Food and Agriculture Organization of the United Nations

LABORATORY MAPPING TOOL TRAINING FOR THE PACIFIC ISLAND COUNTRIES AND THE LABORATORY MAPPING TOOL ASSESSMENT FOR THE FIJI VETERINARY PATHOLOGY LABORATORY AND BIOSECURITY AUTHORITY OF FIJI

TCP/SAP/3802 (OT.SAPDD.OTCP200020279)

CONTENTS

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This assessment report is authored by Dr Chris Morrissey (Australia) under the supervision of Dr Sonevilay Nampanya (FAO) and Dr Scott Newman (FAO) with the support from Ms Temwanoku Ioakim, Dr Peter Thornber, Dr Kennet Cokanasiga, Dr Kachen Wongsathapornchai, Dr Filip claes. The assessment work was funded by TCP/SAP/3802 - Strengthening Capacities to Improve Animal Health and Enhance Livestock Production in the Pacific Region

ACRONYMS

AI	Avian influenza
AMR	Antimicrobial resistance
ASF	Africa swine fever
BAF	Biosecurity authority of Fiji
Brucellosis	Brucella Abortus
CSF	Classical swine fever
FAO	Food and Agriculture Organization of the United Nations
FMD	foot and mouth disease
FVL	Fiji veterinary pathology laboratory
LMT	laboratory mapping tool
LMT-C	laboratory mapping tool – core
LMT-S	laboratory mapping tool – safety
QA	quality assurance
QAS	quality assurance system
QM	quality management
QMS	quality management system
PT	proficiency testing
SPC	Secretariat of the Pacific Community
TB	tuberculosis

EXECUTIVE SUMMARY

The Food and Agriculture Organization of the United Nations (FAO) laboratory mapping tool (LMT) is based on a standardized format that allows data to be captured either by external evaluators or through self-assessment. The tool is designed to facilitate the assessment of laboratory functionality in a systematic and semi-quantitative manner. Application of the FAO laboratory mapping tool in Asia and Africa facilitated standardized assessments of a large number of laboratories and the evaluation of strengths and weaknesses at the national and regional levels. Results served to measure general progress of laboratories and targeted interventions, e.g. improvement of quality assurance (QA) and biosafety/safety systems.

The FAO LMT- Core (LMT-C) over many years has been used to measure the laboratory performance for core activities and aid laboratory assessment. Laboratory safety and biosafety is an important issue for all laboratories, the FAO LMT for laboratory - safety module (LMT-S) based on a questionnaire to assess safety in areas such as biosafety, electrical, fire and chemical hazards, and the use of PPE. Both these tools are used to determine gaps in laboratory functionality and safety and define mechanisms and targets for capacity building to fill these gaps.

The FAO LMT training for the six Pacific countries; Cook Islands, Tonga, Samoa, Fiji, Solomon Islands and Vanuatu and the FAO LMT assessment of the Fiji laboratories; Fiji Veterinary Pathology Laboratory and biosecurity authority of Fiji, were part of the technical support under TCP/SAP/3802 “Strengthening capacities to improve animal health and enhance livestock production in the Pacific region”. This project included the assessment of disease surveillance, communication and reporting capacities and the laboratory capacity of animal health and production services for the six Pacific countries. The detailed report on laboratory and surveillance capacity for the six Pacific countries is included in the end of assignment report on the information gathered from meetings with the stake holders in animal health and production services in each country and included public health laboratory participants.

The six countries; Fiji, Tonga, Samoa, Solomon Islands, Vanuatu and the Cook Islands, have food safety, research and plant protection laboratories with different capacities. Fiji is the only country with active veterinary diagnostic laboratory, the veterinary pathology laboratory (FVL), and has the biosecurity authority of Fiji (BAF) laboratory and plant biosecurity laboratory with both these laboratories having some PCR capacity. Fiji (plant & biosecurity laboratories), Tonga (food safety & plant laboratory), Samoa (Scientific Research Organization Laboratory) and Solomon Islands (plant & public health laboratories) have some PCR capacity. The six countries also have some links to public health laboratories; the Solomon Islands had links to the medical laboratory for testing and Samoa had an AMR program with Melbourne University. Fiji, Samoa and Vanuatu had parasitology capacity.

All six countries lacked resources for the animal health and production services for both field and laboratory activities including the lack of Veterinarians, with Samoa having no Veterinarians and only Fiji with a veterinary laboratory. All the six countries lacked the resources to do disease diagnosis and disease surveillance, while Fiji was able to implement some surveillance activities for tuberculosis (TB) and brucellosis (*Brucella Abortus)*. All the

countries have sent samples or have the opportunity sending samples for testing to New Zealand (Samoa & Vanuatu) or to Australia (Solomon Islands), but this was not easy and does rely on support from New Zealand and Australia. The permit to send samples takes a long time to complete (it has taken up to three months), currently Australia is supporting the Pacific Islands with African swine fever (ASF) diagnosis confirmation and training in use of rapid test with Secretariat of the Pacific Community (SPC). Countries don't have the laboratory resource to allow rapid diagnosis of disease outbreaks.

It is recommended that countries have a veterinary laboratory with a molecular laboratory that has a basic realtime PCR (small laboratory based portable realtime PCR machine) capacity that allowed them to do diagnosis for disease outbreaks/problems and disease surveillance, a serology laboratory for disease surveillance and a bacteriology laboratory for bacterial culture/identification and antimicrobial resistance (AMR), pathology for gross pathology as part of disease diagnosis and a parasitology laboratory as required. This will give countries a national laboratory and the laboratories needed a starting point for providing diagnostic support to farmers and the animal health field staff in controlling disease and in early detection of diseases of importance e.g. Avian Influenza (AI), ASF, classical swine fever (CSF), foot and mouth disease (FMD) & bacteria (E-coli & Salmonella etc) and for disease surveillance.

The minimum requirements to start disease diagnosis and surveillance would be a capability to do realtime PCR for viral and key bacterial diseases in the laboratory and the capability to culture identify bacteria would further increase a countries capability and a bacteriology laboratory would also allow AMR testing.

It is important the countries only commit to a national laboratory if it has the resources, particularly operational budget for the laboratory and for carrying out surveillance, that allows the laboratory to test samples and the budget for field staff to collect samples. It was recommended that countries consider using medical/biological science graduates to resource laboratories as countries lack veterinarians. All countries need to commit a budget that is required to allow a laboratory to operate at international best practice for quality assurance for accurate and correct laboratory results and for biosafety/safety and biosecurity for safety of staff and the environment. The countries will need assistance in establishing a laboratory in their country, including laboratory management system and budget and training in quality assurance, laboratory management system (including budget) and safety/biosafety and biosecurity.

It is important to establish FVL as Fiji's national laboratory with an international recognised diagnostic laboratory and it is also recommended that FVL to be one of the regional leading laboratory to provide support to the Pacific Islands countries. Having a regional reference laboratory as a confirmation laboratory and to assist in ensuring laboratories are giving the correct results (through proficiency testing: PT) is a important part of setting up Pacific country laboratories and a laboratory network

INTRODUCTION

Following a request from the countries, FAO has provided support in the Pacific to the development of the livestock sector through various programmes and projects. This TCP/SAP/3802 entitled "Strengthening capacities to improve animal health and enhance livestock production in the Pacific". This project will review current livestock situation in the targeted countries to support and develop regional livestock development and enhance sustainable livestock production for income generation, food security, and nutrition while reducing the risks and impacts of transboundary animal and zoonotic diseases. The project aims to build technical capabilities for animal health and welfare, and veterinary public health; and support key work to improve livestock production. The project will:

- support activities to improve the national animal health, welfare and production capacities in project countries;
- encourage regional collaboration through improved communications and sharing e.g. animal health data, animal welfare standards;
- help countries demonstrate their disease status through implementing disease surveillance, testing and reporting;
- support efforts by governments to establish and improve slaughter facilities through training of meat inspectors and butchers on humane killing of livestock and hygienic meat processing including the slaughter of animals for custom reasons;
- assist countries in improving their technical capacity to strengthen biosecurity policies and operations (e.g. zoning of diseases and inter-island movement controls) at the national and farm level to reduce risks of Transboundary animal diseases (TADs) such as African swine fever (ASF)[1] and rabies;
- review animal nutrition and feed, pasture management, and guidelines to improve pig housing design, health, welfare, and management;
- develop a training course in beekeeping, bee diseases and honey production to improve crop production through pollination, and recommend honey production as a small business opportunity; and
- support government engagement of women staff and farmers to participate and be involved in the project activities.

Under this project support the laboratory assessment was conducted. This is the first time the FAO LMT tool has been used for Fiji with a FAO LMT-Core assessment and a FAO LMT-Safety assessment of FVL and BAF. Both laboratories will need support to implement the improvements from the gaps identified in the assessments and it is important the laboratories receive support from International experts to ensure a standardised approach and to develop national experts in laboratory assessment, safety/biosafety and quality assurance (QA) to make the program of capacity building sustainable. The FAO LMT

[1] Each country will develop a 'whole of government' emergency response plan for ASF to initiate arrangements to deal with emergency disease events.

assessments for FVL and BAF are attachments to this report (Annex 2), the LMT – C and LMT - S assessments include a comparison with the FVL self-assessment (Annex 2). The BAF LMT – C and LMT - S assessments were a joint assessment (Annex 2). The self-assessments by FVL & BAF were carried out as part of the FAO LMT Assessment training workshop and used the procedure for self – assessment/online/desktop laboratory FAO LMT assessment (Annex 1).

Methodology

The assessment of the FVL & BAF laboratories was conducted as part of a training workshop for the six Pacific Island countries over five days, on 8,9,14,15 & 16 December 2021 (See LMT program & schedule for LMT workshop in Annex 4) in using the FAO laboratory mapping tool – core module (LMT-C), excel result sheet attached to this report (Annex 2), and the FAO laboratory mapping tool – safety module (LMT-S), excel result sheet attached to this report (Annex 2). The training was virtual with lectures in the morning section of the agenda and hands on offline work in the afternoon supported as required by the FAO expert via Zoom or WhatsApp. As part of the training FVL did a self-assessment for LMT – C & LMT – S which was compared to LMT – C & LMT – S assessment carried out by FAO expert. The BAF assessments were a self-assessment by BAF and completed by the FAO expert to have one joint assessment

The training also allowed the participants to see what was required to have the laboratory operate to international best practise and what would be required in setting up a laboratory in all the Pacific Islands.

Results and recommendations

The 2021 overall LMT-C score for FVL was 46.9 percentand gaps are shown in, Figure 1 LMT-C Assessment 2021 and Figure 2 shows comparison of LMT-C assessments between FVL and the FAO expert, 49.5 percent to 46.9 percent in 2021. The FVL overall LMT-S assessment score was 38.4 percent in 2021 (Figure 4) and Figure 5 the comparison of LMT-S assessments between FVL and the FAO expert, 44.4 percent to 38.4 percent in 2021. The 2021 overall LMT-C score for BAF was 43.1 percent and gaps are shown in Figure 3, LMT-C assessment 2021. The FVL overall LMT-S assessment score was 28.6 percent in 2021 (Figure 6). Both FVL & BAF scores were good scores for a first assessment and gaps reflex the lack of international exposure to laboratory best practise, ISO17025 and the lack of a quality system and training in laboratory safety.

