

**ANSI Gap Analysis Report  
Voluntary Pilot Program  
FDA Food Safety Modernization Act (FSMA)  
Third Party Implementation  
21 CFR Parts 1, 11 and 16**



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## I. GENERAL INFORMATION

The American National Standards Institute (ANSI), coordinator of the U.S. voluntary standardization system, initiated a Voluntary Pilot Program to perform a gap analysis between existing standards for ANSI-accredited food safety certification bodies and the new Food and Drug Administration/Food Safety Modernization Act (FDA/FSMA) regulations for Accreditation of Third-Party Certification Bodies (CB) to Conduct Food Safety Audits to Issue Certifications (21 CFR Parts 1, 11 and 16; Subpart M - Final Rule). The pilot program was initiated in May 2016 and completed in March 2017.

The purpose of the Voluntary Pilot Program was to perform a gap analysis of ANSI-accredited Food Safety certification bodies' implementation of FDA/FSMA Final Rules and the ISO/IEC 17065:2012 requirements. The purpose of the assessment was not to complete the accreditation process and issue accreditation certificates but to gauge the readiness of applicant accredited certification bodies to implement the FDA/FSMA Final Rules. Reports were issued to each applicant and a letter of appreciation was sent to the seven applicants that completed the process.

The FDA released the final guidance on "Third-Party Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA staff" and Fee Structure after the start of this pilot program. ANSI is planning to submit an application to the FDA when the process for accepting applications to become an FDA/FSMA-recognized accreditation body is announced. After the FDA formally recognizes ANSI as an accreditation body, ANSI will officially launch the accreditation program in accordance with FDA/FSMA requirements.

This represents the final report on the outcome of the Voluntary Gap Analysis Pilot Program conducted by ANSI.

## II. PREPARATION

ANSI held an information session with all certification bodies accredited by ANSI to Food Safety Scope(s) on May 20, 2016 to review the FDA/FSMA "21 CFR Parts 1, 11 and 16" and the future role of third-party certification for the Foreign Supplier Verification Program (FSVP) and the Voluntary Qualified Importer Program (VQIP) as well as the Model Accreditation Standards that had been issued for public comment. The objective of this session was to explore the level of interest in participating in a voluntary pilot program to perform a Gap Analysis with Food Safety certification bodies accredited by ANSI.

A total of 45 individuals attended the May 2016 meeting. This total included 35 representatives from 20 certification bodies, 8 ANSI staff members and 2 members from the ANSI Accreditation Committee for Product Certification (ACC).

The objectives of the meeting were to:

- (1) Present the GAP Analysis process;
- (2) Answer questions on the process;
- (3) Present the status of the FDA program; and
- (4) Determine the potential interest of attendee ANSI Accredited Certification Bodies (ACB) in this voluntary Gap Analysis.

At the meeting, ANSI staff and assessors presented the process for the Voluntary Gap Analysis Pilot Program and sought input on the process from stakeholders. Based on positive input from all parties, ANSI launched the Voluntary Gap Analysis Pilot Program, accepting applications from June 9, 2016, to July 8, 2016.

ANSI developed forms for this Voluntary Gap Analysis Pilot Program as well as a cross reference to the ISO/IEC 17065 requirements. (See Annex 1 to this report.) Each certification body reviewed the process, prepared supporting documentation, and submitted the entire package to ANSI. An assessment team was assigned to and accepted by each certification body applicant. The assessment team contacted the certification body to make arrangements for both the remote office assessment and an observation (witness assessment) of an audit conducted by the certification body on its client. The assessment team was composed of a lead assessor and a technical assessor. The lead assessor prepared agendas and conducted a remote office assessment, while the technical assessor performed an on-site assessment and if applicable, a witness assessment.

During this Voluntary Gap Analysis Pilot Program, ANSI staff and assessment teams responded to several e-mails and participated in many conference calls with representatives of the accredited certification body participants in this pilot to provide information and clarify requirements related to the FDA/FSMA documents.

ANSI received twelve (12) applications. ANSI had already accredited all applicants in accordance with ISO/IEC 17065, in food safety scopes. Seven (7) of the applicant accredited certification bodies completed the process by March 31, 2017. Five (5) applicants were not able to complete the process for various reasons. For example, the personnel of one applicant did not have sufficient time to fully document and implement the recently released rules. Each participant completing the process received a report on the conformance of its current certification processes with FDA/FSMA requirements.

