

**FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION**

**SAFETY AND OCCUPATIONAL HEALTH PROGRAMS**

**FDA ON-SITE MANAGEMENT REVIEW SAFETY PROGRAM EVALUATION**

Transmittal Number 88-90 -- Date: 07/11/1988

1. Purpose
2. Background
3. Policy
4. Responsibilities

**1. PURPOSE**

To establish policy and to identify responsibilities for the conduct of the Safety Evaluation portion of the FDA On-Site Management Review Program.

**2. BACKGROUND**

The Division of Ethics and Program Integrity, Office of Management and Operations, is responsible for conducting and scheduling the FDA On-Site Management Review Program. The program includes consideration of the Agency's safety policy and seeks to determine the status of safety and occupational health conditions at Agency establishments in light of that policy. The FDA Safety Office has a responsibility to evaluate the safety and occupational health programs of the Offices of the Commissioner and Associate Commissioners and Centers, and advise FDA's Designated Safety and Health Official (Associate Commissioner for Management and Operations) of the status of these programs. The On-Site Management Review Program provides one method for conducting evaluations of Agency safety and health activities.

**3. POLICY**

It is the policy of the FDA Safety Office to cooperate with the Division of Ethics and Program Integrity and to provide qualified individuals to conduct the Safety Evaluation portion of the FDA On-Site Management Review.

**4. RESPONSIBILITIES**

- A. Division of Ethics and Program Integrity. This office is responsible for organizing and managing the FDA On-Site Management Review Program. This includes the establishment of the "Review Schedule" and the

provisions of funds for travel, per diem and other costs related to the conduct of the Review.

B. FDA Safety Office. This Office is responsible for the management of the Safety portion of the FDA On-Site Management Review Program. The FDA Safety Office shall:

1. Follow the overall On-Site Management Review Program guidelines established by the Division of Ethics and Program Integrity, OMO, when planning for and conducting On-Site Reviews.
2. Maintain the Safety Checklist to be used in the conduct of the Review; such list to be maintained current in regard to newly identified requirements for occupational safety and health and pollution control, and updated at least annually.
3. Conduct and arrange for qualified personnel to conduct the Safety Evaluation, provide that information required by the Division of Ethics and Program Integrity to document the findings of the review, and make associated recommendations for needed improvements.
4. Provide training workshops for Safety Team members for the purpose of preparing members for the conduct of On-Site Reviews.

C. Safety Team Members. Team members are responsible to prepare for, conduct, and document the safety portion of the On-Site Management Review Program. Personnel conducting the Safety Evaluation portion of the On-Site shall:

1. Utilize the current Safety Checklist and any special instruction received from the FDA Safety Office for the purpose of performing an On-Site Review. Copies of field notes, checklists, findings, and recommendations should be forwarded to the FDA Safety Office at the time the On-Site Review is completed.
2. Work under the direction of the team leader appointed by the Division of Ethics and Program Integrity.
3. In advance of the On-Site Review, contact the responsible safety and occupational health officer for the establishment to be reviewed. Identify their part in the up-coming review, indicate what documents, files, and records should be available during the review, or which of these documents, files, and records, if any, should be forwarded to the Safety Team Member prior to the Review, acquire necessary background information regarding the establishment, and answer any

questions which the responsible safety officer has concerning the Review.

4. Attend any training workshop arranged for Team Members in preparation of the On-Site Review.