Report

Roadmap for the Introduction of a Quality Assurance Management Program for Animal Health Laboratories in the SAARC Region

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Abbreviations and acronyms

AAHL	Australian Animal Health Laboratory
AI	Avian Influenza
ASEAN	The Association of Southeast Asian Nations
BSCII	Biological Safety Class 2 Cabinet
BSL	Biosecurity Level
BSO/ABSO	Biosafety Officer/Assistant Biosafety Officer
CT	Cycle Number Threshold
ECTAD	Emergency Centre for Transboundary Animal Disease
ELISA	Enzyme Linked Immunosorbent Assay
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FMD	Foot and Mouth Disease
HI	Haemagglutination Inhibition
HPAI	Highly Pathogenic Avian Influenza
HPEDs	Highly Pathogenic Emerging Diseases
IQC	Internal Quality Control
LPB-ELISA	Liquid Phase Blocking ELISA
OIE	World Organization for Animal Health
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
PPR	*Peste des Petits Ruminants*
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control

QM	Quality Management
RLDLs	Regional Leading Diagnostic Laboratories
RSU	Regional Support Unit
RT-PCR	Reverse Transcription Polymerase Chain Reaction
rRT-PCR	Real-time RT-PCR
SAARC	South Asian Association for Regional Cooperation
SAARC LDF	SAARC Laboratory Directors' Forum
SOP	Standard Operating Procedures
VI	Virus Isolation

1. Summary

The SAARC Laboratory Directors' Forum (LDF) meetings have proven to be a useful mechanism for communication between all the SAARC laboratories and in implementing improvements into the SAARC laboratory network. The 2nd meeting of SAARC LDF and workshop identified the willingness to put in place improved Quality Assurance (QA) and Biosafety in all laboratories but did identify the need for improve resourcing including budget to allow this to happen. Also there is a need for training of laboratory staff and support from experts, donors and International organisations.

The FAO Sub-regional ECTAD Unit in Kathmandu, Nepal is important supporter of SAARC and the implementation of the SAARC LDF and they will be important in coordinating the ongoing establishment of the SAARC LDF and the formation of a technical advisory group (TAG) to provide advice to the SAARC LDF. The SAARC LDF and SAARC Laboratory Network needs to find regional support so it can stand alone as a funded entity.

SAARC Regional Leading Diagnostic Laboratories (RLDLs) have been established in Bangladesh (PPR), India (FMD) and Pakistan (HPAI) and the laboratories will play a key role in establishing improved QA of laboratory tests. To do this the RLDLs need to establish good relationships with regional laboratories and this can be done through the SAARC LDF and through support to the countries in providing PT and reference controls and technical support.

The SAARC LDF needs to forge a collaboration with the ASEAN LDF in establishing a QA Management system using information that the ASEAN LDF already have to develop policy, guidelines and regional SOPs.

This report outlines a QA Management Roadmap for the SAARC region and a separate Roadmap for implementation of a QA system into each laboratory. To implement the Roadmap the SAARC LDF will need to work with a Laboratory Expert and to do this they will need funding from donors and/or government and continued support from international agencies and reference laboratories. To maintain a QA system in laboratories the laboratory will need to have an ongoing budget to maintain QA and Biosafety in the laboratory.

2. Background

The Food and Agriculture Organization of the United Nations (FAO) is implementing an European Union (EU) funded regional project entitled "Regional Cooperation Programme on Highly Pathogenic and Emerging Diseases (HPED) in South Asia" under the umbrella of the South Asian Association for Regional Cooperation (SAARC) at FAO Sub-regional ECTAD Unit in Kathmandu, Nepal. The overall objective of the project is to strengthen and empower SAARC countries in their ability to prevent, control and eradicate HPED, including HPAI, through improved veterinary and public health services and inter-sectoral collaboration on a regional basis.

