Regulatory Services News

Vol. 60, No. 1 Feed - Fertilizer - Milk - Seed - Seed Testing - Soil Testing Spring 2017

Director's Digest

The fall of 2016 was a time of providing education on the Veterinary Feed Directive (VFD) for our staff. Dr. Harrison, myself and our inspection staff were involved in four VFD meetings for manufacturers and distributors. These were held in Lexington, Somerset, Glasgow and Princeton. We had over 100 attendees at these meetings and truly hope they were helpful. Dr. Harrison and I also spoke at several cattlemen's gatherings during the fall to educate producers. These have continued into this year. All of our inspectors have and continue to provide information on this important new rule.

The VFD rule is now in effect and based on questions we have received there is still a lot of confusion. The FDA realizes there are many situations they haven't thought of and will be cautious on how they approach enforcing this rule. Please don't hesitate to contact us if you have questions. If we don't know the answer, we will contact FDA for clarification. Please read Dr. Harrison's article to find answers for some common misconceptions we hear.

The New Year is upon us and we certainly face many changes. We have a new legislature in Frankfort, new leadership in Washington and many challenges in agriculture including increased implementation of the Food Safety Modernization Act. No one knows what the new administration in Washington may do, but at this time it would be wise to proceed with preparations for FSMA. Two of our inspectors will be attending training in February to learn more about the process.

We have had some incidents during this past year that required feed manufacturers to submit a report to the Reportable Feed Registry (RFR). In case you are unfamiliar with this requirement, please read the article on the RFR in this newsletter.

Also remember that changes were made to the seed law last year that change the reporting period for seed inspection fees from quarterly to semiannual. Please read the notice later in the newsletter.

The Division of Regulatory Services received a large grant this past fall from the FDA to implement the Animal Food Regulatory Program Standards (AFRPS). If we do our part and the federal money holds out, this grant will continue for 5 years. You can read more about this in Jim True and Dr. Webb's articles but basically there are two parts to this grant. One part is to improve our inspection program and hopefully make inspection programs more standardized between states. Feed laws and fees may still be different between states but the intent is that the inspection process will be more uniform.

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What's Inside

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The other part is to make our lab ISO 17025 compliant. Both of these will make our program better able to protect food safety for both animals and man. We already feel we have one of the best feed inspection programs in the country but look forward to getting even better. We will keep you posted on how this is progressing.

Hopefully, 2017 will provide each of you many opportunities in addition to the challenges we know we will face. Please let us know of anything we can do to be of assistance.

"Quality is not an act, it is a habit" - Aristotle

Dr. Darrell Johnson,
Executive Director

Seed Regulatory Program 2016 Highlights

The seed regulatory program ensures Kentucky farmers and urban consumers of quality seed while promoting fair and equitable competition among seed dealers and labelers through inspection and analysis of products found in the marketplace. The Division, which administers and implements the Kentucky Seed Law, promotes compliance through facility inspections, sampling and analysis of seed offered for sale. The law requires proper labeling of seed which includes kind, variety and lot designation, purity percentages, noxious weeds, origin, test date and a germination guarantee. The Division is also responsible for maintaining registration of seed labelers, seed conditioners, and seed dealers in the state.

2016 Highlights:

- Collected and tested 1,951 official seed samples.
- Issued stop-sale orders on 267 official seed samples and 178 violative seed lots at seed dealer and seed processor locations.
- Cooperated with the USDA-Seed Branch regarding shipments of seed into the state that was in violation of the Federal Seed Act.
- Reviewed and issued 216 permits to label agricultural seed and 57 permits to label vegetable and flower seed.
- Registered 633 seed dealers and 34 non-certified custom seed conditioners.
- Provided training to firms on labeling requirements, retail sales procedures, stop sale release procedures, and record keeping requirements.

Stephen McMurry,
Director of Fertilizer and Seed Programs

Seed Inspection Fee changing from Quarterly to Semi-Annual Reporting Periods

Due to last years KY Seed Law and Regulation changes, the reporting period for Seed Inspection Fees has changed from Quarterly to Semi-Annual. So starting in 2017, Semi-Annual reporting of Seed Inspection Fees will be from January – June and July – December. Reports are still due 30 days after the reporting period ends (July 30, 2017 and January 30, 2018) and considered delinquent 45 days after the reporting period ends (August 14, 2017 and February 14, 2018). No fee changes occurred.

