
GENERAL REVIEW AND ENFORCEMENT POLICIES

PREPARATION OF COMPLIANCE PROGRAMS, ASSIGNMENTS AND
OTHER FIELD GUIDELINES

Compliance programs, Assignments, Bulletins, Field Alerts and Memo's are formally written program plans and instructions which direct and specify the work that is to be done by the Food and Drug Administration's (FDA) field personnel. Compliance programs provide specific guidance to ensure a uniform approach for regulatory/administrative action; to accumulate data (monitoring) on a known problem to determine long-range trends on a statistically valid basis; and to gather product or industry information (make surveys) within a specific time frame to determine the existence or extent of a problem. Assignments, Bulletins, Field Alerts and Memo's are directed to the field to amend or supplement existing compliance programs, and to provide special program instructions in a problem area for which no compliance program exists and for which one is not deemed necessary or appropriate.

1. Purpose:

This document defines and assigns responsibilities for the development, clearance, issuance, and evaluation of compliance programs, assignments, bulletins, field alerts and memo's (hereafter referred to as: other field guidelines).

2. FDA Policy:

FDA policy requires that each Center provide definitive guidance to the field organization (ORA) through compliance programs and other field guidelines for utilizing the resources allocated to it.

3. Responsibility for Program Development:

New and revised compliance programs and other field guidelines must be developed in adherence to the schedule agreed upon by CVM Center Management. This schedule requires that all programs are to be fully approved and available for implementation by the field before the start of each new fiscal year or in accordance with their scheduled start-up date. Responsibility for development of the programs, assignments, bulletins, field alerts and memo's are as follows:

Program Manager

Program managers are responsible for assuring that compliance programs, assignments, bulletins, field alerts and memo's are developed and resources are allocated for field activities associated with their respective projects. Specific responsibilities include:

- (1) Specifying, in coordination with managers, compliance program, assignments, bulletins, field alerts, memo's and resource requirements. This is done during the field work planning cycle, approximately eight months in advance of the beginning of each fiscal year.
- (2) Identifying, through the center program managers staffs, the CVM Field Committee, and ORA offices such as DPEM, DFS, DFI, DFSR and DIOP, current program needs that can be dealt with by the field organization.
- (3) Ensuring that adequate administrative guidelines exist for situations likely to arise in the course of implementation of the program. This may require development and issuance of new administrative guidelines in collaboration with the Office Director for Surveillance and Compliance.
- (4) Maintaining constant awareness of compliance program progress and difficulties being encountered, and ensuring that compliance program revisions are drafted and communicated to the Division of Compliance (HFV-230) when necessary.
- (5) Identifying and disseminating, in conjunction with HFV-230, information developed through compliance programs and the other field guidelines to the appropriate organizational elements (headquarters and field) which have need for it or an interest in it.
- (6) Each compliance program should be evaluated, at a minimum, every 3 years. Specific Assignments (i.e., milk residue) receive an evaluation at the end of the assignment period to determine outcomes and need (if any) for additional work at a later date.

CALENDAR OF EVENTS

A. CVM FIELD WORKPLAN

- (1) Workplan preparation procedure begins:
 - CVM works with ORA to develop program operation modules. (January)
CVM Field Committee meets to discuss past, current and future program and workplan goals and needs. (February)
 - CVM receives the Call Document from ORA regarding resources (March)
 - HFV-230 sends Call Document requesting new and revised programs to program managers. (March)
 - HFV-200, Program Managers, HFV-220 and HFV-230, and HFV-10 discuss projections for program needs in order to communicate the budget and begin development of the workplan. (March)
 - Program Managers meet with HFV-230 to discuss each program managers resource needs based on their program area and its relation to call requirements, and to resolve differences in resource requirements. (April)
 - HFV-200, in conjunction with Program Managers, HFV-220 and HFV-230, decides on final resource allocations, and then meets and resolves resource issues with the Field Committee before final submission to ORA. (April)
- (2) Final CVM workplan sent to ORA. (April/May)
- (3) CVM workplan submitted to Field Managers and CVM Field Committee for review and comments. DPEM/ORA discuss and resolve comments. CVM and the Field Committee discuss and resolve comments. (May-July)
- (4) Draft workplan submitted to Centers/Field for final review (August)
- (5) Final Field Workplan issued to Centers/ORA HQ/Field (September).

B. COMPLIANCE PROGRAMS

New or reissued Compliance Programs written and reviewed. (December-April)

Identify Team for preclearance review purposes:

- CP Manager
- ORO (Inspections and laboratory branches)
- CVM program writer (HFV-220/230)
- Compliance (CVM and ACRA)
- CVM Field Committee

C. CLEARANCE

- CVM submits program to CVM Field Committee and HFC-100 review and comment on programs. Final changes made to programs before issuance. (April-July)
- Cleared programs forwarded to Management Methods Branch (HFA-250) for printing and distribution. (June-August)

D. EVALUATIONS

- Evaluations completed by HFV-220/230 in conjunction with CP Manager and sent to HFV-200 and HFV-1. (February -August)

E. CVM - ORA FIELD COMMITTEE MEETINGS

- Meetings for the purpose of discussing current fiscal year program problems which may impact on programs to be written in December-April. Other meetings may be held with ORA Field Committee based on availability of parties concerned. (Spring/Fall)