Process Management

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Seed Quality Assurance and Seed Enterprise Management Short Course - UON

Introduction

- Process management is a series of techniques, skills, tools, and methods used to control and manage a business process within a large system or organization. It involves activities of planning and monitoring the performance of a process.
- Process management is the application of knowledge, skills, tools, techniques and systems to define, visualize, measure, control, report and improve processes with the goal to meet customer requirements.
- The term is most commonly used in business analysis, productivity studies, and systems engineering.
- The purpose of process management is to clearly identify and document all the steps and actions taken to complete a process or work flow.
- This type of work requires a great attention to detail, excellent written communication skills, analysis skills and the ability to objectively meet the requirements of the project.

Process management

- ISO 9001 promotes the process approach to managing an organization.
- ...promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Source: clause 0.2 of ISO 9001:2000

Process management

Process management involves:

1. documenting the current process,
2. evaluating of time and level of effort,
3. analysis of efficiency, bottlenecks, and overall process costs.

- These three items remain the same, regardless to the industry or sector.
- Exercises in re-engineering or business process management often start with process analysis.

Advantages of process management

- Minimizing/managing costs - a strict adherence to a formal management process is an acknowledged cost containment method. A complete and thoughtful review of all the steps of a business process helps save significant money and resources across the organization.
- In the standard process management process, the first step is the review of the existing process. This usually includes reading the operations manual, discussions among staff, and observing activities.
- The actual process can vary from the written steps. This is often due to out of date manuals, or failure of the manual to truly capture all the steps and their implications.
- Observing staff is one way to determine the time required for each step in a process. Another way is to simply measure the time required to complete an entire process and determine the average time for each step. The most effective way is to actually spend a short period of time in each role.
- Working in a position quickly highlights the issues, strengths and weaknesses of the current process. Discussions between staff and supervisors helps understand individuals' ideas and see where improvements can be made.

Advantages of process management

- Tracking, recordkeeping, testing and other measures with appropriate oversight management systems are essential parts of process management
- Since maintaining a seed variety's trueness to type is critical for market acceptance and use, robust quality management practices are needed in seed quality systems.
- Quality management systems, such as ISO 9001, provide structure and rigor to business practices by way of managing key process variables, thereby establishing routine and consistent output from their processes.
- These systems, further facilitate ease of doing operations, meeting customer expectations and mechanisms for continually improving the quality management system.
- An significant consideration of a process management system is the importance of communication with clients.

Steps in process management

Step 1: Process Definition

- For an organization to function well, it needs to develop a common language for its operations. This language is in the form of flow charts and their associated standard operating procedures (SOP's), which are clearly documented.
- Useful documentation can only be generated by the people who actually execute the process. Operators should be involved in the preparation of documentation so that they understand it and own it.
- Documentation written in the language of the operator becomes a invaluable training tool for new operators.
- Documentation should always reflects the current state of the process. This is the key step in converting intangible (stored in volatile human memory) into tangible (documented) knowledge.
- This foundation step is formalized in the requirements of ISO9000 certification which requires that the processes be documented and that they be executed in accordance with that documentation.
- This is an essential starting point for process management. However, ISO9000 does not currently go beyond this step.

Steps in process management cont'd

- **Step 2: Simplification (Re-engineering)**
- **Process Simplification** is a process design technique that helps us make a process more feasible and manageable through dividing this process into relatively simple tasks.
- Every task is carefully observed to detect and remove redundant or wasteful actions and to estimate precise time necessary for implementing corrections.
- This technique aims to design and plan a process in a manner that is least expensive and consistent with the process's objectives.

- Simplification of a process allows reaching greater productivity through reduced use of mental and/or physical employee effort. Productivity improvements also result from minimization of money and time involved in the process. Employees do more simplified jobs with greater performance. Meanwhile, the process keeps to the same objectives; only the process's structure and resources are changed in order to reach simplification and continuous improvement.

Steps in process management cont'd

Step 2: Simplification (Re-engineering)

- In general, process simplification involves the following activities:
  - Eliminate wasteful or non-value adding actions
  - Reduce process cycle time
  - Remove defects or disconnections between process tasks
  - Increase employee involvement
  - Reduce process cost

Steps in process management cont'd

- **Step 3: Characterization and Idealization**
- Once we have a trim, well documented process, we are prepared to continue with its management.
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    - "You can't manage what you don't measure."
    - "You get what you measure."
    - "If you're not keeping score, you're only practicing."
    - "If you don't measure it, it will not improve; if you don't monitor it, it will get worse."

