How to Prepare for a Program Audit

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What is a program audit?

A planned, systematic process, conducted by an independent third-party qualified auditor, to verify that appropriate stewardship programs and quality management systems are in place.

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Program Audit Scope

- Applicable only to the ETS or PBI Management Program member's specific biotechnology-related activities and operations
- Conducted at a systems level
  - Auditors verify and document, by examination of objective evidence, that the auditee has established and implemented stewardship programs and quality management systems consistent with the program's principles and management practices
  - Audits are not designed to measure the technical merit or operational performance of the systems
- Focused on assessing conformance with the organization's own

  internal standards for meeting their program obligations
  - Audits do not evaluate additional processes that have been

    specifically established to address regulatory compliance

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The Program Audit Process

Step 1 - Prepare for the Program audit

Step 2 - Conduct the audit

Step 3 - Take corrective actions, if applicable

Step 4 - Receive recognition for successful completion of Program audit

Step 5 - Conduct ongoing program maintenance

Step 6 - Repeat the Program audit cycle every three years

Note: The following information is intended to be helpful in planning for an audit, but not prescriptive. Please tailor this advice to your individual operation.

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Roles and Responsibilities

- Auditor: An independent, third-party associate, certified as a "Qualified Auditor" who conducts the audit

- Auditee: Program member organization

  - Auditee Contact: Individual at the member organization who is the point of contact with Auditor

  - Audit Participants: Individuals in the member organization involved in the audit, such as:

    - Management

    - Operators

    - Supervisors

    - Technicians

Step 1: Prepare for the Audit

- Pre-audit Activities
  - Scope
  - Self-assessment
  - Logistics
  - Organize
    - Facilities
    - Evidence
  - Employee Preparedness

Step 1: Prepare for the Audit

- Scope - Identify applicable auditable elements:
  - Stewardship
  - Maintaining Plant Product Integrity
  - Product Launch Stewardship
  - Product Discontinuation
 - Incident Response Management

Step 1: Prepare for the Audit

- Scope - Identify which facilities/operations are to be audited based on your organization's Approved Audit Plan

  - Example facilities:

    - Laboratory

    - Contained facility

    - Confined field trial

    - Seed or plant multiplication facilities/operations

    - Commercial seed or plant distribution facilities/operations

    - Headquarters

Step 1: Prepare for the Audit

- Self-Assessment
  - Conduct an internal self-assessment/review
    - The Audit Checklists and Self-assessment Tool are excellent resources detailing items the Auditor may review
    - Use internal expertise or consultants to verify compliance with the program and identify opportunities for continuous improvement of the stewardship program
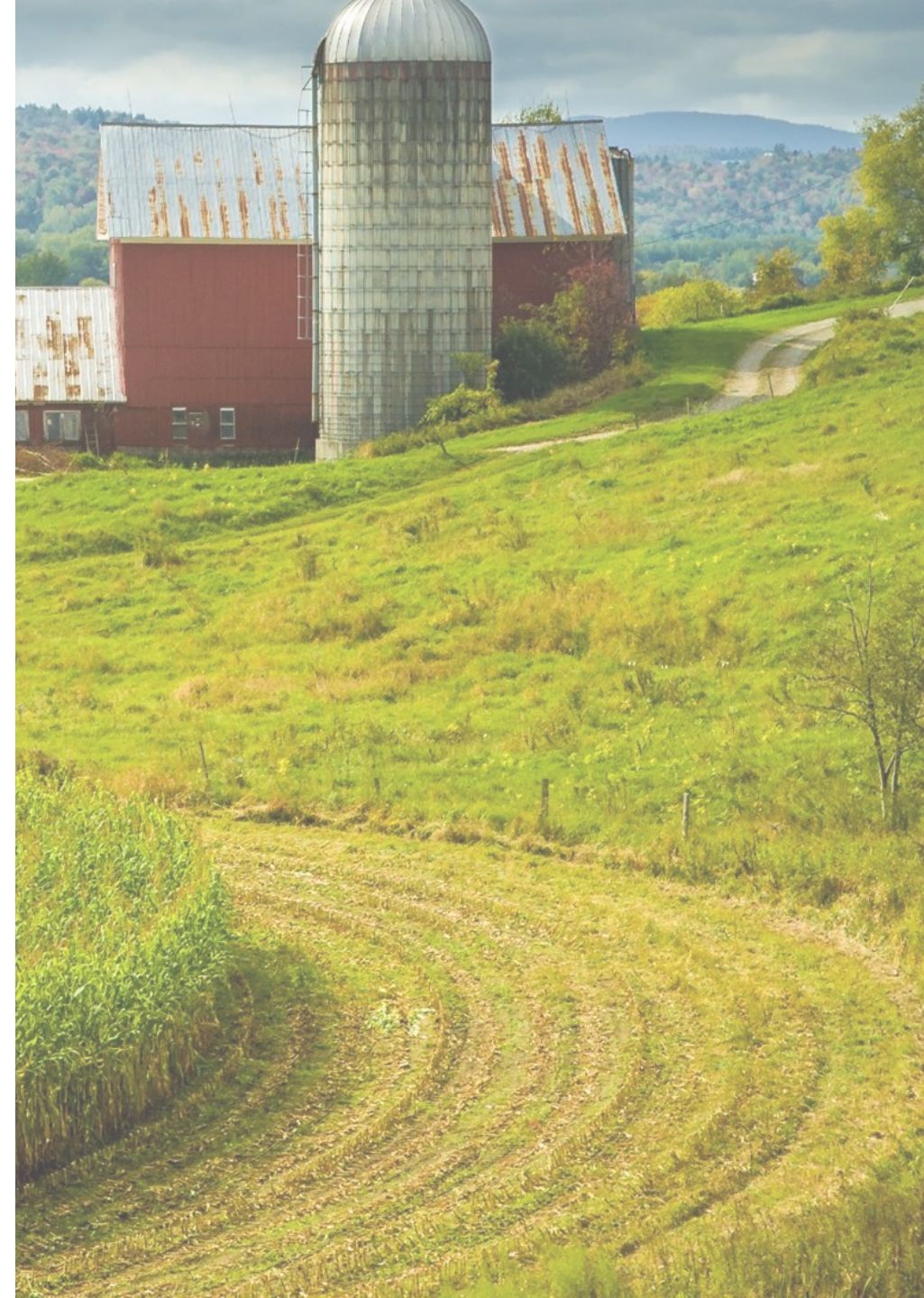
Step 1: Prepare for the Audit

- Self Assessment
  - Self-assessments/reviews should evaluate your program in-depth, including the technical merit and operational performance of the systems, as well as system design and implementation
  - Items identified during the self-assessment/review should be addressed to strengthen your program prior to the Program Audit

Step 1: Prepare for the Audit Logistics

- Identify who's involved – Auditor, Auditee Contact & Audit Participants

  - Establish contractual agreement with Auditor

  - Determine if confidentiality agreement is needed

- Identify locations where the audit will take place

  - Facilities

  - Conference rooms

 - Travel arrangements

Step 1: Prepare for the Audit

- Logistics/Scheduling
  - Schedule the audit with the Auditor to accommodate:
    - Seasonality of the work
    - Modules to be audited and availability of people
    - Auditor's availability
  - Develop an audit plan (purpose, scope, and duration) in conjunction with the Auditor
  - Conduct a pre-audit meeting/call to collectively review the plan and address any questions

