QCS is Certification Body of Florida Certified Organic Growers and Consumers, Inc. (FOG)

QCS
CERTIFICATION MANUAL
for
QCS US Food Safety Regulatory Compliance Program - FDA Third Party Certification (USFSRC-TPP)

This document contains the certification standards, policies and procedures for the operation of USFSRC offered by Quality Certification Services (QCS). QCS operates in accordance with the International Organization for Standards (ISO)/IEC 17065 *General Requirements for Bodies Operating Product Certification Systems*.

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Foreword

1. FSMA objective

Objective

FDA's implementing regulations for the Food Safety Modernization Act (FSMA) include Subpart M and Model Accreditation Standards, which sets out the requirements for the certification of human and animal food products with the objective to assure safe production. Subpart M and Model Accreditation Standards (MAS) Guidance establish the requirements for conducting audits of eligible entities, including farms and facilities, and to issue food and facility certifications.

FSMA/USFSRC Certification

Section 801(q) of the FD&C Act established a risk-based determination to require imported food or food offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act.

The system relies on independent third-party certification of eligible entities by a certification body (CB) accredited by a FDA recognized accreditation body (AB). These CBs conduct both consultative and regulatory (unannounced) onsite farm and facilities audits throughout the year. The CBs issue certificates to eligible entities who have successfully demonstrated compliance with the applicable 21 CFR rules and regulations.

2. Principles of USFSRC Certification

Quality Certification Services (QCS) provides impartial third party facility certifications in accordance with Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications (21 CFR Part 1, Subpart M) as well as FDA's Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff (MAS). QCS is the certification body of Florida Certified Organic Growers and Consumers, Inc (FOG). FOG is a not-for-profit grassroots membership organization committed to safe, ethical, and environmentally sound production of food and the preservation of natural resources, through good and sustainable farming practices. QCS is committed to providing transparent, impartial and quality certification services to its clients and constituents of the food industry. This Certification Manual contains the policies and procedures for those seeking USFSRC-TPP certification.

QCS meets the requirements for operating the USFSRC certification program, and is currently accredited as an ISO/IEC 17065 accredited CB by the ANSI National Accreditation Board (ANAB).

The purpose of the Certification Manual is to provide a basis of communication between clients and QCS, a guideline of the certification process for USFSRC certification, overview of the standards, and notification of fees for QCS services.

01 General Provisions

1.0 QCS Provisions

QCS offers impartial third-party certification in a non-discriminatory, impartial, confidential, transparent and competent manner.

1.1 Non-Discriminatory Certification Services[1]

QCS responsibly operates a non-discriminatory certification service. QCS does not make undue financial or other conditions nor discriminates against applicants based on the size or type(s) of operation(s).

QCS grants certification solely on compliance related to the scope of certification being considered. QCS does not certify or issue conditions to its clients based on the number of certifications already issued, nor on the basis of any of the clients' membership affiliations and/or associations to organic and food related industries. QCS will not place any undue financial or other consideration on clients to obtain certification services.

QCS services are also designed not to discriminate against any member because of race, creed, religion, marital status, sex, ancestry, age or national origin, and are administered in a non-discriminatory manner, which does not impede or inhibit applicant(s) access to the certification services of QCS.

1.2 Safeguarding Impartiality

QCS has identified that by the nature of this business there are several risks to the impartiality of certification. There may be conflicts that may rise from its relationships, activities and persons responsibly connected to the certification process. To prevent risks from arising that cause conflict with objectivity, QCS has systems in place to safeguard impartiality.

1.2.1 Risk from Type(s) of Service(s) & Scope(s) offered by QCS

QCS provides only those services as outlined in section 03 (Scope of Certification). QCS cannot design, produce, operate, install, supply, distribute products, process and provide services of the type(s) it certifies. QCS does not provide products or services that could compromise the confidentiality, objectivity or impartiality of its certification processes. QCS undertakes to remain free from commercial, financial, or other pressures that may influence the results of the certification process. As such, QCS does not provide consultancy services to its applicants or certified clients, pertaining to matters dealing with barriers to overcoming certification; nor does QCS imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used. QCS may direct applicants to resources on good agricultural practices for production and handling, and may answer questions regarding how standards are interpreted or applied.

