

FSMA Compliant
2nd Party Audit Programs

Patricia Wester

The Association for Food Safety
Auditing Professionals

Food Safety Summit 2017



FSMA'S Use of Audits

Certification

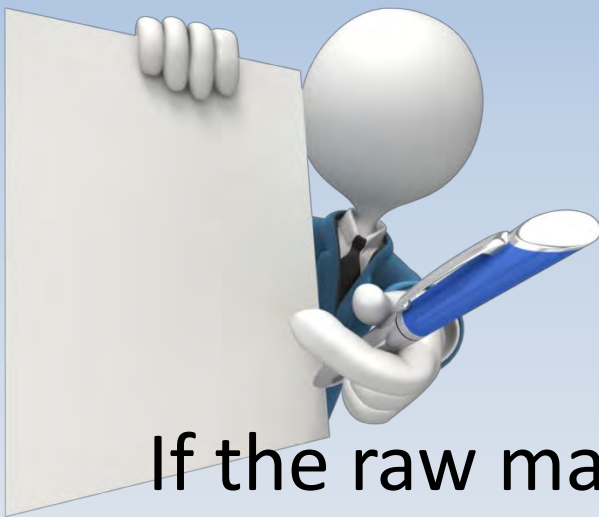
- MIC
- VQIP

Supplier Verification

Onsite Audits - 2nd and/or 3rd Party Audits

- “Applicable FDA Regulation”
 - PC Rules
 - HACCP Rules
 - Others





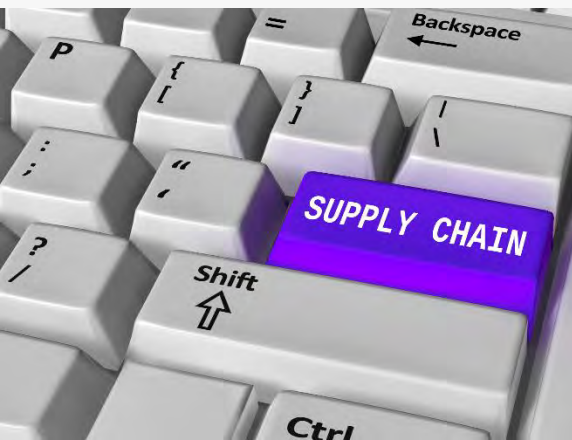
Onsite Audits

If the raw material or other ingredient at the supplier is subject to **one or more FDA food safety regulations**, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled



Onsite Audits

- An onsite audit may consider relevant laws and regulations of a country whose food safety system *FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.*



Qualifying Audits

GFSI schemes that consider FDA food safety regulations and include

- a review of the supplier's written HACCP plan (or other food safety plan), if any, and its implementation, with respect to the hazard being controlled
 - are likely to satisfy the requirements for an onsite audit.



Use of GFSI Audits

- To be used to satisfy the requirements of this rule, a GFSI-benchmarked audit, as with any audit, must address all requirements of this rule,
- including the requirement to consider applicable FDA food safety regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any.



“Implementing Records”



- Implementation of the plan is distinct from the plan itself
- § 117.126(c) establishes the recordkeeping requirement for the food safety “plan,” and
- § 117.190 lists implementation records.



Audits and Qualified Auditor

- Response 699: We (FDA) expect that a facility will adopt an approach to audits that works best for the facility and minimizes the number of audits conducted for the same facility.
- An employee of a receiving facility may perform an audit, provided that the employee satisfies the criteria established in the rule for qualified auditors.



Qualified Auditor

- A qualified auditor is a qualified individual and has technical expertise obtained through education, training or experience (or a combination thereof) necessary to perform the auditing function.



Qualifying Audits

- We expect that audits being conducted for other purposes will also be used to satisfy supplier verification audit requirements and such audits will be adjusted as needed to conform to the requirements of this rule.





ISO and FSMA
AUDIT PROGRAM TERMINOLOGY



AUDIT TERMINOLGY

ISO 19011 an audit is

- a “systematic, independent and documented process for obtaining **audit evidence** [records, statements of fact or other relevant and verifiable information] and evaluating it objectively to determine the extent to which the **audit criteria** [set of policies, procedures or requirements] are fulfilled.



