Every now and then a discussion ensues on the U.S. Food and Drug Administration (FDA) electronic listserv in which a retailer/producer/vendor subscriber describes the “horrors” of inspections and inspectors, and conversely, in which an inspector wonders at the obstinate behavior of a food producer or retailer. While it is not my purpose to enter into the fray of who’s right or wrong, I do feel compelled to view this argument from both sides with some objectivity. In this two-part series I would like to present the expectations industry deserve from the inspector and what the inspector should expect from a client.
First, We’ve Come a Long Way
Sanitation inspectors have been around for well over a century; the institutionalizing of public health began just after the Civil War. Early efforts in environmental health by the public health pioneers were directed toward stemming the onslaught of many communicable diseases that ravished both our urban and rural populations. While wars always exacted a toll, they paled before such diseases as small pox, cholera, tuberculosis, malaria, yellow fever, typhoid, diphtheria and a host of other environmentally mediated maladies. It was through sheer determination and the absolute need to control these epidemics that public health and indeed, the “sanitationists” were born. As some of the historical diseases were brought under control, new ones emerged and the profession evolved to meet the current demands and concerns of the community. Food safety is a rather recent addition to the traditional public health emphasis.
As a recognized profession, the credentialed sanitarian has a relatively short history that parallels the general acceptance of the germ theory of disease and asepsis as a form of prevention. Although licensure of inspectors has been around since the early 1900s, the formation of a professional society, the National Association of Sanitarians (now the National Environmental Health Association, or NEHA), only dates back to 1937. Professional credentialing has even a shorter history. To put this into some perspective, my chosen vocation has only received its own SIC code within the last decade. We are relatively new kids on the block and we are still trying to define ourselves, both in education and in application.

When I first started as a state sanitarian in the mid 1960s, my professional efforts, as those of my colleagues, were largely centered on the dairy, meat, poultry and egg, and seafood producers. Among other things, we monitored pasteurization at dairy plants; reviewed retort temperature logs at canneries; checked meats for fat content and adulteration; took water samples and conducted sanitary surveys of shellfish beds; graded eggs at egg breakers; and looked for insect infestations in stored granary products. Although we had the U.S. Public Health Service (USPHS) 1962 Food Service Sanitation Manual, it really wasn’t until the 1976 update of that publication that emphasis was given to time and temperature controls at the retail level and we started codifying the things we inspect. But until we were presented with the 1999 USPHS/FDA Food Code, there was really no uniformity. We are still trying to find a “comfort” level in our enforcement—which often means that we are in conflict between good science, common sense and the law.
In the meantime, life goes on. Consumer demand for wholesome and safe foods and the food industry’s farm-to-fork technological advances have grown exponentially to that of the public health discipline’s ability to respond accordingly. I’ve heard it estimated that it takes about 10 years for an institution of higher learning to ramp up curricula to meet new demands, and even longer for government to catch up. As it stands, more money is spent on marketing a burger, fries and cola than to train and retrain competent food safety professionals, specifically those whose avocation is in the regulatory community. By the way, to the best of my knowledge, no college or university teaches the art and science of inspection—at least within its environmental health curriculum. It is a learning curve for all of us, and most particularly, we must learn from each other, including challenging the paradigms that motivate us and by which we operate.

To set the stage for expectations from the inspector, I would like to quote from Richard North’s book, Some Observations on Food Hygiene Inspections: “...staring them in the face is the ultimate truth—that inspection is a unique discipline in its own right, with an unimpeachable scientific base. And the discipline of inspection—whether it is applied in the context of...food hygiene—has every right to claim impeccable scientific credentials.” Having said that, here is what we all should expect from a regulatory inspection and the sanitarian conducting it.
Purposes of a Regulatory Inspection

There are two purposes of a regulatory foodservice inspection. The primary purpose is to determine conformance to applicable laws, rules and regulations. We do this by first determining if the controls that are in place are adequate to meet the requirements. For instance, we check to see if there are accurate, easily readable and properly placed thermometers in hot and cold holding equipment. Second, we try to determine if the controls are effectively implemented and maintained. It's all well and good to have a thermometer in a walk-in refrigerator, but we also have to determine if it is used. In this instance, we look for a temperature log or some indication that the thermometer is periodically read.

The secondary purpose of a regulatory food service inspection is to identify changes in circumstances or arrangements that can put the public at risk. No local inspector can spend a week at an establishment to witness hand washing frequency and the monitoring of time and temperature, or to identify all of the potential cross-contamination possibilities at each operation inspected. Therefore, we have to get this information in a different way. To do this, our first choice is to rely on a well-planned and well-implemented Hazard Analysis & Critical Control Points (HACCP) program for high-risk, potentially hazardous foods. This removes the ambiguity and worry of guessing without witnessing the actual procedures and practices used within an establishment.
In the absence of HACCP plans, inspectors are forced to look at surrogate procedures or equipment with a very critical eye. For instance, the depth of hotel pans or stock pots in the cooler containing prepared foods; the separation of economic poisons from foods and food preparation materials; date labeling in storage; retention of shell fish tags; and verification of manager training in food safety. When we do this, however, potential conflicts arise where either side claims it is right, and neither side capitulates to the other. I cannot stress the importance and urgency of establishing working HACCP programs, if for no other reasons than to usher inspectors out the door and keep litigants at bay.

As part of the secondary purpose of inspection, we try to identify failures in equipment and procedures, policy and practice, or human error, which are not necessarily regulation driven, but perceptibly may exacerbate risk of foodborne disease. While this may sound a bit more subjective, remember, we inspectors have evaluated many establishments and chased down numerous foodborne illnesses that have shaped our ideas and paradigms. We are quite confident in knowing what works and what doesn’t, and often, for good or bad, we couch these observations and ideologies into regulatory interpretation.

