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

QCS
QUALITY 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 operation in accordance with Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications (21 CFR Subpart M Parts 1, 11 and 16 and the Model Accreditation Standard Guidance Document (MAS). 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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TERMINOLOGY

Definitions used are derived from Subpart M and MAS.

(a) **The FD&C Act** means the Federal Food, Drug, and Cosmetic Act.

(b) Except as otherwise defined in paragraph (c) of this section, the definitions of terms in section 201 of the FD&C Act apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

Accreditation means a determination by a recognized accreditation body (or, in the case of direct accreditation, by FDA) that a third-party certification body meets the applicable requirements of this subpart.

Accreditation body means an authority that performs accreditation of third-party certification bodies.

Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third-party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

Assessment means:

(i) With respect to an accreditation body, an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of this subpart for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of this subpart.

(ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of this subpart.

Audit means the systematic and functionally independent examination of an eligible entity under this subpart by an accredited third-party certification body or by FDA. An audit conducted under this subpart is not considered an inspection under section 704 of the FD&C Act.

Audit agent means an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited third-party certification body.

Consultative audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices;

(ii) The results of which are for internal purposes only; and

(iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

Direct accreditation means accreditation of a third-party certification body by FDA.

Eligible entity means a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under this subpart conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under subpart H of this part.

Facility means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purposes of this subpart are not limited to facilities required to be registered under subpart H of this part.

Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food certification means an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food safety audit means a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

Foreign cooperative means an autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit third-party certification bodies under this subpart.

Regulatory audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and

(ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

Relinquishment means:

(i) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this subpart; and

(ii) With respect to a third-party certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this subpart.

Self-assessment means an evaluation conducted by a recognized accreditation body or by an accredited third-party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

Additional Definitions defined by QCS USFSRC program to verify compliance

Certification Decision: An attestation of a statement based on a decision following review that fulfillment of specified requirements has been demonstrated. Review and Certification Decisions may be performed concurrently.

Complaint: Expression of dissatisfaction other than appeal by any person or organization to QCS relating to the activities of QCS; whereas a response is expected.

Concurrently: An existing, happening, or done at the same time; review and certification decisions.

Conflict (direct, indirect): An issue declared by a person involved in the certification services that if not handled to safeguard the impartiality of the process must then be eliminated accordingly.

Declaration: The first party attestation.

Direct Accreditation: Accreditation of a third-party certification body by FDA.

Evaluation: includes 1) selection, 2) pre-review of application determination, 3) audit, 4) review of audit and certification decision.

Farm: FDA defines two types of farms under FSMA: Primary Production Farms and Secondary Activities Farms. A **Primary Production Farm** is an operation under one management in one general (but not necessarily contiguous) physical location devoted to growing and harvesting crops. The term "farm" also includes operations that:

1) Pack or hold raw agricultural commodities;
2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management; and
3) Manufacture/process food, provided that:
    a) All food used in such activities is consumed on that farm or another farm under the same management; or
    b) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
        i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (i.e. drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (i.e. slicing);
        ii) Treatment to manipulate the ripening of raw agricultural commodities (i.e. treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
        iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (i.e. irradiation).

A **Secondary Activities Farm** is an operation, not located on a Primary Production Farm, devoted to harvesting (i.e. hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm.

FDA-FSMA Rule(s): A term which refers to the FDA's seven Final Rule(s) described in 21 CFR (e.g. 21 CFR Parts 11, 16, and 112: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule). The names of specific FDA-FSMA Rule(s) may be abbreviated by QCS for internal purposes (e.g. Produce Safety Rule (PSR), Preventive Controls for Human Food (PCHF)).

Foreign Cooperative: An autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

Impartiality Mechanism: QCS Stakeholder Committee

Independent Contractor

Openness: To make policy(s) for certification available to the public; transparency.

Operator: A participant in the application and certification services.

Outsourced Service: Independent contractor that provides services for QCS; including inspection, sampling and laboratory(s).

Peer Assessment: Stakeholders demonstration that specified requirements of QCS for safeguarding impartiality.

Pre-review of application determination: Information on fulfillment of specified requirements (i.e. Letters request for more information).

Product: An operator's end product that is identified in the scope of certification.

Review: Verification of the suitability, adequacy and effectiveness of selection and determination activities and the results of these activities with regard to fulfillment with specified regulations. Review and Certification Decisions may be performed concurrently.

Safeguarding Impartiality: The Stakeholder's responsibility providing input and insuring polices and principles of impartiality are maintained throughout the certification process, ensure that prevention of commercial or other considerations do not affect impartiality of decision. Additional input on matters affecting impartiality and confidence in certification, including openness.

Self-assessment: An evaluation conducted by an accredited third-party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of accreditation. This involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Surrender: An operator's request to discontinue or not renew certification with QCS.

Withdrawal: An operator's request to withdraw from the application for certification.

1. Introduction

Florida Certified Organic Growers and Consumers, Inc. (FOG) is a not-for-profit grassroots membership organization that is committed to safe and environmentally sound production and processing of food and fiber. FOG encourages the preservation of natural resources, the improvement of soil quality and health through organic and sustainable farming practices. FOG operates an independent third party certification body, Quality Certification Services, (QCS) to verify organic production, handling and processing methods as well as several food safety and ethical schemes.

This manual is designed to comply with the general requirements of International Standards Organization (ISO) ISO/IEC 17065:2012, and the requirements of the FDA's TPP rule, (Subpart M) and the Model Accreditation Standard Guidance Document (MAS).

