AFRPS

Animal Feed Regulatory Program Standards

OFFICE OF THE TEXAS STATE CHEMIST
Texas Feed and Fertilizer Control Service • Agriculture Analytical Service

11 Standards of AFRPS

Standard 1 – Regulatory Foundation

Standard 2 – Training

Standard 3 – Inspection Program

Standard 4 – Auditing

Standard 5 – Feed Related Illness or Death and Emergency Response

Standard 6 – Enforcement Program

Standard 7 – Outreach Activities

Standard 8 – Planning and Resources

Standard 9 – Assessment and Improvement

Standard 10 – Laboratory Services

Standard 11 – Sampling Program

Purpose

- Establish a uniform foundation for the design and management of State programs responsible for the regulation of animal feed.
- Achieve and maintain programmatic improvements that help ensure the safety and integrity of the U.S. animal feed supply.
- Ensure a uniform and consistent approach to feed regulation among jurisdictions such as the sharing of information and the coordination of resources.

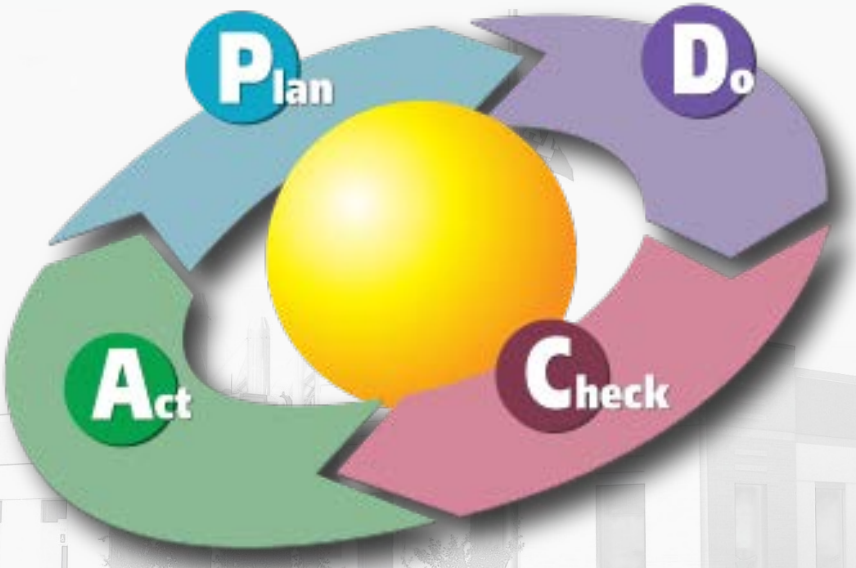
What that means to us

- Take advantage of funds available over the next five years to implement Standards that will improve our organization
- Align procedures used between the Field, AAS and FFCS
- Provide a system that can accurately produce a clear picture of our organization
- Make information and reports easier to retrieve through the creation or purchase of new software
- Provide feedback to management so that we can ensure that resources are being properly utilize
- Create an environment of continuous improvement
- Make our jobs less stressful while increasing efficiency

All OTSC employees will participate in the implementation

- Defining responsibilities/procedures
- Writing SOPs
- Learning how to use new software applications
- Conducting audits
- Being audited
- Documentation
- Continuous improvement

Shewhart Cycle (Plan-Do-Check-Act)



The Shewhart Cycle is a four-step management method used in business for the control and continuous improvement of processes and products.

