QUALITY ASSURANCE RESPONSIBILITIES

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QUALITY ASSURANCE RESPONSIBILITIES

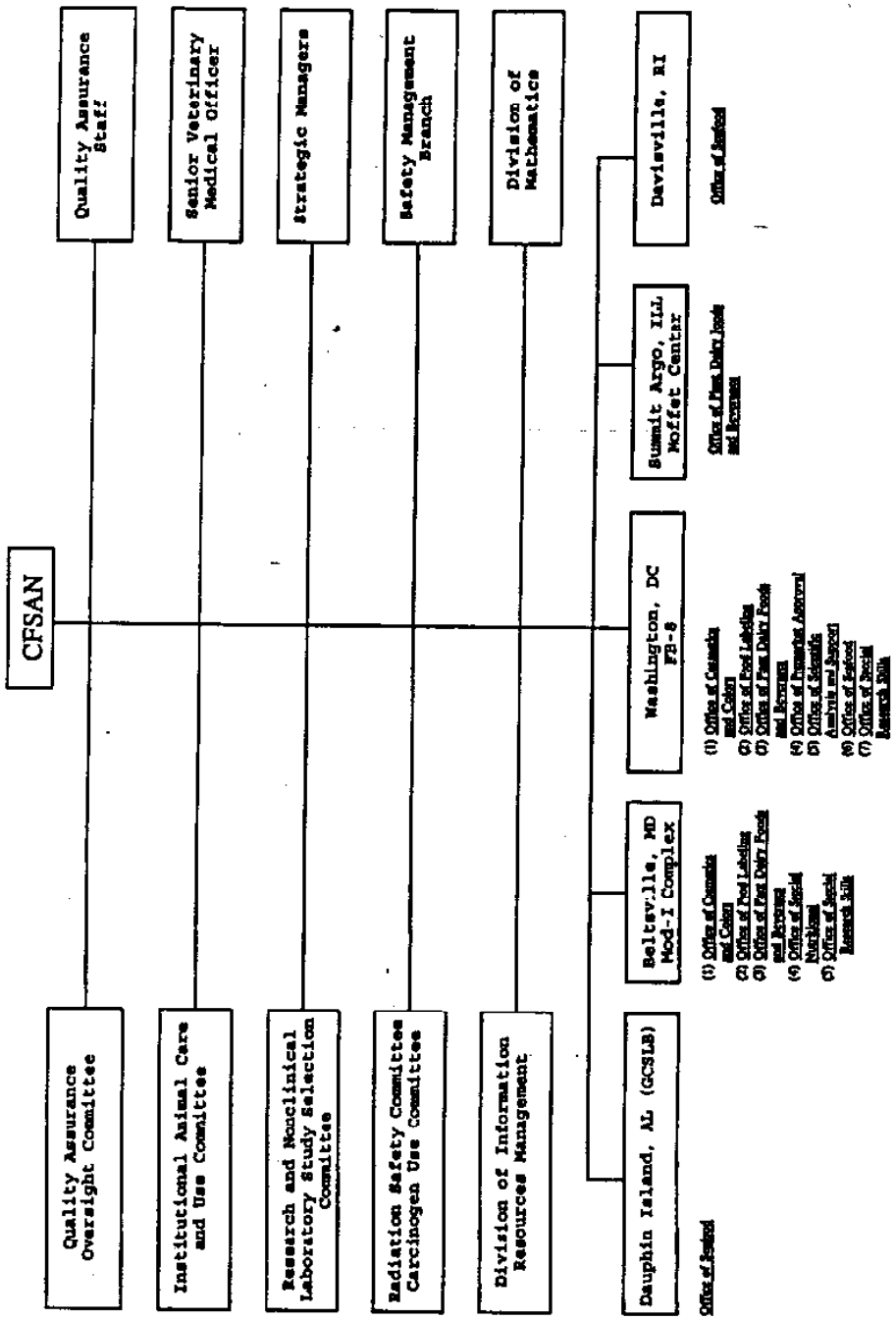
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, COMMITTEES AND SUPPORT UNITS

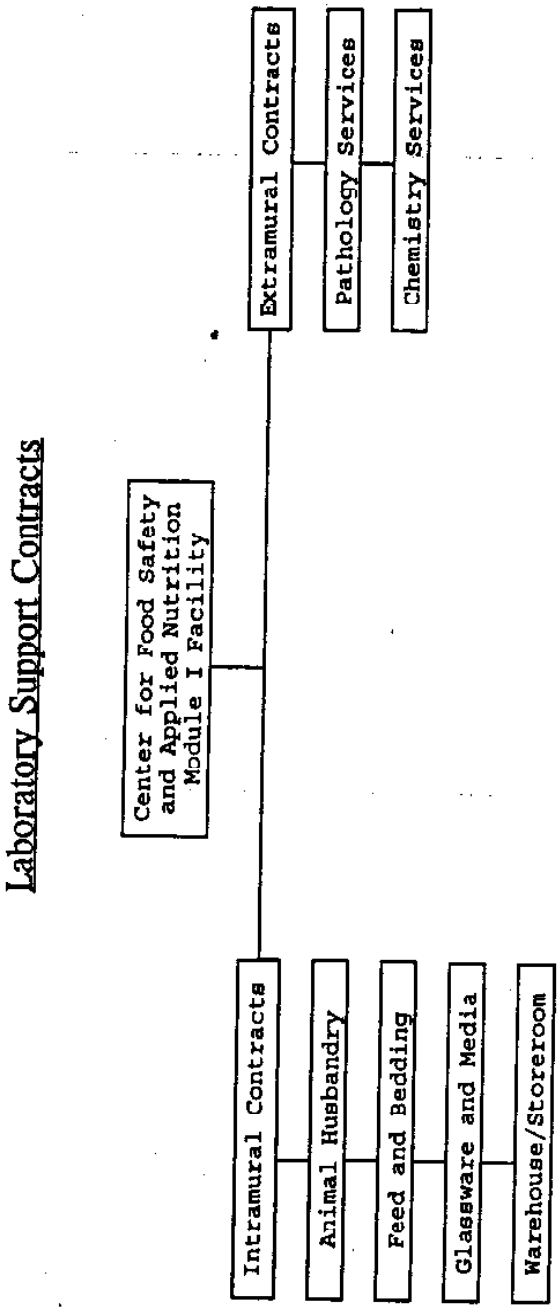
1. PURPOSE This Guide provides an organization chart highlighting the Center for Food Safety and Applied Nutrition (CFSAN) laboratories, committees and support units included in the CFSAN Quality Assurance Program (Attachment A).