External Audits

Product Audit

- An examination of a particular product or service to evaluate whether it conforms to requirements;
- specifications, performance standards, and customer requirements

Process Audit

- A verification that processes are working within established limits.
- Evaluates an operation against predetermined criteria or standards to measure conformance to these standards and the effectiveness of the instructions.



Process Audits

- Check conformance to defined requirements
 - time, accuracy, temperature, pressure, composition, responsiveness, amperage, and component mixture.
- Examine the resources applied to transform the inputs into outputs
 - (equipment, materials, people), the environment, the methods (procedures, instructions) followed, and the measures collected to determine process performance.
- Check the adequacy and effectiveness of the process controls
 - procedures, work instructions, flowcharts, and training and process specifications.



System Audits

- An audit conducted on a management system to verify by examination and evaluation of objective evidence, that applicable elements of the system are appropriate and effective and have been developed, documented, and implemented in accordance and in conjunction with specified requirements.
 - A quality management system audit evaluates an existing quality program to determine its conformance to company policies, contract commitments, and regulatory requirements.
 - An environmental system audit examines an environmental management system,
 - a food safety system audit examines a food safety management system, and
 - safety system audits examine the safety management system.



General Audit Terms



- **Audit client:** *the organization or person requesting an audit.*
- **Guide:** *a person appointed by the auditee to assist the audit team.*
- **Management system:** *a system to establish policy and objectives and to achieve those objectives.*
- **Observer:** *a person who accompanies the audit team but does not audit.*



Audits 1-2-3

- A **first-party audit** is performed within an organization to measure its strengths and weaknesses against its own procedures.
- A first-party audit is an internal audit conducted by auditors who are employed by the organization being audited but who have no vested interest in the audit results of the area being audited.
- It does not meet the requirements for Supplier verification.



Audits 1-2-3

- A **second-party audit** is an external audit performed on a supplier by a customer or by a contracted organization on behalf of a customer. A contract is in place, and the goods or services are being, or will be, delivered.
- Second-party audits are subject to the rules of contract law, as they are providing contractual direction from the customer to the supplier.
- Second-party audits could influence the customer's purchasing decisions.



2nd Party Audits

Building an Audit Program for Supplier Verification



Audits 1-2-3

- A **third-party audit** is performed by an audit organization independent of the customer-supplier relationship and is free of any conflict of interest.
- Third-party audits may result in certification, registration, recognition or award certificate issued by the third-party organization.



Audit Criteria



audit criteria

- A set of policies, procedures or requirements used as a reference against which audit evidence is compared
 - Statutory or Regulatory Requirement
 - Organization Process/Policies/Procedures, etc.
 - Customer Requirements



Audit Scope



audit scope

- Extent and boundaries of an audit
 - includes a description of the physical locations, organizational units, activities and processes and
 - the time period covered.
- **Objective, Scope** and **Criteria** form the basis of the audit content that must be defined for the 2nd party audit



Audit Evidence



audit evidence

- records, statements of fact or other information which are relevant to the audit criteria and verifiable
- Audit evidence can be qualitative or quantitative.



Audit Findings

- **Audit findings:** *the results of the evaluation of the objective audit evidence collected against audit criteria.*
- Audit findings indicate conformity or nonconformity. Findings can lead to the identification of opportunities for improvement or recording good practices.
 - Audit criteria selected from legal or regulatory requirements is termed compliance
 - Conformity or nonconformity is used for other standards.



Audit Conclusion

- Outcome of the audit
 - Evaluate findings against objectives and criteria
 - *Audit conclusions* are drawn by the audit team after the audit has been completed and after audit findings and objectives have been considered.





