

## E-2. Regulatory Agency Inspections and Incident Reporting

### I. Purpose/Scope

This chapter provides guidelines for employee conduct during regulatory agency inspections and for prompt notification in the event of regulatory agency inspections and certain specified environmental and safety incidents at the main NCI-Frederick campus and all off-site locations managed/leased by NCI-Frederick or the OTS Contractor. Application of this procedure is limited to circumstances involving regulatory compliance and interaction with regulatory personnel. Guidance on accident and other reporting is provided in other chapters of the NCI-Frederick Safety and Environmental Compliance Manual.

### II. Definitions

**Hazardous Material** - A substance or material, including a hazardous substance, which has been determined by the U.S. Department of Transportation (DOT) as posing an unreasonable risk to health, safety, and property when transported in commerce (see 49 CFR 173).

**Hazardous Substance** - Any substance designated pursuant to 40 CFR 302 (see CFR 302, table 302.4).

**Hazardous Waste** - A solid, liquid, or gas that is no longer suited for its intended purpose and that is ignitable, corrosive, toxic, reactive, or listed by the U.S. Environmental Protection Agency (EPA) 40 CFR 261. In general, excess or spent hazardous material to be disposed of or recycled is considered hazardous waste.

**Incident** - Any of the following events:

- A. All unpermitted accidental releases to land, air, or water involving a hazardous substance or hazardous waste that occurs at the NCI-Frederick facility, off-site facilities, or concerns NCI-Frederick activities.
- B. All spills, fires, or explosions involving a hazardous substance or which require notification of government regulatory agencies and/or assistance from external emergency responders.

- C. All spills of hazardous materials shipped by NCI-Frederick and off-site facilities.
- D. Receipt of advance notice of a regulatory agency inspection, audit, or similar review.
- E. All regulatory agency inspections, audits, or similar reviews.
- F. Any unplanned or unexpected event that would require notification of a regulatory agency or client (e.g., release or violation of an agreement or permit) or result in a violation of an applicable regulatory requirement.
- G. Any serious deviation or discrepancy of Occupational Safety and Health Agency (OSHA) regulations or NCI-Frederick safety policies or procedures that pose a substantial probability that death or serious physical harm may occur.

Minor Deviation or Discrepancy - A condition existing in the workplace where the worst injury or illness scenario likely to result from the deviation or deficiency cannot be reasonably predicted to indicate death or serious physical harm to exposed employees.

Regulatory Agency - OSHA, EPA, DOT, Nuclear Regulatory Commission (NRC), Food and Drug Administration (FDA), U.S. Drug Enforcement Administration (DEA), Centers for Disease Control and Prevention (CDC), Maryland Department of the Environment (MDE), or Maryland Occupational Safety & Health (MOSH).

### III. Responsibilities

#### A. Employee

Promptly notify your supervisor of any incidents, as defined above.

#### B. Supervisor

Train all appropriate project staff in the definition of an incident and the proper reporting chain.

#### C. EHS

Promptly notify senior management of the NCI-Frederick and the OTS Contractor upon occurrence of any incident defined above.

D. Senior Management, OTS Contractor

1. Immediately notify the NCI-Frederick Contracting Officer of any incident as defined above.
2. Assume primary responsibility, unless specifically delegated in writing, for directing response to any incident defined above, and any potential or alleged violation of environmental or safety laws or regulations. Response will include, but not be limited to, corrective measures, training, disciplinary actions, measures for resumption of work, and correspondence with client and/or regulatory agencies.
3. All correspondence to agencies or clients regarding an incident must be reviewed by the Contracting Officer prior to submittal.

IV. Requirements

- A. Notification must include all pertinent information regarding the inspection or incident, such as date, time, and type of inspection or incident, any written report or summary prepared, and employees involved in or aware of the incident.
- B. For incidents involving releases of a hazardous substance, hazardous waste, or hazardous material, record specific details including:
  1. The amount and type of material spilled or released.
  2. Potential impacts to employees, the public, and/or the environment.
  3. Corrective actions taken.
  4. Names of agencies contacted and details of the information given to the agency.

V. Regulatory Agency Inspection Guidance

- A. The major environmental and safety laws and regulations empower regulatory agencies or their authorized contractors to conduct inspections of regulated facilities and determine the extent of facility compliance. The scope of these inspections may include, at a minimum, review of facility records, walk-through of premises, and interviews with employees.

- B. Because of the agencies' right to conduct inspections, employees must be cooperative and courteous with inspectors. Do not, however, answer questions you do not understand, or for which you do not have an answer based on personal knowledge. Keep in mind that a simple inspection may provide the basis for a subsequent civil or criminal enforcement action.
- C. The following are general guidelines to be followed during an inspection:
1. The Director, EHS or designee is the single point of contact and serves as liaison with inspectors and is responsible for initiating the actions described in Sections V and VI.
  2. Require that inspectors sign in with NCI-Frederick Protective Services. Log entries should include the date and time of the inspector's arrival, the purpose of the visit, the agency represented, and the inspector's telephone number.
  3. If the inspector arrives at the facility with a search warrant, administrative warrant, or subpoena, contact the OTS Contract Administrator and Contracting Officer or Project Officer immediately, prior to conduct of the inspection.
  4. Ask the inspector what is the purpose of and authority for the inspection.
  5. Attempt to restrict the inspector(s) to those areas/records that are applicable to the stated purpose of their inspection.
  6. If the inspector(s) request pictures, approval must be obtained from the NCI-Frederick. If approved, and before the inspectors departure, make a written request for copies of all photographs and for an opportunity to make appropriate business confidentiality claims. Compile a list of all pictures taken.
  7. Split any samples taken of wastewater, solid or hazardous waste, or hazardous materials. Attempt to determine the analysis to be performed by the agency and promptly use an approved laboratory to perform the same analyses. Request in writing, prior to the time that the inspector departs, copies of any chain of custody or sample collection forms completed by the inspector while on the site.