2. Mission Statement

The mission of Florida Certified Organic Growers and Consumers, Inc. (FOG), is to support and promote organic and safe and sustainable agriculture, and to create a more just food system. This mission is carried out through 1) educational programs to increase awareness of and demand for certified organic products and enhance public support of the industry; 2) organic and food safety certification programs for growers, processors, handlers and retailers; 3) promotion and support of policies that protect and encourage organic and safe and sustainable agriculture; and 4) complimentary programs that address viable local agriculture, food safety and security, farm land preservation, environmentally responsible farm management, workers and animal welfare, and organic production research.

3. Quality Statement

QCS is committed to providing a top quality certification body and consumer service, which enables buyers to purchase certified products with the assurance that they are certified according to 21 CFR (all applicable parts).

QCS's purpose is to manage and promote a quality certification body for on-farm and processed grown products. This is achieved with:

a) strict performance and compliant certification standards,
b) competent, trained auditors
c) being responsible for operating transparent and impartial certification services
d) a certification process that ensures thorough review and effective decision making
e) a staff of qualified and competent individuals.

QCS refrains from making false or misleading claims about its accreditation status, the ANSI National Accreditation Board (ANAB) accreditation program for certifying agents, or the nature or qualities of products identified.

QCS does not exclude from participation in or deny the benefits of the certification program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. Access to certification is not conditional upon the size of the supplier or membership of any association or group, nor is certification conditional upon the number of certificates already issued by QCS.

QCS management ensures that this policy is understood, implemented and maintained by having all personnel at all levels of the organization sign the Quality Policy Acknowledgement found on the last page of this manual.

4. Legal Status

Florida Certified Organic Growers and Consumers, Inc. dba Florida Organic Growers (FOG), is incorporated in the State of Florida as a non-profit corporation with membership comprised of organic processors, handlers, retailers, consumers, farm input suppliers, agricultural information providers, and growers either involved or interested in organic or safe and sustainable agriculture. FOG is a 501(C) (3) organization with the primary purpose of educating its members and the public about policies and practices that concern organic agriculture, certifying organic growers, processors and handlers, and promoting policies that protect and encourage organic and safe and sustainable agriculture. Quality Certification Services (QCS) is a registered "doing business as, dba" name to FOG.

5. QCS Organizational Structure

The Board of Directors delegates authority to the QCS staff to implement the certification body on its behalf.

The USFSRC Program Manager with designated FSGAP personnel assigns independent auditors for each operation that applies for certification.

Audit

1. Operations are audited according to QCS USFSRC Certification Manual STEP THREE Audit. The relationship between QCS and auditors, as well as the auditor requirements are described in Section 5.3 of the QCS USFSRC Certification Manual.

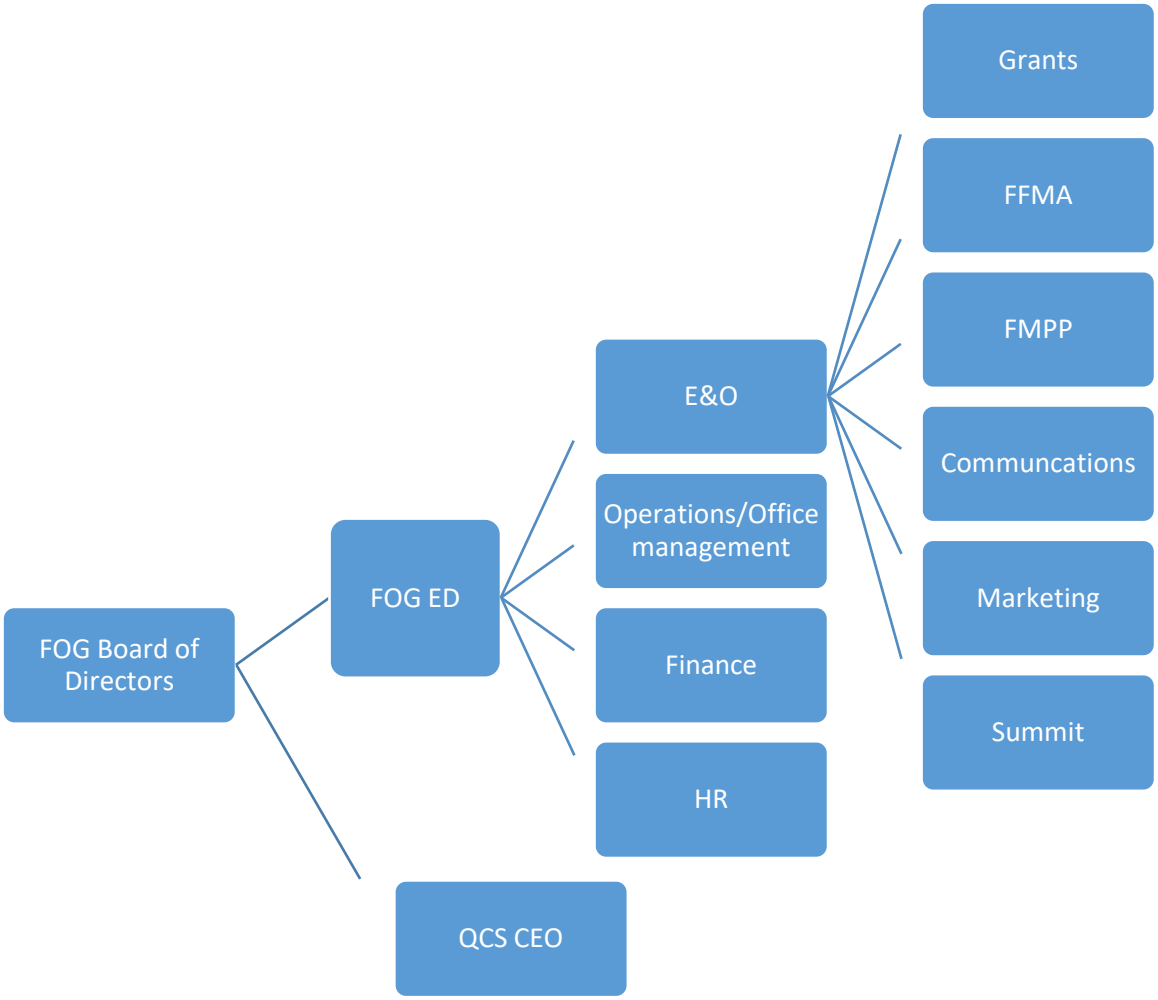
2. Auditors may not inspect anyone with whom they have a declared conflict of interest as described in QCS USFSRC Certification Manual Section 1.2 Safeguarding Impartiality.