[1] ISO/IEC17065 4.2.3

1.2.2 Risk from Type(s) of Services & Scope(s) offered by FOG (related entity)

FOG provides education and marketing resources that are available to the public and not customized for a specific operator. FOG may also direct QCS applicants to resources on good agricultural practices for production and handling, and may answer questions regarding how standards are interpreted or applied.

FOG strives to support and maintain QCS's provisions by providing products or services that would not compromise the confidentiality, objectivity or impartiality of QCS certification. FOG prevents impartiality by:

- Not designing, producing, operating, installing, supplying, and distributing products, processes and services of the type QCS certifies.
- Not having a direct influence or authority to put pressures on the QCS certification process.
- Not providing consultancy services to QCS applicants or certified clients, pertaining to matters dealing with barriers to overcoming certification.
- Not marketing or offering as linked with the activities of an organization that provides consultancy.
- Not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

If and when FOG were to offer or produce the certified product (including products to be certified) or offers or provides consultancy, the QCS management, those evaluating (records review and on-site audit) personnel in the review and making certification decisions are not to be involved in the activities of FOG, vice versa, the personnel of FOG are not involved in the management of QCS, the evaluation or the certification decision. The consultancy from the personnel must be well recorded, available upon request by QCS and personnel involved must have agreed to the confidentiality and impartiality requirements.

As FOG is a not-for-profit organization, at times product and cash donations are pursued for educational programs, workshops and project-based initiatives. The QCS program staff does not solicit any donations from certified entities or applicants for certification. The QCS program may not accept donations from certified entities or applicants for certification. Any knowledge of donations from an operation that is certified by QCS must not bias the management of an operations file and final decision of certification. The FOG personnel are the only personnel that are to know what donations are received and from whom the donations are received. In circumstances where QCS personnel are privy to discussions about donations, personnel must remove themselves from the discussions and/or declare those operations as potential conflicts on the Conflict of Interest Agreement.

1.2.3 Risks from Certification

QCS takes full responsibility for the granting, maintaining, suspending or withdrawing of certification, particularly regarding decisions on certification, considering appeals, and handling

complaints and disputes. QCS may contract evaluation services to auditors and may contract testing services to approved laboratories. This includes laboratory consideration for FSMA testing.

At all levels of QCS, provisions are taken to ensure that independence is maintained and conflict of interest is avoided.

- QCS's main method for preventing a conflict of interest from occurring is requiring all persons responsibly connected to the certification services of QCS; including Board members, committee members, personnel, contractors, subcontractors, to annually complete a conflict of interest disclosure. The Conflict of Interest Agreement describes the commitment to objectivity and by which persons disclose any perceived conflicts that could directly affect the objectivity of an operation'(s) certification (i.e. commercial, financial, family or relationship, or other pressures that could be perceived to compromise impartiality; including any consultancy provided within the last 24 months to an operation. Also, any bias that could indirectly create conflict to arise (i.e. over-familiarity, pressures, advocacy, intimidation, competition). QCS reviews all declarations and identify(s) any risk(s) to the impartiality of its evaluation, review and certification decision.
- Board members, committee members, employees, auditors, contractors and other personnel are not permitted to own, operate, have a financial interest in, manage or otherwise control an operation to be certified or any affiliate, parent or subsidiary of that operation; including those financial interests of spouses and children younger than 18 years of age.
- Board members, committee members, employees, auditors, contractors and other personnel cannot own or be owned by, managed by or controlled by any person that owns or operates an eligible operation to be certified.
- Employees, auditors, contractors and other personnel are not permitted to accept payment, gifts or favors of any kind, other than prescribed fees, from any business inspected and provided certification services.
- Auditors are obligated to refuse work beyond their realm of competence.
- Auditors may not audit anyone with whom they have a declared conflict of interest as described in QCS Certification Manual for USFSRC-TPP and the FDA-FSMA-TPP Rules Section 1.2 Impartiality.
- Auditors are assigned by Food Safety/GAPs Program Director or their assignee, based on scope of the audit, qualification of the auditor, proximity to operation and/or availability, cost and assessing any potential COI. Audit arrangements between operation and auditor are outlined in Section 5.3 of the QCS Certification Manual for USFSRC-TPP.
- QCS USFSRC-TPP personnel involved in the Certification process are bound by QCS, Confidentiality and Conflict of Interest policies. In the event a conflict of interest is identified with a USFSRC file, the committee member immediately notifies the Chief Executive Officer and excuses him/herself from the file review. The Chief Executive Officer appoints a temporary alternative qualified member.