FSMA represents a regulatory framework of requirements. Each certification body was expected to complete certification scheme requirements within the FSMA regulatory framework. Annex 1 also references the ISO/IEC 17065 clauses that are not addressed by the Final Rule. After the voluntary pilot program, ANSI determined the CBs had not developed the scheme requirements and several had not been able to develop a scheme document. FDA finalized "The Third-Party Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA staff in December 2016". The Guidance document and the regulatory framework together constitute the scheme document to be used for future accreditation activities.

In summary, each certification body must develop documentation that will meet all the following:

- (1) Scheme/regulatory requirements unique to FDA/FSMA as defined in the "Third-Party

Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA staff”;

- (2) ISO/IEC 17065 standard ; and
- (3) 21 CFR Parts 1, 11 and 16, Subpart M - Final Rule and the FDA/FSMA Certification Scheme requirements.

The ANSI accreditation program determines conformance to ISO/IEC 17065 and the certification scheme. The scheme must not contradict ISO/IEC 17065 or result in any regulatory requirements not being required for implementation by the certification body.

### **III. GAP ANALYSIS STEPS**

The following are the steps completed after receipt of the certification body’s application:

- (1) Assessment team assigned (lead and technical assessors)
- (2) Certification body applicants accepted the ANSI assessment team
- (3) Lead assessor contacted the applicant to request documentation and reviewed the request to schedule a witness assessment
- (4) Lead and technical assessors reviewed the documents submitted
- (5) Lead assessor requested any additional information needed for the review
- (6) Lead assessor scheduled a remote office assessment
- (7) Technical assessor scheduled the on-site visit and witness assessment (observation of certification body conducting audit of its client), if applicable. (Note: witness assessments were requested of all applicants. Several applicants could not locate clients within the timeframe of the voluntary gap analysis pilot program. Four of the seven applicants completed witness assessments.)
- (8) Technical assessor wrote the report for the witness assessment (ANSI-PRO-FR-119), if applicable
- (9) Technical assessor wrote the office visit report and completed the check lists in Annexes C to F, as applicable
- (10) Lead assessor wrote the remote report and completed the check list in Annex B, with observations from the technical assessor
- (11) The assessors identified opportunities for improvements (OFIs) and included these OFIs in the report and on the checklists completed by assessors. The checklists indicate: “fully complies” “partially complies” “does not fully comply” and “not applicable”.
- (12) A combined report of the lead and technical assessors was submitted to the certification body within one month after completion of the assessment.

### **IV. RESULTS OF GAP ANALYSIS ASSESSMENT**

The assessment was performed by using the criteria from 21 CFR Parts 1, 11 and 16, Subpart M - Final Rule and ISO/IEC 17065:2012. These were presented to the certification body in the form of checklists that the assessors completed and included in the report to the certification body. The checklists were ANSI-PRO-FR-105-17065 (Annex A), 21 CFR Parts 1, 11 and 16 (Annex B) and the following technical checklists:

- Mitigation Strategies to Protect Food Against Intentional Adulteration [Food Defense] – Part 121 Final Rule (Annex C)
- Preventive Controls for Human Food - Final Rule - Part 117 (Annex D)
- Preventive Controls for Animal Food - Final Rule - Part 507 (Annex E)
- Irradiation In The Production, Processing, and Handling of Animal Feed and Pet Food – Final Rule - Part 579 (Annex E)
- Produce Safety - Final Rule - Part 112 (Annex F)

**Note:** The Annexes A to F are part of the report submitted by ANSI to the certification bodies

The ANSI assessment team also used the following documents:

- FDA’s Voluntary Qualified Importer Program Guidance for Industry
- 21 CFR Parts 1, 11, and 111 Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Final Rule

The 12 applicant participants in the Voluntary Gap Analysis were: (listed alphabetically)

Certification Body Name
BSI Group ANZ Pty Ltd. - BSIG
Bureau Veritas Certification North America, Inc. - BVCNA
Ceres Certifications, International Inc.
DNV GL Business Assurance USA, Inc. – DNV
Eagle Food Registrations Inc. – Eagle
Global Standards S.C. - GSSC
Perry Johnson Registrars Food Safety, Inc. -
Quality Certification Services - QCS
SAI Global Certification Services Pty Ltd - SAI
SGS NA, Inc. - SGSNA
UL Registrar, LLC - ULR
W.Q.S, LLC

Five of the applicants did not complete the process due to scheduling difficulties and lack of readiness for the assessment. Some applicants were visited and some applicants only completed a document review. Seven applicants completed the voluntary gap analysis and received a report. Each certification body had the option of being assessed to all the Final Rules or only a partial listing of the Rules.

