

JFS Audit and Conformity Assessment Program Document

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Japan Food Safety Management Association

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1. PROGRAM OUTLINE

1.1 Purpose

The JFS Audit and Conformity Assessment Program (hereinafter referred to as the "Program") is a program established by the Japan Food Safety Management Association (hereinafter referred to as "JFSM") which verifies that food-related business operators are implementing food safety management systems that conform to the requirements of the JFS Standards utilizing third-party audits conducted by audit companies approved by JFSM.

This program aims to enable food-related business operators, particularly small and medium-sized businesses, to improve the level of their food safety by utilizing the conformity assessments of the JFS Standard (hereinafter referred to as "this Standard").

1.2 Features of this Program

The main features of this program are that the auditor conducting the audit can provide guidance and advice to the organization in the audit, and consulting by the audit company. This ensures the independence of the audit and consulting services and maintains the impartiality of the audit, thereby ensuring its credibility as a third-party audit.

The program also aims to standardize food safety management systems throughout the food chain, promote HACCP initiatives recommended by the Codex Alimentarius Commission, further improve food safety management levels, and optimize food safety-related costs through audits and conformity assessment. The letter of conformance can be used as proof of conformity to the requirements of the JFS standard for the organization's business partners, and the auditing company issuing the letter of conformance is responsible for the adequacy and validity of the letter of conformance.

This program was developed by JFSM, and the copyright and other rights relating to this program are the property of JFSM.

1.3 Standard Documents and Applicable Sectors

The standards and corresponding sectors and subsectors that will be used as reference documents for auditing organizations in this program are listed in Annex 3.

2. PROGRAM OWNERSHIP REGULATIONS

2.1 Program Owner

This program is operated and managed by JFSM.

2.2 Organizational Structure

- (1) JFSM establishes a Board of Directors as an executive body, an inspector to conduct business operations audits, a Board of Trustees to decide on important matters, and a Secretariat to conduct the affairs of the association at the direction of the Board of Directors.
- (2) JFSM establishes a Stakeholder Committee and an audit company and Training Course Recognition Committee (hereinafter referred to as the "Recognition Committee") with the approval of the Board of Directors. The duties of each committee are as follows.
- ① Audit Company and Training Course Recognition Committee A committee to review audit companies and training institutions and their training courses to determine recognition, suspension, withdrawal, or renewal of recognition.
Based on a proposal from JFSM Secretariat, The Committee shall consist of the following members approved by the Board of Directors.
- (1) Experts in the food and food raw material manufacturing industry
 - (2) Experts from the distribution industry
 - (3) Consumer representatives
 - (4) Experts in accreditation or certification
 - (5) Academic experts (food safety and audit training)
- The establishment and operation of the audit company and training course recognition committee shall be stipulated in the "Rules of the audit company and training course recognition committee".
- ② Stakeholder Committee This committee is an advisory body composed of stakeholders to enable this program to be operated fairly and equitably.
It shall consist of the following members, appointed and dismissed by the President with the approval of the Board of Directors
- (1) Representatives of the food and food ingredient manufacturing industry
 - (2) Representatives of the distribution industry
 - (3) Consumer representatives
 - (4) Representatives of auditing companies

(5) A representative of a training organization (if necessary)

(6) Food safety experts

(7) Experts on specific issues (technical experts on specific sectors or sub-sectors and/or representatives of relevant businesses, if necessary)

Each member will provide expert advice in consultation with the Board of Directors or the President, and each member will provide independent stakeholder input. The committee is stipulated in the "Stakeholder Committee Establishment and Operation Rules".

- (3) With the approval of the Board of Directors, JFSM establishes working groups to develop this program document, standard documents for applicable sectors, and other standard documents (hereinafter referred to as "standard documents"). The establishment and operation of the Working Groups shall be stipulated in the "Rules for Establishment and Operation of Working Groups for JFS Audit and Conforming assessment Program".

2.3 Maintenance of Conformity Assessment Program

- (1) JFSM is comprehensively responsible for establishing, operating, and maintaining this program.
- (2) JFSM develops and revises criteria documents with the advice of the Working Group. JFSM prepares a draft and distributes it on JFSM website to call comments for a certain period. JFSM makes a revision or amendment based on the received feedback and finalizes the document at the Scheme Committee. The Scheme Committee provides the proposal document to the Board of Directors. The approved document is published on JFSM website.
- (3) JFSM meets at least once a year to adjust levels with the participation of audit companies to accept and discuss proposals for the operation of this program and exchanging opinions on improving the competence of auditors and reviewers (hereinafter referred to as "Harmonization Meeting").
- (4) JFSM shall review this program at least once a year through management review and internal audit, and revise it as necessary after consultation with the Stakeholder Committee. When reviewing, JFSM confirms that the standard documents of the program are up-to-date and that opinions, questions, and complaints from stakeholders are taken into account.
- (5) If a standard document requires a modification (wording correction) that does not involve a change in content, a revised version may be issued after consultation with the Stakeholder Committee and with the approval of the Board of Directors.
- (6) When an update of the standard document occurs, JFSM will issue a notification letter to the audit company and the conforming organization indicating the transition procedure to the new standard document.

2.4 Communication with Stakeholders

JFSM establishes a contact point for opinions, inquiries, and complaints from stakeholders regarding the Program. JFSM establishes and discloses rules regarding the handling of objections and complaints relating to the Program.

2.5 Registration, Publication, and Changes of Information by the Program Owner

JFSM shall publish the following information on audit companies and compliant organizations:
Registration in JFSM-DB shall be made under JFSM Database System Operation Manual.

Registration Field	Announced Data
① Recognized Audit Company	Name and location of the audit company Date of the contract with JFSM Registered sector (subsector in the case of sector E) Contact information (URL, etc.)
② Compliant Organizations	Name and location of the conforming organization (prefecture) Product (group) Sector (or subsector in the case of the food manufacturing sector) The version of the applicable standard Issue date of conformity assessment (date of initial registration is the issue date of conformity assessment) JFSM registration number The expiry date of the conformity assessment

2.6 Activity Report

JFSM shall prepare the annual report on its activities, including the results of the analysis of inquiries and complaints received by JFSM regarding the Program, and report the results of such analysis to the Recognition committee. In addition, the annual activity report is submitted to the Stakeholder Committee, audit companies, approved training organizations, and other stakeholders.

3. REQUIREMENTS FOR AUDIT COMPANY

3.1 Audit Company Criteria

The audit companies shall be:

- (1) Companies, local governments, and trade associations which conduct, for instance, audits, consultations, and inspections related to food safety,

Or

- (2) Food-related organizations (retailers, manufacturers, distributors, and so on) that conduct second-party audits,

The audit company must have made an institutional decision to state or specify audit and conforming assessment services in its articles of incorporation or other documents and must have positioned auditing as a business. The articles of incorporation must be amended at least one year after registration as an audit company.

The audit company shall be an organization that meets the following requirements.

- (1) The company has auditors and reviewers who have the competence specified in 5.1 (including auditors and reviewers based on outsourcing contracts).
- (2) shall have reviewers or an Assessment Review Committee capable of evaluating the audit results of the auditors and determining the assessment of conformity.
- (3) shall have procedures for conducting Audit and Conformity Assessment activities. The procedures shall include internal audits, management reviews, and procedures for maintaining the competence of auditors and reviewers.
- (4) shall document and maintain records of the procedures deemed necessary for executing their activities. At least the following shall be documented.
 - ① Operational procedures for conducting audits and reviews and issuing a letter of conformance
 - ② Internal audit procedures and records
 - ③ Management review procedures and records
 - ④ Procedures and records concerning the maintenance of competence of auditor and reviewer.
- (5) shall have the resources (personnel, equipment, and funds) necessary to continually conduct Audit and Conformity Assessment activities.
- (6) shall have a system in place based on ISO19011:2018, Paragraph 4 (Audit Principles) for auditors, reviewers, and other personnel involved in auditing activities to conduct independent and fair audits.
- (7) A structure for the management of impartiality and independence of auditing and conforming assessment activities shall be in place under ISO 17021-1:2015 5.2.1 to 5.3. This structure shall include top management commitment to impartiality and independence in auditing and conforming assessment activities.
- (8) The auditor shall be able to perform audit and conforming assessment services under the requirements of each standard document, annex, regulation, procedure, and notification document established by JFSM

3.2 Impartiality and Independence of Audit and Review (Including Relationship between Consultation and Audit Activities)

3.2.1 Prerequisites for an impartial audit

For the concept of points to be considered in the investigation of impartiality in auditing and reviewing, please refer to "Appendix 1 of the Audit Protocol: Concept of Investigation of Impartiality in Auditing and reviewing".