QCS reconsiders a certified operation's or applicant's application for certification and if necessary performs a new audit if it is determined within 24 months of certifying the operation that any person participating in the certification process has or had a conflict of interest involving the applicant. All

costs associated with a reconsideration of application, including audit costs, shall be borne by QCS. QCS may refer a certified operation or applicant to a different accredited certifying agent for recertification and reimburse the operation for the cost for the recertification when it is determined that any responsibly connected person involved in the certification decision had a conflict of interest involving the applicant at the time of certification.

- QCS does not allow auditors to audit anyone with whom they have a declared a conflict of interest(s);
- Auditors are not permitted to conduct consecutive consultative or regulatory audits of the same client within 13 months. If there is insufficient access to qualified auditors in the country or region where the client is located, QCS will submit an online waiver request to FDA and assign the Auditor only once FDA has granted the waiver.
- QCS ensures that persons who make certification decisions are different from those who carried out the evaluation of the operation (i.e. the audit, closing of noncompliances).

1.3 Confidentiality

All persons responsibly connected to QCS; Board members, committee members, personnel, contractors and others maintain strict provisions for confidentiality with respect to QCS clients and do not disclose to third parties (with exception of compliance with the law, accreditation bodies, government agencies (i.e. FDA) or subpoena (when applicable) any business related information concerning any client obtained while implementing any regulations of the certification program exceptt for information routinely provided to the public by QCS, the AB, and FDA.

1.4 Public Information

QCS will maintain on its web site an up-to-date list of the eligible entities to which QCS has issued food or facility certifications under this program. For each such eligible entity, the web site will identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid the accredited third-party certification body any fee or reimbursement associated with such audit or certification. Other information deemed public by FDA and other Federal agencies will be made public available upon request.

1.4.1 QCS USFSRC-TPP Certification Manual

The QCS USFSRC Certification Manual is designed to outline QCS policies for consultative and regulatory audits in accordance with Accreditation of Third-Party Certification Bodies to conduct Food Safety Audits and to Issue Certifications (21 CFR Part 1, Subpart M) and MAS.
This manual includes a description of the relevant FDA-FSMA rules in the scope of QCS accreditation and information on the certification procedures for those rules operated by QCS.

The QCS Certification Manual is made available to the public upon request.

1.5 Competency

QCS operates USFSRC programs with competent individuals with the required experience, education and/or training. QCS, USFSRC auditors and decisions makers meet strict requirements before allowed to audit any eligible entity in accordance to FSMA standards and monitors them on

an ongoing basis. QCS also welcomes any constructive feedback from the operators on auditor performance.

02 Audit Categories

QCS provides consultative and regulatory audits for 21 CFR parts 112 and 21 CFR parts 117 in accordance with 21 CFR Part 1, Subpart M and the MAS Guidance document; as well as, 120: Hazard Analysis and Critical Control Point (HACCP) [Juice HACCP] and 123: Fish and fishery Products [Seafood HACCP]. Eligible entities must complete a regulatory audit and any other activities that may be necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations in order to receive certification. A single regulatory audit may result in issuance of one or more certifications, provided that the requirements of issuance are met as to each such certification.

2.1 Preventive Controls for Human Food (PCHF)

On September 17, 2015, FDA published Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. It creates new requirements for the production of human food by registered food facilities and revises previous requirements. This rule applies to foreign and domestic businesses that are required to register with FDA as food facilities because they manufacture/process, pack, or hold food for consumption in the U.S.

2.2 Produce Safety Rule (PSR)

On November 27, 2015, FDA published Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. The rule focuses on conditions and practices identified as potential contributing factors for microbial contamination of produce. It establishes requirements addressing routes of contamination including agricultural water; biological soil amendments of animal origin; worker health and hygiene; equipment, tools, buildings and sanitation; domesticated and wild animals; and conditions for growing, harvesting, packing and holding activities.