Continuous Improvement Model for FFCS

Tasks	Objectives
1. Plan: Establish processes that incorporate the AFRPS	1: Develop an Operations Manual (OM) 2: Create a regulatory plan of work to manage risk. 3: Identify and provide adequate resources to implement the regulatory plan.
2. Do: Implement regulatory process improvement that incorporates the AFRPS	4: Implement the regulatory plan of work following the OM. 5: Implement the improvement plan that incorporates the AFRPS.
3. Check: Monitoring and measurement of processes and products against the regulatory and improvement plans	6: Measure implementation of the regulatory plan processes and products 7: Measure progress of the improvement plan implementation
4. Act: Take action to improve the process	8: Take action to improve the regulatory and improvement process using the AFRPS

Plan

Establish processes that incorporate the AFRPS

Objective #1
Operations Manual

- **The operations manual (OM) development represents an essential element in the OTSC implementation of the AFRPS. The OM will be comprised of two volumes:**
  - **Volume I contains the FFCS Regulatory Compliance Policies.**
  - **Volume II contains the FFCS Regulatory Compliance Procedures.**

Operations Manual

OM Section	OM Section/Subsection Title	AFRPS	Completion Status
	Foreword		Done
Volume I: Section 0 – Introduction			
0.1	Overview Operations Manual	Standards 1, 8, 9	Done
0.2	Continuous Improvement Approach	Standards 1, 8, 9	TBC
0.3	Compatibility with other management Systems	Standards 1, 8, 9, 10	TBC
Volume I:Section 1 – Scope			
1.1	General	Standards 1, 6	Done
1.2	Application	Standards 1, 6	Done
Volume I:Section 2 – References			
2.1	Exercising Regulatory Authority	Standard 1, 3,5,6	Done
2.2	Enforcement Remedies	Standards 1, 3,5,6,8	Done
Volume I:Section 3 – Terms and Definitions			
3	Terms and Definitions	Standards 1, 8	
Volume I:Section 4 – Management Systems			
4.1	OTSC Organization	Standards 1, 8, 9,10	Done
4.2.1	FFCS System Policy	Standards 1, 8, 9	Done
4.2.2	Operations Manual	Standard 9	Done
4.2.3	Control of Documents	Standard 9	Done
4.2.4	Control of Records	Standards 2,3,4,5,6,7, 11	TBC
Volume I: Section 5 – Management Responsibility			
5.1	Management Commitment	Standard 8	Draft
5.2	Stakeholder Focus	Standard 9	Draft
5.3	Continuous Improvement Policy	Standards 8,9	Draft
5.4.1	Planning: Continuous Improvement Plan Objectives	Standard 3,5,6, 11	Draft
5.4.2	Planning: Developing and Implementing a Continuous Improvement Plan		Draft
5.5.1	Responsibility, authority and communication: FFCS Roles & Responsibilities	Standards 2,3,4,5,6,7,10,11	Done
5.5.2	Responsibility, authority and communication: Management Representative	Standard 9	Draft
5.5.3	Responsibility, authority and communication: Internal Communication	Standard 9	Draft
5.6.1	Management Review: Annual Assessment of Continuous Improvement Plan	Standard 3,4,5,9,10,11	Draft

