Plan to apply for ISO 17025:2017 certification scope of Antimicrobial Susceptibility Testing (AST)

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1) Background and Problem Statement

In response to the global agenda on AMR and Thailand's NSP-AMR 2017-2021, the Department of Livestock Development (DLD) is taking clear action. Since 2016, ten laboratories under DLD including the National Institute of Animal Health (NIAH), the Bureau of Quality Control of Livestock Products (BQCLP), and the Regional Veterinary Research and Development Centers implemented standard methods of antimicrobial susceptibility testing (AST) for AMR before starting the national surveillance of AMR in 2017. At present, the quality assurance is necessasary for monitoring the laboratory in the organization. ISO/IEC 17025:2017 is an international standard that specifies the general requirements for laboratories' competence, impartiality, and consistent operation. No laboratory of DLD is ISO/IEC 17025:2017 accredited for the extent of antimicrobial resistance. BQCLP recognizes the importance of ISO/IEC 17025:2017 certification and has plans to request ISO/IEC 17025:2017 certification scope of AST in 2025. Therefore, it is necessary to prepare documents and important steps to achieve accreditation. The development of a functioning quality management system and the various programs, procedures, documentation, and verification activities that must be put into place to become ISO/IEC 17025:2017 compliant will be examined to understand better how a laboratory becomes ISO accredited.

2) Project Objectives

1. To prepare a document for applying ISO/IEC 17025:2017 certification scope of AST.
2. To plan to apply for ISO/IEC 17025:2017 certification scope of AST "Antimicrobial susceptibility testing for *Salmonella* spp. and *E.coli* by broth microdilution method" within 2025.

3) Methods Used

1. Team meeting
   - 1.1 1st meeting was held on March 15, 2024, with 5 participants. To understand the requirements outlined in the ISO/IEC 17025:2017 standard. This includes the general requirements for the competence of testing and specific requirements related to AST.
   - 1.2 2nd meeting was held on April 1, 2024, with 5 participants. These were the topics:
     - 1.2.1 Review current activities and operations of AST.
     - 1.2.2 Identify and define the specific testing/calibration services or products to be covered under the certification scope.
     - 1.2.3 Assess the current state against ISO/IEC 17025:2017 requirements.
     - 1.2.4 Identify gaps, areas needing improvement, and resources required to meet certification standards.
     - 1.2.5 Documentation needed for ISO 17025:2017 compliance.
2. Created a checklist of requirements for the ISO/IEC 17025:2017 certification scope of AST, including management and technical requirements.

3. Coordinate with the Department of Medical Sciences, which is a supporting agency for proficiency testing, inter-laboratory testing, and method verification“
4. Makeup plan for ISO/IEC 17025:2017 certification scope of AST. This plan outlines activities timeframe based on the lab needs and available resources. Assign responsibilities for creating, updating, and maintaining required documentation.

4) Results

1. A team meeting was held on March 15 and April 1, 2024 with 5 participants. The meeting results were:

1.1 Review current activities and operations of AST: The national surveillance of AMR in food-producing animals has been conducted in broiler chickens and pigs since they are highly consumed in the country. This surveillance was conducted across the food chain from slaughterhouses (cecum and meat samples) to retail stores (meat samples). A total of 5,900 samples were obtained from all over the country. The target bacteria of AMR surveillance included zoonotic bacteria (*Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (*Enterococcus* spp. and *E. coli*). AST was performed based on the CLSI, ISO 20776-1, and EUCAST. The tested antimicrobials included colistin, ciprofloxacin, cefotaxime, ceftazidime, gentamicin, meropenem, chloramphenicol, sulfamethoxazole, and trimethoprim.

1.2 The scope for requesting competence certification was selected Antimicrobial susceptibility testing for *Salmonella* spp. and *E.coli* by broth microdilution method. The Sensititre platform was conducted for AST.

1.3 Assess the current state against ISO/IEC 17025:2017 requirements: We found documented procedures for AST testing, competent staff has received training on AST, procedures and demonstrated competence, a record for AST data and report, equipment calibration, and control practices for AST materials.

1.4 Identify gaps, areas needing improvement, and resources required to meet certification standards: There were;

- To develop documentation for all AST procedures.
- To conduct a training needs assessment and provide training for AST personnel.
- To implement a program for conducting regular internal audits of the AST quality management system.
- To develop a documented system for continual improvement of the AST quality management system through regular audits, data review, and identifying areas for improvement.

