Laboratory Management System in CAMTC

Meng Zhang
China Agricultural Machinery Testing Centre

5th Training of Trainers of the Asian and Pacific Network for Testing of Agricultural Machinery

September 05-11, 2019 Beijing and Changsha, China
What kind of quality activities are involved in CAMTC?

Why should we establish the management system?

How do we achieve quality control by operating the system?
A. Brief introduction of laboratory centre of CAMTC

B. Relevant requirements

C. Quality manual & Quality procedure
I. Brief introduction of laboratory(centre) of CAMTC

China Agricultural Machinery Testing Centre (CAMTC) was founded in 1951, directly led by the Ministry of Agriculture and Rural Affairs.

Since 1978, CAMTC was accredited as Agricultural Machinery Accreditation Laboratory, Agricultural Machinery Quality Supervision, Inspection and Testing Center of the Ministry of Agriculture and Rural Affairs, National Tractor Quality Supervision and Inspection Center (Beijing), OECD Official Laboratory for Testing Rules of Agricultural and Forestry Tractor, etc. Hereinafter referred to as laboratory(centre) of CAMTC.
I. **Brief introduction of laboratory(centre) of CAMTC**

Laboratory(centre) activities of CAMTC mainly be classified as below:

- Extension and appraisal of agricultural machinery
- Sample inspection for quality supervision of authorized agricultural machinery
- Consignment inspection of agricultural machinery

- Develop instruments and equipment for testing agricultural machinery
- Compiling standards, measures, outlines for testing agricultural machinery

China Agricultural Machinery Testing Centre
A Brief introduction of laboratory(centre) of CAMTC

B Relevant requirements

C Quality manual & Quality procedure
Due to the functions of the laboratory(centre) of CAMTC, two key tasks are involved in laboratory management:

1. **Qualification recognition**
   - Compulsory
   - Nationwide

2. **Laboratory accreditation**
   - Voluntary
   - Regional

**Recognition requirements**
- Assessment of qualification recognition ability of inspection and testing institutions (General requirements of inspection and testing institutions (RB/T 214-2017))

**Accreditation requirements**
- Accreditation criteria for the competence of testing and calibration laboratories (CNAS-CL01:2018)
A Brief introduction of laboratory (centre) of CAMTC

B Relevant requirements

C Quality manual & Quality procedure
111. Quality manual & Quality procedure

Importance:

Quality manual is the programmatic document for ensuring quality control, which is also the criteria and code of appraising and testing.

Basis:


Revision:

The quality manual was first implemented on 1st, March, 1987 and have experienced 12th revisions. The last version was implemented on 1st, January, 2019.
III. Quality manual & Quality procedure

Content of the quality manual

- Chapter I-I Self-declaration ........................................................................................................4
- Chapter I-II Release order ...........................................................................................................5
- Chapter I-III Impartiality commitment ..........................................................................................6-7
- Chapter I-IV Comparison table of criteria of relevant regulations and the articles of the management system ..................................................................................................................8-12
- Chapter I-V Revision page ...........................................................................................................13
- Chapter I General introduction of CAMTC laboratory(centre) ....................................................14
- Chapter II Quality policy statement ............................................................................................15
- Chapter III Management of the quality manual .........................................................................16-17
- Chapter IV General requirements ...............................................................................................18-19
- Chapter V Structural requirements ..............................................................................................20-21
- Chapter VI Resource requirements ..............................................................................................22-31
- Chapter VII Process requirements ..............................................................................................32-46
- Chapter VIII Management system requirements .........................................................................47-55
- Chapter IX Other requirements ..................................................................................................56-58
- Appendixes (content of quality procedures, plane figure of the laboratory …….)

China Agricultural Machinery Testing Centre
Chapter I-I  Self-declaration

BASIS: Chapter five, article 37 of Administrative Measures for the qualification recognition of Inspection and Testing Institutions was promulgated on April 9, 2015 and was implemented since August 1, 2015.

Inspection and testing institutions shall publish their self-declarations of compliance with laws and regulations, independent and impartial practice, and fulfillment of social responsibility on their official websites or in other public ways, and shall be responsible for the authenticity of the declarations.
III. Quality manual & Quality procedure

Chapter I-II Issue order

Authorize the issue of the quality manual by the director of laboratory(centre) of CAMTC.

