

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

SAFETY AND OCCUPATIONAL HEALTH PROGRAMS

**FDA SAFETY AND OCCUPATIONAL HEALTH MANAGEMENT PROGRAM
Authorities, Policy, Scope, Responsibilities**

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1. PURPOSE

The purpose of this Staff Manual Guide is to set forth the Food and Drug Administration's authority, policy, scope, and assignment of responsibility as pertains to the establishment and management of a comprehensive safety and occupational health program.

2. BACKGROUND

The Food and Drug Administration acts to assure that food, drugs, medical devices, and radiological products are safe and effective for consumption or use by the Nation's population. The Agency's scientific and support personnel perform this critical health service through the examination of product samples, investigation of manufacturing establishments and product distribution channels, conduct of applied research, and a public information and training effort. The FDA responds to public health emergencies involving those foods, drugs, and devices regulated by the Agency.

In addition to conducting Agency business in diverse industrial, institutional, and commercial settings nation-wide, FDA employees perform scientific research and analyses in laboratories at multiple locations throughout the

continental United States, Puerto Rico, and Hawaii. The Agency's employees handle, analyze, manage, and conduct research on a variety of substances and/or devices which present biological, chemical, radiological, and/or physical risks to Agency personnel, and which may present potential health and environmental hazards to the communities in which the Agency's facilities are located.

Safety and occupational health issues related to these activities are both dynamic and complex because of: changing scientific knowledge regarding environmental factors and the effects such factors have on human health and the community environment; changing public and employee perceptions of these relationships; and the high visibility of these topics amongst the various legislative bodies of the U.S. Congress, State, and local governments, labor unions, and public interest groups. The FDA Safety and Occupational Health Program is charged with contributing to the Agency's mission through the provision of a proactive technical and administrative service to plan, coordinate and support Agency compliance actions regarding Federal, State, and local occupational safety and health requirements, pollution control standards, and additional related good-management practices adopted by the Agency.

3. AUTHORITIES

- A. The safety and occupational health program within the Food and Drug Administration is established in accordance with the following references:
 - 1. Executive Order 12196, Occupational Safety and Health Programs for Federal Employees, February 26, 1980.
 - 2. Section 19(a), Public Law 91-596, Williams-Steiger Occupational Safety and Health Act, Federal Agency Safety Programs and Responsibilities.
 - 3. Part 1960 - Basic Program Elements for Federal Employees, OSH Programs and Related Matters, Occupational Safety and Health Administration, Department of Labor, revised 1985, or latest revision.
 - 4. Other references found in Attachment A.

- B. The provisions stated in this Guide do not supplant the HHS Employee Health Program prescribed by Personnel Instruction 792-1. The provisions of that Instruction shall be applied in conjunction with the provisions of this Guide where appropriate.

4. POLICY

It is the policy of the FDA to select operational strategies which accomplish regulatory, research and public information objectives of the Agency and which foster a safe and healthful environment for all employees and for those communities in which the FDA operates.

5. APPLICABILITY AND SCOPE

The FDA Safety and Occupational Health Management Program is applicable to all FDA operations and activities; it is directed toward the prevention of all types of accidents and health hazards present in the performance of official duties.

Included in the scope of applicability are:

1. Employees (civilian and Commissioned Officers) of the FDA or other individuals when utilized by and in the service of the Agency and the public (including patients and visitors).
2. Contractor employees, as provided for contractually.
3. Facilities operations, equipment, material or property owned, leased or used by and under the control of the FDA.
4. Non-government property when incidental to an activity of the FDA or on premises under its control.

6. DEFINITIONS

A. Safety and Occupational Health Management Program - that program which encompasses:

(1) employee safety including environmental control of occupationally related diseases, radiation exposure, chemicals, and/or physical hazards, (2) fire safety, (3) motor vehicle safety, (4) public safety which includes employees of contractors and others working for the Agency on the premises or under the control of the FDA, (5) property damage resulting from accidental occurrences, and (6) control of pollution from activities on premises occupied FDA employees and/or others working for the Agency.

B. Designated Safety and Health Official - the individual who is designated or appointed by the Commissioner, as having responsibility for the management of the safety and occupational health program throughout the Agency. Within the FDA, this is the Associate Commissioner for

Management and Operations.

