**Purpose of Module for Potential Regulatory Compliance Incidents:** This module provides an example template for use in potential regulatory compliance incidents that your organization might use as part of your organization’s quality management practices relevant to APHIS regulations found at 7 CFR Part 340.

**Biotechnology Quality Management Support:** APHIS Biotechnology Regulatory Services has developed this module as one of a series of modules. Biotechnology Quality Management Support is useful for any organization that wishes to develop or improve quality management practices related to the APHIS regulations cited above.

**Approach:** The module includes a template (below) that your organization can customize specific to your needs and operational practices for potential regulatory compliance incidents involving regulated GE organisms. Each section of the template has examples of what might be included in a standardized form for potential regulatory compliance incidents. The template is not a standard, but should be considered as a tool to modify to meet your organization’s needs.

The example template is found on the APHIS BRS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/bqms>. Note that the template text in blue font serves as a prompt for describing your organization’s approach.

**Disclaimer:** This module provides a generalized guide for your organization’s quality practices relevant to your obligations under APHIS regulation found at 7 CFR Part 340.  Use of these modules and its content does not guarantee that the user’s activities are in compliance with 7 CFR part 340, and it does not eliminate the user’s obligations under any other statute or regulation.  If your organization wishes to use formal quality management systems, it is best to rely on qualified quality management professionals.

**1.0 PURPOSE:** *This procedure describes the controls your organization uses for potential regulatory compliance incidents with regulated genetically engineered (GE) organisms; identification of those organisms; the way in which the process is monitored; and whether the monitoring and verification, as well as any changes in those activities, are effective. The procedure also explains the way in which potential regulatory compliance activities are handled by your organization.*

**2.0 DEFINITIONS:** *Insert any terms, acronyms or reference to a glossary here that may apply to this procedure. For the sake of clarity, indicate any deviations in your terminology from the definitions and terms used in 7 CFR part 340.*

**3.0 RESPONSIBILITIES**

**3.1** *Identify and record the relevant personnel involved in addressing potential regulatory compliance incidents with GE organisms regulated under 7 CFR part 340. For example, this could be accomplished with an organizational chart or defined directly in the procedure. The level of specificity might identify any quality management representatives, corporate staff, field supervisors, or someone else engaged in the procedures for post-harvest handling and transfer. In some cases, the procedure might require your organization to obtain information from multiple departments according to your organization’s structure (i.e.; legal, regulatory) — each of which could be described in this section.*

**4.0 REPORTING OF POTENTIAL REGULATORY COMPLIANCE INCIDENTS PROCEDURE**

**4.1** *Describe how your organization addresses potential regulatory compliance incidents. For example, describe any relevant rules, regulations, and guidance your organization follows, roles for relevant personnel, how your organization conveys that information to those performing tasks, and how your organization documents tasks related to potential regulatory compliance incidents*

**4.2**  *Describe how your organization documents the nature and extent of a potential regulatory compliance incident. For example, the description might include details of location, responsible personnel, communication modalities, a flowchart to describe the flow of information, decisions made, and responsibilities assigned at each step.*

**4.3** *Describe how your organization communicates internal requirements of your organization for the prompt resolution and remediation of potential regulatory compliance incidents.*

**4.4** *Describe how your organization’s methods for documenting resolution activities are used for the prompt remediation of potential regulatory compliance incidents*

**4.5** *Describe how your organization’s methods for reporting the potential regulatory compliance incident to appropriate regulatory authorities according to applicable rules and regulations. For example, the description might include information on specific contact persons or offices, who in your organization is responsible for making contacts, and at what point the contact or communication is made.*

**4.6** *Describe how your organization trains relevant individuals involved in regulatory compliance reporting requirements. For example, the description might include who does the training, how frequently is the training done or renewed, and how does your organization evaluate the relevance and effectiveness of the training.*

**4.7** *Describe how your organization monitors and verifies the effectiveness of the above planned activities and of any changes to those activities. For example, the description might include the type and extent of monitoring or measurement appropriate to each process in relation to its impact on compliance with APHIS regulations found at 7 CFR part 340.*

**4.8** *Describe how your organization keeps records on all the above activities.*

**5.0 REFERENCES**

**5.1** *List here any references that apply to this procedure.*

 *Examples might include:*

 *Control of Documents*

 *Control of Records*

 *Responsibility and authority*

 *Competence, Awareness and Training*

 *Infrastructure*

* 1. *List here any records or forms that apply to this procedure.*

*Examples might include:*

 *Potential Regulatory Compliance Incident Reporting and Resolution Form*

 *Master List of Documents*

 *Training record(s)*