

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

SAFETY AND OCCUPATIONAL HEALTH PROGRAMS

SAFETY AND OCCUPATIONAL HEALTH STANDARDS

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1. PURPOSE

This Chapter provides for the adoption, development, and implementation of safety and occupational health standards for use throughout the Food and Drug Administration. Such standards include safety of employees, fire protection, pollution control and radiation protection.

2. REFERENCE

Executive Order 12196, February 26, 1980, requires the Head of each Federal department and agency to establish an occupational safety and health program in compliance with the requirements of Section 7902 of Title 5 of the United States Code and Section 19(a) of the Occupational Safety and Health Act of 1970. The Act and Executive Order require that such programs be consistent with the standards prescribed by Section 6 of the Safety Act, and that the Agency Head furnish to employees places and conditions of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm. The HHS Safety Management Manual conveys these responsibilities to the head of each component of the Department. The PHS further delegated this responsibility to the Head of each PHS Agency (reference Authorities, Policy, Scope and Responsibilities, Chapter PHS:2-00).

Additionally, Executive Order 12088, October 13, 1978, states that each Agency Head is responsible for ensuring that all necessary actions are taken for the prevention, control, and abatement of environmental pollution with respect to Federal facilities and activities under control of the Agency. Each Agency Head is responsible for compliance with applicable pollution control standards (i.e., "the same substantive, procedural, and other requirements that would apply to a private person,"). These responsibilities have been

subsequently conveyed to the Head of each PHS agency through the provisions of PHS Chapter hf:3-400 Environmental Management: Pollution Control in PHS Facilities, dated October 14, 1980, Facilities Engineering and Construction Manual.

The Nuclear Regulatory Commission (NRC) requires that specific procedures be followed for persons who receive, possess, use, or transfer material licensed by the Commission and that certain standards for protection against radiation hazards arising out of activities under licenses issued by the NRC be complied with. Further, the FDA has established a radiation safety policy and administrative direction on the use of ionizing and non-ionizing radiation in FDA workplaces. The Radiation Safety Handbook for Ionizing and Non-ionizing Radiation, FDA publication 76-8007, dated October 1976, contains Agency policy and procedures regarding radiation safety.

3. POLICY

Safety and Occupational Health standards will be used throughout the FDA as a basis for the conduct of field investigations, laboratory analyses, research and related support activities; design, construction, alteration, renovation and operation of facilities; for the leasing and/or utilization of facilities; for the purchase of equipment and supplies; for the purchase of contractual services; for environmental and procedural criteria to insure a safe and healthful working environment; and to provide for the protection of the public.

4. RESPONSIBILITIES

A. FDA Safety Office, Division of Management Services

The FDA Safety Office is responsibility for:

- *1. Establishing and adopting safety and occupational safety and health standards for use throughout the Food and Drug Administration.
- *2. Providing guidance on the use and interpretation of standards.
- *3. Coordinating the development of specific standards for use Agency-wide.
- *4. Coordinating the promulgation and implementation of applicable safety, fire and health standards.
- *5. Reviewing and approving variances or deviations from the basic intent of applicable standards.

- *6. Serving as contact point, approval point, and coordinator on all interagency and interoffice matters concerning occupational safety and health standards affecting employees and the public being served.
7. Conducting, coordinating, or arranging for the evaluation of compliance with the provisions of this Staff Manual Guide, through the FDA On-Site Management Review process or other procedures developed by the Agency.
8. On behalf of the Associate Commissioner for Operations and Management, conducting periodic reviews of the FDA Radiation Safety Program in regard to responsibilities delegated to CDRH as identified in the FDA Radiation Safety Handbook.

* with the exception of the FDA Radiation Safety Program - see section B. below.

B. Center for Devices and Radiological Health (CDRH)

The CDRH is responsible for:

1. Providing policy, direction, guidance and administration of the FDA Radiation Program in accordance with the Radiation Safety Handbook for Ionizing and Non-ionizing Radiation, HEW Publication (FDA) 77-8007, and for maintaining the Handbook current with changing regulations and the acquisition of additional knowledge regarding radiation hazards.
2. Providing cooperation and assistance to the FDA Safety Office in performing evaluations of agency activities in regard to paragraph 4.A.7. above.

C. Centers, Office of Regulatory Affairs, Offices of Associate Commissioners

The heads of Centers, the Office of Regulatory Affairs and the Offices of the Associate Commissioners are responsible for:

1. Complying with the provisions of this Staff Manual Guide in the use of designated safety, fire protection, pollution control, radiation protection, and occupational health standards.
2. Developing standards covering specific conditions or situations peculiar to a given operation not covered in existing codes or standards and, where appropriate, forwarding such standards to the FDA Safety Office for possible Department-wide adoption.

3. Requesting in writing deviations or variances from the basic intent of applicable standards when such standards cannot be met. Such requests should contain that information necessary to understand and evaluate the requested variance, and should be forwarded to the FDA Safety Office for action.
4. Assisting the FDA Safety Office in developing Agency standards for use throughout the FDA. Such assistance shall include the providing of specialized staff support in those disciplines necessary to the development of a specific standard or procedure.
5. Maintaining a current master file of those safety and health standards recognized and adopted by the FDA, and making the references available to those line and staff personnel responsible for their implementation, enforcement or conformance.
6. Providing training to Center/Program Office personnel for the purpose of developing and maintaining a familiarity with applicable safety and occupational health standards.

5. STANDARDS AND CODES

- A. Safety and Occupational health standards developed by 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 standards will be used throughout the FDA as applicable and shall be considered as minimum requirements in accordance with Section 3 Policy.

The following Federal Government agencies and nationally recognized professional organizations develop such standards and codes:

1. U.S. Department of Health and Human Services
2. U.S. Department of Labor
3. U.S. Department of Transportation
4. U.S. Department of Energy
5. Nuclear Regulatory Commission
6. National Bureau of Standards

7. General Services Administration
 8. American National Standards Institute
 9. The National Fire Protection Association
 10. The American Society for Testing and Materials
 11. The American Society of Mechanical Engineers
 12. International Conference of Building Officials
 13. American Insurance Association
 14. Environmental Protection Agency
 15. State and Local Pollution Control Agencies
 16. The Manufacturing Chemists Association
 17. American Conference of Governmental Industrial Hygienists
 18. National Sanitation Foundation
 19. National Council on Radiation Protection and Measurements
- B. With the exception of pollution control regulations, Government owned facilities and operations are not subject to State and local codes and ordinances. However, such codes and ordinances shall be investigated for use or application in the design of structures and facilities and for procedural control. In these cases, when State or local codes exceed the minimum requirements contained in the standards and codes developed by organizations such as those listed in "5.A." above, they will normally be followed after determination has been made that the best interest of the Government will be served.