2.3 Seafood HACCP

On December 18, 1995, FDA published Seafood HACCP, which are the procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" that requires processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations.

2.4 Juice HACCP

On January 19, 2001, FDA published Juice HACCP that requires processors of juice to develop and implement Hazard Analysis and Critical Control Point (HACCP) for their processing operations

03 Scope of Audit

Applicants must specify on their application the scope of their audit. QCS only accepts FSMA Third-Party Food Safety Audit applicants whose audit scope is limited to the following FDA-FSMA Rules and FDA regulations in their scope of accreditation:

1) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR Part 112) (PSR)

2) Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food (21 CFR Part 117) (PCHF).

3) Hazard Analysis and Critical Control Point (HAACP) Systems [Juice HAACP] (21 CFR 120)

4) Fish and Fishery Products [Seafood HAACP] (21 CFR 123)

Applicants must specify if the request is for a Consultative audit or a Regulatory audit. Once initiated, the audit type cannot be changed.

The term consultative audit applies to audits used in preparation for a regulatory audit. Procedures for consultative audit is same as regulatory audit. For Regulatory and consultative audit requests, the applicant must provide a 30-day schedule of operations when products to be certified are being produced.

04 Labeling

4.1 QCS Certification Logo

Unauthorized or misleading use of the QCS logo and/or any FDA logo is prohibited and is treated as an infringement of copyright, and subject to penalty provisions to the full extent of any applicable civil or criminal laws governing fraud. Incorrect references to the certification system or misleading use of Sublicenses and Certification Agreements, certificates or marks found in advertisements, catalogues, or any other published documents is dealt with by suitable actions.

4.2 Use of FDA logo

The FDA logo is for the official use of the U.S. Food and Drug Administration (FDA) and not for use on private sector materials. To the public, such use would send a message that FDA favors or endorses a private sector organization or the organization’s activities, products, services, and/or personnel (either overtly or tacitly), which FDA does not and cannot do. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability*

From https://www.fda.gov/about-fda/website-policies/fda-logo-policy

05 Certification Steps

QCS certification steps are the overall process by which QCS ensures client's conformance with applicable standards.

5.1 STEP ONE - Application

Application forms and general information of the certification procedures and fees are available through QCS website or supplied to any applicant upon request.

The applicant is responsible for familiarizing him/herself with this information and the FDA-FSMA Rules. The application per each type of category of food safety audit must be completed and returned to QCS. If requested, additional application information is provided to the applicant.

5.2 STEP TWO - Application Check

Once QCS receives the application, QCS checks it for completeness and compatibility to comply with QCS requirements and the FDA-FSMA Rules. QCS determines if all regulatory issues indicated in the Regulatory Standing section of the application have been resolved.

If no further information is required a quote estimate of the cost of certification is developed and sent to the client for acceptance. Upon acceptance of the quote estimate by the client a Service Contract Agreement with QCS is sent to the client for signage. Furthermore, QCS ensures its capability to perform the certification services with respect to the certification criteria requested, the location of the operation and any special requirements such as language used by the applicant. If the applicant is not within scope of QCS accredited certification services, QCS declines services.

Once QCS receives the signed Service Contract Agreement, FSGAP staff registers the client in the QCS Database.

The applicant may withdraw his or her application at any time. An applicant must inform QCS in writing of his or her decision to withdraw an application. An applicant who withdraws his or her application shall be liable for the costs of services provided up to the time of application withdrawal.

5.3 STEP THREE – Audit

An initial audit shall be conducted for each operation requesting certification and will include the unit, facility and site(s) that produces and/or handles products/food included in an operation for which certification is requested. The applicant must provide 30-day operating schedule for such facility that includes information relevant to the scope and purpose of the audit.

To maintain USFSRC certification the registration of the client and the proposed products for the relevant scopes must be reconfirmed with QCS annually before the expiry date of the certificate. Subsequent recertification is conducted annually.

