**Purpose of Module 4.2.3 for Control of Documents**: This module provides an example template for use in the control of documents 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 the design and implementation of the control of documents. Each section of the template has examples of what might be included in a standardized form for document control. 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. **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 documents, this document outlines how documents pertaining to regulated genetically engineered plants are established, maintained, and retained.*

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

1. **RESPONSIBILITIES**
   1. *Identify and record the relevant personnel in charge of control of documents for your organization. For example, some organizations identify a quality management representative such as a document control manager to ensure that all required documents are controlled.*
   2. *Identify and record the person(s) responsible to make sure that documents, forms and records, internal or external, are updated (may be the same person).*
   3. *Describe and identify the roles of other staff, field coordinators, outside collaborators, or managers who may handle, fill out, create, store or receive documents.*
2. **CONTROL OF DOCUMENTS**

Note to user: Your organization might choose to establish a master list of documents. For example, a master list of documents might include procedures, work instructions, forms, and any other documents that your organization controls. A master list of documents typically shows the most current version of your organization’s documents. A master list can be paper-based, electronic or in any other format that can be continually updated, maintained and controlled.

* 1. *Describe the process that your organization uses to approve documents for adequacy prior to being issued or used. Before documents are used, they are typically reviewed for content to make sure they are appropriate for the intended purpose. For example, your organization might use electronic signatures, review panels, hard copy reviews or any other method to approve documents prior to being used.*
  2. *Describe your organization’s procedure for how you review, revise, and re-approve these documents so that the documents remain current, relevant and updated to your organization’s operations. For example, this review might be part of a management review meeting within your organization.*
  3. *Describe how your organization ensures that the current revisions of documents are identified. For example, this might be done by referencing a document revision form that has a space for any changes (e.g. document status form).*
  4. *Describe how your organization ensures that applicable documents are available at point of use. This might be in electronic formats such as software, company internet, or in paper format in a file cabinet or folder in the “work” area.*
  5. *Describe how your organization ensures that documents remain legible and readily identifiable at point of use (include electronic documents, and ensure that documents that have writing on them can be read). For example this might be addressed by having file cabinets that protect documents from sunlight fading, fire, and pest damage.*
  6. *Describe how your organization identifies external documents and controls their distribution. For example, audit documents might be relevant external documents.*

* 1. *Some external documents might be kept with their original identification and added to the document status form. This form might then be scanned and kept with other controlled documents in electronic or hard-copy format to make it easier to see if documents are up to date.*
  2. *Describe how your organization prevents unintended use of obsolete documents, such as archiving them in the computer so no one without the appropriate authority can gain access, or by destroying the documents by shredding in the case of paper documents. If obsolete documents are to be retained, describe how your organization identifies or marks any obsolete documents as obsolete. For example, this could be with a stamp or by simply writing on them the word “OBSOLETE”.*

1. **REFERENCES**
   1. *List here any references that your organization uses in the control of its documents. Examples might include:  
       Communication*

* 1. *List here any records or forms that your organization uses in the control of its documents.   
      Examples might include:   
      Document Status Form  
      Master List of Documents*