To fulfil the mandate of the project, SAARC Regional Leading Diagnostic Laboratories (RLDLs) have been established in Bangladesh (PPR), India (FMD) and Pakistan (HPAI) as agreed by the member countries. These laboratories are co-coordinating and leading a

network of national diagnostic laboratories, primarily focusing to maintain uniform diagnostic standards, support training of laboratory scientists/technicians from the member states, and backstop regional surveillance and epidemiological studies. The activities are also being supported by the international OIE and FAO reference laboratories like Australian Animal Health Laboratory, Geelong, Australia and High Security Animal Disease Laboratory, Bhopal, India.

The RLDLs implemented a number of laboratory activities including trainings in laboratory diagnostic protocols for regional priority diseases and implementation of proficiency testing (PT) programmes in the region. The Proficiency testing of National FMD laboratories is ongoing since September 2012 in Bangladesh, Bhutan, Nepal and Sri Lanka. The RLDLs also supported the standardization of diagnostic technologies and instrumentation besides setting up FMD virus typing facilities in Bhutan and hands-on PCR training on HPAI diagnosis in Bangladesh.

The laboratory networking was initiated in March 2011 followed by the First Laboratory Directors' Meeting and Workshop on Laboratory Networking and Proficiency Testing for Priority HPEDs in SAARC Countries in January 2012 in Dhaka, Bangladesh. One of the important recommendation of the First Meeting include: The Laboratory Director/s Forum could provide guidelines for all laboratories in a number of areas like biosafety, quality assurance (QA), testing requirements for test validation, equipment calibration (e.g. BSL II cabinets, PCR machines) etc. Another important recommendation agreed by the participants in the workshop was that the quality assurance system needs to be implemented and supported and National laboratories should seek accreditation from their own country.

To take forward these recommendations, it is essential that these laboratories are engaged in quality assurance programs and participate successfully in proficiency testing schemes. Additionally, a laboratory should implement a quality management program that is appropriate for its mandate, clients, needs and goals, and that can be shown to be effective in meeting quality objectives. Many factors affect the quality management program, the OIE standards on this subject is a useful guideline for laboratories seeking accreditation (ISO/IEC 17025).

The Regional Support Unit, based in the FAO's Sub-regional ECTAD Unit in Kathmandu organized the "Second Laboratory Directors' meeting and workshop on enhancing the laboratory expertise through quality management systems in SAARC countries" from 7 – 8 March 2013 in Colombo, Sri Lanka with support from the European Union.

3. Objective

Organizational objective: Reduced animal disease and associated human health risks, by enhancing capacity to implement and maintain national and regional approaches to animal disease prevention and control which will contribute to the increased sustainable livestock production.

The overall objective of the project is to strengthen and empower SAARC countries in their ability to prevent, control and eradicate HPED, including HPAI, through improved veterinary and public health services and inter-sectoral collaboration on a regional basis.

4. Participants

The workshop was attended by 23 participants from the SAARC countries including Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka with technical support from the Australian Animal Health Laboratory (AAHL), World Health Organization (WHO) and FAO ECTAD, Kathmandu, Nepal.

5. Expected Outcomes

- The outputs expected are; a structured, accurate, and detailed five year road map for a quality management programme for participating animal health laboratories in the SAARC Region.

6. Activities

- Based on inputs from the meeting, prepare a structured, accurate and detailed five year roadmap for the introduction of a quality management programme for participating animal health laboratories in the SAARC region.

7. Report on Activities

7.1 Roadmap for the Introduction of a Quality Assurance Management Program for Participating Animal Health Laboratories in the SAARC Region

7.1.1 Regional QA Management Roadmap

The regional roadmap is a guideline for the introduction and implementation of a QA management program for the SAARC region to establish a QA system and management structure in each National Laboratory and RLDL. Once the National laboratory has implemented the regional roadmap the regional roadmap can then be applied to the laboratories in the National/Country laboratory network.

