Regulatory Services News

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Director's Digest

"Character is not the same thing as reputation. Character is what you are. Reputation is what people say you are." –Josephson, 2002

Most businesses will have training programs for their employees. In my previous position we had training twice a year for our sales staff and it can be a challenge to come up with new material that will challenge them. I recently read about a 4-H development program called "Character Counts" that has been put together by the Josephson Institute to teach youth the pillars of character that define us at our best. The quote at the start of this column is from the founder of this organization which provides material for training on ethics in several aspects of life.

These six pillars and traits that define them are shown below:

Trustworthiness – Be responsible. Don't deceive, cheat, or steal. Be reliable-do what you say you'll do. Have the courage to do the right thing. Build a good reputation. Be loyal-stand by your family, friends, and country.

Respect – Treat others with respect; follow the Golden Rule. Be tolerant and accepting of differences. Use good manners, not bad language. Be considerate of the feelings of others. Don't threaten, hit or hurt anyone.

Responsibility – Do what you are supposed to do. Plan ahead. Persevere: keep on trying! Always do your best. Use self-control. Be self-disciplined. Think before you act – consider the consequences. Be accountable for your words, actions, and attitudes. Set a good example for others.

Fairness – Play by the rules. Take turns and share. Be open-minded; listen to others. Don't take advantage of others. Don't blame others carelessly. Treat all people fairly.

Caring – Be kind. Be compassionate and show you care. Express gratitude. Forgive others. Help people in need.

Citizenship – Do your share to make your school (company) and community better. Cooperate. Get involved in community affairs. Stay informed; vote. Be a good neighbor. Obey laws and rules. Respect authority. Protect the environment. Volunteer.

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Director's Digest, continued

I think we can all agree that these are good pillars upon which to build character and I am glad there is a program to instill these characteristics in our young people. A survey of Iowa farmers asked if ethics had declined over the last ten years for selected groups and their responses are shown in the table below:

	% Decline in past 10 years
Clergy	24
Neighbors	31
Local Merchants	36
Local Agribusiness	37
Lenders	41
Farmers	45
Youth and young adults	68
Local elected officials	70
Elected state officials	72

I don't think any of us are surprised that politicians were not felt to be highly ethical but I was disappointed in the overall decline of all groups. A reputation is easy to ruin and hard to rebuild. We could all benefit from an occasional reminder on the value of ethics and perhaps having a training session on this topic would be a positive resolution to make for 2016.

Darrell Johnson,
Executive Director

Inspector News

Our department has eight inspectors that are responsible for the feed, fertilizer and seed programs in Kentucky. The major job duties for the inspectors are collecting samples and completing inspections to make sure the products sold in Kentucky are in compliance with the state and federal laws and regulations. During 2015 the inspectors collected 3,156 feed samples, 2,484 fertilizer samples and 1,779 seed samples.

The feed samples include samples from livestock industry and the pet food industry. Feed sampled includes bulk ingredients, bulk feed, bagged feed, custom mixed products, and liquid samples. There are approximately 450 pet food companies with about 12,000 registered products being sold in Kentucky. The inspectors have just completed the canned pet food sampling during the month of February. They also sample pet treats and dry pet food during the year.

The fertilizer samples include bulk material, custom mixed material, bagged fertilizer, liquid, and small package specialty products found in lawn and garden centers.

The seed samples include agricultural seed, lawn and garden seed, and vegetable seed. One area of focus for the seed program by the inspectors is to make sure the seed tag test dates are in compliance. The inspectors try to visit each agricultural business and each lawn and garden center two times a year.

One of the major inspection programs for the feed program is where the inspectors conduct 79 FDA/BSE and medicated feed mill inspections during the fall and winter months. These inspections ensure that the medicated feed being manufactured in the state meets the guidelines set by FDA and the drug manufacturer. As of the end of January, we have almost finished these inspections for the year.

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Inspector Report, continued

This past year the inspectors have also attended training conducted by FDA on the Food Safety Modernization Act (FSMA) and the Veterinary Feed Directive (VFD). In addition the inspectors have also participated in several web based trainings for both the FSMA and VFD implementation. The inspectors are available to assist you with questions about these two changes in the feed industry. They have handouts and informational resources available to help answer any questions you might have.