Both FVL and BAF have a low throughput of samples and in updating the laboratories there is a need to have a budget for surveillance as well as for upgrading and maintaining the laboratory. Both FVL & BAF would benefit from laboratory information system (LIMS) which could be a excel sheet initially, with the low sample numbers. FVL and BAF have no ISO17025 accreditation, however both are keen to obtain accreditation in the future, and no QA system according to ISO17025 and calibration and maintenance of equipment is not routine and supported by a budget.

FVL & BAF would benefit from international exposure to laboratory best practise, including training in QA & safety/biosafety and need assistance in setting up an internal training program for QA/ISO17025 and safety/biosafety.

Recommendation for Pacific Island Countries: that all countries have a laboratory capacity for disease surveillance to allow them to identify disease outbreaks and to do surveillance for disease agents, initially for important diseases and high-risk diseases. The country needs to commit to an operational budget and resources required for the laboratory to operation under international best practice QA System (ISO17025 & ISO35001).

- a basic realtime PCR capacity: small laboratory designed to ISO17025 requirements for PCR and based on the use of portable PCR machine: e.g. Indical PCR machine- cost from USD10 000 to 15 000) that allowed them to do diagnosis for disease outbreaks. PCR reagents that can be used for all PCR tests using primer/probes for each agent;
- a serology laboratory for disease surveillance, a pathology unit for gross pathology, a bacteriology laboratory for bacterial culture/identification and AMR and a parasitology laboratory as required;
- it is important the countries only commit to a laboratory if it has the resources an operational budget for the laboratory and for surveillance; and
- it was recommended that countries consider using medical/biolology science graduates to resource laboratories as countries lack veterinarians.

Recommendation for Pacific Island countries: all countries need assistance in establishing a laboratory in their country, including laboratory design and management, budget required and training in quality assurance, laboratory management and safety/biosafety.

Recommendation for Pacific Island countries: it is important to establish FVL as Fiji's national laboratory with an international recognised diagnostic laboratory. It is also recommended that FVL to be one of the regional leading laboratories to provide support to the Pacific Islands countries. The national animal health and food testing laboratory (NAHFTL) in the Papua New Guinea is receiving support from Australia and is also a possible leading laboratory resource for PacificIslands countries. The regional leading laboratories along with Reference Laboratories would support confirmation testing and assist in PT to ensure laboratories are giving the correct results.

FAO LMT assessment aps and strengths

The LMT-C identified the following strengths and gaps for FVL:

LMT-C strengths

- general laboratory profile including location, organisation and basic supply (water & electricity) except for laboratory budget;
- stable, motivated & experienced staff;
- international collaborations/projects; and
- proficiency testing for TB and brucellosis.

LMT-C gaps

- Infrastructure, equipment & supplies.
    - The laboratory facility is old and needs to be upgraded and there is need for to update equipment.

- The laboratory operational budget is insufficient for FVL to put in place its activities under a quality assurance (QA) system/ISO17025 to ensure accuracy of tests and as well as the biosafety/safety of laboratory staff and the environment (biosecurity) .
    - There needs to be a budget for testing, reagents, maintenance & calibration of equipment, support of a QA system and as well as biosafety/safety.
- Lack an internal training program for QA/ISO17025 and safety/biosafety
    - Need to establish QA & safety experts to help laboratory put in place a QA system (ISO17025) and quality management structure for the laboratory.
    - FVL needs training in laboratory management including budgeting for laboratory resources.
- Lacks pathology post-mortem room and specimen reception.
    - Upgraded post-mortem room should be considered if FVL is carrying out regular post-mortems.
    - A dedicated specimen reception area with a BSCII is recommended to improve sample processing.
- There is no molecular diagnostics capacity that is the major tool for disease diagnosis in national laboratories, but FVL have a plan to build a molecular laboratory. It is recommended FVL have a dedicated PCR laboratory to cover testing for all agents (virus, bacteria & parasites including aquaculture) and takes into account the need for sequencing capability.
    - The PCR laboratory plan is included as an attachment (Annex 2). The plan needs to be reviewed by a laboratory expert to ensure design meets best practice (see laboratory assessment section for recommendation).
    - There is a need for bioinformatics capability and a process for external sequencing and sequencing data returned to FVL Bioinformatics group.
    - Recommend virology & serology are one section and include molecular diagnostics. I don't recommend putting in place cell culture unless there is a particular need identified.
- Quality assurance (QA) system required improvements, e.g. SOPs and documentation lacked detail (e.g. Test quality control, training and safety requirements) and internal quality control (IQC); the laboratory needs a QA/ISO17025 audit to give more detail on the QA gaps.
    - Support in documentation required for QA & safety/biosafety with help in SOP writing and in development of a QA & safety manual.
- Biosafety and biosecurity measures in FVL were deficient (detail is summarised in the gaps found in the FAO LMT-safety below).
- Networking and communication, lack of international exposure and collaboration and limited access to scientific journals.
    - National laboratory network/animal health network needed.

- FVL need in-service training in laboratory management, preferably by international experts.
- Lacked safety/biosafety and QA experts.

The LMT-S identified the following gaps for FVL:

- Administrative matters concerning a lack of policies, guidelines, procedures, documentation for safety/biosafety and a safety/biosafety manual, limited staff training and medical surveillance.
    - Risk assessments for agents, procedures and equipment
- Operation matters concerning training, variability in handling chemical hazards, waste disposal management, equipment maintenance, cleaning & housekeeping, disinfection, signage, and improvements needed in the sample reception area, pathology facilities and histology skills.
- Infrastructure/engineering matters covering deficiencies in electrical supply to some areas, chemical security, building condition and furniture, pathology facilities, improving fire safety & emergency procedures and preventative maintenance for building & equipment .
- Quality management improvements areas such as risk assessment, biosafety/safety standard operating procedures (SOPs), waste management and training of staff in safety and biosafety/biosecurity.
- Improvement in supply, use, maintenance and disposal of personal protective equipment (PPE).

The LMT-C identified the following strengths & gaps for BAF:

LMT-C strengths

- General laboratory profile including location, organisation and basic supply (water & electricity) except for laboratory budget.
- Stable, motivated & experienced staff.
- BAF had a good understanding of gaps identified in their self-assessment and what was needed to improve their laboratory.

LMT-C gaps

- The laboratory operational budget is insufficient for BAF to put in place its activities under a quality assurance (QA) system/ISO17025 to ensure accuracy of tests and as well as the biosafety/safety of laboratory staff and the environment (biosecurity).
    - There needs to be a budget for testing, reagents, maintenance & calibration of equipment, support of a QA system and as well as Biosafety/Safety.
- Lack an internal training program for QA/ISO17025 and safety/biosafety.

  - Need to establish QA & safety experts to help laboratory put in place a QA system (ISO17025) and quality management structure for the laboratory,
  - Support in documentation required for QA & safety/biosafety with help in SOP writing and in development of a QA & safety manual.
  - Need training in laboratory management including budgeting for laboratory resources.

- Specimen reception.
  - A dedicated specimen reception area with a BSCII is recommended to improve sample processing.
- Quality assurance (QA) system required improvements, e.g. SOPs and documentation lacked detail (e.g. Test quality control, training and safety requirements) and internal quality control (IQC); the laboratory needs a QA/ISO17025 audit to give more detail on the QA gaps.
- Biosafety and biosecurity measures in BAF were deficient (detail is summarised in the gaps found in the FAO LMT-safety below).
- Networking and communication, lack of international exposure and collaboration and limited access to scientific journals.
  - National laboratory network/animal health network needed.
- BAF need training in laboratory management and lacked safety/biosafety and QA experts.

The LMT-S identified the following gaps for BAF:

- Administrative matters concerning a lack of policies, guidelines, procedures, documentation for safety/biosafety and a safety/biosafety manual, limited staff training and medical surveillance.
  - Risk assessments for agents, procedures and equipment.
- Operation matters concerning training, variability in handling chemical hazards, waste disposal management, equipment maintenance, cleaning & housekeeping, disinfection, signage, and improvements needed in the sample reception area, pathology facilities and histology skills.
- Infrastructure/engineering matters covering deficiencies in electrical supply to some areas, chemical security, building condition and furniture, pathology facilities, improving fire safety & emergency procedures and preventative maintenance for building & equipment.
- Quality management improvements areas such as risk assessment, biosafety/safety standard operating procedures (SOPs), waste management and training of staff in safety and biosafety/biosecurity.
  - BAF lack safety/biosafety experts and international exposure to GLP and laboratory best practice.

    - BAF lack training in safety & biosafety requirements.
- Improvement in supply, use, maintenance and disposal of personal protective equipment (PPE).

Recommendation: It is recommended that FVL & BAF are given support and budget to build laboratory capacity and upgrade and maintain the laboratory to international standards to meet ongoing requirements for diseases control in Fiji.

- Budget to support laboratory activities, QA System/ISO17025 & ISO35001, safety/biosafety and training.
- FVL need new & upgraded laboratory faculties including new molecular techniques, pathology/post-mortem, and specimen reception area, BSCII and LIMS system and upgrades to virology/serology, bacteriology and parasitology as part of capacity update *(Important to get expert advice on the design/workflow of the upgrades to the laboratory and to plan for 10 years into the future taking into account technologies used for diagnostics).*
- BAF needs a dedicated specimen reception area, BSCII and LIMS system.
- Technical, QA, safety/biosafety and laboratory management training.
- Budget to support surveillance activities for disease control.

Recommendation: It is recommended that FVL & BAF receive support to implement best practice QA/ISO17025, biosafety/safety/ISO35001, and to implement recommendations from the laboratory assessments to put in place international QA and biosafety/safety standards

Note: *Requirement for a QA system can be found in* ***Annex 3:*** *Plan & roadmap for a quality management (QM) system for laboratory quality assurance and safety/biosafety.*

Recommendation: It is recommended that FVL & BAF to be given support to build laboratory capacity to put in place a QM system with a QA officer & biosafety officer, QA & safety positions and expertise and a QA/biosafety committee to implement the recommendations given to them to put in place international QA and biosafety/safety standards. In-house training by International experts is recommended.

Recommendation: The FAO laboratory mapping tool (LMT) – Core (LMT-C) and FAO laboratory mapping tool for laboratory - safety module (LMT-S) is followed up and include training to develop national LMT experts and laboratory focal points for laboratory assessment. The uptake of the FAO LMTs give countries the tools to identify gaps and improve safety and quality of laboratory tests in their laboratories. Reports from LMT assessments help laboratories justify increased funding.

Recommendation: It is recommended that FVL & BAF receive support develop the panel of experts in laboratory assessments, QA, biosafety/safety and technical experts. Carried as part in-house training by International experts is recommended.

