**Purpose of Module on Control of Records**: This module describes how your organization can develop a record control procedure as part of a quality management system for activities subject to APHIS regulations 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 the design and implementation of record control procedures. Each section of the template has examples of what might be included in a standardized record control procedure, such as how records are established, maintained, retained, and destroyed. The template is not a standard, but should be considered 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. **PURPOSE:** *Describe the purpose of this document is in this section. For example, the purpose might state the following: In order to maintain control of records, this document will outline how records pertaining to regulated genetically engineered plants are established, maintained, and retained.*

**2.0 DEFINITIONS:** *Insert any terms, acronyms or reference to a glossary here that may apply to this procedure.*

**3.0 RESPONSIBILITIES**

**3.1** *Identify and record the relevant personnel in charge of the control of records for your organization (e.g.: some organization identify a quality management representative such as a document control manager to ensure that all required records are controlled)*

**3.2** *Describe of the roles of other staff, outside collaborators, or managers who may handle, fill out, create, store or receive records.*

**4.0 CONTROL OF RECORDS**

**4.1** *Describe the controls your organization uses to ensure that records will remain legible, readily identifiable, and retrievable.*

**4.1 1** *Describe in general terms your filing system and storage system.*

**4.1.2** *Describe how your organization’s records are identified, e.g., this is often done with a title or name on the record, date that the record was made, etc.*

**4.1.3** *Describe how your organization tracks changes to its document.  An example for written records might include drawing a single line through the incorrect entry, writing the correction above the incorrect entry and initialing the correction.  Another example might include numbering the place that is crossed off and writing the corresponding number and correction in the margin of the record.*

**4.1.4** *Describe your organization’s established methods for reliably retrieving relevant records that are in electronic and written formats.  For example, consider how records are retrieved from storage, while a person is in remote locations, etc.*

**4.2.** *Describe your organization’s criteria for record storage.  For example, describe any established criteria for when, where, how, and how long are records stored? If record storage criteria and practices are not yet established within your organization, identify or develop such criteria.*

**4.3** *Describe how your organization disposes of written and electronic records that are outdated, superseded by subsequent records, etc.*

**4.4** *Describe how your organization protects records in written and electronic formats, including information about backup systems.*

**5.0 REFERENCES**

**5.1** *List here any references that your organization uses in the control of its records.*

*Examples might include:*

 *Control of Documents*

 *Control of Records*

 *Communication*

**5.2** *List here any records or forms that apply to how your organization controls records.*

*Examples might include:*

 *Management Review Form*