Laboratory Management System in CAMTC

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WHAT
WHY
HOW
What kind of quality activities are involved in CAMTC system
Why do we establish quality management system
How to operate the system

CONTENTS

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

CONTENTS

II. Relevant requirements

Due to the functions of the laboratory(centre) of CAMTC, two key tasks are involved in laboratory management:

Qualification recognition

Compulsory

Nationwide

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

Recognition requirements

Laboratory accreditation

Voluntary

Regional

Accreditation criteria for the competence of testing and calibration laboratories (CNAS-CL01:2018)

Accreditation requirements

CONTENTS

III. 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:

CNAS-CL01:2018 （ISO/IEC 17025:2017）, RB/T 214-2017, etc.

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

The same as the structure of CNAS-CL01:2018

III. Quality manual& Quality procedure

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.

农业农村部农业机械试验鉴定总站实验室、国家拖拉机质量监督检验中心（北京）、农业农村部农业机械质量监督检验测试中心质量手册

2018年第12版 第4页 共58页

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农业农村部农业机械试验鉴定总站
国家拖拉机质量监督检验中心（北京）
农业农村部农业机械质量监督检验测试中心

实验室（中心）主任：

2018年12月3日

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.

III. Quality manual& Quality procedure

Chapter I-III Impartiality commitment

Laboratory (centre)

CAMTC

Superior authority

Ensure the independence, objectivity, authenticity and impartiality of appraising and testing activities.

III. Quality manual& Quality procedure

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 .

农业农村部农业机械试验鉴定总站实验室、国家拖拉机质量监督检验中心（北京）、农业农村部农业机械质量监督检验测试中心质量手册

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实验室认可准则条款		资质认定评审准则条款	实验室质量手册条款	程序文件
	6.3.5	4.3.2	6.3.2.1、6.3.2.3	
6.4 设备	6.4.1	4.4.1	6.4.2.1	设备管理程序
	6.4.2	4.4.2	6.4.2.2	
	6.4.3	4.4.3	6.4.2.3	
	6.4.4	4.4.3	6.4.2.4	
	6.4.5	4.4.3	6.4.2.5	
	6.4.6	4.4.3	6.4.2.6	
	6.4.7	4.4.3	6.4.2.7	
	6.4.8	4.4.3	6.4.2.8	
	6.4.9	4.4.5	6.4.2.9	
	6.4.10	4.4.3	6.4.2.10	期间核查程序
	6.4.11	4.4.3	6.4.2.11	
	6.4.12	4.4.3	6.4.2.12	
	6.4.13	4.4.4	6.4.2.13	
6.5 计量溯源性	6.5.1	4.4.3	6.5.2.1	测量设备的检定/校准程序
	6.5.2	4.4.3	6.5.2.3	
	6.5.3	4.4.6	6.5.2.4～6.5.2.6	
6.6 外部提供的产品和服务	6.6.1	4.5.6	6.6.2.1	服务与供应品的采购程序
	6.6.2	4.5.5	6.6.2.3～6.6.2.16	
	6.6.3		6.6.2.2	
7 过程要求				
7.1 要求、标书和合同评审	7.1.1	4.5.4	7.1.2.1、7.1.2.2	合同评审程序
	7.1.2	4.5.4	7.1.2.2	
	7.1.3	4.5.4	7.1.2.3	
	7.1.4	4.5.4	7.1.2.8	
	7.1.5	4.5.4	7.1.2.9	
	7.1.6	4.5.4	7.1.2.9	
	7.1.7	4.5.4	7.1.2.10	
	7.1.8	4.5.4	7.1.2.11	
7.2 方法的选择、验证和确认	7.2.1			鉴定检测方法控制程序
	7.2.1.1	4.5.14	7.2.2.1	
	7.2.1.2	4.5.14	7.2.2.2	
	7.2.1.3	4.5.14	7.2.2.3	

III. Quality manual& Quality procedure

Chapter I-V Revision page

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%

III. Quality manual& Quality procedure

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.

Appraisal department 4

File administrator

Organize the revision of the quality manual.