- C. Other Definitions - definitions of other terms referred to in this guide are found in ATTACHMENT B.

7. RESPONSIBILITIES

- A. The Associate Commissioner for Management and Operations - As the Agency's Designated Safety and Health Official, exercises the authority of the Commissioner, FDA for the safety and occupational health program. The Associate Commissioner has redelegated all necessary authorities for the development and implementation of the FDA program to the Director, Division of Management Services.
- B. Director, Division of Management Services - The Director, Division of Management Services (DMS), has redelegated to the FDA Safety and Occupational Health Manager the responsibility to assure the development and implementation of the FDA safety management program.
- C. FDA Safety and Occupational Health Manager - The FDA Safety and Occupational Health Manager manages the FDA Safety Office and is assigned those responsibilities found in Attachment C.

- D. Staff Offices, Office of the Commissioner, FDA

Heads of staff offices will actively support the Agency's safety and occupational health program within the area of their responsibility and to the full extent of their authority. Further, they shall coordinate actions involving safety and occupational health with the FDA Safety and Occupational Health Manager to assure uniformity of compliance with applicable standards, codes, and procedures throughout the Agency.

- E. Center Directors, Associate Commissioner for Regulator Affairs, Associate Commissioner for Management and Operations.

Center Directors, the Associate Commissioner for Regulatory Affairs (ACRA), and the Associate Commissioner for Management and Operations (acting on behalf of the Office of the Commissioner and other Associate Commissioners except ORA) are responsible for those actions listed below (each responsibility is described more fully in Attachment D):

1. Designating a safety and occupational health officer
2. Establishing a comprehensive safety and occupational health program

3. Supporting the Agency's safety program at the executive level
4. Publishing a policy statement
5. Ensuring compliance with standards
6. Developing a functional statement
7. Issuing procedures/job elements in selected employee performance evaluation plans
8. Maintaining accident prevention objectives
9. Establishing a standards file
10. Making standards available to affected employees
11. Providing training
12. Promoting safety awareness
13. Ensuring receipt of applicable health examinations
14. Establishing procedures for safety review of planned actions
15. Maintaining records!
16. Establishing an accident investigation and reporting system
17. Analyzing accidents
18. Providing leadership in accident prevention
19. Advising management of accident experience
20. Inspecting workplaces
21. Consulting with employees
22. Protecting employees from reprisal
23. Posting employee rights and obligations
24. Providing information to employees

25. Establishing safety and health committees
26. Establishing procedures regarding employee reports of unsafe or unhealthful working conditions
27. Establishing emergency preparedness plans.

F. Supervisors.

1. Complies with all occupational safety and health standards adopted by the FDA.
2. Maintains a continuous alertness for the identification of unsafe or unhealthful conditions in operations for which they are responsible, and to the need for new occupational safety and health standards which are applicable to those activities for which they are responsible; and coordinates all activities related thereto with his/her Safety and Occupational Health Officer.
3. Enforces applicable safety and health standards, pertaining to the activities immediately under their jurisdiction.
4. Instructs and trains employees in safe practices and methods of job performance as such pertains to their assignment.
5. Encourages employee suggestions as they pertain to improving safety and occupational health within their work environment; strives to develop positive attitudes regarding accident prevention.
6. Assures that sick and injured employees performing official duties receive appropriate first aid and/or medical attention.
7. Reports each accident and injury in accordance with established procedures of the Agency.
8. Initiates, to the limit of their authority and capability, such actions as may be appropriate to the correction of unsafe or unhealthful working conditions determined to exist. (9) Promptly advises management when unsafe or unhealthful conditions are determined to exist which are beyond their authority and capability to correct.
10. Conducts regular surveys of their operations to assure compliance with those safety and occupational health standards identified by their Safety and Occupational Health Officer as being applicable to the

establishment concerned.

11. Ensures that employees are aware of their responsibilities under this Guide.

G. Employees.

1. Complies with such safety and occupational health standards issued by the Food and Drug Administration as are applicable to an employee's action and conduct.
2. Develops and maintains a personal safety awareness of such scope as to encompass both self, fellow workers, and (as appropriate) the public served.
3. Maintains a continuous alertness to the early detection of unsafe or unhealthful working conditions; report them promptly to the employee exercising supervisory responsibility or the appropriate Safety and Occupational Health Officer in accordance with procedures as herein established.
4. Immediately advises their supervisor regarding all work related accidents resulting in personal injury, illness, and property damage.