- (1) To conduct an impartial audit, the audit company shall investigate in advance whether any potential threats could impair impartiality and independence. A threat to impartiality and independence is a relationship that may affect judgment in the audit and judgment. Audit companies shall not conduct audits of organizations where threats remain that cannot be eliminated. Investigations of threats to impartiality and independence shall be conducted by the audit company's manager to identify and address threats to the impartial performance of the audit. The results of the investigation of threats to impartiality and independence shall be recorded.
- (2) Before agreeing to an audit and conformity assessment with an organization that intends to undergo an audit and conformity assessment, the relationship between the organization and the audit company shall be investigated for any possible threats to impartiality and independence. This investigation shall include the relationship between the organization and the person who has been awarded the audit, as well as the relationship between the consulting party and the audit company.
- (3) Before each audit and review, an investigation shall be conducted to determine whether there are any potential threats to impartiality and independence in the relationship between the organization and the auditor/reviewer. This investigation shall include the relationship with the consulting party and the auditor/reviewer's relationship with the organization, both public and private.
- (4) If the impartiality or independence of an audit or review conducted by an audit company is questioned, JFSM will investigate the audit company and, if the impartiality or independence is determined to be impaired, JFSM will discuss with the audit company the suspension of the public disclosure of the organization in question and the suspension or revocation of the conformity assessment.

3.2.2 Consultation and Audit Activities

Audit companies may provide consulting to an audited organization at a different date and time than the audit. However, a person who has provided consulting to an organization shall not, as an auditor or reviewer, conduct an audit of the same organization or review the audit until two years have passed since the consulting ended.

The consulting and the audit shall be performed independently, and the person who performed the consulting shall not influence the audit or review. If consulting is performed by a person

belonging to an audit company (including outsourced consultants), the consultant shall not be present at the audit or review of the organization until two years have elapsed from the date of completion of the consulting.

3.3 Recognition review of auditing companies

A legal entity seeking recognition as an audit company (hereinafter referred to as the "Applicant Company") The initial registration audit and registration shall be conducted under the "JFS Audit and Registration Rules for Audit Companies Engaged in Conformity Assessment Services". The initial registration audit and registration shall be conducted under the Initial Registration Audit of Audit Companies for JFS Auditing and Conformity Assurance Services.

3.4 Audit Company Registration and Announcement

The audit company shall submit or report information on the audit company, including auditors and reviewers, conforming organizations, and audits by submitting them to JFSM or entering them in JFSM-DB based on the following table.

Event	Notification/reporting items	Notification/reporting method	Notification /reporting deadline
Contract for Audit Services Conclusion	Information on the audit company's structure	Notification to JFSM using the required form. The information is entered into JFSM-DB after confirmation by JFSM.	Immediately after signing the contract
	Information on the competence of auditors and reviewers		
Modification of the audit company's system	Information about the audit company's structure that has been modified.		Within 30 days after a modification
Expansion of the audit company sector	Expanding sectors and information on sector expansion for auditors and reviewers	Notification to JFSM using the required form. The information is entered into JFSM-DB after confirmation by the committee.	When the sector of the audit company expands.
Annual Activity report	Annual activity report (including information on the status of internal audits and management reviews, information on the maintenance of the competence of auditors	Submit to JFSM in written form.	At the time of surveillance office review by JFSM.

	(and reviewers, and the results of questionnaires and other feedback from the audited organization)		
Additional registration of auditors and/or reviewers	Information on the competence of auditors or reviewers	Notification to JFSM using the required form. The information is entered into JFSM-DB after confirmation by JFSM.	When additional auditors and/or reviewer is registered
Change of registered information on auditors and reviewers	Information on the competence of modified auditors and/or reviewers		Within 30 days after the modification.
Initial or renewal audit	Information on the first or renewed audit of the organization and the conformity, and the audit information	Enter in JFSM-DB.	By the 15th of the month following the month of conformity assessment
Surveillance audit	Surveillance audit information		By the 15th of the month following the month of the surveillance audit
Change of registered information on the conforming organization	Registered information on the changed conforming organization	Report to JFSM by email after entering JFSM-DB.	Within 30 days after the change. If the change is made after a review, from the date of completion of the review to the 15th of the following month.
Suspension and lift of suspension of the conforming organization	Information on the organization that suspended/unsuspended and the reason for suspension/unsuspension	Notification to JFSM by the written form.	In principle, within 5 business days of the decision to suspend. Within 5 business days after the suspension is lifted. (See 4.12.2)
Cancellation of	Information on the	Notification to JFSM	In principle, within 5

Conforming organization, Partial Sector Cancellation	canceled organization and the reason for the cancellation	using the required form.	business days from the date of cancellation. (See 4.12.3)
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3.5 Renewal, Suspension, Withdrawal of Audit Company Recognition, and Takeover of conforming organizations

3.5.1 Renewal of Recognition

JFSM conducts Surveillance audits of the audit company once a year, in principle, based on the content of 3.4, to confirm the conformity and effectiveness of the requirements of the audit company as specified in this program. JFSM may also conduct extraordinary audits if there is a risk that the audit company may not meet the requirements of 3.1. The audits performed by JFSM are separately stipulated in the "Rules on the procedures for surveillance and extraordinary audits of audit companies for JFS audits and certifications of conformity".

JFSM may attend audits and reviews conducted by the audit company, depending on the risk to the reliability of the audit and review. The audit company must agree with the organization when JFSM requests to be present at auditing and reviewing. JFSM reports the results of the audit company to the Recognition Committee and, decides on maintaining the recognition of the audit company based on the decision of the committee.

3.5.2 Suspension of Recognition

(1) If an audit company falls into any of the following categories and appropriate corrective action is not taken within 30 days, JFSM may request a decision from the Recognition committee and, based on that decision, suspend the approval.

- ① The audit company has neglected to notify or report to JFSM or has given a false notification or report.
- ② The audit company has intentionally misused the logo provided by JFSM.
- ③ The audit company cannot provide sufficient evidence to confirm that the requirements of 3.1 are satisfied.

(2) Upon suspension, JFSM shall evaluate the effectiveness of the audit and review of the organization, and JFSM shall request a determination from the Recognition Committee, which determines the treatment of the Conforming organization's certification of conformance and the scope of the audit company's activities during the suspension. If it is determined that the validity is not assured, JFSM shall suspend the public disclosure of the organization in question and discuss with the audit company the suspension or withdrawal of the Conforming organization's certification. If the validity of the audit and review of the organization is determined to be assured, the conforming organization's conformity assessment shall be maintained.

(3) After the decision of suspension, the audit company shall submit a corrective action plan to JFSM within 30 days, and JFSM shall review the audit company's compliance with the requirements of 3.1 and the effectiveness of the corrective actions by an extraordinary review,

in principle within 30 days of the submission of the corrective action completion report. The suspension shall be lifted. The audit company shall be notified of the lifting of the suspension, together with the reasons.

3.5.3 Withdrawal of Recognition from JFSM

If the audit company falls under any of the following cases, JFSM may seek a decision from the Recognition Committee and withdraw the recognition of the audit company based on the committee's decision.

- (1) The contract between JFSM and the audit company has been terminated.
- (2) No effective corrective action has been taken by the audit company within a considerable period after the suspension.
- (3) Refuses, interferes with, or evades an office audit by JFSM without justifiable reason.
- (4) JFSM has determined that it will damage the reputation of the JFS Standard or cause undue disadvantage to the organization.

In the event of withdrawal following the decision of the Recognition Committee, JFSM notifies the audit company in advance of the reasons.

3.5.4 Decline of Recognition from Audit Company

- (1) If an audit company seeks to decline its recognition, it shall consult with JFSM before declining its recognition. At that time, the following information must be submitted to JFSM.
 - ① Acceptance of the conforming organization's response to the letter of conformance.
 - ② Whether or not the conforming organization is to be taken over, and to whom.
 - ③ Scheduled completion of the handover
- (2) The audit company shall be responsible for taking over the conforming organization, if any, from the audit company so that the conforming organization is not disadvantaged. When taking over a conforming organization, the audit company agrees to submit information on the conforming organization (including audit reports and other audit documentation) to the succeeding audit company and JFSM.
- (3) The audit company shall be responsible for the conformity status of the conforming organization until the takeover of the conforming organization is completed. JFSM may terminate the agreement between JFSM and the audit company and withdraw its recognition after completion of the takeover of the organization; JFSM will report the withdrawal to the Recognition committee, which may seek the advice of the Recognition committee as necessary in making its decision on the withdrawal.
- (4) The contract between the audit company and JFSM will continue until the transition of the conforming organization is completed.

3.5.5 Taking over of Conforming Organization

An audit company may transfer a conforming organization to another audit company. The

transfer shall be performed by the "Procedures for Transferring a conforming organization".

3.6 Retention of Documents and Security of Confidential Information

Audit companies shall retain documents related to their audit and letter of conformance services to conforming organizations (including audit and letter of conformance applications, contracts, audit reports, a letter of conformance, and audit evidence (including checklists, auditors' notes, etc.), hereinafter referred to as "Audit Reports, etc.") for at least 6 years.

Even after the contract with a conforming organization has been terminated, the audit company shall not disclose the business secrets of the conforming organization obtained during the audit and conformity assessment to a third party without the consent of the organization.

The audit company shall handle audit reports and documents as confidential information. In principle, the audit company shall obtain written consent from a conforming organization when providing or disclosing audit reports and documents to a third party. However, audit reports and documents may be provided to JFSM to confirm that the auditor has properly performed the audit by the requirements. The audit company shall obtain the prior written consent of the conforming organization that the audit reports and documents will be provided to JFSM for review of the audit company by JFSM.