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

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

III. Quality manual& Quality procedure

Chapter V Structural requirements

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

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

III. Quality manual& Quality procedure

Chapter V Structural requirements

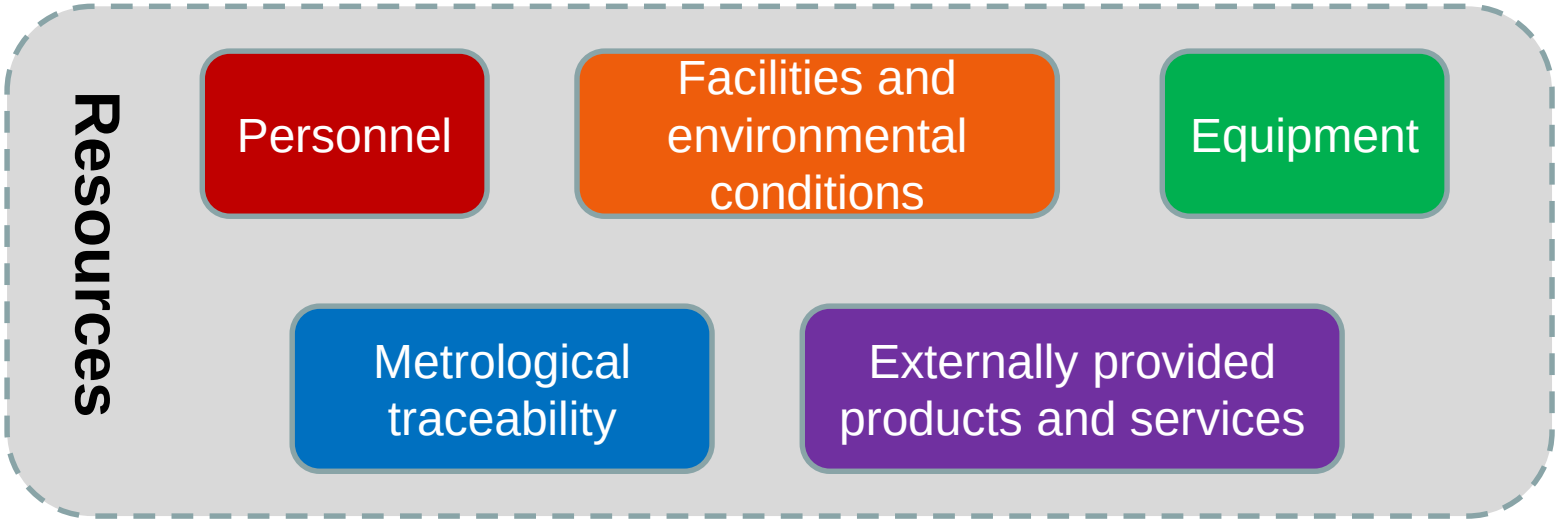
The **range** of laboratory(centre) of CAMTC activities for which it conforms with CNAS-CL01:2018 is defined and documented.

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)

III. Quality manual& Quality procedure

Chapter VI Resource requirements

The laboratory(centre) shall have and control resources to guarantee the effectiveness of the appraising and testing results.



III. Quality manual& Quality procedure

Chapter VI Resource requirements

Personnel

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.

III. Quality manual& Quality procedure

Chapter VI Resource requirements

Personnel

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

III. Quality manual& Quality procedure

Chapter VI Resource requirements

Personnel

3) Training of personnel

NZ QP04-2018 Personnel training management procedure

III. Quality manual& Quality procedure

Chapter VI Resource requirements

Personnel

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

III. Quality manual& Quality procedure

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 ?

III. Quality manual& Quality procedure

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

III. Quality manual& Quality procedure

Chapter VI Resource requirements

Equipment

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

III. Quality manual& Quality procedure

Chapter VI Resource requirements

Metrological traceability

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

Externally provided products and services

•*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.

III. Quality manual& Quality procedure

Chapter VII Process requirements

7.1 Review of requests, tenders and contracts

Before

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.

In the process

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

After

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

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.

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**

Verification

Validation

- **Non-standard methods, self-making methods or standard methods used beyond the range** should be validated so as to meet the expected requirements.