8. GENERAL

- A. Center Directors, the Associate Commissioner for Regulatory Affairs (ACRA), and the Associate Commissioner for Management and Operations (acting on behalf of the Office of the Commissioner and other Associate Commissioners except ACRA) are not relieved from duties imposed upon them as occupants of space provided by the General Services Administration or other Agency; specifically, the development and maintenance of sound occupational safety/health and fire safety programs for such facilities; the conservation of services and supplies; the use of good housekeeping methods; the preservation of a healthful working atmosphere; and participation in a Facility Self-Protection Plan for dealing with occupational safety and health emergencies.
- B. Nothing in this Guide shall serve to modify or negate any provision of an existing Labor-Management Agreement. Any conflicts determined to exist shall be promptly reduced to writing and brought to the attention of the Director, Division of Management Services.
- C. Management officials are reminded that in implementing any facility policy, they must comply fully with the requirements of Executive Order 11491, as

amended concerning consultation and/or negotiation as appropriate.

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AUTHORITIES

The safety and occupational health program within the Food and Drug Administration is established in accordance with the following references:

1. Executive Order 12196, Occupational Safety and Health Programs for Federal Employees, February 26, 1980.
2. Section 19(a), Public Law 91-596, Williams-Steiger Occupational Safety and Health Act, Federal Agency Safety Programs and Responsibilities.
3. Part 1960 - Basic Program Elements for Federal Employees, OSH Programs and Related Matters, Occupational Safety and Health Administration, Department of Labor, revised 1985, or latest revision.
4. Recordkeeping and Reporting Guidelines For Federal Agencies, Occupational Safety and Health Administration, Department of Labor, revised 1986, or latest edition.
5. 29 CFR, Part 1910, General Industry OSHA Safety and Health Standards, Occupational Safety and Health Administration, Department of Labor, OSHA 2206, Revised 19136, or latest edition.
6. Section 7902, Title 5, United States Code.
7. Department of Health and Human Services Safety Management Manual.
8. Employee Occupational Safety and Health Policy, Department of Health and Human Services, August 8, 1986.
9. Chapter PHS: 2-00 Authorities, Policy, Scope and Responsibilities, PHS TN 76-1 (5/12/76), Safety Management.
10. Executive Order 12088, Federal Compliance with Pollution control Standards, October 23, 1978.
11. Chapter PHS:hf:3-400 Environmental Management: Pollution Control in PHS Facilities, October 14, 1980, Facilities Engineering and Construction Manual.
12. Environmental Auditing Policy Statement, U.S. Environmental Protection Agency, November 8, 1985, 50 FR 46504.
13. Title 10, Code of Federal Regulations, Part 19, Notices, Instructions, and Reports to Workers; Inspections.

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14. Radiation Protection Guidance to Federal Agencies for Occupational Exposure, U. S. Environmental Protection Agency, January 27, 1987, 52 FR 2822.
15. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.
16. FDA Radiation Safety Handbook for Ionizing and Nonionizing Radiation, HEW Publication (FDA) 77-8007, October 1976, or latest edition.
17. Federal Property Management Regulations, Subpart 101-20.5.
18. FDA Staff Manual Guides in the 2130 series.

