

Unofficial translation

**MINISTRY OF AGRICULTURE
AND RURAL DEVELOPMENT**

**SOCIALIST REPUBLIC OF VIET NAM
Independence - Freedom – Happiness**

No. 16/2011/TT-BNNPTNT

Hanoi, 01 April 2011

CIRCULAR

**Laboratory audit, designation and management in agriculture and rural
development**

Pursuant to the Decree No. 01/2008/ND-CP of 3 January 2008 defining the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development; Decree No. 75/2009/ND-CP of 10 September 2009 amending Article 3 of the Decree No. 01/2008/ND-CP of 3 January 2008;

Pursuant to the Law No. 68/2006/QH11 of June 29, 2006 on Standards and Technical regulations;

Pursuant to the Decree No. 127/2007/ND-CP of August 1, 2007 of the Government detailing a number of articles of the Law on Standards and Technical regulations;

Pursuant to the Law No. 05/2007/QH12 of 21 November 2007 on Product and Goods Quality.

Pursuant to the Decree No. 132/2008/ND-CP of December 31, 2008 of the Government detailing a number of articles of the Law on Product and Goods Quality;

Pursuant to the Ordinance No. 12/2003/PL-UBTVQH of July 26, 2003 by Vietnamese Standing Committee of National Assembly on Food Hygiene and Safety.

Pursuant to the Decree No. 163/2004/ND-CP of September 7, 2004 detailing some provisions of the Ordinance on Food Hygiene and Safety.

Hereafter is the guide by the Ministry of Agriculture and Rural Development on requirements, procedure for laboratory audit, designation and management in agriculture and rural development.

Chapter I

GENERAL PROVISIONS

Article 1. Scope and objects of application

1. Scope of application: This Circular lays down procedure for laboratory audit, designation and management in areas under jurisdiction of the Ministry of Agriculture and Rural Development.

2. Objects of application: This Circular applies to laboratories, competent authorities related to laboratory audit, designation in agriculture and rural development.

Article 2. Definition

For the purpose of this Circular, the following definitions shall apply:

1. *Laboratory* means a technical facility which performs determination of properties or characteristics of a product, goods, material, equipment, organism, physical phenomenon, process or service in accordance with established procedures.

2. *Inter-laboratory comparisons* mean assess quality of testing results performed by 02 or many laboratories by comparing testing results in the homogenized samples with mean value of measurement results of participating laboratories.

3. *Laboratory audit* means examination and assessment of conformity of quality management system and testing capability for each quality criteria in comparison with specific requirements or standards.

4. *Audit and designation body* means Competent Authority performing laboratory audit and designation.

Article 3. Audit and designation bodies

1. Directorate of Forestry is the audit and designation body for laboratories of plant varieties used in forestry, wood, wooden products and other forestry products;

2. Directorate of Irrigation and Water Management is the audit and designation body for laboratories of irrigational works, water management and dikes;

3. Directorate of Fisheries is the audit and designation body for laboratories of fishery breed; feed and raw materials thereof, additives, bio-products and water used in aquaculture;

4. Department of Crop Production is the audit and designation body for laboratories of plant varieties, soil, fertilizer and raw materials thereof, bio-products used in crop production;

5. Department of Livestock Husbandry is the audit and designation body for laboratories of livestock breed, feed and raw materials thereof, preservatives used in feed, bio-products used in livestock husbandry;

6. Department of Plant Protection is the audit and designation body for laboratories of plant quarantine, pesticides, pesticide residues in agricultural and forestry products;

7. Department of Animal Health is the audit and designation body for laboratories of animal diseases, veterinary drugs and raw materials thereof;

8. National Agro-Forestry-Fisheries Quality Assurance Department is the audit and designation body for laboratories of food and non-food quality of agricultural, forestry and fishery products;

9. Department of Processing and Trade for Agro-forestry-Fisheries Products and Salt Production is the audit and designation body for laboratories of salt and salt products, agricultural machines and equipments;

10. Science, Technology and Environment Department is the audit and designation body for interdisciplinary laboratories.

Article 4. Common principles

1. Laboratory audit and designation shall be performed by Competent Authorities laid down in Article 3, considering laboratory competency meets requirements laid down in respective technical regulation and other related requirements.

2. Analyzing methods designated by Competent Authorities laid down in Article 3 shall be performed in inspection and audit of product and goods quality.

Article 5. Legal bases for audit

1. TCVN ISO/IEC 17025:2007 General requirements for the competence of testing and calibration laboratories or equivalent standards.

2. Regulations on relevant technical requirements and analyzing methods.

Article 6. Modes of audit

1. Initial audit shall be applied to:

a. Laboratories which apply at the first time for audit and designation in accordance with this Circular;

b. Laboratories which had been designated but the designation decisions have been terminated in compliance with Article 19, item 2.