**Structure of Regulatory Inspection**

Although it’s not always obvious, each inspection has a distinct structure consisting of an introduction, methods and materials, results, statistical analysis, conclusion and references. The structure of an inspection gives validity to the findings and guides the inspector in his or her decision-making process.
• The introduction includes the presentation of credentials to both sides, an explanation of the purpose of the inspection (routine, complaint, forensic, etc.); a cursory overview of the facility including, but not limited to, a review of the menu, hours of operation, names of purveyors, demographics of customers, quantity of food prepared and served and food safety training of the cooks and wait staff.

• The methods and materials consists of the inspector explaining the conduct of the inspection and asking about the flow of foods through production, so that the inspection itself can demonstrate good contamination control and safety practices, such as going from clean to soiled, dry to wet and cooked to raw. Additionally, the inspector has an obligation to inform the client about the instruments he or she is about to use; particularly, their calibration or validation history.

• The results, presented on a score sheet or in written format, should detail the findings in an objective manner. Since everything is measurable, all finding should include actual temperatures (the beef stew was at 90F), times (the lasagna was allowed to remain on the counter for three hours without refrigeration), percentages (approximately 10% of the cleaned eating utensils had food residue on them), or gradients (although the cutting boards were cleaned to sight and touch, their surfaces have not been sanitized, or the hand washing sink in the production area was dry to the touch). Findings that are not presented in an objective manner have little chance of being corrected because the inspector gives no reference point from which to measure ameliorative efforts.
• Any measurement taken by the inspector implies some statistical analysis. It does not have to be to the detail of a six-sigma study, but it should include whether the sample(s) or measurement(s) were judgmental, stratified or randomly selected. This is essential if the findings are disputed and the sampling or measuring must be repeated; it provides guidance for subsequent monitoring.

• The conclusion is as much a statement of risk associated with the various findings as it is a validation of things done correctly and within compliance of the law. It should detail those areas of the facility and practices that may contribute to the propagation of organisms, both illness producing and spoilage types, the potential for adulteration by foreign materials and to a lesser degree, aesthetics and safety. The conclusion also should list those areas of the operation that are exceptional and may serve as a model for other similar businesses.

• Finally, every good inspector will provide references, whether they are specific citations from the code or informational documents. These references are absolutely essential for all parties to understand what is expected and what is allowed.
The Conduct of an Inspection

The inspector has the responsibility and obligation to review his or her inspection plans with the owner or operator. This includes the path of travel through the facility, what and where samples and measurements will be taken, and the approximate length of time that the inspection will take. This will ensure access where necessary, safety of the inspector and attention by the operator. I also think it important that the inspector comment on the inspection during its progress. This permits for timely questions and answers and provides a valuable teaching point, but moreover, it helps to diffuse any misunderstandings or disagreements. At the exit meeting, every professional sanitarian should ask if the findings are fully understood and if there are any questions. It is the inspector’s obligation to detail expectations.

Finally, I strongly believe that every regulatory official should present themselves in a professional manner, both in dress and in action. I have made it a habit to wash my hands at the beginning, during and at the end of the inspection, demonstrating a full 20-second wash each time. I may be old fashioned, but I believe that clothes should befit the position. If the inspector’s deportment is that of a professional, the inspector will be professional.

Client Contact

Several years ago, I copied the following common sense client contact rules for inspectors. The rules come from an American Society for Quality (www.asq.org) publication, but for the life of me, I cannot remember which one. To the author, I would like to extend my apologies for the lack of a proper citation, as well as my gratitude for having written it. These guidelines have served me well as a practicing sanitarian and I sincerely hope that they serve as a guide to all those in the “inspection” business, as well as those being inspected.
• Do not disclose proprietary information to others.
• Be honest and impartial by avoiding conflicts of interest.
• When an unethical activity is observed, verify it, record it and report it.
• Protect any property entrusted to you.
• Ensure sufficient resources are available for the inspection.
• Communicate expectations and methodology.
• Verify conformance to requirements.
• Stay within scope unless the degree of risk necessitates other actions.
• Justify sampling scheme; ensure samples are representative.
• Comply with establishment rules.
• Communicate progress of inspection.
• Report results truthfully and in a clear, concise and complete manner.
• Communicate the importance of findings.
• Ensure results are traceable to requirements.
• Do not take ownership of problems found.

In the next issue, I will discuss some of the things that I expect from the foodservice operator when I conduct a regulatory inspection. And as a gentle reminder, Food Safety Magazine welcomes any comments and anecdotes you may have regarding this series. We look forward to seeing them.

**Great Reading**


Forensic sanitarian Robert W. Powitz, Ph.D., MPH, RS, CFSP, is principal consultant and technical director of Old Saybrook, CT-based R.W. Powitz & Associates, a professional corporation of forensic sanitarians who specialize in environmental and public health litigation support services to law firms, insurance companies, governmental agencies and industry. Among his honors, Powitz was the recipient of the NSF/NEHA Walter F. Snyder Award for achievement in attaining environmental quality, and the AAS Davis Calvin Wagner Award for excellence as a sanitarian and advancing public health practice. He is the first to hold the title of Diplomate Laureate in the American Academy of Sanitarians.

Dr. Powitz welcomes reader questions and queries for discussion in upcoming columns.

> **Categories:** Contamination Control: Allergens; Facilities: GMPs; Regulatory: HACCP, Inspection; Sanitation: Cleaners/Sanitizers