

EQAsia: National EQA provision pilots (NEQAs)

Module 1: Introduction to NEQA and SOP development

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DTU

Outline

- EQAsia NEQA objectives
- Definitions
- General requirements
- Standard operating procedures (SOPs)
- Process requirements
- EQAsia overview



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EQAsia NEQA Objectives

- Build capacities for NEQAs.
- Empower NEQAs to operate independently with confidence.

Definitions

- **Proficiency Testing (PT):**

- PT demonstrates laboratory competence and highlights potential issues.
- Involves interlaboratory comparisons for evaluating performance.
- Interlaboratory Comparisons (ISO 17043)

- **Purposes:**

- Evaluation of laboratory performance for specific tests, measurements, calibrations, or inspections.
- Identification of underlying problems (e.g., methods, training, calibration).
- Establishing method effectiveness and result comparability.
- Providing confidence to users of test results.
- Identifying result discrepancies.
- Educating labs based on comparison outcomes.

Definitions

- **External Quality Assessment (EQA) programs:**
 - Offer diverse interlaboratory comparisons, extending beyond traditional PT schemes.
 - Focus on complete laboratory workflow insight, not limited to specific measurement or test processes.
 - Typically, continuous programs with long-term monitoring of laboratory performance.
 - Emphasize participant education and quality improvement through advisory and educational feedback.

General Requirements

- **Impartiality and Confidentiality:**

- The PT provider must ensure the impartiality of its activities, free from commercial or other pressures.
- Continuous monitoring of activities and relationships to identify threats to impartiality.
- Confidentiality of participant and customer information is strictly maintained.
- Information received from external sources (e.g., complaints, regulators) is kept confidential.
- Identity of the source is protected and not disclosed unless agreed upon by the source.
- Personnel and external parties involved in PT activities are bound by confidentiality agreements.
- Participant identities are confidential and disclosed only to authorized personnel unless waived by the participant or customer.

General Requirements

- **Organizational structure:**
 - Define organization and management structure.
 - Clarify place within any parent organization.
 - Outline relationships between management, technical operations, and support services.
- **Personnel responsibilities:**
 - Specify responsibilities, authority, and interrelationships of all personnel involved in PT activities.
 - Include those who manage, perform, or verify work affecting PT results.
- **Documentation procedures:**
 - Document procedures comprehensively to ensure consistent application and validity of PT activities.

General Requirements

- **Key personnel requirements for PT providers:**
 - Authority for management system:
 - Personnel must have authority and resources for implementing, maintaining, and improving the management system.
 - Deviations identification:
 - Ability to identify deviations from the management system or procedures during PT activities.

General Requirements

- **Key personnel requirements for PT providers:**
 - Action initiation:
 - Authority to initiate actions to prevent or minimize deviations encountered.
 - Reporting responsibilities:
 - Responsibility to report to management on the performance of the management system and suggest improvements.
 - Ensuring PT effectiveness:
 - Ensuring the effectiveness of PT activities through authority and resource allocation.

General Requirements

- **Ensuring validity of PT activities:**

- PT provider must ensure appropriate facilities for PT scheme operations.
- Document environmental conditions that can impact PT items, measurements, or tests.
- Control, monitor, and periodically review environmental conditions.
- Stop activities if environmental conditions compromise validity.

- **Examples of environmental conditions:**

- Biological sterility
- Dust
- Electromagnetic disturbances
- Radiation
- Illumination (light)
- Humidity
- Electrical supply
- Temperature
- Sound and vibration levels

Summary

- **Key points in PT and EQA provider requirements:**
 - General Requirements: Impartiality and Confidentiality
 - Organizational structure and documentation
 - Personnel authority and responsibilities
 - PT vs EQA programs
 - Ensuring validity of PT activities

Standard operating procedures (SOPs)

- **Definition:**
 - SOPs are written documents containing step-by-step instructions for laboratory procedures.
- **Purpose:**
 - Provide guidance for meticulous execution of procedures by laboratory staff.
- **Usage:**
 - Each laboratory procedure is associated with its own SOP for standardized execution.



Standard operating procedures (SOPs)

- **Benefits of written SOPs:**

- **Consistency:** Ensures uniformity in procedure execution across all laboratory staff, enabling reliable and comparable results over time.
- **Accuracy:** Reduces errors and enhances result precision by providing structured guidelines that prevent steps from being overlooked.
- **Quality:** Upholds the laboratory's commitment to delivering consistent, accurate, and reliable results, reflecting the essence of quality in laboratory operations.