2. Renewal shall be applied to:

a. Laboratories undergoing initial audit but incompetent to be designated;

b. Laboratories which have been designated but designation decisions are no longer in force;

c. Laboratories which have been audited and designated but designation decisions are suspended in compliance with Article 19, item 1;

3. Extension audit shall be applied to laboratories which have been designated and additionally apply for audit of new parameters or fields.

Article 7. Modes of designation

Based on audit report and assessment report of audit report,

1. Designation bodies laid down in Article 3, Items 1 to 9 issue laboratory designation decisions and make report to the Ministry (via Science, Technology and Environment Department).

2. Designation body laid down in Article 3, Item 10 shall submit to Minister designation decisions of interdisciplinary laboratories for approval.

Article 8. Laboratory identification number

1. Ministry of Agriculture and Rural Development shall consistently issue and manage identification numbers for designated laboratories.
2. The identification numbers are laid down in the designation decisions.
3. The identification numbers shall be displayed in the seals in compliance with requirements laid down in Appendix 5.

Article 9. Audit fee

1. Audit body is allowed to collect fees for the following cases:
 - a. Initial audit;
 - b. Renewal audit;
 - c. Extension audit;
2. Audit fees shall be managed and used in compliance with regulations in force.

Chapter II

AUDIT AND DESIGNATION

Article 10. Application dossier

1. Initial audit
 - a. Application (Appendix 1. Form BNN-01);
 - b. Laboratory competency report (Appendix 2. Form BNN-02);
 - c. Copy of Certificate of Accreditation to ISO/IEC 17025:2007 or equivalent document; certified true copy required in case dossiers submitted by post.
 - d. Proficiency testing reports relating to parameters applied for designation;
 - e. Copy of laboratory service registration certificate.
2. Renewal audit
 - a. Application (Appendix 1. Form BNN-01);
 - b. Reports on corrective actions (if any);
 - c. Report on laboratory services since the designation decision.
3. Extension audit

Application dossiers include those as laid down in Article 1, Points 1.a and 1.d.

Article 11. Acknowledgement of application

1. Application dossiers as laid down in Article 10 shall be submitted to the audit and designation bodies as laid down in Article 3 in person or via postal.
2. Within five (05) working days since receipt of application dossiers, audit and designation body shall assess the document's adequacy, accuracy and require the applicant to complete the application.

Article 12. Setting up audit team

1. Within ten (10) working days since receipt of completed application, the audit and designation body shall issue the decision setting up the audit team, and inform laboratory of audit plan.

2. Decision setting up the audit team shall specify audit scope, audit content, members of audit team and responsibilities of each member. Members of the audit team shall include 5 – 7 members who have professional knowledge and experience on the field and representative from relevant competent authority.

Article 13. Audit content

1. Compliance and conformity of the laboratory quality management system with the regulation in force.

2. Compliance of analyzing methods for quality criteria applied for designation with provisional regulation on requirements for laboratory competence and requirements of relevant competent authorities.

3. In case that the laboratory has been accredited to ISO/IEC 17025:2007 or equivalent standards granted by accreditation bodies, audit content will be considered to decrease in the accredited fields and analyzing methods.

Article 14. Audit methods

During the audit, audit team shall apply all of the following methods:

1. Interviewing manager and staff of the laboratory;
2. Document check;
3. On-site inspection to premise layout, environment and facilities' conditions, other test facilities and test performance;
4. Assessment of inter-laboratory comparisons result and corrective action report (if any).

Article 15. Audit report

1. Non-conformities observed during the audit shall be mentioned in the audit checklist (Appendix 3. Form BNN-03).

2. Audit report shall be announced at closing meeting. Audit report must include audit content and be signed by laboratory representative and leader of audit team.

3. In the case that laboratory representative does not accept the audit report, any complaints shall be written at the end of the report with signature and seal. Audit report is still authentic without signature of laboratory representative.

Article 16. Submit audit report

Within five (05) working days since the audit, leader of audit team must submit to the audit and designation body the audit report (Appendix 4. Form BNN-04) and audit profile.

Article 17. Processing audit report

Within ten (10) working days since receipt of audit report, audit and designation body conducts verification of audit report and takes appropriate measures:

1. Towards applicant meeting requirements laid down in Article 5, within five (05) working days, audit and designation body laid down in Article 3, Items 1 to 9 submit audit report to the Ministry (via Science, Technology and Environment Department) for approval of a laboratory identification number. Within five (05) working days, Science, Technology and Environment Department shall grant identification number by written. On receipt of the identification number, audit and designation body laid down in Article 3, Items 1 to 9 shall issue decision of designation and make report to the Ministry (via Science, Technology and Environment Department); audit and designation body laid down in Article 3, Item 10 shall submit the decision of designation to the Ministry for approval.