Auditors

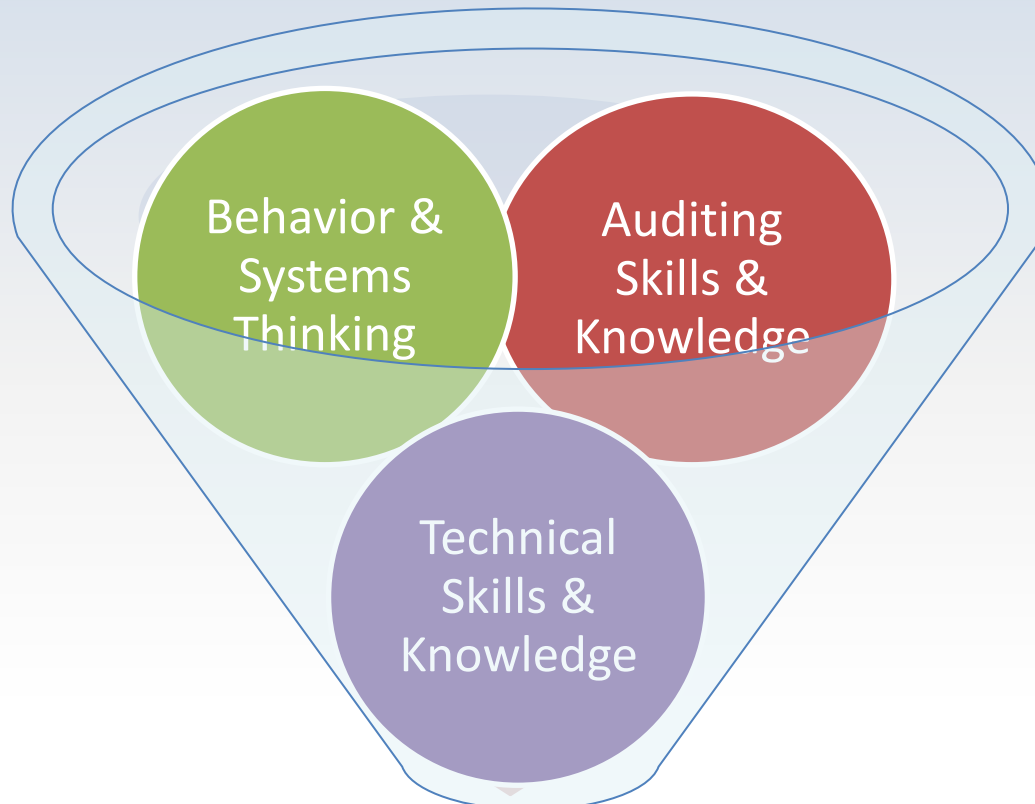
- Auditors collect **OBJECTIVE** evidence in order to **evaluate** how well audit criteria are being met.
- Knowledge of the audit criteria is **KEY**
- Auditors must be objective, impartial, independent, and competent.



Auditor Attributes

These auditor attributes are acknowledged by GFSI and FDA

...”With respect to the GFSI’s auditor competency model, the provisions for auditor competency for GFSI are consistent with our definition of a qualified auditor. “