- **Revision**: demonstrates the quality manual (NZ QM-2018, 12th version) was revised based on the quality manual (NZ QM-2016, 11th version)

- **Basis**: RB/T 214-2017, CNAS-CL01:2018

- **Importance**: describes the quality manual is the programmatic document for ensuring quality control and must be the criteria and basis for appraising and testing

- **Demands** all personnel in laboratory(centre) of CAMTC to learn, realize and effectively applicate the quality manual.
Chapter I-III Impartiality commitment

Ensure the independence, objectivity, authenticity and impartiality of appraising and testing activities.
Chapter I-IV Comparison table

Lists article numbers of *RB/T 214-2017*, *CNAS-CL01:2018* respectively. Also lists article numbers of the quality manual and the name of quality procedures, which makes it intuitive to find out the quality manual meets all applicative requirements and quality procedures are made corresponding to all requirements.
During the application of the quality manual, partial modification may be required due to changes, which is not necessary to revise the whole quality manual.

Therefore, the partial modification should be recorded in this page, which includes the revised content, reviser and the effective date of the revision.
III. Quality manual & Quality procedure

Chapter I  General introduction of CAMTC laboratory (centre)

Chapter II  Quality policy statement

Quality policy:

Scientificalness, Justice, Standardization, Efficiency, Integrity

Quality objectives:

1. Correctness rate of testing results reach 100%
2. Correct reports issue rate reach 100%
3. Modification rate of issued reports less than 2%
4. Timely reports completion rate over 96%
5. Customer satisfaction rate over 95%
Chapter III  Management of the quality manual

The person in charge of quality
Organize the compiling, auditing and revising of the quality manual.

Director
Authorize the issue of the quality manual.

File administrator
Hand out, the quality manual is under control, including recycle and register process.

Appraisal department 4
Organize the revision of the quality manual.

China Agricultural Machinery Testing Centre
III. Quality manual & Quality procedure

Chapter IV  General requirements

4.1 Impartiality

*NZ QP01-2018 Impartiality guarantee procedure.*

4.2 Confidentiality

*NZ QP02-2018 Confidentiality procedure*
According to CNAS-CL01:2018, management that has overall responsibility for the laboratory (centre) of CAMTC is identified.

- Director
- Quality person in charge
- Technology person in charge

**management**

In charge of 1) communicating the importance of the effectiveness of the management system and meeting customers’ and other requirements; 2) maintaining the integrity of the management system when changes to the management system are planned and implemented.
Chapter V  Structural requirements

The range of laboratory(centre) of CAMTC activities for which it conforms with CNAS-CL01:2018 is defined and documented.

Moreover, only the range conformed with CNAS-CL01:2018 is claimed, which excludes externally provided laboratory activities on an ongoing basis. (subcontracting range is not included in the quality manual)
The laboratory(centre) shall have and control resources to guarantee the effectiveness of the appraising and testing results.
1) **Determining the competence requirements**

The competence requirements for each function influencing the appraising and testing results, including requirements for education, qualification, training, technical knowledge, skills and experience, are documented and recorded as an appendix in the quality manual.

Responsibilities and authorities of each personnel in the laboratory(centre) of CAMTC are demonstrated by the management.
2) Selection of personnel

➢ Personnel engaged in appraising and testing activities shall have college degree or above with relevant major. 10 years’ relevant experience are required if mayor or degree is not satisfied to the requirements. Additionally, key technical personnel should also have 3 years’ or above appraising and testing experiences in the current field.

➢ Personnel engaged in appraising and testing activities shall not work in more than one institution at the same time.

_NZ QP03-2018 Personnel management procedure_
Chapter VI  Resource requirements

3) Training of personnel

Targets

Plan training based on current and expected development

Organization

Evaluation

NZ QP04-2018 Personnel training management procedure

China Agricultural Machinery Testing Centre
III. Quality manual & Quality procedure

Chapter VI Resource requirements

4) Authorization of personnel

Personnel that take charge of:

• sampling
• Testing
• issuing reports
• operating complex equipments
• developing, modifying, validating and verifying methods
• stating conformity
• review and approve reports

Shall be trained and be confirmed the qualification before authorized.

Personnel engaged in appraising and testing should have the certification of agricultural machinery appraiser
Chapter VI Resource requirements

Personnel

5) Supervision of personnel

6) Monitoring of competence of personnel

NZ QP05-2018 Supervision and monitoring procedure

Comparison supervision VS monitoring

Different objects

5) New personnel, new projects

6) All personnel

Different aim

5) If the personnel is competent?

6) If the personnel is on-going competent?
Chapter VI   Resource requirements

Facilities and environmental conditions

Measures to control facilities and environmental conditions shall be implemented, monitored and periodically reviewed.