1.5 Required documents for compliance with ISO/IEC 17025:2017 were listed below.

- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Services to the client
- Complaints
- Test conformity and/or calibration
- Testing and calibration methods
- Method selection
- Method development
- Validation of methods
- Evaluating measurement uncertainty
- Control of computerized data
- Management of equipment

- Corrective action
- Preventive action
- Continual improvement
- Control of records
- Internal audits
- Management reviews
- Staff organization and management
- Installation and environmental conditions
- Measurement traceability
- Sampling
- Handling samples and test items
- Quality assurance of testing
- Reporting results
- Presentation of reports
- Interpretation and declaration of compliance
- Transmission of reports

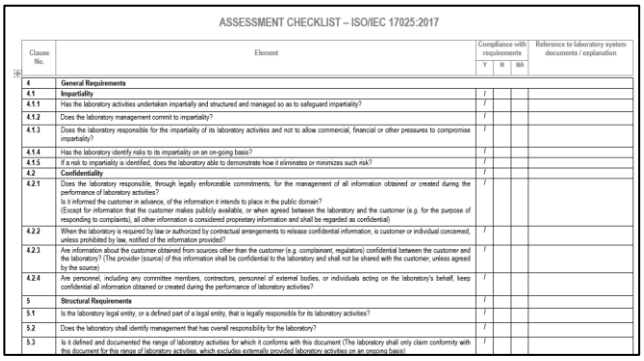
Figure 1: The meeting of the ISO/IEC 17025:2017 standard.

Figure 2: AST equipment Sensititre platform

2. We created a checklist for ISO/IEC 17025:2017 certification scope of AST involves detailing both management and technical requirements. Below was a comprehensive checklist covering various aspects of the standard
   - Management Requirements: documentation, organization, management system, management review, resource management, internal audits, corrective actions
   - Technical requirements: general requirements, quality control, sampling, testing methodology, reporting of results, records and data management, proficiency testing, uncertainty of measurement.
3. Coordinate with the Department of Medical Sciences (DMSc)
   - We discussed with DMSc via line to make up a plan for inter-laboratory testing, and method verification. BQCLP will prepare test samples and drug plates for 60 samples to be tested on *Salmonella* and *E.coli.* This round, three laboratories were participating including DMSc, BQCLP, and NIAH.
4. Makeup plan for ISO/IEC 17025:2017 certification scope of AST: The time frame for assessment by the accreditation body would be within September 2025. There were 15 steps with 6 completed, and 9 remaining continuing as shown in Table 1.

Table 1: Plan to apply for ISO/IEC 17025:2017 certification scope of AST

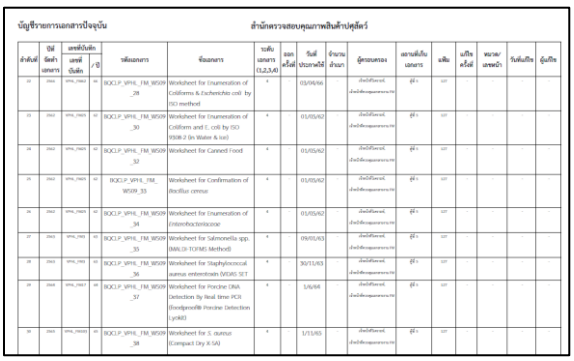
Steps	Timing	Status
1. Review the requirements of ISO/IEC 17025:2017 and related documents.	April 2024	complete
2. Quality Policy Statement by the Top Management	April 2024	complete
3. Appoint a Quality Manager, a Technical Manager, a Document Controller, and other positions as necessary, along with deputies for key positions, and define the roles and responsibilities for each position.	April 2024	complete
4. Implement quality assurance measures for test results, including participation in proficiency testing programs and/or inter-laboratory comparisons.	April 2024	complete
5. Conduct internal quality audits to ensure the effectiveness and compliance of the quality management system.	April 2024	complete
6. Conduct a management review meeting.	April 2024	complete
7. Provide training to personnel on relevant courses, such as ISO/IEC 17025:2017 requirements, internal quality monitoring, testing methods, and various basic techniques.	May 2024	In process
8. Prepare documentation for the quality management system, including the Quality Manual, Standard Operating Procedures (SOPs), test methods, work instructions, and other supporting documents.	May 2024	In process
9. Procure equipment, reference standards, and reference materials	June 2024	In process
10. Verify/validate the effectiveness of test methods.	October 2024	In process
11. Assign critical responsibilities to testing personnel	December 2024	In process
12. Testers must participate in internal proficiency testing.	December 2024	In process
13. Process all relevant documentation to integrate it into the quality management system.	May 2025	In process
14. Apply for laboratory accreditation to the Thai Accreditation Organization.	June 2025	In process
15. Undergo an assessment by the accreditation body, following the procedures and requirements established by the accreditation body.	September 2025	In process