III. Quality manual& Quality procedure

Chapter VII Process 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

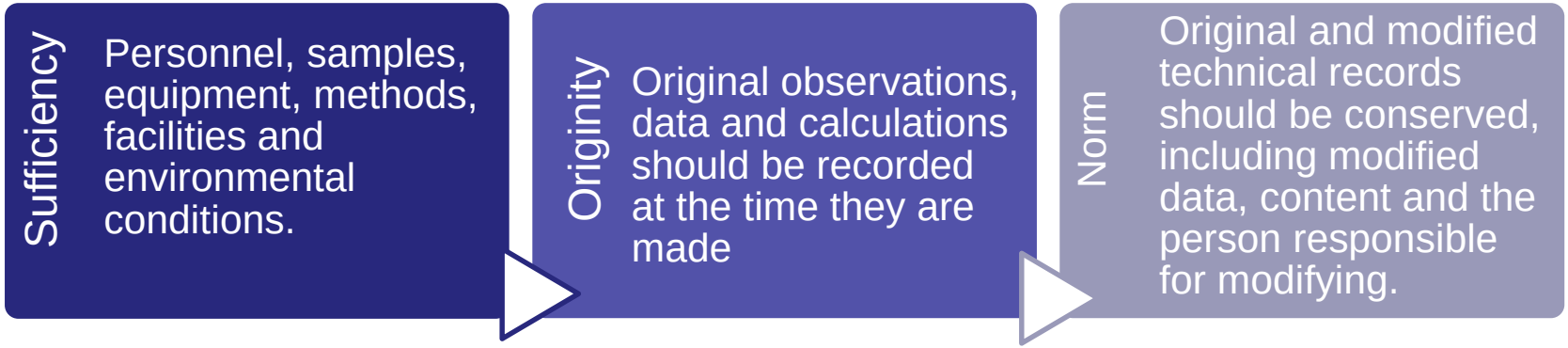
NZ QP18-2018 Sample management procedure

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.

III. Quality manual& Quality procedure

Chapter VII Process requirements

7.5 Technical records



- 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.

III. Quality manual& Quality procedure

Chapter VII Process requirements

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*.