3.7 Objections from Audit Companies

An audit company or applicant company (see 3.3 (1)) shall be able to respond with an objection to any unfavorable decision made by JFSM only within 30 days from the day following the date that the decision is received. The objection shall be filed in the designated form or by a method that makes the contents of the objection clear (including electromagnetic methods such as e-mail). In the event of such an objection, JFSM shall respond to it under the "Rules for Handling Objections to Audits and Conformity Assurance Programs".

3.8 Participation in Harmonization Meetings

The audit company shall participate in the Harmonization Meeting specified in 2.3. Audit companies shall educate auditors/reviewers who have not participated in the harmonization meeting on the content of the meeting and assess their level of understanding. Records of implementation and evaluation of understanding shall be submitted to JFSM by the deadline required by JFSM.

At the request of JFSM, audit companies shall participate in meetings and training sessions designated by JFSM.

3.9 Feedback from Conforming Organization

The audit company shall have a structure to obtain feedback from the audited organization regarding the audit and conformity assessment from the conforming organization after the completion of the audit, e.g., through questionnaires. The feedback shall include, at a minimum, an assessment of the auditor's performance. The results of the feedback shall be reviewed during the management review.

4. AUDIT AND CONFORMITY ASSESSMENT

4.1 Validity of Audit and Conformity Assessment

The period of validity of a letter of conformance under this program shall be until the day before the same day of the same month three years later*1 In the case of an initial audit, the starting date shall be the date of review (date of initial conforming assessment), and in the case of a renewal audit, the starting date shall be the day after the expiration date of the original letter of conformance.

*1 In the case of an audit conducted on February 29, the letter of conformance shall be valid until February 28, three years later.

Upon agreement with the conforming organization that the expiration date of the conformity assessment (including the period subject to the registration fee) will be shortened, the audit company may set the starting date of the new conformity assessment to a date before the expiration date of the current conformity assessment. The agreement with the conforming organization shall be documented.

In principle, one letter of conformance shall be issued for one site and one sector. For the food production sector, one letter of conformance may be issued for several sub-sectors (CI to CIV); if one site covers both the food production sector and the chemical production sector, a letter of conformance must be issued for each sector.

The audit company audits, in principle, once a year to confirm whether the conforming organizations are conforming to the requirements of the Standard. Audits include the following:

Audit type	Content	Implementation period
Initial audit	Confirm that the organization that seeks to receive the conformity assessment has established and effectively operates a system that conforms to the requirements of the JFS Standard.	When the application (4.2) is received from the organization
Renewal audit	Confirm and evaluate that the conforming organization has continually conformed to the requirements of the JFS Standard and has been operating effectively throughout the valid period (3 years) of the conformity assessment.	In principle, the review shall be completed before the expiration of the period of validity of the letter of conformance. Failure to complete the review by the expiration date will result in the revocation of the letter of conformance.
Surveillance audit	Verify that conforming organizations continue to meet and maintain the JFS Standard	In principle, the on-site audit shall be conducted within three months before or after the first letter of conformance or one

	requirements.	or two years after the date of the renewal of the letter of conformance. When an audit is postponed for more than 3 months, a risk assessment shall be made and recorded based on the results of previous audits, the status of response to non-conformities, and the impact on the state of conformity due to the event that is the reason for the postponement of the audit. The reasons for the postponement and the results of the risk assessment shall be submitted to JFSM for approval to postpone the audit.
Additional Audit	An audit was conducted to expand the scope of conforming assessment. For the expanded scope, it is confirmed that a system conforming to the requirements of the JFS standard has been established and is being effectively operated in the same manner as the initial audit.	When necessary
Extraordinary audit	If an event as specified in 4.12.1 occurs, the audit is conducted temporarily to confirm the conformity and effectiveness of the conforming organization.	When necessary
re-audit	Audits were conducted on organizations that have been suspended under 4.12.2 to lift the suspension.	When the suspension occurs. The suspension is to be completed, including the review, within six months from the date of notification to the conforming organization of the suspension, up to and including the lifting of the suspension.

4.2 Application for Audit and Conformity Assessment

The audit company accepts applications for an audit and conformity assessment from organizations seeking to receive an audit and conformity assessment that are submitted using an Application Form on Audit and Conformity Assessment (for the organization to be audited)

To conduct an impartial audit, upon receiving an application from an organization seeking to be

audited and conforming organization, the audit company shall investigate any potential threats to impartiality under 3.2. The results of the investigation shall be recorded. Audit companies shall not conduct audits of organizations for which threats remain that cannot be eliminated.

4.3 Contracting and Management of Audit Conforming Assessment Services

If an audit company receives an Application Form on Audit and Conformity Assessment as stipulated in 4.2 from an organization seeking to receive a conformity assessment, the audit company shall specify the labor hours for performing the audit and conformity assessment, the auditor in charge, and other necessary items related to the audit, and upon the agreement of the organization to be audited with such terms, a contract for the audit and conformity assessment shall be concluded.

The audit company shall record the number of man-hours to perform the audit and conforming organization, the auditor/reviewer in charge, whether or not consulting services are provided to the audit company and the organization to which the audit and review are entrusted, and if so, the person in charge of consulting services and the date of completion of such services.

4.4 Appointment of Auditors and Reviewers, and Determination of Audit labor-hours

- (1) The auditors audit the activities of the organization seeking to be audited to confirm that it conforms to the JFS Standard requirements relevant to the organization and that the organization's systems are functioning effectively.
- (2) The audit company may outsource the audit work to auditors who do not have a direct employment relationship with the audit company and meet the requirements outlined in this program (called "outside auditors"). When outsourcing to external auditors, it must also be ensured that they are competent as auditors under the 5 Requirements for Personnel.
- (3) Audit services may be outsourced to an organization registered as an audit company under JFS standards. Have procedures and agree with the contractor to ensure that the competence of the auditors conducting the audit and the audit process is equivalent to those of the contractor. The procedures shall include a process for receiving information on the auditor determined by the contractor and determining the availability of the auditor. The outsourcing of audit services shall be agreed upon with the organization to be audited. The information of the outsourced organization shall be notified to JFSM in the designated form. Even when audit services are outsourced, the responsibility for the audit remains with the outsourced audit company.
- (4) The audit company shall appoint auditors and reviewers registered with JFSM and shall notify the organization to be audited of the names of the auditors in advance, after confirming the following.
 - (1) The auditor shall be an auditor registered in the sector to be audited (or in the case of the food manufacturing sector, in the sub-sector). However, in the case of multiple auditors in the food manufacturing sector and the chemical products manufacturing sector, at least one auditor shall be an auditor registered in the sector (or subsector in the case of the food manufacturing sector) to be audited. The scope of expertise required for each sector/subsector shall be performed by an auditor registered in the sector (or subsector in the case of the manufacturing

sector of food products) to be audited. The other auditors shall be auditors registered in either the food manufacturing sector or/the chemical manufacturing sector.

- ② The reviewer (in the case of a review committee, at least one of the members of the committee) must be a reviewer registered in the sector to be reviewed. However, in the case of a reviewer, a reviewer registered in the sector of manufacturing food products may review the sector of manufacturing chemical products.
- ③ There is no potential threat to impartiality and independence in auditing and review. Threats to impartiality and independence are judged under 3.2.
- (5) An auditor who has performed audit work for an organization may not concurrently serve as a reviewer for that audit.
- (6) The audit company shall determine the labor hours to be audited based on Annex 1 and keep a record as a basis for the calculation.
- (7) If the audit company allows observers to participate, it must agree with the organization being audited on rules to ensure that observers do not influence the audit. If observers are allowed to participate, the organization is being audited and the audit company shall agree on rules to ensure that observers do not influence the audit. The presence or absence of observers and the results of confirming that they do not influence the audit shall be documented.