3. Auditors are assigned by the USFSRC Program Manager or delegate based on scope of the audit, qualification of the auditor, proximity to operation and/or availability, cost and assessment of any potential COI. Auditors participating in the program must agree in writing to the notification requirements found in 1.650 Audit arrangements between operation and auditor are outlined in Section 5.3 of the QCS USFSRC Certification Manual.

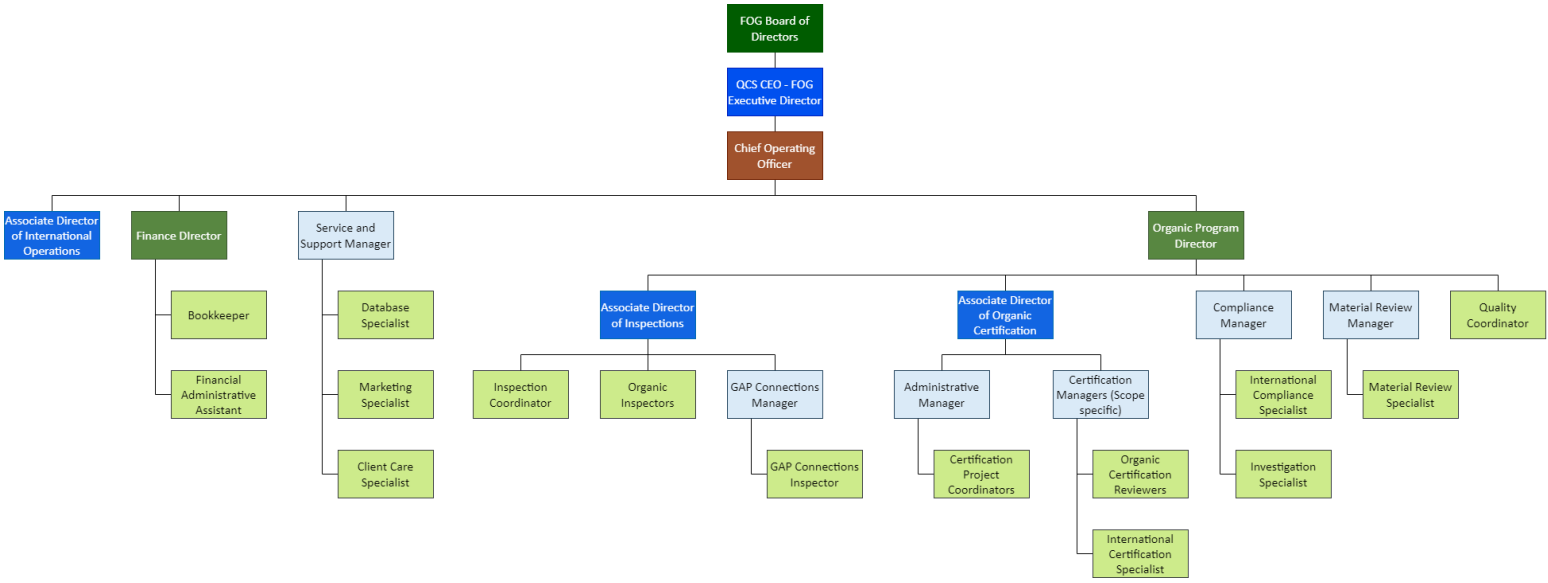
4. The completed Audit Report and Checklist(s) is sent to the Certification Committee. Auditors are required to provide information to the inspected operation, FDA and the third-party accreditation body as stipulated in Section 5.3 of the QCS USFSRC Certification Manual.

Certification Appointee The Certification Appointee remains responsible for certification decisions as specified in Section 5.4 STEP FOUR Certification Decision of the QCS USFSRC Certification Manual. The Chief Executive Director is responsible for overseeing the Certification Appointee .

