Handling Regulatory Inspections SOP

Purpose

- To establish guidelines for food service personnel in handling a regulatory and/or third party inspection.

Scope

Food service employees who handle regulatory and/or third party inspections.

Key Words

Regulatory Inspections, Third-Party Inspections, FDA Form 482, FDA Form 483, FDA Form 484

Instructions

1. Preparations for inspections are an ongoing process.
2. Regulatory agencies may conduct unannounced inspections of the facility. The Food, Drug and Cosmetic Act & FSMA grants the right for their personnel to enter food establishments during "reasonable" hours. It is unlawful to deny permission for inspection.
3. All company personnel that have direct contact with outside (non-company) personnel should understand and have access to this procedure.
4. The FDA gives inspection contracts to many organizations in individual states, i.e., the Department of Agriculture or a state/county health department(s). The purpose of these contracts is to have State personnel undertake FDA regulatory inspections. This may lead to more than one audit occurring in any given timeframe.
5. Inspectors shall provide proper identification upon arrival at the facility. Inspectors must also produce a Form 482, which he or she must sign and date in your presence. State or other non-Federal inspectors may or may not use a similar form.
6. Once proper identification is established, the regulatory inspector should be instructed to wait in the lobby (or similar area) until the appropriate official(s) can be notified.
7. Director of Food Service, Manager or other previously designated official shall be notified when the Inspector arrives on site.

8. During the inspection, the regulatory inspector **shall always** be accompanied by the appropriate representative(s).
9. As set forth by food service dept policy, no one shall be allowed to take in any cameras, video recorders, or other audio/video recording devices unless authority is given by the Owner and a variance form completed. (2.5.1)
10. FDA law grants access to the following records only:
    a. Records of raw materials received via interstate commerce;
    b. Finished products shipped via interstate commerce.
    c. NOTE: State inspectors may request records pertaining to those business practices conducted within that given state.
11. The district is not required to show or provide records or documents pertaining to production specifications, pricing or cost information or any other information considered proprietary in nature. If an inspector requests any records in which he or she is not entitled, the official's reaction should be, "We respectfully decline turnover of such information."
12. The inspector may request actual samples of raw materials and/or finished product. The inspector should be very clear as to what analysis he/she intends to have performed. Any sample taken by the inspector should be physically "split" with a sister sample given to a Food Service Management Representative to have the same analysis performed. A sufficient quantity should be taken to allow the Food Service dept to retain a sample even after an analysis sample has been sent.
    a. The Food Service Management Representative should retain its duplicate sample pending the results of any analysis.
    b. The inspector is required to provide a completed Form 484 for any sample taken.
    c. The FDA inspector is also required to pay for any product taken. If the company requires a payment, a receipt should be given to the inspector. USDA is exempt.
13. Following the inspection, the inspector may call for a meeting to discuss his or her observations. The appropriate representatives should be present for the meeting.
14. Violations of the CFR 21, FSMA, GMP's, labeling, etc. should be covered in the meeting and an FDA Form 483 provided to the facility noting all deficiencies found.

Date Implemented _____ By _____

Date Reviewed _____ By _____

Date Revised_____ By _____