- This step deals with process performance measurement or metrics and is among the most difficult and least developed of the steps.
- A process can be characterized by an appropriate set of results and process metrics.
- Results metrics measure the output of the process in terms related to its customer's explicit requirements. They are measures of process effectiveness.
- Process metrics represent the key independent variables that are the internal drivers of change in the results metrics. They often are the critical factors in determining process efficiency.
- In general, each type of metric can characterize either the average value of a measure or its variability.
- So we in general have results and process metrics that measure the average and variation of critical process measures.
- Without an estimate of the process capability associated with each metric, we cannot set rational goals nor decide on the priorities for redesign .

Steps in process management cont'd

- **Step 4: Control**
- The control step assures that the metrics associated with the process remain stable. In this way, the fraction of output that fails to meet customer requirements can be predicted with a specified level of statistical confidence. With this assurance, the customer can effectively manage their inevitable non-conforming inputs through either 100% inspection (done by them or their supplier) or defect correction.
- Control is a prerequisite for process improvement. Without it, it is difficult or impossible to do experiments to identify root causes. Root cause analysis is central to both incremental improvement and process redesign.

Steps in process management cont'd

- **Step 5: Decision: Improve Existing Process?**
- There should be a sound criteria for redesign or incrementally improving decision.
- A newly redesigned process, with its unfamiliar technology and/or organizational structure will not instantly achieve its ultimate capability. Much process learning is required to significantly narrow the initial performance gap (typically 30% to 40%).
- Continuous improvement tools and techniques currently produce the fastest rates of improvement for newly re-designed processes.
- Over time, a point of diminishing returns is reached for processes that are core competencies, and the process needs to be re-designed in order to achieve or maintain competitive leadership.
- Process redesign is very expensive in both fiscal and human capital terms. Hence, process management must ebb and flow between redesign and incremental improvement.
- A newly redesigned process often generates the same defects as the old one. The carrier of this disease is ignorance of their root causes. A prudent process owner will want to know as much as possible about the root causes of defects in the old process in order to minimize the risk before making the very costly decisions associated with process redesign.

Steps in process management cont'd

- **Step 6: Incremental Improvement**
- We need to keep this in mind ,

"incremental improvement is the essence of evolution and an ever-present human activity, ongoing since the very dawn of humankind three million years ago. What has changed most in the last half-century are the principal players in this activity"

Wher are we coming from?

- Industrial revolution to the middle of the 20th century - responsibility for process improvement increasingly lay with management or their designees, the industrial engineers.
- Result ?? - the process worker was told "don't think, just follow the standard operating procedures." The worker became nothing more than a pre-robot.
- Early 1950's - the Japanese tried a different process improvement paradigm: empower all process workers to not only do their daily job, but also to improve the *way* they did that job.
- But, empowerment is different from delegation. Japanese managers went on to train the workers in the basic scientific methodology, set aside a portion of their workday (about 5-10%) for improvement activities, and reward and recognize their success to catalyze the required cultural changes.
- The answer is not to flit from step-to-step, but to recognize that an integrated approach, though very difficult, is essential. No single step can serve as a silver bullet for very long.

Steps in process management cont'd

- **Step 7: Re-design**
- Over time, incremental improvement yields diminishing absolute returns. This results from both the technological and organizational constraints imposed upon the process.
- Incremental improvement can exponentially gnaw away at the gap between current performance and these process limits. If organizational success requires breaching these barriers, only process redesign holds the answer: new technology or new organization (in- or out-sourcing, functional to process re-organization, risk taking or shedding, etc.).
- There is much mystique associated with process re-design. Yes, there may be some cases where "thinking outside the box" is required, but in the vast majority of cases, the next wave is well known to both the process owners and their suppliers. Whether it's through vendors, the trade press or benchmarking activities, we usually know what's coming next. The issue really is a resource allocation question: where should we invest our scarce human and capital resources?
- Sometimes process redesign is justifiable on the basis of cost savings alone. Redesigns involving automation (replacing labor with capital) usually fall into this category. The more challenging redesign decisions, however, flow from strategic imperatives.
- The half-life method provides another important link between incremental improvement and process redesign. The half-life, which depends on process complexity, tells us the rate at which the gap between current and potential performance can be closed. It allows us to easily predict where we will be at any future point in time if we improve incrementally. What if that's not good enough to beat the competition? The only remaining choice is process redesign.