Laboratory assessment

The FAO LMT assessments for Fiji were carried out as an online/desktop assessment due to the restrictions on travel with COVID-19 and as part of FAO LMT training for the six Pacific

countries; Cook Islands, Tonga, Samoa, Fiji, Solomon Islands and Vanuatu. To assist the laboratory in how to do the assessment and ensure the assessor, Chris Morrissy FAO consultant, covered all aspects of the laboratory, the countries, including FVL & BAF, were given a procedure for an online/desktop assessment which is included in this report in Annex 1: *Procedure for self-assessment/online/desktop laboratory FAO LMT assessment.*

The FAO assessment and self-assessment of the FVL was using the FAO laboratory mapping tool – core module (LMT-C) ver.092016 (attached to this report Annex 2) and the FAO laboratory mapping tool – safety module (LMT-S) ver.102016 (attached to this report Annex 2) and includes a comparison to LMT-C assessment and the LMT-S assessment by the FAO assessor & FVL for December 2021.

The 2021 LMT-C assessment for FVL gave overall LMT-C score of 46.9 percent (Figure 1 LMT-C assessment 2021) and figure 2 shows comparison of LMT-C assessment for FVL of 49.5 percent for the self-assessment to 46.9 percent for FAO assessment, December 2021. FVL overall LMT-S assessment score was 38.4 percent for December 2021 (Figure 4) and figure 5 shows comparison of LMT-S assessment for FVL of 44.4 percent for the self-assessment to 38.4 percent for FAO assessment, December 2021 . The expected scores for a national laboratory would be in the high 70s to low 80s for the LMT-Core and in the low 80s for the LMT – S and reflex the laboratory having a best practice laboratory management system with a QA system and biosafety/safety and biosecurity.

The LMT-C and LMT-S scores for FVL were acceptable for a first LMT assessment, the gaps reflected a lack of exposure to international training for QA/ISO17025 & safety/biosafety. FVL has a low throughput of samples and in updating the laboratory there is a need to have a budget for surveillance as well as for upgrading and maintaining the laboratory. FVL needs a budget to upgrade the laboratory and then ongoing budget to support a QA system, biosafety/safety and internal/external training. FVL has dedicated staff with experience which is important in building capacity and resources, and in training of new staff to build a strong national laboratory for Fiji

FVL needs a new molecular techniques laboratory to allow it to have PCR (Realtime PCR is main need) and sequencing diagnostics covering all agents, viruses, bacteria, parasites and including aquaculture. FVL has a plan (see attached plan from FVL in annex 5) and it is recommended that this plan is reviewed by a laboratory expert to ensure plan has workflow for best international practice for PCR and include area to allow sequencing setup. The current plan is missing a template room and the clean room should be kept separate to the other areas for PCR testing. Verbal feedback was given to FVL on changes needed to the current plan.

FVL needs a new separate specimen reception & BSCII including a LIMS system for receiving and processing samples and needs to update pathology/post-mortem and histology laboratories especially with a focus on safety/biosafety for staff. The virology/serology, bacteriology and parasitology sections need to be upgraded so the laboratories meet international standards.

FVL needs to put in place a QA system meeting ISO17025 requirements and including international standards for safety/biosafety/ISO35001 and biosecurity. FVL needs improvements with QA/ISO17025 documentation, including test SOPs and safety/biosafety documentation, including SOPs, risk assessments, waste management and cleaning procedures. It is recommended FVL follows ISO35001 for biosafety/biosecurity. FVL to put

place guidelines for both QA & safety/biosafety to allow it to develop its documentation for the laboratory. FVL were given example guidelines, regional SOPs, risk assessment and operational SOPs by FAO consultant to develop and update FVL SOPs, guidelines, risk assessment, documentation, etc, and have one standard laboratory approach to implementing documentation across all laboratory sections.

FVL has had little support or training for safety/biosafety and Bbiosecurity and this is an area along with assistance to implement a QM structure and better internal training program that FVL need external support to ensure FVL operates safety and delivers accurate test results and meets international standards for QA and safety. There is a need to establish experts in laboratory assessment, QA and safety to implement best practice at FVL and allow an internal training program to be established.

FVL has little expertise in use of disease-related web resources and e-platforms for epidemiology and Fiji lack national laboratory network/animal health network. Networking and communication is important and FVL has some international collaborations, but lack of international exposure and collaboration and limited access to scientific journals. International collaboration are important to establish FVL as Fiji's national laboratory with an international recognised diagnostic laboratory. It is also recommended that FVL to be one of the regional leading laboratory to provide support to the Pacific Islands countries.

The FAO assessment and self-assessment of the BAF was using the FAO laboratory mapping tool – core module (LMT-C) ver.092016 (attached to this report Annex 2) and the FAO laboratory mapping tool – Safety module (LMT-S) ver.102016 (attached to this report Annex 2) for December 2021. The 2021 LMT-C assessment for BAF gave overall LMT-C score of 43.1 percent (Figure 3 LMT-C assessment December 2021) and the LMT-C assessment for BAF was a self-assessment by BAF that was updated by the FAO assessor. BAF overall LMT-S assessment score was 28.6 percent for December 2021 (Figure 6) and the LMT-S assessment for BAF was a self-assessment by BAF that was updated by the FAO assessor. The BAF LMT assessments were based on less information than the FVL assessments (FVL supplies pictures and documents),with the FAO assessor relying on the BAF self-assessment and answers from BAF.

BAF LMT-C and LMT-S scores and gaps reflected a lack of exposure to international training for QA/ISO17025 & safety/biosafety. BAF has a low throughput of samples and in updating the laboratory there is a need to have a budget for surveillance as well as for upgrading and maintaining the laboratory. BAF needs a budget to upgrade the laboratory and then ongoing budget to support a QA system, biosafety/safety and internal/external training. BAF has dedicated staff with experience, which is important in building capacity and resources, and in training of new staff to build a strong national biosecurity laboratory for Fiji.

BAF needs a new separate specimen reception & BSCII including a LIMS system for receiving and processing samples. The PCR and other sections need to be reviewed in more detail to recommend if the laboratories meet international standards for safety/biosafety and for testing workflow. It is recommended the PCR laboratory is reviewed to ensure its workflow meets international standard to ensure no problems with cross-contamination.

BAF needs to put in place a QA system meeting ISO17025 requirements and including international standards for safety/biosafety/ISO35001 and biosecurity. BAF needs improvements with QA/ISO17025 documentation, including test SOPs and safety/biosafety documentation, including SOPs, risk assessments, waste management and cleaning

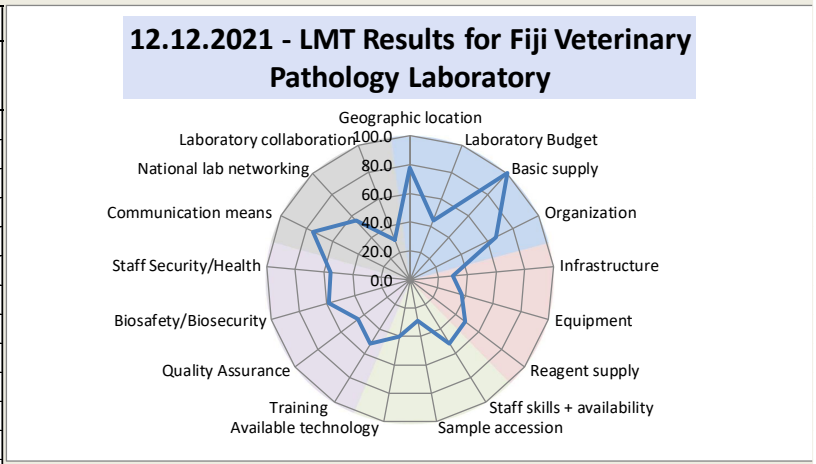
procedures. It is recommended BAF follows ISO35001 for biosafety/biosecurity. FVL to put place guidelines for both QA & safety/biosafety to allow it to develop its documentation for the laboratory. BAF has had little support or training for safety/biosafety and biosecurity and this is an area along with assistance to implement a QM structure and better internal training program that BAF needs external support to ensure BAF operates safety and delivers accurate test results and meets international standards for QA and safety. There is a need to establish experts in laboratory assessment, QA and safety to implement best practice at BAF and allow an internal training program to be established.

FVL & BAF have different functions, and both have a role to play as national laboratories for Fiji. It is important to not duplicate activities in both laboratories to ensure budget for the Fiji laboratory is not wasted on duplication of resources at each laboratory. It is recommended to form a National laboratory network to help build expertise and this should include public health laboratories and other public and private laboratories to allow technical meetings to discuss QA, testing, safety/biosafety etc as part of building a strong laboratory system and for training. FVL & BAF can also be part of a regional network with their areas of expertise, regional support to all Pacific Island countries will be important in building a strong regional laboratory network via regional leading laboratories and reference laboratories

Figure 1: FAO laboratory mapping tool – Core assessment FVL 12/12/2021

12.12.2021 - LMT-Core results : Summary for Fiji Veterinary Pathology Laboratory

Current Assessment*		
LMT -Core Category	12.12.2021 - LMT Results for Fiji Veterinary	Reliability **
Geographic location	77.8	100
Laboratory Budget	44.4	100
Basic supply	100.0	100
Organization	66.7	100
Infrastructure	29.6	100
Equipment	37.5	100
Reagent supply	48.1	100
Staff skills + availability	52.4	100
Sample accession	29.2	100
Available technology	40.0	83
Training	52.4	100
Quality Assurance	45.5	100
Biosafety/Biosecurity	58.3	100
Staff Security/Health	55.6	100
Communication means	75.0	100
National lab networking	55.6	100
Laboratory collaboration	29.6	100
Veterinary Pathology	**46.9**	**98**



021 - LMT Areas * Results for Fiji Veterinary Pathology Lab	TOTAL (%)
TOTAL General laboratory profile	73.3
TOTAL Infrastructure, equipment, supplies	38.5
TOTAL Laboratory performance	40.0
TOTAL QA, Biosafety/Biosecurity	51.7
TOTAL Lab collaboration and networking	45.8

*Numbers displayed in percentage; Scoring based on the ideal situation (100%): numbers in each cell represent the achieved p ercentage compared to the optimum (100% being the ideal laboratory). Color coding: 0-20% , 20-40% 40-60% 60-80% 80-100%

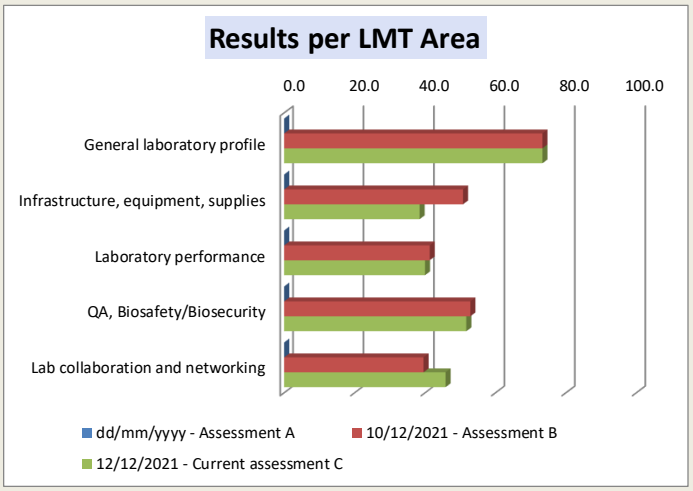
** Reliability of the result depends on the percentage of questions filled or left blanck per category in the LMT questionnaire. From 100 to 90%, the LMT scoring is reliable (green). From 90 to 70%, realiability of the scoring is medium (orange), from 70 to 0%, reliability is low (red).