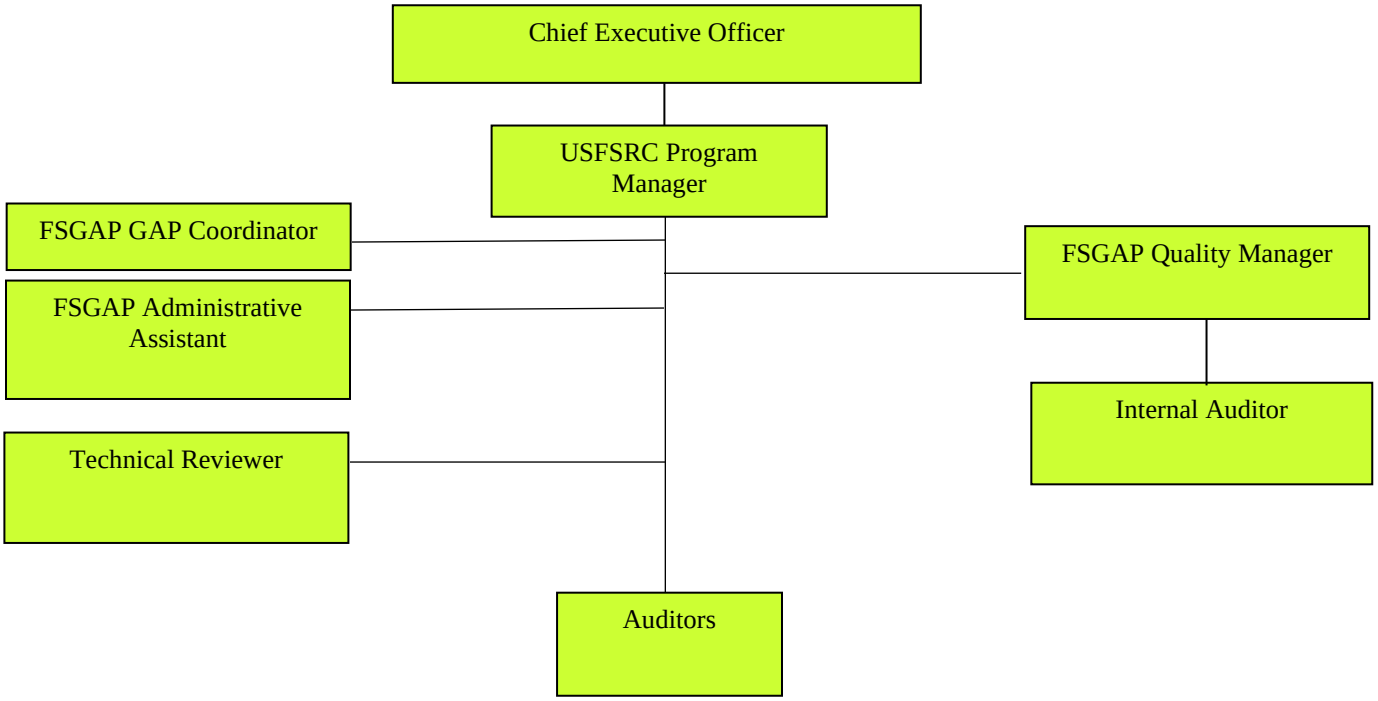
5.1 FOG/QCS Organizational Structure



QCS Organizational Chart



5.2 QCS USFSRC Organizational Structure



6. Board of Directors[1]

[1] ISO/IEC 17065 5.2

The Board of Directors is subject to the FOG Bylaws and the provisions of Florida Nonprofit Corporation Law. The FOG Board of Directors is comprised of key stakeholders with backgrounds in organic or sustainable agriculture, environmental stewardship, consumer advocates and/or research. The Board is selected by the Chief Executive Officer based on 1) that they are not certified operators of QCS and 2) consist of a balanced representation; such that no single interest predominates a single interest by vote; including but not limited to: internal and external persons, programs offered by QCS and scopes of operations certified by QCS.

For a current list of FOG Board of Director members, go to https://www.foginfo.org/about-us/our-team/.

The Board of Directors is authorized by QCS as the Stakeholder Committee. In this capacity, the QCS Stakeholder Committee is authorized as the mechanism for safeguarding impartiality for QCS. The committee oversees the policies and procedures implemented by QCS for preventing and handling conflicts are per the impartiality requirements of the QCS USFSRC Certification Manual. QCS provides resources to the Stakeholder Committee; including Management Reviews, any updates to the Quality Manual and other manuals, documents and agreements used to demonstrate QCS's commitment to providing objectivity certification services.

The Board is responsible for providing feedback to the Chief Executive Officer any issues with QCS's system for offering objective certification services. If the Chief Executive Officer does not follow the input related to impartiality, the Stakeholder Committee has the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders); only after appropriate action is taken to first try and resolve by both parties; which includes, respecting confidentiality; feedback that is in conflict with the operating procedures of the certification body or other mandatory requirements should not be followed until determined otherwise and Management should document the reasoning behind the decision to not follow the input to the Board. If this is unsatisfactory, the Board may take independent action. The FOG Board of Directors is also subject to the same Impartiality policies as the QCS staff, see Impartiality Policy, QCS USFSRC Certification Manual. Annually, the QCS CEO or his designee requires members of the Board to sign QCS documents; including the QCS Conflict of Interest and Confidentiality Statement Commitment Agreement. All COI will be countersigned by CEO or his designee.

Board Position	Name	Representation
President	Logan Petrey	Processor Handler, Food safety specialist of a large organic farm
Treasurer	Jesse Haskins	Attorney Food Regulatory
Secretary	Teresa Pemberton	Farmer and Sustainable food system advocate.

7. Safeguarding Impartiality Committee

Due to the nature of the balanced representation of stakeholders on the FOG Board of Directors, QCS authorizes the FOG Board of Directors as the mechanism for safeguarding impartiality for QCS, the Safeguarding Impartiality Committee.

As the Safeguarding Impartiality Committee, the FOG Board of Directors is delegated to oversee the policies and procedures implemented by QCS for preventing and handling conflicts are per the impartiality requirements of the QCS GLOBALG.A.P. Scheme Certification Manual.

QCS provides resources to the Safeguarding Impartiality Committee once per year via the Management Review report per Section 11, Management Review report. The Management Review report includes an overview on the inputs analyzed by management; including a review of the Risk to Impartiality Analysis report, statistical data on how many issues relating to conflicts of interest that QCS handled over the course of the report, any changes to policies and procedures pertaining to safeguarding impartiality in the Quality Manual, Certification Manual and supporting documents and the management's recommendation of output to improve, sustain or make changes to the structure for safeguarding impartiality.

