**Purpose of Module for Environmental Release Planning and Monitoring:** This module provides an example template for use in competence awareness and training that your organization might use 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 competence awareness and training for activities with regulated GE organisms. Each section of the template has examples of what might be included in a standardized form for competence awareness and training. 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 method by which your organization will ensure that relevant personnel performing work affecting the organization’s quality management practices are qualified and adequately trained.*

**2.0 DEFINITIONS:** *Insert any terms, acronyms or reference to a glossary here that may apply to this procedure. For example, this section might be used to define “relevant” personnel and “relevant” aspects related to your organization’s quality management practices. 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 competence awareness and training for activities with 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 for competence awareness and training. The description might list the roles and responsibilities of a lead trainer or human resources manager who ensure that relevant training is done. This section might also describe that all current relevant personnel were trained as of certain date, and that this procedure will apply to all relevant personnel hired after that date.*

**4.0 COMPETENCE, AWARNESS AND TRAINING PROCEDURE**

**4.1** *Describe how your organization determines the necessary competency of people performing work affecting your organization’s conformance with its quality management practices and its compliance with relevant regulatory requirements. For example, this might be done by referencing a job posting or job description that is already established.*

**4.2** *Describe how your organization provides training to satisfy those needs for conformance with your organization’s quality management practices and its compliance with relevant regulatory requirements. For example, this might be done by describing a formal training or mentoring program, in which case a training schedule and sign offs might be the records that are referenced in the description.*

**4.3** *Describe how your organization ensures that people responsible for monitoring, corrections and corrective actions are trained. For example, this might be by a sign off on a training or a mentoring program.*

**4.4** *Describe how your organization ensures that the training is implemented and effective. For example, this might be done by monitoring trainees, by testing, or by other appropriate means.*

**4.5** *Describe how your organization ensures that personnel are aware of the relevance and importance of their work and how they contribute to achievement of the quality objectives. For example, this might be done through training and/or by providing personnel with information in performance reviews, meetings, newsletters or one-on-one discussions.*

**4.6** *Describe how your organization keeps records on all above activities. For example, the description might include record retention time after the training event.*

* 1. **REFERENCES**

 **5.1** *List here any references that apply to this procedure.*

 *Examples might include:*

 *Control of Documents*

 *Control of Records*

 *Communication*

**5.2**  *List here any records or forms that apply to this procedure.*

 *Examples might include:*

 *Master List of Documents*

 *Training record(s)*

 *Competency record*

 *Training log*

 *Effectiveness measurement record (assessment or sign off by mentor)*