4.5 Implementation of Audit

- (1) Auditors shall conduct audits under the "Audit Protocol."
- (2) The audit company shall send a written audit plan to the organization to be audited in advance. The audit plan shall include at least the following.
 - ① Audit type (Initial audit, Surveillance audit, Renewal audit, etc.)
 - ② Scope of audit (sector/subsector, products/types covered (in the case of food services), etc.)
 - ③ Audit standard (name and version of the standard)
 - ④ Audit man-hours
 - ⑤ Audit Date
 - ⑥ Names of all auditors
 - ⑦ Schedule an on-site audit
 - ⑧ The availability and scope of observers and training auditor candidates on the audit side. If there are training auditor candidates, the scope of their activities.
- (3) Auditors shall prepare an audit report immediately after the audit of the organization to be audited, and submit requests for correction requests and reports to the organization as necessary. Auditors shall confirm the completion of the correction based on the correction request and report submitted by the organization, and promptly submit the necessary documents for review, including the audit reports, checklists, and correction requests and reports to the reviewer or Review Committee.
- (4) At a minimum, the following must be included in any of the documents used for review, including audit reports, audit checklists, and corrective action requests and reports.
 - ① Name of the audit company

- ② Name, address, and representative of the audited organization (management or management-level representative *see Annex 6 Definition of Terms)
 - ③ Type of audit (Initial audit, Surveillance audit, Renewal audit, etc.)
 - ④ Scope of audit (sector/subsector, products/types covered (in the case of food services), etc.)
 - ⑤ Audit standard (name and version of the standard)
 - ⑥ Audit man-hours
 - ⑦ Audit date
 - ⑧ Audit location (only if part of the audit was conducted at a location other than the organization being audited)

(For example, when interviews with management were conducted at the head office, which is different from the factory that is the subject of the audit when some processes such as interviews and initial and closing meetings were conducted in a rented conference room, etc.)
 - ⑨ If remote audits were conducted, the scope of such audits
 - ⑩ Names of all auditors who conducted the audit and their registered sectors/subsectors
 - ⑪ Summary of audit results, conclusions
 - ⑫ Individual evaluation results for all requirements and the basis for judgment (conformity/nonconformity) necessary for the reviewer to judge conformity (nonconformity).
 - ⑬ Details of Nonconformities and Observations and Basis for Determination
 - ⑭ Guidance and advice (only if implemented)
 - ⑮ Whether the JFS standard logo is used and the appropriateness of its use (if applicable)
 - ⑯ Persons present at the audit other than the audited organization and auditors and their impact (if applicable)
 - ⑰ Follow-up results of nonconformities in previous audits
 - ⑱ The availability and scope of observers and training auditor candidates. If there are candidate training auditors, the scope of their activities
- (5) The corrective action request/report shall have at least the following items.
- ① Nonconformity found and the section number of the applicable requirement
 - ② Nonconformity Category
 - ③ Basis for determination of nonconformity
 - ④ Deadlines for correction and corrective actions in the audited organization
 - ⑤ Date of correction completed
 - ⑥ Causes of nonconformity
 - ⑦ Corrective action (planned or completed) and date implemented
 - ⑧ A record and date of the auditor's confirmation of the completion of correction and corrective actions or confirmation of plans for corrective actions
 - ⑨ A record and date of the reviewer's confirmation of the completion of correction and corrective actions or confirmation of plans for corrective actions

4.6 Remote Auditing using ICT

Audit companies may conduct audits by remote auditing using ICT. When conducting remote audits, the "Provision for Remote Audits for JFS Audits and Conformity Assessment Programs" shall be followed.

4.7 Conformity Assessment Criteria

- (1) After receiving the documents necessary for review, including the audit plan, audit report, audit checklist, corrective action request/report, and evidence of correction/corrective action for nonconformity submitted by the auditor, the reviewer or review committee shall determine whether the audited organization is in conformity with the standard and is functioning effectively, and shall decide whether to grant or maintain the conformity assessment. The reviewers or the review committee shall decide on whether or not to grant or maintain the conformity assessment. The reviewer or the review committee shall keep a record of the results and basis for their decision.
- (2) In making a review, the reviewer or review committee shall
 - a) Is the content of the audit report sufficient in light of the requirements of the JFS standard and the scope of the audit?
 - b) Have the corrections and corrective actions been reviewed and validated for all nonconformities? Details of the method and criteria for reviewing conformity shall be described in Annex 2.
- (3) Upon reviewing the organization's compliance with the standard and determining that it is functioning effectively, the audit company shall certify the conforming organization's compliance. The audit company shall document the basis for its review.
- (4) When a person other than the reviewer (observer), including the auditor, is present at the assessment, it must be ensured that he/she does not influence the assessment, and a record of this must be kept.
- (5) A person who has provided consulting services to an organization undergoing a review shall not be involved in the review until two years have elapsed from the date of completion of the consulting services.
- (6) The audit company may outsource the review work to reviewers who meet the requirements outlined in the Program (so-called "external reviewers") and who do not have a direct employment relationship with the audit company. However, it shall be clarified that the audit company shall be responsible for the review. Even when outsourcing to external reviewers, it must be ensured that they are competent as reviewers within "Requirements for Personnel" in 5. Review services may not be outsourced to another audit company.

4.8 Guidance and Suggestions during Audit

Auditors are encouraged to provide guidance and suggestions during the audit, keeping in mind that the organization shall remain autonomous. If any guidance or suggestions have been given, the auditor shall record this fact.

4.9 Audit Results Notification

The audit company shall inform JFSM and the auditee of the result determined by the reviewer or the Assessment Review Committee. In case the letter of conformance is not issued, the audit company shall provide the auditee reasons with the result.

4.10 Issue of a Letter of Conformance

- (1) When an audit company determines an organization to conform to the initial audit, it issues a letter of conformance to the organization after entering the information into JFSM-DB and confirming it by JFSM. The validity period of the conformity assessment shall be under 4.1.

When an organization is reviewed as conforming organization in the renewal audit, an audit company shall enter into JFSM-DB and issue a letter of conformance to the organization. However, in the case of a change in the registered items of the letter of conformance, it shall be under 4.14.

- (2) The letter of conformance shall have the registration number assigned by JFSM (hereinafter referred to as the "JFSM registration number") written below the JFS Standard logo and shall include the following items. The audit company may separately write a uniquely determined registration number at a position decided by the audit company.

- ① Conforming organization name
- ② Site name
- ③ Location of the site (if the site spans multiple addresses, only the address representing the site may be used)
- ④ Product group
- ⑤ Sector (or subsector in the case of the food manufacturing sector)
- ⑥ JFSM registration number
- ⑦ Conformity to applicable standards Evidence of conformity in writing
- ⑧ Applicable standards and their version numbers
- ⑨ Date of initial conforming assessment (date of initial audit review)
- ⑩ Date of review (date of the most recent review of any review conducted at the time of issuance of the conformity assessment)
- ⑪ Date of issuance (in case of reissuance after the initial conforming assessment)

For example: when there is a change in the description of a product group, etc., at the time of a renewal audit of a conforming organization, after an additional audit, when a change in the name of the Organization occurs, when there is an upgrade of the standard, etc.

- ⑫ Expiration date of the letter of conformance
- ⑬ Name and location of the audit company (prefecture)
- ⑭ Audit company representative name and seal
- ⑮ Name of representative auditor
- ⑯ Name of the reviewer or representative of the Assessment Review Committee

- (3) When a conforming organization uses the logo of the JFS standard, the audit company shall ensure that the conforming organization complies with the "JFS Standard Logo Handling Rules".

- (4) JFSM may investigate any misrepresentation found in the Letter of conformance and require the audit company to take corrective action.

4.11 Registration of conforming organization

- (1) Audit companies shall register information on conforming organizations with JFSM by entering it into JFSM-DB, following the "JFSM Database System Operation Manual". If requested by JFSM, the audit company shall submit documents related to the audit, including the audit report, to JFSM (see 3.4).
- (2) The audit company shall collect the registration fee from the conforming organization and pay it to JFSM. The registration fee shall be determined separately by JFSM.
- (3) Audit companies shall submit documents related to the audit to JFSM when requested by JFSM. The handling of confidential information is specified in 3.6.

4.12 Renewal, Suspension, and Withdrawal of Conformity Assessment

4.12.1 Extraordinary Audit

- (1) When any of the following ① and ② applies, the audit company shall receive a report from the conforming organization without delay that the incident in ① and ② has occurred. If ③ applies, JFSM shall receive a report from the conforming organization upon completion of the initial response by the conforming organization.
- The audit company shall report to JFSM within three business days of being contacted by the conforming organization.
- ① If products manufactured on lines subject to conformity assessment are seized (recalled) or voluntarily collected for food safety reasons
 - ② If the conforming organization receives an administrative action, such as administrative guidance or a business suspension order, due to a food safety problem
 - ③ If there is a possibility that the product may not conform to the requirements of the standard due to a natural disaster, fire, etc.
- (2) The audit company shall determine whether it is necessary to conduct an extraordinary audit to confirm the status of the conforming organization's conformity. When a situation described in (1) ①, ②, or ③ occurs, the audit company shall report to JFSM in writing the details of the occurrence, the response taken, and whether or not an extraordinary audit will be conducted and the basis for the decision. (In principle, the report shall be made within 5 business days after the decision on whether or not to conduct an extraordinary audit.)
- (3) The audit company shall conduct an extraordinary audit when it is considered necessary. When an extraordinary audit is conducted, the results shall be reported to JFSM by the 15th of the month following the date of completion of the review by inputting them into JFSM-DB and submitting audit documents (audit report, nonconformity, and corrective action report, review record, etc.).
- (4) Upon request of JFSM, the audit company shall submit additional information regarding the

events in (1) ①② and ③ and the extraordinary audit.