I want to thank the inspectors for their effort in assisting you in meeting compliance for the products you manufacture and sell. The inspectors are available to help you so if you have questions please let them know.

Jim True,
Inspector Coordinator

Building a Better Feed Regulatory Program

In 2014, a joint effort by the American Association of Feed Control Officials (AAFCO) and the Food and Drug Administration (FDA) resulted in the development of the Animal Feed Regulatory Program Standards (AFRPS). AFRPS is modeled after the FDA's Manufactured Food Regulatory Program Standards (MFRPS). This program has been well received with 41 states participating in MFRPS, including Kentucky. While MFRPS focuses on the safety of the human food supply, AFRPS was designed to help build a more robust integrated food safety system by concentrating on animal feed production.

The goals of AFRPS are to:

- Increase consistency & uniformity among regulatory agencies.
- Improve communications, cooperation and coordination among agencies.
- Allow Federal and State agencies to use each other's findings for effective, timely, and efficient regulatory actions.
- Improve staff training.
- Help identify what resources are needed to accomplish specific goals.
- Improve documentation of procedures and processes.
- Provide a framework that links inspection findings to compliance.
- Provide a better and structured mechanism for self-assessment.

The Feed Program of the Division of Regulatory Services was one of the initial states that agreed to participate in AFRPS in 2014. During the first year, we conducted an assessment of how our program compared to the 11 standards developed by AAFCO and FDA. The 11 standards (or program areas) are regulatory foundation, training, inspection program, auditing, feed related illness/death and emergency response, enforcement program, outreach activities, planning and resources, assessment and improvement, laboratory services, and sampling program. The assessment exercise allowed us to take an objective look at our overall program, identify areas that needed improvement, and begin development of improvement plans. We are currently in our second year of the program.

For the Kentucky feed industry, there are measurable benefits to a strong state regulatory feed program. Improving our training program will ensure that current inspectors understand new federal regulations and are able to provide support to Kentucky firms in complying with these regulations. When new inspectors are hired, a strong training program will allow them to develop the skills needed to meet the needs of the industry and consumers. An emergency response plan is critical to minimizing harm to the feed industry and the public if we are faced with an animal feed-related emergency.

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Feed Regulatory Program, continued

It is important to note that the feed program standards are not a vehicle to make all state feed programs the same. State feed laws and regulations differ and each state has a unique feed industry. First and foremost, a state feed program must be designed to meet the needs of their feed manufacturers and distributors as well as consumers within their state. The standards are the minimum requirements for a state feed regulatory program but states are expected to tailor these standards to fit the needs of their state's feed industry.

Our decision to participate in AFRPS is consistent with our mission of service and consumer protection of Kentucky citizens, businesses, and industry. Participation in AFRPS supports our philosophy of regulation through education. The Feed Program of the Division of Regulatory Services has historically been one of the stronger state programs but there's always room for improvement. It is our sincere hope that enhancing our program results in benefits for both consumers and the industry.

Dr. Alan Harrison,
Director Feed and Milk Programs

Fertilizer Regulatory Program Update

Annual Registration

Our registration for 2016 is progressing quite well. As of January 29, 2016 about 70% of our 2015 registrants/licensees had applied for renewals. We will shortly be sending out notices to those who have not responded. If you are one of the "procrastinators" then you will be getting a notice with a deadline after which Stop Sales will be issued on any unregistered products. If you need assistance please call 859-257-2668 or email: june.crawford@uky.edu or smcmurry@uky.edu.

Annual Bulletin Published

Our annual report of the analysis of official fertilizer samples has been published and mailed. If you have not received your copy go to: http://www.rs.uky.edu/ click on "Fertilizer" and then "Annual Report of Fertilizer Analysis". It is "REGULATORY BULLETIN NO. 327 ANNUAL REPORT ANALYSES OF OFFICIAL FERTILIZER SAMPLES July 2014-June 2015.

Tonnage Reports

We have recently refined our tonnage reporting procedures. Here are the steps:

1. Each company scheduled to report tonnage is sent a blank report form in the last month of the reporting quarter. It will have your company number and name and address pre-printed on the form. If we have an email for your company, this will be emailed. Please let us know if an email update is needed.
2. If you are reporting for more than one company, a separate report is sent for each company and they cannot be combined on one report.
3. The report form has the due dates and delinquent dates. About 10 days before the "delinquent" date for a report, we will try to notify all non-reporters so they can beat the delinquent date. Your report must be postmarked on or before the delinquent date. As always, "ZERO" reports are required. With notifications we provide, there is no excuse for a late report and the late fee is $50.