Figure 2: FAO laboratory mapping tool – Core assessment comparison FVL between FAO Assessor assessment, 12/12/2021, & FVL self-assessment, 10/12/2021

Compilation - all LMT results* for Fiji Veterinary Pathology Laboratory

LMT Category	dd/mm/yyyy - Assessment A	10/12/2021 - Assessment B	12/12/2021 - Current assessment C
Geographic location	N/A	77.8	77.8
Laboratory Budget	N/A	33.3	44.4
Basic supply	N/A	100.0	100.0
Organization	N/A	100.0	66.7
Infrastructure	N/A	42.9	29.6
Equipment	N/A	42.9	37.5
Reagent supply	N/A	66.7	48.1
Staff skills + availability	N/A	57.1	52.4
Sample accession	N/A	50.0	29.2
Available technology	N/A	27.8	40.0
Training	N/A	52.4	52.4
Quality Assurance	N/A	51.5	45.5
Biosafety/Biosecurity	N/A	66.7	58.3
Staff Security/Health	N/A	22.2	55.6
Communication means	N/A	66.7	75.0
National lab networking	N/A	33.3	55.6
Laboratory collaboration	N/A	29.6	29.6
Overall level of Fiji Veterinary Pathology Laboratory functionality (%)	**N/A**	**49.5**	**46.9**

*Numbers displayed in percentage; Scoring based on the ideal situation (100%): numbers in each cell represent the achieved percentage compared to the optimum (100%).



reas results* for Fiji Veterinary Pathology Laboratory

	dd/mm/yyyy - Assessment A	10/12/2021 - Assessment B	12/12/2021 - Current assessment C
General laboratory profile	N/A	73.3	73.3
Infrastructure, equipment, supplies	N/A	50.8	38.5
Laboratory performance	N/A	41.3	40.0
QA, Biosafety/Biosecurity	N/A	52.9	51.7
Lab collaboration and networking	N/A	39.6	45.8

Details of all LMT-Core results* for Fiji Veterinary Pathology Laboratory

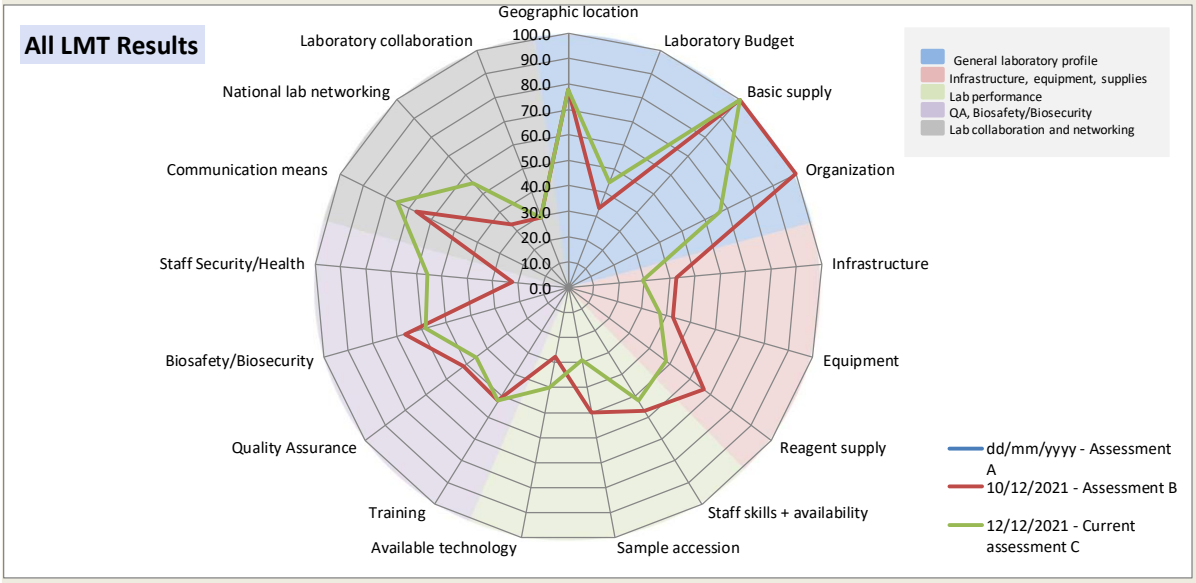
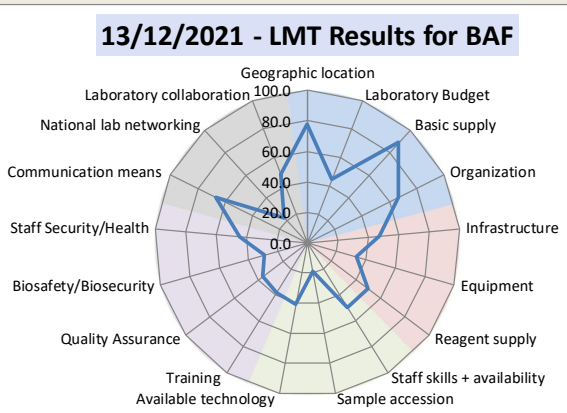


Figure 3: FAO laboratory mapping tool – Core assessment BAF 13/12/2021

12/13/2021 - LMT-Core results : Summary for BAF

Current Assessment*		
LMT -Core Category	13/12/2021 - LMT Results for BAF	Reliability **
Geographic location	77.8	100
Laboratory Budget	44.4	100
Basic supply	88.9	100
Organization	66.7	100
Infrastructure	47.6	78
Equipment	33.3	88
Reagent supply	50.0	89
Staff skills + availability	50.0	86
Sample accession	19.0	88
Available technology	40.7	75
Training	38.1	100
Quality Assurance	36.4	100
Biosafety/Biosecurity	29.2	100
Staff Security/Health	44.4	100
Communication means	66.7	100
National lab networking	22.2	100
Laboratory collaboration	48.1	100
Grand total (%) BAF	43.1	92



13/12/2021 - LMT Areas * Results for BAF	TOTAL (%)
TOTAL General laboratory profile	70.0
TOTAL Infrastructure, equipment, supplies	43.9
TOTAL Laboratory performance	36.4
TOTAL QA, Biosafety/Biosecurity	35.6
TOTAL Lab collaboration and networking	47.9

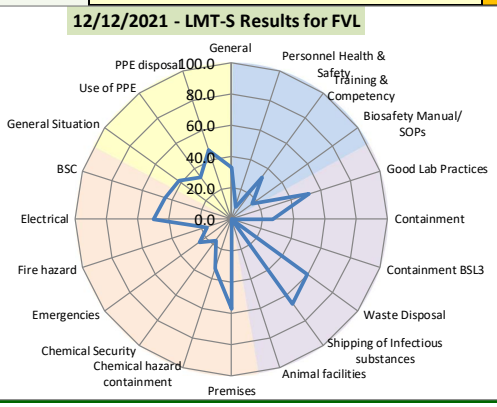
*Numbers displayed in percentage; Scoring based on the ideal situation (100%): numbers in each cell represent the achieved percentage compared to the optimum (100% being the ideal laboratory). Color coding: 0-20% , 20-40% 40-60% 60-80% 80-100%
** Reliability of the result depends on the percentage of questions filled or left blanck per category in the LMT questionnaire. From 100 to 90%, the LMT scoring is reliable (green). From 90 to 70%, realiability of the scoring is medium (orange), from 70 to 0%, reliability is low (red).

Figure 4: FAO laboratory mapping tool – safety assessment FVL 12/12/2021

12/12/2021 - LMT-Safety Module. Results : Summary for FVL

Current Assessment*			
Area	Category	12/12/2021 - LMT-S Results for FVL	Reliability **
Administration	General	33.3	100
	Personnel Health & Safety	8.3	100
	Training & Competency	33.3	100
	Biosafety Manual/ SOPs	16.7	100
Operational	Good Lab Practices	52.4	100
	Containment	26.7	83
	Containment BSL3	N/A	0
	Waste Disposal	60.0	100
	Shipping of Infectious substances	66.7	100
	Animal facilities	0.0	29
Engineering	Premises	57.1	100
	Chemical hazard containment	33.3	17
	Chemical Security	16.7	100
	Emergencies	25.0	100
	Fire hazard	16.7	100
	Electrical	50.0	100
	BSC	44.4	100
PPE	General Situation	41.7	100
	Use of PPE	33.3	100
	PPE disposal	46.7	100
Grand total (%) FVL		38.4	81

Current Assessment*	
12/12/2021 - LMT-S areas results for FVL	TOTAL (%)
Administration	24.4
Operational	47.2
Engineering	37.0
PPE	41.0



*Numbers displayed in percentage; Scoring based on the ideal situation (100%): numbers in each cell represent the achieved percentage compared to the optimum (100% being the ideal laboratory). Color coding: 0-20% , 20-40% , 40-60% , 60-80% , 80-100%

** Reliability of the result depends on the percentage of questions filled or left blank per category in the LMT questionnaire. From 100 to 90%, the LMT scoring is reliable (green). From 90 to 70%, realiability of the scoring is medium (orange), from 70 to 0%, reliability is low (red).

Figure 5: FAO laboratory mapping tool – Safety assessment comparison FVL between FAO assessor assessment, 12/12/2021, & FVL self-assessment, 10/12/2021

Compilation - all LMT-S results* for FVL

Area	Category	00/01/1900 - Assessment A	10/12/2021 - Assessment B	12/12/2021 - Current assessment
Administration	General	N/A	33.3	33.3
	Personnel Health & Safety	N/A	8.3	8.3
	Training & Competency	N/A	41.7	33.3
	Biosafety Manual/ SOPs	N/A	16.7	16.7
Operational	Good Lab Practices	N/A	71.4	52.4
	Containment	N/A	38.9	26.7
	Containment BSL3	N/A	38.1	N/A
	Waste Disposal	N/A	73.3	60.0
	Shipping of Infectious substances	N/A	73.3	66.7
	Animal facilities	N/A	14.3	0.0
Engineering	Premises	N/A	71.4	57.1
	Chemical hazard containment	N/A	16.7	33.3
	Chemical Security	N/A	25.0	16.7
	Emergencies	N/A	33.3	25.0
	Fire hazard	N/A	16.7	16.7
	Electrical	N/A	66.7	50.0
	BSC	N/A	66.7	44.4
PPE	General Situation	N/A	50.0	41.7
	Use of PPE	N/A	55.6	33.3
	PPE disposal	N/A	53.3	46.7
Overall level of FVL functionality (%)		**N/A**	**44.4**	**38.4**

*Numbers displayed in percentage; Scoring based on the ideal situation (100%): numbers in each cell represent the achieved percentage compared to the optimum (100%).