Example: Process Management

Seed Production Operations

- **Scope -** Operations that are applicable to process elements where seed is prepared, planted, harvested, conditioned, or stored.

Seed Production Operations

Planting Preparation: Site Selection, Soil Preparation, Equipment Preparation

- **A. Analysis of Product Integrity and Control Concerns**
- Appropriate isolation not established or maintained
- Producer unexpectedly plants the same crop within the area of isolation
- Planter not properly cleaned and contains seed of a different product
- Natural disaster and vandalism vulnerability of site
- Presence of sexually compatible plants in the area of isolation
- Improper removal of volunteer plants from earlier growing seasons
- Crop rotation is not adequate
- Seed source is infected with pathogens or pests
- Proximity to plants harboring pests or pathogens of concern
- Weed control in borders and adjacent fields is not adequate
- Inspection or testing for pathogens and pests in transplants, if used

Planting Preparation

B. Determine Control Points

- Site/field/producer selection and method of isolation
- Proper planter and equipment cleanout and management
- Movement of seed in and out of isolation area
- Presence of sexually compatible plants in the area of isolation
- Observation of weeds in and adjacent to the field to prevent weed seed contaminants
- Seed inspection for foreign material and evidence of improper storage during seed preparation

Planting Preparation

- **C. Establish Preventive Measures**
- Establish parameters of isolation from other crops of the same species as required by applicable regulations and/or company standards
- Establish isolation maintenance plan and timing
- Establish that the site or field is not adjacent to any areas prone to unauthorized access
- Implement proper crop rotation and field selection to keep pest levels as low as possible
- Establish producer access to the land through ownership, lease or grower agreement
- Establish grower contract
- Establish procedures for proper cleaning and inspection of field equipment, including for possible pest infested or pathogen infected material
- Establish communication with neighboring seed growers, farms and residences as appropriate.
- Establish procedures to detect presence of and destroy sexually compatible plants in the area of isolation
- Appropriate elimination of infected plant debris during land preparation

Planting Preparation

- **D. Establish Monitoring Procedures**
- Prior to planting, inspect all land within the area of isolation to establish that no crops of the same species are planted.
- Communicate with neighboring producers to establish that they are not planting sexually compatible species or types within the isolation distance
- Prepare site map to identify locations of any sexually compatible wild relatives
- Inspect fields for evidence of pests and pathogens of phytosanitary concern prior to planting
- Inspect field equipment for possible sources of contamination
- Inspect field for unintended plants

- **E. Establish Corrective Measures**
- If the isolation parameters are not met, find a different, more suitable site or field
- If a producer unexpectedly plants the same crop species within the isolation zone, negotiate to remove the conflict
- If the planter has seed in it prior to planting, thoroughly clean it and re-verify
- If infected debris or pathogen infected plants of phytosanitary concern are detected, properly dispose of or destroy them

Planting Preparation

- **F. Establish Verification Procedures**
- □ Verify that the isolation parameters are met
- □ Verify isolation with other seed producers
- □ Prior to planting verify that the site/field location and acreage meets specifications
- □ Prior to planting, verify that the planter is clean of seed
- □ Verify phytosanitary condition of seed, site, and planting equipment

- **G. Establish Record Keeping and Documentation Procedures**
- □ Maintain records of planter cleanout and verification.
- □ Create a preliminary site/field map to be finalized after planting
- □ Maintain a copy of the signed producer contract
- □ Maintain site/field inspection records
- □ Maintain records of phytosanitary conditions

Planting: Planting and Equipment Cleaning

- **A. Analysis of Product Integrity and Control Concerns**
- □ Seed is planted at the wrong site, such as through:
- □ insufficient cleanout of the planter after planting seed
- □ insufficient cleanout of the tractor after planting seed
- □ mistakenly planting the crop out of compliance with instructions and/or map
- □ Area of isolation does not satisfy minimum requirements, internal and/or external
- □ Mixing with more than one product occurs because of insufficient cleanout of the planter or improper loading of the planter
- □ Seed is planted on pathogen or pest contaminated soil or soil with pathogen infected debris of phytosanitary concern
- □ Movement of field equipment between sites or fields