The Safeguarding Impartiality Committee is responsible for providing feedback via the FOG Board of Director's minutes to the Chief Executive Officer regarding any issues with QCS's system for offering objective certification services. If the Chief Executive Officer does not follow the input related to impartiality, the Safeguarding Impartiality Committee has the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders); only after appropriate action is taken to first try and resolve by both parties; which includes, respecting confidentiality; feedback that is in conflict with the operating procedures of the certification body or other mandatory requirements should not be followed until determined otherwise and Management should document the reasoning behind the decision to not follow the input to the Board. If this is unsatisfactory, the Board may take independent action

8. Chief Executive Officer

The Chief Executive Officer is authorized by the Board of Directors to operate the QCS certification body; including responsibilities for:

- Ensuring adequate resources are available to operations (i.e. human resources, quality management)
- Delegation of responsibilities to competent committee members, personnel, contractors and subcontractors;
- Supervise the competency and monitoring of human resources;
- Supervise the QCS finances for the certification program(s);
- Supervise the management system; including the development and implementation of policies and procedures used to operate reputable certification program(s) (i.e. FSMA Rules);
- Supervise the activities and requirements for certification, evaluation, review, decisions on certification and related appeals;
- Supervise all complaints received by QCS related to the operations of QCS and/or FOG.
- Final decisions on all contractor and subcontractor agreements;
- Signatory of the Certificates issued by QCS.
- Ensuring that processes and procedures needed for the management system are established, implemented and maintained;
- Reporting on the performance of the management system and any need for improvement and/or resources, see Management Review.

For more information on other roles and responsibilities, refer to the Job Descriptions in the Human Resource folder in the Quality System.

9. Food Safety Director/Program Manager

For information on the roles and responsibilities of the Food Safety Director, refer to the Job Description found in the Quality System.

10. Auditors

I. Basic Job Requirements for Auditors

Auditors who are not staff considered employees of QCS but rather work as independent contractors. Auditors may be members of, employees of, and/or certified by certifying bodies, to support the principle of separation of the audit from certification decision-making and do not engage in activities that violate the conflict of interest statement as outlined in QCS USFSRC Certification Manual Section 1.2 Safeguarding Impartiality. Auditors are obligated to refuse work beyond their realm of competence. Any person interested in applying to be **an approved QCS auditor** may inquire through the QCS office and request the necessary information. Audits must be conducted in a professional manner. Auditors must complete audit reports and checklists as soon as possible after performing the audit and send to QCS administrative personnel within 9 calendar days. If deficiencies are raised during the audit the final report and evidence of corrective action(s) are sent to QCS administrative personnel within 9 calendar days after the last raised deficiency is closed by the client or at the time the deadline to close raised deficiencies is reached, whichever comes first.

II. Requirements of Auditors and Auditor Training

QCS's approved auditors perform audits as independent on-site auditors. Because these audits constitute an important source of information used in the development of a certification profile, only those individuals with extensive experience and requisite background are entrusted to perform these functions. QCS only contracts with auditors that meet **the criteria for CB auditors**. Auditors are required to provide information to the auditee/eligible entity as stipulated in Section 5.3 of the QCS USFSRC Certification Manual. Auditors are expected to complete QCS onboarding training and have full knowledge of QCS's certification program and requirements.

QCS' general process for approving auditors, determining requirements for approval to audit in a product/sector/scope will include at least 1 observed/witnessed audit before final approval. QCS will carry out witness and/or re-inspection for each of its auditors at least once every 4 years to verify competence. Where and if applicable, QCS will accept witness of its auditor from the accreditation body or FDA in-lieu of its own.

A complete list of QCS approved auditors can be found in the QCS USFSRC QUALS Log.

III. QCS Auditor Assignment

QCS generally attempts to assign the approved auditor who is nearest or least expensive for the eligible entity, but only to the extent that the auditor possesses the necessary expertise to conduct the particular audit, the auditor is available to conduct the audit in the necessary time frame, and the auditor is free from conflicts of interest in auditing the operation. QCS reserves the right to group audits in such a way as to allow an auditor from outside

the region to travel to conduct the audit when this becomes logistically or financially advantageous to the client. QCS assigns auditors solely at its own discretion.

IV. QCS Policy on Staff Members Working as Independent Contractor Auditors

Members of QCS staff who otherwise meet the QCS auditor qualifications to be an independent auditor may be engaged as an independent contractor to conduct audits for QCS or any other accredited certifier who chooses to contract with staff member, but such staff members engaged as independent contractors are governed by the following policies:

1. The privilege of allowing a staff member to conduct audits for QCS as an independent contractor outside of the staff member's regular work hours is granted or suspended solely at the discretion of the Chief Executive Officer.

2. The staff member operating as an independent contractor only performs contracted audits outside of their regular work hours.

3. Audits conducted as an independent contractor do not interfere with the staff member's regular duties or result in the staff member being absent during their regularly scheduled hours at QCS.

If a QCS staff member conducts an audit of an operation for certification as an independent contractor, that staff member does not play any further role in the decision to grant or deny the certification, nor the discussion of the decision to grant or deny certification to the inspected operation. The staff member may clarify what was written in their inspection report or clarify what they observed during the inspection. This prohibition is in effect for 12 months following the inspection.

The Chief Executive Officer approves all audit assignments to QCS staff members acting as independent contractors outside of their regular work hours.

No QCS staff member acting as an independent contractor providing audit services is assigned a particular audit if assigning the QCS staff member would result in the entity's audit costs being higher than if the auditor located closest to the audited party conducted the audit.