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DEFINITIONS

1. **Establishment** - a single physical location owned, leased, or regularly occupied by the Agency where FDA business is conducted or where services or operations are performed.
2. **Safety and Health Specialist** - a person or persons meeting the Civil Service Standards for Safety Manager/Specialist, GS-018; Safety Engineer, GS-803; Fire Prevention Engineer, GS-804; Industrial Hygienist, GS-690; Fire Protection and Prevention Specialist, GS-081; Health Physicist, GS-1306, or equally qualified Commissioned Corps personnel.
3. **Safety and Occupational Health Manager** - the safety and health specialist responsible for managing the FDA safety and occupational health program. Within the FDA this is the FDA Safety and Occupational Health Manager, Division of Management Services, Office of Management and Operations.
4. **Safety and Occupational Health Officer** - that individual appointed by a Center Director, the Associate Commissioner for Regulatory Affairs (ACRA) or the Associate Commissioner for Management and Operations (acting on behalf of all Offices of the Commissioner's program offices except ACRA) to be responsible, on a full-time basis, for developing, implementing, and maintaining an effective and comprehensive safety and occupational health program in their respective program offices, district office operations, and Centers. This individual shall meet the requirement of a "Safety and Health Specialist" as defined in this section.
5. **Collateral Duty Safety Officer** - an employee appointed by Center Directors, the Associate Commissioner for Regulatory Affairs or other Associate Commissioners to discharge, on a part-time basis, the responsibilities of a safety management program for their respective organization. Such appointments to be made only where that Director or Associate Commissioner deems that safety management obligations of the Center/Program Office can be effectively met without the services of a full-time Safety and Occupational Health Officer. Personnel assigned as part-time safety officers shall be an official who is at such a management level in the organization that they exercise considerable influence over the operations and activities of the installation. Collateral duty safety officers shall minimally be provided that training required by paragraph 1960.58 of the Basic Program Elements for Federal Employee OSH Programs and Related Matters, OSHA, Department of Labor.
6. **Safety and Occupational Health Committee** - that group of qualified individuals appointed by a Center Director, Associate Commissioner, or

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Regional and District Directors to assist management in carrying out its safety and occupational health responsibility.

- 7. Radiation Safety Coordinator** - that person assigned by the Director, Center for Devices and Radiological Health to administer the FDA Radiation Safety Program as described in the FDA Radiation Safety Handbook for Ionizing and Non-ionizing Radiation.
- 8. Radiation Safety Council** - that group of highly qualified individuals, appointed by Center Directors and the Associate Commissioner of Regulatory Affairs, to provide policy, direction and guidance to the FDA Radiation Safety Program. Membership shall include a physician with expertise in the biological effects of ionizing and non-ionizing radiation.
- 9. Radiation Safety Committee** - that group of individuals appointed by the Director of those FDA Centers, district laboratories, and other FDA facilities where radioactive materials and/or radiation-producing equipment are used, stored, or analyzed that require specific license of broad scope for by-product material. These committees shall have jurisdiction over radiation sources and activities in their respective locations. Responsibilities and duties of these Committees are described in the FDA Radiation Safety Handbook for Ionizing and Non-Ionizing Radiation.
- 10. Radiation Safety Officer** - that qualified individual appointed by the laboratory director to be responsible for the safe use of all ionizing and non-ionizing radiation sources within the laboratory. This individual derives his/her authority from the Radiation Safety Committee and shall be the committee's authorized representative regarding measures concerning radiation protection within the confines of that facility.
- 11. Safety Management** - the management of safety and occupational health resources in such manner as to effectively administer a total safety and occupational health program encompassing all elements of accident prevention, risk analysis, fire safety, system safety, and occupational and community environmental hazard control.
- 12. Imminent Danger** - conditions or practices in any place of employment which can reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through normal abatement procedures.
- 13. Field Federal Safety And Health Councils** - those organizations established by the Secretary of Labor in various geographical locations to facilitate the exchange of ideas and information throughout the Government about occupational safety and health.

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- 14. Agency Safety and Occupational Health Council** - that group of FDA safety and occupational health officers/managers which meet to review the Agency safety and occupational health program, and to provide the FDA Designated Safety And Health Official (ACMO) with advice of an administrative and technical nature regarding recommended actions on new safety and occupational health issues and challenges of interest to the FDA.
- 15. Standards** - those safety and occupational health standards developed by the agencies of the Federal Government, including those established under Section 6 of the Occupational Safety and Health Act of 1970, pollution control regulations promulgated by State and local governments and authorities, and nationally recognized consensus standards and code producing bodies.