Operations Manual

Volume I:Section 6 – Resource Management			
6.1	Provision of Resources	Standard 8	Done
6.2.1	Human Resources: General	Standard 2	Done
6.2.2.1	Human Resources: Training	Standard 2, 3, 4,5,6,7, 10,11	TBC
6.2.2.2	Human Resources: Working in the Field	Standards 3, 11	Done
6.2.2.3	Human Resources: Safety		NBR
6.2.2.4	Human Resources: Ethics & Conduct		Done
6.2.2.5	Human Resources: Disclosure of Information		Done
6.3	Infrastructure, Equipment & Supporting Services	Standard 5, 6, 7, 8, 10, 11	TBC
Volume I:Section 7 – Product Realization			
7.1	Work planning and Resource Evaluation	Standard 8	Draft
7.2.1.1	Requirements : Enforcement Program	Standard 6	Done
7.2.1.2	Requirements: Inspection Program	Standard 3	Done
7.2.1.3	Requirements: Sampling Program	Standard 11	Done
7.2.1.4	Requirements: Labeling	Standard 3, 6, 11	Done
7.2.1.5	Requirements: Recall Strategy	Standard 5	Done
7.2.1.6	Requirements: Licensing, Registration and Permits	Standard 3, 6, 11	Done
7.2.2.1	Stakeholder Communication : Emergency Response	Standard 5	TBC
7.2.2.2	Stakeholder Communication : Other Agencies	Standard 5	TBC
7.2.2.3	Stakeholder Communication : Public	Standard 5	TBC
7.3.1	Design & Development: Developing a Plan of Work	Standard 3, 5, 6, 11	NBR
7.3.2.1	Design & Development: Maintaining Feed Inventory	Standard 3	Done
7.3.2.2	Design & Development: Reviewing and Revising Plan of Work	Standard 3, 5, 6, 11	NBR
Volume I: Section 8 - Measurement, analysis and improvement			
8.1	Continuous Improvement Plan	Standards 9, 8	Draft
8.2.1	Handling Customer / Industry Complaints	Standard 5	NBR
8.2.2	Auditing Plan for Inspection and Sampling Program	Standard 4	TBC
8.3	Review of Auditing Records	Standard 4	TBC
8.4	Analysis of Inspection and Sampling Data	Standard 3, 6, 9, 10,11	NBR
8.5.1	Improvement: Develop Continuous Improvement Plan	Standard 3, 4,6, 9, 11	Draft
8.5.2	Improvement: Develop corrective action plan based on Auditing Records	Standard 3, 4,6, 9, 11	TBC
8.5.3	Improvement: Risk-based approach to enforcement	Standard 3, 4,6, 9, 11	Draft

Operations Manual

Volume 2: Section 4: Management Systems		
SOP F0007	FFCS Operations Manual	
SOP TBD	Control of FFCS Documents	TBC
SOP TBD	Control of FFCS Records	TBC
SOP F0042	Identifying Departures from Regulatory Compliance Procedures in Operations Manual	Done
Volume 2: Section 6: Resource Management		
SOP F0008	Automobile Safety Requirements and Recommendations	Done
SOP F0009	Safety Requirements and Recommendations for Conducting Inspections	NBR
SOP F0010	Safety Requirements and Recommendations for Handling Microbiological Hazards	NBR
SOP F0011	Safety Requirement for the Use of Protective Equipment	NBR
SOP F0012	Reporting Safety Hazards in the Field	NBR
SOP F0013	Safety Requirements and Recommendations for Safe Sample collection	NBR
SOP F0014	Safety Requirements and Recommendations for Safe Use of Wireless Devices	NBR
SOP F0016	Adhering to OTSC Standards of Ethics and Conduct	Done
SOP F0019	Tracking and Documenting Training for FFCS Investigators	NBR
SOP F0025	Completing a Travel Voucher	Done
SOP F0039	Completing the Monthly Use Report for state-issued vehicles	Done
SOP F0040	Completing Weekly Itineraries	Done

Operations Manual

Volume 2: Section 7: Product Realization		
SOP F0017	Conducting BSE, GMP, and BMP Inspections	NBR
SOP F0018	Conducting Animal Death and Crop Damage Investigations	NBR
SOP F0022	Conducting an Ammonium Nitrate Inspection	Done
SOP F0024	Implementing a Stop-sale Order	Done
SOP F0026	Communication	NBR
SOP F0028	Feed Licensing Application Processing	Done
SOP F0029	Fertilizer Permit Application Processing	Done
SOP F0030	Initiating an Informal Meeting	Done
SOP F0031	Mixer Testing	Done
SOP F0032	Plan of Work	NBR
SOP F0033	Conducting a Recall	Done
SOP F0034	One Sample Strategy Monitoring and Corrective Actions	Done
SOP F0035	One Sample Strategy Pre-Season Planning	Done
SOP F0036	One Sample Strategy Proficiency Evaluation	Done
SOP F0037	One Sample Strategy Corn Exemption	Done
SOP F0038	Label Review	Done
SOP TBD	Use of Enforcement Matrix	TBC
SOP TBD	Planning, Implementing and Evaluation of Outreach Activities	TBC
Volume 2: Section 8 - Measurement, analysis and improvement		
SOP TBD	Handling Customer/Industry Complaints	TBC
SOP TBD	Auditing	TBC