Step 1: Prepare for the Audit

- Organize - Facilities
  - Conduct housekeeping walk-through
    - Remove clutter
    - Ensure the work areas are clean
    - Verify all postings are current; remove those that are out of date
    - Check signs, labels, and tags
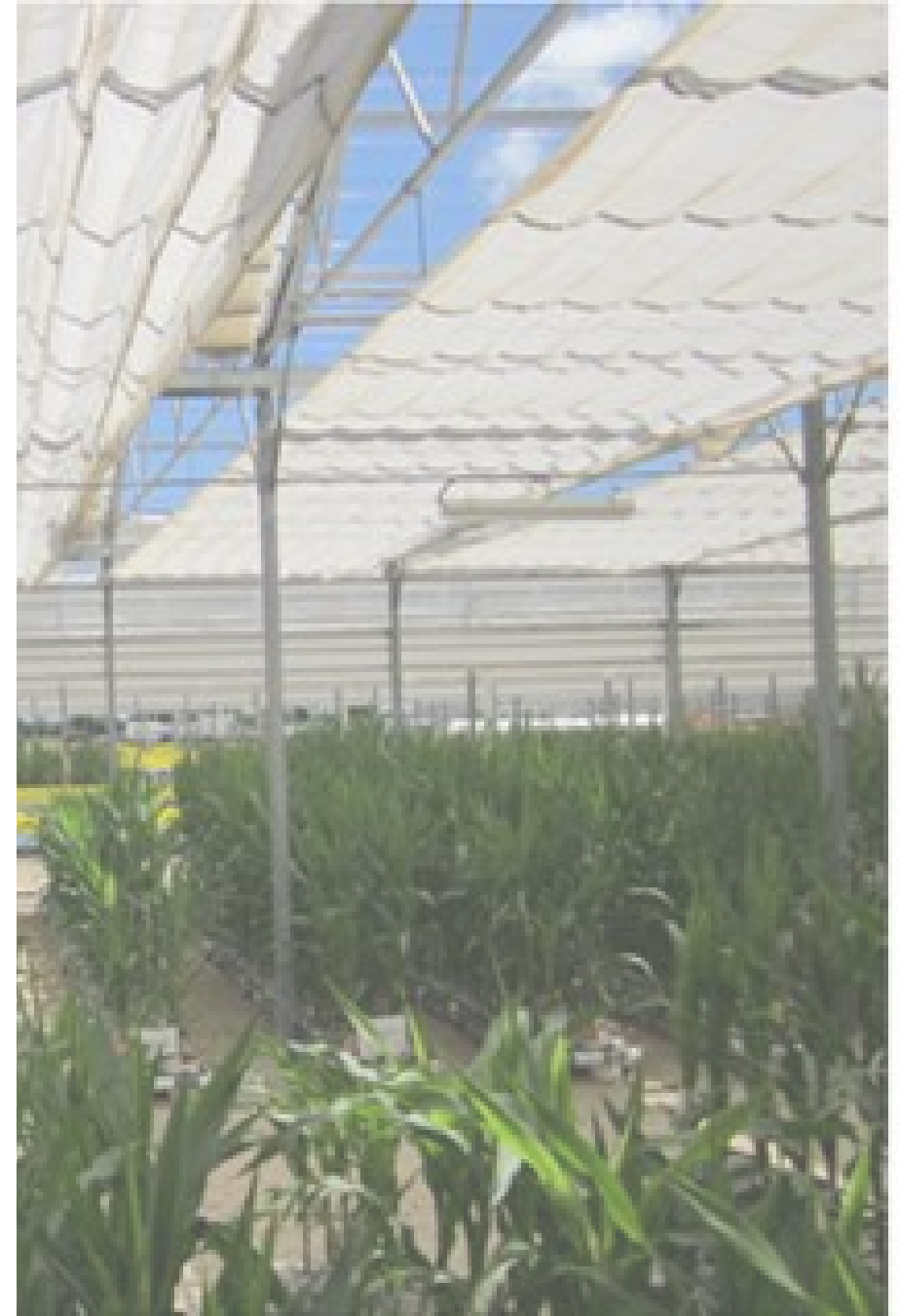
Step 1: Prepare for the Audit
Organize - Collect evidence for the audit

- Good organization of the audit evidence will facilitate completion of the audit
  - One document may provide evidence for several of the audit questions
  - Don't waste your Auditor's time searching for records
- Have documents and records in the scope of the audit easily accessible, or know where they are stored for easy retrieval
  - Binders
  - Electronic databases
  - Folders

