**Purpose of Module for a Management Review Meeting**: This module provides a sample form for use in a Management Review Meeting that your organization might use as part of your organization’s quality management practices relevant 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 management review meetings. Each section of the template has examples of what might be included in a standardized form for a management review meeting. 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.

**Management Review Meeting**

A Management Review Meeting is typically held at least annually to ensure the continuing suitability, adequacy and effectiveness of the organization’s quality management practices. The timing of the meeting often coincides with the review of the organization’s yearly activities and when the organization can report on the agenda items.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The section below can be used to list the names of all employees, contract employees, or guests present at the meeting.

Meeting Attendees:

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**Agenda**

1. Call meeting to order and take roll.

*This section typically describes any invited attendees who are not present, and indicates who their replacement is, if applicable.*

**Inputs for Agenda Items:**

*Note to user: The following agenda items typically have inputs at a management review meeting. Notes or inputs might include attached reports, graphs, charts or other documents that would address the agenda item.*

1. Review audit results (internal and third party).

*This section typically includes report on findings from evaluations and/or audits conducted since the last Management Review meeting. In some cases, this meeting might include a summary of inspections by the organization or APHIS of regulated field sites.*

1. Review process performance and conformity with established processes and procedures.

*This section might include the organization’s reports on quality management procedures, standard operating procedures, work instructions, forms, records, etc. Typically, any updates or changes from the last management review meeting might be reviewed in this section.*

1. Review status of any corrective and preventive actions to your organization’s quality management practices.

*This section might be used to review information on the status of previous actions or any new actions identified since the last Management Review. This might include open and closed preventive and corrective actions, their results, summaries of root causes and effectiveness of the actions, etc.*

1. Review follow-up actions from previous management reviews.

*This section might be used to review your organization’s actions from the previous management review meetings and /or other meetings that are relevant to the management review meeting or any other aspects of your organization’s quality management practices.*

1. Review changes that could affect your organization’s quality management practices.

*This section might be used by your organization to review past or upcoming events, new items, reports from internal or external meetings relevant to your organization’s quality management practices.*

1. Review recommendations for improvement.

*This section might be used by your organization to review results from surveys that come from formal or informal sources. Other examples for this section might include reports on meetings with external associates and/or internal employees. In some cases, sources may come from research, meetings on infrastructure, etc.*

**May be added to inputs:**

1. A report of monitoring and verification activities that may have an impact on your organization’s quality management practices, including any verification that conformance with planned practices have been met.

*This section might be used by your organization to report about the way it verifies that service providers conform to planned practices and procedures. This might include cost, timeliness of delivery, quality of the product, contract and deliverable oversight, etc.*

2. Review and analyze data providing information relating to regulatory compliance and how this data could influence conformance with your organization’s quality management practices.

 *Possible examples of information:*

 *a. Applicable rules and regulations*

 *b. Conformity to your organization’s quality management practices*

*c. Characteristics and trends of processes and external associate performance including opportunities for preventive actions*

 *This section might also include information on data being analyzed, analysis methodology, conclusions, and recommendations.*

3. Review and evaluate where continuous improvements have been made.

*Your organization may want to keep a log or file of improvements made since the last management review meeting. A report can be made and added to the agenda items for continuous improvements. These improvements might come from external associates, internal groups, research, marketing, quality objectives, etc.*

**Typical Outputs:**

*Outputs typically have actions associated with them, including clear expectations, assignment of responsibilities and due date. Reports on these actions typically are reported on at the next management review meeting. (See agenda item 4.)*

1. Improvement of the effectiveness of your organization’s quality management practices.
2. Improvement of processes and procedures related to regulatory compliance.
3. Resource needs.
4. Revisions of the organization’s quality policy and related quality objectives.

**Optional agenda item(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Other business

*Note any other business discussed during the meeting that was not included in the original meeting agenda.*

Approval: Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*This section of the meeting form provides a place to record approval for the contents of the meeting form. For some organizations, the quality management representative (QMR) or other person would typically approve the form.*