Planting: Planting and Equipment Cleaning

- **B. Determine Control Points**
- □ Evaluation of the site and surrounding isolation zone prior to planting
- □ Planter cleanout
- □ Disposition of planting material
- □ Testing or documentation to properly identify the intended seed used for planting
- □ Adequate land and irrigation preparation to manage possible pests and pathogens of phytosanitary concern

- **C. Establish Preventive Measures**
- □ Prior to planting, verify correct location of site/field, isolation parameters and identity of seed
- □ Transport the seed to the field/site in a fully enclosed, secure container
- □ Use planters that can be cleaned and will not retain seed
- □ Load the seed in the planter only at the proper field/site
- □ Adequate control of seed, such as maintaining seed in secure location when left unattended
- □ Planters adequately cleaned before being transported away from the field/site
- □ All seed cleaned out of the planter properly disposed of, if appropriate
- □ All seed bags should be properly ”contained”
- □ All other containers used for seed should be cleaned and verified before leaving the field/site
- □ If field has a risk or history of pest or pathogen problems, implement sanitation/disinfestation measures

Planting: Planting and Equipment Cleaning

- **D Establish Monitoring Procedures**
- □ Reconciliation of intended and actual seed inventory
- □ Isolation parameters
- □ Planters and related equipment inspected after use to establish they have been cleaned
- □ Any other containers used are cleaned and inspected

- **E Establish Corrective Measures**
- □ If seed is planted at the wrong site, develop a remedial action plan
- □ If discovered that seed may have been mixed with other seed for any reason, determine appropriate remedial action
- □ If the isolation parameters are not correct, determine appropriate remedial action
- □ Have a cleaning and monitoring plan for field/site to address improper disposition of plant material
- □ If planting field has pest or pathogen infected debris, implement appropriate sanitation/disinfection procedures
- □ Manage irrigation water to minimize pathogens of phytosanitary concern

Planting: Planting and Equipment Cleaning

- **F. Establish Verification Procedures**
- □ Verify that the field/site is correct
- □ Verify that the isolation parameters are correct
- □ Verify that the correct seed is being planted at the field/site
- □ Verify that the planter is clean after use
- □ Verify that all containers used for seed were cleaned prior to removal from the field/site
- □ Verify land is properly prepared and irrigation properly sourced

Planting: Planting and Equipment Cleaning

- **G. Establish Record Keeping and Documentation Procedures**
- Maintain field/site maps
- Maintain records of the identity of the seed planted
- Maintain records of isolation parameters
- Maintain records of quantity of seeds or plants planted
- Maintain records of planter cleanout and verification
- Maintain records of method of disposition of any remnant seed
- Maintain records of phytosanitary conditions of planted fields

Cultivation/Husbandry

- **A. Analysis of Product Integrity and Control Concerns**
- □ The isolation parameters are not met
- □ Volunteer plants of the same species, as well as sexually compatible plants, in the area of isolation flower concurrently with the crop causing a potential loss of confinement
- □ Natural disaster causes an accidental release and loss of confinement
- □ Site vandalized resulting in a loss of confinement
- □ Failure to follow internal company product integrity policy
- □ Volunteer plants may be hosts for pests and pathogens
- □ Weediness of field and adjacent areas not properly managed
- □ Improper crop rotations
- □ Sanitation practices for field equipment and personnel not followed

- **B. Determine Control Points**
- □ Maintenance of the method of isolation
- □ Sanitation and movement of equipment and personnel into and out of the field/site
- □ Intensive inspection/observation for pathogen infection and pest infestation during reproductive stages

Cultivation/Husbandry

- **C. Establish Preventive Measures**
- Establish cleaning procedures for equipment used for seed/crop production
- Standard operating procedures in place regarding personnel movement from one site or field to another
- At regular intervals until flowering of the crop is complete, establish procedure for monitoring area of isolation for volunteers and/or unexpected plantings,
- Establish natural disaster contingency plan
- Establish appropriate field management practices before planting
- Monitor development of plant diseases and other pests at different growth stages

- **D Establish Monitoring Procedures**
- Establish inspection procedures for plants/field, including inspections for vandalism, animal and weather damage
- Establish and follow best practices for "hand pollinations" where technique is used
- Rogue off-type plants
- Establish procedure for area of isolation to monitor for unexpected plantings and identify and eliminate unintended plants,
- If temporal isolation is used, establish procedure to verify that the isolation was effective or to correct potential problems before they occur
- Establish procedures to conduct phytosanitary field inspections