2. Towards applicant not meeting requirements laid down in Article 5, audit and designation body shall inform in written non-conformities and time frame for corrective actions. Following report of corrective actions by the applicant, audit and designation body shall review the report, verify corrective actions if need be. If non-conformities have been corrected, within (05) working days, audit report shall be submitted to the Ministry (via Science, Technology and Environment Department) for approval of laboratory identification number. On receipt of the identification number, audit and designation body laid down in Article 3, Items 1 to 9 shall issue decision of designation and make report to the Ministry (via Science, Technology and Environment Department); audit and designation body laid down in Article 3, Item 10 shall submit the decision of designation to the Ministry for approval.

3. If non-conformities have not been corrected, audit and designation body shall suspend the audit till the applicant completes corrective actions and requests for designation again.

Article 18. Validity of designation status

1. Validation of designation status is three (3) years.

2. 3 months prior to the expiry of designation status, laboratory must submit application for renewal audit to audit and designation body laid down in Article 3 if they wish to be designated again.

Article 19. Suspension or withdrawal of designation status

1. Suspension of designation status:

Based on non-conformities found in surveillance audit or unexpected audit and specified in verification report, considering the request by Head of audit team, within fifteen (15) days, audit and designation body shall decide total or partial suspension of designation scope.

2. Withdrawal of designation status applies to the following cases:

a. Laboratory found with any non-conformities against requirements laid down in Article 13 or non-conformities beyond laboratory's competence of corrective actions or six (6)-month overdue non-conformities;

b. Laboratory's bankruptcy or no longer operation in designation scope.

c. Based on non-conformities found in surveillance audit or unexpected audit and specified in verification report, considering the request by Head of audit team, or according to designated laboratory's report on their bankruptcy or no longer operation in designation scope, within fifteen (15) days, audit and designation body shall decide withdrawal of designation status.

3. Audit and designation body shall inform relevant competent authorities, agencies and food business operators about the suspension or withdrawal of designation status right after the decision.

Chapter III

LABORATORY MANAGEMENT

Article 20.

Science, Technology and Environment Department is the contact point for laboratory audit and designation management in agriculture and rural development nation-wide.

Article 21.

Audit and designation bodies laid down in Article 3 shall conduct surveillance audit once a year and unexpected audit on request.

Chapter III

RIGHTS AND RESPONSIBILITIES

Article 22. Audit and designation body

1. To issue laboratory designation decisions, suspension or withdrawal.

2. Science, Technology and Environment Department shall annually promulgate list of designated laboratories and designated analyzing methods thereof in the website.

3. To receive and deal with complaints by laboratories in accordance with regulations in force.

Article 23. Members of audit team

1. To assess compliance of laboratory to the legal basis laid down Article 5.

2. To assure objectiveness of the audit.

3. To report to Leader of the audit body for measures against cases beyond audit team's jurisdiction.

4. To keep secret all information of audited laboratory in compliance with regulations in force.

5. To be authorized to interview, take notes, request for documents, data, performance and proofs relating to the audit.

Article 24. Designated laboratories

1. To assure reliability and accuracy of testing results regarding to designated criteria.

2. To be authorized to perform analysis of criteria within designation scope.

3. To print analyzing methods in analysis reports.

4. To complain to audit and designation body about audit results.

5. To be given instructions for participation in proficiency tests and inter-laboratory comparisons.

6. To be subject to laboratory inspections and surveillance by internal and external inspection delegations by request of competent authorities.

7. To create good conditions for audit team during the audit.

8. To make annual (before 31 December) or unexpected reports to audit and designation bodies laid down in Article 3 about their testing activities within designation scope according to requirement of competent authorities.

9. To pay audit and designation fee.

Chapter V

EXECUTIVE PROVISIONS

Article 25. Entry into force

1. This Circular shall come into force in 45 (forty five) days after date of signature.

2. This Circular shall annul Decision 139/1999-QD-KHCN of 11 October 1999 laying down Regulation on approval and management of agricultural laboratories; Decision 116/2008/QD-BNN of 3 December 2008 laying down Regulation on audit and designation of laboratories for agricultural, forestry, fishery products; Articles 4 & 7; Article 11, Point 1; Article 12, Point 1, Article 13, Points 1 & 2, Article 16 and definition “Laboratory” in Article 19, Point 1, Article 14, Point 1 and Article 15, Points 1 & 2 of the Circular 32/2010/TT-BNNPTNT laying down regulation on designation and management of sample collectors, auditors, laboratories, certification body for quality of varieties, plant products and fertilizers; Decision 187/QD-CN-TACN of 31 October 2008 of Director General of the Department of Livestock Husbandry laying down Regulation on audit and designation of feed laboratories; Circular 08/2011/TT-

BNNPTNT of 14 February 2011 laying down procedures for audit and accreditation of fishery diagnosis and analysis laboratories.

