INTRODUCTION

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INTRODUCTION

BACKGROUND - LABORATORY QUALITY ASSURANCE MANUAL

1. Purpose
2. Background
3. Policy

1. PURPOSE. This manual establishes the policies, procedures, and instructions relating to laboratory quality assurance in or for the Center for Food Safety and Applied Nutrition (CFSAN).

2. BACKGROUND. In order to help fulfill its regulatory mission, FDA must be assured that its laboratory work products are of the highest quality and reliability. Consistent with this commitment, the CFSAN on March 6 1981, established the Quality Assurance Task Force (QATF) and Oversight Committee. Their responsibility was to develop and recommend to the Office of the Director a revised Center Laboratory Quality Assurance Program.

   The Task Force considered and made recommendations on all laboratory work conducted in the Center. This was accomplished by dividing the QATF work into two phases. Phase I dealt with an extensive review and development of a quality assurance plan for the conduct and support of nonclinical laboratory studies, which the Commissioner directed must be conducted in full accordance with the regulation governing such studies (21 CFR part 58). Phase II addressed the development of a quality control program for the remaining CFSAN laboratory work.

   The Oversight Committee reviewed and reported to the Office of the Director on all Task Force recommendations. This included consideration of the effectiveness and appropriateness of the recommended actions, and their consistency with existing agency, department and federal policies and procedures.

   The Office for the Director acted on the recommendations and the revised CFSAN Quality Assurance Program become operational in mid 1981. The Laboratory Quality Assurance Manual outlines the Quality Assurance Program for the Center for Food Safety and Applied Nutrition.

From 1981 to the present, the original Laboratory Quality Assurance Manual was the source for the CFSAN QA Program guidelines. In 1992 the Center had a major reorganization which affected the structure and operations of the laboratory personnel and facilities. This Laboratory Quality Assurance Manual (2nd Edition) defines and describes the Center's Quality Assurance Program as it relates to the current organization and facilities.

3. GENERAL POLICY. The CFSAN Quality Assurance Program is intended to serve in maintaining the highest level of quality and integrity for Center data. The policies, procedures and instructions contained in this manual establish a quality assurance program uniformly applicable to all Center laboratory facilities. This manual covers nonclinical laboratory studies, other laboratory studies and regulatory samples. All laboratory personnel who are associated with the supervision or conduct of laboratory work are responsible for following the instructions contained in this manual.

INTRODUCTION

DEFINITIONS

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

1. PURPOSE. This Guide defines Center for Food Safety and Applied Nutrition nonclinical laboratory studies, other research (non-GLP) and regulatory sample analyses.

2. DEFINITIONS.

   A. Nonclinical Laboratory Study (GLP): A nonclinical laboratory study is any in vivo or in vitro experiment: (1) in which a test article is studied prospectively in a test system under laboratory conditions to determine its safety; and (2) in which the test article is under the jurisdiction of the Food, Drug and Cosmetic Act; and (3) in which the data from the study may be used in a regulatory decision or be cited in a court case; and (4) in which the test system is any animal, plant, microorganism, or subparts thereof, to which the test or control article is administered or added for study.

   B. Other Research: All other laboratory work not including the analysis of regulatory samples or research associated with nonclinical laboratory studies (eg. methods deveopment, range finding studies, "round robin" analyses).

   C. Regulatory Sample Analysis: This includes analysis where the sample is classified as (1) Official, Domestic, and Domestic Import, (2) Investigation, domestic and (3) Import. Regulatory samples include compliance samples, official or investigational factory samples, official or investigational surveillance samples, official or investigational complaint samples, official or investigational documentary samples, and official post seizure samples. "Regulatory sample" refers to all samples except (1) those clearly designated as research, (2) those collected to gather authentic data, and (3) those clearly designated as Laboratory Quality Assurance samples.

3. POLICY. All laboratory work conducted in the CFSAN is defined as identified in this Guide. Any exceptions to these definitions must be approved in writing by the Center Director. All nonclinical laboratory studies are subject to the Good Laboratory Practice Regulations.

4. RESPONSIBILITIES. Management is responsible for assuring that proposed studies are properly defined and conducted according to the appropriate instructions as set forth in this manual. The QAS is responsible for identifying any nonclinical laboratory study misclassified or not conducted in conformance to the Good Laboratory Practice Regulations.

INTRODUCTION

MANUAL MAINTENANCE

1. PURPOSE. This Guide establishes procedures for disseminating policy, procedures, and instructions relating to laboratory quality assurance in or for the Center for Food Safety and Applied Nutrition.

2. DEFINITIONS.

   A. Guides. A guide is used to issue continuing instructions or information and remains in effect until rescinded or superseded. Guides are grouped by subject matter into chapters and are distributed under cover of a transmittal.