(NBR = Needs to be Revised TBC = To Be Completed TBD = To Be Determined)

Objective # 2
Create a regulatory plan-of-work (POW) to manage risk

The plan-of-work distributes effort among agency priorities and the strategic plan goals outlined below:

1. Surveillance and monitoring of animal and human health and environmental hazards;

2. Conformance to the Texas Commercial Feed Control Acts;

3. Availability and best use of resources; and

4. Production of reliable and timely laboratory results.

Attributes of the POW include:

1. **Scalability: Ability to adjust sample numbers based on state-wide tonnage, shifts in the use of different ingredients, and weighted by establishment's risk factor and tonnage;**
2. **Adaptability: Continuous updating of POW, including quarterly review;**
3. **Real-time assessment: Ensures conformance to the POW;**
4. **Automatic assignment of POW tasks: Accomplished via project management software;**
5. **Flexibility: Easy transition to facility process-control regulatory oversight including co- regulation and HACCP adoption; and**
6. **Portability: Enables field investigators to perform work at any place in the state and to avoid duplication.**

Objective #3
Identify and provide adequate resources to implement the Continuous Improvement Plan

Do

Implement regulatory process improvement that incorporates the AFRPS

Objective # 4
Implement the regulatory plan of work following the OM

- Sample collection and inspections are performed in conformance with the OM
- Sample shipments conform to chain-of-custody procedures
- Approximately 80% of samples are pre-assigned in the POW, while the other 20% of samples are collected from new firms or products, animal death investigations, customer complaints, or at the direction of management
- Inspections performed for FDA under contract are identified in the POW.
- Other investigations are performed in response to industry violations detected during sample analysis, animal death, consumer complaints or other high risk targets
- POW execution follows the seasonal cycle of agriculture and product utilization.

Objective # 5
Implement the improvement plan that incorporates the AFRPS

- Implementation of the continuous improvement roadmap for all 11 standards
- Implementation timeline and activities in the OTSC AFRPS Gantt Chart.
- James Embry will receive ISO 17020 training and be equipped to audit OTSC field investigators.
- The auditing process will begin in year 3 as described in the improvement plan.
- James Embry will also be responsible for implementing the improvement plan and tracking OTSC conformance to the tasks, objectives, activities and timeline

Regulatory Information Management System (RIMS)

1. Track investigator training and continuing education records,;
2. Integrate the development and assessment of a risk-based plan of work based on risk categories for feed facilities;
3. Integrate the receiving, tracking, evaluation, closing, and maintenance of records for feed recall effectiveness audits, industry complaints and consumer complaints;
4. Integrate the collection, tracking, evaluation, and maintenance of field investigator audits and related corrective actions data;
5. Select enforcement tools based on the enforcement matrix
6. Document the presentation and evaluation of outreach activities; and
7. Track corrective actions within the continuous improvement plan

Check

Monitoring and measurement of processes and products against the regulatory and improvement plans