V. Disciplinary Action

The Chief Executive Officer has the right to remove auditors from the approved list if they fail to perform their duties in a satisfactory way.

1. The Chief Executive Officer or USFSRC Program Manager reviews any complaints received concerning individual auditors. Such complaints must be submitted in writing to QCS.

2. The FSGAP Senior Coordinator and/or designated person notifies the auditor of the complaint(s) and a discussion of the issues may be conducted in writing, in person or by telephone.

3. The USFSRC Program Manager is responsible for process certification, document control, internal audit activities and addressing any deficiencies.

4. If the Chief Executive Officer feels there are sufficient problems to warrant an official warning, the Administrative Manager submits a memo to the auditor's file with a copy sent to the auditor. The auditor has the opportunity to respond.

5. The Chief Executive Officer and USFSRC Program Manager have the authority to remove an auditor from the approved list if deemed appropriate.

6. Auditors may be released from their contracts at will. Grounds for immediate removal of an auditor may include the following: theft, dishonesty, falsification of an inspection report or other QCS documents, solicitation of growers, acceptance of a gratuity that may influence the judgment of the auditor, breach of confidentiality, or other offences that violate QCS policy or procedure.

11. Certification

QCS certification appointees are selected and authorized by the Chief Executive Officer to have the overall responsibility for the decisions on certification and have the technical basis for granting certification.

QCS certification decisions are typically made by the CEO or designee During the initial launch of a new program, certification appointees are comprised of program personnel with the following experience:

- At least five years' full-time experience in food or associated industry, including two years' work in quality assurance or food safety functions in food production or manufacturing, retail, inspection, or enforcement, or the equivalent;
- Other formal qualifications (e.g., an advanced degree) as a substitute for a maximum of three years of working experience towards five years of experience.

QCS certification appointees are bound by QCS Confidentiality and Conflict of Interest policies. In the event a conflict of interest is identified with a file, the proposed appointee immediately notifies the Chief Executive Officer and excuses him/herself from the file review. The Chief Executive Officer appoints a temporary alternative qualified certification appointee .

12. 3rd Party Services Contracting

QCS contracts all testing services with competent third party laboratories. All laboratories used in food safety programs must be accredited to ISO/IEC 17025.

The hiring of 3rd party services does not absolve QCS from its responsibilities for the services of granting, denying, maintaining, suspending or withdrawing certification, and as such QCS takes full responsibility for work done by contracted service providers such as laboratories. When QCS contracts work related to certification to an external body, or person, an agreement covering conflict of interest and confidentiality is signed.

Auditors must meet QCS requirements described in Section 11 to be approved. See Section 8 for auditor evaluation and review procedures.

13. Human Resource Requirements

The Chief Executive Officer is authorized to oversee all responsibly connected to operating the daily functions of the certification programs.

The QCS Human Resources Tracking Form provides a current list of QCS personnel, contractors, and committee members.

The Personnel Manual includes the procedure for the recruitment, selection, training, and monitoring of personnel. Minimum competencies for all staff and auditors are outlined in the QCS Job Descriptions. The qualifications and experience of each employee can be found in the individual's personnel file.

All QCS staff must sign an acknowledgment that they have read and understand the Personnel Manual and the Quality Manual.

QCS employs a sufficient number of qualified staff to perform certification functions as determined by the Chief Executive Officer.

Conflict of Interest
All persons responsibly connected to FOG & QCS certification services including the Board of Directors, personnel, committee members, contractors, contractors must agree to the QCS USFSRC Certification Manual, Section 1.2 Safeguarding Impartiality.

Confidentiality
All persons responsibly connected to FOG & QCS certification services including the Board of Directors, personnel, committee members, contractors, subcontractors must agree to the QCS USFSRC Certification Manual, Section 1.3 Confidentiality.

Performance Monitoring
The QCS Chief Executive Director is evaluated annually by the Board of Directors.

All other certification staff and subcontractors receive annual performance reviews from the Chief Executive Officer or their delegate. The review includes full knowledge of the QCS USFSRC Certification Manual and standards, knowledge of the Certification Process, accuracy in file maintenance, interaction with staff and certification applicants, as appropriate.

The USFSRC Program Manager reviews auditors on an annual basis. Auditors are reviewed regarding the timeliness of their Audit Reports and Checklist and the clarity and completeness of these documents. Auditor

evaluation forms are sent to clients and are filled out on a voluntary basis. These reviews are kept in the auditor's file and used during the annual review of the auditors.

These performance reviews, along with internal audits, are to ensure that the certification process is carried out efficiently and in compliance with 21 CFR (all applicable parts) requirements, ISO/IEC 17065 guidelines and QCS standards.

All staff is informed of the outcome of their evaluation. Any corrective action is expected immediately. All performance evaluations are filed in the individual's file.

14. Certification Procedures

Certification Flow Chart
See Section 5.5 of the QCS USFSRC Certification Manual for the Certification Process flow chart.

Application
See Section 5.1 of the QCS USFSRC Certification Manual for Administrative Procedures for applying for certification.

Audit
See Section 5.3 Audits of the QCS USFSRC Certification Manual.

Certification Review
See Section 5.2 Application Check and 5.4 Certification Decision of the QCS USFSRC Certification Manual for the certification review process.

Noncompliance, Suspension and Withdrawal
It is the responsibility of the client to understand and comply with 21 CFR (all applicable parts) and standards of certification. See Section 5.4 Certification Decision of the QCS USFSRC Certification Manual for procedures regarding deficiencies, suspension and withdrawal of certification.

Appeals
The procedural steps in the appeals processes are addressed in Section 6 Appeals of the QCS USFSRC Certification Manual.

