**Purpose of Module for Storage**: This module provides information that your organization might use storage as part of your organization’s quality management practices relevant to APHIS regulations found 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**: The module includes a template (below) that your organization can customize specific to your needs and operational practices for storage of regulated GE organisms, the way in which the storage procedures are monitored, and whether the monitoring and verification are effective. Each section of the template has examples of what might be included in a standardized form for a storage procedures. 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 for storage of regulated genetically engineered (GE) organisms; the way in which the storage process is monitored; and whether the monitoring and verification, as well as any changes in those activities, are effective. 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 storage of 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 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 STORAGE PROCEDURES**

**4.1** *Describe how your organization’s storage procedures keep regulated GE organisms will be segregated from other organisms. For example, procedures might describe marking or clearly labeling the containers and storing the containers in a separate location; this may be in the same storage room.*

**4.2**  *Describe how your organization marks and/or labels storage areas. For example, color-coded labels might be used to show a separated item. Another example for when many items are stored in the same room, a line on the floor might be used to indicate separate storage areas, as well as a sign in the storage room describing color-coding and separations.*

**4.3** *Describe what type/kind of containers your organization uses for storage. Describe the ways in which your organization ensures that the containers are appropriate. For example, one criterion might be that the containers must be strong enough to withstand being stacked and moved from place to place.*

**4.4** *Describe how your organization marks, labels, and identifies your storage containers. For example, containers might all be one color, have labels, or be distinguished via a bar-coding system.*

**4.5** *Describe how your organization limits access to storage areas to authorized personnel and verifies that only the personnel you have authorized can enter storage areas.*

**4.6** *Describe how your organization monitors and verifies the effectiveness of the above planned activities and of any changes to those activities. For example, when determining suitable monitoring methods, your organization might consider the type and extent of monitoring or measurement practices relevant to the activities relevant to APHIS regulations.*

**4.7** *Describe how your organization’s relevant personnel receive training applicable to their defined roles and responsibilities.*

**5.0 REFERENCES**

**5.1** *List here any references that your organization uses in its procedures for storage.*

 *Examples might include:*

 *Control of Documents*

 *Competence, Awareness and Training*

 *Infrastructure*

* 1. *List here any records or forms that apply to your organization’s procedures for storage.*

*Examples might include:*

*Master List of Documents*

 *Training record(s)*