Standard operating procedures (SOPs)

- **Characteristics of a good SOP:**
 - Detailed, Clear, and Concise: Provides comprehensive step-by-step instructions including critical details such as ambient temperature requirements and precise timing instructions for consistent execution.
 - Accessible to New Personnel: Easily understood by individuals new to the procedure or undergoing training, ensuring consistent performance across staff levels.
 - Review and Approval: Regularly reviewed and approved by laboratory management, demonstrated by signatures and dates, to ensure procedures are current and suitable for use.
 - Regular Updates: Subject to periodic updates to reflect evolving practices and maintain relevance in laboratory operations.

Standard operating procedures (SOPs)

- **Standardized format for SOPs:**

- Importance of Headers: Headers play a critical role in the standardized format of SOPs, providing essential information to users at a glance.
- Complete Standardized Header: Typically appears on the first page of each SOP, containing comprehensive details for quick reference by staff.
- Reduced Standardized Header: Used on subsequent pages, featuring a condensed version of the header to maintain clarity and consistency throughout the document.

TLM/MSH Microbiology Department Policy & Procedure Manual	Policy # MI/RESP/11/v05	Page 1 of 5
Section: Respiratory Tract Culture Manual	Subject Title: SPUTUM (Including Endotracheal Tube and Tracheostomy Specimens)	
Issued by: LABORATORY MANAGER	Original Date: September 25, 2000	
Approved by: Laboratory Director	Revision Date: September 14, 2006	
	Annual Review Date: August 13, 2007	

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Respiratory Tract Culture Manual		

Standard operating procedures (SOPs)

- **Preparing SOPs:**
 - **Scientific Validity Assessment:** Prioritize assessing the scientific validity of the procedure before preparing the SOP to ensure accuracy and reliability.
 - **Inclusion of Detailed Steps and Instructions:** Write comprehensive step-by-step instructions detailing how to perform the procedure accurately and effectively.
 - **Reference Relevant Procedures:** Incorporate references to any related procedures, such as sample collection instructions or quality control protocols, for comprehensive guidance.
 - **Establish Mechanism for SOP Updates:** Implement a systematic approach for regularly updating SOPs to reflect changes in practices and maintain relevance.

Standard operating procedures (SOPs)

- **Key components of SOPs:**

- **Title:** Clearly states the name of the test or procedure outlined in the SOP.
- **Purpose:** Provides information about the test's significance, use case (e.g., screening, diagnosis, treatment follow-up), and relevance to public health surveillance.
- **Instructions:** Detailed step-by-step guidance covering the entire testing process, including pre-examination, examination, and post-examination phases.
- **Authorship:** Includes the name of the individual who prepared the SOP, ensuring accountability and clarity of responsibility.
- **Approval Signatures and Dates:** Indicates the endorsement of responsible officials, along with the dates of approval, aligning with laboratory quality policies and regulatory requirements.

Standard operating procedures (SOPs)

- **Pre-examination instructions:**

- Sample Collection and Transport: Detailed guidance on proper sample collection, transport to the laboratory, and necessary conditions for sample handling (e.g., use of preservatives, refrigeration, freezing, or room temperature storage).
- Sample Labelling: Clear instructions reflecting laboratory policies for sample labelling, including requirements for patient identification verification, collection date on sample labels, and completeness of test request forms.

- **Examination instructions:**

- Laboratory Procedures: Step-by-step instructions for conducting laboratory procedures accurately and efficiently.
- Quality Control Procedures: Guidance on implementing quality control measures to ensure the accuracy, precision, and reliability of test results.

