



# AFRPS

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# Animal Feed Regulatory Program Standards

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# 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**

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# 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

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# 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.

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# Continuous Improvement Model for FFCS

Tasks	Objectives
<b>1. Plan: Establish processes that incorporate the AFRPS</b>	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.
<b>2. Do: Implement regulatory process improvement that incorporates the AFRPS</b>	4: Implement the regulatory plan of work following the OM. 5: Implement the improvement plan that incorporates the AFRPS.
<b>3. Check: Monitoring and measurement of processes and products against the regulatory and improvement plans</b>	6: Measure implementation of the regulatory plan processes and products 7: Measure progress of the improvement plan implementation
<b>4. Act: Take action to improve the process</b>	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

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# 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

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# Operations Manual

<b>Volume 2: Section 4: Management Systems</b>		
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
<b>Volume 2: Section 6: Resource Management</b>		
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)

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# 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**

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## **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.

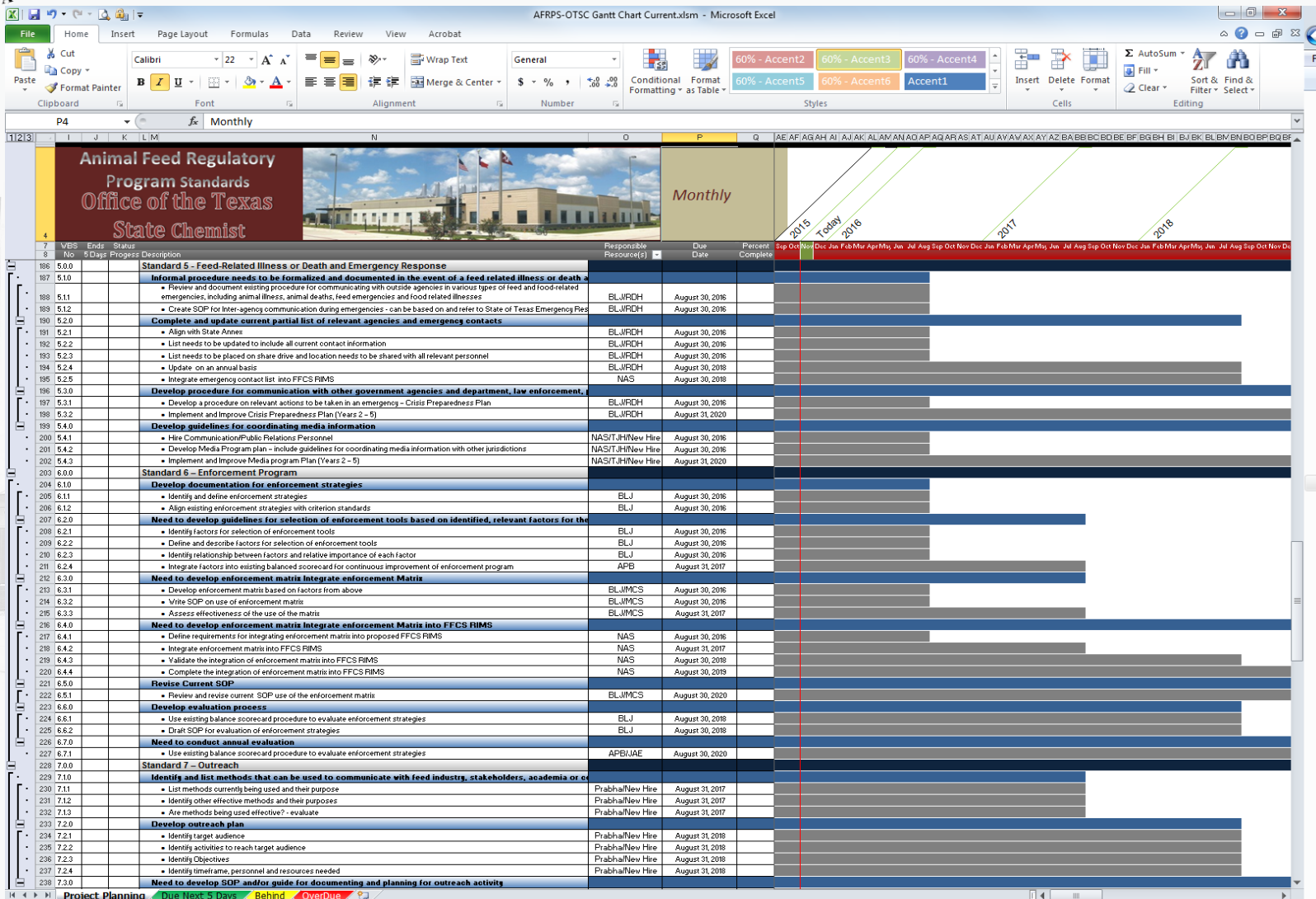
### **Financial Resources:**

Methods to track investigational and sample collection efficiencies.





# Gantt Chart







# 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

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

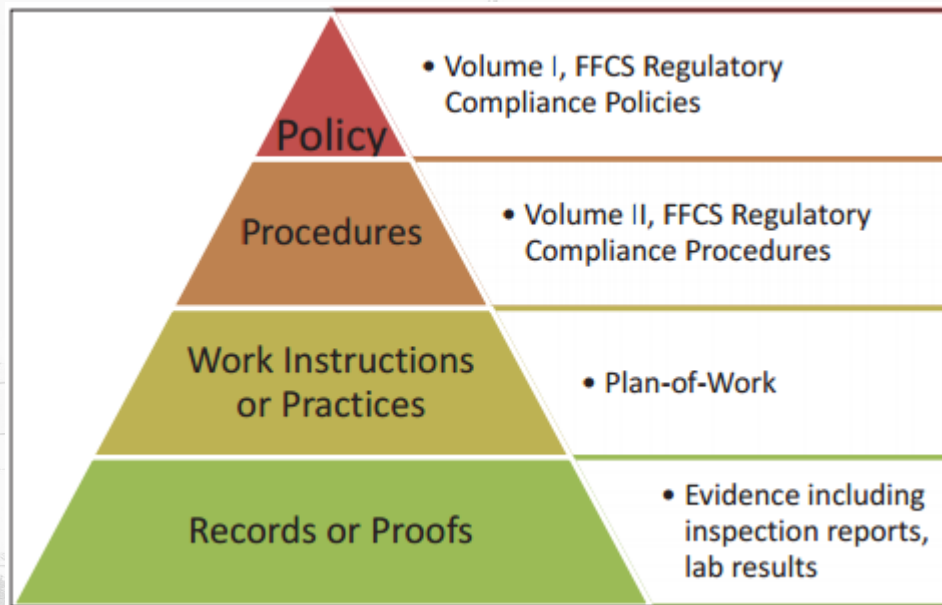
## Steps to improve the process in AAS laboratories

### *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.

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