All LMT-S areas results* for FVL	00/01/1900 - Assessment A	10/12/2021 - Assessment B	12/12/2021 - Current assessment
Administration	N/A	26.7	24.4
Operational	N/A	49.5	47.2
Engineering	N/A	43.7	37.0
PPE	N/A	52.8	41.0

Details of all LMT-S results* for FVL

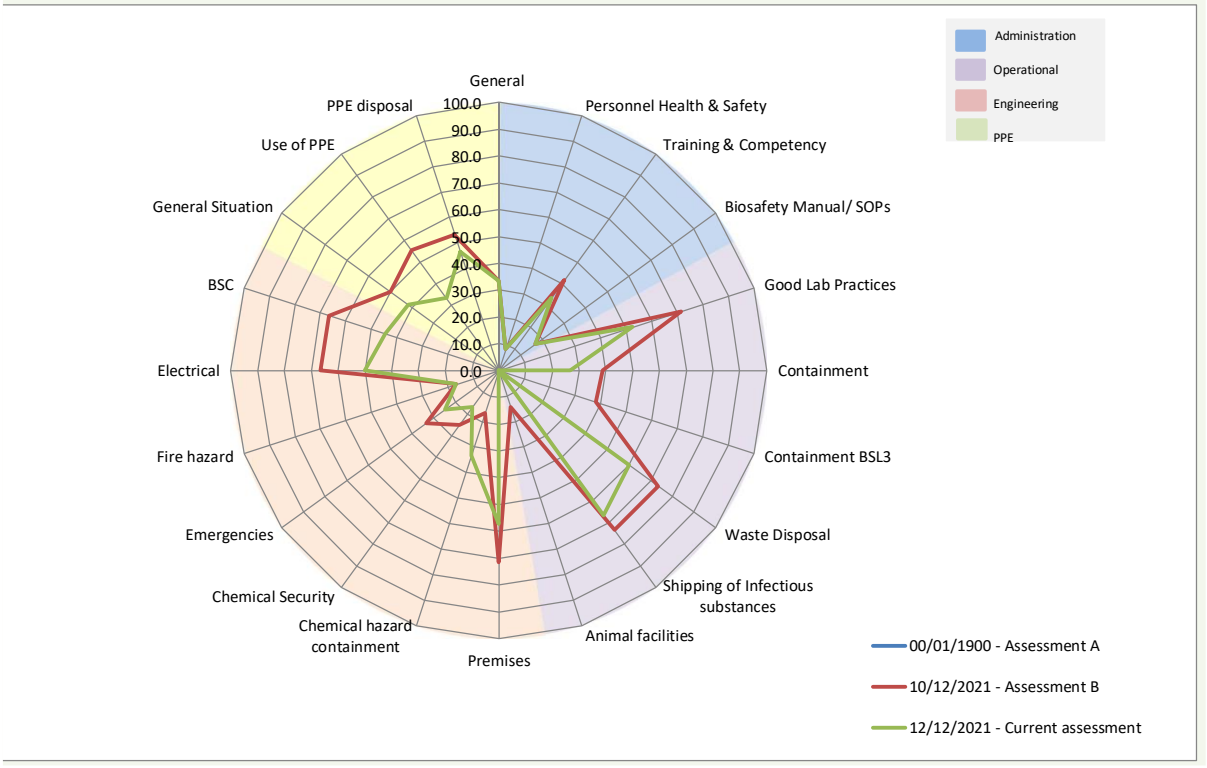
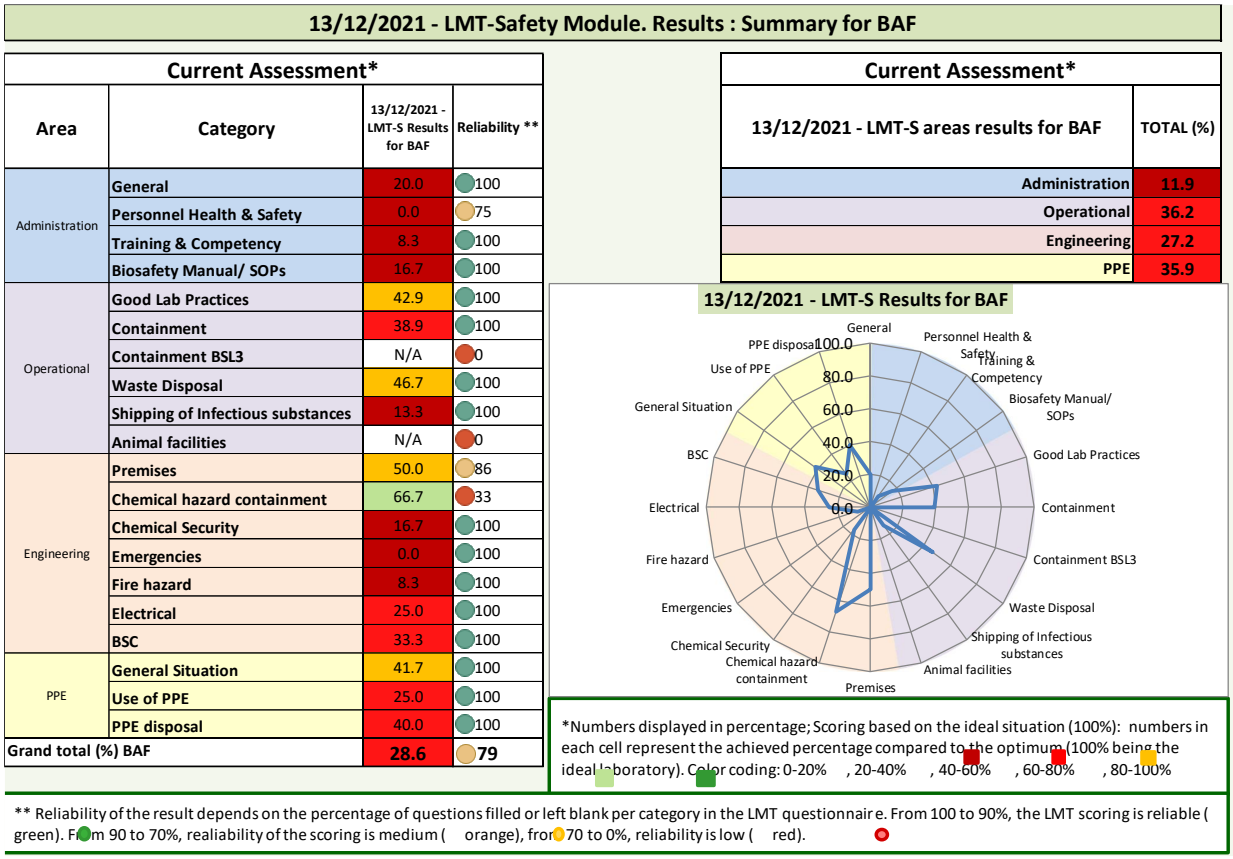


Figure 6: FAO laboratory mapping tool – Safety assessment BAF 13/12/2021



13/12/2021 - LMT-Safety Module. Results : Summary for BAF

Current Assessment*

Area	Category	13/12/2021 - LMT-S Results for BAF	Reliability **
Administration	General	20.0	100
	Personnel Health & Safety	0.0	75
	Training & Competency	8.3	100
	Biosafety Manual/ SOPs	16.7	100
Operational	Good Lab Practices	42.9	100
	Containment	38.9	100
	Containment BSL3	N/A	0
	Waste Disposal	46.7	100
	Shipping of Infectious substances	13.3	100
	Animal facilities	N/A	0
Engineering	Premises	50.0	86
	Chemical hazard containment	66.7	33
	Chemical Security	16.7	100
	Emergencies	0.0	100
	Fire hazard	8.3	100
	Electrical	25.0	100
	BSC	33.3	100
PPE	General Situation	41.7	100
	Use of PPE	25.0	100
	PPE disposal	40.0	100
Grand total (%) BAF		28.6	79

Current Assessment*

13/12/2021 - LMT-S areas results for BAF	TOTAL (%)
Administration	11.9
Operational	36.2
Engineering	27.2
PPE	35.9

*Numbers displayed in percentage; Scoring based on the ideal situation (100%): numbers in each cell represent the achieved percentage compared to the optimum (100% being the ideal laboratory). Color coding: 0-20% , 20-40% , 40-60% , 60-80% , 80-100%

** Reliability of the result depends on the percentage of questions filled or left blank per category in the LMT questionnaire. From 100 to 90%, the LMT scoring is reliable (green). From 90 to 70%, realiability of the scoring is medium (orange), from 70 to 0%, reliability is low (red).

General recommendations for the FVL & BAF laboratories:

- the laboratory network needs biosafety, safety and QA experts, who could assist the laboratories with gaps to improve laboratory's functionality. National experts should be developed to support the laboratory network;
- risk assessments should be completed for all agents, activities and equipment by all staff working in each section. It is recommended to complete risk assessments using FAO examples supplied, e.g. avian influenza (H5N1) as a template to develop their own risk assessments;
- Fiji (FVL & BAF) should develop national laboratory guidelines & policy for QA & Safety/Biosafety that can then be used develop laboratory guidelines & policy, a manual for biosafety/biosecurity & safety and a QA manual and all QA documentation for ISI17025 & ISO35001. These national guidelines for biosafety/biosecurity, safety and QA can be developed and used by all Fiji laboratories in the future;

  Note: example documents for ASEAN are available to be used to develop SOPs, procedures and manuals specific for FVL & BAF. The development of SOPs, procedures and manuals can be shared between FVL & BAF laboratories;

- waste management guideline and SOP should be developed. National guideline could be developed to be used to develop laboratory-specific SOPs (e.g. all infectious and biological waste must be autoclaved before disposal or incineration);
- validation of autoclaving of waste, equipment and reagents with biological indicators should be implemented. Records of each autoclave run, load and indicator performance should be documented;
- SOP for decontamination and washing of glassware and equipment should be developed. Laboratory contaminated equipment and glassware should be decontaminated using appropriate disinfectants and autoclaved (if applicable) before cleaning;
- guideline and SOP for chemical handling, storage and disposal should be developed. training of staff in chemical safety and containment should be organised;
- a national guideline for the use and disposal of PPE to guide the laboratories in writing SOPs and to standardise the use of PPE is recommended;
- guideline and procedures for electrical safety for equipment should be developed;
- emergency response and fire evacuation plans and SOPs should be developed;
- overall training program for all staff in the NAHFTL should be organised in a systematic manner. Training of staff should include not only test techniques but also biosafety, safety and QA. An internal training program is important and should be standardised where possible across all the laboratories and complimented with external training where possible;
- all new staff need an induction and training and NAHFTL need to develop an induction procedure and an internal training program to update staff yearly to ensure technical, QA and safety competency;
- the laboratories operational budget that should cover (i) maintenance, including electrical testing, equipment calibration, (ii) QA, including test IQC (production and purchase of reference controls) and validation of tests, (iii) safety, including UPS for equipment and safety consumables (PPE); and
- Fiji needs to develop career for laboratory staff to retain staff in the laboratories to prevent loss of senior staff and expertise and consider use university medical science graduates in resourcing laboratories.