ASSESSMENT CHECKLIST – ISO/IEC 17025:2017

Clause No.	Element	Compliance with requirements Y	N	NA	Reference to laboratory system documents / explanation
4	**General Requirements**				
4.1	**Impartiality**	/			
4.1.1	Has the laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality?	/			
4.1.2	Does the laboratory management commit to impartiality?	/			
4.1.3	Does the laboratory responsible for the impartiality of its laboratory activities and not to allow commercial, financial or other pressures to compromise impartiality?	/			
4.1.4	Has the laboratory identify risks to its impartiality on an on-going basis?	/			
4.1.5	If a risk to impartiality is identified, does the laboratory able to demonstrate how it eliminates or minimizes such risk?	/			
4.2	**Confidentiality**	/			
4.2.1	Does the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? Is it informed the customer in advance, of the information it intends to place in the public domain? (Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential)	/			
4.2.2	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is customer or individual concerned, unless prohibited by law, notified of the information provided?	/			
4.2.3	Are information about the customer obtained from sources other than the customer (e.g. complainant, regulators) confidential between the customer and the laboratory? (The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source)	/			
4.2.4	Are personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities?	/			
5	**Structural Requirements**	/			
5.1	Is the laboratory legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities?	/			
5.2	Does the laboratory shall identify management that has overall responsibility for the laboratory?	/			
5.3	Is it defined and documented the range of laboratory activities for which it conforms with this document (The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis)	/			

Figure 3: Checklist for ISO/IEC 17025:2017 certification scope



บัญชีรายการเอกสารปัจจุบัน — สำนักตรวจสอบคุณภาพสินค้าปศุสัตว์

ลำดับที่	ปีที่จัดทำเอกสาร	เลขที่บันทึกเอกสาร	เลขที่บันทึก / ปี	ชื่อเอกสาร	ชื่อเอกสาร	ระดับเอกสาร (1,2,3,4)	ออกครั้งที่	วันที่ประกาศใช้	จำนวนสำเนา	ผู้ครอบครอง	เอกสารที่เกี่ยวเอกสาร	แก้ไขครั้งที่	หมายเหตุ/เหตุผล	วันที่แก้ไข	ผู้แก้ไข
22	2562	VPHL_FM03	80	BQCLP_VPHL_FM_WI509_28	Worksheet for Enumeration of Coliforms & Escherichia coli by ISO method	4		03/09/66	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
23	2562	VPHL_FM05	43	BQCLP_VPHL_FM_WI509_30	Worksheet for Enumeration of Coliform and E. coli by ISO 9308-2 (In Water & Ice)	4		01/05/62	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
24	2562	VPHL_FM05	42	BQCLP_VPHL_FM_WI509_32	Worksheet for Canned Food	4		01/05/62	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
25	2562	VPHL_FM05	60	BQCLP_VPHL_FM_WI509_33	Worksheet for Confirmation of Bacillus cereus	4		01/05/62	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
26	2562	VPHL_FM05	40	BQCLP_VPHL_FM_WI509_34	Worksheet for Enumeration of Enterobacteriaceae	4		01/05/62	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
27	2563	VPHL_FM03	85	BQCLP_VPHL_FM_WI509_35	Worksheet for Salmonella spp. (MALDI-TOFMS Method)	4		09/01/63	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
28	2563	VPHL_FM03	83	BQCLP_VPHL_FM_WI509_36	Worksheet for Staphylococcal aureus enterotoxin (MDMS-TET)	4		30/11/63	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
29	2564	VPHL_FM07	48	BQCLP_VPHL_FM_WI509_37	Worksheet for Porcine DNA Detection By Real time PCR (Biodiproof® Porcine Detection Lyo60)	4		1/4/64	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			
30	2565	VPHL_FM05	45	BQCLP_VPHL_FM_WI509_38	Worksheet for S. aureus (Compact Dry X-SA)	4		1/1/65	-	เจ้าหน้าที่ห้องปฏิบัติการ	ผู้จัดการ	107			

Figure 4: Document list

5) Conclusions and Next Steps

ISO/IEC 17025:2017 certification for AST has been planning, comprehensive understanding, and effective collaboration. We began by convening team meetings to thoroughly grasp the requirements outlined in the ISO/IEC 17025:2017 standard, ensuring a clear comprehension of the general testing competencies and the specific demands pertinent to AST. Subsequently, we systematically created a detailed checklist encompassing the diverse requirements for certification, spanning both management and technical

aspects. Furthermore, in coordination with supporting agencies such as the Department of Medical Sciences, we have laid a strong foundation for proficiency testing and method validation, essential components of ISO/IEC 17025:2017 compliance.

Next steps: We are committed to diligently executing our plan and leveraging our collective expertise to achieve ISO/IEC 17025:2017 certification for AST.

6) Challenges identified and lessons learned

Planning and collaboration among laboratory management, staff, and stakeholders were devoted carefully. Seeking assistance from experienced consultants, and learning from best practices could lead to ISO/IEC 17025: 2017 accreditation.