2. POLICY The quality assurance policies and procedures identified in this manual apply to all CFSAN laboratories regardless of the location and to all units that support CFSAN studies. All contracted laboratory work must also conform to the CFSAN quality standard.

3. REFERENCES The remaining Guides in this chapter identify functions of key positions, organizational units, contracts and committees that have a role in assuring the quality of the laboratory work performed. The overall functions and responsibilities of these organizational units are further identified in the Staff Manual Guide.

CFSAN Laboratories, Committees and Support Units




Laboratory Support Contracts
Center for Food Safety and Applied Nutrition Module I Facility
Extramural Contracts
Pathology Services
Chemistry Services
Intramural Contracts
Animal Husbandry
Feed and Bedding
Glassware and Media
Warehouse/Storeroom

QUALITY ASSURANCE RESPONSIBILITIES

CENTER MANAGEMENT

1. Purpose.
2. Policy.
3. Responsibilities.

1. PURPOSE. This Guide describes the Center quality assurance duties and responsibilities of the Office of the Center Director, Office Directors, Division Directors, Branch Chiefs and Section Chiefs in directing and maintaining an effective quality assurance program.

2. POLICY. Management shall assure that a quality assurance program is established and maintained to help assure the quality and integrity of data produced by the Center for Food Safety and Applied Nutrition (CFSAN).

3. RESPONSIBILITIES.

A. Office of the Center Director

1. Develop Center for Food Safety and Applied Nutrition Quality Assurance Policy.

2. Establish and direct a Center for Food Safety and Applied Nutrition Quality Assurance Program.

3. Receive external (ORO) nonclinical study investigator; respond to inspection results at exit interview.

4. Develop overall Center scientific policy and laboratory programs to support the policy.

5. Review reports of Center quality assurance monitoring of nonclinical laboratory studies.

6. Establish priority for Center Scientific Programs.

7. Maintain overall responsibility to insure that all GLP deviations are corrected.

8. Serve as the final decision point for determining which studies are subject to the GLP Regulations.

B. Office Director

1. Develop Office laboratory quality assurance policy.

2. Coordinate quality assurance activities between Center scientific policy and Office scientific programs.

3. Advise the Office of the Center Director on developing and maintaining a CFSAN Quality Assurance Program.

C. Division Director

1. Coordinate the development of Quality Assurance plans for Laboratories conducting work within the Division.

2. Serve as the focal point for the development of a Division quality assurance plan.

3. Update the Division quality assurance plan as needed to assure an effective Division QA Program.

4. Provide support and guidance necessary to maintain an effective Quality Assurance Program.

5. Review Quality Assurance Inspection reports resulting from inspection of Branches within the Division.

6. Support Strategic Managers by providing information on Division resources relevant to the planning, conducting and reviewing of Programs affecting the Division.

7. Aid in insuring that Division personnel are apprised of and adhere to the Good Laboratory Practice Regulations.

D. Branch Chief

1. Monitor adherence to Division QA Plans through an active Branch inspection program.

2. Advise the Division Director on status of quality assurance within the Branch.

3. Assure that the Good Laboratory Practice Regulations and associated Center policies and procedures are adhered to in the conduct of any Branch laboratory work subject to the regulation.

E. Section Chief (Group Leaders and Team Leaders)

1. Assure that all supervised personnel are familiar with and adhere to the Division QA Plan.

2. Assure that affected personnel are familiar with and adhere to the Good Laboratory Practice Regulations and associated Center policies and procedures.

3. Apprise the Branch Chief on effectiveness of current quality assurance measures, provide suggestions on improvements.

QUALITY ASSURANCE RESPONSIBILITIES

QUALITY ASSURANCE STAFF

1. Purpose
2. Policy
3. Responsibilities

1. PURPOSE This Guide describes the duties and responsibilities of the Quality Assurance Staff (QAS).

2. POLICY The Quality Assurance Staff must carry out its responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition (CFSAN).

3. RESPONSIBILITIES

A. For all laboratory studies subject to the Good Laboratory Practice (GLP) Regulations initiated by the Center for Food Safety and Applied Nutrition the QAS shall:

1. Maintain a master schedule of all GLP studies.

2. Review all protocols for compliance to GLP's and maintain copies.

3. Assign Center for Food Safety and Applied Nutrition Quality Assurance Number (BFQ-No.) to each study upon approval.

4. Inspect studies, maintain record of inspections and report deviations to management.

5. Determine that no deviations from approved protocol or SOP's are made without authorization and documentation.

6. Audit final report and supporting study data for compliance with GLP regulations.

7. Sign a statement outlining inspection dates.

8. Monitor all GLP studies for, but not limited to, the following:

A. Characterization of test and control articles and records maintained.

B. Correction of deviations.

C. Labeling of reagents.

D. Identification of animals.

E. Labeling of storage containers for test and control articles.

F. Storage of reserve samples of test and control articles and records maintained.

G. Records for identification, receipt, and distribution of study samples and test and control articles.

H. Testing performed for homogeneity, stability, and concentration of test article/carrier mix and testing records maintained.