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RESPONSIBILITIES OF THE FDA SAFETY AND OCCUPATIONAL HEALTH MANAGER

FDA Safety and Occupational Health Manager - The FDA Safety and Occupational Health Manager manages the FDA Safety Office and is assigned those responsibilities listed below:

1. Serves as principal advisor to the FDA in all matters pertaining to safety and occupational health management; and is responsible for overall program management agency-wide.
2. Recommends, through the Director, Division of Management Services, to the Associate Commissioner for Management and Operations, FDA those resources (funds, safety and occupational health staff, equipment, material), training and management initiatives required to ensure an effective safety and occupational health program throughout the Agency.
3. Provides executive leadership in the development, promulgation, and implementation of safety and occupational health policies, standards, and procedures. Coordinates such activities with the Public Health Service, staff offices, Office of the Secretary, and others (as appropriate) for effective management of the overall safety program.
4. Prepares and coordinates the Agency's position on proposed legislation and regulations pertaining to safety, industrial hygiene, pollution control engineering, fire prevention, occupational and community environmental hazards control, safety and occupational health education, training, and promotion. Coordinates and monitors research for the development of innovative accident and occupational injury and illness prevention methods and concepts.
5. Provides technical safety and occupational health support and assistance to the FDA Centers and field activities.
6. Evaluates safety and occupational health programs throughout the Agency and performs such workplace inspections as are considered appropriate to making a determination regarding the effectiveness therefor. Conducts and/or assists in the conduct of investigations as such requirement develops.
7. Represents the Agency on the Field Federal Safety and Health Council and provides official Agency representation to the Department of Labor, General Services Administration, the Environmental Protection Agency, and other Federal Agencies on safety and occupational health management issues.

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8. Provides Agency liaison and representation with the National Fire Protection Association, National Safety Council, American Society of Safety Engineers, American Conference of Governmental Industrial Hygienists, and other governmental and professional organizations on matters pertaining to safety and occupational health management.
9. Organizes and participates in an Agency Safety and Occupational Health Council comprised of the primary Safety and Occupational Health Officers of the Offices of the Associate Commissioners and the Centers. Such Council shall meet at least once each year and other times as necessary to address special needs of the Agency. The Council shall review the Agency program and special topics of significance to the FDA. The Council shall provide advice to the FDA Designated Safety and Health Official of an administrative and technical nature regarding action on new safety and occupational health issues and challenges of interest to the FDA.
10. Administers an accident analysis and reporting program and associated Safety Management Information System encompassing the entire Agency.

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RESPONSIBILITIES OF CENTERS DIRECTORS, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, ASSOCIATE COMMISSIONER FOR MANAGEMENT AND OPERATIONS

This section contains more detailed description of those responsibilities outlined in paragraph 7.E.

1. Designates a Safety and Occupational Health Officer and provide such officers with adequate staff, funds, training and equipment to effectively administer the respective Center's/Office's safety and occupational health programs.
 - a. Immediate Office of the Commissioner, Offices of the Associate Commissioners for Health Affairs, Public Affairs, Management and Operations, Planning and Evaluation, Legislative Affairs, Consumer Affairs. The Associate Commissioner for Management and Operations (ACMO) shall have responsibility for coordinating and providing safety support staff for the safety and occupational health programs of these offices, and shall appoint a Safety and Occupational Health Officer to carry-out this role. This individual may be a Collateral Duty Safety Officer (CDSO) meeting the standards for a CDSO as described in Attachment B of this Guide. The Office of the Commissioner and the Offices of the Associate Commissioner shall each identify a Collateral Duty Safety Officer, who shall meet the standards described in paragraph 5 of Attachment B, and who shall cooperate with the Safety Officer appointed by the ACMO to coordinate the safety programs for these offices.
 - b. Centers. A primary Safety and Occupational Health Officer shall be appointed for each Center. Individuals appointed as primary Safety and Occupational Health Officers by the Centers shall meet the Civil Service standards set forth in Attachment B of this Guide for a "Safety and Occupational Health Officer." Exceptions to meeting these criteria will be considered in those circumstances in which the involved Center receives concurrence from the Agency's Designated Safety and Health Official (Associate Commissioner for Management and Operations) based on information which clearly demonstrates that an equally effective alternate is acceptable. Additional officers shall be appointed for each Center establishment and shall meet either the requirements for a "Safety and Occupational Health Officer" or "Collateral Duty Safety Officer" as found in Attachment B of this Guide.
 - c. Office of the Associate Commissioner For Regulatory Affairs. The primary Safety and Occupational Health Officer appointed by the Associate Commissioner shall meet the criteria for a "Safety and

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Occupational Health Officer" as defined in Attachment B of this guide.