THE FOURTH QUARTER (2015) TONNAGE REPORT IS DUE NOW. It will be delinquent as of February 15, 2016.

Tonnage reports are published quarterly in hard copy and on our website at the address noted above. Click on "fertilizer" and "Distribution of Tonnage quarterly Reports".

Steve McMurry,
Director Fertilizer and Seed Programs

COMMERCIAL FERTILIZER VALUES FOR 2016

Commercial fertilizer values are determined and published each year. A state-wide survey was conducted in December 2015 to determine the averages for 2016. Under the provisions of Chapter 250.401 of the Kentucky Fertilizer Law, the following unit values are announced for use in determining and assessing penalties of deficient fertilizer. They represent the average of responses from throughout the state for retail value of bulk mixed fertilizers.

NUTRIENT	DOLLARS/UNIT (20 LBS.)
Total Nitrogen (N)	$9.74
Avail. Phosphate (P_2O_5)	$8.11
Soluble Potash (K_2O)	
*Tobacco (low Cl)	$16.17
*Non-Tobacco	$6.83
Calcium (Ca)	$7.03
Magnesium (Mg)	$30.09
Sulfur (S)	$8.89
Boron (B)	$127.00
Copper (Cu)	$133.71
Iron (Fe)	$16.50
Manganese (Mn)	$31.43
Molybdenum (Mo)	$20.20
Zinc (Zn)	$56.19

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 15 (distributed) tonnage for ammonium nitrate, Urea, DAP, TSP, MAP, and ammonium sulfate.

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

What is Accreditation and Why it is Important, Part 2

In the previous article regarding accreditation, we went through general definitions of terms specifically applied to accreditation and ISO. We also discussed a general overview of the importance and some steps to become accredited to the ISO-IEC 17025:2005 standard. As a quick review, accreditation is the process by which a laboratory is certified to perform certain analyses. ILAC (International Laboratory Accreditation Cooperation) sets the standard (eg. ISO/IEC 17025:2005) and the standard is used to assess quality and competency of the laboratory. There are a number of independent accrediting bodies in the United States. Support from management is absolutely necessary, a clearly defined Management System must be in place, a Quality System Manual (QSM) in place, and all methods and their purpose must be clearly defined demonstrating the scope of accreditation is met.

In our discussion about the QMS (Quality Management System), we talked about the importance of having written organizational policies, a Quality System Manual (QSM), and Standard Operating Procedures (SOPs)

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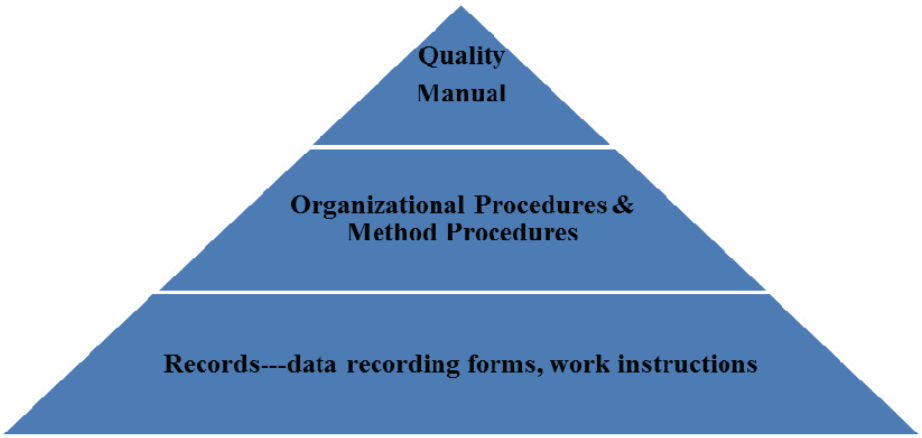
for all management system policies and procedures and for all technical procedures. However we handle daily, weekly, monthly, or even yearly duties must be written down exactly as we actually perform them. The same holds true for any methods of analyses, quality check-points, reporting of the analytical data, and instrumentation calibration and/or maintenance. The management system document structure can be pictured as a pyramid with all work instructions and data recording forms that will be used by the analysts/techs in the laboratory on the bottom. The second layer would be documents that outlined the overall organizational and analytical methods procedure. The apex on the pyramid is the quality manual.