4.12.2 Suspension of Conforming assessment

- (1) The audit company shall suspend the conformity assessment of the conforming organization if any of the following applies.
 - ① If the conforming organization does not conform to the requirements of the standard and there is no prospect of correction (including cases in which the organization's operations are continually stopped due to a natural disaster, fire, etc.)
 - ② If there is a major nonconformity with the requirements of the standard at the conforming organization
 - ③ When a nonconformity to the requirements of the standard is found in a conforming organization and the audit company requests correction and corrective actions (or corrective plans in case of minor nonconformities) within a reasonable period (in principle, within three months), but appropriate corrective actions are not taken within this period
 - ④ The conforming organization does not allow a surveillance or renewal audit to be conducted
- (2) The audit company shall notify the conforming organization and JFSM in writing of the suspension of the conformity assessment with the reasons for the suspension, in principle within 5 working days of the decision to suspend.
- (3) Audit companies must ensure that the letter of conformance and logo is not used in principle by the conforming organization during the suspension, or that the use of the logo does not mislead the public into believing that the organization has been certified as conforming during the suspension.
- (4) The period of the suspension of the conformity assessment shall, in principle, be six months from the date of notification to the conforming organization. The audit company shall cancel the suspension after confirming that the nonconformity that caused the suspension has been corrected. The audit company shall notify the relevant conforming organization and JFSM in writing of the lifting of the suspension and the basis for it. The notification shall be made within 5 business days of the lifting of the suspension. Audit companies are encouraged to provide appropriate guidance and advice to the conforming organization in correcting the nonconformity.

4.12.3 Withdrawal of Conforming Organization

- (1) The audit company shall withdraw the conformity assessment of the conforming organization if any of the following applies.
 - ① If no corrective action has been taken by the conforming organization within six months, in principle, after the suspension of the conformity assessment and the conformity and effectiveness of the identified nonconformity cannot be confirmed.
 - ② If the contract between the audit company and the conforming organization has been

canceled.

- (2) The audit company shall notify the relevant conforming organization and JFSM of the withdrawal of the conformity assessment in writing with the reason for the withdrawal. Notification to JFSM shall be made within 5 working days of the revocation in principle. If a conformity assessment is expired without conducting a renewal audit before the expiration date, the conforming organization concerned and JFSM shall be notified in the same manner.
- (3) The audit company shall ensure that the letter of conformance and the logo are not used in principle by the conforming organization whose letter of conformance has been withdrawn.

4.13 Reinstatement of Conforming Assessment

Failure to complete a renewal audit review within the period of validity of the letter of conformance will result in the letter of conformance being revoked. A conformity assessment may be reinstated if a renewal audit review is completed within 6 months of the expiration date of the expired conformity assessment. The effective date of the reinstated letter of conformance shall be the date of the renewal audit review, and the letter of conformance shall be valid for three years from the day after the expiration date of the expired conformity assessment.

4.14 Minute Changes of Registration Data on Letter of conformance

If any part of the information described in the letter of conformance needs to be changed, the conforming organization shall submit a copy of the letter of conformance that describes the changes to the audit company that issued the letter of conformance.

If the audit company deems it necessary to change the registered items of the letter of conformance, the company shall change the registration of JFSM-DB and send the changed letter of conformance to JFSM (See 3.4).

4.15 Announcement of Conforming Organization

JFSM announces the information specified in 2.5 ② about conforming organizations on JFSM website.

5. Requirements for Personnel

5.1 Competence Requirements for Auditor or Reviewer

Regardless of whether or not the personnel are outsourced, the audit company shall ensure that the auditor possesses the competence stipulated in (1) to (3) below and that the reviewer possesses the competence stipulated in (1) to (4) below.

(1) Audit skills and knowledge to

- ① Effectively plan and organize the audit
- ② Conduct audits within the agreed period
- ③ Communicate with people at all levels of the audited organization
- ④ Conduct interviews and gather evidence
- ⑤ Gather evidence by observation and investigation
- ⑥ Review materials and records and gather evidence
- ⑦ Analyze, verify, and organize audit evidence and summarize audit findings
- ⑧ Prepare audit reports

(2) Technical skills and knowledge of sector and subsector

- ① Management system standards
- ② Codex HACCP
- ③ Good Manufacturing Practices (GMP)
- ④ Food safety laws and regulations

(3) Behavior and systematic thinking

- ① Leadership and behavior
- ② Systematic thinking (problem-solving, root cause analysis)
- ③ Organization and social code of conduct

(4) Skills to review conformity

- ① Auditing or consulting experience
- ② Ability to understand and confirm the content of the audit report
- ③ Ability to review conformity

5.2 Auditor or Reviewer Registration

(1) Initial registration

The audit company evaluates whether the person has the competence stipulated in 5.1 by the following method, and submits an application for registration of the auditor to JFSM along with documents supporting the evaluation.

If a person whose registration as an auditor/reviewer has been suspended due to the requirements in 5.4 (1) (ii) or (3) or a person whose registration as an auditor/reviewer has been withdrawn due to the requirements in 5.5 (1) registers for the first time, the completion of correction of the nonconformity that was the reason for suspension or revocation shall be confirmed and the record of such correction shall be submitted to JFSM.

- ① Confirm that the prospective auditor has completed training conducted by a training organization

approved by JFSM or designated by JFSM within the past 10 years. (ii) Confirm that the candidate has been registered with another audit company as an auditor for the sector concerned under JFSM standards.

- ② Confirm that each potential auditor has a minimum of three audits/consulting experiences in food safety, including HACCP, with different organizations.
- ③ The competent assessor specified in 5.6 shall attend an audit of a prospective auditor within one year before the date of application for registration with JFSM to assess the auditor's competence to audit.
- ④ At least one year of work experience in food safety for each sector (or sub-sector in the case of the food manufacturing sector, same below). Three audits or consulting experiences, each conducted by a different organization, shall be considered equivalent to one year of work experience. The head of the audit company shall confirm that the applicant has competence in sector-specific audits. Sector-specific food safety-related work experience is specified in Annex 4. Audits in ② through ④ of this section include internal audits, two-party audits, substitute two-party audits, and third-party audits related to food safety, including HACCP, and mock audits of JFS standards conducted under this program document (letter of conformance is not given) Including audits in which you participated as a training auditor candidate (see Annex 6) in an audit of JFS standards.

One person may be registered as an auditor and a reviewer at the same time. The audit company shall maintain a record of these assessments and shall submit this record to JFSM if requested by JFSM.

(2) Maintaining registration (Requirements for auditors in the JFS-A/B standard)

- ① To maintain audit competence, auditors must conduct at least one audit per year of the food manufacturing sector or the chemical manufacturing sector according to JFS standards. Auditors who have not performed at least one audit engagement per year shall complete maintenance training.
- ② To maintain the knowledge required for auditing, auditors must pass the annual auditor/reviewer examination provided by JFSM. If they fail or have not yet taken the auditor/reviewer examination, they must complete follow-up training.
- ③ If required by JFSM, auditors shall complete an examination or training course designated by JFSM.

(3) Competence assessment of auditors (Requirements for auditors in the JFS-A/B standard)

The audit company shall have a mechanism for a competence auditor, as defined in 5.6, to periodically attend the auditor's audits and evaluate the auditor's auditing skills. This mechanism shall include one assessment within three years of initial registration and at least once every five years thereafter. Include a mechanism for training or reassessment on a risk-based basis (for example,

when competence is called into question during JFSM office audits, complaints, reviews in judgments, internal audit reviews, etc.).

(4) Expansion of Sector or Subsector

If an audit company wishes to expand the registration of auditors' subsectors (CI-CIV) in the food manufacturing sector or the chemical manufacturing sector (K), the responsible person of the audit company shall evaluate the competence of the auditors to audit each sector or subsector according to the procedure specified in 5.2 (1) (iv), and shall apply to JFSM for the expansion of the sector or subsector together with the results of the evaluation. (2) (1) (iv), and apply to JFSM for the sector or subsector expansion with the results of the evaluation.

5.3 Renewal and Suspension of Reviewer Registration

(1) Initial registration

The audit company shall evaluate that the reviewer has the competence specified in 5.1, in addition to 5.2 (1), by the method specified below, and apply for registration of the reviewer to JFSM with documents supporting the evaluation, and JFSM shall assess the competence of the reviewer and register the reviewer.

- ① Confirm that the candidate for reviewer has audit experience according to JFS standards or other food safety management standards including HACCP.
- ② The candidate for reviewer shall conduct at least one mock review of an audit report by JFS standards or other food safety management including HACCP within one year before the date of application for registration to JFSM, and the competent assessor specified in 5.6 shall evaluate the candidate's skills as a reviewer base on the contents of the mock review.

One person may be registered as an auditor and a reviewer at the same time. The audit company shall maintain a record of these assessments and shall submit this record to JFSM when requested by JFSM.

(2) Maintaining registration (Requirements for reviewers of the JFS-A/B standard)

- ① To maintain competence in reviewing, reviewers must conduct at least one review per year using JFS standards in the food manufacturing sector or the chemical product manufacturing sector. Reviewers who have not conducted at least one review per year shall complete maintenance training.
- ② To maintain the knowledge necessary for review, the auditor/reviewer must pass the auditor/reviewer examination provided by JFSM. If an auditor/reviewer fails or does not take the exam, the auditor/reviewer shall complete the follow-up training.
- ③ Reviewers shall complete examinations or training designated by JFSM if requested by JFSM.

