidence of checking and approving by a Key Technical Person (KTP) and checking of final report.
6. Training Records – all staff need comprehensive records kept of their testing and quality control experience.
7. KTP Appointments – these technicians are responsible for the release of test results and their appointment must be as per the process documented in the Quality Manual.
8. Health and Safety – as well as all the usual personal safety requirements, all contaminated glassware, cultures and instruments must be autoclaved before washing or disposal.
9. Environmental Monitoring – weekly checks of the air in the laboratory should be carried out as per the prescribed method. Once pathogen testing has commenced, then weekly environmental swabs looking for Salmonella (and Listeria if appropriate) should be carried out.
10. Quality Control Requirements – control cultures for all tests should be purchased from a recognised collection, such as the Institute of Environmental Science and Research in Wellington, New Zealand. Media validations – as specified above. Monitoring of reagent water for media preparation – method for daily pH and conductivity tests and monthly APC of supply. Yearly testing of Reagent Water Toxicity and Detergent Residues – methods and records needed to demonstrate compliance.
11. Inter-Laboratory Comparison Program – participation in a program supplied by an accredited ILCP provider is necessary to demonstrate competency.
12. Calibration – thermometers six-monthly; spatials on water baths, incubators and ovens every two years; daily temperature readings on all incubators, water baths and fridges; daily mass checks on all balances and six-monthly in-house repeatability testing. Autopipettes – every three months at the volumes used. pH meter – daily records of calibrations with at least two standard buffers.
13. Equipment register – all equipment must have a unique number with a record system that allows for easy identification for recalibration.
14. Non-Conforming Work and Complaints – staff must be familiar with these requirements and keep records of the appropriate actions taken to address each issue.

8 THE WAY FORWARD TO ACHIEVE ACCREDITATION

There are two options for how to approach the accreditation process, dependent upon resource availability and expectations regarding potential timeframes for accreditation to be achieved.

Option 1 – Accreditation within 3 years

With appropriate commitment from SIG (via the Ministry of Health and Medical Services) and the staff of NPHL and EHD, and application of adequate and appropriate resourcing by PHAMA and other development partners, it is considered that accreditation to ISO 17025 standards for microbiology is achievable. However, this will require concerted and sustained assistance being provided by all parties to address the underlying key issues identified.

In addition to the required commitments by SIG, a key element of this resourcing would be utilisation for an extended period in Honiara of someone with significant experience in an accredited commercial laboratory to initiate and effect the changes necessary to put the laboratory on the path to accreditation. This need is estimated to be the equivalent of six months' work, either in one block of full-time work, or split into three two-month staggered inputs over the course of 18–24 months. This longer-term mentoring would help change the institutionalised approach, enable training of new staff, encourage existing staff, assist in developing a customer base and ensure the quality assurance requirements were addressed. For this approach, it would be essential that two additional staff be employed.

The current workload in the laboratory needs to be increased five-to-tenfold over the next 1–2 years to ensure there is enough data for audit purposes across the range of tests performed. This can only be realised by developing a greater commercial customer base for the laboratory, which would be a high priority for the consultant during the first visit. This would also help offset the additional cost of new staff.

Option 2 – Gradual improvement of laboratory capability

If the prerequisite changes identified cannot be effected by NPHL and EHD in the short-to-medium term, then a more gradual process has to be considered.

Expert technical assistance would still be required, but could be scaled back to a four week visit (possibly split into two visits) each year for the next three years. The main thrust of these visits would be to ensure that the basic work is being carried out to a good standard, and that the quality assurance and quality control work is progressing. This could include setting work plan objectives for periods between visits, and measuring performance and capacity progress via a form of internal audit. Depending on the outcome of the internal audits, further training may be required. Helping to establish a customer base for the laboratory would also bring in much needed work. The final timeframes for potential accreditation would be determined by the progress made in this initial three-year staging of support.

If this approach is to be taken, then at least one new trainee staff member should be employed as soon as possible, with a second added if and when funds are available.

Regardless of the option taken, ongoing negotiations are required with government agencies to try to speed up the processes by which the laboratory purchases consumables and obtains plant and equipment maintenance support. The ongoing engagement of a technical expert

should be able to assist with the purchase of consumables, which would help alleviate some of this problem.

At this stage, assuming NPHL and EHD commitment to resolving the identified issues, and that an appropriate level of internal and external resourcing is available, then **Option 1** is the recommended course. Detail of the content and costings of the work for this option are provided below.

