
GENERAL PROCEDURAL POLICIES

ESTABLISHMENT OF CENTER POLICY/PROCEDURES

The Center for Veterinary Medicine shall ensure that there is a consistent, uniform, and even-handed application of the laws it is charged with enforcing. Short cuts and informality in reviewing, evaluating, consulting, and reporting policies and procedures are prone to result in real or imagined inequities to either industry, consumers or our own personnel. The policies and procedures developed by the Center are intended as guides to consistent interpretation of laws and regulations under a particular set of circumstances and should be followed insofar as practicable. Reasons for deviating from significant policies in given situations should be documented in the appropriate file.

1. Purpose:

This guide defines when policies/procedures are required and assigns responsibility for their development and approval.

2. Policy/Procedure Development:

a. Situations Requiring Policies and/or Procedures

A policy and/or procedure should be developed when situations requiring a similar decision occur or may occur repeatedly. In some cases a proposed regulation or guideline may be more appropriate. When developing a policy, opinions expressed or actions taken in similar situations are helpful for establishing a basically consistent and uniform approach. Precedent material must be carefully evaluated to ensure that it constitutes appropriate support.

b. Situations Not Requiring Policies or Procedures

It is not practical or desirable to establish Center policies or procedures covering all situations. In some cases written criteria or checklists are more useful for repetitive type operations. These, however, should only be used as points of reference and not as substitutes for sound administrative and scientific judgment.

c. Responsibility

- (1) Office Directors are specifically charged with the responsibility for ensuring that policies and procedures affecting their respective areas of activity are developed, approved, and copies forwarded to the CVM Policy and Procedures Manager (HFV-12).
 - (2) The Policy and Procedures Manager is responsible for ensuring that approved policies and procedures are incorporated into the CVM Policy and Procedures Manual.
3. Policy and Procedures Approval Process:
- a. General Center Policy and Procedures:
 - (1) All matters of general Center policy and/or operating procedures which cross major organizational lines shall be referred to the CVM Council where they will be decided by a simple majority. (See Attachment A - Council of the Center for Veterinary Medicine.)
 - (2) All CVM Council decisions will be subject to review by the Center Director.
 - b. Policy and Procedures which do not cross major organizational lines.
 - (1) All policies and operating procedures which do not cross major organizational lines shall be approved by the appropriate Office Director. If there is any possible impact on other organizational units, these units should be consulted prior to final approval.
 - (2) All policies and operating procedures which do not cross major organizational lines will be subject to review by the Center Director.

ATTACHMENT A

COUNCIL OF THE CENTER FOR VETERINARY MEDICINE

I. NAME:

The name of this body shall be the Council of the Center for Veterinary Medicine or more briefly, CVM Council.

II . PURPOSE:

The CVM Council shall be the primary originator of general Center policy and operating procedures which cross major organizational lines. The establishment of or changes in existing policies and procedures of this nature shall be passed by the Council in the manner prescribed below. The Council will in no way contravene: Statutory law; Food and Drug Administration policy and regulations; Department of Health and Human Services policy and regulations; etc. All aspects of Council deliberations promulgations shall be subject to the approval of the Commissioner of the FDA and/or the Secretary of HHS. It is, however, within the prerogative of the Council to recommend changes or additions to existing statutes, regulations, or policies subject to approval by aforementioned official(s).

III . MEMBERSHIP:

The membership of the Council shall consist of: the CVM Director; the CVM Deputy Director or whomsoever is designated in this position by the Director; the Office Directors of CVM; the Director, Office of Management and Communications; the Division Directors of CVM; others as may be designated by the Director with the concurrence of the Council. Members unable to attend shall designate a surrogate who will attend with all rights of the member.

IV. OFFICERS:

The Director and Deputy Director shall serve as Chairman and Vice-Chairman of the Council. The Director shall appoint a permanent Secretary of the Council. The Secretary shall be a CVM employee not a member of the Council.