5.3.1 Assignment and Scheduling of Auditor

QCS assigns a QCS approved auditor, based on the following criteria or combination thereof for the specific type of operation to be evaluated:

a) Confirmation of appropriate education, training and experience to comply with FDA-FSMA TPP Rules for auditor competency;
b) Knowledge of the language; and
c) No prior affiliation or business relationship with applicant or certified operation being evaluated within an amount time as established by FSMA or QCS impartiality requirements as per Section 1.2 of this document.
d) An auditor is not assigned to conduct a regulatory audit of a facility if they have already conducted a consultative or regulatory audit of the same facility within a 13-month period. If there is insufficient access to auditors within the region of the facility, QCS submits a waiver request electronically to FDA. The auditor is then assigned only upon receipt of the waiver.
e) For USFSRC audits, an auditor is not to conduct more than 4 consecutive audits of the same eligible entity. The number of consecutive times an entity has been audited by the same auditor is tracked on the USFSRC Clients Deadlines excel document.
f) An assigned QCS approved auditor must meet the TPP program requirements for field observations prior to assignment once the QCS program has sufficient audit requests to make this practical.

5.3.2 Audit Plan Requirements

The auditor issues the applicant an audit plan to establish the time frame for the records review. The audit is scheduled in a reasonable time to cover all applicable FSMA rules and, for consultative audits, applicable industry standards and practices. The audit plan for a consultative or regulatory audit does not include the date or time of the unannounced on-site audit, which will occur after the records review and **within the established 30-day time frame indicated by the client in their application**.

For an USFSRC audits, the auditor contacts the applicant and both shall agree on the audit logistics. The auditor issues the applicant an audit plan to establish the audit date.

5.3.2.1 Prior to Audit

Before performing an audit, QCS provides auditors with the audit tools and guidance necessary for the auditor to complete a successful audit, including at minimum:

1) The applicable audit checklists and guidance documents for the audit scope requested;
2) Audit results of previous audits, and a record of any recent regulatory actions, and any
3) Requirements for audit report writing.

5.3.2.2 During the Records Review

The auditor reviews documents, records, record-keeping systems, and interviews personnel as needed to complete this phase of the audit. These activities may be performed on or off site.

The auditor confirms the product scope of audit if this step is performed onsite and communicates any discrepancies to the CB.

5.3.2.3 During the On-site Audit

The auditor conducts an Opening Meeting with an authorized agent of the operation in order to confirm the scope of the audit, explain methods of assessment, and recording of noncompliances. The auditor inspects all food, production units, facilities, premises and sites that produce or handle products and that are included in the request for certification according to the applicable FSMA rules and, for consultative audits, applicable industry standards and practices. Applicants must allow the auditor to have complete access to the production and handling operation, including non-certified production and handling areas, structures and offices. At present, auditors do not perform any sampling activities during an audit. Any future sampling activities will utilize a laboratory that is accredited in accordance to ISO/IEC 17025:2017.

5.3.2.4 Exit Meeting

The auditor conducts an exit meeting with an authorized agent of the operation in order to confirm the accuracy and completeness of the audit observations and the information gathered during the on-site audit.

At this time the auditor notifies the operator of the findings, observations, or of anything out of compliance with the standard and it will be presented in writing in the Draft Audit Report(s). The operator is expected to read all items described in the Draft Audit Report(s) and sign this document as acknowledgement that such items have been explained to him/her. The Draft Audit Report(s) and Checklist(s) is sent as soon as possible within 9 days to QCS as-is after the on-site audit.

QCS issues a Letter of Noncompliance with a specified timeframe for compliance, if operator does not comply with the standard. The operator may respond in writing to the noncompliances with information supporting its corrective actions. When compliance is achieved through methods that are reliably verify that correctives were taken and result that noncompliances are unlikely to recur, the auditor, as soon as possible within 9 days, forwards the Audit Report to QCS for CB technical review. For regulatory audits, as well as consultative audits, QCS makes the final certification decision within a maximum of 28 calendar days.

If necessary, the cost of any additional on-site audit to attest the implementation of corrective action(s) taken by client to close the raised noncompliances is the responsibility of the client. QCS may at any time of the certification decision process make request(s) for more information to determine compliance with the relevant standards.

5.4 STEP FOUR – Certification Decision

The QCS USFSRC Certification appointee is the sole authority to grant, deny, renew, suspend or cancel certification.