I. Adherence to protocol and standard operating procedures (SOP's).

J. Labeling of specimens.

K. Recording of data.

L. Retention of raw data.

9. Document compliance/non-compliance of study director in performing all required functions.

10. Accompany external investigators during inspections and audits of Center nonclinical laboratory (GLP) studies.

11. Provide advice as to which studies are subject to the GLP Regulations.

B. For all other Center for Food Safety and applied Nutrition research the QAS shall:

1. Maintain copies of all Division Quality Assurance Plans and copies of research protocols.

2. Inspect laboratories for adherence to Division Quality Assurance Plans.

3. Maintain records of inspections, report deviations to management.

C. Submit periodic reports to the Office of the Center Director on status of all laboratory studies.

D. Maintain the Center for Food Safety and Applied Nutrition Laboratory Quality Assurance Manual.

QUALITY ASSURANCE RESPONSIBILITIES

STRATEGIC MANAGER

1. PURPOSE This Guide describes the quality assurance duties and responsibilities of Strategic Manager for areas that include scientific research conducted in a CFSAN laboratory.

2. POLICY All Strategic Managers for research areas must carry out their responsibilities as identified below to assure the quality and integrity of the laboratory work conducted in the Center for Food Safety and Applied Nutrition (CFSAN).

3. RESPONSIBILITIES

   A. Attend pre-planning meetings held by Directors of offices for research activities which fall within their strategic area. Advise Office Directors and their staffs regarding important activities, trends, regulatory concerns, potential policy issues, research priorities etc., in their area of responsibility which could materially effect the direction and scope of research projects.

   B. Review and approve all Tactical Plan Project descriptions for their strategic area which have a laboratory research component. Assure that the proposed project activities are scientifically sound, fall within the scope the Center's mission and Strategic Plan and are designed to address important regulatory issues related to the safety of foods and cosmetics.

   C. Review and approve proposals for Extramural Projects which include laboratory research activities. Assure that activities described in the extramural project descriptions are designed to conduct or effectively support laboratory research related to food or cosmetics safety. Participate in Extramural Review Committee discussions to establish extramural contract priorities.

D. Review and approve protocols for laboratory research studies to assure that the proposed work is directly related to that described in a Tactical Plan Project Description or an amendment thereto. Evaluate the proposed study as to its scientific merit, relevance to the program's mission and regulatory/policy significance.

E. Review semiannual progress reports prepared on research studies in their strategic area. If questions or concerns are identified, discuss them with the Strategic Manager for Research and/or direct them to the researcher through the Office's line management system.

STRATEGIC MANAGERS

Biotechnology Strategic Manager

Food Processing and Packaging Strategic Manager

Microbiology Strategic Manager

Nutrition Strategic Manager

Pesticides and Chemical Contaminants Strategic Manager

Regulatory Policy Strategic Manager

Research Liaison Strategic Manager

Risk Assessment/Risk Communication Strategic Manager

Strategic Planning Strategic Manager

QUALITY ASSURANCE RESPONSIBILITIES

SENIOR VETERINARY MEDICAL OFFICER

1. PURPOSE This Guide describes quality assurance duties and responsibilities of the Center for Food Safety and Applied Nutrition (CFSAN) Senior Veterinary Medical Officer (SVMO).

2. BACKGROUND The Senior Veterinary Medical officer assigned to the Beltsville Technical Operations Staff has the authority and responsibility to assure adequate veterinary care is provided. The MOD I facility is a shared facility and as such, the CFSAN SVMO is a member of the Animal Care Directorate (ACD) with the SVMO from CDER. The ACD has the authority and responsibility for implementation and maintenance of the animal care program and compliance with the applicable regulations and policies. The chairmanship of the ACD rotates between the SVMO's and reports to the Governing Board for MOD I.

3. POLICY The CFSAN Senior Veterinary Medical Officer must carry out his responsibilities as identified below to help assure the quality and integrity of the research animals used in laboratory work conducted by the Center for Food Safety and Applied Nutrition.

4. RESPONSIBILITIES The SVMO supervises a staff that includes a veterinarian and a research facility manager to assure the following responsibilities are preformed to a standard that complies with the regulations for proper animal care.

   A. Senior Veterinary Medical Officer

      1. Acclimate all animals obtained from approved outside vendors prior to use in laboratory studies.

      2. Quarantine all animals obtained from non-approved vendors prior to use in laboratory studies.

3. Receive animals when delivered to the MOD I facility. Designate alternate when SVMO is not available.

4. Account for the receipt, health status, housing, care and feeding of research animals during the quarantine period.

5. Provide records of receipt, health certification and release to study director at the end of the acclimation period.

6. Provide upon request by the study director, consultation and all veterinary care to animals on study.

7. Establish approved Standard Operating Procedures (SOP's) as necessary for receipt, health status (certification), housing, care and feeding of animals while they are under control of the CFSAN SVMO.

8. Serves as a member of the CFSAN Institute Animal Care and Use Committee for review of protocols and SOPs to assure they meet the requirements of the Animal Welfare Act.

9. Provide training for animal care to all CFSAN employees and contractors in MOD I to meet standards for AAALAC accreditation.

B. Research Facility Manager

1. Serves as assistant to Animal husbandry contract project officer in monitoring day to day operation within the barrier.

