

NRL QUALITY FRAMEWORK

Redefining Quality in Infectious Disease Testing

INTRODUCTION

To assure accurate, high-quality infectious disease testing, human and animal health laboratories and point of care (POC) testing sites need to perform testing and conduct **quality assurance** activities within the guidelines of a **quality management system** (QMS).

These activities should be encouraged by the Ministries of Health (MOH), however, national laboratories often do not have the staff and resources to develop or implement the required activities. In addition, there are few published international standards that define how these quality activities should be designed and implemented in each country.

Many countries have elements of quality management in place, but these often do not include all requirements. A gap in these required quality management elements limits the potential to ensure high-quality test results, thus increasing the risk of incorrect results. The consequences of incorrect results can be extremely serious, **for example:**

- On-going transmission of infection with associated health and economic impacts
- Waste of resources (staff time, reagents, consumables, hospital beds etc.)
- Poor epidemiological data and incorrect prevalence of infection, which adversely affects public health planning
- Societal implications, for example, stigma and discrimination for patients falsely diagnosed with infectious diseases
- Deterioration of public trust in medical laboratory testing
- Hampering of national and international efforts to reduce the burden of disease



THE NRL QUALITY FRAMEWORK

For more than three decades, the National Serology Reference Laboratory (NRL) Australia has partnered with MOH, laboratories and other in-country stakeholders supporting the quality management and quality assurance of infectious disease testing. As such, NRL has a good understanding of the causes of incorrect test results and the challenges that testing facilities face in the region.

NRL has utilised this extensive and specialised experience, to develop a Quality Framework to clearly describe the necessary quality activities that each country should aim to implement. As NRL undertakes each of these quality services on a routine basis, it is uniquely placed to train, support and mentor in the implementation of each of the Quality Framework elements.

ACTIVITIES IN NRL'S QUALITY FRAMEWORK INCLUDE:

- of new batches or shipments of test kits.
- requirements.
- 5 including EQA and competency assessment for individual testers.
 - advanced testing settings.

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Quality Management Systems - Develop and implement QMS systems, procedures and processes for clinical and animal health laboratories, including assessments against ISO 15189, ISO 17025, or ISO 9001 requirements.

Principles of Good Manufacturing Practice (GMP) - Develop and implement GMP systems, procedures and processes for the manufacture of blood/blood components, and in-vitro diagnostic medical devices, including assessments against the Code of GMP (cGMP), ISO 13485, or ISO 9001 requirements.

Test Kit Evaluations – Develop infrastructure, procedures, sample banks and the knowledge to perform test kit evaluations on behalf of MOHs or other national regulatory bodies, thus ensuring good guality test kits are promoted for use in-country. Where required, provide batch testing services

External Quality Assessment Schemes (EQAS) - Design, develop and implement national or regional EQAS programs to monitor the testing performance of in-country facilities; including assessments against ISO 17043

Quality Assurance for Point of Care Testing (POC QA) - Design, develop and implement POC QA programs to monitor the quality of testing in POC settings, where traditional quality assurance might not be fit for purpose;

Quality Control Methods - Support real-time performance monitoring of the analytical process to detect and rectify adverse events before they impact on patient safety. This includes methods and systems to monitor quality controls used for different laboratory sections and is appropriate for more

Train-the Trainer - Train Quality Champions to ensure the specialised expertise on quality activities and quality management is available locally to support the sustainability of the capacity building program. These Quality Champions can use NRL's Framework Modules to train and mentor Biosafety and Biosecurity independently on completion of the program.



THE NRL APPROACH

CULTURALLY SENSITIVE, SUSTAINABLE, AND LOCALLY ALIGNED

NRL's Quality Framework forms the basis for its capacity building support to countries, which includes in-country assessments against the Framework, development and implementation of country-specific and needs-based workplans over the medium to long-term.

NRL's methodology for training and mentoring is effective, with all training programs being followed by a series of customised mentoring sessions. This approach enables the NRL Trainers to reiterate requirements, answer questions and discuss site-specific challenges the participants may be experiencing with implementation. Sustainability of the program is ensured by selecting and mentoring in-country experts as Quality Champions who will have the knowledge to maintain and improve activities once the program is completed.



STEP-BY-STEP

Assessment of in-country gaps in existing Quality Activities

- Develop unique checklists.
- Assess laboratories and POC testing sites.
- Meet with in-country stakeholders.

Develop country specific work plan

- in-country stakeholders and based on available budget.

Support Quality Champions

Identify in-country personnel to become Quality Champions.

Conduct four-pronged capacity building plan that includes:

- Virtual introductory training.
- On site practical training.
- Mentoring during implementation.
- Training of Trainers for Quality Champions, including:
 - Trail an NRL Trainer during NRL Training activities.
 - Become co-trainers, delivering training with NRL Trainers under supervision

 - Become the in-country expert.