8. Each inspector must be accompanied at all times. Inspectors are never to be allowed unrestricted access to the facility/site. If multiple inspectors are present, ensure that each individual or group is accompanied by an inspection liaison or designated alternate.
9. If questions regarding the reasonableness of this inspection, or unusual requests arise, halt the inspection and contact the NCI-Frederick Contracting Officer.
10. Do not allow inspectors to interview employees without the presence of the employee's supervisor or the inspection liaison. For interviews other than those normally expected for routine site inspections, contact appropriate Public Affairs Officer.
11. Ensure that all privileged, trade secret, or business confidential documents are clearly marked as such prior to examination by inspectors. In general, privileged, secret, and confidential documents should not be reproduced for or by an inspector without obtaining prior clearance for release by the Contracting Officer.
12. Take extensive notes during the inspector's in-brief, close-out brief, and throughout the inspection process.

#### VI. Report of Inspection Results

- A. At the inspection close-out brief, inquire about findings, the significance of findings; request a copy of any notes, photographic data, and laboratory analysis reports.
- B. Prepare a memorandum, detailing the inspection and discussions with the inspector and forward it to the Contracting Officer and Project Officer.

#### VII. Correspondence Regarding Incidents

- A. Senior management, OTS Contractor has primary responsibility for preparing written correspondence relating to:
  1. Any incident, as defined above; or
  2. Any potential or alleged violation of environmental or safety laws and regulations.

- B. All correspondence noted in VII.A above must be reviewed and approved by the OTS Contract Administrator.
- C. All correspondence noted in VII.A above must also be reviewed by the NCI-Frederick Contracting Officer.

#### VIII. Other Incident Reporting

The OTS Contractor is contractually obligated to inform the Contracting Officer of deviations and discrepancies in NCI-Frederick safety rules and regulations. Below are guidelines on how the OTS Contractor addresses the reporting requirements for most plausible incidents.

##### A. Formal Safety Inspections

At the conclusion of a formal safety inspection, whether scheduled or unannounced, EHS will summarize the findings of the inspection into a written report to the applicable Principal Investigator/Program Director. A copy will be provided to the area supervisor for corrective action.

The OTS Contractor will report any serious deviation or discrepancy immediately to the Contracting Officer or Project Officer.

##### B. Informal Safety Inspections

Informal inspections consist of those observations made by EHS staff in the course of their duties that are not intended as inspections (e.g., consultations, waste pickups, worksite visits, etc.) of a minor deviation or discrepancy from safety rules and regulations. EHS will verbally inform the area supervisor of these infractions, and an understanding on the remediation requirements and a time frame will be reached.

##### C. Conditions Immediately Dangerous to Life or Health (IDLH)

When EHS judges that emergency remedial action (including termination of operations and evacuation of a work area) is required, EHS is contractually authorized to execute such action. The NCI-Frederick Contracting Officer and the NCI-Frederick Project Officer will be verbally notified of this action by the Director, EHS or designee as soon as is practicable. Others to be notified include: the applicable Principal Investigator/Program Director and the area supervisor.

D. Fatality or Hospitalization of >2 Employees

In the case of a work-related fatality or the hospitalization of three or more employees due to one incident, the Director, EHS or designee will verbally notify OSHA of such as soon as is practicable but not more than 8 hours after the incident. Others to be notified include: the NCI-Frederick Contracting Officer and the NCI-Frederick Project Officer, the respective Principal Investigator/ Program Director and the area supervisor.

E. Failure to Remediate Hazard

The Director, EHS or designee will notify (and confirm in writing) the NCI-Frederick Contracting Officer of failure of NCI-Frederick employees to adequately and promptly remediate hazards. The Contracting Officer may issue an order stopping all or part of the contractors work until they have taken satisfactory corrective action. Others to be notified include: the applicable Principal Investigator/Program Director and the area supervisor.

F. Disciplinary Action

Failure to comply with NCI-Frederick safety rules and regulations and, particularly, failure to remediate an identified hazard, constitutes misconduct or unacceptable performance. EHS will notify the NCI-Frederick OTS Contracting Officer of specific incidents of safety-related misconduct or unacceptable performance, who will in turn advise the pertinent supervisor to initiate appropriate disciplinary action in consultation with Human Resources. The range of disciplinary action available to a supervisor includes verbal warning, written reprimand, suspension, or termination. Those circumstances, where an employee fails to comply with an established safety procedure may have endangered the life or health of another, generally warrant the more severe disciplinary actions.