2. Project officer for vermin control contract at MOD I.

3. Coordinates the ordering and receipt of animals for CFSAN research studies.

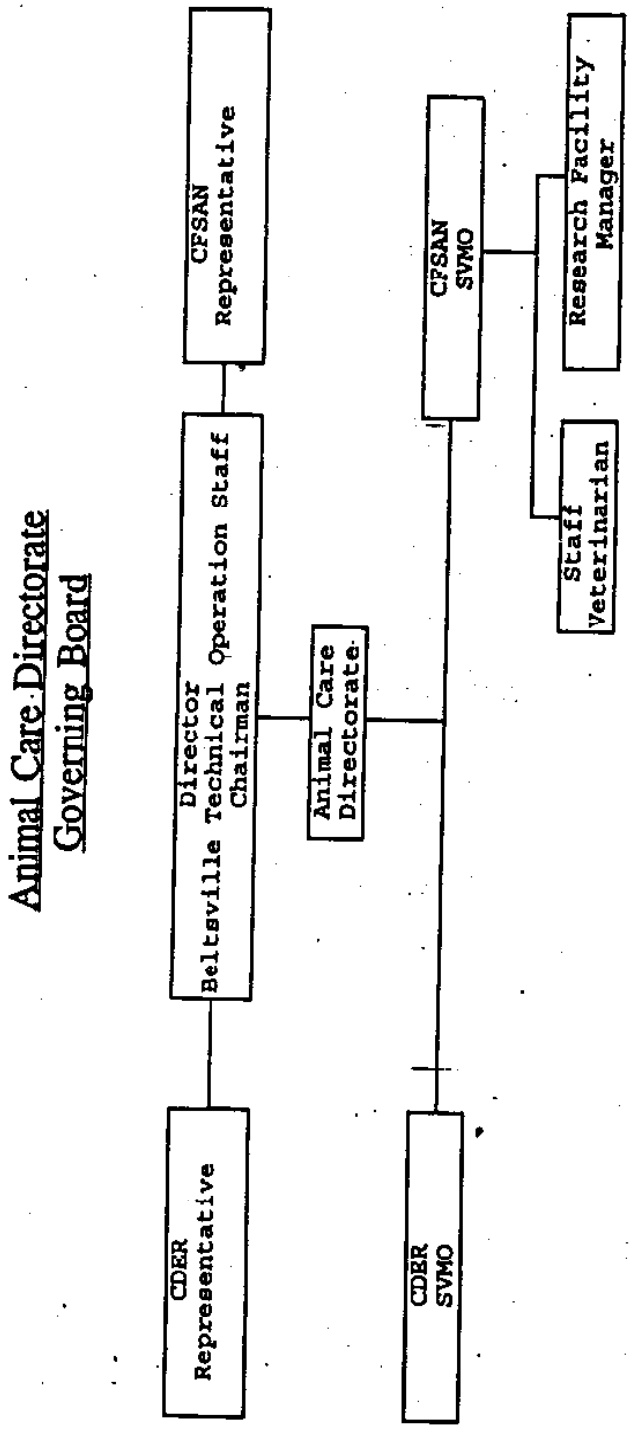
4. Assigns rooms within the barrier to research personnel for the conducting of animal studies.

5. Prepares daily maintenance requests for equipment and facility problems within the barrier.

6. Assures that cage washing equipment and products are functioning properly and that animal housing, water bottles, feeders, etc. are cleaned to standards required by the Animal Welfare Act.

7. Trains government and contract personnel in proper techniques such as animal identification with tattoos and use of euthanex system.

8. Conducts pre-study meetings prior to the initiation of all CFSAN animal studies in MOD I to assure that all study personnel (government and contractors) understand protocol procedures and requirements.


Animal Care Directorate
Governing Board
CFSAN Representative
Director Beltsville Technical Operation Staff Chairman
Animal Care Directorate
CDER Representative
CFSAN SVMO
Research Facility Manager
Staff Veterinarian
CDER SVMO

QUALITY ASSURANCE RESPONSIBILITIES

STUDY DIRECTOR

1. Purpose
2. Policy
3. Responsibilities

1. PURPOSE This Guide describes the quality assurance duties and responsibilities of a Study Director.

2. POLICY The Study Director must carry out this responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition (CFSAN).

3. RESPONSIBILITIES The Study Director has overall responsibility for the technical conduct of the nonclinical laboratory study. This includes responsibility for the collection, reporting, and interpretation of all study information. In addition, the Study Director shall:

   A. Obtain firm written commitments from support units in preplanning studies prior to protocol approval.

   B. Establish in writing all extramural contract support during protocol development if applicable.

   C. Develop the study protocol and obtain approval using form 3224 A (hardcopy or computer disk).

   D. Assure that summaries of training and experience are prepared for individuals assigned to the study.

   E. Hold pre-study meeting with CFSAN Contract support personnel to discuss their functions and responsibilities during the conduct of the study.

   F. Assign a trained technician to check temperature and humidity in each animal room daily while the study is in progress and record the data if applicable.

   G. For animals purchased from outside sources provide animal purchase orders and delivery information to the Center's Animal Facility Manager at MOD I. Provide delivery date to the QAS, Animal Facility Manager and Contractor.

H. Interact on a regular basis with Contractors who provide study support.

I. Maintain records detailing the characterization of test and control articles.

J. Maintain records indicating location of reserve samples.

K. Maintain records concerning amount and distribution of test and control articles.

L. Maintain results of all analyses as part of the raw data for the study.

M. Maintain records of homogeneity, concentration, and stability testing of test and control articles.

N. Assure all study data is properly and accurately recorded.

O. Submit (as necessary) protocol amendments.

P. Assure that corrective action is taken for any circumstances which may adversely affect quality and integrity of study data, and document the action.