We will try to communicate this change every chance we get. Please contact our seed office at 859-218-2468 or mm.smith@uky.edu or smcmurry@uky.edu if you have any questions.

Implementation of the New Veterinary Feed Directive Rules – Myth Busting

On January 1, 2017, the new veterinary feed directive (VFD) rules on antibiotics in animal feed and water became the law of the land. For the most part, it appears that our Kentucky feed industry and producers are adjusting to the new realities of dealing with antibiotics in animal feed and water. However, we continue to receive questions on the rules and have heard a few comments regarding implementation that suggest that we still have some work to do.

A feed dealer has a milk replacer with neomycin & oxytetracycline with a label that lists control of bacterial enteritis as the indication for use but does not contain the new caution statement restricting medicated feed containing the VFD drug to use by or on the order of a licensed veterinarian. A producer can purchase this milk replacer without obtaining a VFD from their vet since the label does not contain the VFD caution statement.

False: The product cannot be purchased or fed without a valid VFD. Furthermore, if our inspectors find these products in the market, they will be placed under a withdrawal from distribution until the label is corrected. In this case, the indication for use (bacterial enteritis control) is allowed, but the VFD statement should be on the label.

A dairy producer has been purchasing a custom mix from their local feed mill that contains monensin (Rumensin) and wishes to continue the use of this product. The purchase and feeding of this product will not be affected by the change in the VFD rules.

True: Monensin is not used in human medicine and is not considered a medically important antibiotic. Monensin and lasalocid (Bovatec) are not under the VFD rules unless included in a combination with a VFD drug.

A beef producer purchased a 50 lb bag of CTC 50 (a Type A medication) and wants to use this drug to mix medicated feed on farm for use with his own animals. The producer can purchase the medication without a VFD but must obtain a VFD prior to feeding the final mix to his cattle.

True: The Type A medication is considered a drug and not a feed and therefore does not require a VFD to be purchased. However, the same rules apply to feeding the medicated feed – a VFD will be required to feed the final mix regardless of whether it was mixed at a feed mill or made on farm.

In November 2016, a beef producer purchased a beef mineral with chlortetracycline (CTC) with a label that lists control of anaplasmosis as the indication for use. On January 1, the producer still has 500 lbs of mineral remaining on the farm. The producer can feed the remainder of the product purchased prior to January 1 without a VFD but must have a VFD to purchase more of this product after January 1.

False: The rules changed on January 1 and the mineral remaining cannot be fed unless the producer obtains a VFD from their veterinarian. In this case, the indication for use (anaplasmosis control) is allowed, but the VFD is required for the product to be fed regardless of the purchase date.

By feeding a product that requires a VFD without a VFD, the producer risks regulatory action by the Food and Drug Administration.

True: FDA has indicated that they will conduct VFD surveillance investigations by tracing forward and tracing backwards. In other words, they will start with the dealer selling the feed, check paperwork at the dealer and the veterinarian, and could visit the farm as well.

The primary reasons why the VFD rules changed were to enhance veterinarian's income and provide more work for state regulators.

False: The rule changes are a response by FDA to public concerns regarding antibiotic resistance in humans and animals and the impact of feeding medically important antibiotics to livestock. Veterinarians will be involved in the process of implementing these rules but writing VFD's is not going to be a windfall for veterinarians. State regulators are not looking for more to regulate.

VFD, continued

To enforce the new VFD rules, we expect state and federal regulatory agencies to hire more inspectors.

False: Given the political climate in both Washington DC and Frankfort, I expect that we will need to make do with our current regulatory staff.

In the last issue of our newsletter, I outlined regulatory strategy for enforcing the new VFD regulations and it bears repeating.

FDA is responsible for enforcement and this will be "phased" enforcement. They will start with education and training and then move to risk-based surveillance and for-cause inspection. They will work closely with both state regulators and state boards of veterinary medicine. FDA has the authority to make unannounced farm visits. Kentucky is not currently under contract with FDA to conduct VFD inspections and we will focus more on labeling. For medicated feeds requiring a VFD but without proper VFD labeling, products will be withdrawn from distribution until re-labeled. For medicated feeds with drug on VFD list and only weight gain / feed efficiency claims, products will be withdrawn from distribution permanently and cannot be relabeled.