Cultivation/Husbandry

- **E. Establish Corrective Measures**
- If crop tissue is found on or in equipment during a post-cleanout inspection, establish corrective measures, such as re-cleaning and re-inspecting the equipment
- Destroy any plants of the same species (volunteer or planted) or sexually compatible plants found within area of isolation
- If it is determined prior to, or during, flowering of the crop that the temporal isolation is likely to be ineffective, develop alternate plan with neighboring growers
- If vandalism or natural disaster occurs that results in a loss of confinement, take appropriate remedial action
- Establish sanitation procedures to mitigate pathogen infected and pest infested debris

- **F. Establish Verification Procedures**
- Verify cleanout of all equipment
- Verify that isolation parameters are met
- Verify no plant or seed is removed without authorization
- Verify phytosanitary conditions of plants and products to be harvested

Cultivation/Husbandry

- **G. Establish Record Keeping and Documentation Procedures**
- Maintain records documenting all equipment cleanout and verification
- Maintain routine site inspection records documenting agronomic conditions, any damage that may have occurred due to weather, animals or vandalism and monitoring of the isolation distance (physical and temporal)
- Maintain reports on any corrective or remedial actions that were taken throughout production
- Maintain records of plant pathogens and other pests detected and resulting actions

Harvest and Post-Harvest

- **A. Analysis of Product Integrity and Control Concerns**
- Seed identity or containment is lost by:
- accidental spill during harvest and/or transport
- mixing with other grain/leaf tissue harvested from food/feed crop production
- tampering with, vandalizing or removal from the site
- spontaneous seed shedding and dispersal before or during harvest
- Seed mistakenly sent to the wrong post harvest conditioning location
- Seed infected by pathogens or infested by pests of phytosanitary concern in the field
- Seed lots not properly managed such that infested and clean lots are at risk of being co-mingled
- Procedures are not in place to prevent potential contamination during and after harvest and transportation

- **B. Determine Control Points**
- Harvest and transport equipment inspection
- Seed harvest and transport
- Packaging for shipment to post harvest conditioning location
- Bins/containers used for seed transport

Harvest and Post-Harvest

- **C Establish Preventive Measures**
- □ Training of all field operations personnel on specific job responsibilities
- □ Training is documented
- □ Cleaning of harvest, in-field conditioning and transport equipment after previous use
- □ Disposition of residual grain/leaf tissue in accordance with internal and/or external requirements
- □ Prior to next use, equipment visually inspected for cleanliness and safe operation
- □ Established criteria for decision to harvest
- □ Seed is dried or otherwise initially conditioned according to specific work process protocol
- □ Seed is packaged in durable container and contents of container documented
- □ Upon arrival at the post harvesting conditioning location, the seed is processed and stored properly
- □ Establish pathogen and pest preventive control measures to protect against comingling and post harvest pest infestation

- **D. Establish Monitoring Procedures**
- □ Monitor to verify that the cleanout or equipment adjustment was done properly
- □ Seed sampling for characterization of lot

Harvest and Post-Harvest

- **E. Establish Corrective Measures**
- If crop tissue is found on or in equipment during a post-cleanout inspection, establish corrective measures, such as re-cleaning and re-inspection of the equipment
- If it is determined that a loss of containment has, or may have occurred, implement appropriate remedial action
- If error in shipment occurs, implement appropriate remedial action
- Establish control actions if pests or pathogens of phytosanitary concern are detected

- **F. Establish Verification Procedures**
- Before shipment, verify that the movement is authorized
- Verify that all equipment is thoroughly cleaned before and after use and inspected
- Verify shipping containers and packages are clean, intact and sealed
- Verify that the correct seed has arrived at the post harvest conditioning location
- Verify that all appropriate samples have been taken
- Verify that the correct seed has arrived at the proper post harvest conditioning facility in a timely manner

Harvest and Post-Harvest

- **G. Establish Record Keeping and Documentation Procedures**
- Maintain records of job responsibilities for field operations personnel
- Establish documentation that equipment is cleaned or inspected for operational condition
- Establish documentation that before shipment all necessary procedures were followed
- Documentation listing shipment contents should accompany each shipment
- Documentation by receiver to show that container arrived intact and that the contents are as listed on the packing slip
- If grain/leaf tissue must be stored prior to conditioning, maintain records by the receiver indicating storage location of such materials
- Maintain records of pests and pathogens detected