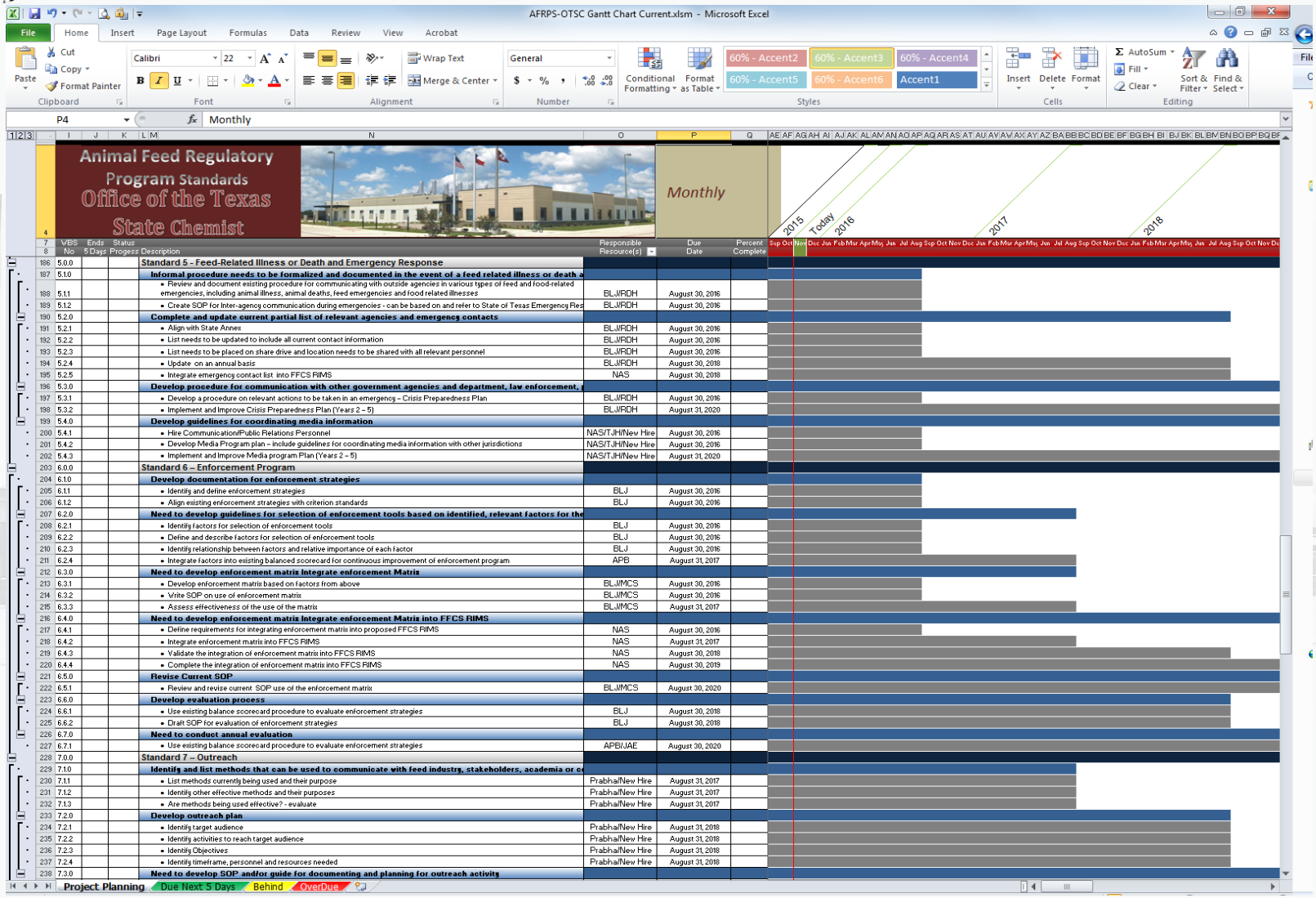
Objective # 6
Measure implementation of the regulatory plan processes and products

- Employ a balanced scorecard approach to identify performance measures and track progress both for OTSC and the regulated community.
- The Balanced Scorecard performance measures are updated quarterly
- The Balanced Scorecard approach will be used to translate the roadmap into performance measures
- These performance measures will be constructed in year 1 of the project and refined as AFRPS is implemented.

Balanced Scorecard performance measures used to evaluate AFRPS implementation

Mission: "Long-term improvement in the regulatory oversight of animal feed in Texas through the adoption of the AFRPS."
Customer Focus: Includes both the manufacturers/distributors and consumers of feed
Internal Processes: Identification of performance measures that track implementation of standards and will included elements from investigator audits and data entry accuracy
Knowledge and Data: Building and maintain a new FFCS RIMS that will enable the agency to track FFCS and the regulated communities' performance.
Financial Resources: Methods to track investigational and sample collection efficiencies.

