

UNIVERSITY OF TOLEDO

SUBJECT: INSPECTION PROCEDURES
(REGULATORY AGENCIES)

Procedure No: S-08-045

PROCEDURE STATEMENT

To provide guidelines to University of Toledo personnel when university facilities, sites, and operations are being inspected by an outside regulatory agency.

PURPOSE OF PROCEDURE

To ensure cooperation with all regulatory agencies and their representatives, and to ensure compliance with all governing regulations.

PROCEDURE

A. REGULATORY AGENCIES

Regulatory visits should be reported to the appropriate administrator by the visited department or Environmental Health and Radiation Safety (EHRS). The most common regulatory agencies likely to visit the campus, are:

1. Medical Center and Campus Clinical Locations

- College of American Pathologists (CAP) – Pathology Laboratories (Announced)
- The Joint Commission (JC) – Inpatient and Outpatient Clinical Facilities (Unannounced) (**See Section “E” on Special Considerations for JC and CMS Survey**)
- Ohio Department of Health (ODH) Mental Health Division – Kobacker (Announced)
- Ohio Department of Health (ODH) Proxy agent of Centers for Medicare/Medicaid (CMS) (Unannounced) (**See Section “E” on Special Considerations for JC and CMS Survey**)
- Ohio Department of Health (ODH) Division of Radiation Protection (Radiology, Cardiovascular and Nuclear Medicine (Announced and Unannounced)

2. University Campus Areas

- Drug Enforcement Agency (DEA) – Pharmacy and Research Labs (Announced)
- Federal Aviation Administration (FAA) – Shipping of hazardous materials (Unannounced)
- Food and Drug Administration (FDA) – Medications, Medical Devices (Unannounced)
- Local Health Department (Toledo/Lucas County)- Food Inspections, Infectious Waste Management (Announced)
- Ohio Department of Health- Use of any radioactive material and radiation generating devices (Announced, and Unannounced)
- Department of Transportation (DOT)– Shipping of hazardous materials (Unannounced)
- Ohio Environmental Protection Agency (OEPA) – Hazardous Waste, Air Pollution Permitting (CAA-City of Toledo proxy agent), Water (CWA-City of Toledo proxy agent) (Unannounced)
- Public Employees Risk Reduction Program (PERRP) – Jurisdiction over employee safety and health in Ohio Public Institutions (Unannounced)
- State/Local Fire Marshals - Jurisdiction over fire protection of UT facilities, Underground Storage Tanks (UST) (Announced)
- United States Environmental Protection Agency (USEPA) – Same as OEPA; but at federal level. (Unannounced)
- United States Department of Transportation (USDOT) – Shipping of hazardous materials (Unannounced)
- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) – Animal Facility (Announced)
- Centers for Disease Control (CDC) – Inspection of BSL3 Facility (Announced)
- United States Department of Agriculture (USDA) – Animal and BSL2/3 Facilities (Announced)
- Department of Energy (DOE) – Labs holding grants (Announced)

- Ohio Department of Natural Resources (ODNR) (Announced/Unannounced)
- Insurance Agency (General Liability Inspection)

B. RESPONSIBILITIES

1. Deans, Directors, or Department Heads
 - a. Contact EHRS, 419-530-3600 or through University Police at 419-530-2600/419-383-2600, immediately upon notice of pending inspection or arrival of inspector(s).
 - b. Designate appropriate management, or supervisory staff, to accompany inspection agency representative(s).
2. UT EHRS
 - a. Accompany inspector(s) when timely notification and access to the site permits.
 - b. Provide guidance to area representative(s) when notification is timely, if travel to the location is not possible.
 - c. Visit the location and contact Dean, Director or Department Head, and/or individual who accompanied the inspector(s).
 - d. Notify Administration/President's Office, Risk Management, General Counsel's Office, and Research and Grants, as appropriate.
3. General Counsel
 - a. Analyze legal issues and provide advice as needed.
 - b. Determine when legal representation is necessary.
 - c. Access engagement of outside counsel as recommended by Executive leadership, or as necessary.

C. GUIDELINES

1. Inspections will be allowed without requiring a warrant to enter University facilities. Inspections usually fall into four categories:
 - a. complaint,
 - b. compliance,
 - c. fatality/accident resulting in severe injury(s), or
 - d. spill or release to the environment.
2. An opening conference is required to agree on the scope of the visit. (Formal/Informal)
3. A closing conference is required to review the findings. (Formal/Informal)

D. INSPECTION PROCEDURES

1. Inspected Departments
 - a. Notify UT EHRS immediately. During non-work hours call University Police Dispatch at 419-530-2600/419-383-2600.
 - b. Appoint a responsible management, or supervisory employee, page senior EHRS staffer to represent UT, and accompany inspection agency inspector(s).
 - c. Request to see identification/credentials of the regulatory agency inspector(s).
 - d. Inquire as to the reasons for the inspection and its scope.
 - e. Whoever accompanies the inspector(s) must take notes, and when possible, take photos of possible citable items.
 - f. Hold a closing conference with inspector(s) to discuss findings.
 - g. Write a report/memo to the Dean, Director or Department Head of your impressions and findings of the visit.
 - h. If EHRS personnel were not present, notify UT EHRS about the findings and whether citations were, or will be issued.
2. UT EHRS

- a. Assist Dean, Director or Department Head with their request, and if accompanying inspector(s), then follow items 1(a) through 1(h) above.
 - b. Notify Administration, Human Resource Director, Risk Management, and General Counsel's Office; plus Dean, Director or Department (if not previously notified) about findings and whether citations were issued.
 - c. Ensure citation is posted, if received and required, at the specified location, and for the requested time period. Act as liaison to, and coordinate all responses to, regulatory agency if responsible for that area.
 - d. Notify the regulatory agency, within their established time period, after receipt of findings/citation and advise them of UT's intent to contest the findings and/or citation, if appropriate. Coordinate responses through the General Counsel's Office.
 - e. Follow up and assist departments to ensure compliance with all recommendations and citations issued.
3. Risk Management
 - a. Determine if notification to the insurance broker/insurers is necessary when property damage or UT liability is involved.
 - b. As requested or necessary, assist UT in responding to regulatory agency.
 4. General Counsel's Office
 - a. Assist UT in determination to accept or contest the citation, as necessary.
 - b. Provide for defense of appeal of the citation as appropriate.

E. SPECIAL CONSIDERATIONS FOR JC/CMS VISIT

1. Make contact with the Regulatory Compliance Coordinator in Quality Management at 419-383-4848. (Cell phone information is available at each registration desk). Additionally, alternate personal with contact information is located at each registration or entry area of the hospital.
2. Ask Guest Surveyors to remain seated in lobby area to wait for escort.
3. The Quality Department will arrive to perform identity validation, initiate survey, and escort surveyor.

F. EVALUATION AND CRITIQUE OF INSPECTION

1. All findings will be collected by the lead Department involved in the inspection and the Department Director/Manager of area that was inspected and a comprehensive action plan will be developed in response to the inspection.
2. Recommendations will be made by all involved as to where improvements can be made prior to the next inspection.
3. Findings and recommendations from JC/CMS will be the responsibility of the Office of Quality and Patient Safety to document.

Source: Safety & Health Committee

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