--NZ QP06-2018 Laboratory internal affairs management procedure
--NZ QP07-2018 On-site testing control procedure
--NZ QP08-2018 Accident handling procedure

Continuous control to ensure the effectiveness of the measures
Chapter VI  Resource requirements

1. The equipping rate should be greater than 98% 

2. All equipment in use should be in good condition (accuracy, uncertainty)

3. Managed by equipment administrators

- NZ QP09-2018 Equipment management procedure
- NZ QP10-2018 Equipment verification/calibration procedure
- NZ QP11-2018 Intermediate checks procedure

Valid results

China Agricultural Machinery Testing Centre
III. Quality manual & Quality procedure

Chapter VI  Resource requirements

The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, linking them to an appropriate reference. (Calibration certificate)

--NZ QP10-2018 Equipment verification/calibration procedure
--NZ QP12-2018 Reference materials traceability and management procedure
III. Quality manual & Quality procedure

Chapter VI Resource requirements

- CNAS-CL01:2018 combined the requirements from previous subcontracting and purchasing services and supplies.
- RB/T 214-2017 still has the requirements about subcontracting.

-- NZ QP13-2018 Purchasing services and supplies procedure
-- NZ QP14-2018 Subcontracting management procedure

1. Program shall not be subcontracted when is prohibited by laws, regulations or relevant technical standards. (e.g., State supervision and spot checks of agricultural machinery)

2. Suppliers shall be continuous evaluated and monitored so as to ensure only the suitable externally provided products and services are used.

China Agricultural Machinery Testing Centre
Chapter VII Process requirements

7.1 Review of requests, tenders and contracts

If contract review results are different from customers’ requirements, each contract shall be agreed by both the laboratory(centre) and customers before signing the contract.

Any deviations from contracts must be informed to customers timely during appraising and testing.

Review is required again if contracts are required to be modified. The modified content should be noticed to all influenced personnel.

NZ QP15-2018 Contract review procedure
III. Quality manual & Quality procedure

Chapter VII  Process requirements

7.1 Review of requests, tenders and contracts

Contract of regular appraising and testing

Within the accredited or authorized range. Mainly review the engaged personnel, equipment and deadline, etc. Only review one time before signing the first contract is required if the contract is repetitive and customers’ requirements are not changed.

Contract of special appraising and testing

Comprehensive review is required, which includes but not limited to customers’ requirements, appraising and testing methods, equipment and personnel competence.

Customers shall be informed the testing is beyond the accredited or authorized range before signing the contract. Moreover, the data and results can only be used internally, which is required to be specified in the contract.

China Agricultural Machinery Testing Centre
III. Quality manual & Quality procedure

Chapter VII  Process requirements

7.2 Selection, verification and validation of methods

NZ QP16-2018 Appraising and testing methods control procedure

Ensure using suitable methods and procedures.

• On-going verification should be operated to ensure the correctness of using the standard methods

• Non-standard methods, self-making methods or standard methods used beyond the range should be validated so as to meet the expected requirements.
7.3 Sampling
Samples shall be sampled according to:

*NZ QP17-2018 Sampling control procedure*

Sampling plans and methods shall be conveniently obtained at the sampling sites.

7.4 Handling of samples

*NZ QP18-2018 Sample management procedure*

Demonstrates the requirements of transporting, receiving, handling, storing, keeping, discarding or returning samples so as to protect the integrity of samples and meet all requirements of laboratory(centre) and customers.
7.5 Technical records

Sufficiency: Personnel, samples, equipment, methods, facilities and environmental conditions.

Originity: Original observations, data and calculations should be recorded at the time they are made.

Norm: Original and modified technical records should be conserved, including modified data, content and the person responsible for modifying.

- Identify factors affecting the measurement result and its associated measurement uncertainty
- Enable the repetition of the appraising and testing under conditions as close as possible to the original.
7.6 Evaluation of measurement uncertainty

• Measurement uncertainty, including those arising from sampling, can be evaluated according to NZ QP19-2018 Measurement uncertainty evaluation procedure.

7.7 Ensuring the validity of results

• Review and approve annual plan to monitor the results in reports according to NZ QP20-2018 Testing results validity monitoring procedure.
• Proficiency testing and interlaboratory comparisons. -- NZ QP21-2018 Proficiency testing procedure
7.8 Reporting of results

- Report calibrator
- Report reviewer
- Signed by directors of appraising division
- Authorized signatory by the director
- Technical examination
- Formal examination
- Issue

NZ QP22-2018 Report control procedure

China Agricultural Machinery Testing Centre
III. Quality manual & Quality procedure

Chapter VII  Process requirements

7.8 Reporting of results

Different report formats are made and authorized, which are suitable to corresponding laboratory activities (appraising, testing).