Step 1: Prepare for the Audit
Employee Preparedness - Ensure employee readiness

- Approach audit with a positive attitude

- Embrace the opportunity to validate your program, and identify ways to make it even better

- Meet with others in your work area to discuss preparations

- If unfamiliar with audits, ask others for tips and suggestions

- Being prepared for the audit will:

  - Reduce anxiety

  - Improves the results and outcome of the audit

Step 1: Prepare for the Audit

Employee Preparedness - Coach employees on how to respond to questions

- For open ended questions – a response of "yes" or "no" is not enough, provide detail

- For process questions, it's OK to reference the procedure

- Only answer the question asked. Seek clarity, if needed

- Tell the truth

- Be confident; you know your work

- If you are not the knowledgeable expert, refer the question to the appropriate expert

- Avoid saying "sometimes" or making excuses

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Step 2: Conduct the Audit

- Know the Auditor
  - Know your Auditor's style and prepare accordingly. The Auditor may:
    - Stay in a conference room and review SOPs and records
    - Request a facility tour to discuss operations
    - Interview many different individuals
    - Request the records, quality manual, or other evidence ahead of time and then during the audit, target areas of concern for additional scrutiny
  - Some Auditors will ask
    - The audit checklist questions:
      - In order
      - At random or in a different order
    - Additional questions or follow-up questions

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Step 2: Conduct the Audit

- During an audit, **don't**:
  - Forget safety (personal protective equipment, emergency exits, etc.)
  - Be late
  - Delay the audit with long lunches or extensive tours
  - Get lost in details that are not useful
  - Bring up long-term future plans that are not relevant to the audit scope
 - Lie

Step 2: Conduct the Audit

- Audit day logistics
  - Reserve a quiet office or conference room for the Auditor to use during the day
  - Arrange access to buildings, storage areas, facilities or other secure areas
  - Brief the Auditor about any site-specific safety requirements
  - Provide transportation to fields or facilities
  - Arrange a "working lunch" so time is not wasted
  - Traveling to an outside restaurant
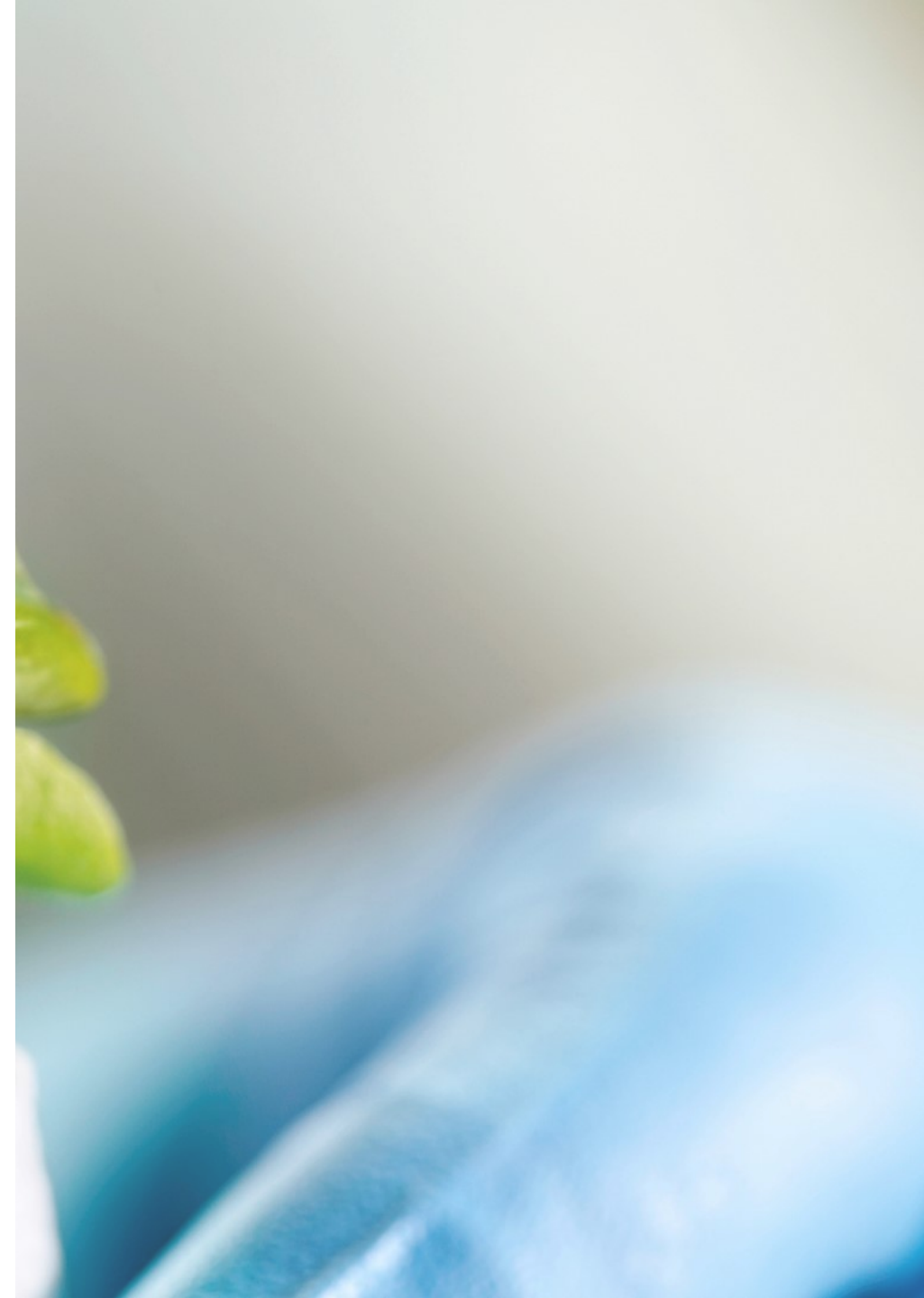
Step 2: Conduct the Audit