The following table provides a listing of the technical areas reviewed and the certification bodies completing a witness observation. The certification bodies names are not identified in order to preserve their confidentiality.

The Rules selected for review by the seven certification bodies completing the process. (Listed by Final Rules requested)

Certification Body	Witness Performed	Rules
#	No	Preventive Controls for Human Food
#	Yes	Preventive Controls for Human Food
#	No	Preventive Controls for Human Food
#	No	Preventive Controls for Animal Food Preventive Controls for Human Food Mitigation Strategies to Protect Food Against Intentional Adulteration [Food Defense] Produce Safety
#	Yes	Preventive Controls for Animal Food Preventive Controls for Human Food Mitigation Strategies to Protect Food Against Intentional Adulteration [Food Defense] Produce Safety
#	Yes	Preventive Controls for Animal Food Preventive Controls for Human Food Mitigation Strategies to Protect Food Against Intentional Adulteration [Food Defense] Produce Safety
#	Yes	Preventive Controls for Animal Food Preventive Controls for Human Food Mitigation Strategies to Protect Food Against Intentional Adulteration [Food Defense] Produce Safety

Some certification bodies had to revise client agreements and their auditors will require training in the certification scheme and FDA/FSMA requirements. One of the certification body's documents were not currently updated to the latest versions of the Final Rule.

Some certification bodies are in the process of completing auditor checklists or their documents are already completed. One certification body does not have evidence of implementation as of the assessment date. All applicants' certification bodies have systems to address the ISO/IEC 17065 requirements but the FDA/FSMA Final Rules (Certification scheme) are not fully identified in the current systems. The certification bodies were planning to use similar types of processes for the FDA/FSMA regulatory requirements.

The Final Rule and other guidance documents raised questions from ANSI and the certification bodies. These questions are listed in Annex 2 of this report. To ensure consistent implementation of the Final Rule, it would be critical to receive FDA guidance to address these questions and provide more information on how to meet ISO/IEC 17065 requirements Annex 1 of this report.

The FDA/FSMA Final Rule uses statements that imply that the requirements are not mandatory through the use of the word “should” rather than “shall”. Each certification body developed certification requirements that are missing in the FDA/FSMA regulatory framework of the Final Rule, and developed requirements to complete the requirements of ISO/IEC 17065. These requirements also were written to ensure all “should” s” are handled as requirements. After the recent ANSI review it was determined that the regulatory framework and the Model Accreditation Standards: Guidance for Industry and FDA Staff documents specifies the requirements for the certification bodies to address in their procedures and process. ***Since the additional clarification or optional information is addressed in the Guidance documents the need for the certification body to develop a “Certification Scheme” document of its own is not necessary.***

Opportunities for Improvements were identified and presented in certification bodies’ reports. It was the assumption of ANSI that regulatory statements with “should” signified requirements and indicated to the individual certification body the need for a certification scheme procedure and records to support meeting the “should” statements. A sampling of the OFIs is presented in Annex 3 of this report.

The Voluntary Gap Analysis demonstrated that the certification bodies and their clients do not have a full understanding of the FDA/FSMA expectation for reports for this program and for the non-accredited supplier audits. The sections using the word “should” need further clarification from the FDA to improve certification body understanding of the FDA’s expectations, exemptions and qualified facility applications/withdrawal/appeals.

## V. SUMMARY

The process for accreditation in this voluntary Gap Analysis was implemented and demonstrated as viable for determining conformance to the Final Rules defined by FDA/FSMA. The ISO/IEC 17065 framework was found appropriate to the FDA/FSMA Rules since the Final Rules define most elements of a scheme required by ISO/IEC 17065 when the text of the Final Rule is read with the word, “shall” rather than “should”.