Q. Assure all applicable Good Laboratory Practice Regulations are followed.

R. Assure all unforeseen events are documented.

S. Prepare final report and submit it and all supporting data to the QAS for audit.

T. Make all necessary additions/corrections to the final in a timely fashion.

U. Assure all raw data, documentation, protocols, specimens and final reports are archived at the close of the study.

QUALITY ASSURANCE RESPONSIBILITIES

PRINCIPAL INVESTIGATOR

1. PURPOSE This Guide describes the quality assurance duties and responsibilities of the Principal Investigator.

2. POLICY The Principal Investigator must carry out his/her responsibilities as identified below to assure the quality and integrity of the laboratory studies.

3. RESPONSIBILITIES

A. Non-GLP Studies

1. Obtain written commitments from support units in preplanning studies when the study involves more than one division.

2. Develop protocol using Form 3224 A or the Computer disk.

3. Route form through line management, strategic manager, safety office, IACUC and QAS assignment of a BFQ number.

4. Brief CFSAN and Contract personnel on their functions and responsibilities prior to the start of a study by holding prestudy meeting.

5. If animals are involved and purchased from an outside vendor, provide animal purchase orders and delivery information to the Center's Veterinary Medical Officer and MOD I Animal Facility Manager as soon as possible.

6. Assure all study data is properly and accurately recorded.

7. Assure the Center for Food Safety and Applied Nutrition Quality Assurance Procedures are followed throughout the study.

8. Submit copy of the Manuscript or summary write-up of findings to QAS at the conclusion of the study.

B. GLP Studies

1. Carry out duties assigned by the Study Director.

2. For duties assigned, properly record and maintain accurate records.

3. For assigned duties, assure that the Good Laboratory Practices are followed.

QUALITY ASSURANCE RESPONSIBILITIES

OFFICE OF MANAGEMENT SYSTEMS

1. PURPOSE This Guide describes the quality assurance duties and responsibilities of the Office of Management Systems.

2. POLICY The Office of Management Systems must carry out its responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition (CFSAN).

3. RESPONSIBILITIES

   A. Ensure that systems operated by OMS for handling data from nonclinical laboratory studies are in conformance with the requirements of the Good Laboratory Practice Regulations.

   B. Provide scientific and technical editorial services.

   C. Coordinate review, clearance and publication of scientific publications and presentations.

   D. Manage the FB-8 and MOD I Libraries.

   E. Provide nomenclature and literature searching services.

   F. Plan and coordinate the Center records management and reporting program.

QUALITY ASSURANCE RESPONSIBILITIES

GLASSWARE AND MEDIA SERVICES CONTRACTORS

1. PURPOSE This Guide describes the quality assurance duties and responsibilities of those individuals charged with providing glassware and media services.

2. BACKGROUND Glassware service at the FB-8 facility are provided by a combination of contract employees and FDA personnel from the Laboratory Services Unit, Division of Facilities and Engineering Management. Media services at the FB-8 facility are provided solely by contract. Both the glassware and media service contracts at FB8 are monitored by a project officer from the Division of Facilities and Engineering Management. Glassware and media services at the MOD I facility are provided by a contract monitored by a project officer from the Beltsville Technical Operations Staff.

3. POLICY The glassware and media services contractors must carry out their responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition.

4. RESPONSIBILITIES

A. Glassware Services

1. Maintain a central facility for the cleaning and storage of laboratory glassware.

2. Provide a mechanism for the ordering of specialized or new standard laboratory glassware.

3. Provide delivery of clean and the pick-up of dirty glassware.

   A. At FB-8 request for glassware are to be made by completing form FDA 1903 (attachment A) which is available from the Laboratory Services Unit, DFEM. The form is to be hung in the hallway near the door of the laboratory for pick-up. Glassware orders will be delivered in plastic tote boxes to the requesting laboratory within 48 hours. Dirty Glassware is to be placed in tote boxes and set in the hallway for pickup. Special instructions for cleaning stock or special purpose glassware may be requested using form FDH-2071 (attachment B). This form is also available from the Laboratory Services Unit, DFEM.

   B. At MOD I, request for glassware are to be made by completing a modified version of form FDH-1903 revised 03/17/93 (Attachment C). This form is either picked up from the requesting laboratory by the contractor of glassware service or submitted to the office of the glassware services contractor by laboratory personnel. Clean glassware is delivered to the requesting laboratories in plastic covered tote boxes where responsible laboratory personnel will be required to sign for the receipt of the order. Dirty glassware is to be placed in tote boxes along with a Record of Dirty Glassware Form (Attachment D) for pick-up from the laboratory by glassware services personnel.

4. Provide the storage, handling and distribution of sterile laboratory glassware.

B. <u>Media Services</u>

1. Prepare and distribute sterile culture media.

2. Prepare and distribute selected buffers and saline solutions. (See CFSAN/QA Laboratory Guide 3007.08 for instructions for requesting prepared media, selected buffers and Saline Solutions).

GLASSWARE ORDER SHEET

DATE _____

NAME _____ ROOM NO. _____ DIVISION _____ MAILING CODE _____

1. BEAKERS, GRIFFIN, LOW FORM

1 ml.		250 ml.	
5 ml.		400 ml.	
10 ml.		600 ml.	
15 ml.		800 ml.	
30 ml.		1000 ml.	
50 ml.		1800 ml.	
100 ml.		2000 ml.	
150 ml.		3000 ml.	

2. BOTTLES

Centrifuge

R.B.		250 ml.	
R.B.		500 ml.	
F.B.		250 ml.	
F.B.		500 ml.	
Culture (Roux)		1000 ml.	

