

(Unofficial)

Announcement of the Food and Drug Administration
Re: Criteria and Conditions about Qualifications and Experiences of Auditors
for Food Production Premises under Regulated Criteria

It is appropriate to revise Announcement of the Food and Drug Administration Re: Criteria and Conditions about Qualifications and Experiences of Auditors for Food Production Premises under Regulated Criteria for effective and consistent operation of food production premises auditing. The Food and Drug Administration has issued the announcement as follows:

Clause 1 Announcement of the Food and Drug Administration, Re: Criteria and Conditions about Qualifications and Experiences of Inspectors for Food Production Premises under Regulated Criteria dated 27th February B.E.2555 (2012) shall be repealed.

Clause 2 Authorized officers under the Food Act B.E.2522 (1979) and auditor of certification bodies registered with the Food and Drug Administration shall implement criteria, evidences presenting of experience and procedures of assessment of auditors as follows:

(1) Criteria and Conditions about Qualifications and Experiences of Auditors for Food Production Premises under Regulated Criteria in List No. 1 enclosed to this announcement.

(2) Evidences of auditing experiences in List No. 2 enclosed to this announcement.

(3) Work instruction for assessment of auditors' competency at food production premises under regulated criteria in List No. 3 enclosed to this announcement.

So that from now onwards.

Announced on 29th May B.E 2558 (2015)

(Signed) Boonchai Somboonsook

(Mr. Boonchai Somboonsook)

Secretary-General of Food and Drug Administration

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

List No.1

Criteria and Conditions about Qualifications and Experiences of Auditors for Food Production Premises under Regulated Criteria
-----**1. Scope**

This document prescribes definitions, levels and qualifications of auditors, and ethics including other relevant factors for recognition in competency of auditors for food production premises under regulated criteria. Auditors are either authorized officers or registered certification bodies by the Food and Drug Administration to ensure effectiveness and consistency of such audit.

2. Reference

2.1 Food Act B.E. 2522 (1979).

2.2 ISO 19011:2011 Guidelines for auditing management systems or TIS 19011:2013 Guidelines for auditing management systems.

2.3 Criteria, Procedures and Conditions for Registration of Bodies Providing Audit and Certification for Food Production Premises under Regulated Criteria (RL-F5-13).

2.4 Criteria, Procedures and Conditions in Registration of Registered Courses and Training agencies for Legal requirements by the Food and Drug Administration (RL-F5-15).

3. Definition

Definitions of terms in this document are as follows

3.1 Office means the Food and Drug Administration

3.2 Secretary-General means the Secretary-General of the Food and Drug Administration.

3.3 Certification body means an applicant that passed through an evaluation of attached evidence documents submitted with an application form and has been approved by the Office for competency to function for audit and certification of food production premises under regulated criteria.

3.4 Auditors mean person who have qualification to audit food production premises under regulated criteria.

3.5 Audit means systematic, independent and documented process to attain audit evidence and having decision openly in consideration of conformity assessment against criteria under the Food Act B.E. 2522 (1979), relevant Ministerial regulation, and audit criteria of the Food and Drug Administration

4. Level of auditors

4.1 Training auditor.

4.2 Auditor.

4.3 Lead auditor.

5. Character and qualifications of auditors

5.1 Auditors in Clause 4.1 -4.3 shall have personnel character as follows:

- 5.1.1 Ethical - fair, truthful, sincere, honest, and prudent.
- 5.1.2 Open-mind, willing to consider alternative ideas or points of view.
- 5.1.3 Observant – actively aware of culture or value of organizations including physical surroundings and activities.
- 5.1.4 Perceptive- instinctively aware of and able to understand needs for changes and improvement.
- 5.1.5 Versatile – adjust readily to different situations and giving alternative answers constructively.
- 5.1.6 Tenacious persistently focused on achieving objectives.
- 5.1.7 Self-reliant – acts and functions independently while interacting effectively with others.
- 5.1.8 Capability in decision making and can provide reasons in a timely manner by logic and analysis.
- 5.1.9 Capability in communication – be able to listen and coordinate with employees in each level and having confidence and sensitivity with organization's culture.
- 5.1.10 Acting with responsibility and ethics, effectively time management.
- 5.1.11 Teamwork – be able to work with other effectively and capable of leadership.

5.2 Auditors in clause 4.1 -4.3 shall have knowledge as follows:

5.2.1 Education

Shall have at least B.Sc. Degree in Food Science or other Science based areas with certificate of education.

5.2.2 Training

Shall pass the following training courses from registered training agencies:

- (a) Food Act and application for permission course, duration for training at least 16 hrs.
- (b). Legal requirements for food production premises audit course (prerequisite is course (a) as above and also be able to select the issues of standards or criteria that have been authorized to audit or to apply for registration or registered certification bodies by the office).
- (c) Course of ISO 19011: Guidelines for auditing management systems, duration of training at least 28 hrs (if Auditor/Lead Auditor ISO 9001, ISO 22000 course are attended and pass the tests or training course on Hazards Analysis and Critical Control Points that registered with International Register of Certificated Auditors; IRCA (if any), this course can be exempt if such evidence are attached).

In case of being authorized officials under the Food Act B.E. 2522 (1979) and carry on inspection of food production premises under regulated criteria for at least 5 years, training on the above courses can be exempted as well as an assessment of audits' competency on food production premises under regulated criteria required in section 5.4 of Criteria, Procedures and Conditions for Registration of Bodies Providing Audit and Certification for Food Production Premises under Regulated Criteria (RL-F5-13) can be exempted.