15. Self Assessment (Internal Audits)

Internal Audits

Performing internal audits is a preventive measure taken by QCS to ensure that the certification body is operating efficiently and in compliance with appropriate criteria and standards and results of previous internal and external audits, the Lead Auditor performs various internal audit activities during the course of each year. QCS's internal audits are normally be performed at least once every 12 months, or completed within a 12- month time frame for any additional or segmented internal audits. Internal Activities may include performing document reviews, completing checklists for accreditation reviews, reviewing certification and personnel files, interviewing management, etc. QCS may perform internal audits to demonstrate preparedness for accreditation visits, compliance to standards updates and effectiveness for operating certification in compliance with requirements and standards.

Internal Audit activities are carried out in accordance to ISO/IEC 19011. At the beginning of each activity, the Lead Auditor issues an Internal Audit Plan to the USFSRC Program Manager. The Internal Audit Plan is presented to the management at an Opening Meeting. If approved, the management signs and dates the report. The Internal Audit Plan identifies the primary scope(s) to be verified for compliance during the course of activities. The Internal Audit plan also identifies references that may be used, as well as an overview of any conflict of interest issues (i.e. backups for auditing areas for which the auditor cannot audit their own work). The plan also provides a tentative schedule for the timeframe for which activities are to be conducted. This timeline is flexible and is reissued at the closing meeting, as well as reset at the next Opening Meeting. The intent of the schedule is to ensure over the course of 12 months that all necessary activities are performed to conclude that all areas of compliance have been verified by the Lead Auditor. The Internal Audit Plan also identifies the type(s) of activities that may be used by the Lead Auditor to perform verifications (i.e. document reviews, interviews, etc.).

For performing the internal audit, the Lead Auditor sets up an internal audit folder in the Quality System that is active; meaning it's not a controlled folder but one that transparently demonstrates the various activities, records and verifications that the Lead Auditor is working on during the course of an internal audit. The Lead Auditor uses an Excel Checklist that is loaded with various compliance criteria and activity notes. The Lead Auditor is only responsible for marking which areas have been performed; notes are only required when a noncompliance is identified. The Lead Auditor may opt to provide as many notes as necessary to record activity(s).

Once the Lead Auditor comes to a reasonable stopping point, an Internal Audit Report is issued to the management at an Exit Meeting. The report contains a brief overview of activities and the number of noncompliance(s) found during the activity(s). It also includes a schedule, which identifies areas that may need to be transferred to the next internal audit activity(s) and lists all the noncompliance(s) identified by the Lead Auditor. During the Exit Meeting, management review these findings, and may dispute or challenge any of the findings with the Lead Auditor. If the Lead Auditor finds the dispute(s) justifiable, the findings may be dropped and the reasons for that are recorded in the Internal Audit report in the notes section. After the meeting, the updated Internal Audit report is then sent to top management for their signatures of approval.

The Lead Auditor should explicitly should state in the Internal Audit Report compliance their assessment for the requirement of Subpart M § 1.622

After each Closing Meeting, the Internal Audit Report is sent to the Quality Manager who then creates a Corrective Actions report and loads it with the criteria and noncompliance(s) from the Internal Audit Report. The

report is then provided to the USFSRC Program Manager and handled in accordance to the Corrective Actions Process.

A copy of the complete Internal Audit Report is submitted to the accreditation body within 45 days of the anniversary date of its accreditation. A copy of the complete Internal Audit Report is also submitted electronically to FDA upon request within 60 days of the request, along with an up-to-date list of all auditors qualified by QCS to conduct USFSRC audits.

To conduct internal audits, QCS uses persons knowledgeable in certification, auditing and the requirements of ISO/IEC 17065 and have experience performing internal audits. Additionally,

1. Auditors do not audit their own work;
2. Auditors work is independent of the evaluation, review and certification decision making process.
3. Personnel responsible for the area audited are informed of the outcome of the audit;
4. Any actions resulting from internal audits are taken in a timely and appropriate manner; and
5. Any opportunities for improvement are identified.

16. Corrective Actions Process

QCS identifies and manages deficiencies in its operations received from internal and/or external audits. QCS then takes action(s) to eliminate the causes of deficiencies in order to prevent recurrence. QCS implements corrective actions, appropriate to the impact of the problems encountered.

QCS's Corrective Actions Process:

1. identifies deficiencies (e.g. from complaints and internal audits);
2. determines the causes of deficiencies;
3. corrects the deficiencies;
4. evaluates the need for actions to ensure that deficiencies do not recur;
5. determines and implements the actions needed in a timely manner; and
6. records the results of actions taken;

The USFSRC Program Manager is responsible for ensuring that Corrective Actions are carried out in a timely manner. The Administrative Manager; along with Quality Manager and USFSRC Program Manager and any other necessary personnel key to the success of the corrective actions may meet to perform any of the above processes. The Administrative Manager sets up monthly meetings; sometimes more frequently based on the number of issue(s) to continuously monitor progress and effective implementation and communicate as necessary to the Lead Auditor, Accreditation Body(s), etc.

17. Preventive Actions Process

QCS takes preventive actions to eliminate the causes of potential deficiencies. The preventive actions are appropriate to the probable impact of the potential problems. The preventive actions process includes the following:

1. Identification of potential deficiencies and their causes;
2. Evaluation of the need for action to prevent the occurrence of deficiencies;
3. Determination and implementation of the action needed;
4. Recording the results of actions taken; and
5. A review of the effectiveness of the preventive actions.