Milk Dilution

Screw Cap		160 ml.	
Dropping, w/pipette			
		30 ml.	
		60 ml.	

Prescription Bottle

1 oz.		8 oz.	
2 oz.		8 oz.	
3 oz.		16 oz.	
4 oz.		32 oz.	

Reagent, Plain, G.S. Stopper

60 ml.		500 ml.	
125 ml.		1000 ml.	
250 ml.			

Wheaton Storage S.C.

125 ml.		500 ml.	
250 ml.			

Weighing

T.F.		7 ml.	
T.F.		45 ml.	
L.F.		50 ml.	

Vial, Specimen, S.C. Disco

1 dr.		4 dr.	
2 dr.		6 dr.	
3 dr.			

Aspirator		2000 ml.	

3. BURET, CLASS A, TEFLON PLUG

10 ml.		50 ml.	
25 ml.		100 ml.	

4. DISHES

Petri, Glass

15x100	
15x150	
20x100	
20x150	

Porcelain Tops	

Disposable Petri Dishes

15x100 mm.	

5. FLASKS

Boiling R.B.L.N. S 24/40

100 ml.		500 ml.	
250 ml.		1000 ml.	

R.B.S.N. S 24/40

50 ml.		500 ml.	
100 ml.		1000 ml.	
200 ml.		2000 ml.	
250 ml.		3000 ml.	
Florence F.B.L.N.		6000 ml.	

Erlenmeyer, N.M. Screw Cap

125 ml.		500 ml.	

Erlenmeyer, N.M. w/o Stopper

10 ml.		300 ml.	
25 ml.		500 ml.	
50 ml.		1000 ml.	
125 ml.		2000 ml.	
200 ml.		3000 ml.	
250 ml.		4000 ml.	
		6000 ml.	

Erlenmeyer, N.M.G.S.

10 ml.		250 ml.	
25 ml.		500 ml.	
50 ml.		1000 ml.	
125 ml.			

Erlenmeyer, W.M. w/o Stopper

125 ml.		500 ml.	
250 ml.			

Filtering, Glass Sidearm

125 ml.		1000 ml.	
250 ml.		2000 ml.	
500 ml.			

Volumetric, Class A, G.S.

5 ml.		200 ml.	
10 ml.		250 ml.	
25 ml.		500 ml.	
50 ml.		1000 ml.	
100 ml.		2000 ml.	

Hex Base Class A, G.S.

5 ml.		10 ml.	

Kjeldahl Flask		100 ml.	

6. FUNNELS

Buchner, Glass

Small		Large	
Medium			

Porcelain

Small		Large	
Medium			
Powder 80 mm.		125 mm.	
80 mm.		150 mm.	
100 mm.			

Chemical L.S.

45 mm.		100 mm.	
55 mm.		125 mm.	
65 mm.		150 mm.	
75 mm.			

FORM FDA 1903 10/ED

Page 1 of 2 pages

Chemical Funnels
S.S. 25 mm. _____ 90 mm. _____
50 mm. _____ 100 mm. _____
65 mm. _____ 150 mm. _____
75 mm. _____

Separatory, Squib (Pear Shape) with Teflon Plug
30 ml. _____ 500 ml. _____
60 ml. _____ 1000 ml. _____
125 ml. _____ 2000 ml. _____
250 ml. _____

7. GRADUATES
Pour Out, Double Metric Scale
5 ml. _____ 250 ml. _____
10 ml. _____ 500 ml. _____
25 ml. _____ 1000 ml. _____
50 ml. _____ 2000 ml. _____
100 ml. _____

Mixing, G.S.
10 ml. _____ 250 ml. _____
25 ml. _____ 500 ml. _____
50 ml. _____ 1000 ml. _____
100 ml. _____

8. JARS, WARING BLENDER
Glass _____
Jars, Osterizer _____

9. MORTAR, WITH PESTLE
Porcelain Small _____ Large _____
Medium _____
Glass Small _____ Large _____
Medium _____

10. PIPET
Serological, Color Coded Cotton Plug, Sterile in Cans
1/10 ml. _____ 10 ml. _____
2/10 ml. _____ 25 ml. _____
1 ml. _____
5 ml. _____

Serological, Sterile in Individual Wrap
1/10 ml. _____ 5 ml. _____
2/10 ml. _____ 10 ml. _____
1 ml. _____ 25 ml. _____

Measuring
1 ml. in 1/10's _____ 5 ml. _____
1 ml. in 1/100's _____ 10 ml. _____
2 ml. _____ 25 ml. _____

Ostwald-Folin
1 ml. _____ 3 ml. _____
2 ml. _____ 5 ml. _____

Volumetric, Class A, Serialized
1 ml. _____ 10 ml. _____
2 ml. _____ 15 ml. _____
3 ml. _____ 20 ml. _____
4 ml. _____ 25 ml. _____
5 ml. _____ 50 ml. _____
6 ml. _____ 100 ml. _____
7 ml. _____ 200 ml. _____
8 ml. _____

11. TUBES
Centrifuge
P.H.D.,F.H.S. 13 ml. _____ 50 ml. _____
P.H.D. 100 ml. _____
G. 10 ml. _____ 50 ml. _____
15 ml. _____
G.H.D. 12 ml. _____ 40 ml. _____
G.,H.D.,G.S. 10 ml. _____ 35 ml. _____
G.,G.S. 15 ml. _____ 50 ml. _____
G.,S.C. 15 ml. _____ 50 ml. _____

Tubes, Screw Cap
13x100 mm. _____ 20x150 mm. _____
16x125 mm. _____ 38x200 mm. _____
16x150 mm. _____