5.4.1 Certification Review

QCS Certification appointee conducts a ccertification and technical rreview of the Audit Report and supporting documentation (e.g. checklist) to determine the client's compliance with the regulatory standards per category and scope of certification to make the certification decision.

When a decision is reached, an appropriate communication or letter (i.e. granting), and certificate(s), if applicable, is sent to client. For regulatory audits, copies of completed Audit Reports are submitted to ANAB and FDA electronically, in English, within 45 days of the date the audit was completed.

5.4.2 Granting of Certification

If the applicant's operation is in compliance with the requirements of the applicable certification criteria, and QCS determines that the applicant has been and is able to operate in accordance with all applicable FDA-FSMA Rules and QCS's contractual agreements, then certification is granted. A single regulatory audit may result in the issuance of one or more food or facility certifications, provided the requirements of issuance are met and food or facilities are within the scope of certification.

If QCS has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, QCS may deny certification. FDA may refuse to accept any certification, if FDA determines that the certification is not valid or reliable.

5.4.2.1 Certificate

When certification is granted, QCS issues a paper certificate to the legal entity that meets FDA guidelines as established in 21 CFR § 1.653(b) 2015.

QCS notifies ANAB and FDA third party program before issuing the certificate and uploads the required documents in FDA's FURLS database.

5.4.3 Re-Certification (Continuation of Certification)

In order for a client to maintain certification with QCS, the certificate holder must:

a) Maintain compliance to the relevant FDA-FSMA Rules in the scope of certification,
b) Inform QCS of any regulatory actions initiated and/or changes in the operation (e.g. company and location information, production site(s)/product handling unit information, contact names, product information, production increases, etc.),
c) Annually pay the certification and audit fees, and
d) Successfully complete an annual audit per Section 5.3 Audit

5.4.3.1 Re-Certification On-Site Provisions

As a general rule, no more than 12 months should lapse without having an audit and preferably before the expiry date of the certificate. The registration of the client and the proposed products for the relevant scopes must be reconfirmed with QCS annually before the expiry date of the certificate.

5.4.3.2 Re-Certification Decision

Section 5.4.1 Certification Review applies.

5.4.4 Monitoring

Clients are required to inform QCS, in writing, of any regulatory deviations, or operational modifications, which extend or reduce their scope of certification already granted. These modifications may include, but are not limited to, changes in organizational structure or management and/or significant changes in the production process. If QCS has reason to believe that a client may no longer be in compliance with any applicable FDA-FSMA Rules, monitoring (including an on-site audit) will be conducted. QCS immediately notifies FDA electronically if it withdraws or suspends a certification. Records of monitoring will be maintained in English and made available to FDA and the accreditation body upon request.

5.4.5 Withdrawing Certification

Withdrawing certification is considered under the following circumstances:

1) QCS finds evidence of fraud and/or lack of trust in the operation's ability to comply with FDA regulatory requirements;
2) The establishment unduly delays, limits, or denies QCS access to the establishment, products, or records needed to verify compliance;
3) QCS finds that the establishment's status as described in the Regulatory Standing section of the Application has changed (e.g. a warning letter has been issued, an Official Action Indicated (OAI) classification has been made, an Import Alert has been issued, etc.)
4) The establishment cannot demonstrate evidence of the implementation of an effective corrective action
5) Contractual violation or non-conformance.

FDA is notified electronically immediately if Subpart M certification is withdrawn, as well as the basis for withdrawal.

5.4.6 Discontinuance of Food Safety Audit (Consultative or Regulatory Audit)

At any time clients may withdraw from QCS through written notification and are liable for the costs of services provided up to the point of withdrawal.