The certification bodies require sufficient time to prepare documentation and train auditors in the requirements of these Final Rules since they differ from current certification programs operated by those certification bodies. As well, the producers/suppliers/importers of food products need more time to implement the FDA/FSMA and certification scheme requirements than the deadlines set forth in the Final Rule. Other items for further clarification are audit duration and product categories.

All applicants gained understanding from this Voluntary Pilot Gap Analysis Program about the requirements of the FDA/FSMA Final Rules and strove to prepare for this process. All certification bodies cooperated with the ANSI assessors and staff. The opportunities for improvement presented to the certification bodies will help them to complete the Gaps existing in their current programs.

The number of days related to this project are:

- a) Preparation for the May 20, 2016 meeting with Certification Bodies: 8 days
- b) Development of Checklists and procedures: 8 days
- c) Voluntary GAP Analysis assessments (ANSI assessment teams): 75 days
- d) ANSI Accreditation Committee member participation in this project: 6 days
- e) This Final Report: 4 days



## VI. ANNEX 1 – Cross Reference Table

List of ISO/IEC 17065 Clauses Making Reference to certification Scheme	List FSMA Clauses NF = Not Found*	Does FSMA Contradict ISO/IEC 17065 (Y/N)	Comments
4.1.2.2 f)	NF	N	CB requires as part of ISO/IEC 17065 conformance
4.1.2.2 g)	NF	N	CB requires as part of ISO/IEC 17065 conformance
4.1.2.2 h)	NF	N	CB requires as part of ISO/IEC 17065 conformance
4.1.2.2 i)	NF	N	CB requires as part of ISO/IEC 17065 conformance
4.1.3.1	NF	N	CB requires as part of ISO/IEC 17065 conformance
4.1.3.2	NF	N	CB requires as part of ISO/IEC 17065 conformance
4.2.6 e)	1.657	N	
4.6 a)	NF	N	CB Requires as part of ISO/IEC 17065 conformance
6.1.1.1	1.642	N	
6.1.1.3	1.655 1.657	N	
6.1.2.1 a)	1.650	N	
6.1.2.1 b)	1.644 1.650	N	
6.2.1	1.650 1.651	N	
6.2.2.1	1.650 1.651	N	Not specific to outsourcing. Competency defined by CB scheme
7.1.1	1.651	N	
7.1.3	1.656	N	
7.2	1.651	N	
7.3.2	1.651	N	
7.4.4	1.651 1.653	N	
7.4.5	NA	N	Prior evaluation data possible, defined by FDA
7.7.1 f)	1.652	N	
7.8	1.657	N	Directory of certified products/process
7.9.1	1.640	N	Annual audit required. (CB must conduct any monitoring if applicable)
7.10.1	1.656	N	
7.10.3	NF	N	Implementation of changes to FSMA will be addressed by FDA

List of ISO/IEC 17065 Clauses Making Reference to certification Scheme	List FSMA Clauses NF = Not Found*	Does FSMA Contradict ISO/IEC 17065 (Y/N)	Comments
7.11.3	1.656	N	
7.11.4	1.654	N	
7.11.5	1.654	N	
7.12.1	1.645 1.652 1.694	N	
7.12.3	1.658	N	4 years
8.2.1	NF	N	References ISO/IEC 17065

## VII. ANNEX 2 - Questions and Comments for FDA to Consider

After a review of 21 CFR Parts 1, 11 and 16 – Part 1 General Enforcement regulations – Subpart M, and discussions with the FDA, a conclusion was reached that the FDA is not a Scheme owner for purposes of the FSMA rules cited.

FDA has specified some scheme requirements in Subpart M. In that regard, we would appreciate clarification on the following:

1. What records requirements must an accreditation body that has been recognized meet? (§ 1.625)
  - a. An accreditation body that has been recognized must maintain electronic records (including documents and data) for five (5) years created during that period of recognition in order to demonstrate its compliance with this subpart, including records relating to:
    - i. (6) Regulatory audit reports, including any supporting information that an accredited third-party certification body may have submitted.

What records and notifications must an accredited third-party certification body submit (§ 1.656)?

- b. Reporting results of regulatory audits. An accredited third-party certification body must submit a regulatory report, as described in § 1.652, electronically, in English to FDA and to the recognized accreditation body that granted its accreditation (Where applicable, no later than 45 days after completing such audit.)