The Regional laboratory Directors' Forum will be the group that will implement the Regional Roadmap. The TAG will be an important part of the regional network advising the Directors' Forum. The TAG will need advice from experts and it is recommended the experts are from diagnostic laboratories that have best practice QA and Biosafety/Biosecurity in place and accreditation to ISO17025. SAARC should also use other networks for advice and access guidelines from these networks to help produce guidelines for SAARC region. The Directors forum and/or TAG may need to establish smaller working groups to assist with implementation and establishment of guidelines.

Regional Policy and Guidelines need to be established and from these National Policy and Guidelines:

- Guidelines for minimum standards (diagnostic capacity/capability) for each laboratory level, RLDL, National laboratory, Country Regional, Province or District laboratory. The ASEAN regional guideline is in ANNEX 1 for reference.
- Guidelines for QA in the laboratory including Regional and National IQC reference controls
- Guidelines for Biosafety and Biosecurity (ASEAN guideline ANNEX 2)
- Investigate regional and or national resource for equipment and laboratory calibration and maintenance (trained maintenance staff in each country and or regionally to support laboratories). It is recommended this is done in collaboration with human health to spread/reduce the cost.

The Regional Roadmap (5 year plan) for the Introduction of a Quality Assurance Management Program to SARRC region:

Year 1: Activities

1. The Laboratory Directors' Forum to establish a TAG group made up of RLDLs, regional reference laboratories and International reference laboratory to provide technical advice to the Laboratory Directors' Forum and to establish regional guidelines for QA, Biosafety and Biosecurity and minimum laboratory capacity/standards. Laboratory Directors' Forum also needs to establish regional policy for QA, Biosafety and Biosecurity and minimum laboratory capacity/standards and advocate for resources and funding from country governments to support introduction of best practice QA system and Biosafety and support from International agencies and donors. Also the Regional Support

Unit, based in the FAO's Sub-regional ECTAD Unit in Kathmandu can be used for support by the Laboratory Directors' Forum.

2. All RLDL and National laboratories in the SAARC laboratory network to establish a QA management committee (see section on Implementation of a QA system for detail) to cover laboratory QA and Biosafety and Biosecurity and appoint a QA Officer and Biosafety Officer and deputies.

    - Establish duty statements for QA Officer and Biosafety Officer and deputies

3. QA/Biosafety expert contracted to carry out a gap analysis/audit of the SAARC laboratory network, RLDL and National laboratories, for diagnostic capacity (based on regional minimum laboratory capacity guidelines), QA including management structure and Biosafety and Biosecurity.
    - The gap analysis/audit must follow ISO17025 format and the expert must be an experienced auditor under ISO17025 in a diagnostic laboratory and have experience with biosafety and biosecurity
    - A workshop should be held back to back with the SAARC LDF and TAG meetings inviting QA & Biosafety Officers and other key Laboratory technical managers as required to review report from audit and plan the start date for implementing roadmap and accessing assistance needed with identified gaps.

4. Awareness training programs for all laboratory staff, including laboratory Director, administration staff and any field and epidemiology staff directly associated with the laboratory on implementing QA and Biosafety system in the laboratory

5. Training programs for laboratory staff who are implementing QA and Biosafety in each laboratory e.g. QA Officers, Biosafety Officer and key technical managers in each laboratory. The training will cover implementation of QA system in the laboratory under ISO17025 and Biosafety and include the following
    - ISO17025 QA system and accreditation
    - QA requirements and how to implement (also see section on Implementation of a QA system for detail and suggested plan for implementation)
    - Risk Assessment, Workflow and Biosafety
    - Disinfection and Decontamination
    - IQC laboratory test controls and Regional and National IQC
    - Harmonisation of laboratory tests in SAARC region including Regional SOPs (ASEAN protocols can be used as reference: these are based on OIE recommended test SOPs)
    - External QA and PT
    - Audit training

6. All laboratories to start with implementation of ISO17025 requirements for QA of a Laboratory Test. Each section (e.g. virology, serology, bacteriology, pathology and PCR) in the laboratory should start with one or two routine tests to put in place required QA for these tests, e.g. virology/serology, AI PCR tests and HI

tests and FMD tests. Laboratory staff meetings need to have QA and Biosafety as part of the Agenda (at start of meeting) to discuss progress in implementing roadmap and issues. The following processes need to be implemented according to ISO17025:

- Documentation, Record Keeping and Data Management
  - Tests including all reagents and equipment used in the tests
  - Test coversheets and result sheets, reagent records and equipment records, sample submission forms and IQC records
- Internal Quality Control (IQC): Positive and Negative controls for each test including use of reference controls
  - Production and validation of IQC controls
- Test SOPs and procedures
- Maintenance and calibration of equipment used for testing including SOPs
- Begin establishing or reviewing duty statements for all staff according to ISO17025 and start to establish a staff record or update current staff records to meet ISO17025 requirements

7. Laboratories must participate in the available PT programs (e.g. SAARC FMD RLDL PT program and PT programs available through AAHL/FAO ASEAN PT programs for AI, CSF, PRRS, NDV, Rabies and ASF) starting with the key diseases; AI, FMD and PPR, and begin using Regional Reference controls to validate laboratory IQC controls.

Year 2: Activities

1. Audit the progress on implementing a QA system in each laboratory by external expert and QA Officer and Biosafety officer at each laboratory. It is recommended one or two nominated regional experts (nominated by TAG or from TAG) carry out the audit/review with the expert and laboratory QA & Biosafety Officers. Alternatively regional experts can be chosen from the QA & Biosafety Officers from each laboratory to form a regional expert panel to carry out future audits, regardless experts from the laboratory QA & Biosafety Officers should be added to the nominated experts to form an expert panel to be used in SAARC countries.

2. A review workshop should be help back to back with the SAARC LDF and TAG meetings inviting QA & Biosafety Officers and other key Laboratory technical managers as required to review report from audit and develop an action plan to deal with issues raised in the report and plan assistance to laboratories as required.

3. Carry out further training at laboratories to cover gaps identified in year 2 audit and include training in:
   - ISO17025 and requirements, starting to look at QA manual and administration processes including training in writing a QA Manual
   - Production and use of IQC national controls
   - Workflow and Biosafety in the laboratory
   - Audit training

4. All laboratories to start implementation of ISO17025 requirements for QA of a Laboratory Tests to all tests in the laboratory.

5. All laboratories to start writing a QA manual as required by ISO17025, including administrations processes, e.g. purchase of reagents, staff training and professional development and maintenance of equipment and the laboratory

6. All laboratories to start implementation of ISO17025 processes to sample collection and to improving field data. Note: This can be started in Year 1 if resources allow.

Year 3: Activities

1. Audit the progress on implementing a QA system in each laboratory by external expert, QA Officer and Biosafety officer at each laboratory and members of SAARC expert panel.

2. A review workshop should be help back to back with the SAARC LDF and TAG meetings inviting QA & Biosafety Officers and other key Laboratory technical managers as required to review report from audit and develop an action plan to deal with issues raised in the report and plan assistance to laboratories as required.

3. Carry out further training at laboratories to cover gaps identified in year 3 audit and include training in:
    - For QA staff: technical managers, internal and external auditors and backup's/deputies or replacements to the QA and Biosafety Officers
    - Further training in writing a QA Manual and associated documents and in requirements for laboratory to apply for accreditation to ISO 17025
    - Advanced training of members of SAARC expert panel to take over annual laboratory audits

Year 4 and 5: Activities

1. Audit the progress on implementing a QA system in each laboratory by SAARC expert and QA Officer and Biosafety officer at each laboratory.

2. A review workshop should be held back to back with the SAARC LDF and TAG meetings inviting QA & Biosafety Officers and other key Laboratory technical managers as required to review report from audit and develop an action plan to deal with issues raised in the report and plan assistance to laboratories as required.

3. Carry out further training at laboratories to cover gaps identified in year 4 audit as required in each laboratory. Training to be organised by SAARC LDF and TAG utilizing expertise from expert panel and SAARC laboratories and if required external expert.