CONCLUSIONS AND RECOMMENDATIONS

The six Pacific Island countries lacked resources for animal health and production services for both field and laboratory activities including the lack of veterinarians, with only Fiji with a veterinary laboratory. While other Pacific countries lacked the resources to do disease diagnosis and disease surveillance, Fiji carried out surveillance for tuberculosis (TB) and brucellosis (*Brucella Abortus)*. The countries did send samples for testing to New Zealand & Australia, but this was not easy to do and relied on support from New Zealand & Australia.

It is recommended that countries have a laboratory that has a basic realtime PCR (small laboratory based portable realtime PCR machine) capacity that allowed them to do diagnosis for disease outbreaks/problems, serology laboratory for disease surveillance, a bacteriology laboratory for bacterial culture/identification and AMR, a pathology unit for gross pathology and parasitology laboratory as required. It is important the countries only commit to a laboratory if it has the resources for an operational budget for the laboratory and for surveillance. The minimum requirements to start disease diagnosis and surveillance would be a capability to do realtime PCR for viral and key bacterial diseases in the laboratory and the capability to culture identify bacteria would further increase a countries capability and a bacteriology laboratory would also allow AMR testing.

It was recommended that countries consider using medical/biology science graduates to resource laboratories as most countries lack veterinarians. All countries need to commit a budget required to allow a laboratory to operate at international best practice and need assistance in establishing a laboratory in their country, including laboratory management and budget and training in quality assurance, laboratory management and safety/biosafety.

It is important to establish FVL as Fiji's national laboratory with an international recognised diagnostic laboratory and it is also recommended that FVL to be one of the regional leading laboratory to provide support to the Pacific Islands countries. The FAO LMT mapping tool training gave countries without veterinary laboratories a indication of what is required to have a best practice laboratory.

The FAO LMT assessments has highlighted the need for a capacity building program for strengthening biosafety/safety and quality systems at FVL & BAF, as an important part of building the status of the laboratories to give confidence both in-country and internationally in the laboratory results which will lead to increased use of the laboratory. There is a need to train experts at FVL & BAF to be actively involved in the establishment of biosafety/safety and quality systems program including technical support.

The assessments and this report summarized the strengths and gaps at FVL & BAF and gives recommendations for capacity building and updates to FVL & BAF infrastructure and equipment, which included strengthening biosafety/safety and quality systems and building new & upgraded laboratory faculties including a new molecular techniques section for FVL and new specimen reception area for FVL & BAF. Upgrades are needed for pathology/post-mortem, virology/serology, bacteriology and parasitology as part of FVL capacity update. BAF needs a review of it PCR area to confirm its testing workflow meets international ISO17025 standard and a review of all sections for safety & biosafety.

The FAO LMT allows countries to use the assessments as a useful tool to identify the gaps and as a mechanism to get more funding. Training national LMT assessors helps the countries to have national expertise for ongoing self-assessments. FVL & BAF have experience and dedicated staff as a basis to build expertise and trainers.

Currently FVL & BAF lacks budget and operating budget to function as a national laboratories to support disease control in Fiji, there is an urgent need to upgrade the laboratories, especially for a new molecular laboratory for FVL, and provide operational funding for, testing, to establish and maintain a QA system (including maintenance & calibration of equipment) and establish best practice safety/biosafety and biosecurity. There is also a need for a budget to support surveillance activities for disease control to ensure FVL & BAF are active and this will create opportunities to offer more support to clients, e.g. disease diagnosis and import & export testing.

It is important FVL & BAF have one standard laboratory approach to implementing documentation across all laboratory sections and use the FAO example documentation will assist in updating current FVL & BAF documents.

Recommendation for Pacific Island countries: that all countries have a laboratory capacity for disease surveillance to allow them to identify disease outbreaks and to do surveillance for agents. The country needs to commit to an operational budget and resources required for the laboratory to operationalize under international best practice QA System (ISO17025 & ISO35001).

- A basic realtime PCR capacity: small laboratory designed to ISO17025 requirements for PCR and based on the use of portable realtime PCR machine: e.g. indical PCR machine-cost from USD 10 000 to 15 000) that allowed them to do diagnosis for disease problem. PCR reagents that can be used for all PCR tests using primer/probes for each agent. Training to use this system should also be provided as part of the purchase
- A serology laboratory for disease surveillance and a bacteriology laboratory for bacterial culture and AMR and parasitology laboratory as required.
- It is important the countries only commit to a laboratory if it has the resources an operational budget for the laboratory and for surveillance.
- It was recommended that countries consider using medical/biology science graduates to resource laboratories as countries lack veterinarians.

Recommendation for Pacific Island countries: all countries need assistance in establishing a laboratory in their country, including laboratory design and management, budget required and training in quality assurance, laboratory management and safety/biosafety. Recommended the support and training is from international experts.

Recommendation for Pacific Island countries: it is important to establish FVL as Fiji's national laboratory with an international recognised diagnostic laboratory. It is also recommended that FVL to be a regional leading laboratory to provide support to the Pacific Islands countries. The national animal health and food testing laboratory (NAHFTL) in the

Papua New Guinea is receiving support from Australia and is also a possible leading laboratory resource for Pacific Islands countries.

Recommendation: It is recommended that FVL & BAF is given support and budget to build laboratory capacity and upgrade and maintain the laboratory to international standards to meet ongoing requirements for disease control in Fiji.

- Budget to support laboratory activities, QA system/ISO17025, safety/biosafety.
- Budget for maintenance and calibration of equipment including a fund for equipment replacement and new equipment.
- New & upgraded laboratory faculties including new molecular techniques & specimen reception laboratories for FVL and specimen reception laboratory for BAF and upgrades including pathology/post-mortem, virology/serology, bacteriology and parasitology as part of capacity update as required *(Important to get expert advice on the design/workflow of the upgrades to the laboratory and to plan for 10 years into the future taking into account technologies used for diagnostics)* technical, QA. Laboratory management & safety/biosafety training. Recommended the support and training is from international experts.
- Budget to support surveillance activities for disease control.

Recommendation: It is recommended that **FVL & BAF** receive support to implement best practice QA/ISO17025, biosafety/safety/biosecurity/ISO35001, and to implement recommendations from the laboratory assessments to put in place international QA and biosafety/safety standards**.** Recommended the support and training is from international experts.

Note: *Requirement for a QA system can be found in* Annex 3: *Plan & roadmap for a quality management (QM) system for laboratory quality assurance and safety/biosafety.*

Recommendation: It is recommended that FVL & BAF to be given support to build laboratory capacity to put in place a QM system with a QA officer & biosafety officer, QA & safety positions and expertise and a QA/biosafety committee to implement the recommendations given them to put in place international QA and biosafety/safety standards. Recommended the support and training is from international experts.

Recommendation: It is recommended that FVL & BAF receive support to develop the panel of experts in laboratory assessments, QA, biosafety/safety and technical experts.

- Workshop shops for general biosafety/safety & QA training for all staff
- Workshop shops for specific biosafety/safety & QA training for the QA & safety office and for senior technical staff and deputies.
- Recommended the support and training is from international experts.

ANNEX 1: PROCEDURE FOR SELF – ASSESSMENT/ONLINE/DESKTOP LABORATORY FAO LMT ASSESSMENT

Preparation & procedure for laboratory FAO LMT assessment: self-assessment, online assessment or desktop assessment by LMT expert

This document outlines the information, documents and photos, required for an assessor to carry out a laboratory assessment using the FAO LMT assessment tools. The document is guidance for a participant/assessor preparing for a LMT training workshop, assessors doing a LMT self-assessment, or an assessment of another laboratory and the information required to allow a desktop assessment or online assessment from a trained assessor when the assessment cannot be done by a physical visit to the laboratory.

The LMT assessment can also be carried out online (e.g. via zoom) by the expert with the laboratory staff, the laboratory still needs to send the information, documents and photos outlined in this document prior to the online assessment, the document and information are required for an assessor to carry out laboratory assessment using the FAO LMT assessment tools and allow the assessor to prepare for the online audit.

A desktop audit will require the assessor to also meet (e.g. via zoom) with the laboratory staff to ask questions after reviewing the information from the laboratory and to complete the LMT assessments.

The FAO LMT-assessment holds an entry and exit meeting with all laboratory staff as part of the LMT assessment:

- At the entry meeting the assessors explain the FAO LMT assessment, LMT-core & LMT-safety, purpose and procedure of the assessment. This question and general questions for the laboratory are asked at an entry meeting with the laboratory director & key staff or all staff.
- At the exit meeting the assessor(s)s explain the FAO LMT assessment key outcomes, gaps, strengths and any immediate recommendations to improve QA or safety. The assessor explains the next steps and the reporting process. This is also another opportunity for general questions and clarification with the laboratory director & key staff or all staff for any unanswered questions for the laboratory LMT assessments, LMT-core & LMT-safety.

The list documents and photos for a LMT assessment, LMT – core and LMT – cafety are listed below and can be emailed to the assessor prior to the workshop/assessment:

1. Each laboratory to send an example of laboratory documents used at their laboratory and photos as part of the assessment:
    - *Description of what the laboratory is responsible for and the tests they are carrying out in their laboratory. Comment on the laboratory budget, ability to do renovations and experience of the staff and if the laboratory has enough staff.*

    Note: FAO LMT-assessment. Hold an entry meeting: The assessors explain the FAO LMT assessment, LMT-core & LMT-safety, purpose and procedure at the

entry meeting. This question and general questions for the laboratory are asked at an entry meeting with the laboratory director & key staff or all staff.

- List tests performed at the laboratory and of the number of samples each section receives each year and the number of tests preformed.
- Staff organizational chart.
- Example test SOP from laboratory;
  – virology, serology, bacteriology, pathology & PCR.
- Equipment list.
- A risk assessment.
- PPE requirements.
- Training requirements: SOP, guidelines.
- Staff record.
- Waste disposal SOP & workflow.
- Workflow for samples in your laboratory
- Calibration & maintenance SOP & reports;
  – e.g. pipettes, autoclave, incubators, PCR machine.
- Internal quality control (IQC)/ test positive & negative controls progressive records.
- Proficiency testing (PT) reports.
- QA manual & safety/biosafety manual specific to the laboratory.
- Photos of signage in the laboratory;
  – entrances & exits, safety, equipment, temperature charts.
- Photos of laboratory sections and equipment.
- Photos of biosafety cabinets (BSCII) and staff wearing PPE.
- Laboratory floorplan.