(3) Assessment of the competence of reviewers (Requirements for reviewers of the JFS-A/B

standard)

Audit companies shall have a mechanism in place to assess the competence of reviewers by a competent assessor as specified in 5.6 at least once every three years. The assessment mechanism shall include a mechanism for training or reassessment, as appropriate to the risk (for example, when competence is questioned during JFSM office audits, complaints, internal audit reviews, etc.).

5.4 Withdrawal of Auditor / Reviewer Registration

- (1) JFSM suspends the registration of auditors or reviewers who fall under any of the following cases.

① Persons who have not conducted at least one JFS standard audit or review per year and have not completed the maintenance training prescribed in 5.2 (2) and 5.3 (2)
② Persons who have not, as a result of the examination by JFSM, conducted appropriate audits or reviews and who have not had their audit or review competence confirmed
③ Those who have not taken or failed the auditor/reviewer examination and have not attended or completed the follow-up training. or have not completed the follow-up training.

When JFSM suspends the registration of an auditor or reviewer, JFSM shall notify the audit company in writing.

Auditors or reviewers whose registration has been suspended shall not conduct audits or reviews.

- (2) An auditor/reviewer who has been suspended under the above requirements may lift the suspension in the following cases (1) When more than one of ①, ②, or ③ applies, all requirements for lifting suspension must be met to lift the suspension.

An auditor or reviewer who has been suspended under ① above may have the suspension lifted upon completion of maintenance training.

An auditor or reviewer who has been suspended under ② above may lift the suspension upon confirmation by JFSM that the correction of the nonconformity has been completed.

The suspension of an auditor or reviewer who has been suspended under ③ above may be lifted upon passing the auditor/reviewer examination or upon completion of follow-up training.

- (3) If the audit company cannot confirm that the auditor or reviewer is not performing proper audit or review work and is competent to perform audit or review, the audit company shall, at its discretion, suspend the registration of the auditor or reviewer. Suspended auditors or reviewers may have their suspension lifted upon confirmation of completion of correction of nonconformities and fulfillment of the requirements in 5.2 (2) or 5.3 (2). The audit company shall notify JFSM in writing when it suspends the registration of an auditor or reviewer and when it lifts the suspension.

5.5 Cancellation of Registration of Auditors and Reviewers

- (1) If the audit company determines that an auditor/reviewer does not meet the competence requirements of 5.1, the audit company shall notify JFSM of such determination, and JFSM may cancel the registration of such auditor/reviewer based on such notification.
- (2) If the audit company, at its discretion, cancels the registration of an auditor or reviewer, or cancels

the registration of a sector or subsector in part, it shall notify JFSM of such cancellation and JFSM shall cancel such registration.

5.6 Requirements for Competent Assessors

(1) Appointment of competent assessors

Persons assessing the competence of auditors or reviewers under the requirements of 5.2(1)③, 5.2(3), 5.3(1)②, and 5.3(3) shall be competent assessors registered with JFSM.

Only if there is an agreement between the audit company and the organization to be audited, it is also possible to outsource the work as an auditor to a person who has been assessed and registered by another audit company.

When a witness is provided to the auditor conducting the on-site audit, the evaluation shall be conducted in accordance with the rules for witness evaluations.

(2) Competence and Registration of Competent Assessors

The audit company shall ensure that the competent assessor meets the requirements of ① through ④ below.

If the audit company wishes to register a new competent assessor, it shall evaluate the candidate for a competency auditor to ensure that he/she meets the following criteria ① to ④ and apply to JFSM for registration as a competency auditor with documentation supporting such evaluation.

- ① Possess the competencies specified in 5.1.
- ② Registered and maintained as either an auditor or reviewer for the sector concerned in the JFS standard. If before audit company recognition, meet the requirements for initial registration as an auditor.
- ③ Competence to evaluate the performance of auditors and reviewers in light of the requirements of the standard.
- ④ Have the necessary knowledge and skills for each sector or subsector covered and the competence to apply them in assessing the performance of auditors and reviewers.

As an example of the evaluation basis for ③ and ④, the auditor must have experience in auditing and reviewing food safety management systems in the relevant sector or sub-sector*1 for at least five cases, must have experience as an audit and review leader, must be confirmed to have appropriate competence in the evaluation of competence in auditing, must have experience in at least three cases of review and the content must be confirmed to be appropriate, and must conduct an appropriate evaluation of the competence of other auditors and reviewers. The applicant must have experience as an audit/audit leader, must be confirmed to have appropriate competence in the evaluation of competence in audits, must have at least 3 cases of experience in reviewing, and must appropriately evaluate the competence of other auditors/reviewers. The basis for evaluation is not limited to the above.

※1 Auditing/audit experience includes internal audits of food safety management systems, two-party audits, substitute two-party audits, third-party audits, and mock audits of JFS standards conducted under this program document (No letter of conformance is given), including audits participated in as a candidate for training auditor (see Annex 6) for JFS standard audits.

Annex1 Determination of Audit man-hours (JFS-A/B standard)

(1) Preparation of man-hours

The minimum audit man-hours for the preparation of the audit plan and document review the for initial audit is 0.25 man-days the for JFS-A standard and 0.5 man-days for the JFS-B standard. For Surveillance audits, Renewal audits, Re-audit, Additional audits, and extraordinary audits, the changes from the previous audit in the organization shall be investigated, and if necessary, the man-hours for preparation shall be determined.

(2) Calculation of man-hours for the on-site audit

The audit company shall calculate the number of audit man-hours (man-days) that will allow the organization being audited to adequately perform the audit, based on the formula for calculating the number of on-site audit man-hours outlined in this section. Records of the basis for such calculation shall be maintained.

The audit company may increase or decrease the number of audit man-hours from the number of man-hours calculated based on the calculation formula if it deems it necessary to conduct an appropriate audit and there are reasonable reasons*1 such as HACCP plan, facility size, and whether the audit is a JFS-A/B audit. However, the basis for man-hour calculation must be recorded

Even if increased or decreased for any reason, the number of man-hours shall not be less than the minimum number of man-hours specified below.

In principle, each man-day is 8 hours (excluding travel time and including lunch break. However, if audit activities are conducted while traveling, the travel time may be included.) (However, if audit activities are conducted while traveling, the time spent traveling may be included.

*1 Examples of cases where man-hours are subtracted from the man-hours based on the calculation formula are shown below. However, this is not limited to the following.

- In the JFS-A standard, the organization is very small, with only one or two rooms, and the on-site audit takes only about one hour, so the minimum man-day was set at 0.5 man-days.
- Only one target product and a simple manufacturing process.
- Initial audit of the JFS-B standard, which is a step up from the JFS-A standard to the JFS-B standard, focusing on the gap between the JFS-A and JFS-B standards.

① Formula for calculating man-hours for on-site audits for initial and Renewal audits

The formula and criteria for calculating the on-site audit man-hours (T_s) for initial and Renewal audits shall be as follows. If the result of the man-hour calculation is a fraction, the audit time may be rounded up to the nearest half-day and adjusted accordingly. The minimum man-days for the JFS-B standard are 1.0 man-days, even if it is increased or decreased from the formula; the minimum man-days for the JFS-A standard is 0.5 man-days.

$$T_s = T_D + T_H + T_{FTW} + T_{GMP}$$

T_D	Basic audit labor hours for conducting on-site audits (0.5 man-days in principle)
T_H	Additional audit man-hours when the number of HACCP plans exceeds 2 (as shown in Table 1) Even if there are multiple products to be audited, the number of HACCP plans can be set to 1 if the plan to control the hazards related to the target products (groups) based on the 7 principles of HACCP 12 procedures can be said to be the same. (as shown in Table 1)
T_{FTW}	Audit duration according to the number of workers (as shown in Table 1) The number of employees shall be taken as the number of full-time equivalent employees (full-time workers), calculated on the basis of an eight-hour working day, five days a week. Where shifts are worked (including seasonal workers) and the products and/or processes are similar, the number of full-time equivalents shall be the number of employees involved in the main shift plus administrative staff.
T_{GMP}	Audit labor hours for GMP (in principle, 0.5 man-days)

Table 1 Criteria for calculating durations of the on-site audit

Sector	T_D	T_H	T_{FTW}	T_{GMP}
CI~IV/K	0.5	Number of HACCP plans 1~2=0 3~4=0.25 5~6=0.5 7~8=0.75 $\geq 9=1.0$	1~50=0 51~100=0.25 101~500=0.5 501~1000=1.0 1001~5000=1.5 $\geq 5000=2.0$	0.5

② Surveillance audit

The minimum man-days for Surveillance audit for JFS-B standard is 65% of T_s calculated by the formula shown in ① above. 0.5 man-days for JFS-A standard. However, in such cases, the on-site audit shall be the main focus of the audit.

③ Extraordinary audits, reaudits, and additional audits

Calculate based on the number of applicable requirements, the time required for an on-site audit of the audit scope, etc. The basis for the calculation must be documented.

Annex 2 Audit and Conformity Assessment Flow and Procedure

(1) Conformity assessment criteria and handling method

Table 1 shows the assessment criteria and handling methods for each conformity or nonconformity category.