For more on the new VFD regulations
VFD Central: http://feedstuffs.com/vfd.aspx
University of Kentucky Regulatory Services: http://www.rs.uky.edu

Dr. Al Harrison,
Director of Feed and Milk Programs

Inspector News

The Food Safety Modernization Act (FSMA) and the Veterinary Feed Directive (VFD) are certainly changing the role of the Division of Regulatory Services. There are lots of questions for our inspectors on these regulations from the Kentucky feed industry and also concerning livestock products that are new this year. Our inspectors have been to trainings and have information that will assist you in answering your questions for these new regulatory programs. There are guidance documents available that discuss these programs in great detail and will give you the information you need in the manufacturing and feeding of livestock feed.

The Animal Feed Regulatory Program Standards (AFRPS) were developed by the American Association of Feed Control Officials in partnership with FDA in part to assist with the implementation of FSMA. There are 11 standards in total.

The purpose of the AFRPS are;

- To enhance animal feed safety.
- Provide the tools and resources to enable state feed regulatory programs to build strong infrastructures and systems that complement national uniformity and promote an integrated food safety system.
- Promote quality regulatory programs through continuous self-improvement.
- Improve communication among regulatory partners.

Of the 11 standards, Standard 2 is "Training" for the inspectors and consists of 2 parts.

1. Basic Feed Inspector Training for inspectors to complete during their first 24 months from their start date. There are 13 subject content areas that the new inspector is required to complete during this time period.
2. Advanced Feed Inspector Training is required for inspectors from 2 years to 5 years of on the job activities. There are an additional 10 subject content areas that inspectors will be trained in during this 3 year period to be able to perform their job responsibilities.

We are currently assessing our KY inspection staff and providing the additional training required to meet the AFRPS along with the new FSMA and VFD regulations.

Dave Mason and Terry Prather will be attending a FDA meeting in February to learn about the new Preventative Controls for Animal Feed.

If you have questions about any of these new laws or regulations please ask your feed inspector for their assistance or call us here at the office.

We want to assist you in obtaining compliance with these new regulations.

Jim True,
Inspector Coordinator

Fertilizer Regulatory Program 2016 Highlights

The fertilizer regulatory program ensures Kentucky farmers and urban consumers of quality fertilizer while promoting fair and equitable competition among fertilizer manufacturers and dealers through inspection and analysis of products found in the marketplace. The Division, which administers and implements the Kentucky Fertilizer Law, promotes compliance through facility inspections, sampling and analysis of fertilizer offered for sale. The law requires proper labeling of fertilizer which includes the grade and guaranteed analysis of nutrients. The Division is also responsible for maintaining registration of fertilizer products.

2016 Highlights:

- Administered actions on 2,744 official and 12 unofficial samples of fertilizer involving over 7,350 chemical tests.
- The official samples represented about 51,796 tons out of the approximately 846,811 tons of fertilizer distributed in Kentucky during 2016, or about 5.48%.
- Reviewed labels and registered over 4,850 products from 419 firms and issued licenses to 190 companies that manufactured custom-blended fertilizers.
- Analyzed laboratory check sample materials from Magruder®, UAN, and AFPC.
- Provided support for 15 different analytical methods that yield results for 28 analytes and contaminants.

Stephen McMurry,
Director of Fertilizer and Seed Programs

COMMERCIAL FERTILIZER VALUES FOR 2017

Under the provisions of Chapter 250.401 of the Kentucky Fertilizer Law, the following unit values are announced for use in assessing penalties of deficient fertilizer.

NUTRIENT	DOLLARS/UNIT (20 LBS.)
Total Nitrogen (N)	$8.33
Avail. Phosphate (P_2O_5)	$7.09
Soluble Potash (K_2O)	
*Tobacco (low Cl)	$14.48
*Non-Tobacco	$5.29
Calcium (Ca)	$6.76
Magnesium (Mg)	$25.65
Sulfur (S)	$9.50
Boron (B)	$119.68
Copper (Cu)	$141.43
Iron (Fe)	$16.50
Manganese (Mn)	$35.71
Molybdenum (Mo)	$20.20
Zinc (Zn)	$50.74

Calculation Note:

(1) The *N* value for DAP & MAP was assigned from anhydrous ammonia (AA).

(2) The value of P from DAP and MAP was calculated using the assigned value of *N* from AA.

(3) The final values for *N* and P are weighted averages based on FY 16 (distributed) tonnage for ammonium nitrate, Urea, DAP, TSP, MAP, and ammonium sulfate.

These values are state-wide averages taken from the December 2016 survey. They represent the average of responses from throughout the state for retail value of bulk mixed fertilizers.