Conduct mid-term review

Scale up of in-country or regional programs

involving the Quality Champions.

Facilitate the development of a Community of Practice

- POC testing sites.
- offering technical support based on their areas of expertise.



Analyse results and prioritise areas for support in collaboration with Develop workplan and customised modules including curriculum, on-line resources, knowledge assessments and certificates of attendance.

- Be mentored through active review and assessment of training.

Assess the progress of the activities, making necessary adjustments.

Support trainees to expand their new programs nationally or regionally,

Enable the sharing of ideas and best practices to support laboratories and

• Together with other partners, support the Community of Practice by

MEET THE TEAM



INNOCENT MUPUNGA

Innocent Mupunga is a Senior Scientist and Consultant with over two decades of expertise in laboratory diagnostics, quality management systems, biosafety, biosecurity, and capacity building. He specialises in training laboratory professionals and providing scientific consultancy and advisory services globally. Innocent's experience includes leading clinical laboratories, implementing quality and safety systems, and strengthening public health laboratory capacity in Africa and Asia-Pacific regions.



VEE ARMSTRONG

Vee Armstrong is a Senior Scientist and Consultant with more than thirty years of experience in quality management systems, GMP, and regulatory affairs. She has worked with WHO on the development of Guidance documents for blood services and with APEC on QMS capacity building to identify and establish Centres of Excellence among blood services in Vietnam. Vee has also supported capacity building of clinical and blood testing laboratories in the Asia-Pacific region through virtual and on-site training and assessments.



SANDY WALKER

Sandy Walker is an NRL Senior Scientist with over 20 years of expertise in quality assurance for infectious disease testing. She has extensive experience in the Asia-Pacific region, including five years with the World Health Organization's Western Pacific Regional Office in the Philippines, where she supported laboratories in strengthening quality assurance processes and enhancing global testing standards.



GERALDINE KONG

Geraldine Kong, Scientific Consulting and Training Manager at NRL, brings over 20 years of experience collaborating with international partners across government and the non-governmental sector. She has worked in partnership with organizations such as the Global Fund, the World Health Organization, the Mérieux Foundation, and the Australia Indonesia Health Security Partnership. Geraldine specializes in managing and coordinating capacity-building projects focused on Strengthening laboratory quality in Asia, the Pacific, and Africa, overseeing activity plans, budgets, and reporting requirements.

EXAMPLE A

IMPLICATIONS OF HAVING INCOMPLETE **QUALITY ACTIVITIES IN-COUNTRY**

A country may have excellent External Quality Assessment Activities and Quality Control programs to monitor individual laboratory results, but this may offer limited value if the country does not also have a strong test kit evaluation and licensing program in place to ensure the use of high-quality test kits.

In this situation, the EQA or QC can effectively identify laboratories that are producing incorrect test results, which in some cases may be due to ongoing poor kit performance. Without a test kit evaluation program there are no systems in place to prevent the use of ineffective test kits and there is no central body to use the data generated from the EQA to have ineffective kits withdrawn.

This leaves the onus on individual laboratories to have the expertise and time to identify inadequate test kits. In addition, laboratories not participating in the EQA would continue to use the ineffective kits and unknowingly report incorrect patient results.





CASE STUDY: Supporting EQAS Implementation in India



OBJECTIVE:

To enable 17 scientific institutes across India to become providers of External Quality Assessment Schemes (EQAS) for serology and molecular testing. The program was coordinated by the Indian Council of Medical Research (ICMR) with funding from WHO's South-East Asia Regional Office (SEARO).

PARTNERS:

- Indian Council of Medical Research (ICMR)
- ICMR-National Institute of Virology, Pune
- 17 selected scientific institutes across India

PHASE 1: **VIRTUAL TRAINING** (APRIL - JULY 2023)

Five virtual workshops introduced 20-45 trainees to the EQAS process, covering:

- Sample sourcing, characterisation, and storage.
- Designing, producing, and validating panels.
- Data management, analysis, and report preparation.

Trainees worked through real examples using HIV

serology and SARS-COV-2 panels. Institutes began using the EQAS Planning Tool to methodically plan out each step of their EQAS to support implementation.

PHASE 2: **PRACTICAL TRAINING** (AUGUST 2023)

An eight-day workshop in Pune, India, led by NRL trainers, guided 35 participants through the full EQAS process whereby:

- understanding.

PHASE 3: MENTORING (OCTOBER 2023 -**DECEMBER 2024**)

Four virtual mentoring sessions supported the pilot EQAS implementation:

- feedback from NRL.
- Institutes provided

NRL and ICMR transformed India's diagnostic landscape, equipping 17 institutes to deliver EQAS programs, ensuring sustainable, high-quality testing nationwide.