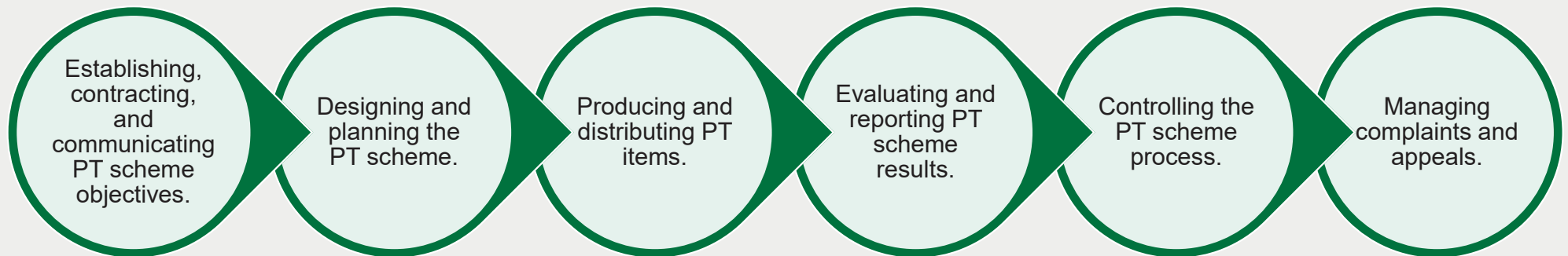
Standard operating procedures (SOPs)

- **Post-examination instructions:**
 - Reporting Results:
 - Detailed guidance on how to report test results, including specifications for units of measurement, normal (reference) ranges, and identification of life-threatening ranges (e.g., "panic values").
 - Dealing with Urgent Reports:
 - Instructions for handling urgent or critical results, outlining procedures for immediate notification and follow-up actions.
 - References to Published Sources:
 - Incorporation of references to published sources of procedures, demonstrating scientific validity and ensuring adherence to established standards.

Standard operating procedures (SOPs)

- **Manufacturer's instructions:**
 - Test Performance Guidelines: Manufacturers provide test-specific instructions, detailing how to perform the test accurately.
 - Limitations of Manufacturer's Instructions: Manufacturer's instructions may lack laboratory-specific information such as result recording procedures, testing algorithms, and safety practices.
 - Quality Control Recommendations: Manufacturers may suggest quality control procedures, but these recommendations may not align comprehensively with laboratory protocols.
 - Developing Laboratory-Specific SOPs: Emphasize the importance of using manufacturer's instructions as a reference but developing laboratory-specific SOPs to encompass all necessary procedures and policies.

Process Requirements



Process Requirements

- **Detailed information for PT scheme participants:**
 - Objective and Scheme Details: Clear objectives and relevant details of the PT scheme.
 - Participation Criteria: Criteria required for participation in the PT scheme.
 - Performance Evaluation Criteria: Criteria for determining assigned values and evaluating performance.
 - Confidentiality Arrangements: Protocols for ensuring confidentiality of participant information.
 - Timelines: Critical timelines for various phases of the PT scheme.
 - Participation Fees: Any associated fees for participation in the PT scheme.
 - Application Process: Details on how to apply for participation.

Process Requirements

- **Detailed information for PT scheme participants:**
 - Communication and Change Management:
 - Timely communication of PT scheme changes to participants and customers.
 - Maintenance and retention of records for relevant communications by the PT provider.

EQAsia Overview

- **Objective:**

- Strengthening External Quality Assessment (EQA) services in the One Health sector across South and Southeast Asia.

- **Components of EQAsia:**

- Rounds of proficiency tests (PT; named EQAs) for antimicrobial susceptibility testing (AST) using WHO and FAO priority pathogens.
 - Interpretative criteria based on international guidelines such as CLSI and EUCAST.
- Rounds of training through workshops and webinars covering AST and quality management systems (QMS).
 - Consultation visits for selected underperforming laboratories post each EQA round.