If you have any questions, please call me at (859)-257-2785; or, email: smcmurry@uky.edu

Stephen McMurry,
Director of Fertilizer and Seed Programs

What is the Reportable Food Registry (RFR) and why should you care?

There has been some confusion over the purpose of the Reportable Food Registry (RFR) in regards to animal feed. If you are in the business of manufacturing livestock or pet food in Kentucky, then you need to be familiar with the RFR and when you are required to use it. Hopefully, the information below will be helpful.

What is the RFR?

If you are in the business of manufacturing, processing, packing, or holding food for animal consumption, you should be registered with the Food and Drug Administration (FDA). "Responsible party" is defined by the FDA as the person who submitted the registration information.

The RFR was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 and signed into law by President Bush. The RFR requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods." Federal, state, and local public health officials may also use the portal to voluntarily report information that may come to them about reportable foods. The electronic portal opened on September 8, 2009. As of May 10, 2010, the RFR portal became part of the Department of Human Services Safety Reporting Portal. It can be accessed at www.safetyreporting.hhs.gov.

When should I use it?

Whenever you manufacture a food/feed that may have caused illness or death in pets or animals you are expected to report this through the RFR **within 24 hours** of determining that you have a reportable food. Basically, if you have reason to suspect that a food/feed that you manufactured may have caused illness or death in animals, you should report it immediately. Failure to report a reportable food is a prohibited act under the Federal Food, Drug, and Cosmetic Act. Failing to report the incident is frowned upon heavily by the FDA. Just a few examples of incidents include microbial contamination (e.g. *listeria*, *e.coli*, botulism), drug toxicity (e.g monensin, lasalocid, chlortetracycline), or improper mixing of feed (e.g. urea toxicity). It is much better to report an incident and be exonerated later than to not report an incident and be found at fault later.

A responsible party is not required to submit a reportable food report if all or the following three conditions are met:

1. The adulteration originated with the responsible party; AND
2. The responsible party detected the adulteration prior to any transfer to another person of the article of food; AND
3. The responsible party corrected the adulteration or destroyed or caused the destruction of the article of food.

If you have a reportable food and are unable to access the Safety Reporting Portal, then you should contact the district FDA office which for Kentucky is the Cincinnati office at (513) 679-2700. Alternatively, you may call 1-888-SAFEFOOD (Monday-Friday, 8:00 AM to 4:00 PM, Eastern Time).

What do I need to report?

Information that a responsible party may include in initial and follow-up RFR reports to FDA:

- Food Facility Registration Number
- Date the article of food was determined to be reportable
- Description of the food, including quantity and amount
- Extent and nature of the adulteration
- Results of the investigation of the root cause of the adulteration if it may have originated with the responsible party, when known
- Product information typically found on packaging sufficient to identify the article of food
- Contact information for the immediate previous sources (suppliers) and/or immediate subsequent recipients (customers) of the article of food, when required by FDA.

What happens after I report?

When you file a report it will be assigned a unique number called the Individual Case Safety Report (ICSR) number. This identifies the report and allows FDA to properly link associated reportable

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RFR, continued

food reports in the registry.

You must provide amended reports as necessary. The cause of the adulteration may not be known when you file during the first 24 hours of the incident so further reports may be needed on the cause of the problem and the disposal of the reportable food.

You must consult with the FDA to follow up as necessary and must maintain records related to each report for 2 years.

Why should you care?

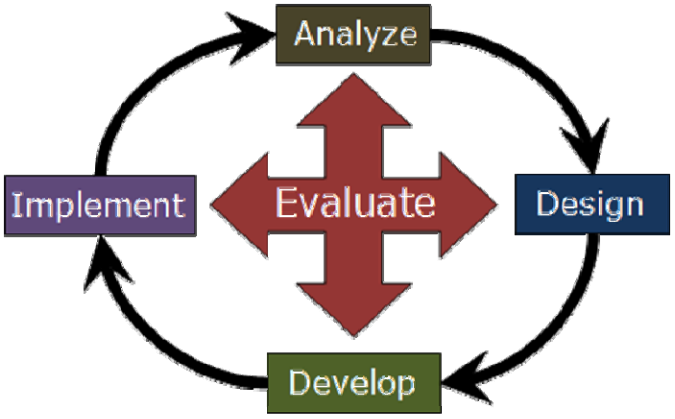
We all hope that you never need to use the RFR but realize that mistakes do happen and food/feed may be manufactured that leads to animal illness or death. It is only right that steps should be taken to minimize the damage and prevent future problems. Besides, it is the law and the quicker you respond the more favorably you will be viewed. I encourage you to be prepared to report an incident should it occur. The information for this article and further information on the Reportable Feed Registry may be found at: www.fda.gov/ReportableFoodRegistry.