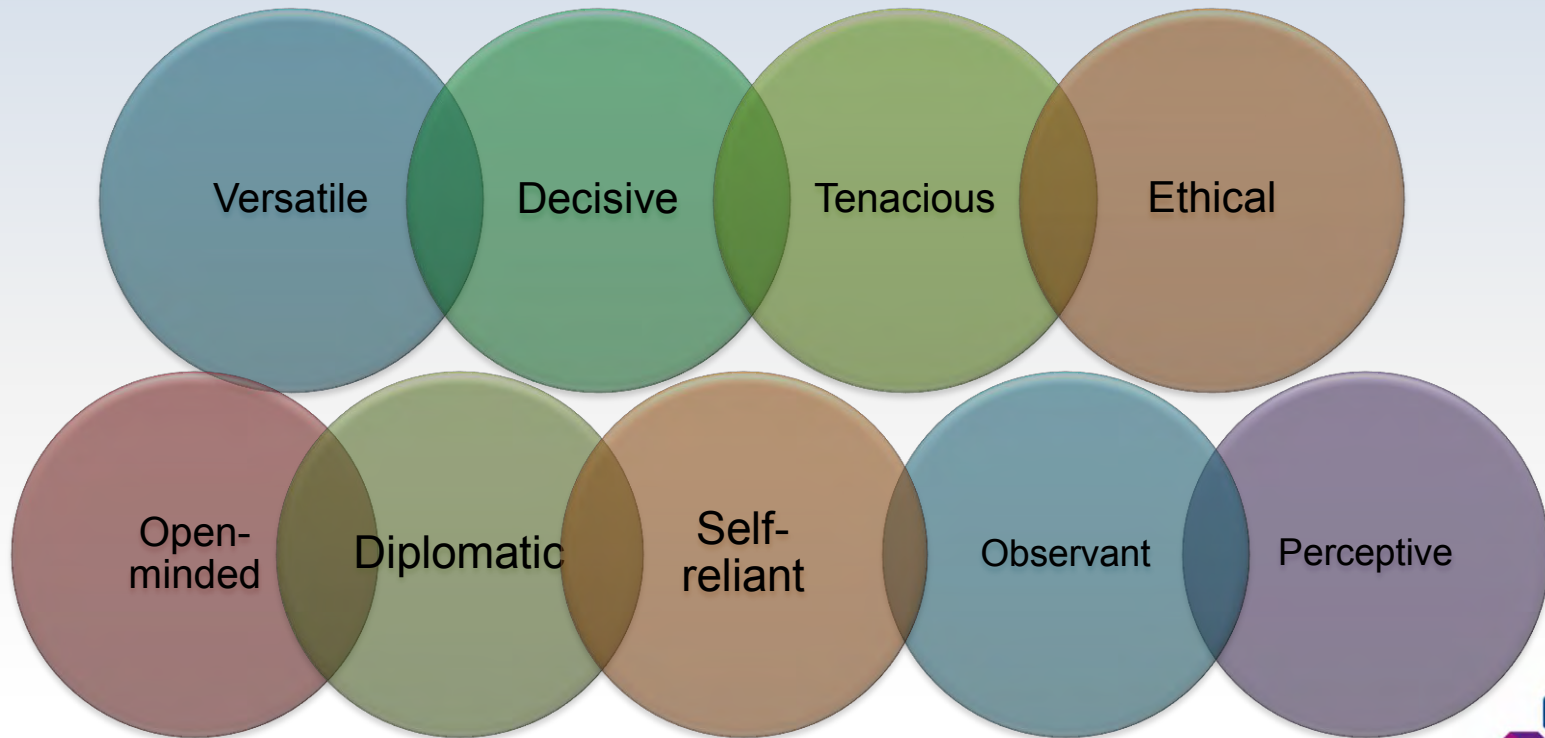


Auditor Competence



Auditor Personality Traits

ISO-recognized certain auditor personality “traits” that enable fair, consistent and systematic application of audit requirements.



Auditors should also possess the ability to:

- plan and organize work effectively
- prioritize and focus on matters of significance
- collect information through effective interviewing, listening, observing and reviewing documents, records, and data.
- use work documents to record audit activities.
- prepare audit reports accurately.
- maintain the confidentiality and security of information.
- speak and communicate effectively



ISO 19011 Key Clauses

- Clause 3 sets out the key terms and definitions used in this International Standard.
- Clause 4 describes the principles on which auditing is based. These principles describe the essential nature of auditing
 - Important in understanding the guidance in Clauses 5 to 7.
- Clause 5 provides guidance on
 - establishing and managing an audit program,
 - establishing the audit program objectives, and
 - coordinating auditing activities.



ISO 19011 - Clauses

- Clause 6 provides guidance on planning and conducting an audit of a management system.
- Clause 7 provides guidance relating to the competence and evaluation of management system auditors and audit teams.
 - Annex A illustrates the application of the guidance in Clause 7 to different disciplines.
 - Annex B provides additional guidance for auditors on planning and conducting audits.



4 Audit Phases

- **Audit preparation** – Audit preparation consists of everything that is done in advance by interested parties, such as the auditor, the lead auditor, the client, and the audit program manager, to ensure that the audit complies with the client's objective. The preparation stage of an audit begins with the decision to conduct the audit. Preparation ends when the audit itself begins.