Individuals shall be designated as "Safety Officers" in each District Office and shall meet either the criteria defined for "Safety and Occupational Health Officers" or "Collateral Duty Safety Officers" as defined in Attachment B of this Guide.

2. For each establishment occupied by personnel under their control, establishes and maintains a comprehensive safety and occupational health program in accordance with the requirements set forth in the authoritative references found in this Guide, other Guides published in the 2130 series of the FDA Staff Manual Guide, or other guidance as may be issued by the FDA Safety Office. Such a comprehensive program shall be described in writing for each establishment occupied by the organization and shall describe the implementation of each responsibility contained in this Section.
3. Actively supports the Agency's safety and occupational health program within the area of their responsibility and to the full extent of their authority.
4. Publishes a concise safety and occupational health policy statement; such statement to be consistent with Agency policy and targeted toward providing employees a place of employment which is free of unsafe or unhealthful working conditions.
5. Ensures compliance with safety, fire, pollution control, radiation protection, and occupational health and emergency response standards of the Agency and take prompt corrective action as deficiencies are determined to exist.
6. Develops an approved functional statement which includes consideration of the responsibilities of the safety and occupational health program and the associated Safety and Occupational Health Officer, or Collateral Duty Safety Officer, as appropriate, appointed to manage the safety and occupational health program.
7. Issues such operating procedures, directives, etc., as are appropriate to effective program management. This shall include the provision of a job element in employee performance evaluation plans for full and collateral duty safety officers and for those selected other managers, supervisors and employees who's responsibilities clearly identify the individual as being in a position which critically impacts on the ability of the involved Center or Office to meet the Agency's safety and occupational health obligations and goals.

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8. Maintains goals and objectives for the reduction and elimination of occupational accidents, injuries, and illnesses and pollution incidents; develop specific plans aimed at the attainment thereof.
9. Establishes a master file of those safety and occupational health standards adopted by the Agency, identifies those which are applicable to the various workplaces, and assigns to an individual the responsibility to establish and maintain such a file.
10. Ensures that applicable standards are either distributed or are readily available to those line and staff personnel responsible for their conformance, implementation and enforcement.
11. Provides training, for Safety and Occupational Health Officers, safety staff, and employees, designed to address specific safety and occupational health issues peculiar to the individual establishment and educate personnel in the area of accident prevention and hazard awareness/avoidance.
12. Promotes safety awareness by supporting the involvement of appropriate personnel in the activities of the local Field Federal Safety and Health Council, through the use of safety posters, distribution of information, and participation in local safety and health councils and professional societies.
13. Ensures that employees receive physical examinations in accordance with the safety and occupational health standards applicable to the work performed. In the event the applicable standards do not specify the frequency of examination, the Safety Officer concerned shall promptly establish such frequency following appropriate consultation with the Director of her/his Center/Office, competent medical authority and notification of the affected employees.
14. Establishes procedures which assure that research, administrative and engineering actions, that have a significant potential for impacting on occupational and community safety and health, are identified and coordinated with the organization's safety and occupational health officer/manager. Consideration should include planned research projects, analytical methodologies, renovation and new construction plans, and space reassignment.
15. Develops and maintains such management techniques and records as are required to reflect both the scope and effectiveness of the safety and occupational health program.
16. Implements a comprehensive accident and injury investigation and

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reporting system, and a pollution incident investigation and reporting system, in accordance with the requirements set forth by the FDA Safety Office.