3. All difficulties in implementation of this Circular should be submitted to the Ministry of Agriculture and Rural Development for consideration and appropriate amendment.

MINISTER

(signed)

Cao Duc Phat

Appendix 1 FORM BNN-01

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Place....., date

**APPLICATION FOR LABORATORY DESIGNATION
OF AGRICULTURE AND RURAL DEVELOPMENT**

ATTN: (Audit and designation body)

1. Name of laboratory supervisor:

Address:

Telephone:

Fax:

2. Name of laboratory:

Address:

Telephone:

Fax:

3. Expected mode of audit:

Initial audit Renewal audit Expansion audit

4. Designation scope (laid down in Article 3 of the Circular):

5. Analyzing method applied for designation:

a. List of criteria applied for designation:

(Note () for criteria and analyzing method accredited with ISO/IEC 17025)*

No.	Criteria / Type of product	Analyzing method / Technique	Reference method	Limit of Quantification (LoQ)	Limit of Detection (LoD)
I	Field 1				
1	Analyzing method 1				
2	Analyzing method 2				
II	Field 2				

b. List of analysts performing analysis of criteria applied for designation:

No.	Name of analyst	Qualification	Position	Criteria to be performed
-----	-----------------	---------------	----------	--------------------------

--	--	--	--	--

6. We commit to comply with the Circular on laboratory audit, designation and management in agriculture and rural development by the Ministry of Agriculture and Rural Development.

7. The laboratory will be available for audit on (date)

Representative of laboratory
(Name and signature)

Laboratory supervisor
(Signature and stamp)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Place....., date

REPORT ON LABORATORY CAPABILITY

1. Name of laboratory supervisor:

Address:

Telephone:

Fax:

2. Name of laboratory:

Address:

Telephone:

Fax:

3. Name and title of laboratory manager:

4. List of analysts:

No.	Name of analyst	Year of birth	Qualification	Current duties	Working duration in analysis	Note

5. Equipments

5.1. Main equipments

No.	Name of equipment	Use purpose	Frequency of audit/validation	Date of the latest audit/validation	Auditing/validating body	Note

5.2. Other equipment

Name of equipment	Technical specifications	Date of operation	Use purpose	Note

6. Laboratory space and environment.

6.1. Laboratory layout and surface (m²) of each laboratory

6.2. Working environment

- Laboratory layout, cross-contamination possibility;
- Temperature, humidity recording;
- Ventilation system (for release of heat and toxic gas);
- Other conditions (anti-vibration, prevention of dust, anti-noise, light, radioactivity...)

6.3. Conditions of labour safety

7. List of performed analysis

No.	Criteria	Analyzing method	Limit of detection	Total analysis / year	Type of sample	Accreditation body
1	2	3	4	5	6	7

Representative of laboratory
(Name and signature)

Laboratory supervisor
(Signature and stamp)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

LABORATORY AUDIT CHECKLIST

1. Laboratory correspondance:

2. Audit team:

3. Observed non-conformities:
 - Laboratory staff:
 - Equipments:
 - Laboratory layout and surface:
 - Working environment and labour safety:
 - Result of inter-laboratory comparisons:
 - Others:

4. Laboratory's feedback:

5. Conclusion by audit team:

6. Recommendations by audit team

The report is made in 2 copies being equally authentic: 01 for each.

Representative of laboratory
(Signature and stamp)

Head of the audit team
(Name and signature)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Place....., date.....

AUDIT REPORT

ATTN: *(Audit and designation body)*.....

Based on audit checklist made on (date)

1. Laboratory correspondance:

2. Recommendations

2.1. General

2.2. Audit and designation body should designate the above laboratory for the following analyzing methods:

No.	Name of analysis	Analyzing method	Type of sample	Limit of detection (LoD)	Note

Head of audit team

(Nam and signature)

DESIGNATED LABORATORY'S SEAL

1. Seal:

Seal of the designated laboratories of the Ministry of Agriculture and Rural Development shall comply with the following requirements (template in Item 3):

- In 3,0cm side square form;
- Divided into 2 parts by a horizontal line in the upper two-thirds of the square;
- Printed "LAS – NN" in the upper and "identification number" in the lower;
- Purple-inked.

2. Use of the seal:

2.1. Seal shall be stamped in analysis report perform by the designated laboratory itself;

2.2. Only analysis reports of designated analyzing methods shall be sealed;

2.3. Head of the laboratory shall be responsible for management and use of the seal.

2.4. Loss of the seal shall be reported immediately to the laboratory supervisor, who shall then report the case to the Ministry.

2.5. Any unintentional or intentional violation by designated laboratory to the regulation on use of the seal shall be punished from criticism, warning, pecuniary penalty...to prosecution according to seriousness and consequence.

3. Seal template:

LAS-NN
<Identification number>