4 Audit Phases

- **Audit performance** – The performance phase of an audit is often called the fieldwork. It is the data-gathering portion of the audit and covers the time period from arrival at the audit location up to the exit meeting. It consists of activities including on-site audit management, meeting with the auditee, understanding the process and system controls and verifying that these controls work, communicating among team members, and communicating with the auditee.



4 Audit Phases

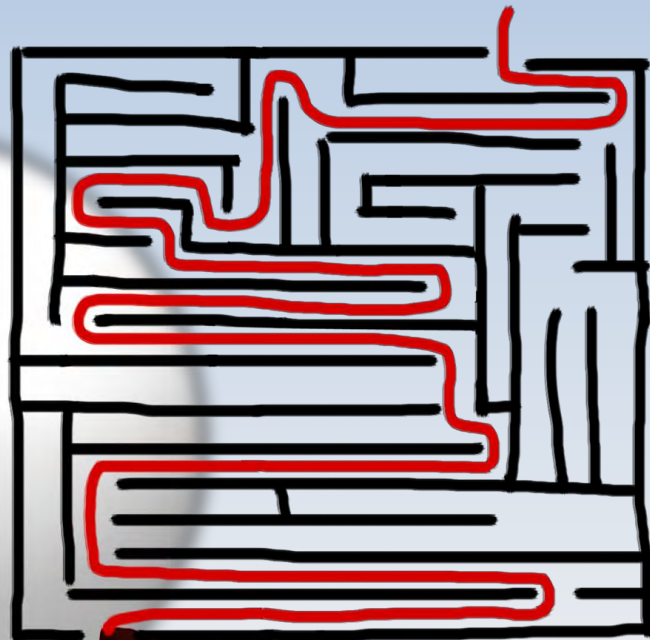
- **Audit reporting** – The purpose of the audit report is to communicate the results of the investigation. The report should provide correct and clear data that will be effective as a management aid in addressing important organizational issues.
- The audit process may end when the report is issued or after follow-up actions are completed.



4 Audit Phases

- **Audit follow-up and closure** – According to ISO 19011, clause 6.6, “The audit is completed when all the planned audit activities have been carried out, or otherwise agreed with the audit client.”
- Clause 6.7 of ISO 19011 continues by stating that verification of follow-up actions may be part of a subsequent audit.





AUDIT MANAGEMENT



Audit Programs

- An audit program may include one or more audits, depending upon the size, nature and complexity of the organization to be audited.
- Multiple audit objectives could be
 - FSMA Compliance
 - FSMA Compliance for Suppliers
 - GFSI Compliance
 - Internal supplier verification