2. The laboratory workflow (diagram or step by step workflow/procedure) for PCR testing in the laboratory and also the laboratory design/floorplan for PCR testing in the laboratory including sample reception & all rooms involved in PCR testing. Also include photos of the PCR areas and equipment.
3. *Each laboratory to prepare a list of questions to be covered after doing or reading the LMT assessment for a LMT workshop/training, after a self-assessment or in preparation for an online or desktop LMT assessment by an external LMT assessor. Questions can cover LMT assessment & recommendations from previous LMT assessments and for quality assurance (QA) and safety/biosafety & biosecurity*

Note: FAO LMT-assessment. Hold an exit meeting: The assessor(s) explain the FAO LMT assessment key outcomes, gaps, strengths and any immediate recommendations to improve QA or safety. The assessor explains the next steps and the reporting process.

This is also another opportunity for general questions and clarification with the laboratory director & key staff or all staff for any unanswered questions for the laboratory LMT assessments, LMT-core & LMT-safety.

ANNEX 2: LIST OF ATTACHMENTS TO THIS REPORT.

1. **FAO LMT- core assessments**
    - FAO LMT CORE Fiji FVL Chris FAO 12122021
    - FAO LMT CORE Fiji FVL Comparison 12122021 Chris
    - VET LAB FAO LMT CORE Fiji FVL 09122021
    - BAF Fiji FAO LMT CORE BAF Chris 13.12.2021

2. **FAO LMT- safety assessments**
    - FAO LMT SAFETY Fiji FVL Chris FAO12122021
    - FAO LMT SAFETY Fiji FVL Comparison 12122021 Chris
    - VET LAB FAO LMT SAFETY Fiji FVL
    - BAF Fiji FAO LMT SAFETY BAF Chris 13.12.2021

3. **FAO LMT- core & safety templates**
    - Annex 10.3 FAO LMT CORE EN2 ver092016
    - Annex 10.5 FAO LMT SAFETY EN2 ver102016

4. **FINAL Rev. 5 Koronivia agriculture PCR lab**

ANNEX 3: PLAN & ROADMAP FOR A QUALITY MANAGEMENT (QM) SYSTEM FOR LABORATORY QUALITY ASSURANCE AND SAFETY/BIOSAFETY.

Plan & roadmap for a quality management (QM) system for laboratory quality assurance and safety/biosafety.

1. **QM & QA system requirements to implement a QA system and to gain accreditation to ISO17025:2017**
2. **Safety/biosafety requirements: ISO35001**
3. **Roadmap to accreditation to ISO17025:2017**

The FAO program will assist in implementing the plan and has example documents for laboratories to be used to make their own QA and safety/biosafety documents.

Laboratories would aim to get a small number of tests accredited and the PCR tests & serology tests would be used as an example of the requirements needed for accreditation of a test, including biosafety/safety procedures. Other sections: bacteriology, parasitology & pathology etc can also be included.

QM & QA system requirements to implement a QA system and to gain accreditation to ISO17025 or ISO15189

1. **QA management structure (including biosafety)** needs to be implemented:
    - appoint QA & biosafety officers & technical managers and there terms of reference (TORs) for their positions and have these staff carry out their roles as per TOR;
    - QA committee needs to be established and also develop a TOR for their role in the QA system:
        - committee to establish a QA system & biosafety in laboratory;
        - support & resources are needed from government;
        - TORs for QA officer & biosafety officer;
        - technical managers appointed and TORs/duty statements written; and
        - TORs for staff.
    - QA committee (should be established first to implement QA system & safety):
        - director, head of laboratory,QA officer, biosafety officer, technical managers;
        - deputies needed for each position to share workload and to have more trained resources; and
        - laboratory supervisors included when there is no technical manager.
    - All meetings need to have minutes taken as part of the QA system.
    - Establish an internal audit system with trained internal auditors to carry out internal audits to monitor progress of implementing the QA system:
        - establish corrective action reports (CARs).
    - All staff meetings include QA & biosafety/safety (monthly: helps built a culture for QA and biosafety).
    - Equipment maintenance and calibration needs to be established:
        - pipettes, thermometers, balances, BSCII, autoclaves, ELISA reader & PCR machines etc.
2. **Specimen reception and reception**
    - The laboratory needs to put in place a central system for receiving samples, tracking samples and keeping records including condition of samples on arrival:
        - specimen reception needs to be setup to receive all samples submitted to the laboratory, e.g. as part of pathology and/or epidemiology;

        - record each sample submission in a book and on the sample submission form, giving each submission a unique laboratory number (sample submission number/case number/laboratory code);
        - establish a excel sheet & improve reporting;
        - allow epidemiology(Epi) to input field information in the report;
        - improve understanding of each other's areas (Epi/lab) ;
    - a reception also for visitors which will improve biosafety & biosecurity;
        - allow monitoring of entry of visitors to the laboratory; and
        - visitors recorded in visitor book.

3. Test documentation

- Sample submission form and unique number for all samples submitted to the laboratory (unique number format: year - number for submission e.g. 17-0001).
- Test result and/or worksheet and SOPs need to be completed for each test:
    - result sheet /worksheet for each test;
    - test controls/ internal quality control (IQC); and
    - a IQC progressive record for each test needs to be put place starting with PCR and serology.
- Reporting format and forms.
- SOPs completed in QA format for each test or section.
- Sample storage records needed :
    - where samples are and rules for disposal of samples need to be written in operational SOP and in test SOP;
    - SOP for storing isolates, RNA, serum etc;
    - biosecurity rules for storage: freezers or rooms locked; and
    - inventory system for storages of samples.
- Records for reagents & equipment:
    - equipment record with all equipment numbered and what calibration and maintenance required;
    - record to document receipt of reagents, storage and testing to confirm quality;
    - reagents all need batch numbers for identification; and
    - inventory system for reagents: recommend use of excel initially.

4. QA documentation

- Guidelines for QA, staff training & safety/biosafety:
    - induction form and procedure.

- Staff records:
  - TORs written Technical managers and QA officer; and
  - TORs for staff.
- Operational SOPs needed for QA, safety/biosafety, workflow, and use of equipment (e.g. autoclave, BSCIIs):
  - *e.g. method for autoclaving waste, waste disposal SOP, record for use of autoclave, workflow for processing samples, PCR workflow etc; and*
  - all laboratory activities to be documented with general guidelines and SOPs which are then used to write laboratory section operational and test SOPs.
- Equipment record/list: unique number for all equipment.
- All sections need to implement the audit recommendations for QM and QA and from biosafety from external/internal audits:
  - a corrective action record (CAR) needs to be put in place to identify responsible staff for carrying out audit actions and to track completion.

5. Test SOPs

- SOPs need updating to ensure there is detail of what is done in test: QA, biosafety, sample preparation, workflow staff training, etc (SOPs need to follow the recommended format for accreditation): **Write what you do**
  - bench method (short test method) needed for each test/SOP to use in lab; and
  - worksheet (coversheet) and/or result sheet for each test.
- All tests need to have QC and/or use IQC (test low positive & negative controls) and use progress record for IQC to record test information (reagents used etc) and IQC results:
  - also used to show staff competence;
  - number tests and positive samples; and
  - reagents used.

List of tasks for implementing a quality management & quality assurance

Laboratories need to use the example documents from FAO to put in place the QA management structure (including biosafety/safety) recommended and to establish a QA system in the laboratory including all laboratory sections:

- QA committee needs to be established;
  - committee to establish a QA system & biosafety in the laboratory;
  - support & resources needed from director, DG & ministry;
  - TORs for QA officer & biosafety officer and deputies and appointed;
  - technical managers appointed and TORs written; and
  - TORs for staff.

- QA committee (should be established this month);
    - head of Laboratory, QA officer, biosafety officer, technical managers;
    - deputies needed for each position to share workload; and
    - laboratory supervisors (section chief) included when not technical manager.
- All staff meetings include QA & biosafety (monthly).

QA documents needed for a QA system:

- sample submission form and number for all samples submitted to the laboratory;
- result sheet /worksheet for each test;
- test controls/ internal quality control (IQC);
- IQC progressive record for each test;
- reporting format and forms;
- SOPs completed in QA format for each test or section;
    - e.g. pathology/biochemistry/istology has test methods in one SOP;
    - e.g. virology tests methods separated by disease or discipline or both;
    - e.g. bacteriology test methods in one SOP and separate media/sterility testing SOPs;
- bench method: short one page test method to use when doing test;
- reagent record and current use document (e.g. list of current reagents in use for bacteria culture and identification);
- equipment record;
- staff records and ToRs/duties (Job descriptions for all staff and positions e.g senior technical officer, technical assistant, QA officer, etc);
- operational SOPs e.g. workflow for samples and testing, equipment use, working in a BSCII;
- calibration & maintenance of equipment; and
- ***QA manual: QA officer & admin to write.***

Each laboratory section needs to write these documents for QM & QA (A general laboratory document can cover all sections):

1. **Test SOP**
    - SOPs need updating to ensure there is detail of what is done in test: including QA and IQC, biosafety, sample preparation, workflow, staff training, etc ***write what you do****;*
    - method (short test method) needed for each test/SOP to use in lab; and
    - worksheet/coversheet and result sheet for each test.

2. **Operational SOPs (where a general laboratory operational SOP can't be written)**
    - workflow: for samples and testing;
    - staff training: QA, biosafety, GLP & technical (refer to training guidelines & SOP);
    - working a BSCII cabinet;
    - equipment maintenance and calibration;
    - waste management: decontamination, autoclaving and final disposal;
    - cleaning laboratory & equipment;
    - how to do a risk assessment on laboratory activities;
    - housekeeping: cleaning laboratory & equipment;
    - equipment SOPs: e.g. how to use autoclaves;
    - specimen reception and sample submission; and
    - Sample storage
    - ***A SOP needed for all laboratory activities***

3. **Staff record**
    - each staff needs a staff record (use example supplied); and
    - staff competence needs to be documented (see examples) or just use staff record.

4. **Staff ToR/duties**
    - each staff and position (section head, QA officer, technical manager etc) needs a duty statement or terms of reference (ToR) (use examples supplied): write what you do;
        – staff need to be made responsible for equipment;e.g. staff member responsible for autoclaves,fridges & freezers; and
    - staff need to be made responsible for activities;
        – housekeeping: cleaning laboratory and equipment.

Safety/biosafety requirements

1. **Guidelines and SOPs for all safety/biosafety/biosecurity activities**
    - risk assessments;
    - training;
    - safety/biosafety/biosecurity of laboratory;
    - visitors: scientists, clients & visitors;

- sample, chemical and reagent storage;
- waste management; and
- emergencies

2. **Risk assessment (RA)**
    - each laboratory section needs a risk assessment on laboratory activities and on zoonotic agents separately (e.g. COVID-19 general RA, COVID-19 PCR); and
    - risk assessments used to write SOPs.

3. **Guidelines and SOPs for emergencies**

    NAPHRI needs to put in place an emergency plan for all emergency situations and put in place signage for emergency/fire exits and for meeting point.

    - fire plan (yearly practice);
    - emergencies exit plan and meeting point;
    - electrical safety plan;
    - biosecurity plan for entry to;
    - staff exposure to biological agent; and
    - staff exposure to chemical agent.