Gantt Chart



WBS No	Ends 5 Days	Status Progess	Description	Responsible Resource(s)	Due Date	Percent Complete
5.0.0			**Standard 5 - Feed-Related Illness or Death and Emergency Response**			
5.1.0			**Informal procedure needs to be formalized and documented in the event of a feed related illness or death a**			
5.1.1			• Review and document existing procedure for communicating with outside agencies in various types of feed and food-related emergencies, including animal illness, animal deaths, feed emergencies and food related illnesses	BLJ/RDH	August 30, 2016	
5.1.2			• Create SOP for Inter-agency communication during emergencies - can be based on and refer to State of Texas Emergency Res	BLJ/RDH	August 30, 2016	
5.2.0			**Complete and update current partial list of relevant agencies and emergency contacts**			
5.2.1			• Align with State Annex	BLJ/RDH	August 30, 2016	
5.2.2			• List needs to be updated to include all current contact information	BLJ/RDH	August 30, 2016	
5.2.3			• List needs to be placed on share drive and location needs to be shared with all relevant personnel	BLJ/RDH	August 30, 2016	
5.2.4			• Update on an annual basis	BLJ/RDH	August 30, 2018	
5.2.5			• Integrate emergency contact list into FFCS RIMS	NAS	August 30, 2018	
5.3.0			**Develop procedure for communication with other government agencies and department, law enforcement,**			
5.3.1			• Develop a procedure on relevant actions to be taken in an emergency - Crisis Preparedness Plan	BLJ/RDH	August 30, 2016	
5.3.2			• Implement and Improve Crisis Preparedness Plan (Years 2 - 5)	BLJ/RDH	August 31, 2020	
5.4.0			**Develop guidelines for coordinating media information**			
5.4.1			• Hire Communication/Public Relations Personnel	NAS/TJH/New Hire	August 30, 2016	
5.4.2			• Develop Media Program plan - include guidelines for coordinating media information with other jurisdictions	NAS/TJH/New Hire	August 30, 2016	
5.4.3			• Implement and Improve Media program Plan (Years 2 - 5)	NAS/TJH/New Hire	August 31, 2020	
6.0.0			**Standard 6 - Enforcement Program**			
6.1.0			**Develop documentation for enforcement strategies**			
6.1.1			• Identify and define enforcement strategies	BLJ	August 30, 2016	
6.1.2			• Align existing enforcement strategies with criterion standards	BLJ	August 30, 2016	
6.2.0			**Need to develop guidelines for selection of enforcement tools based on identified, relevant factors for the**			
6.2.1			• Identify factors for selection of enforcement tools	BLJ	August 30, 2016	
6.2.2			• Define and describe factors for selection of enforcement tools	BLJ	August 30, 2016	
6.2.3			• Identify relationship between factors and relative importance of each factor	BLJ	August 30, 2016	
6.2.4			• Integrate factors into existing balanced scorecard for continuous improvement of enforcement program	APB	August 31, 2017	
6.3.0			**Need to develop enforcement matrix Integrate enforcement Matrix**			
6.3.1			• Develop enforcement matrix based on factors from above	BLJ/MCS	August 30, 2016	
6.3.2			• Write SOP on use of enforcement matrix	BLJ/MCS	August 30, 2016	
6.3.3			• Assess effectiveness of the use of the matrix	BLJ/MCS	August 31, 2017	
6.4.0			**Need to develop enforcement matrix Integrate enforcement Matrix into FFCS RIMS**			
6.4.1			• Define requirements for integrating enforcement matrix into proposed FFCS RIMS	NAS	August 30, 2016	
6.4.2			• Integrate enforcement matrix into FFCS RIMS	NAS	August 31, 2017	
6.4.3			• Validate the integration of enforcement matrix into FFCS RIMS	NAS	August 30, 2018	
6.4.4			• Complete the integration of enforcement matrix into FFCS RIMS	NAS	August 30, 2019	
6.5.0			**Revise Current SOP**			
6.5.1			• Review and revise current SOP use of the enforcement matrix	BLJ/MCS	August 30, 2020	
6.6.0			**Develop evaluation process**			
6.6.1			• Use existing balance scorecard procedure to evaluate enforcement strategies	BLJ	August 30, 2018	
6.6.2			• Draft SOP for evaluation of enforcement strategies	BLJ	August 30, 2018	
6.7.0			**Need to conduct annual evaluation**			
6.7.1			• Use existing balance scorecard procedure to evaluate enforcement strategies	APB/JAE	August 30, 2020	
7.0.0			**Standard 7 - Outreach**			
7.1.0			**Identify and list methods that can be used to communicate with feed industry, stakeholders, academia or c**			
7.1.1			• List methods currently being used and their purpose	Prabha/New Hire	August 31, 2017	
7.1.2			• Identify other effective methods and their purposes	Prabha/New Hire	August 31, 2017	
7.1.3			• Are methods being used effective? - evaluate	Prabha/New Hire	August 31, 2017	
7.2.0			**Develop outreach plan**			
7.2.1			• Identify target audience	Prabha/New Hire	August 31, 2018	
7.2.2			• Identify activities to reach target audience	Prabha/New Hire	August 31, 2018	
7.2.3			• Identify Objectives	Prabha/New Hire	August 31, 2018	
7.2.4			• Identify timeframe, personnel and resources needed	Prabha/New Hire	August 31, 2018	
7.3.0			**Need to develop SOP and/or guide for documenting and planning for outreach activity**			