4. Laboratories should be looking at applying for accreditation to ISO17025 if not already accredited earlier by their country accreditation body. If no country accreditation available then the laboratory can still operate under ISO17025 and not have accreditation but recognition they have operating at ISO17025 standard by SAARC LDF and TAG.

5. National laboratory networks should be now implementing the QA Roadmap in its national laboratory network following the same process.

7.1.2 Roadmap to Implementation of a Laboratory QA system

A Quality Assurance (QA) System ensures tests are preformed to a standard:

- Gives the laboratory a management structure
- Documentation of all Test and Laboratory protocols/procedures: SOPs
- International credibility to Test Results
- Laboratory Accreditation to a Standard (ISO17025)
- QA and Biosafety important for ISO 17025

The key components of a QA system are (Note: starting points for implementing a QA system are highlighted in bold with essential process to be introduced in red):

- **QA management structure**
- **SOPs and Test Records and Documentation**
- **Internal Quality Control (IQC)**
- Proficiency Testing
- **QA Officer**
- **Trained Staff**
- Biosafety & Biosecurity (Safe working Environment)
- Equipment maintenance and calibration
- Equipment & Reagent Records
- QA Manual
- **All Staff (YOU)**

Roadmap (steps) for setting up a QA system in a laboratory

1. Establish a QA Management Structure as required under ISO17025 starting with the establishing a QA committee: Director, QA Manager, Biosafety Officer Technical Managers and Head of Laboratory or Laboratory Supervisor (if exists). The QA committee provides support and advice for implementation of the QA system into laboratory and ensures the laboratory carries out its testing under QA system (ISO17025). If the positions indicated in the QA committee do not exist then the Laboratory Director needs to appoint a QA Manager (Officer), Biosafety Officer, Technical Manager for each disciple and Head of Laboratory/Laboratory Supervisor (this position is required if the laboratory Director cannot function as the daily operations manager for the laboratory to ensure samples are processed in a timely manner). All staff involvement need to be involved in the implementation to ensure success, e.g. regular updates through all staff and laboratory section meetings.

2. What is required for a laboratory QA system (*starting point for a QA System):
   - ***QA Management Structure**
     - **— Including QA Committee**
   - ***Documentation, Record Keeping and Data Management**
   - ***Internal Quality Control (IQC) & Proficiency Testing (PT)**
   - QA Budget
   - Culture of Quality

- Reporting & Data Management
- QA Manual

All laboratories to start with implementation of ISO17025 requirements for QA of a Laboratory Test. Each section (e.g. virology, serology, bacteriology, pathology and PCR) in the laboratory should start with one or two routine tests to put in place required QA for these tests, e.g. virology/serology AI PCR tests and HI tests and FMD tests. The following are more detailed instructions on each step in implementing a QA system in the laboratory.

Documentation, Record Keeping and Data Management

1. Specimen Reception records for receiving samples are carried out in the laboratory in a separate Laboratory Specimen Reception often run by the Pathology or the Epidemiology section. There is often a standard form filled out that is either supplied by the laboratory or is a standard field collection form for the whole country. Specimen reception needs to:
    - **Specimen Submission/Data Sheet from field**
        - follow up missing information with field
            - **record contact with field (separate sheet)**
        - record condition of samples on arrival (including temperature)
        - send samples for testing

2. Laboratory test records needed to be put in place in each laboratory section for all tests, starting with one or two routine tests (e.g. key regional/national diseases: FMD, AI and PPR). Coversheets and Result Sheets need to be used for all tests:
    - **e.g. PCR, Serology and Virus Isolation (VI) test records (coversheets and result sheets: ASEAN Regional record sheets can be used as reference)**
        - Record all test information on test record sheet: reagents used, operators, results and expected results of IQC, sample results, storage information and must be signed off by supervisor
        - **Batch Numbers for reagents**
        - **Important calculations**

3. All laboratory sections need to record IQC results (test positive and negative controls) on a progressive record that records all reagents used in the test as well as test operator and comments. The record can also be used to record the number of tests and samples that are positive (useful for reports). Positive and Negative controls (IQC) must be used in each test and these must be standardised against Reference Controls from Reference Laboratory. Local IQC reference controls for use in each test need to be produced in large batches and then standardised against a reference control e.g. HI control with known titre (20 - 50ml). It is important that IQC controls are produced in large batches so they can be used for a minimum of a 100 tests, this allows the laboratory test to be compared day to day, month to month and laboratory to laboratory when standardised against National, Regional or International reference controls.