17. Maintains a continuous analysis of occupational accidents, injuries, and illnesses and pollution incidents; and based thereon, place priority emphasis on those areas requiring preventive or corrective measures.
18. Provides continuous leadership in the prevention of injuries or illnesses to employees and the public, damage to equipment and facilities, or pollution of the community environment, by encouraging safe and healthful practices, which either eliminate or significantly reduce the risk.
19. Establishes and maintains a procedure whereby top management is regularly advised regarding accident and injury trends, to include preventive actions being taken, and events occurring at the establishment relating to actual or alleged violations of pollution standards.
20. Inspects all workplaces, including offices, at least annually in accordance with guidance established by the FDA Safety Office.
21. Provides for consultation with employees and/or consultation or appropriate negotiation with the recognized representatives of employees in the implementation and operation of the safety and occupational health program.
22. Ensures that no employee is subjected to restraint, interference, coercion, discrimination or reprisal by virtue of such employee's participation in the Agency occupational safety and health program; such participation to include the filing of a report of an unsafe or unhealthful working condition, the initiation of any proceeding under or related to the program, by comment or testimony in such proceedings or the exercise by such employees, of any other right offered by Section 19 of the Occupational Safety and Health Act and Executive Order 12196. Written procedures shall be developed which incorporate the following provisions:
 - a. Policy statement stating that the taking of reprisal action against an employee for identifying unsafe or unhealthful working conditions or for other involvement in the safety and health program is not to be condoned.
 - b. Investigation of reprisal complaints by an official with the necessary ability and authority to conduct an effective inquiry within appropriate time frames and to recommend redress if warranted.

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- c. The right of appeal to the agency head or an appropriate deputy if the employee is dissatisfied with the initial denial of the reprisal complaint.
 - d. A means of informing the appropriate agency safety and health office of allegations of reprisal and their disposition if these officials are not involved in the investigation or adjudication.
 - e. Inclusion of criteria in the agency's self evaluation program which will provide information regarding the effectiveness of the reprisal program.
23. Posts and keep posted a notice or notices informing employees regarding the protections and obligations provided for in the Occupational Safety and Health Act and Executive Order 12196.
- a. Notices shall be posted in each establishment in a conspicuous place or places where notices to employees are customarily posted; they shall not be altered, defaced, or covered by other material and shall be kept up to date. All notices so posted shall be readily recognizable and in such form as to be highly visible.
 - b. The FDA Safety and Occupational Health Manager will provide a uniform poster to Offices of the Associate Commissioners and the various FDA Centers. All recipients will ensure that the following items, along with such others as are determined to be required, are included in such notices; specifically:
 - (1) Details regarding those requirements as delineated in Section 1960.31. Basic Program Elements for Federal Employees OSH Programs and Related Matters, U.S. Department of Labor.
 - (2) The location where employees will be able to obtain information regarding the safety and occupational health program to include specific applicable standards and relevant information regarding any established safety and occupational health committee.
 - (3) The location of procedures governing the submission of reports alleging unsafe and/or unhealthful working conditions.
 - (4) The right of an employee/representative of employees to appeal the final decision of the Designated Safety and Health Official to the Office of Federal Agency Safety Programs, U. S. Department of Labor (Information copy to the Designated Safety and Health Official) to include the location to the procedure pertaining thereto.
24. Makes copies of the Act, Executive Order, "Part 1960-Basic Program

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- Elements for Federal Employee OSH Programs and Related Matters," Department of Labor and details of the safety and occupational health program to include applicable safety and occupational health standards or summaries of any of the foregoing items, available to employees or recognized representatives of employees upon their request, in order that they may review such material in the establishment where they are employed. Subsequent to receipt of such request the material requested will be made available at the earliest practicable date mutually acceptable to both parties.
25. Establishes safety and occupational health committees to assist management in carrying out its safety and occupational health responsibilities and keep the committee informed regarding safety and occupational health matters within its area of concern.
- a. Each establishment having an assigned personnel strength of fifty (50) or more employees shall establish a safety and occupational health committee. When an establishment has an employee population less than 50, it shall be represented by a committee established at the next higher management level. The composition of the committee shall consist of management and recognized representatives of employees.
 - b. At least two meetings shall be convened annually and in the event only two meetings are held within a calendar year one meeting shall not follow the other at an interval of less than four (4) calendar months. Committee meetings shall be documented.
 - c. Committee organization, duties and related matters shall be consistent with the requirements of the HHS Safety Management Manual.
26. Establishes a procedure and assures that all employees and recognized representatives of employees are advised regarding their rights and procedures as they pertain to a safety or occupational health hazard that they believe exists in the workplace wherein they are employed. The employee may request that an inspection of his workplace be conducted by giving notice of the alleged unsafe or unhealthful condition directly to his/her immediate supervisor, to the appointed Safety Officer for their organization, to the FDA Safety and Occupational Health Manager, the PHS Safety Officer, or Office of the Secretary, DHEW.
- a. Notices submitted to Safety and Occupational Health Officers/Managers or the Office of the Secretary, HHS, or their designees must be in writing over the signature of the employee or representative of employees initiating the notice and must set forth with reasonable particularity the grounds therefor. Nothing as herein stated

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shall be interpreted as negating the provisions of Section 1960.28, Part 1960 - Basic Program Elements for Federal Employees OSH Programs and Related Matters.