Benefits of using a Gantt Chart to manage a project

- Allows you to see what the various activities are
- When each activity begins and ends
- How long each activity is scheduled to last
- Where activities overlap with other activities, and by how much
- Easy to expand as more activities are added to the project

Objective# 7
Measure progress of the continuous improvement plan implementation

- Make updates to the assessment and improvement plan, listing AFRPS elements not met
- Include improvements to the improvement plan not previously incorporated
- Document new completion date for task past due (not met) based on projections in Appendix 9.1; and
- Respond to findings from the FDA audit, including implementation of a corrective action plan.

Act

Take action to improve the process

Objective # 8

Take action to improve the regulatory and improvement process using the AFRPS

The OTSC director will:

- **Establish a quarterly review of AFRPS implementation progress**
- **Annually assess the POW**
- **Annually review and improve the OM**
- **Annually update the roadmap for continuous improvement using the AFRPS.**
- **The director shall be present during the FDA auditor review and will review audit results,**
- **Ensure changes that are needed in the OTSC continuous improvement plan are implemented.**
- **Staffing and budget decisions will incorporate results from both industry and OTSC performance measures, which are collected and tracked as part of the balanced scorecard benchmarking process.**

Continuous Improvement Plan for AAS

Tasks	Objectives
1. Plan: Establish processes to prepare laboratories to implement ISO 17025:2005	1: Develop plan to expand ISO 17025:2005 standard in AAS labs.
2. Do: Implement the ISO 17025:2005 general requirements for the competence of testing in all laboratories	2: Implement ISO 17025:2005 general requirements for the competence of testing in all AAS laboratories.
3. Check: Monitor and measure the process and laboratory results for accuracy	3: Perform internal and external audits and proficiency testing of AAS labs in current building.
4. Act: Take action to improve the process	4: Take action to improve the laboratory process using the ISO 17025standard and continuous improvement plan

Plan
Timeline for expanding ISO accreditation in AAS Laboratories

Activity	Calendar of Events 2015-2020				
	Year 1	Year 2	Year 3	Year 4	Year 5
AAS laboratory ISO 17025 Accreditati-on	Mycotoxins and FERN TOX1 and TOX2 methods	Elemental analysis laboratory; Prepare for audit of previously accredited laboratories	Testing of vitamins and drugs; Prepare for audit of previously accredited laboratories	Spectral analysis methods; Prepare for audit of previously accredited laboratories	Industrial contaminant analysis using Calux and GC-MS Prepare for audit of previously accredited laboratories