   B. Division Quality Assurance Plans. Division Quality Assurance Plans clearly identify how individuals are to perform certain laboratory related functions to assure quality. These are tailored to meet the requirements of each unit. The criteria for development and approval required for each are detailed in Chapter 5, Employee Management.

3. POLICY. This manual system will be used to consolidate all Center-wide directives (Guides) concerning laboratory quality assurance and will serve as a repository for Division Quality Assurance Plans.

4. RESPONSIBILITIES.

A. Quality Assurance Staff, HFS-031. The QAS is responsible for the content of Guides issued as part of the CFSAN/QA Laboratory Manual. This includes

1. Developing and revising Guides required to communicate policy, procedures or instructions to Center staff.

2. Supervising the development or revision of Guides for which other Center organizational units have responsibility.

3. Clearance of all Guides regardless of whether developed by the QAS or by any other Center unit.

4. Preparing issuances for final publication and distribution.

5. Controlling the assignment for appropriate CFSAN/QA Laboratory Manual Guide numbers prior to issuance.

6. Establishing and maintaining functional distribution lists for CFSAN/QA Laboratory Manual Guides.

7. Preparing Table of Contents and Transmittal Notices.

8. Maintaining permanent record copies of CFSAN/QA Laboratory Manual Guides.

9. Maintaining a supply of extra copies of each Guide.

B. Division Directors. Each Division Director supervising laboratory personnel is responsible for Division Quality Assurance Plans. This includes:

1. Developing and revising Division Quality Assurance Plans as required in Chapter 5, Employee Management.

2. Distributing Quality Assurance Plans to affected staff members and the QAS.

C. Manual Holders. All manual holders are required to file Guides and Quality Assurance Plans in their Laboratory Quality Assurance Manual as received.

5. PROCEDURES FOR ISSUANCE.

A. Guides.

1. General. Draft CFSAN/QA Laboratory Manual Guide can be prepared by any unit that needs to convey policy, procedures, and instructions to CFSAN laboratories. All Guides will be prepared in accordance with instructions set forth in this Manual.

2. Coordination. Once drafted, CFSAN/QA Laboratory Manual Guides are to be sent to the Quality Assurance Staff for coordination and clearance. Prior to clearance the QAS must assure that the document is properly formatted and its content is acceptable.

3. Clearance. The Quality Assurance Staff is responsible for obtaining clearance of the Guides prior to issuance. Clearance is accomplished by using Form FD 2306, "Clearance Record" (see Attachment A). The form is prepared listing the unit(s) responsible for the subject matter contained in the Guide and the organizations directly or indirectly affected by its content. The members of the Center Quality Assurance Oversight Committee will be used for this purpose as necessary (see CFSAN/QA Laboratory Manual Guide 3002.12, Quality Assurance Oversight Committee). When new or revised Center policy is concerned, the final signature will be the Center Director or one of the Deputy Center Directors.

4. Printing and Distribution. The cleared document is sent to the QAS for carrying out the administrative functions associated with printing and distribution. Distribution of the Guides is accomplished in accordance with a distribution list maintained by the QAS. Request for additions or deletions to this list should be referred to that office.

B. Division Quality Assurance Plans

1. General. Division Plans are primarily the responsibility of the Division Director. The requirement for coordinating and clearing standards are detailed in Chapter 5 (see CFSAN/QA Laboratory Manual 3005.04, Division Laboratory Quality Assurance Plans).

2. Distribution. Once the Quality Assurance Plans are approved by the QAS, they should be distributed to the required personnel. Each Quality Assurance Plan should contain a distribution list. It is necessary to assure that all holders of the plan and the QAS receive changes as they occur. The indexing, numbering and maintenance of these standards are the sole responsibility of the unit involved. All Laboratory Quality Assurance Manual holders should file their Quality Assurance Plans on Chapter 11 of their Manual.

6. FORMAT.

A. Guides.

1. Forms to be Used. Form pages to be used in preparing Guides are available from Quality Assurance Staff.

2. Paragraphing. The captions of paragraphs are to be selected from the following as appropriate. Those selected would follow in sequence.

Purpose
Background
References (related Daily Operating Guides, etc.)
Definitions (when new terms are used)
Policy
Responsibilities
Procedures
Additional paragraphs are required

3. Identification and Numbering. Each Guide is identified by a three part identification consisting of:

A. 30 in the first two digits - signifies the Laboratory Quality Assurance Manual (30_)

B. 2nd two digits - signifies chapter within the Manual (3001 indicates Chapter 1 in the Laboratory Quality Assurance Manual)

C. two digits to the right of decimal signifies the Guide number within the chapter. (3001.02 indicates the 2nd Guide in Chapter 1 of the Manual)

Number are assigned only at time of printing by the QAS.