The two (§) sections mentioned above do not together define the same requirement to accredited CBs. One is obligatory and the other is not.

In § 1.625 uses the language .... “may have submitted”

In § 1.656 uses the language....“must submit a regulatory report”,

**Clarification:** Please advise if the accredited certification body has to submit all mandatory audit reports to the AB.

2. To implement § 1.625 and to maintain for the duration of 5 years the regulatory audit reports (including any supporting information that an accredited third-party certification body may have submitted). The AB requests the following clarification:

**Clarification:** To reduce cost and time for all parties, would it be possible to have an electronic platform (database) that can be shared between the AB and the certification body?

3. In § 1.611 a.(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of a third- party certification body that is an individual, such individual) conducting a representative sample of audits;

Without FDA guidance, the CB scheme may determine the process for selection. Determination by the CB scheme to identify witness assessment(s) candidates may be insufficient without FDA guidance

**Clarification:** Does FDA intend to develop guidance or clarification on the requirement (for selecting witness assessments to perform a representative sample of its agents)?

4. § 1.620 a. (3) In conducting a review and audit under paragraph (a)(1) or (2) of this section, an observation of a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations as conducted by the third-party certification body or its agents (or, in the case of a third-party certification body that is an individual, such individual).

Without FDA guidance, the capacity of a CB to determine its scheme related to the process for selection may be insufficient.

**Clarification:** Does FDA intend to develop guidance or clarification on the requirement for an observation of a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations...?

5. § 1.621b A recognized accreditation body must conduct onsite observations of a representative sample of regulatory audits performed by the third-party certification body (or its audit agents) (or, in the case of a third-party certification body that is an individual, such individual) accredited under this subpart

Without FDA guidance, the capacity of a CB to determine its scheme related to the process for selection may be insufficient.

**Clarification:** Does FDA intend to develop guidance or clarification on the requirement to conduct onsite observations of a representative sample of regulatory audits performed by the third-party certification body (or its audit agents)?

6. In § 1.624 (b) A recognized accreditation body may accept the payment of fees for accreditation services and the reimbursement of direct costs associated with assessment of a certification body only after the date on which the report of such assessment was completed or the date of which the accreditation was issued, whichever comes later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

**Clarification:** Please clarify this statement since payment is often obtained before the certificate is issued. When the certificate is not issued due to non-conformances still pending or withdrawal by the CB from the process, when should payment be made?

7. In § 1.625 a) An accreditation body that has been recognized must maintain electronically for 5 years records created while it is recognized (including documents and data) demonstrating its compliance with this subpart, including records relating to: (8) records of fee payments and reimbursement of direct costs.

**Clarification:** What are the types of records or objective evidence that FDA is looking for related to the requirement under this § (a) (8)? Is only the invoice to the CB required or is all the supporting documentation needed e.g., receipts, time charged, etc.

8. In § 1.640 a to c A foreign government, agency of a foreign government, foreign cooperative, or any other third party may seek accreditation from a recognized accreditation body (or, where direct accreditation is appropriate, FDA) to conduct

food safety audits and to issue food and facility certifications to eligible entities under this subpart.

**Clarification:** Does a foreign government, agency of a foreign government, foreign cooperative, or any other third party that seeks accreditation have to have clients certified to food safety scopes in order to be accepted as an applicant by a recognized AB?

9. § 1.641 a. (1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively examine for compliance with applicable FDA food safety requirements of the FD&C Act and FDA regulations, conformance with applicable industry standards and practices, and issuance of valid and reliable certifications; and

**Clarification:** Please clarify the meaning of applicable industry standards and practices.

10. In § 1.663 (a) An accredited third-party certification body may submit a request to FDA to waive the requirements of § 1.650 (c) preventing an conducting a regulatory audit of an eligible entity if the audit agent (or, in the case that the third-party certification body is an individual, the third-party certification body) has conducted a food safety audit of such entity during the previous 13 months.

**Clarification:** ANSI would like to know if the accreditation body that accredits the CB that requests FDA waiver of the requirements of § 1.650 will receive copies of the FDA response.

12. "Accreditation" by FDA-recognized ABs.