Culture, Tubes w/o Lip (Disposable)
6x50 mm. _____ 16x150 mm. _____
10x75 mm. _____ 20x150 mm. _____
13x100 mm. _____ 25x200 mm. _____
16x125 mm. _____

SPECIAL INSTRUCTIONS _____

LEGEND

G.-Graduated	F.H.S.-Flat Head Stopper
P.-Plain	L.S.-Long Stem
S.-Sterile	N.M.-Narrow Mouth
F.B.-Flat Bottom	R.B.-Round Bottom
G.S.-Glass Stopper	S.C.-Screw Cap
H.D.-Heavy Duty	S.N.-Short Neck
L.F.-Low Form	S.S.-Short Stem
L.N.-Long Neck	W.M.-Wide Mouth
T.F.-Tall Form	

Date Order Received _____
Order Filled By _____
Checked By _____
No. of Tote Boxes _____
Delivered By _____
Date Delivered _____
Order Received By _____

FORM FDA 1903 (6/82)

Page 2 of 2 pages

ROOM NO.	PHONE NO.	DATE SENT TO LSB

INVENTORY OF GLASSWARE

SPECIAL INSTRUCTIONS

DATE RECEIVED BY LSB	DATE RETURNED

DELIVERED BY	RECEIVED BY AND TIME

FDH FORM 2071 (1/68) PREVIOUS EDITION MAY BE USED. SPECIAL GLASSWARE

GLASSWARE ORDER FORM DATE_____

NAME_____ROOM NO._____DIVISION_____PHONE #_____

1. BEAKERS, GRIFFIN, LOW FORM
   5 ml._____ 400 ml._____
   10 ml._____ 600 ml._____
   15 ml._____ 800 ml._____
   30 ml._____ 1000 ml._____
   50 ml._____ 1500 ml._____
   100 ml._____ 2000 ml._____
   150 ml._____ 3000 ml._____
   250 ml._____ 4000 ml._____

2. BOTTLES
   MILK DILUTION S.C 160 ml._____
   REAGENT, PLAIN, G.S.
   125 ml._____ 500 ml._____
   250 ml._____ 1000 ml._____
   WHEATON STORAGE S.C.
   125 ml._____ 1000 ml._____
   500 ml._____
   VIAL, SPECIMEN, S.C. DISPO.
   1 dr._____ 4 dr._____
   2 dr._____ 6 dr._____
   3 dr._____

3. BURET, CLASS A, TEFLON PLUG
   50 ml._____

4. DISHES, PETRI, GLASS
   20 x 100 mm._____
   20 x 150 mm._____

5. FLASKS
   BOILING, R.B.L.N.S 24/40
   250 ml._____ 1000 ml._____
   BOILING, R.B.S.N.S. 24/40
   50 ml._____ 250 ml._____
   100 ml._____ 1000 ml._____
   200 ml._____
   FLORENCE F.B.L.N.
   6000 ml._____
   ERLENMEYER, N.M., SCREW CAP
   125 ml._____ 500 ml._____
   ERLENMEYER, N.M. w/e STOPPER
   10 ml._____ 250 ml._____
   25 ml._____ 500 ml._____
   50 ml._____ 1000 ml._____
   125 ml._____ 2000 ml._____
   150 ml._____ 3000 ml._____
   4000 ml._____
   ERLENMEYER, N.M.G.S.
   50 ml._____ 500 ml._____
   125 ml._____ 1000 ml._____
   250 ml._____

   ERLENMEYER, N.M. w/e STOPPER
   125 ml._____ 500 ml._____
   250 ml._____

   FILTERING, GLASS SIDEARM
   125 ml._____ 1000 ml._____
   250 ml._____ 2000 ml._____
   500 ml._____

   VOLUMETRIC, CLASS A, G.S.
   5 ml._____ 200 ml._____
   10 ml._____ 250 ml._____
   25 ml._____ 500 ml._____
   50 ml._____ 2000 ml._____
   100 ml._____

   KNF BASE, CLASS A, G.S.
   5 ml._____ 10 ml._____

7. FUNNELS

   POWDER
   60 mm._____ 125 mm._____
   80 mm._____ 150 mm._____
   100 mm._____

   CHEMICAL L.S.
   65 mm._____ 100 mm._____
   75 mm._____ 150 mm._____

   CHEMICAL S.S.
   25 mm._____ 75 mm._____
   50 mm._____ 100 mm._____
   65 mm._____

   SEPARATORY SQUIB, PEAR SHAPED, PLUG
   250 ml._____ 500 ml._____

8. GRADUATES, POUR OUT, SINGLE SCALE
   10 ml._____ 250 ml._____
   25 ml._____ 500 ml._____
   50 ml._____ 1000 ml._____
   100 ml._____ 2000 ml._____

   GRADUATES, POUR OUT, DOUBLE METRIC
   5 ml._____ 50 ml._____
   10 ml._____ 100 ml._____
   25 ml._____ 500 ml._____

   MIXING, G.S.
   10 ml._____ 100 ml._____
   25 ml._____ 500 ml._____
   50 ml._____ 1000 ml._____

9. PIPETS
MEASURING
1 ml 1/100 _____ 5 ml_____
10 ml_____
SEROLOGICAL, IND. WRAPPED, STERILE
DISPOSABLE
1 ml 1/100_____ 5 ml._____
1 ml 1/10_____ 10 ml._____
2 ml 1/100_____
VOLUMETRIC, A, SERIALIZED
25 ml._____ 50 ml._____
100 ml._____
10. TUBES, CENTRIFUGE
P.H.D.,F.H.S 50 ml._____
G. 15 ml._____ 50 ml._____
G.H.D. 40 ml._____
G.,H.D.,G.S. 10 ml._____ 40 ml._____
G.,G.S. 15 ml._____ 50 ml._____
G.,S.C. 15 ml._____
TUBES, SCREW CAP
16 x 125 mm._____ 38 x 200 mm._____
13 x 100 mm._____