   IQC controls for each test need to include as a minimum a low positive control and a negative control, other controls can be included as required.

   e.g. IQC for PCR tests

- **Positive and Negative Extraction (must be included)**
  - Positive Allantoic fluid CT 29 – 31
  - Negative Allantoic fluid, swab or tissue
- **PCR controls**
  - Positive RNA CT 29 – 31
  - Negative No Template Control(NTC)

4. All laboratories need to write test SOPs and these need to follow the ISO17025 format. The OIE guidelines for tests are used as reference and SAARC can use the ASEAN regional SOPs also as a reference. ASEAN regional test SOPs are based on AAHL SOPs (test methods). Methods follow ISO17025 format need to include:
   - Staff training needed
   - Sample preparation
   - Test method
   - Workflow for processing samples including sample preparation (e.g. heat inactivation of serum)
   - Quality Assurance outlining IQC that is expected to be used in test and the expected result
     - What to do if the test fails
     - Cut-off for a positive result
   - Storage of samples: storage time, where

   e.g. PCR Test:
   - Methods for extraction in SOP for PCR
   - Sample preparation
   - Workflow for PCR
   - Staff preparation
   - QA & Biosafety
   - Short bench top method

   In writing a SOP the laboratory needs to write down what it does (if you do it then write it down).

5. All laboratories need to update laboratory procedures. A procedure is needed for each laboratory activity, e.g. how to work in BSCII cabinet and waste disposal.
   SOPs need to be put in place for all laboratory procedures/tasks:
   - Workflow for sample processing (can be included in Test method)
   - PCR workflow included in test method
   - Biosafety: waste disposal, PPE, disinfection (use Virkon not UV or alcohol)
   - Working in BSCII cabinet
   - Staff training
   - QA & IQC
   - Sample Preparation
   - Reagents & Equipment

6. All laboratories need to maintain Reagent & Equipment records for tests used in the laboratory (ASEAN Regional records can be used as reference):
    - All equipment and reagents received need to be recorded and given a unique number (reagents are given a batch number)
    - Need to record validation data for reagents used
    - Need to record calibration and maintenance dates and records
    - Temperature charts/records for equipment

7. All laboratories need to prepare a QA Manual and Supporting Documents but this does not need to be done immediately and it is recommended this is done once test QA has been implemented in the roadmap year 2 or 3. The QA manual document all processes in the laboratory and to support the laboratory in maintaining accreditation to ISO17025. The ASEAN/AAHL example QA manual is available for Reference and ISO17025 has guidelines. Examples of documents in QA manual:
    - QA Policy
    - Specimen Receival Procedure
    - Purchasing Policy
    - Forms for purchasing diagnostic reagents
    - Audit Procedure
    - Corrective Action Record
    - Bio-safety Policy
    - Procedure Staff Records & Training
    - Staff Record

8. Reporting & Data Management is important and again is an area that is worked on overtime to get improvement. Results receive back from laboratory usually go to the Epidemiology or Pathology section, put into a report and them to the Director for signing. Epidemiology or Pathology section enter results in book and on computer (Excel or into a laboratory information management system (LIMS) It is important that results are checked against information from field to ensure results match field information, if there is any doubt the Epidemiology or Pathology section need to ask for more testing from laboratory, if necessary.

    Laboratory results on Report and IQC need to be checked by a second person and signed on coversheet to confirm results on report are correct (e.g. lab supervisor) before going to the Director for signing.