It should be noted that the costs do not include the fees or audit costs for supporting the International Accreditation New Zealand (IANZ) accreditation audit itself. It is estimated that, should the laboratory reach the level of operations to receive an audit, costs for that would be in region of $40,000. Continuation of accreditation would require participation in an ILCP (three rounds of water and food sample testing) and subsequent annual audits by IANZ, with estimated total minimum annual costs of $11,000.

Table 8-1 Proposed pathway and estimated cost to accreditation within three years

Action	Expected outcome	Timeframe	Cost structure	Estimated cost	Priority
Appoint a technical expert to oversee the running of the laboratory	Establish current methods; develop Quality Assurance procedures; generate commercial income from local industry; train existing and new staff	Ideally 1 x 6 months at earliest convenient date. Realistically 3 x 2 month visits over an 18–24 month period	Fees for 6 x 21 = 126 days @$700/day Airfares $1,500 Accommodation and daily allowance 30 x 6 = 180 days @$350**	$88,200 $4,500 $63,000	High
Negotiate with the Health Department to allow the laboratory to proceed more independently with purchasing to avoid long delays in receipt of essential supplies	Ability to order direct from supplier and be able to react more quickly to increased demand for work	During initial visit of technical expert	Included in the technical expert's fees	$0	High
Appointment of two new technical staff, either experienced or at trainee level	To allow the laboratory to increase its workload and to provide cover for holidays and sickness	As soon as possible	Trainee $7500 per annum Technician $8400 per annum	SIG cost	High

Action	Expected outcome	Timeframe	Cost structure	Estimated cost	Priority
Training of new staff	Basic training in methodology, routine procedures in quality control and quality assurance by the technical expert. Possible additional training externally	Ongoing during visits	Included in technical expert's fees	$0	Internal High
Training of existing staff in Solomon Islands	In-house by the technical expert, including development of commercial work and customer service. Expansion of current methodology and quality assurance	Ongoing during visits	In house: included in technical expert's fees	$0	Internal
Training of staff at Cawthron, New Zealand	Immersion in ISO 17025 laboratory, experiencing all systems and procedures in process	Three training periods, for one Trainee each, for four weeks	Training fee $5,000 per week, airfares $1500, daily allowance at $200 per day* (30 days), total $27,500 per training period	$82,500	High, external
Estimate of total costs for external training support			**Total (AUD)**	**$238,200**	

** Daily allowance in New Zealand based on backpacker-type accommodation ($210 per week) plus $170 per day pp*

*** Daily allowance in Honiara based on New Zealand Aid Programme rates (15 April 2015) – https://www.aid.govt.nz/funding-and-contracts/contracting/diem-rates*

Assuming availability of the proposed funding to progress implementation, a potential training and implementation schedule is provided below.

Table 8-2 Proposed training and implementation schedule

Location	Mid/late 2015	Late 2015 / early 2016	Early/mid 2016	Mid/late 2016	Early/mid 2017	Mid/late 2017
NPHL	Tech Expert (2 months)		Tech Expert (2 months)		Tech Expert (2 months)	IANZ audit
Cawthron		Technician (4 weeks)		Trainee 1 (4 weeks)	Trainee 2 (4 weeks)	

9 LIMITATIONS

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APPENDIX A DISPOSABLE, SEMI DISPOSABLE AND PERMANENT ITEMS TO BE PURCHASED (AUD)

	Item	Price AUD (est.)	Unit	Quantity	Total cost AUD	Disposable (D) Semi disp. (SD) Permanent (P) (>2 years)	Priority	Minimum stock
1	Test tubes (150 x 18)	60	125	8	480	SD	High	2
2	Test tubes (125 x 16)	75	250	4	300	SD	High	2
3	Caps for 1	300	500	1	300	P	High	N/A
4	Caps for 2		500	1		P	High	N/A
5	Test tube racks	35	1	20	700	P	High	N/A
6	Glass pipettes (10mL)	15	1	100	1500	SD	High	50
7	Plastic pipettes (10mL)	140	400	1	140	D	Medium	50
8	Pipette gun	450	1	2	900	P	High	N/A
9	Pipettors (100–1000ul)	450	1	3	1350	P	High	N/A
10	Petri dishes	80	500	10	800	D	High	5
11	Pipette tips	50	1000	10	500	D	High	2
12	Sterile containers (120mL)	200	250	5	1000	D	Medium	2
13	Stomacher bags	100	500	2	200	D	High	1
14	Steriliser roll	300	1	1	300	D		0.5
15	Wooden applicator sticks	50	1000	2	100	D	Medium	1
16	Gauze swabs (sterile)	5	10	50	250	D	Medium	20
17	Membrane filters	250	300	2	500	D	Medium	1
18	1 oz universal containers	250	144	2	500	P	High	1

