**Purpose of Module for Site Selection Planning**: This module provides an example template for use in site selection planning that your organization might use as part of your organization’s quality management practices relevant to APHIS regulations at 7 CFR Part 340 for certain genetically engineered (GE) organisms.

**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**: This module includes a template (below) that your organization can customize specific to your operational practices for the design and implementation of site selection planning. Each section of the template has examples of what might be included in a standardized form for a site selection planning. 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 site selection planning for environmental releases of 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 planned activities are achieved and regulated activities are conducted. For example, species of regulated GE organism addressed in this procedure is [species name].*

**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 the planning of sites selected for environmental releases. 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 procedure to plan site selection. In some cases this 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 SITE SELECTION PLANNING PROCEDURE**

**4.1** *Describe how your organization addresses surrounding land use and proximity to sexually compatible species. For example, field trial maps could be used in the description of physical separation distances and orientation.*

**4.2**  *Describe how your organization obtains information on the historical land use and topography of the environmental release site. For example, what information of past cropping practices and field maps does your organization have access to, and what is the nature of the information (anecdotal, written cropping records, contract or lease agreements?*

**4.3** *Describe how your organization establishes provision of rights to access to the release sites for the term needed for the release and subsequent monitoring of plant volunteers and/or mitigation activities?*

**4.4** *Describe how your organization monitors and verifies the effectiveness of the above planned site selection activities and of any changes to those activities.*

**4.5** *Describe how your organization will keep its records on all the above activities.*

**5.0 REFERENCES**

**5.1** *List here any references that your organization uses in its procedure for site selection planning.*

*Examples might include:*

 *Control of Documents*

 *Control of Records*

* 1. *List here any records or forms that apply to this procedure for site selection planning.*

*Examples might include:
Training record(s)*