**Purpose of Module for Reporting Form for Potential Regulatory Compliance Incidents:** This module provides an example template of a form for 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 reporting 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 reporting a potential regulatory compliance incident. 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.

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| **Regulatory Compliance Incident Reporting Form**For Potential Incidents of Regulated Genetically Engineered Organisms Title 7, Code of Federal Regulations, part 340 |
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| *Provide instructions for how your organization might use such a form, such as:* * *List personnel in your organization who would use the form to record written or verbal reports of compliance incidents.*
* *How this form might be used to record a required verbal report of an accidental or unauthorized release of a GE organism regulated under 7 CFR part 340.*
* *Describe which other types of compliance incidents for which your organization would use this form. For example, if your organization misapplied the conditional exemption described in 7CFR part 340.2(b) for certain regulated articles (i.e. certain GE E.coli, Arabidopsis).*
* *For accidental/unauthorized releases, information on this form is required to be submitted verbally to APHIS BRS immediately upon discovery of the incident. A written version must be submitted to APHIS BRS within 24 hours.*
* *Written reports of incidents other than accidental/unauthorized release must be submitted to APHIS BRS within 5 working days of discovery.*
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| **Permit or Notification Number** |  |
| **Responsible person on permit or notification** |  |
| **Submitter’s Name** |  |
| **Date & Time of Report to APHIS BRS** | *[Fill-in this information when you verbally call APHIS BRS]* |
| **Type of report made**  | [ ] VerbalIf so, name of Regulatory Specialist:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Voicemail |
| **Regulated organism(s)** |  |
| **Location Description** | *[Describe County, State and GPS coordinates if applicable]* |
| **Incident Date(s)** |  |
| **Discovery Date(s)** |  |
| **Incident Type** | [*Specify: confinement, permit issue, mixing, volunteers, specific performance standard(s)*] |
| **Brief Description** | [*Describe the incident so APHIS BRS has a clear understanding of the nature and circumstances of the incident*] |