    It is recommended all laboratory records including the report are maintained in one file to allow easy access to results from sample submitted to the laboratory.
    - Information from Field, Coversheet, Results & Report all filed together
    - Note books can still be used to record information on work done but all test information needs to be on coversheet and result sheets
        - e.g. reagents used (e.g. antigen used for HI and dilution used), operators, controls used, PBS batch etc all need to be recorded on the coversheets
        - Positive and negative control (IQC) recorded on the result sheet

9. All laboratories need to participate in External Quality Assurance Proficiency Testing (PT) Program where they are available e.g. SAARC FMD PT program. Proficiency testing is part of an overall Quality Assurance (QA) Program:
    - aims to assure that results from a laboratory can be relied on as correct
    - enhances the user's general QA status and specific assay proficiency
    - provides reference data to help identify and solve systematic and random errors
    - provides an organized and transparent mechanism to enhance credibility of results
    - assists in verifying national/regional control and eradication campaigns
    - is a requirement of ISO 17025

10. The final requirement is for the laboratory to have the resources needed to put in place a QA system. To do this the laboratory Director needs to have the budget necessary to put in place QA:
    - Trained staff (staff competence)
        - Staff numbers
        - QA Officer & QA staff
        - Biosafety Officer
        - Auditors
        - 10 – 20% increase in workload (save time once in place)
    - Equipment maintenance & calibration
    - Reagents (reference controls & IQC)
    - Testing of New Reagents
    - Accreditation costs & Ongoing cost for ISO17025

Support from all management levels is needed to implement and maintain a QA system, the Government (ministry), Director General and the Director of Laboratory and stakeholders support are all important to achieve QA system in the laboratory.

11. Changing staff culture to make QA and Bio-safety routine is often the most difficult task in implementing QA and Bio-safety in a Laboratory. It is important to achieve this change to have all levels of management supporting the implementation of a QA system and also have all staff involved: Some feedback from other laboratory indicate some of the difficulties :
    - It's too slow heat inactivating the sera
    - Easier to do on the bench
    - Paperwork slows down doing the test
    - Controls are too expensive
    - Drinking in the lab is not the same as eating

8. Conclusion and Recommendations

The SAARC LDF has now had two meetings and even at this early stage shows promise as the best mechanism for communication between all SAARC laboratories and in implement improvements into the SAARC laboratory network. The meeting and workshop identified the willingness to put in place improved QA Assurance and Biosafety in all laboratories but did identify the need for improve resourcing including budget to allow this to happen. Also there is a need for training of laboratory staff and support from experts, donors and International organisations.

The FAO Sub-regional ECTAD Unit in Kathmandu, Nepal is important supporter of SAARC and the implementation of the SAARC LDF and they will be important in coordinating the ongoing establishment of the SAARC LDF and the formation of a TAG to provide advice to the SAARC LDF.

The SAARC LDF needs to forge a collaboration with the ASEAN LDF in establishing a QA Management system using information that the ASEAN LDF already have to develop policy, guidelines and regional SOPs.

SAARC Regional Leading Diagnostic Laboratories (RLDLs) have been established in Bangladesh (PPR), India (FMD) and Pakistan (HPAI) and these laboratories need to work with regional laboratories to establish links that lead to improvement in QA of tests. The RLDLs also need to establish regional reference controls that can be used to ensure the performance of laboratory tests.

Recommendations

1. To take forward these recommendations from the second SAARC LDF meeting, it is essential that these meetings continue to allow continued improvements in diagnosis through the SAARC Laboratory network.