Dr. Darrell Johnson,
Executive Director

Working Towards ISO Accreditation-More on What's Involved

Management system in ISO means the quality, administrative and technical systems that govern the operations of a laboratory. This includes organizational structure, policies, planning activities, responsibilities, practices, procedures, processes and resources. The quality system tells how well you do something. The technical system tells how you do something (in the laboratory and in the support services area). The administrative system explains how it all comes together.

The system is used to establish procedures to make sure that the data generated in the laboratory is within acceptable limits of both accuracy and precision by practicing the appropriate quality control measures. It adds an element of accountability of data by sampling and data management procedures and ensures complete and accurate documentation occurs. It stresses confidentiality and strives for the highest ethical standards. Data integrity is sustained through technical data reviews, internal audits, and standard operating procedures that cover all aspects of testing. This includes any spectral or chromatographic manipulations, calculations, documentation of training and competency, and sticking to the error correction protocol. This is illustrated by the cycle below:



The drawing above demonstrates that continual improvement to the technical and quality systems is endlessly pursued. There are many different ways of assuring that the customer's needs are being met. Client satisfaction surveys, internal audits, management reviews, corrective and preventive actions are all ways to evaluate the process. All of these taken together will direct what improvements should occur and what steps are most the most critical. This can be documented in a quality management plan.

The quality management plan has policies and procedures to explain how certain topics will be handled. They include confidentiality, competency & integrity, review of requests, tenders, & contracts, purchasing services & supplies, customer complaints, control of nonconforming work, corrective actions, and training of personnel. The first policy is the quality policy statement which states whose authority quality resides with, the overall objectives, and management's statement of the laboratory's standard of service and commitment to quality of its testing and complying with the ISO/IEC 17025

standard. All personnel must be familiar with these and how to implement them in their own work.

The management requirements under the standard require staff's job descriptions in detail, tells who has decision making authority, and defines resources clearly. It requires for staff to have the proper tools so that they are able to follow the procedures and policies to meet the primary quality objectives. This allows for a more defensible position for violative data.

An important part of this is to have an organizational chart clearly drawn out that shows the relationship of the staff and the supervisory personnel. The quality manager or director should be outside of the laboratory directory and have the authority to halt any and all testing should there be a reason to do so. This person is responsible to see that the quality management system is being followed at all times, should have direct access to the highest level of management at which decisions are made on laboratory policy and use of resources.

In addition to providing an overall management of personnel, facilities, and equipment so that they meet the client's requirements; the management should monitor the standards of performance to ensure compliance to the ISO standard, review quality management system reports, monitor the validity of the analyses performed & data generated to assure reliable data. Management should also ensure the integrity of the management system is maintained when changes are implemented, perform annual management review of the quality system, review training requirements of the staff, and ensure audits are carried out.

Like most systems, communication is the key to assuring that the quality management system is highly effective. This occurs via staff training, meetings for all sections, including administrative and all staff, and strategic planning. Communication is also necessary for project meetings with customers to assess their satisfaction and to convey results from internal audits and management reviews. Staff should be trained how to establish an audit trail to track where errors occurred and make modifications which address the root cause of the problem. They should be able to look at the process and ask questions such as the following:

- What is the problem?

  -We don't want this to happen again.
- When did it happen?
- Where did it happen?

We want staff to not only follow a method, but look for ways to prevent potential challenges and to improve on what is already in place. Quality control is a set of procedures laboratories follow that compares performance against specific requirements and defined standards. This should be continuously monitored to ensure reliability and to study how a process changes over time. It's designed to show that nothing is going wrong in the testing process. Quality control checks are in certain points for a reason and we want to make sure everyone knows "why" they are there! Therefore, understanding the five why's can assist in determining the root cause of why something didn't go as expected. What is the primary effect? What went wrong? When did it go wrong? Where did it go wrong? Then ask why at each point. If the technical ability and knowledge is there for the staff, training the staff in the quality control process will only enhance the laboratory's performance. The staff should be trained to figure out why something did not go according to plan so that the process or procedure can be improved, or minimize points of errors, and to communicate and properly document processes.