Examples of Preventive Actions QCS uses includes the following:

- Implementation of the Quality Manual;
- Publication of a Certification Manual to its Operators;
- Annual Performance of Internal Audits and Corrective Action Process(s);
- Annual Management Review(s) and
- Ongoing Document and Record Control(s).

18. Management Reviews

The Chief Executive Officer and the top management of QCS reviews its quality management system annually in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of ISO/IEC 17065. The management review, decisions and directives are recorded in the official meeting minutes.

Management Reviews consist of defined review inputs and outputs. The QCS top management; review the system and report on the following inputs:

1. Results of internal and external audits;
2. Feedback from clients and interested parties (including scheme owners) related to the fulfillment of ISO/IEC 17065;
3. Feedback from the mechanism for safeguarding impartiality;
4. The status of preventive and corrective actions;
5. Follow-up actions from previous management reviews;
6. The fulfillment of objectives;
7. Changes that could affect the management system; and
8. Appeals and complaints.

After taking the inputs into consideration, the QCS top management provides the decisions and actions QCS provides outputs as follows:

1. improvement of the effectiveness of the management system and its processes
2. improvement of the certification body related to the fulfillment of ISO/IEC 17065:
3. resource needs

As part of providing QCS Stakeholder Committee adequate access to safeguard impartiality, QCS annually or more often as applicable; provides the Management Review report to the Stakeholder Committee to review.

19. Records

The client's certificate, the application, the audit report, checklist and supplemental information are filed at the QCS office and contain up to date, relevant information, including history, and product specifications. The records demonstrate the way in which each certification procedure was applied, maintained transparently, and enabling easy retrieval of information. For QCS clients, separate records are kept for major violations and resulting sanctions, appeals, and complaints, in a way that enables easy retrieval of such data.

Authorized personnel sign audit reports, certification decisions, certificates and other relevant records. The QCS office prints all certificates with the original sealed certificate sent to the applicant and copies placed in the client's files.

QCS database is maintained with up-to-date information. The database is updated annually at the time of renewal or as needed.

Client files are only accessible to QCS employees, certification staff, auditors, Board of Directors, Food & Drug Administration, the accreditation body and law enforcement authorities. See Section 19, Release of Records for policies on the release of documents.

Personnel files are maintained to include the name and address; employer and position held, educational qualification and professional status, experience and training, the assessment of competence, performance monitoring, authorizations held and date of most recent updating of each record.

QCS maintains records to be identifiable, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. QCS must maintain records according to the following schedule:

a)	4 years from their creation	Records pursuant to 21 CFR §1.658
b)	Excluding any records covered by a), must be maintained for not less than 5 years beyond their creation or receipt	Records created or received by QCS pursuant to the accreditation requirements of ANAB

Records in the above schedule must be maintained beyond the allotted time before disposal. Proper disposal may include shredding.

20. Document Control

QCS encourages all persons significantly affected by the policies, principles and functioning of the certification system, to participate in their development and improvements of the Quality System.

The documents used in QCS's Food Safety Program are developed by QCS to address the individual program needs; including general QCS documents, scheme standards and documents and any applicable ISO standards. These documents are located in the QCS Quality System. The most current version of these documents are

registered in the QCS Quality System on the main server. All QCS staff have access to the Quality System at all times.

Document changes can be requested at any time. Staff members are encouraged to communicate with the Chief Executive Officer, the USFSRC Program Manager, Quality Manager, or the Administrative Manager to request a change to a document. If management deems the change necessary, the change is made to the documents by the requester or requested of the Quality Manager to perform the task(s). Once the document has been developed or modified, the Quality Manager presents it to management. Documents are controlled in the Quality System upon their approval and are effective once formalized in the quality system. The process of controlling the document is recorded on the Quality Systems Master List of Documents/Records. The Quality Manager notifies management when the document is controlled. Management is responsible for ensuring that the document is fully implemented by QCS. Every 15 days, the Quality Manager or Administrative Manager issues a notice to management of all documents that have been controlled in the past 15 days.

Staff members are informed of document revisions during weekly staff meetings. Staff must always source their documents directly from the Quality System. All persons operating in accordance to the Quality System; at minimum including adherence to the quality manual and the use of documents located in the quality system must use the most current versions located in the Quality System and may not use any uncontrolled documents. Any use of uncontrolled documents jeopardizes QCS's accreditation and compliance to accreditation criteria and scheme standards.

Documents are effective the day they are added to the Quality System. This date is located in the footer of each document, or in the master list of documents. It is the responsibility of the document user to verify that the document being used is the latest version, particularly before a mass release or usage of such document. The document user may refer to the most recent registered Master List of Documents/Records to verify which version of the document should be used. Users of controlled documents are not allowed to remove the document control numbers from the documents retrieved from the quality system.

In cases of significant changes (i.e. physical location, CEO, scopes, Certification Manuals, Quality Manual, etc.), QCS must notify FDA, in English, within 30 days after making any significant change that would affect the manner in which QCS complies with the USFSRC program. The notification must include a description of the change and the purpose of the change.

21. Release of Records

All QCS staff are authorized to release any records in a member’s file to the public according to the following guidelines. Everyone involved in the certification process including staff, Executive Director, CEO, Managers, Inspectors, and the Board of Directors are required to treat all information and records as confidential except for information routinely available to the public. Any information relevant to an operation’s certification status supplied to QCS by the operator, the public or collected in the course of a QCS inspection becomes the property of QCS.

Audit reports and checklists or other confidential client documents are not normally made available outside the certification system. However, these documents may be released with the following guidelines:

1. The applicant may request in writing the release to a third party his/her audit report and/or checklist.

2. QCS releases any and all documents to law enforcement authorities, Food & Drug Administration, & accreditation bodies as requested.