2. The formation of a TAG is also essential to the ongoing improvement of the SAARC Laboratory network critical to the SAARC LDF getting the correct technical advice and to the SAARC laboratory network implementing the QA Management Roadmap

3. The SAARC LDF and TAG need to establish Regional Policy and Guidelines for the region and these can be used to establish National Policy and Guidelines:

    - Guidelines for minimum standards (diagnostic capacity/capability) for each laboratory level, RLDL, National laboratory, Country Regional, Province or District laboratory. The ASEAN regional guideline is in ANNEX 1 for reference
    - Guidelines for QA in the laboratory including Regional and National IQC reference controls
    - Guidelines for Biosafety and Biosecurity (ASEAN guideline ANNEX 2)

4. The SAARC LDF investigates regional and or national resource for equipment and laboratory calibration and maintenance (trained maintenance staff in each country and or

regionally to support laboratories). It is recommended this is done in collaboration with human health to spread/reduce the cost.

5. It is recommended the RLDLs work with regional laboratories to establish links that lead to improvement in QA of tests. Also RLDLs need to establish regional reference controls that can be used to ensure the performance of laboratory tests.

6. It is recommended that concept of a Regional laboratory network is repeated at the country level with National laboratory networks/Directors Forum established to have annual meetings to discuss national laboratory network issues and a group that can implement regional guidelines for a laboratory QA system in each laboratory which includes PT, Biosafety and Biosecurity.

7. It is recommended the SAARC LDF make use of the information available from the ASEAN LDF, e.g. Regional SOPs and Guidelines. It also would be beneficial for each group to attend each other's meetings.

8. The major constraint identified during the workshop to improve laboratory QA management and diagnostic capacity, included Biosafety and Biosecurity is resources, including a budget to implement and maintain a best practice QA system meeting International Standards (e.g. ISO17025). Also it was identified that there was a need for training to build expertise in the region and countries in QA, PT and Biosafety & Biosecurity. It is recommended that SAARC LDF and FAO Sub-regional ECTAD Unit in Kathmandu, Nepal advocate to government, international organisations and donors for funding and budget to implement and maintain a QA system in including Biosafety and Biosecurity

ANNEX 1

ASEAN Minimum Requirement for Diagnostic Laboratory Biosafety and Quality Assurance

Assay	Recommended Biosafety	Quality control & test reagents
Post mortem/pathology	PM carried out in BSCII for small pigs at laboratory PM carried out wearing breathing protection for large pigs in laboratory or field PPE Waste autoclaved	PT: slides to recognize disease
Serology	Serum processed in BSCII PPE Serum heat inactivated 56 C for 30mins	IQC (Positive and negative) progressive records & coversheets PT
Virus isolation	Samples processed out in BSCII PPE All equipment in room Waste autoclaved	Titration of virus with known titre: H5N1, H1N1, NDV IQC (Positive and negative) progressive records & coversheets
Molecular diagnostic and characterization	Samples processed out in BSCII PPE Waste autoclaved	IQC (Positive and negative) progressive records & coversheets PT

ANNEX 2

ASEAN Minimum Requirement for a Diagnostic Laboratory at each level in the Regional Laboratory Network

Minimum Requirement for each Diagnostic Laboratory Level		
Laboratory level	**Roles & test performed**	**Recommended Biosafety**
Sub-national Laboratory	Serology: Post vaccination surveillance/serosurveillance PCR Rapid tests	Samples processed in BSCII PPE Serum heat inactivated 56 C for 30mins BSL3 practices Waste autoclaved
National Laboratory	Serology PCR (confirmation tests) VI Sequence analysis Differential diagnosis Reference reagents (positive & negative controls PT Training	Samples processed in BSCII PPE Serum heat inactivated 56 C for 30mins BSL3 practices Waste autoclaved
Regional / Key Laboratory	Serology PCR (confirmation tests) VI Sequence analysis Differential diagnosis Virus characterisation Reference reagents PT	Samples processed in BSCII PPE Serum heat inactivated 56 C for 30mins BSL3 practices Waste autoclaved
OIE/FAO Reference Laboratory	Serology PCR (confirmation tests) VI Sequence analysis Differential diagnosis	Samples processed in BSCII PPE Serum heat inactivated 56 C for 30mins BSL3 practices

	Virus characterisation Reference reagents	Waste autoclaved