- Opening meeting
  - Involves management
  - Introductions to Auditees
  - Usually brief
  - Can include presentations from the auditee company and/or the Auditor
  - Provides opportunity to ask questions

- Audit interviews and examination of evidence
  - Confirms program compliance
  - Can include facility tours or may take place in a conference room or office
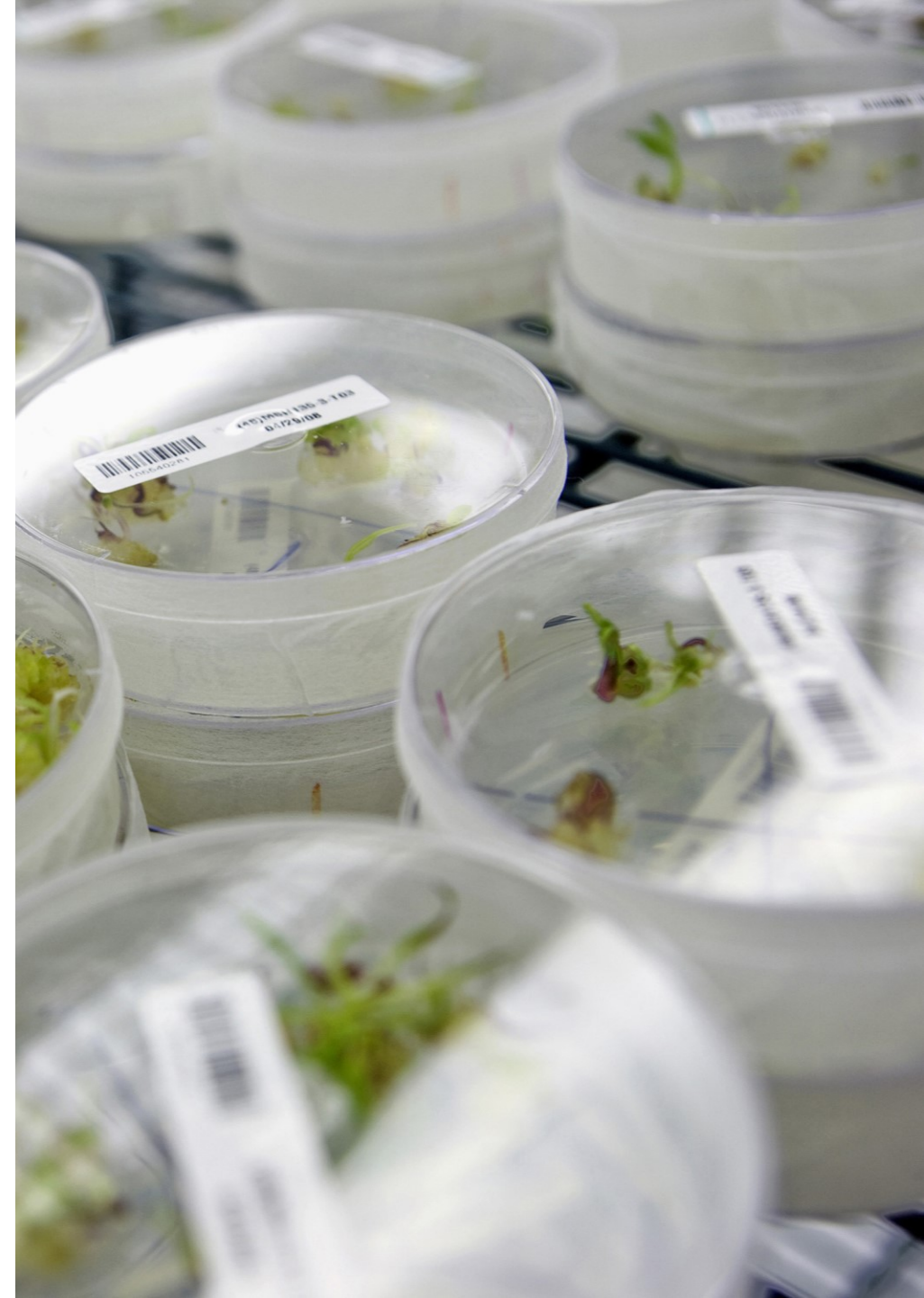
Step 2: Conduct the Audit

- Closing meeting
    - Usually open to management and any interested Auditees
    - Gives the Auditor an opportunity to:
        - Summarize positive comments and findings
        - Provide a timeline for the report
        - Discuss follow-up activities
- Auditees can provide additional information

Step 2: Conduct the Audit

- During an audit
    - The Auditor may point out a gap or request additional information
        - Recognize that these may be opportunities for improvement and learning moments for the organization
    - The audit is not over until the closing meeting
        - If you remember something that addresses a potential nonconformance, share the evidence before or during the closing meeting

Step 3: Take Corrective Actions, if applicable

- Auditor prepares a detailed audit report (confidential between Auditor and Auditee) which is reviewed for correctness with the Auditee

- Auditee addresses corrective action(s), if required

  - Auditor may request evidence of items having been addressed prior to issuing Audit Summary Report

- Auditor prepares the Audit Summary Report

- and submits it to the Global Stewardship Group when directed by the Auditee

Step 4: Program Audit Recognition

- Upon successfully completing the audit, the member will:
  - Receive certificate of successful completion from the GSG office
  - Be recognized on the program website
  - Have access to approved statements promoting successful completion of audit for member use

Step 5: Conduct Ongoing Program Maintenance

- Continuous Improvement

  - For ongoing program maintenance and continuous improvement, Auditee should:

    - Address areas of improvement, if required

    - Consider establishing a routine self-assessment program to continually improve applicable stewardship programs and quality management systems
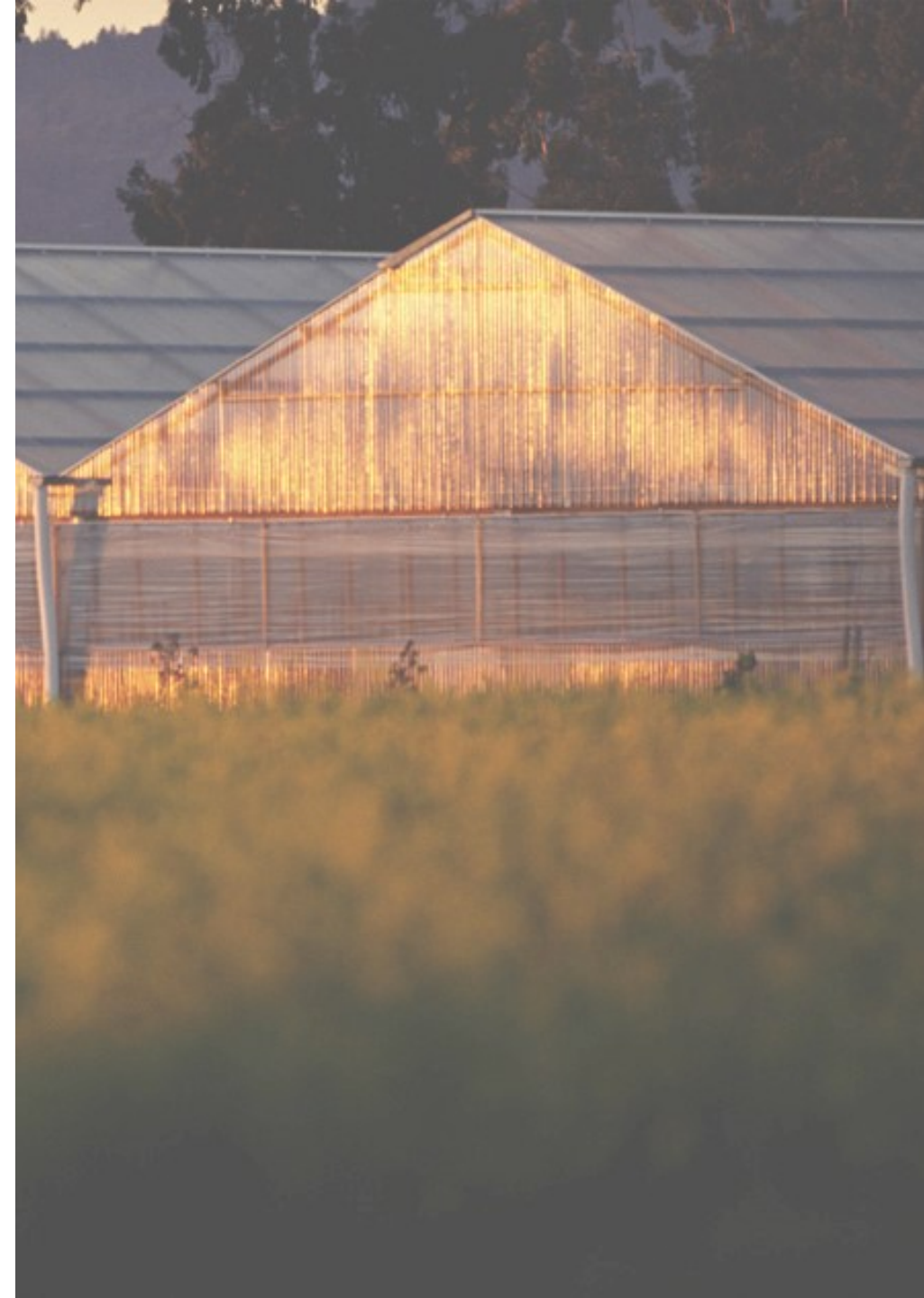
Step 6: Repeat the Program Audit

- To remain a program member:
  - Ensure completion of all required Program Audits within the identified 3-year cycle
  - File an updated Audit Plan for the new 3-year cycle