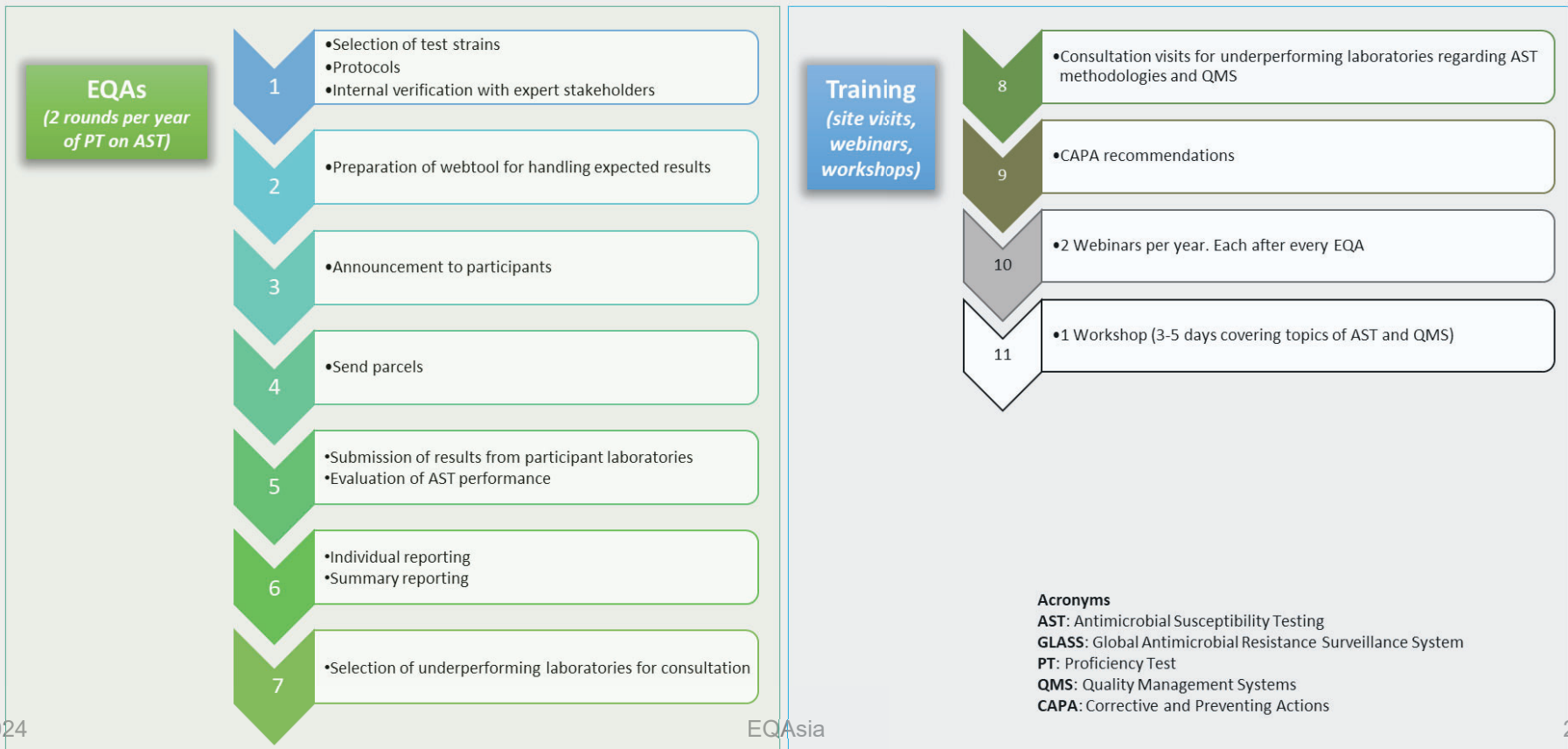
EQAsia Overview

EQAsia program - Building capacity on AST - NRLs and Regional Laboratories

One Health approach

WHO – GLASS priority pathogens (human health)

FAO – Priority pathogens (animal health and food safety)



EQAsia Overview

- **Fundamental tools for running an EQA:**

1. List of bacterial pathogen strains and antimicrobials for AST:

- Includes WHO Global Antimicrobial Resistance Surveillance System (GLASS) and FAO priority pathogens.
- Each EQA provides a suggested list of antimicrobials to test against specific strains.

2. Manuals, Guidelines, Protocols:

- Essential for handling bacterial strains, including revival, growth, and storage protocols.
- Documents are stored and downloadable for participants on a dedicated website managed by EQAsia partners from DTU.

EQAsia Overview

- **Fundamental tools for running an EQA:**

3. Webtool for result handling:

- A dedicated online tool for storing, compiling, and managing EQA participant lab results efficiently.
- Developed by DTU Corporate IT and hosted on the DTU server.
- Handles EQA datasets individually, allowing creation of user profiles and reports.
- Participants access their datasets only; Administrator has access to all datasets.
- Administrator can create summary reports for all labs or by sector (animal/human health).
- Customizable for adding expected results before each EQA round.
- DTU partners are administrators; DTU Corporate IT supports maintenance and improvement.

EQAsia Overview

- **Fundamental tools for running an EQA:**

3. Webtool for result handling:

- NEQA pilot plan implementation:
 - Individual country units created within the webtool for pilot EQA datasets.
 - Units accessible only to country users and administrators.
 - Users can access their datasets for report creation; Administrators customize and compile datasets for summary reports.
 - EQAsia consortium partner granted access to pilot datasets for guidance and support.



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