Land Use Monitoring

- **A. Analysis of Product Integrity and Control Concerns**
- □ Post harvest field treatment is inadequate
- □ Post harvest field volunteer monitoring is inadequate
- □ Post harvest control of plant debris is inadequate
- □ Monitoring/control measures for unintended plants in and adjacent to fields are inadequate

- **B. Determine Control Points**
- □ Post harvest land use
- □ Post harvest volunteer monitoring
- □ Post harvest land management monitoring

- **C. Establish Preventive Measures**
- □ Depending on the crop, the field may be tilled post-harvest, with volunteers allowed to emerge, in order that they be removed
- □ Establish schedule for the monitoring of volunteers by responsible site personnel
- □ Establish schedule for the monitoring of noxious and other types of weeds of concern
- □ Management of plant residues which may harbor pests and pathogens

Land Use Monitoring

- **D. Establish Monitoring Procedures**
- □ Land use and volunteer monitoring, as appropriate
- □ Noxious and other weed species of concern
- □ Residues that may harbor pests or pathogens of concern

- **E. Establish Corrective Measures**
- □ If determined that a loss of containment has or may have occurred, determine appropriate remedial action
- □ If phytosanitary risk is identified, take appropriate action

- **F. Establish Verification Procedures**
- □ Verify post-harvest management of the field
- □ Verify the post-harvest monitoring, including duration, and removal of volunteers and sources of phytosanitary risk

- **G. Establish Record Keeping and Documentation Procedures**
- □ Keep records of training for roles of field operations personnel
- □ Maintain documentation, including date, each time scheduled monitoring for volunteers and sources of phytosanitary risk takes place

Seed Cleaning/Conditioning

- **A. Analysis of Product Integrity and Control Concerns**
- Seed lost to environment during conveyance into or within the seed conditioning facility, around equipment, drying bins, packaging stations and personnel shoes or clothing
- Admixing due to residual seed in equipment, conveyors, drying bins or other conditioning or packaging equipment
- Misidentification of seed
- Improper identification and/or labeling of commercial product
- Potential contamination of seed with pathogens or pests from soil
- Weed seed contaminants at harvesting
- Improper seed clean out between seed lots

Seed Cleaning/Conditioning

- **B. Determine Control Points**
- □ Movement of seed into and out of the facility
- □ Transfer within the facility and between containers and equipment
- □ Facility and equipment cleanout and containment
- □ Disposition of discard material that may or may not contain viable seed, pathogen propagules or pest components
- □ Packaging and inventory entry
- □ Appropriate environmental and sanitary conditions during harvest/transport/cleaning/conditioning
- □ Seed processing (coating, pelletization, treatment)

- **C. Establish Preventive Measures**
- □ Clean equipment and areas around the equipment
- □ Inspect equipment and containers before and after transfer
- □ Dispose of discard material that may or may not contain viable seed
- □ Establish identity verification throughout the process
- □ Verify product identity and the proper labeling of the commercial product
- □ Confirm seed lots to be of no phytosanitary risk
- □ Avoid high humidity conditions predisposing contamination of seed with pathogens and other pests

Seed Cleaning/Conditioning

- **D. Establish Monitoring Procedures**
- □ Document inspection of all equipment periodically for proper mechanical function and loss of seed
- □ Inspect seed for quality
- □ Verify product identity at all critical steps
- □ Verify product identity and the proper labeling of the commercial product
- □ Monitor and document as appropriate conditions at harvesting/transport/cleaning/conditioning

- **E. Establish Corrective Measures**
- □ Re-adjust equipment if loss of seed or if seed does not meet specifications
- □ Determine that all equipment is cleaned after use and re-clean if post-cleaning inspection reveals problems
- □ Take appropriate remedial action to address loss of seed containment
- □ If misidentification or mislabeling of commercial product occurs, take appropriate steps to correct issue or properly dispose of product
- □ If misidentification or mislabeling of commercial product is found, take measures to determine root-cause, clarify SOPs and provide training
- □ If environmental conditions favor pathogen and/or pest contamination, establish control actions

Seed Cleaning/Conditioning

- **F. Establish Verification Procedures**
- Inspect facility and production records and conduct periodic in-progress inspections
- Verify equipment is cleaned before and after use
- Secondary audit procedures in place, as applicable
- Verify container and equipment identification is correct between each transfer of seed
- Confirm and verify commercial product identity matches product label
- Confirm phytosanitary status of harvested product