5.3 Work experience

5.3.1 Training auditors

Not defined.

5.3.2 Auditors shall have experiences on working relevant to food industries for at least 2 years.

5.3.3 Lead auditors shall have experiences on working relevant to food industries for at least 4 years

Original affiliation or certification bodies being applied for registration or registered certification bodies shall have evidences presented about experiences of staffs acting as auditors which certified by their commanders or proof of work letters.

5.4 Experience of audit

5.4.1 Training auditors

Not defined

5.4.2 Auditors

(a) Having experience at least 4 times and not less than 20 days and continued operation for 3 years on auditing of food production premises under regulated criteria in scope assigned to auditor or in scope applied for registration with the office and shall be supervised by a competent lead auditor.

(b) If having experiences in GMP or HACCP or ISO/TS 22002 or ISO 9001 or other equivalent standards on auditing of food production premises shall be not less than 4 times of auditing duration is not less than 20 days and shall be continued operation for 3 years.

5.4.3 Lead auditors

(a) Shall be experienced as lead auditor at least 3 times in duration at least for 15 days for food production premises under regulated criteria in scope assigned to inspect or in scope applied for registration with the office.

(b) If having experiences in GMP or HACCP or ISO/TS 22002 or ISO 9001 inspection of food production premises shall be not less than 3 times of auditing duration is not less than 15 days and shall be continued operation for 3 years.

Original affiliation or certification bodies being applied for registration or registered certification bodies shall have evidences presented of experiences of staffs acting as auditors which certified by their commanders or auditees and having details as in List No. 2

or evidences of registered auditor from recognized agencies and having on-site auditing competent evaluation of food production premises.

5.4.4 In case that auditors in clause 5.4.2 and 5.4.3 have changed original affiliation to a new body providing audit and certification, the experience will be continuously counted from 3 years as specified.

5.5 Assessment of auditors' competency to register under the regulated criteria

Auditors shall pass an assessment of competency of onsite auditing at food production premises under regulated criteria for lead auditor with not less than 80% of assessment criteria of the body and not less than 70% for auditors and being approved by Working Group for Evaluation of Certification bodies' competency including of personnel in food area at least 2 times or duration not less than 2 days.

5.5.1 In case that auditors are failed from the first assessment, the second assessment can be conducted by setting assessment criteria of the lead auditor with not less than 90% and the auditors with not less than 90% and a major defect shall not be found.

For auditors who passed the first assessment but failed for the second assessment, additional criteria shall be implemented. They shall have more experience evidence on inspection of food production premises under regulated criteria for 10 premises with copies of inspection records and the result of competent assessment from lead auditor registered with the office with the ninth and tenth food production premises. In addition, shall pass additional food law courses.

5.5.2 In case that auditors failed in both assessments, the office shall not approve for the registration of such auditors.

5.6 Adjusting level of auditors

Certification body shall follow work manual that submitted to the office by assigning the lead auditor passed the assessment of auditors' competency by the office and have experience as article 5.4.3 (a) to be the assessor of auditors' competency for adjusting level of auditors of such certification bodies. Then, the result of competency assessment shall be submitted to the office for further approval of registration.

5.7 Maintenance of auditors' competency

Certification body shall provide assessment of auditors' competency as determined at least once within 3 years.

6. Ethic

Auditors in Clause 4.1-4.3 shall maintain their ethics and reputation in audit including;

6.1 Acting as professional, impartial, fairness.

6.2 Assist to improve inspection skill, quality and management of staff under their controls or recommendations.

6.3 Not audit beyond their competent scopes or registered scopes with the office.

6.4 Not audit if having relation leading to conflict or impartiality which influence decision-makings.

6.5 Shall keep confidentiality or not disclose any information relevant to audit to others except having written consent from auditees or the office.

6.6 Shall not accept any asset or benefit from auditees, employees or stakeholders or connive with colleague to do so.

6.7 Do not behave to cause damage to the office and fully cooperate when having an investigation of allegation.

6.8 Do not intend to misleading communicate or provide information that may affect to impartiality of auditing.

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List No.2
Evidences of Auditing Experiences

1. Evidences for presenting of audit experiences which are certified by head or auditees' agencies as follows;

1.1 Names and addresses of auditees.

1.2 Names and addresses of employers for audit.

1.3 Duration of each audit with date, month and year.

1.4 Duration of each audit of food production premises and total time of auditing shall be separately presented.

1.5 Role in audit team such as lead auditor, auditor or training auditor.

1.6 Types of audit such as Third party audit, Second party audit, Surveillance.

1.7 Standards or regulated criteria used for inspection or food production premises auditing.

1.8 Number of members in audit teams.

2. Auditing experience shall have details for consideration as follows;

2.1 Shall be independent audit, auditors and agencies shall have organization and service independently from auditee's agency such as,

- Customer's agency does not audit supplier's agency.

- Auditing to certify by the third party.

- A Consultant is hired to audit independently according to the requirements.

2.2 Shall be full audit and entire system according to the ISO 19011 or procedure determined by the office.

2.3 The entire audit shall be complied with the objective of auditing requirements, not including recommendations to develop or improve such food production premises.

List No.3

Work Instruction for assessment of auditors' competency at food production premises under regulated criteria