- b. In the event the individual(s) initiating a notice consider that the unsafe or unsafe or unhealthful condition(s) observed present an "Imminent Danger" situation (see Section 6, Definitions), the following actions will be promptly taken: (a) inform the official in charge of the establishment wherein the unsafe or unhealthful working condition(s) exist; (b) the official receiving such notice shall undertake expeditious corrective measures where appropriate and feasible and shall notify the Safety and Occupational Health Manager of the Agency.
- c. Any employee or representative of employees may, at their sole discretion, request that their name and the names of individual employees referred to in a notice not be disclosed to anyone other than the addressee(s) and authorized representatives of the Secretary of Labor. Except as herein provided such request shall be honored.
- d. In the event the individual conducting the inspection requested is unable to locate the alleged unsafe or unhealthful working condition without the assistance of the individual submitting the notice, the Safety and Occupational Health Manager involved may provide the inspector with the name of the individual submitting the notice; his request for anonymity notwithstanding. This action will only be taken after the Safety and Occupational Health Manager involved has satisfied himself that the name of the person submitting the notice and the name of individual employee(s) referred to therein will not be disclosed to anyone else.
- e. Employees or representatives of employees initiating and submitting notices alleging unsafe or unhealthful working conditions to Safety & Occupational Health Officers or Safety and Occupational Health Managers will receive written responses thereto at the earliest practicable date following the completion of the action thereon. In those instances where a notice of an unsafe or unhealthful working condition is posted as a result of a report filed by an employee or representative of employees, a copy of the notice will be provided the individual submitting such report.
 - (1) Employees or representatives of employees receiving responses from a Safety & Occupational Health Officer or a Safety and Occupational Health Manager indicating there are no reasonable grounds to believe an unsafe or unhealthful working condition exists may return the case to the Safety & Occupational Health

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Officer or Safety and Occupational Health Manager concerned; such resubmission to include the comments of the individual making the initial allegation and any additional information which may assist the officer/manager concerned in again reviewing the initial FDA decision.

(2) Safety Officers and Safety and Occupational Health Managers receiving such rebuttals will act promptly thereon and respond to the individual alleging unsafe or unhealthful working conditions; such responses shall be in writing and will advise the employee or representative of employees involved that, in the event they are dissatisfied with the decision of the involved Safety Officer or Safety and Occupational Health Manager, they may submit the complete report together with appropriate comments to the FDA Designated Safety and Health Official for review and final FDA decision.

- f. Employees or their representative who are dissatisfied with the final disposition by the Agency may forward their report and a summary of subsequent Agency action and/or their objections to the Agency's remedy to the Office of Federal Agency Safety Programs, U.S. Department of Labor. A copy of the Report should be sent to the FDA Safety and Occupational Health Manager (HFA-205).
 - g. Copies of notices, pertaining to alleged unsafe or unhealthful working conditions, shall be filed and maintained intact by all concerned for a period of five (5) years following the date of the last action thereon.
27. Develops and implements an emergency preparedness plan for each establishment occupied by FDA personnel. Such plans shall include procedures for response to those emergencies peculiar to each establishment which could result in injury to persons, damage to property or environmental pollution of the community environment. Such emergencies as fire, medical, bomb threat, utility failure, chemical spill, biological release, radiation exposure should be included as appropriate. The plan should include a description of the involved emergency response organization (including responsible parties), methods of communicating the existence of the emergency event, means for acquiring the services of emergency response personnel and necessary equipment, procedures and schedules for conducting drills designed to exercise the plan, and procedures for documenting the drills and management actions to modify and maintain the plan to assure that it is current. Drills shall be conducted at least once per year.