Table 1-Conformity assessment criteria and handling methods for each conformity or nonconformity category

Symbol	Status of conformity	Definition	Assessment criteria	Handling method
a	Critical nonconformity	Failure to comply with laws and regulations that directly affect or could seriously affect food safety.	If the requirements are not met and the safety of the product has not been ensured, or the laws relating to food safety have not been complied with	In the case of an initial audit, the audit shall be stopped, and after the critical nonconformity is eliminated, the audit shall be conducted again. In the case of a periodic audit, renewal audit, additional audit, or extraordinary audit, the audit and letter of conformance shall be suspended (4.12.2(1)②) and the auditor shall be requested to complete corrective actions within 6 months, and a new audit shall be conducted after the completion of corrective actions. In the case of a re-audit, the audit shall be suspended and a new audit shall be conducted after the critical nonconformity is removed. If the suspension, including review, cannot be lifted within 6 months from the date of notification of the suspension

				to the conforming organization, the organization's conformity assessment shall be withdrawn under 4.12.3.
b	Major nonconformity	Potential food safety implications or failure to comply with food safety laws and regulations	If the requirements are not met and the product may no longer be safe, or the risk to food safety may increase, failure to comply with food safety laws and regulations.	In principle, the completion of correction and corrective actions shall be confirmed within 30 days. If it is unavoidable to exceed 30 days, the basis for justifying the extension of the deadline must be confirmed. In principle, if appropriate corrective action is not taken within a period of three months, the conformity assessment shall be suspended.
c	Minor nonconformity	Less likely to impact food safety.	If the requirements are not met, but the resulting product is safe, or the risk to food safety is unlikely to increase	In principle, correction shall be implemented within 30 days, and a corrective action plan shall be requested and approved. If it is unavoidable to exceed 30 days, the basis for justifying the extension of the deadline must be confirmed. (In principle, if appropriate corrective actions are not taken within a period of three months, the suspension shall be considered a temporary suspension. Completion of the correction shall be confirmed by an audit one year later.
d	Conformity	The		

		requirements are being met.		
	Observations	Same as above	When it can be judged as "conforming" there is a possibility of nonconformity if the operation is continued in the same condition.	Record observations noted as observations in the findings section of the audit checklist.

If the status of the audited organization concerning the requirements is deemed to be excellent, that fact can be noted in the remarks column using an expression such as "good point".

(2) Procedures for non-conformities

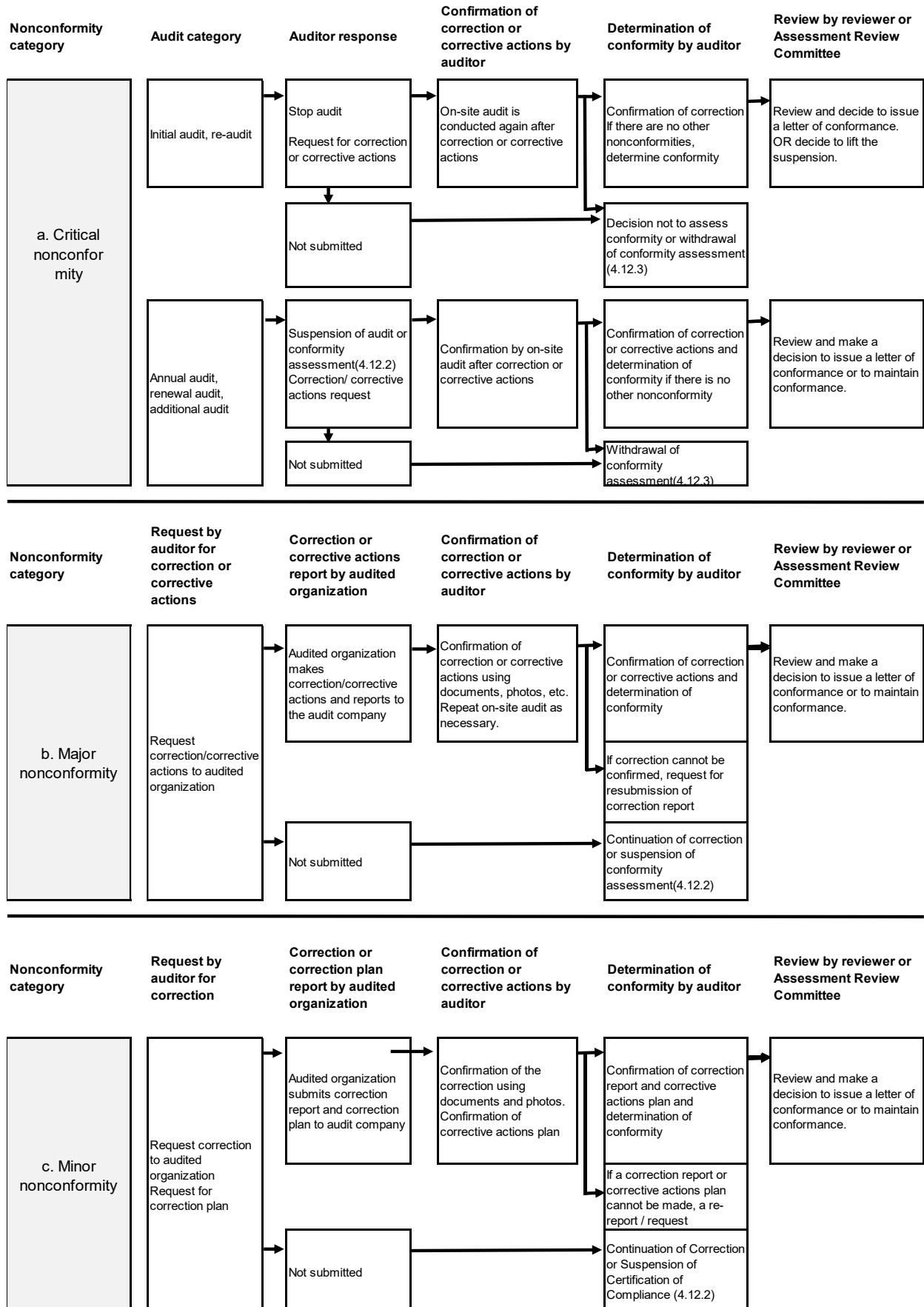
If the audit company and the auditor determine that the audited organization is nonconforming and request the organization to correct the nonconformity or take corrective action, after confirming that the nonconformity has been corrected, a determination of conformity shall be made and a review shall be conducted.

"Corrective action" is a measure taken to eliminate the cause of the nonconformity to prevent the nonconformity identified in the audit from recurring. The audited organization implements the action laterally to other lines and other departments and reviews the risks as necessary to prevent the recurrence of the nonconformity. The audit company shall confirm whether the corrective action is appropriate for preventing a recurrence and whether the nonconformity has recurred.

"Correction" is a measure to eliminate the nonconformity identified in the audit.

The audited organization shall take action to eliminate nonconformities that directly or potentially affect food safety as identified in the audit and to prevent the manufacture and shipment of non-conforming products.

The following figure shows the flow of the response procedure for each nonconformity category.



Annex 3 Standard Documents and Applicable Sectors

The following are the standard documents used for auditing organizations in this program, including the sectors and subsectors corresponding to each standard document.

Regarding the JFS Standard (Food Service) Sector: G, JFS Standard(Food Service · Multisite) Sector: GM, and the JFS Standard for sorting and packing facilities for fruits and vegetables for Thailand, in addition to this program, rules for auditing and conformity assessment shall be established separately.

Standard document	Sector symbol	Subsector symbol	Sector and subsector name
JFS-A Standard JFS-B Standard	C	CI	Processing of perishable animal products
		CII	Processing of perishable plant products
		CIII	Processing of perishable animal and plant products (mixed products)
		CIV	Processing of ambient stable products
JFS-A Standard JFS-B Standard	K	-	Manufacture of chemical products (including biochemical products) (Manufacture of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc.)
JFS Standard (Food Service)	G	-	Food Service
JFS Standard (Food Service)	GM	-	Food Service · Multisite
JFS Standard for Thailand	DT	-	Related to sorting and packing facilities for fruits and vegetables for Thailand JFS Standard

Note: Here, chemical products refer to food-related chemical products (including biochemical products).

Annex 4 Scope of Conforming Assessment, Experience in Work Related to Food Safety (Requirements for Auditors and Reviewers)

Examples of the scope of coverage by sector or subsector in the JFS-A/B standard and this program document and the work experience required for auditors/reviewers related to food safety are shown in Table 1.

Audit companies shall ensure that auditors/reviewers know the risks per the scope of application of the audited organization.

Examples of efforts to obtain knowledge include training, work experience, audit/audit experience, consulting experience, etc.