- **G. Establish Record Keeping and Documentation Procedures**
- Establish that key activity records (e.g. cleaning checklists, conditioning records, seed locations, etc.) are maintained according to the record retention policy
- Maintain sample as required under *Federal Seed Act7*
- Maintain records of pathogens and other pests detected on harvested product and control measures

Viable Plant/Seed Storage, Warehousing and Distribution

- From a phytosanitary standpoint, it is important that systems are in place to maintain seed quality in terms of germination and purity, prevent exposure of product to pests in storage, and to maintain integrity and traceability of seed lots to meet regulatory requirements for documentation of origin, in-transit, and re-export.
- **A. Analysis of Product Integrity and Control Concerns**
- □ Seed/plant transported to an unintended destination
- □ Transport vehicles, packing containers and/or storage containers not properly cleaned after use
- □ Storage or transport containers not properly identified
- □ Loss of containment:
- □ during material transfer from transport vehicle to storage containers via equipment malfunction
- □ spillage during transfer
- □ failure to properly clean transfer equipment after use
- □ accident or natural disaster
- □ facility or transport vehicle vandalized
- □ Environmental and sanitary conditions during storage not adequate to maintain product integrity and quality
- □ Sanitary conditions of equipment at harvesting, transporting and storage warehouse facilities

Viable Plant/Seed Storage, Warehousing and Distribution

- **B. Determine Control Points**
- Transportation equipment and container selection, filling, identification and handling during storage and shipment
- Loading and unloading of the transport vehicle
- Tracking
- Site security
- Loading for transportation of seeds/plants harvested
- Storage/warehouse facilities

- **C. Establish Preventive Measures**
- Inspection of transport vehicles and containers prior to use to determine if there are any defects that would result in a loss of containment
- Containers properly filled, contents documented and containers securely closed
- Arrival notification procedures developed between shipper and receiver
- Upon arrival at the conditioning and/or storage facility, maintenance of proper protocols to avert unintended dispatch
- Material transferred to storage or processing in such a way as to minimize product spillage
- A regular schedule of rodent and pest control maintained during storage
- Access to facility properly controlled
- Contingency plans in place in case of natural disaster or fire
- Inspection of transport vehicles for sanitation conditions (free of dust, debris, and residual material from prior shipments)
- Identify and mitigate any areas where moisture may reside that could become environments for favoring pathogen infection and/or pest infestation

Viable Plant/Seed Storage, Warehousing and Distribution

- **D. Establish Monitoring Procedures**
- Establish inspection procedures for transport vehicles, transport containers and/or storage containers for defects
- Track inventory locations, additions and subtractions
- Track shipments to establish that they reach the intended destination and are appropriately identified
- Monitor any receiving and/or transfer areas for viable plant material
- Monitor storage facilities for signs of rodents and pests
- Monitor for moisture and temperature conditions that could increase phytosanitary risk

Viable Plant/Seed Storage, Warehousing and Distribution

- **E. Establish Corrective Measures**
- If errors in handling occur, retrain personnel in the proper procedures
- If transported to an unintended destination or if incorrect seed shipped, determine appropriate product disposition
- If material misidentified, correctly identify the container or, if identity lost, properly dispose of the material
- If loss of containment occurs, take appropriate corrective measures
- Establish corrective actions for environmental situations in which seeds/plants harvested have potential increased phytosanitary risks
- If product is found to be infected/infested, implement proper control measures to prevent “re-infestation”

Viable Plant/Seed Storage, Warehousing and Distribution

- **F. Establish Verification Procedures**
- Verify that all transportation equipment and containers are cleaned after use
- Verify that access to storage facility is restricted to authorized personnel
- Verify that storage facility is kept clean of all uncontained viable material
- Verify shipping documentation and manifest
- Verify moisture conditions of seed/plant arriving at storage facilities
- Verify temperature and humidity conditions of facility prior to storage

- **G. Establish Record Keeping and Documentation Procedures**
- Establish procedures so that all shipments carry the proper documentation
- Establish procedures to retain records
- Maintain records of potential contaminating sites affecting seed/plant phytosanitary conditions
- Verify that appropriate phytosanitary certificates, import permits, seed analysis reports and other official documents are in place prior to shipment

THANK YOU