Compliance and the Inspection Process

Last Modified:



APHIS verifies compliance with the regulations and permit conditions in permits, or performance standards for notifications, by inspecting field test sites, facilities, and records associated with regulated activities.

Inspections generally occur in-person but may be conducted virtually. Trained inspectors (from BRS, APHIS’ Plant Protection and Quarantine (PPQ) program, or a

participating state inspection program), conduct inspections on behalf of BRS. Methods of verification used for inspection include records review, interview, observation, measurements, and mapping.

BRS determines the frequency and number of field test site inspections by assessing the relative risk of each type of trial and by other criteria described below. BRS conducts at least one inspection of each environmental release permit.

Expand All

Compliance Incidents

Most persons authorized to engage in regulated activities have a successful history of compliance with APHIS regulations. From time-to-time, a noncompliance incident may occur. Instances of noncompliance can include failing to notify APHIS in the event of an unauthorized release, failing to follow permit conditions (such as isolation distances or monitoring for volunteers), or failing to meet notification performance standards (such as failing to manage volunteers or planting at a field test site before or after effective or expiration dates). When noncompliance occurs, BRS assesses the nature and seriousness of the noncompliance and determines appropriate actions, ranging from issuing regulatory correspondence to requesting an investigation and seeking sanctions for alleged noncompliance, if appropriate.

Inspections for Permits

Permits require responsible persons to follow the standard permit conditions and supplemental permit conditions assigned by BRS. BRS ensures compliance with its permit requirements by performing inspections. Plants engineered to produce pharmaceutical or industrial products are inspected up to seven times before, during, and after the planting occurs to verify compliance with permit conditions. These inspections are performed at critical times during field testing, including at planting, during flowering, harvest, after harvest and during the volunteer monitoring period.

View Inspection Overview and Example Inspection Questions

Inspections for Notifications

Notifications require responsible persons to meet performance standards described in 7 CFR 340. BRS ensures compliance with performance standards by performing inspections. These inspections are performed at a critical time during field testing, such as after planting or after harvest. Inspections evaluate dates of planting, whether the trial was planted at an authorized location, acreage planted, and adherence to design protocols to ensure performance standards are met. Inspectors collect GPS coordinates, review records, take photographs, and measure isolation distance or other reproductive control measures to verify confinement.

View Inspection Overview and Example Inspection Questions

Inspection Results

After every inspection, inspectors prepare an inspection report. BRS sends correspondence to the responsible person to communicate the compliance outcome based on findings documented in the inspection report. The correspondence typically falls into one of the following categories:

- Notice of Compliance – the inspection revealed no deviations from the regulations or permit conditions.
    - Note: If the analysis revealed activities or circumstances that could lead to a noncompliance incident in the future, the Notice of Compliance will detail BRS' concerns and possible solutions to prevent potential noncompliance incidents.
- Notice of Noncompliance - the inspection revealed deviations from the regulations or permit conditions. BRS may require corrective action and indicate documentation that must be provided to BRS once corrective action is taken, as appropriate, usually within a given time frame.

BRS also uses these letters to communicate findings not specifically related to inspections, such as noncompliance identified from a self-report or for failure to submit a required report.

Reports and Notices

APHIS requires responsible persons to submit certain reports and notices under the regulations and as part of the requirements of the authorization. Reports and notices provide compliance-related information about regulated articles. Each report and/or notice is associated with a specific permit or notification and has due date and information requirements. BRS uses reports and notices for initiating inspection processes and verifying the status of the authorization and any actions taken under it, such as planting and volunteer monitoring. A report has information on activities that already occurred, and a notice provides information about regulated activities that will occur in the future.

- **ePermits (XML) Instructions for Reports and Notices**

Related Links

How to Report an Unauthorized or Accidental Release

Print