Inspections, Compliance, Enforcement, and Criminal Investigations

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Guidance for FDA Staff and Industry

Compliance Policy Guide
Sec. 130.300
FDA Access to Results of Quality Assurance Program Audits and Inspections
(CPG 7151.02)

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This document supersedes Compliance Policy Guide (CPG) "Sec. 130.300 FDA Access to Results of Quality Assurance Program Audits and Inspections (CPG 7151.02)" that was issued on January 3, 1996.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy

Preface

Public Comment:

Written comments regarding this document may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to

http://www.fda.gov/dockets/ecomments. For questions regarding the use or interpretation of this guidance, contact Jeffrey Governale at 240-632-6851.

Additional Copies:

Submit written requests for a single copy of the guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-001, or FAX your request to 240-632-6861. A copy of the guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' site includes the guidance and may be accessed at http://www.fda.gov/ora/compliance_ref/revisions.htm.

COMPLIANCE POLICY GUIDE

Guidance

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required.

Compliance Policy Guide

Sec. 130.300

FDA Access to Results of Quality Assurance Program Audits and Inspections (CPG 7151.02)

BACKGROUND:

Within all FDA regulated industries, some firms establish quality assurance units (QAU) to perform functions independently from the manufacturing or quality control organization. The QAU may periodically audit and critically review processes and procedures (for example, data collection, manufacturing practices, and quality control processes) to determine whether established protocols and procedures have been followed.

In the preambles to the final regulations on *the Quality System Regulation* - Good Manufacturing Practice for Medical Devices (*61 FR 52602; October 7, 1996*) (21 CFR *Part* 820) and on Good Laboratory Practice for Nonclinical Laboratory Studies (43 FR 59986; December 22, 1978) (21 CFR *Part* 58), FDA announced its policy not to review or copy a firm's records and reports that result from audits of a quality assurance program when such audits are conducted according to a firm's written quality assurance program at any regulated entity. The intent of the policy is to encourage firms to conduct quality assurance program audits and inspections that are candid and meaningful.

POLICY:

During routine inspections and investigations conducted at any regulated entity that has a written quality assurance program, FDA will not review or copy reports and records that result from audits and inspections of the written quality assurance program, including audits conducted under 21 CFR *820.22* and written status reports required by 21 CFR 58.35(b)(4).

FDA may seek written certification that such audits and inspections have been implemented, performed, and documented and that any required corrective action has been taken. District personnel should consult with the appropriate headquarters office prior to seeking written certification.

FDA will continue to review and copy records and reports of such audits and inspections:

1. In "directed" or "for-cause" inspection and investigations of a sponsor or monitor of a clinical investigation;
2. In litigation (for example, and not limited to: grand jury subpoenas, discovery, or other agency or Department of Justice law enforcement activity (including administrative regulatory actions));
3. During inspections made by inspection warrant where access to records is authorized by statute; and
4. When executing any judicial search warrant.

FDA will continue to have access to, review, and copy records and reports required by regulation, relating to quality control investigations of product failures and manufacturing errors.

Material between asterisks is new or revised.