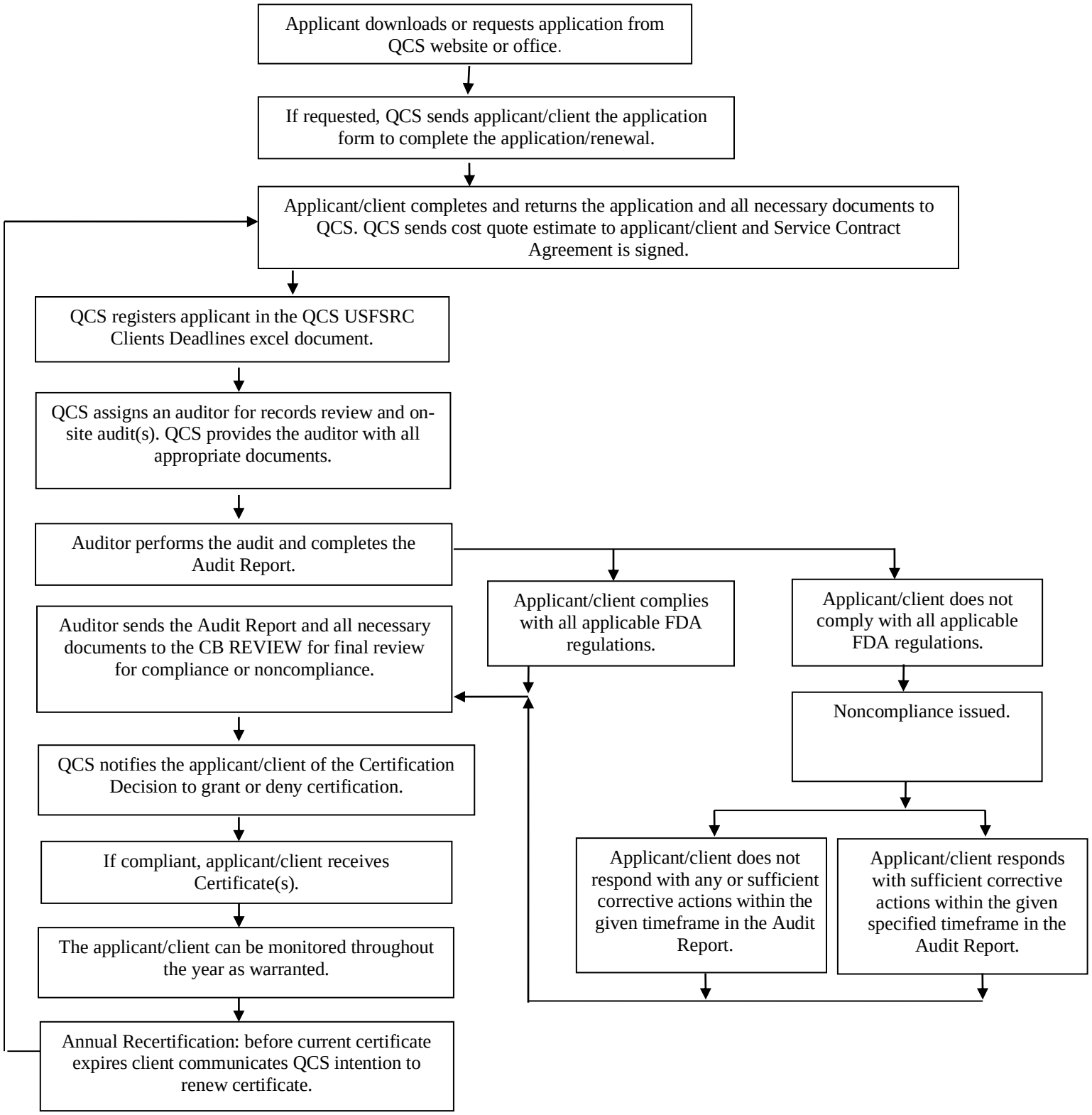
5.4.7 Transferring certification to other Certification Bodies

Clients wishing to change from their existing certifier to QCS or vice versa during the valid period of their certificate must complete a new application for QCS or their new certifier. QCS or the new certifier will conduct a complete check of the client's application.

Certified operations must notify their current Certifier of their intent to certify elsewhere. All applicants must first resolve any outstanding noncompliances before being able to transfer to a new CB or the outgoing CB must communicate knowledge of the noncompliances beforehand to the accepting CB.

The client must provide the new CB with the complete Audit Report issued by the previous CB along with any other necessary information for the new CB's assessment of eligibility for recertification. The new CB will also check the previous CB's web site listing to ensure the client is transferring a valid certification.