Not only is critical thinking involved, everything must be documented! "If it's not written down, it didn't happen!" should be the new mantra. This not only helps to monitor qualifications for personnel and required qualifications for new personnel, but also will help track training for safety, ethics, and data integrity. Documentation is not only applicable to the training, quality control, but also for approval of methods, validation, and authorization of who can perform each method. Documentation must be maintained for equipment, standards, and calibrations.

Management must ensure that the quality management system is reviewed, monitored, and is implemented & followed by all staff. Staff are trained and follow a corrective action procedure. There is a mechanism to identify possible problems and ways to take action to prevent them. Opportunities are identified to improve the effectiveness of the quality system and are implemented.

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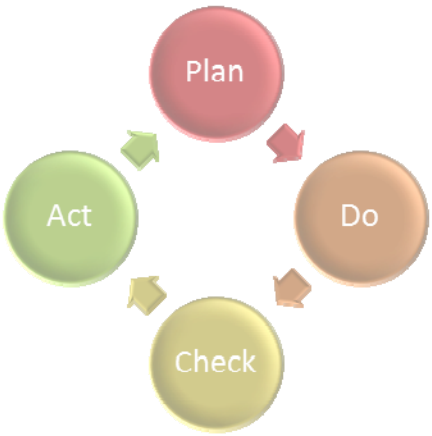
ISO implementation, cont.



Professionals secure the integrity of the data generated in the laboratory by following standard operating procedures or methods. They perform calibration checks. They make sure that quality reference materials or certified reference materials are used in each set of data according to the quality procedure in the method. The laboratories participate in proficiency testing program and the z-scores from them are monitored. Scheduled internal audits are completed. All those involved adequately understand that integrity means there is a lack of contradiction between documents.

As you read these articles I hope that your appreciation of the large task ahead of us continues to grow. We are doing this to not only to benefit us as an organization but also for the consumers, producers, and manufacturers of the Commonwealth. We are committed to continually improve what we do but also how it's done so that our Regulatory Programs keep receiving unbiased, accurate, and timely results.

Dr. Sharon F. Webb,
Director, Quality Program

Personnel Changes

As part of the grant from FDA to implement the Animal Feed Regulatory Program Standards (AFRPS) we were allowed to hire a Regulatory Programs Specialist. We are happy to announce that Jenny Combs was hired for this position this past fall. She will be involved in the development of standard operating procedures, tracking systems, data collection, and document management. She will be working a lot with our inspectors so you may see her with an inspector when they visit. Jenny had worked in our Feed and Fertilizer Lab as a Laboratory Technician Senior since August 2014. She is a native of Woodford County and has a B.S. degree in Agriculture from Eastern Kentucky University. Jenny and her husband Jarrod live in Salvisa with their children Jody (9) and Jordan (6). They have a farm with beef cattle and she enjoys running.

Gary Coleman wins 2016 Poundstone Award

Gary Coleman was presented with Regulatory Services' Poundstone Award for 2016 at our December Christmas luncheon. Gary works as a Laboratory Technician Senior in our Feed and Fertilizer laboratory. Gary is involved in sample receiving and preparation, inventory control, and disposition of old samples. He also performs other laboratory work including mycotoxin analysis and helps deliver packages throughout the building.

Gary and his wife Julia live in Richmond and he enjoys gardening in his time off.

Gary received several nominations for this award and all noted his willingness to do what is needed. As one nominator said: "Gary is always ready to help within the building. If you need someone to carry something, move something or look for something, Gary is always there."

We all appreciate Gary's work ethic and helpful attitude. He is very worthy of this award.

History of the Poundstone Award

The Poundstone Award was created to honor an outstanding employee in the Division of Regulatory Services. The award is named in honor of Bruce Poundstone, who was Director of Regulatory Services for many years. He was nationally renowned for his leadership and innovations in the feed, fertilizer and seed regulatory arena. He was founder of the Feed Microscopy Association, started the AAFCO Feed Control Seminar, and was a participant in the development of the GMP concept for feed manufacturing. Mr. Poundstone was a distinguished leader in the Association of American Feed Control Officials, the Association of American Plant Food Control Officials and the Association of Southern Feed, Fertilizer and Pesticide Control Officials. The Regulatory Services building is named in his honor.

Previous Poundstone Award Winners

Recipient	Year	Department
Stephany Chandler	2015	Reception/Data Entry
June Crawford	2014	Fertilizer
Colleen Steele	2013	Soils
Charlene Vest	2012	Data Entry
Pat Baber	2011	Administration

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