

QUALITY

Be Ready for the FDA



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One of the commonalities in third party audits is a section of regulatory compliance and preparation for visits by the U.S. Food and Drug Administration (FDA). This is a commonsense request and it is a very, very good idea to be sure that your company has developed and implemented such a policy. Implementation in this case must include training of management, office staff, and line workers.

According to federal law, the FDA has the right to come to your plant at any time during business hours. The agency has husbanded their resources and focused more on processing operations

that pose greater risks to the public. Isn't it wonderful that most grain processing and cereal operations are rather low risk? However, they do believe that it is important that all processors and ingredient manufacturers in this country are inspected on a regular schedule. In many cases, the FDA will work with state food and drug or public health agencies to do these investigations. And, given the political environment and the talk about establishing a single food agency, getting into more process operations, even low risk ones, may be a higher priority. Like it or not, the food industry in this country may end up caught in a turf war.

So, expect to be inspected by the FDA or a local agency representing them. And, be sure to develop a program to handle these inspections. This procedure must include the following elements:

- Preparation for an inspection;
- How to act during the inspection; and
- Follow-up to the inspection.

Preparation should include establishing procedures for office personnel, management, and plant people. Let's start with the office people. Unlike third party audits, FDA investigations will be unannounced. When the investigators arrive at the plant and go into the office, the first person they will usually meet is a receptionist or cleric. All of the persons who may fill this role in your facility should be trained in what to do. The goal is to ensure that there is at least one person in the plant at all times who understands the process. This training must include greeting the regulator, requesting credentials, examining paperwork (Do they have Form FD-482?), politely informing them where to wait, and notifying persons who have been trained in working with regulators. The receptionists should also not volunteer any information. This, too, should be part of the training program. Even though they are the government, they should be asked to do all of the steps that

A Food Processing Industry Camera Policy

Policy

This processor and warehouse shall refuse to permit photography within the premises by an FDA inspector unless the inspector presents a warrant explicitly authorizing the taking of pictures. If the inspector has no such warrant, tell the inspector that the camera must be left in the office and may not be taken into the plant or warehouse. If the inspector asks for an explanation of refusal to permit his taking a camera along during the inspection, tell the inspector that it is a company policy not to permit photography without a valid warrant. If a warrant authorizes picture taking of the warehouse only, it is not applicable for taking photographs within the processing operations. Limit photography to the area and object of the warrant.

Procedures to Be Followed When Photographs Are Taken

- 1) Advise the inspector to take photographs from an area or areas that are safe so that the inspector will neither injure himself or herself nor contaminate the product undergoing processing.
- 2) If background or foreground in the picture includes trade secrets, the supervisor accompanying the inspector shall inform the inspector to that effect and request that the photograph be held in confidentiality by the FDA. The supervisor shall note which photograph was to be held as a trade secret.
- 3) The supervisor must have a camera when accompanying the investigator. The camera should be one that uses film and the flash is functioning. Be sure there is fresh film available.
- 4) The supervisor shall take a photograph of the inspector taking a photo of an object. Both the inspector and the object shall be in the same scene if physically possible so that anyone would be able to appreciate the perspective involved in photographing the object. A second photograph should be made of the object from the same place the inspector stood. If the objectionable material is rather small, it would be good to place a ruler or any sanitary, nonhazardous object that could serve as a reference of dimension near the object.
- 5) At the exit meeting, remind the investigator of any photographs taken that the company wishes to be classified as trade secret.

any visitor would do, including signing in and reviewing any sanitation or safety policies.

Your plant should train several persons, including the plant manager, quality manager, and production manager on the agency's inspection policies. These sessions should focus on what investigators are and are not allowed to view and what they can and cannot do when in the facility. Perhaps the most important part of this training is to be sure that managers understand what records FDA investigators can examine. Now, I do not mean to cast aspersions towards agency investigators, but they often ask for more than they are entitled to see. For example, FDA investigators are not allowed to examine quality and manufacturing records, yet they often ask for them. It is, however, within the investigator's right to examine shipping records for articles received in interstate commerce. If your people are not properly trained, they will probably think, "Well, it's the government. I better give them what they want." If this is done, there is a potential that you may create problems for yourself. The proper response would be a polite, "You know you are not entitled to see those records, sir/madam."

The procedure for addressing an FDA investigation should also mandate that one or more trained individuals accompany the investigator at all times. The person accompanying the investigator is not required to explain or give up information about plant operation, however. For bakeries, mills, or grain processors, the investigation will be based on the current good manufacturing practices defined in 21 CFR Part 110.

Most FDA investigators carry cameras. Most companies have a policy that forbids cameras in the plant. This policy should be posted prominently in the office and informing investigators of the policy may even be included in the receptionist's duties. The right to take photographs is still a major issue between the FDA and the industry, but if a company has a policy against cameras, investigators will usually not try and push it. A sample camera policy can be seen in the sidebar. Note that the sample policy states that a camera with film be used. There are concerns about editing of digital photographs.

FDA investigators may also collect samples. They are, however, required to provide a receipt and pay for any samples they collect, although most companies waive payment. To protect yourself, you should collect duplicate samples of every sample collected by the investigator. These should be tested using recommended procedures, that is AACC Intl., AOAC, or other official methods. Lastly, the investigator is required to provide the operation with a copy of the results for each sample collected and indicate whether the food or foods were unfit for consumption.

If there are any violations noted, the investigator should point these out during the inspection. He or she will also discuss them during the exit meeting. Violations will be addressed in their final report and highlighted on Form FD-483. When violations are pointed out during the inspection, make an effort to address them as soon as possible. If you can fix them during the inspection, make a point of showing the corrective action to the investigator. The report will usually acknowledge that the deficiency was addressed, but it won't go away. If the report includes violations, fix them as soon as possible and respond to the agency describing what was done or will be done. And be sure you do what you say. If there is one way to get in hot water with the regulators, it is saying you will do something and not doing it. That does not make them happy and your company could wind up in court.

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An N.P. Analytical Laboratories advertisement appeared here in the printed version of the journal.