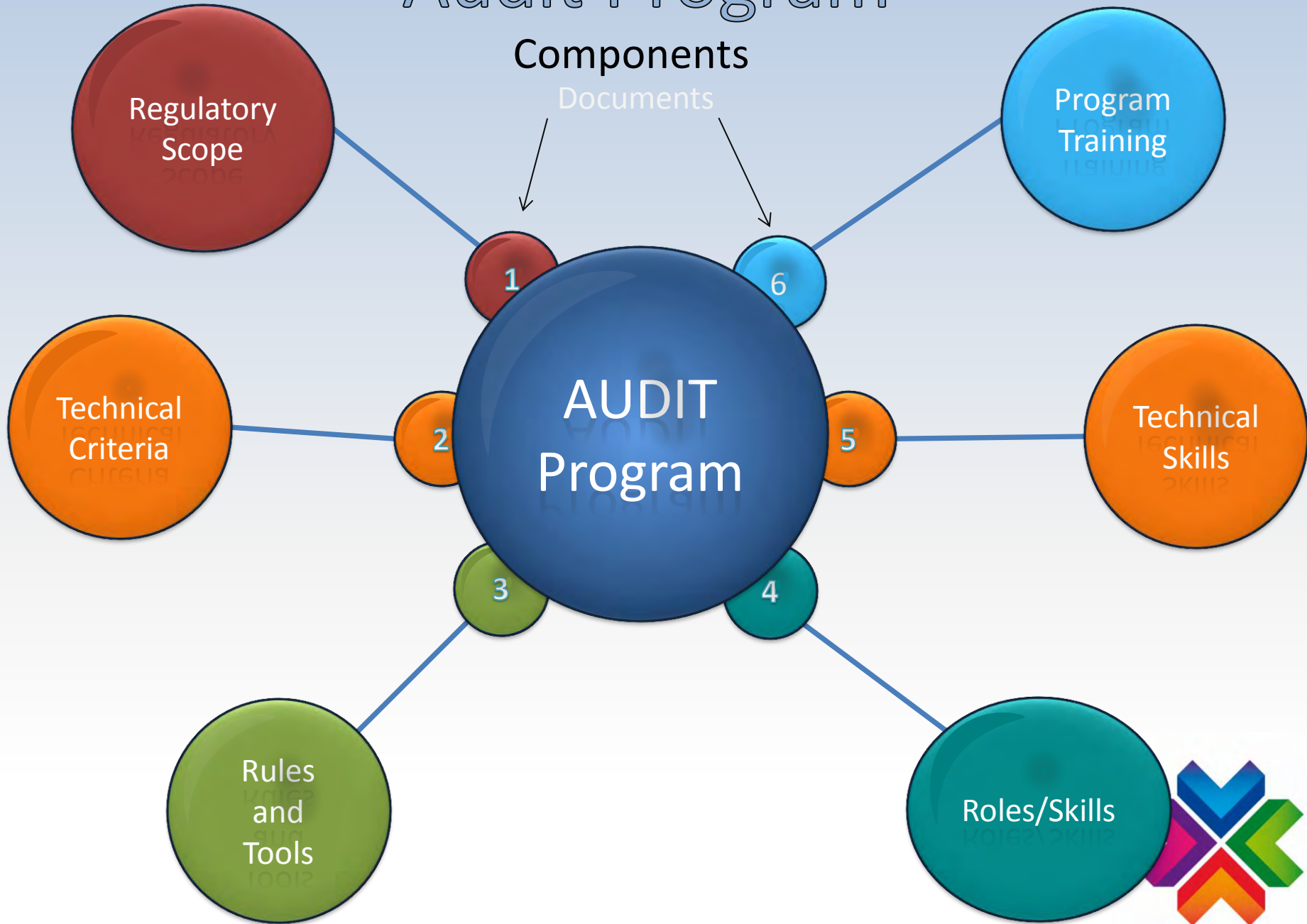
Program Content

An audit program includes all activities for

- planning and organizing the types and number of audits, and
- providing qualified resources to conduct them effectively and efficiently
- within the specified time frames



Audit Program



The 2nd Party Audit Program

Management desiring to use 2nd party audits for FSMA supplier verification should identify and provide the necessary resources to

- establish, implement, monitor, review and improve

all components of the audit program, or...

- Use a third party program that meets FSMA requirements.



What does the audit need to accomplish?

DEFINING AUDIT OBJECTIVES



Program Objectives

What is the objective of the audit program?

- FSMA Supplier Verification Compliance
 - establishes minimum audit requirements
- Other Company considerations;
 - management priorities,
 - commercial intentions,
 - management system requirements,
 - statutory, regulatory and contractual requirements,
 - need for supplier evaluation,
 - customer requirements,
 - needs of other interested parties, and
 - risks to the organization.



Example Objectives

Examples include the following:

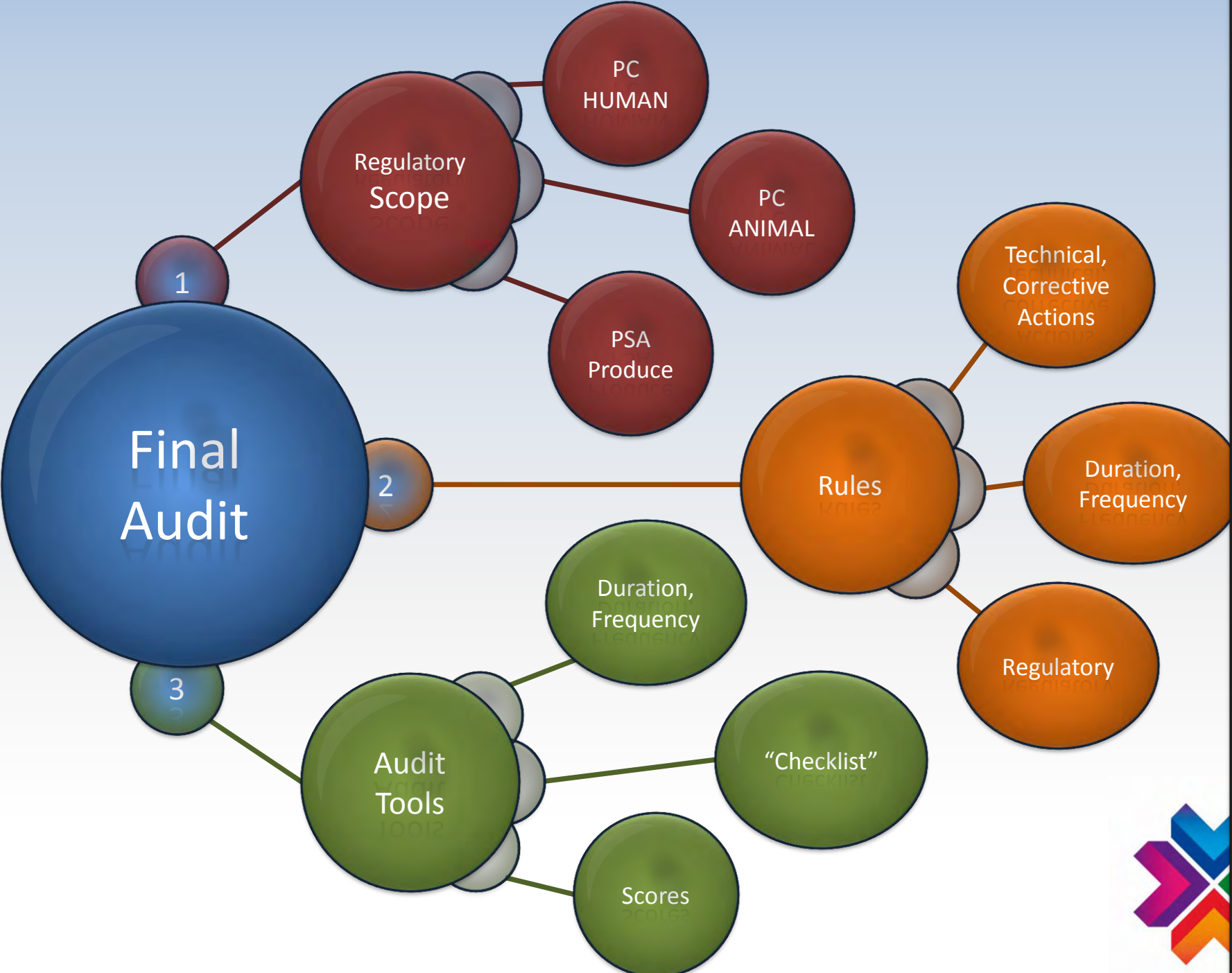
- To meet regulatory requirements
- to meet requirements for certification to a management system standard;
- to verify conformance with contractual requirements;
- to obtain and maintain confidence in the capability of a supplier;
- to contribute to the improvement of the management system.



Key Audit Program Elements

- Responsibilities and Resources
- Objectives and Extent
- Policies and Procedures
- Criteria (content) and Scope
- Implementation and
- Records





Program Guidelines

The scope, objective and duration of each audit to be conducted;

- the frequency of audits to be conducted;
- the number, importance, complexity, similarity and locations of the activities to be audited;
- standards, statutory, regulatory and contractual requirements and other audit criteria;
- the need for accreditation or registration/certification;
- conclusions of previous audits or results of a previous audit program review;
- significant changes to an organization or its operations



Questions?

