

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

SAFETY AND OCCUPATIONAL HEALTH PROGRAMS

ACCIDENT REPORTING AND RECORDS

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1. PURPOSE

This Guide establishes policy, identifies responsibilities, and prescribes procedures concerning investigating and reporting accidents, and associated recordkeeping, involving FDA controlled property or employees of FDA or other individuals when utilized by and in the service of the Agency and the public, including visitors.

2. REFERENCES

HHS and PHS require that the FDA establish and maintain a comprehensive accident and injury investigation and reporting system in accordance with requirements set forth by the HHS and PHS Safety Management Manuals. This Guide establishes those requirements.

3. DEFINITIONS

Definitions utilized in this Guide are contained in FDA's "Procedures For Accident Reporting."

4. POLICY

All accidents involving FDA employees or other individuals when utilized by and in the service of the Agency and the public, including visitors, or FDA controlled property, must be promptly and thoroughly investigated by the involved offices of the Associate Commissioners and Centers and reported as required by this Guide.

5. RESPONSIBILITIES

A. FDA Safety and Occupational Health Manager.

1. Develops, establishes, and monitors the accident analysis and reporting program and associated Safety Management Information System within the Agency.
2. Maintains and reviews accident experience data (statistical information); utilizes such information to determine program effectiveness; and disseminates such information throughout the Agency as appropriate.
3. Advises the Designated Agency Safety and Health Official (Associate Commissioner for Management and Operations) regarding accidents which may, due to either real or potential impact upon FDA activities, require special investigation.
4. Reports serious accidents within eight (8) hours of the occurrence to the Agency's Designated Safety and Health Official (Associate Commissioner for Management and Operations) and shall in turn, promptly notify the Director of Safety, HHS.
5. Notifies immediately following receipt of a notice alleging "Imminent Danger" from an employee, representative of employee~ or any other source, the Safety and Occupational Health Officer of the involved FDA component, the Agency's Designated Safety and Health Official (Associate Commissioner for Management and Operations) and the Director of Safety, HHS, in accordance with Chapter 3-20, the Safety Management Manual, HHS.
6. Provides reports as required by the Office of the Secretary, HHS, by Section 19 of the Occupational Safety and Health Act of 1970, the Congress, General Accounting Office, etc.

B. Associate Commissioners, Center Directors. Associate Commissioners and Center Directors are responsible for establishing within their organizations adequate measures to ensure compliance with the provisions of this Guide. This shall include:

1. the review of accident reports and statistics at a level in the organization which will provide management with that information critical to making decisions and taking action to protect the safety and health of the organization's human resources and to protect its physical assets;

2. assuring that managers, supervisors, and employees are aware of their responsibilities regarding accident reporting, investigation, and corrective action;
 3. coding of information on the "Report Of Accident" (HHS Form 516) for computer input (when such coding is required);
 4. developing a procedure that assures that all recordable cases are posted on a Log of Occupational Injuries and Illnesses at the involved establishment and developing a procedure that assures that the annual summary of occupational injuries and illnesses is posted at each establishment within their organization; and
 5. providing a Quarterly Accident Summary, a copy of the OSHA Log of Occupational Injuries and Illnesses on a quarterly basis, an annual report of safety management activities, and other reports as may be occasionally requested by the FDA Safety Office.
- C. Safety and Occupational Health Officers. Safety and Occupational Health Officers in the Centers, Office of Regulatory Affairs, and the Office of the Associate Commissioner for Management and Operations (acting on behalf of the Office of the Commissioner and other Associate Commissioners except ACRA) shall investigate each accident event, to the extent considered necessary to record the results of such investigations on the appropriate report in accordance with the FDA "Procedures For Accident Reporting" and develop recommendations for corrective action, where practical, for consideration by the involved management.
- D. Supervisors. Supervisors are responsible for ensuring that:
1. all accidents occurring in their areas are reported to their Safety and Occupational Health Officers in order that such Officers may investigate the accident event and complete the appropriate accident reports;
 2. employees are instructed in the procedures to be followed in the event of an accident; and
 3. where possible, corrective action is taken to prevent a recurrence, or when permanent corrective action is beyond the control of the supervisor, the supervisor shall elevate the problem to higher level management for resolution and institute temporary mitigating procedures or other actions which provide interim, reasonable protection for individuals and Agency property.

E. Employees. All FDA employees are responsible for immediately reporting to their supervisors:

1. any accident or injury in which they are involved; and
2. any conditions in their work areas which has a potential to cause injury, or property damage.

6. PROCEDURES

The procedures to be employed in implementing the policy stated in this Guide, and in the fulfilling of these responsibilities included in Section 5 above, are found in FDA's "Procedures For Accident Reporting."