4. **Spill, accident & staff exposure (video/SOP)**
    - a guideline for staff training needs to be prepared;
        i. covering a spill in a laboratory
        ii. spill in a cabinet
        iii. spill in equipment (fridge or centrifuge)
    - each staff needs training and then once a year training after initial training;
    - using a video may be useful;
    - spills kit for each area for large spills and small split kit for laboratory; and
    - emergency shower.

Roadmap to accreditation to ISO17025:2017

The accreditation of a laboratory will normally take from two to five years to complete depending on the resources available to the laboratory. It will take five or more years for the laboratory to have a QA System that is routine.

Quality assurance: What is required?

1. QA management structure
2. ***Documentation, record keeping and data management**
3. ***Internal quality control (IQC) & proficiency testing (PT)**
4. QA budget
5. Culture of quality
6. Reporting & data management
7. QA manual

Note: * recommended starting point for a QA system

The key components of a QA system are:

- QA management structure & QA committee;
- SOPs, workflow, bench methods, operational procedures and test records;
- internal quality control (IQC)/test positive & negative reference controls;
- proficiency testing/external QC (includes confirmation of test results);
- QA officer & deputy;
- trained staff (yearly competence training): records;
- biosafety/safety & biosecurity (safe working environment);
- equipment maintenance and calibration;
- equipment & reagent records: inventory, SOPs bench method;
- QA manual; and
- all staff must be involved to make the system work and for staff to have ownership of the QA system.

Year 1 activities

1. Audit of current situation in the laboratory (External & QA officer).
2. Setup QA committee.
3. Review workshop/update on current situation with management and all staff & training for key staff and an overview for all staff:
    - QM & QA ISO17025:2017
    - Use & production of IQC test controls
    - Workflow
    - Audit training
    - Writing SOPS

4. Write SOPs for tests and processes
5. Start using QA system

Year 2: activities

1. Audit of progress in laboratory (External experts, QA officer & internal auditors)
2. Review workshop/update
3. Training
    - QA staff & backup's
    - General QA for all staff
    - Writing documentation & QA Manual
4. Write QA documentation& QA manual (Start year 1 if resources allow)
5. QA system starting to be routine

Year 3, 4 & 5: activities

1. Audit of progress in laboratory by laboratory staff (Internal auditors with/and external auditor)
2. Review workshop/training/update
3. Accreditation (when budget allows)
    - Once QA system in place and operational and when there is a budget for supporting accreditation
    - Determined by audit results (internal & external)
        - staff need to be running QA system for at least one year
4. QA system is routine part of laboratory activities

ANNEX 4: SCHEDULE AND PROGRAM FOR PACIFIC ISLANDS FAO LMT TRAINING

Schedule and program Pacific Islands

online regional workshop on the application of the FAO laboratory mapping tool (LMT): 8,9,14,15 & 16 December 2021

Daily schedule: detailed schedule below

- Day 1: 3hrs online training FAO LMT assessments & LMT – core and offline laboratory LMT-Core A=assessment by participants and experts
- Day 2: 3hrs reviewing LMT – core assessment and introduction to LMT – safety and offline laboratory LMT – safety assessment by participants and experts
- Day 3: 3hrs online training to Complete LMT- core & LMT safety assessments and LMT assessment report and offline participants to finalize LMT-Core/LMT-safety assessments, write an assessment report/summary presentation (this can be done in word or powerpoint).
- Day 4: 3hrs online training where participants present a presentation on the final LMT assessments and LMT assessment report
- Day 5: Online conclusions, discussion and next steps finalized

Laboratory assessments:

1. **LMT – core/LMT - safety laboratory assessments are done via zoom with experts**
    - participants will assess/audit their own laboratory **(Fiji assessment used in workshop);**
        - participants are given a procedure for assessing an laboratory and what information has to be supplied to the experts to allow the experts to assess your laboratory, and
        - where possible the experts can follow the assessment using Zoom,
    - participants split into groups: 2 groups for each laboratory if staff numbers allow;
    - groups rotate between each laboratory section: 20 minutes/section asking laboratory; supervisor and staff questions so you can assess the laboratory.
        - e.g. Virology/PCR/serology, bacteriology, pathology & specimen reception
        - participating laboratories change the sections to be assessed based on sections in their laboratory
2. **Complete LMT-Core & LMT-Safety assessment document (Excel)**
    - Each group to complete LMT-Core & LMT-Safety assessment document
    - Each participant to complete LMT-Core & LMT-safety assessment document **(Optional)**

3. Report and presentation on assessments

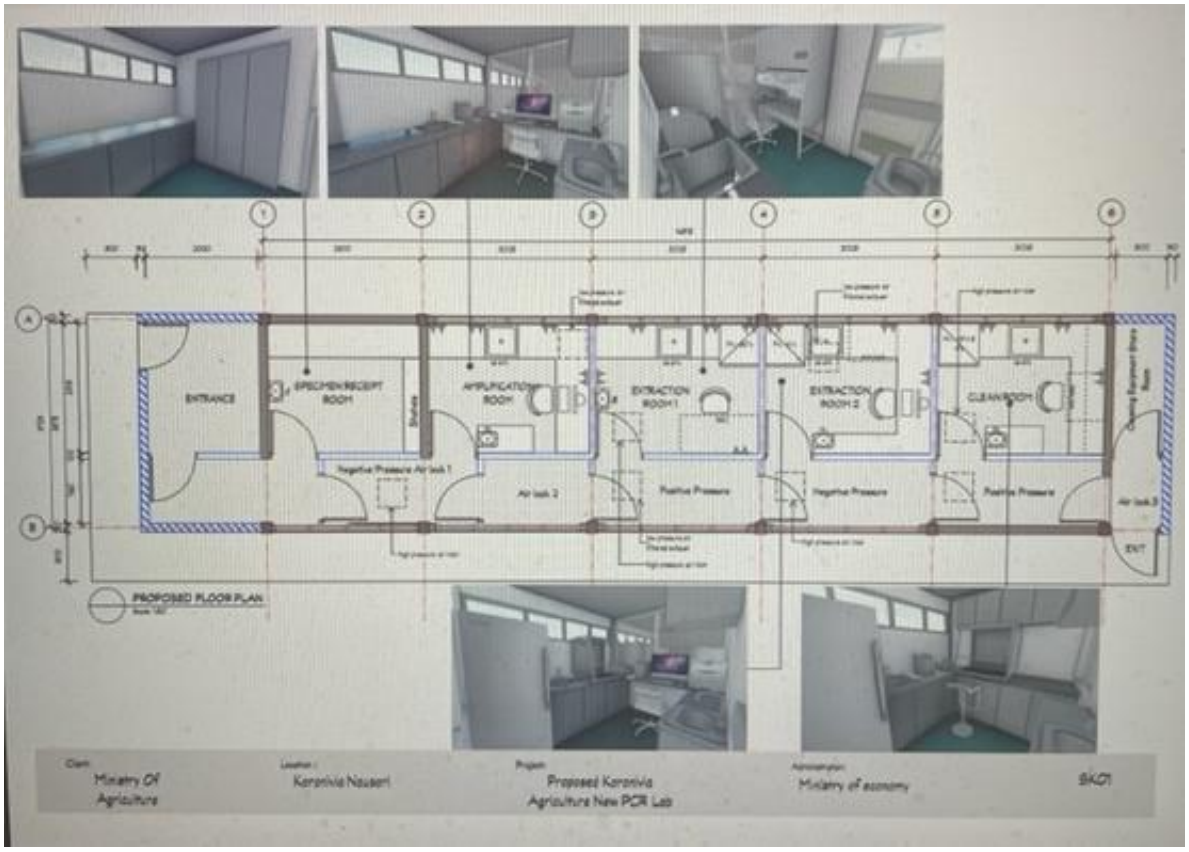
- each group to complete a report to summarise outcomes from assessments and includes recommendations and solutions; and
- each group does a presentation on assessments: presentation & report can be the same

Regional workshop on the application of the FAO Laboratory Mapping Tool (LMT) Shedule

Date	Time	Description	Note
Day 1 8 Dec 2021	9:00 - 9:20	Welcome	FAO/Host Country
	9.20 - 9.40	Participant introductions	Participants
	9:40 - 10:20	Explanation of LMT-Core/LMT- Safety concept	Experts: Chris Morrissy
	10:20 – 11:00	Explanation of LMT-Core Standard questions	Experts: Chris Morrissy
	11:00 - 11:10	BREAK	
	11:10 - 12:00	Explanation LMT - Core Laboratory inspection ***Participants split into groups and rotate between each laboratory section***	Experts: Chris Morrissy Virology/PCR/Serology, Bacteriology, Pathology & Specimen Reception
	14:00 – 17:00 (Offline)	LMT Laboratory inspection done via Zoom with expert **(Fiji laboratory):** 20mins/section • Groups rotate between each section • Complete LMT-Core document	Participants/Experts: Virology/PCR/Serology, Bacteriology, Pathology & Specimen Reception
Day 2 9 Dec 2021	9:00 - 9:30	Complete LMT - Core document	Participants
	9:30 - 11:00	Presentation and comparison of results	Participants/Experts
	11:00 - 11:10	BREAK	
	11:10 - 11:40	Explanation of LMT - Safety Standard questions	Experts

	11:40 – 12:00	Explanation LMT - Core Laboratory inspection ***Participants split into groups and rotate between each laboratory section***	Experts Virology/PCR/Serology, Bacteriology, Pathology & Specimen Reception
	14:00 – 17:00 (Offline)	LMT - Safety Laboratory inspection done via Zoom with MORU: 20mins/section • Groups rotate between each section • Complete LMT-Safety document	Participants/ Experts: Virology/PCR/Serology, Bacteriology, Pathology & Specimen Reception
Day 3 14 Dec 2021	9:00 - 9:15	Review of yesterday's activities	Experts: Chris Morrissy
	9:15 - 10:45	Presentation and comparison of results	Participants/Experts
	10:45 - 11.00	Break	
	11.00 - 12:00	LMT-Core/LMT-Safety Documents & Report on Laboratory Assessment	Participants/ Experts
	12:00 – 17:00 (Offline)	Complete LMT-Core/LMT-Safety Documents & Report on Laboratory Assessment	Participants/ Experts
Day 4 15 Dec 2021	9:00 - 9:15	Review of yesterday's activities	Experts
	9:15 - 10:30	Presentation: Final LMT Assessments and Report	Participants
	10:30 - 10:40	Break	
	10:40 - 12:00	Discussion on Issues and Problems	Experts/Participants
Day 5 16 Dec 2021	9:00 - 10:00	Feedback & Questions	Experts/Participants/FAO
	10:00 - 10:15	Break	
	10:15 - 11:00	Conclusions & Next Steps	Experts/Participants/FAO/Countries
	11:00	Closing	FAO/Countries

ANNEX 5: DRAFT PLAN FOR FVL PCR LABORATORY



CONTACTS:

FAO Subregional Office for the Pacific Islands

SAP-SRC@fao.org

www.fao.org/asiapacific/pacific

Food and Agriculture Organization of the United Nations

Apia, Samoa

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