**Clarification:** Usually, in order to get accredited, CBs must have conducted several audits and must have issued some certificates to be assessed by accreditation assessors. Given provision that FDA will allow CBs to conduct "regulatory audits" before they have become accredited, the recognized ABs may accredit the CBs without witnessing their audits and without the review of records of the "certification".

**Clarification:** Is it possible for recognized ABs to provide cross-frontier accreditations? And is it possible for accredited CBs to provide FSMA certification services to the owners of food producing facilities located in counties other than the countries of the CBs?

## VIII. ANNEX 3 – Summary of Opportunities for Improvements (OFIs)

Following is a sampling of findings reported as OFIs during the ANSI Gap Analysis for certification bodies finishing the assessment process.

**ISO/IEC 17065 4.1.2.1:** The CB client agreement does not identify the business authorized to conduct regulatory audits on behalf of FDA and does not define its functional role as required in FDA criteria 1.641.

**ISO/IEC 17065 4.1.2.1:** The CB client contract does not authorize the CB auditor to collect samples and have them analyzed. It is noted that the CB “should” include in the contract that the CB has authority to collect and analyze samples. It is not clear if this is mandatory due to the use of word “should”.

**ISO/IEC 17065 6.1.2.1:** CB procedure for management of competencies of personnel involved in the FSMA scheme certification does not require the CB to determine the criteria for competency of personnel for application review, technical review and certification decision.

**ISO/IEC 17065 6.1.2.1:** The CB has not developed competency, training, and monitoring requirements for FSMA qualified auditors. The FSMA statements related to the competency for auditors are stated as recommendations and include “should” statements that do not mandate requirements.

**ISO/IEC 17065 7.2:** The CBs application for the clients to complete does not contain all the information in the regulatory program. It is noted that the client “should” complete the application. The requirement in ISO/IEC 17065 states the client must complete the application. It is not clear if the specific information to be included on the application is required due to the word “should”.

**ISO/IEC 17065 7.3.1:** The certification body application contained references to offering for scopes for which they are not currently seeking accreditation.

**ISO/IEC 17065 7.4.3:** All necessary documentation is not yet available for performing the evaluation tasks for the CB FSMA Scheme.

**ISO/IEC 17065 7.4.4:** The CB process for on-site evaluation does not adequately cover all the requirements of section 1.651.

**ISO/IEC 17065 7.4.6:** The certification body classification of nonconformities is not consistent with the regulatory requirements. The CB defines critical, major, and minor, which are categories that are not defined in the regulatory program.

**ISO/IEC 17065 7.7.1:** The CB templates do not include all the requirements of FSMA Voluntary Third Party Certification Programs for Foods and Feeds 1.653. Items 2A, 2ii and 2v were not identified on the documents.

**ISO/IEC 17065 7.12.1:** A procedure is not available for when and how the CB will notify the accreditation body and FDA as required in 1.645.

**ISO/IEC 17065 7.4.9:** The CB does not have a means for to document evaluation activities. Checklists for each regulatory standard have not been developed.

**ISO/IEC 17065 7.7:** The CB has not developed formal certification documentation such as a certificate template to meet ISO/IEC 17065 section 7.7 requirements for the CB FSMA scheme.

**ISO/IEC 17065 7.1.2:** The certification body procedures do not contain all required processes as required by the regulatory standard.

**ISO/IEC 17065 7.11.3:** The certification body does not have procedures for suspension, withdrawal and regulatory notification as defined in the regulatory standard. It is noted that the CB “should” notify FDA (1) immediately if it is reasonable to assume a food safety issues is possible and (2) if certification is suspended or withdrawn.

**ISO/IEC 17065 7.13.1:** The certification body does not have a defined program for complaints and appeals consistent with the regulatory standards. The regulatory program indicates the CB “should”. This language may not imply a requirement. [ANSI defines “should” as not mandatory standards vernacular. In some legal circles, it is assumed that “should” is a requirement (i.e., it means “shall)]. During this GAP Analysis, all “should” in the regulatory requirements were defined as a requirement. The FDA is asked to confirm if the CB scheme for FSMA is based upon the assumption that “should” mandates requirements.

**ISO/IEC 17065 8.3.1:** The CB does not have a documented process for sending information to FDA and the accreditation body as required in Voluntary Third Party Certification Programs for Foods and Feeds 1.656.a, 1.656.b, 1.656.c.