5.5 QCS USFSRC Food Safety Audit Process



06 Appeals

6.1 Appeals

Appeals are of adverse regulatory audit results. Appeals shall be made in writing to QCS and be accompanied by supporting documentation. The written appeal must provide sufficient detail and describe prior involvement in the operation at issue. A written appeal must be submitted within 14 calendar days of receipt of any notification regarding the certification decision. QCS acknowledges appeals received via email or letter.

The burden of establishing the invalidity of a certification decision rests with the filing participant. A record of all appeals will be maintained at QCS. Records of subsequent actions will be maintained along with follow-up to ensure the action was effective. QCS will review appeals in a confidential, impartial and timely manner, and decided by persons not involved with the original decision.

QCS designates qualified individual(s) who are free from bias or prejudice and have not participated in the certification decision or are subordinate to a person who has participated in the certification decision, to investigate and decide appeals. All records of the appeal process, the decision, and the basis for decision, are maintained by QCS as per 21 CFR 1 § 1.658 2015.

At the conclusion of the appeals process, QCS issues the appellant a letter outlining the appeal findings and the reasons for the decision.

07 Complaints

7.1 Investigation

QCS must investigate any complaint regarding clients' activities in relation to the applicable standards and complaints regarding QCS's certification operations. A complaint may come from either clients (e.g., producers, contract producers, processors, handlers, etc.) or from other parties such as interested stakeholders or the general public. Complaints must be submitted to QCS in writing and be accompanied by supporting evidence, including prior involvement in the operation at issue. QCS acknowledges complaints received via email or letter.

The Program Director/CEO or their designate conducts an investigation of the complaint. Personnel directly involved in the complaint do not investigate complaints. The investigation is conducted in a confidential and timely manner. If QCS identifies nonconformities during the course of an investigation, appropriate actions are taken.

7.1.1 Complaints regarding certified operations

QCS investigates complaints of noncompliance with FDA regulations concerning production and handling operations certified by QCS.

If a certified party or applicant refuses to cooperate in an investigation, QCS may deem this sufficient cause for denial or withdrawal of application or certification.

7.1.2 Complaints regarding QCS

If the complaint is against QCS services, QCS investigates the matter and if found valid, takes appropriate corrective and preventive action and resolution of any noncompliances found in products or services. These actions are taken, documented and the complainant notified of the outcome.

QCS maintains a record of all complaints as per 21 CFR 1 § 1.658 2015.

7.1.3 Complaint Monitoring by QCS Operations

QCS requires operators to keep records of complaints made known to it relating to compliance with certification requirements and makes these records available to the QCS when requested, and 1) take appropriate action with respect to such complaints and any noncompliances found in products that affect compliance with the requirements for certification and 2) document the actions taken.

08 Standard Revisions

8.1 Revision of FDA-FSMA Rules

Suggestions for changes to FDA-FSMA Rules must be directed to FDA. Please contact them directly. FDA regulations are subject to change at any time. It is the certified sites obligation to monitor and comply with any changes in a timely manner.

09 Fees

Fee Schedules appropriate for the certification scope may be downloaded from QCS website or are provided to requesting applicants/clients.

9.1 USFSRC Registration Fees

9.2 QCS Fee Structure

QCS evaluates fees periodically and are subject to change. QCS fee structure is formed by the following two components**:**

9.2.1 Certification Fee

Certification Fee is the base annual fee due each year for certification. The amount to be paid depends on the selected certification Option chosen in the application form and the complexity of the operation. This fee is in addition to the audit fees charged.

9.2.2 Audit Fees

Audit fees vary based upon the size and complexity of the operation inspected, the travel distance and the individual auditor assigned. All travel expenses are paid by the party to be inspected as well.

9.3 Collection Policy

Certification fee and FSMA registration fees are due at the time of issuance or denial of certification for a regulatory audit, or completion of a consultative audit. Upon withdrawal of application the entity will be invoiced for all administrative costs incurred to that moment. All invoiced fees are to be paid and are nonrefundable. Checks must be made payable to QCS and sent to the QCS office.

Auditing and certification services and the reimbursement of direct costs associated with an audit of an eligible entity occur only after the date on which the report of such audit is completed or the date a food or facility certification is issued.