Our pyramid can be simplified into two main groups: management and technical procedures. In the management procedures, we include our Division's organizational chart which will demonstrate who reports to whom, and our confidentiality and ethics policies and procedures. Typically this is comprised of contracts, contract reviews, and surveys pertaining to our customer, which is the regulatory program. At the Division of Regulatory Services, our laboratory and regulatory directors report to the same person and we are located in the same physical building. Thus, we are able to have daily communication about samples, methods of analyses, and special requests making some of the ISO/IEC 17025:2005 requirements regarding these procedures second nature. Under management procedures, any sub-contracting of analyses would require specific documentation demonstrating the expertise of the laboratory performing any analyses. Written procedures for purchasing everything from the soap we order to clean our glassware to the major equipment we would only purchase every several years must be in place. We must have a written policy dictating how to handle situations such as when an analysis does not meet expectations, if there is a complaint about the result or even if our results from the proficiency testing programs do not "pass". Our management procedures also have to include written policies on not only how to do internal audits, but who is qualified to do the auditing, when audits occur, and how often. Document control is something quite tedious. The purpose of document control is to ensure that the documents have not been altered without proper consent, contains document tracking information, including the date of the change and who made the change. This is especially effective for training and performing analyses to ensure continuity of performing analyses. Of course, the QMS would not be effective if the documents are static and unchanged, especially if there are improvements that could be made that would be helpful. Therefore, documents are routinely reviewed and any improvements that can be made to overall processes or procedures can be incorporated.

The technical procedures include the training and assessing of personnel, building and environmental conditions, analytical methods, measurement of uncertainty and traceability, equipment, sample handling, and reporting results. We can think of the technical requirements as a wheel with spokes as shown on the next page.

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All personnel must have documentation to show that they are adequately trained and are capable of meeting assessments such as proficiency testing for the analyses they perform. Our building and environmental conditions must be adequate in order to perform the methods defined within the scope of the accreditation. This not only includes our laboratory being maintained in a clean and organized manner, but we must have adequate work space, the work areas must be fit for their intended use, our fume hoods must meet safety guidelines, and our de-ionized water must be compared against a standard and meet certain tests. The analytical methods we use must have been validated and verified that they work for their intended purpose. This is usually done once a method is adopted. Then it is verified as valid by the results of the quality reference materials meeting certain standards. Reference materials and reference standards assist in tracking traceability and for calculating the uncertainty of measurement. All equipment must have documentation that shows they are properly maintained, undergo annual preventative maintenance, and their calibrations verified. Documentation of sample handling not only shows how samples are received but also their path throughout the laboratory and through the reporting process.

As you read these articles about accreditation and what we are doing to meet the standard, I hope you will appreciate the immensity of the tasks ahead of us. This will be a multi-year process that will not only benefit us as an organization, but also the consumers, producers, and manufacturers of the Commonwealth. We are committed to continually improving not only what we are doing but also how we are doing it in order to provide our Regulatory Programs unbiased and accurate results in a timely manner.

The next article will outline the sections of the ISO/IEC 17025:2005 Standard that discusses management review.

Dr. Sharon Webb
Director Quality Control Programs

Stephany Chandler Receives the 2015 Poundstone Award

Stephany Chandler was presented with Regulatory Services' Poundstone Award for 2015 at our December Christmas luncheon. Stephany is technically our receptionist but performs many duties for our division. In addition to directing phone calls and visitors, she distributes the mail, deals with entering payments, entering data for several of our programs and keeping our employee roster up to date. She is also very active in committee work within the division.

Stephany was born, raised and still lives in Winchester. When not working at Regulatory Services she enjoys hiking, four-wheeling, volunteering, and playing softball. She also keeps busy raising two children. Her daughter Kadence is 11 and her son Myles is 2.

We appreciate all that Stephany does for our Division and she is a very worthwhile winner 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. Pound- stone was a distinguished leader in the Association of American Feed Control Officials, the Association of Ameri- can 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
June Crawford	2014	Fertilizer
Colleen Steele	2013	Soils
Charlene Vest	2012	Data Entry
Pat Baber	2011	Administration
Nining Sutardjo	2010	Seed

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