Initial investment required: $9820

Estimated ongoing yearly investment (sample volume dependent): $3790

APPENDIX B PROPOSED MEDIA, CHEMICALS AND KIT-SETS TO BE ORDERED

	Item	Price AUD (est.)	Unit	Quantity	Total cost AUD	Priority	Minimum stock
1	Plate Count Agar	80	500g	4	320	High	2
2	Baird Parker Agar	120	500g	1	120	Medium	0.5
3	MFC Agar	150	500g	1	150	High	0.5
4	Sabouraud Agar	120	500g	1	120	Medium	0.5
5	TBX	500	500g	1	500	High	0.5
6	VRB (Dairy)	120	500g	1	120	High	0.5
7	XLD Agar	120	500g	1	120	High	0.5
8	Chromagar (Salmonella)		500g	1		High	0.5
9	Tryptic Soy Agar	150	500g	1	150	High	0.5
10	Buffered Peptone	100	500g	2	200	High	1
11	EC Broth with MUG	150	500g	1	150	High	0.5
12	MMGM Broth	100	500g	3	450	High	1
13	Proteose Peptone	250	500g	1	250	Medium	0.5
14	Selenite Broth	150	500g	1	150	High	0.5
14	Rappaport V. Broth	100	500g	1	100	High	0.5
15	Tryptic Soy Broth	80	500g	1	80	Medium	0.5
16	Egg Yolk Tellurite	160	100mL x 12	1	160	Medium	0.5
17	Sodium Glutamate	70	130g	4	280	High	1
18	Readycult	100	20	30	3000	High	10

Estimated annual investment required (sample volume dependent): $6420

APPENDIX C SUGGESTED PRICE (AUD) OF TESTS FOR COMMERCIAL CUSTOMERS

Test			Suggested Price (AUD)
APC –	water	cfu/mL	25
	food	cfu/g	25
Coliforms / faecal coliforms / E.coli – water:		Detected/Not Detected	20
MPN Count			30
Membrane filtration		cfu/100mL	35
Enterococci – water membrane filtration		cfu/100mL	30
Swimming pool water (APC / faecal coliforms / Staph)			60
E.coli – food		MPN/g	35
Staph aureus – food		cfu/g	25
Environmental swab (APC)		cfu/g	20
Salmonella – food		Detected / not detected	50

APPENDIX D SUMMARY OF MICROBIOLOGICAL TESTS PERFORMED AT NPHL IN 2014

Month	Samples received	Tests required			
		TC/FC/EC	APC	Enterococcus	Salmonella
January–March	80	80	10	0	0
April–June	178	178	66	0	0
July–September	143	143	51	0	0
October–December	55	55	22	6	5
Total	**456**	**456**	**149**	**6**	**5**

TC = Total Coliforms; FC = Faecal Coliforms; EC = *E. coli*

SAMPLE TYPE:

- Food
  - Ready-to-eat food
  - Confectionary
  - Frozen fish
- Water
  - Borehole
  - Drinking water: portable water, rainwater, river
  - Bottled water
- Environment
  - Rivers, streams

SAMPLE ORIGIN:

- Communities
  - Burns Creek, Gwaimaua, Vatukola
- Emergency response (WASH)
  - Evacuation Centres
  - Nomad water purification systems
- Food outlets
  - Kaibas, hawkers, cafés
- High school student research/assignments
- Hotels
  - Swimming pools
- Hospitals & clinics
  - National Referral Hospital, Gizo Hospital, Mbokona Clinic, Naha Clinic

- Individuals
  - Filtered water
- Industries/companies
  - Coconut industry
  - Fish/cannery
  - Mining company
  - Bottled water companies – local and overseas bottled water
  - Ice cream producers
  - Jelly producers
  - Ice block (confectionary) producers
  - Breweries
- Non-governmental organisations
  - Red Cross, World Vision
- Office buildings
  - Ritaleven
- Outbreak investigation
  - Guadalcanal Province, Western Province
- Point of entry
  - Airport (international and domestic)
  - Wharf/ports
- Schools
  - Tamlan, KGVI, Mbokona, Tenaru, Ruavatu

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URS Australia Pty Ltd
Level 27, 91 King William St
Adelaide, SA 5000
Australia

T: +61 8 8366 1000
F: +61 8 8366 1001

www.urs.com.au