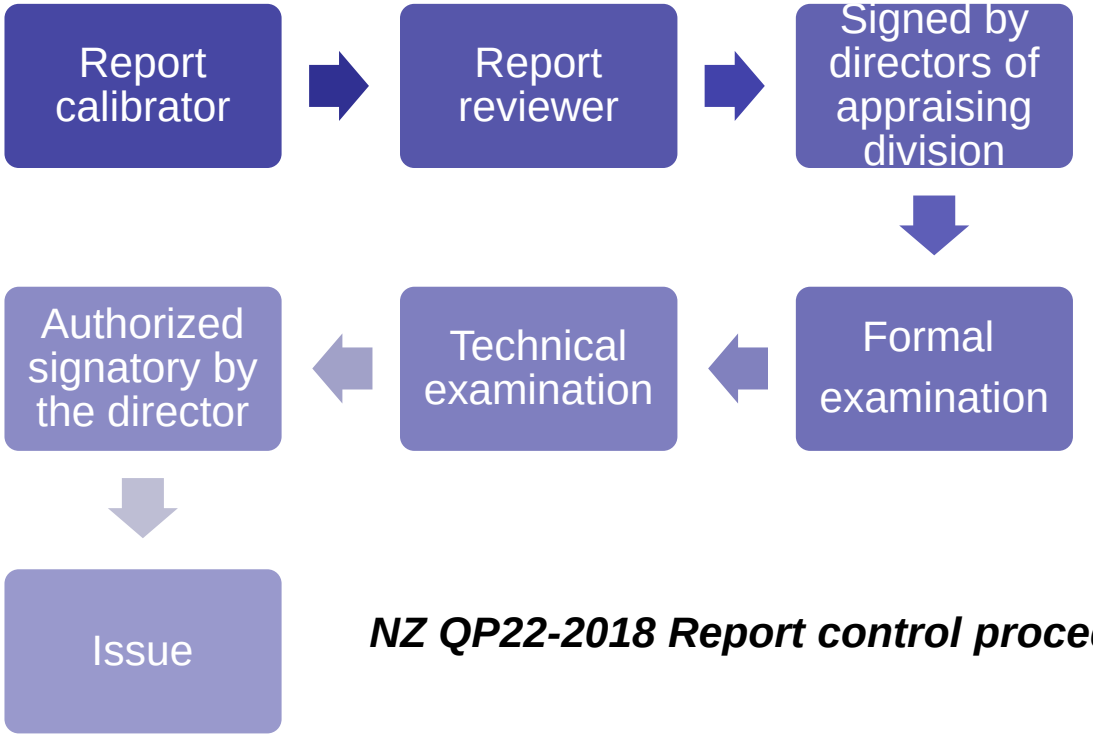
7.7 Ensuring the validity of results

- 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*

III. Quality manual& Quality procedure

Chapter VII Process requirements

7.8 Reporting of results



NZ QP22-2018 Report control procedure

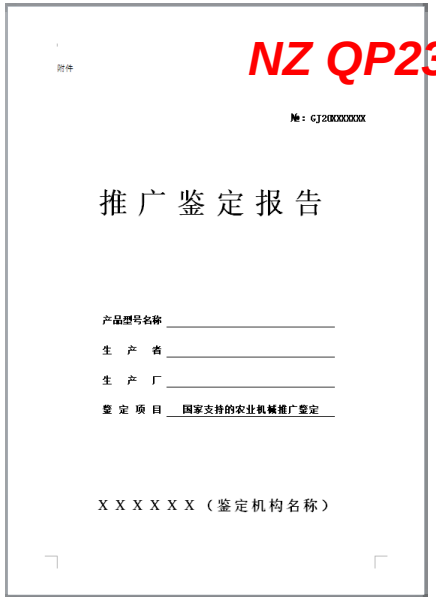
III. Quality manual& Quality procedure

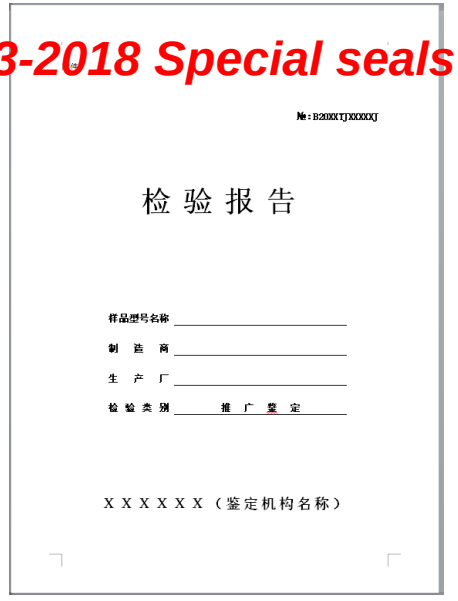
Chapter VII Process requirements

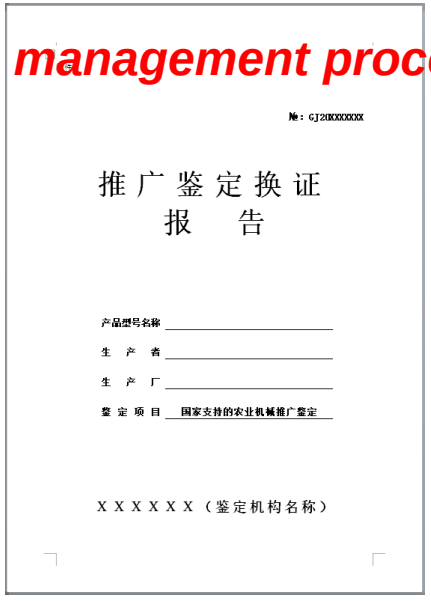
7.8 Reporting of results

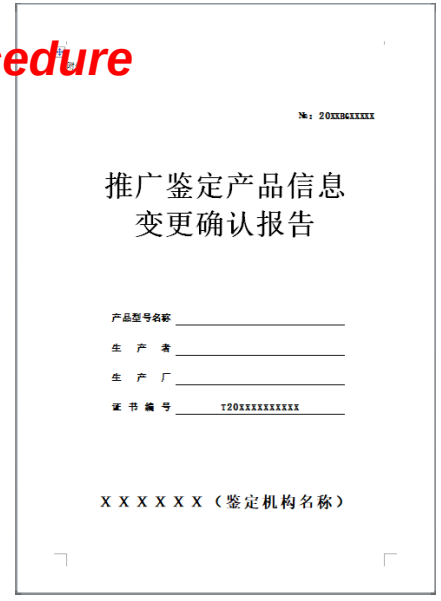
Different report formats are made and authorized, which are suitable to corresponding laboratory activities (appraising, testing).

NZ QP23-2018 Special seals management procedure









III. Quality manual& Quality procedure

Chapter VII Process requirements

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 complains.

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.

III. Quality manual& Quality procedure

Chapter VII Process requirements

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)

Make a decision on the acceptability of the nonconforming work.

unacceptable

Correction and corrective actions

based upon the risk levels established by the laboratory(centre)

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**.

III. Quality manual& Quality procedure

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)

III. Quality manual& Quality procedure

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.***

III. Quality manual& Quality 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

III. Quality manual& Quality procedure

Chapter VIII Management system requirements

8.8 Internal audits

Annually

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

Review the effectiveness of the actions

Report the audit results to relevant management

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

NZ QP34-2018 Internal audits procedure.

III. Quality manual& Quality procedure

Chapter VIII Management system requirements

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.*

III. 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*

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.

CAMTC

Thanks