Do
Steps to implement ISO accreditation in AAS laboratories

1) Conduct at least one internal audit and management review per year to identify non-conformances.
2) Develop an improvement plan to address each non-conformance, including key personnel responsible, timelines, and tasks.
3) Review and update SOPs annually
4) Requirements for all suitable proficiency testing are met.
5) Active participation in the FERN continues.
6) Participation in on-site lab assessments by FDA to determine progress to accreditation, and work with FDA to establish a timeline/plan of incremental steps to accreditation.
7) Implement ISO/IEC 17025:2005 requirements in toxin laboratory for all procedures in year 1; elemental analysis in year 2; vitamins and drugs in year 3; microscopy, spectral analysis and radiological in year 4; industrial contaminants in year 5.

Check
Perform internal and external audits and proficiency testing of AAS laboratories

Site audit -Closure of corrective actions –Certification

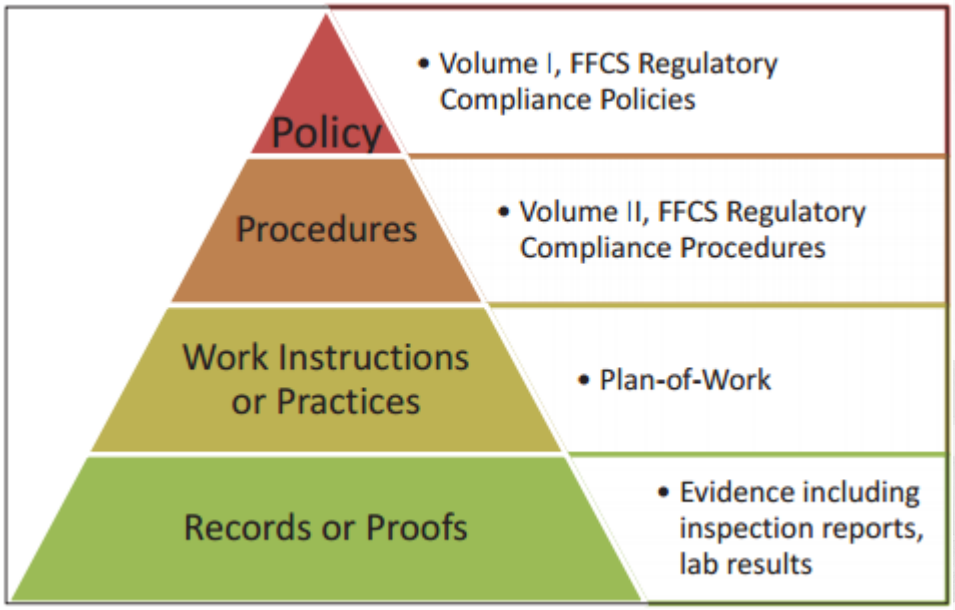
1) Submit completed application to accrediting body to initiate an assessment of the organization.
2) Assessment, or pre-assessment, is conducted by the accrediting body.
3) Laboratory addresses any areas of non-conformance or deficiencies noted by responding with a written corrective action plan.
4) Requirements for all suitable proficiency testing are met.
5) Active participation in the FERN continues.
6) Adequate training for laboratory to keep abreast of scientific and technological advances in relevant areas.
7) All data generated by the laboratory is being entered into eLEXNET and shared with FDA, as requested. Ideally, an automatic, electronic data exchange will be established between the laboratory and eLEXNET.

Act
Steps to improve the process in AAS laboratories

Maintenance of accreditation

1) Continuous improvement of laboratory every year.
2) Continue active participation in the FERN.
3) Adequate training for laboratory to keep abreast of scientific and technological advances in relevant areas.
4) All data generated by the laboratory is being entered into eLEXNET and shared with FDA, as requested.

Result



The documentation pyramid presents the agency's roadmap in pictorial form. The OM Volume I contains OTSC policy and OM Volume II contains procedures. The Plan-of-Work contain the work instructions for regulating the Texas feed industry and the records from samples and inspections provide evidence of the feed industry's conformance to state and federal laws and rules.