4. Miscellaneous. Paragraph numbering, spacing, page numbering, and capitalization should be accomplished according to the methods used throughout the CFSAN/QA Laboratory Manual.

5. Transmittals. All Guides are forwarded under a transmittal notice prepared by the Quality Assurance Staff. The following items should appear as the transmittal: (1) transmittal number and date, (2) title of transmitted material and identification number, (3) superseded material, (4) filing instructions, (5) and explanation of changes. The transmittal number consists of the base year 94, 95, 96, etc. which identifies the calendar year, and a consecutive number which identifies the individual transmittal within that year. See Attachment B for example.

6. Table of Contents. Each chapter contains a Table of Contents. Tables are periodically updated to provide a listing of current issuances for ready reference. The chapter Table of Contents show the Guide identification number, title, transmittal number, and date of issuance. A consolidated Table of contents for the entire Manual is also issued periodically. The Table of Contents for Chapter 11, Division QA Plans is to be completed by each manual holder to maintain record of the current contents of the chapter.

B. Division Quality Assurance Plans.

The format for Division Quality Assurance Plans is left to the discretion of the unit involved. They should, however, be numbered, indexed, and contain a distribution list. Units can use the Guide page forms if they so desire.

7. FILING.

It is the responsibility of each Manual holder to file issuances as received in the appropriate section. The Center for Safety and Applied Nutrition Manual Maintenance Records, Form FDA 3254, is used to record all Guides issued. This Maintenance Record is to be filed in front of this Manual. Additional copies of this Maintenance Record are available from the QAS (see Attachment C).

CLEARANCE RECORD	1. TYPE OF ISSUANCE: Laboratory QA Manual Guide

2. SUBJECT OF ISSUANCE	Labeling of Reagents and Solutions		
3. PREPARED BY	a. NAME AND ORGANIZATION: Alfred J. Flammable, Safety Officer	b. BLDG. AND ROOM NO.: FB-8 Room 6113	c. PHONE NO.: 205-4321

4. PURPOSE *(changes in policy or procedures, instructions or forms cancelled, revised or created.)*

This Guide revises Center-wide procedures designed to insure that reagents and solution containers are identified as to their contents and properties and that deteriorated reagents and solutions are not used.

5. ORIGINATING OFFICE CLEARANCE	a. TYPED NAME, TITLE AND ORGANIZATION: Goodwin L. Precision Quality Assurance Staff HFS-31	b. SIGNATURE	c. DATE SIGNED: 11/01/95

6. CLEARANCE ROUTING

☐ SEQUENCE CLEARANCE *(One draft in review, complete action and forward in_____work days.)*

☐ CONCURRENT CLEARANCE *(Copy to each clearance point, complete action and return by _____.)*

MAILING SYMBOL	SIGN UNDER APPROPRIATE COLUMN			CLEARANCE DATE
	CONCUR	CONCUR *(Recommended change(s) attached)*	DO NOT CONCUR *(Reason attached)*	
Return to HFS-031				

Form FD 2306 (4/95)

CFSAN
LABORATORY QUALITY ASSURANCE MANUAL

DATE	December 12, 1995	TRANSMITTAL	95-1

MATERIAL TRANSMITTED

1. Table of Contents, Chapter 7, Equipment and Reagents

2. Center/QA Guide 3007.01, Labeling of Reagents and Solutions

MANUAL MAINTENANCE

Remove	Insert
1. Table of Contents, Chapter 7 TN 95-1, dated 10/02/95	1. Table of Contents, Chapter 7
2. Center/QA Guide 3007.01 Labeling of Reagents and Solutions, TN 95-1, dated 10/02/95	2. Center/QA Guide 3007.01 Labeling of Reagents and Solutions

EXPLANATION OF CHANGES

1. Provides a Table of Contents for Chapter 7 of the Manual to reflect the issuance of the attached revised Guide.

2. Provides a revised guide in Labeling of Reagents and Solution to reflect a standardized label to be used for all solutions that do not bear commercial labels.

MATERIAL SUPERSEDED

Transmittal 95-1, dated 10/02/95

Goodwin L. Precision
Director, Quality Assurance Staff

CFSAN
LABORATORY QUALITY ASSURANCE MANUAL

TRANSMITTAL		ENTERED BY	TRANSMITTAL		ENTERED BY	TRANSMITTAL		ENTERED BY
NO.	DATE		NO.	DATE		NO.	DATE	

FORM FDA 3254 (4/95)