Table 1: Examples of industries and end products that fall into the sector/subsector

Sector or subsector	Applicable Industry *1	Example of end product *2
CI Processing of perishable animal products	Meat processing	Pork, beef
	Poultry processing	Chicken, duck meat
	Fish processing	Fish sashimi, fish fillets
	Seafood processing	Shellfish, seaweed, squid, cod roe
	Manufacture of meat products	Ham, sausage, roast beef
	Manufacture of fish meat products	kamaboko (fish cake)
	Manufacture of dairy products	Milk, yogurt, ice cream, cheese
	Egg processing	Eggs, boiled eggs
	etc.	Pet foods made exclusively from animal-derived ingredients
CII Processing of perishable plant products	Processing of fruits and vegetables	Pickles, fresh fruits, fresh juices (those requiring refrigeration), cut vegetables
	Processing of grains, nuts, and legumes	Tofu, almond milk, soy milk, soy meat, fried tofu
	etc.	Edible ice, ice cream, pet food made from plant-derived ingredients only, raw noodles
CIII Processing of perishable animal and plant products (mixed products)	Manufacture of meat products	Chilled side dishes, pizza, wheat paste products (shumai, dumplings), hamburgers, men chi-katsu
	Manufacture of fish meat products	Fried horse mackerel, fried fish cake with vegetables
	Manufacture of dairy products	Cakes, cream puffs, fruit yogurt, pudding
	Manufacture of non-heated eating and cooking products	Lunch boxes, side dishes, delicatessen, ready-to-eat foods, sandwiches
	etc.	Fresh pet food of mixed animal and vegetable origin
CIV Processing of ambient stable	Meat Products Processing	Dried meat
	Fish Product Processing	Fish tsukudani, dried fish
	Dairy Technology	Long-life milk (milk that can be stored at room temperature)

products	Food Processing	Freeze-dried products (miso soup, etc.), dressings, seasonings, cup noodles, chocolate
	Heat Processing	Canned products, retort pouch foods
	Baking Technology	Bread, biscuits, baked goods
	Brewery Technology	Miso paste, soy sauce
	Extrusion Forming Technology	Pasta, snack foods, shirataki
	Vegetable and animal fats	Oils and fats, dressings, sesame oil
	Sugar refining	Sugar
	Manufacture of beverages	Soft drinks, drinking water
	Manufacture of alcoholic beverages	Alcoholic beverages, sake
	etc.	Pet food stored at room temperature, salt
K Manufacture of chemical products (including biochemical products) (Manufacture of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc.)	Fermentation technology	Baker's yeast, enzymes
	Chemical engineering	Supplements, Food Additives, Vitamins
	Biochemical engineering	Amino acids, food additives

*1, *2 Not limited to these. May be classified differently depending on raw materials and manufacturing methods.

Annex 5 Experience in working with food safety for auditors and reviewers (JFS-A/B standards)

Auditors and reviewers must have work experience or auditing or consulting experience related to food safety in each sector or subsector in which they are registered. This experience is defined as food safety experience in a manufacturing environment. Examples of applicable experience are listed below. Examples of applicable experience include, but are not limited to.

Applicable Examples)

- Experience in manufacturing, quality control, quality assurance, etc. in food production
- Experience in internal audits, bilateral audits, vicarious bilateral audits, and third-party audits/audits (including non-certified mock audits conducted by the organization) of food manufacturing organizations using food safety-related standards
- Food safety consulting experience
- Development involving manufacturing, hazard factor management, etc.

Not Applicable Examples) *Experience in the following as well as experience listed in "Applicable Examples" may be considered as experience if it was performed at the same time.

- Experience in departments not directly related to food safety, such as sales, accounting, etc. in a food manufacturing company.
- Experience only in inspections in a laboratory.
- Experience only in dealing with insect and rodent control
- Experience in production, sales, quality control, etc. in a restaurant *Applies to food service
- Experience teaching lectures on food safety

Annex 6 Definition of Terms

The terms used in this program are defined as follows.

(1)	Organization	Food-related businesses, organizations, or individuals audited under the Program (hereinafter referred to as "Food-related Businesses")
(2)	Site	Places where food manufacturing, cooking, etc., subject to conformity assessment, is performed. Includes food manufacturing factories, their offices, and their premises.
(3)	Audit company	An audit company that has been approved by the audit company and Training Course Recognition Committee (2.2 (2) ①) and has entered into a contract with JFSM.
(4)	Training organization	An audit company that has been approved by the Training organization and Training Course Recognition Committee (2.2 (2) ①) and has entered into a contract with JFSM.
(5)	Consulting	Proposals that assist in establishing, implementing, or maintaining a food safety management system of an audited organization, and provide specific suggestions, directions, or solutions, that are separate from the audit (see 3.2).
(6)	Guidance	A proposal made by an auditor to an organization to correct or remedy a nonconformity found in an audit.
(7)	Suggestions	A proposal was made by the auditor to the organization to make the audited organization's food safety management system more effective and efficient, even though no nonconformity was found in the audit.
(8)	Conformity assessment	Proof that the initiatives of the audited organization are in compliance with the requirements of the conforming organization and are functioning effectively.
(9)	Remote Audits	An audit conducted remotely by auditors using ICT.
(10)	Observers	In the case of an audit, a person who accompanies the audit team but does not perform the audit (e.g., an auditor of the auditor's competence), and a person other than the audited organization who participates in the audit (e.g., a consultant, a visitor from another organization). In the case of a review, persons who are present at the review but do not perform the review (e.g., scribes, moderators, reviewers in training, etc.)
(11)	Top Management	Managers with executive responsibility for the audit project.
(12)	Training Auditor candidates	A person who is not a registered auditor, but who has completed audit training specified by JFSM, and who performs part or all of the audit process under the supervision of a registered auditor. The

		activities of training auditors are not included in the audit man-hours.
(13)	Stakeholders	All parties involved in food safety, such as organizations, audit companies, members, regulators, consumers, etc.
(14)	Sector	Scope of food-related operations subject to audits and certifications.
		*The scope covered by this program document is shown in Annex 3.
(15)	Subsector	Scope of a subcategory of the sector in consideration of food safety risks.
(16)	On-site audit	An audit is conducted within an audited organization's site by an auditor visiting the organization.
(17)	Walk-through audit	Audits are conducted by auditors on the manufacturing lines, buildings, facilities, equipment, surroundings, storage, etc. of the audited organization.
(18)	HACCP plan	A document or set of documents prepared under HACCP principles to ensure control of critical hazards in food operations. (From Codex General Principles of Food Hygiene 2020)
(19)	JFSM-DB	A database containing information on JFS Standard audit companies, auditors, organizations that have received conformity assessments (hereinafter referred to as "conforming organizations"), and approved training organizations.
(20)	Management or senior management (in the audited organization)	An individual or group that directs and manages an organization at the highest level. Note 1: Management has the power to delegate authority and provide resources within the organization. Note 2: When the scope of the management system applies to only a part of the organization, management is defined as the person or group that directs and controls that part of the organization. Note 2: When the scope of the management system applies to only a part of the organization, management is the person who directs and manages that part of the organization. (Adapted from the definition in ISO 22000:2018 3.41)

Documents for Reference / List of Forms and Templates

List of Forms and Templates

Definition of Forms and Templates		
Form: Documents to be submitted to JFSM, in principle, with the contents of the form.		
Template: A reference document for the documents that audit companies are required to prepare in the program documents. Please refer to these documents for each audit company and utilize them in your audit.		
The file location of forms and templates: Downloadable from the page for audit companies only.		
If you are not an audit company, please contact JFSM.		

List of Forms		
Program Documentation Related Section Numbers	Form #	Form file name
3.4	Form 1	Application for Sector Expansion of JFS Standards Audit and Conformity Assessment Services
5.2、5.3	Form 2	Competence evaluation table of auditors and reviewers for each sector and sub-sector
3.4	Form 3	Form for Application for Change of Registration of Audit Company for JFS Conformity Assessment Services
4.4	Form 4	Form for Notification of Information on Audit Outsourcing
3.5.4	Form 5	Form of Application for Withdrawal of Registration of Audit Company for JFS Conformity Assessment
3.4	Form 6	Form for Application for Additional Change of Registration of Auditor's Reviewer
3.4	Form 7	Form of Application for Withdrawal of Registration of Auditor/Reviewer for JFS Conformity Assessment
5.6	Form 8	Form of Application for Additional Change of Registration of Competence Auditor

List of Templates		
Program Documentation Related Section Numbers	Template #	Template file name
3.9	Template 1	Template Questionnaire for Organizations

4.2	Template 2	Template for Application for Audit and Conformity Assessment (for an organization to be audited)
4.3	Template 3	Template for Audit and Conformity Assessment Agreement (for the organization being audited)
4.3	Template 4	Template for Audit and Conformity Assessment Ledger template
4.9	Template 5	Template for a Letter of Conformance
4.5	Template 6	Audit Plan Template
4.5	Template 7	JFS-A Audit Checklist
4.5	Template 8	JFS-B Audit Checklist
4.5	Template 9	Audit Report Template
4.5	Template 10	Template for Corrective Action Request and Report
4.7	Template 11	Template for Record of Review (Meeting)
5.2, 5.3	Template 12	Template for Competence Evaluation Sheet for Auditors and Reviewers

Supplementary provision

Revision history

Document Number	Revision Number	Revision Date	Details
SP_101_01	R05	November 25, 2022	Establishment of Ver. 3.0

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