V. MEETINGS:

Date, time, and place of the meeting are established by the Council and can be changed by mutual consent of the members provided advance notice is given and provided such change does not result in more than ten working days without a meeting. Regular meetings are open to any CVM employee, representatives of OCC and Division of Personnel Management and other Agency personnel as appropriate. However, executive sessions to include voting members only, may be called at the discretion of the Chairman or, in his absence, the Vice-Chairman. Executive sessions will be announced no later than 24 hours prior to the regular meeting.

VI. AGENDA:

Agenda items should be submitted to the Secretary by Wednesday noon preceding the intended meeting. The agenda and background materials shall be distributed to regular participants, each working unit of the Center and representatives of OCC by COB the Friday before the scheduled Council meeting. Any CVM employee may obtain additional copies from the Council secretary.

VII. MINUTES:

The Secretary shall publish the minutes of each Council meeting and distribute these to each working unit of the Center and representatives of OCC as soon as possible after each meeting but no later than COB three days later. The minutes shall then be subject to review at the next Council meeting and at that time may be amended or corrected.

VIII. ORDER OF BUSINESS:

The order will follow the distributed agenda directly. Opportunity will be provided for each individual present to raise additional items, but normally no decision will be made until such items have appeared on the agenda. No formal discussion of the minutes shall occur unless questions are raised. The Secretary shall record the names of all present and report that listing in the minutes. Meetings shall be one clock hour in length unless extensions are mutually agreed upon. Issues brought to a vote shall be decided by simple majority; however, all Council decisions will be subject to review by the Center Director. Only the regular membership shall be entitled to vote. Conduct of the meeting shall ascribe the Robert's Rules or other procedure established by the Chairman.

IX. CONSTITUENT ORGANIZATIONS:

A. Office Councils

The Office Directors shall hold regular meetings at least twice a month. A record of significant discussions and decisions held or made during these meetings shall be filed with the CVM Council Secretary within three working days following the scheduled meeting. Charters for the Office Councils similar to the CVM Council Charter shall be developed and filed with the Secretary by the first of the year (1979). Membership should consist of the Division Directors and others that report directly to the Office Director. Attendance should be open to any CVM staffer within the Office Director's unit.

B. Division Councils

Division Directors shall hold regular Division meetings at least twice a month. Minutes of significant items discussed during these meetings shall be filed with the CVM Council Secretary within three working days following the scheduled meeting. Charters for the Division Councils similar to the CVM Council Charter shall be developed and filed with the Secretary by the first of the year (1979). Membership should consist of the Team Leaders and others within the respective Divisions and attendance should be open to any Division staffer.

C. Team Meetings

Team Leaders shall hold regular Team meetings twice a month. Minutes of significant items discussed during Team meetings shall be filed with the CVM Council Secretary by the first of each month.

D. CVM General Staff Meetings

The Director shall call a general CVM Staff Meeting at least once per quarter. The format of these meetings shall allow for comments and/or questions by staff members wishing to do so.

X. MEETINGS WITH COMMISSIONER, COMMISSIONER'S STAFF, DEPUTY COMMISSIONER, ASSOCIATE COMMISSIONERS, HHS OFFICIALS,

INTER-AGENCY OFFICIALS, OFFICIALS OF OTHER FDA CENTERS AND UNITS:

Minutes of meetings, Memoranda of Conferences and other pertinent correspondence not related to official files (NADA's, INADA's, Case Jackets, etc.) shall be filed with the CVM Council Secretary. These shall be subject to inspection by any CVM staff member and may be subject to general CVM distribution.

More formally, the Center Director and his/her designee shall represent CVM at the Commissioner's General Staff Meeting, the FDA Policy Board Meeting and the Commissioner's CVM Management Meeting. Representation at the Commissioner's CVM Staff Meeting shall consist of the Director and others associated with the topics under discussion. The Director will apprise those individuals he wishes to make presentations in advance of the meeting and supervisors may request the attendance of other interested persons. In these formal meetings, it shall be the responsibility of the Director to ensure that each work unit in CVM obtains such minutes or memoranda as are issued relative to the respective meeting.