 Serology and Molecular Panels were produced. Participants validated panels, designed forms, packaged samples, and analysed results. Each institute developed SOPs and shared them with the group. A knowledge guiz confirmed participants'

 Institutes presented their panel designs and received

> updates on their progress and identified challenges, which were addressed.

RESULTS:

- The Indian government approved \$2 million USD for three years to support the implementation of EQAS.
- An EQAS Expert Group in India was established to standardise processes.
- 17 new EQAS programs were implemented with different analytes including Dengue, Zika Influenza and chikungunya viruses, with institutes progressing toward ISO 17043 accreditation.

IMPACT:

The NRL and ICMR partnership equipped 17 institutes with the skills to implement their own EQAS programs, building local expertise and paving the way for sustainable, high-quality diagnostic testing in India.

These 17 new EQAS programs will allow the quality and accuracy of laboratory tests to be known, ensuring that laboratories around India can monitor their testing processes to identify and resolve any potential sources of error and where the need exists, laboratories will be supported to improve their testing processes.

OBJECTIVE:

To support the National AIDS Program (NAP) in Indonesia through capacity strengthening and assessment of four nominated laboratories in preparation for the selection of one independent laboratory to develop and deliver a national HIV viral load external quality assurance program (HIV VL EQA).

The program was coordinated by Yayasan KNCV Indonesia (YKI) in collaboration with the Indonesian Ministry of Health.

PARTNERS:

- Yayasan KNCV Indonesia (YKI)
- Indonesian Ministry of Health (MOH)
- 4 nominated laboratories across Java, Sumatra and South Sulawesi

PHASE 1: VIRTUAL TRAINING (JUNE 2023)

Approximately 21 participants attended a one-and-a-halfday virtual workshop led by NRL Trainers to introduce the main activities of the EQAS production process. The activities covered:

- Sample sourcing, characterisation, and storage.
- Designing, producing, validating and despatching panels.
- Data management, analysis, and report preparation.

The participants included representatives from YKI, MOH, the nominated laboratories and other key stakeholders.

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PHASE 2: PRACTICAL TRAINING (JULY 2023)

A 4 day onsite practical workshop was held in Makassar, South Sulawesi, attended by 2 representatives from each of the four nominated laboratories and led by the NRL Trainers. Representatives from the MOH and NAP were also in attendance, while the training was also broadcast to a wide audience of distinguished guests by Zoom.

The participants, working in their laboratory pairs, undertook the planning and design of an HIV VL panel to take back to their laboratories, while the Makassar design was then used to produce and test a panel as a group. Technical aspects that have the potential to affect the integrity of the panel samples were discussed in detail.

PHASE 3: CAPACITY ASSESSMENT (JULY TO AUGUST 2023)

An onsite assessment of the capacity at each of the four laboratories was conducted by the NRL Trainers with two objectives:

- To determine the effectiveness of the current quality management system (QMS) at each laboratory and its potential to adequately manage the quality of national HIV VL EQAS production;
- To review the facilities and resources in place to assess their suitability for national HIV VL EQAS production.

At the conclusion of the assessments, NRL presented the outcomes to the MOH and other relevant stakeholders in Jakarta.

RESULTS:

- The knowledge of EQAS production at each of the 4 nominated laboratories was improved.
- Each laboratory planned and designed one HIV VL EQAS panel for future use.
- Each laboratory received an assessment report highlighting deficiencies in its processes and systems.
- Recommendations were made to the MOH regarding the capacity of each laboratory to undertake national EQAS production.

IMPACT:

The NRL and YKI partnership provided training to the four laboratories that improved their knowledge substantially.

The capacity assessment reports can be used by the laboratories to improve the quality and effectiveness of their EQAS production processes, and their compliance to the Standards ISO 15189 and ISO 17043.

The Indonesian MOH was provided with information and a recommendation on each laboratories' capacity which enabled it to make a decision and appoint a national HIV VL EQAS provider.

> NRL and YKI strengthened HIV VL EQAS capacity in Indonesia, empowering labs and guiding the MoH to select a national provider.



CASE STUDY: Capacity Strengthening of HIV Viral Load EQAS National Reference Laboratories in Indonesia



BENEFIT TO COUNTRIES

OUR REAL WORLD IMPACT

NRL's training and mentoring program will provide countries with an understanding of the quality requirements needed, along with support to design and implement these in accordance with their local infrastructure and budget.

The unique program design that uses a mentoring model to support implementation and the embedding of quality experts in-country, increases the likelihood of significant and sustainable outcomes.



WANT TO KNOW MORE?

Reach out to us at **training@nrlquality.org.au** for all the details!

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