



# 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

- 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





# 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



## 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