NZ QP23-2018 Special seals management procedure

China Agricultural Machinery Testing Centre
7.9 Complaints
Complaints shall be handled according to NZ QP24-2018 Complaints handling procedure to maximize customer satisfaction and provide evidence of on-going improvement of the management system.

A special post is established to handle complain.

① Validating information
② Judge whether the complain is relevant to the appraising or testing

Individual(s) involved in the complaints should take avoidance measures to guarantee the impartiality.
7.10 Nonconforming work

Nonconforming work shall be concerned during every processes according to NZ QP26-2018 Nonconforming appraising and testing procedure.

Evaluate the significance (including an impact analysis on previous results) and make a decision on the acceptability of the nonconforming work.

If unacceptable, correction and corrective actions based upon the risk levels established by the laboratory(centre) are required.
III. Quality manual & Quality procedure

Chapter VII  Process requirements

7.11 Control of data and information management

The information management system shall be validated for functionality. Whenever there are any changes, they shall be authorized, documented and validated before implementation.

The system is protected from unauthorized access and is safeguarded against tampering and loss. The system instruction is made readily available to personnel.

NZ QP27-2018 data control procedure is complied to ensure the integrity, correctness and confidentiality of data.
Chapter VIII  Management system requirements

8.1 Options
The laboratory(centre) take option A to establish the management system.

8.2 Management system documentation
The management system shall be documented. All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents
Documents related to the management system shall be controlled according to NZ QP28-2018 Document control procedure. (e.g., documents are periodically reviewed and updated as necessary; documents are uniquely identified)
Chapter VIII  Management system requirements

8.4 Control of records
The laboratory(centre) shall implement the controls according to NZ QP29-2018 Records control procedure.

Access to these records shall be consistent with NZ QP02-2018 Confidentiality procedure.

Retention time of all records shall be 6 years unless longer retention time is required by laws or regulations.

8.5 Actions to address risks and opportunities
All personnel shall pay attention to risks and opportunities based on analyzing data and information.

Actions shall be taken according to NZ QP30-2018 Risk and opportunities addressing action procedure.
Chapter VIII  Management system requirements

8.6 Improvement

Improvement actions shall be taken according to NZ QP31-2018 Improvement management procedure.

The laboratory(centre) shall seek feedback from its customers, which shall be analyzed and used to improve the management system according to NZ QP32-2018 Customer service procedure.

8.7 Corrective action

Analyze causes of the nonconformity, take actions, review, update risks and opportunities, make changes to the management system

NZ QP33-2018 Correction action procedure

To eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere

China Agricultural Machinery Testing Centre
III. Quality manual& Quality procedure

Chapter VIII Management system requirements

8.8 Internal audits

Anually

Make internal audit programme (frequency, methods, responsibilities, planning requirements and reporting) and define the audit criteria and scope for each audit

Implement appropriate correction and corrective actions

NZ QP34-2018 Internal audits procedure.

All document and records involved in internal audits shall be the input of management review

Report the audit results to relevant management

Review the effectiveness of the actions

China Agricultural Machinery Testing Centre
8.9 Management reviews

Management reviews shall be conducted **annually** to ensure the continuing suitability, adequacy and effectiveness of the management system, according to *NZ QP35-2018 Management reviews procedure.*
111. Quality manual & Quality procedure

Chapter IX Other requirements

Annual report
• Annual summary for CNAS and Department of Safety Supervision Ministry of Agriculture and Rural Areas respectively.
• Self-declaration

NZ QP36-2018 Annual report procedure

Change
• Changes about the management, range, methods, name and address of the laboratory(centre) should be reported and authorized by corresponding institutions.

Special requirements
• Compulsory certification - NZ QP37-2018 Compulsory certification procedure
• Appraising - NZ QP38-2018 Appraising procedure
• National supervision and spot checks - NZ QP43-2018 National supervision and spot checks procedure

China Agricultural Machinery Testing Centre
III. Quality manual & Quality procedure

Brief summary

◆ A quality manual + 43 quality procedures

◆ Make the laboratory management system to be on-going finalized, which also meets all applicable requirements of CNAS-CL01:2018(ISO/IEC 17025-2017) and RB/T 214-2017

◆ All aspects involved in the laboratory activities are managed to ensure quality control and achieve the quality policy and objectives.
Thanks