****
SPECIAL INSTRUCTIONS _____

****

LEGEND

G.- Graduated	H.D.- Heavy Duty	N.M.- Narrow Mouth
P.- Plain	L.F.- Low Form	R.B.- Round Bottom
S.- Sterile	L.N.- Long Neck	S.C.- Screw Cap
F.B.- Flat Bottom	T.F.-Tall Form	S.S.- Short Stem
G.S- Glass Stoppar	L.S.- Long Stem	S.N.- Short Neck
	F.H.S.- Flat Head Stopper	W.M.- Wide Mouth

****
Date Order Received _____

Order Filled By _____

No. of Tote Boxes _____

Delivered By _____

Date Delivered _____

Order Received By _____

REVISED 3-17-93

Record of Dirty Glassware Form #13	Instructions 1. This form is to be securely placed with tape on each tote of dirty glassware. 2. DO NOT PROCESS this form through autoclave.

If glassware you have used needs STERILIZATION, STERILIZE IT IN YOUR OWN AREA. Indicate below that it has been STERILIZED, A SMALL AMOUNT OF WATER should be placed in each tote of glassware before autoclaving to ASSURE COMPLETE STERILIZATION. This slip, properly completed, MUST ACCOMPANY each container returned.

If glassware DOES NOT NEED STERILIZATION, indicate below.

***** HELP PREVENT INJURY TO GLASSWARE HANDLERS *****

DO NOT PUT NEEDLES, SYRINGES (DISPOSABLE OR GLASS), CAPILLARY PIPETTES, CHEMICALS, PLASTICWARE OF ANY KIND, OR TRASH IN TOTES OF GLASSWARE BEING RETURNED.

TO: Rm. 3208 GLASSWARE WASHING SECTION	LABORATORY SUPPORT SERVICES	MODULE 1 LAUREL MD	
FROM: INVESTIGATOR NAME	DIVISION	ROOM NUMBER	TELEPHONE
ITEM 1 AUTOCLAVE STERILIZED	DATE	BY:	AMOUNT
ITEM 2 CHEMICAL DECONTAMINATION	DATE	BY:	AMOUNT
ITEM 3 DOES NOT NEED TO BE STERILIZED OR DECONTAMINATED	DATE	BY:	AMOUNT

QUALITY ASSURANCE RESPONSIBILITIES

DIVISION OF FACILITIES AND ENGINEERING MANAGEMENT

1. PURPOSE This Guide describes the quality assurance duties and responsibilities associated with the Division of Facilities and Engineering Management.

2. BACKGROUND The FB-8 building, Module I and other satellite facilities are operated by the Food and Drug Administration. The Center for Food Safety and Applied Nutrition, as an occupant in these facilities is required to refer building maintenance request to the Division of Facilities and Engineering Management for corrective action.

3. POLICY The Division of Facilities and Engineering Management must carry out their responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition.

4. RESPONSIBILITIES

   A. Serve as project officer on all contracts whose obligations are to provide all aspects of building maintenance for systems and equipment relating to laboratory operations. This includes but not limited to, room and fume hood airflow, cold box and structural maintenance (walls ceilings, floors), water, gas and electrical services.

   B. Provide guidance for the maintenance of all Agency installed equipment. This includes offering technical assistance, making recommendations and preparing requisitions necessary to contract for the required services.

   C. Provide assistance and recommendations on space utilization and assist in relocations.

   D. Provide a mechanism for the control of vermin (ie trays, baits) at the FB-8 facility.

QUALITY ASSURANCE RESPONSIBILITIES

WAREHOUSE/STOREROOM SERVICES CONTRACTORS

1. PURPOSE This Guide describes the quality assurance duties and responsibilities associated with the Warehouse/Storeroom Services Contract.

2. BACKGROUND Warehouse/Storeroom Contract provides support services for the Center for Food Safety and Applied Nutrition (CFSAN) in both the FB-8 and MOD I facilities. The Warehouse/ Storeroom contract at the FB-8 facility is monitored by a project officer from the Division of Facilities and Engineering Management. The Warehouse/Storeroom contract at the MOD I facility is monitored by a project officer from the Beltsville Technical Operations Staff.

3. POLICY The Warehouse/Storeroom Services Contractor must carry out their responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition.

4. RESPONSIBILITIES

   A. Receive and distribute laboratory and other supplies ordered for use in both the FB-8 and MOD I facilities.

   B. Operate and maintain the FDA Scientific Supply Store, located in sub-basement of FB-8 and the ground floor level of the MOD I facility.

   C. Arrange the shipment of appropriately packaged items with the exception of radioactive materials from personnel in the FB-8 or MOD I facilities to their destination via GSA contract approved transportation company or courier service.

   D. Deliver gas cylinders and pick-up empty gas cylinders upon request of laboratory personnel.

E. Provide at the MOD I facility pickup, processing and transportation of medical waste to a centralized location for disposal.

F. Receive and store equipment and supplies for use behind the barrier at the MOD I facility.

QUALITY ASSURANCE RESPONSIBILITIES

QUALITY ASSURANCE OVERSIGHT COMMITTEE

1. PURPOSE This Guide describes the duties, responsibilities, and membership of the Center for Food Safety and Applied Nutrition Quality Assurance Oversight Committee.

2. POLICY The Quality Assurance Oversight Committee must carry out their responsibilities as identified below to assure that recommended changes in the Center's Quality Assurance Program are effective, appropriate, and consistent with existing policies.

3. RESPONSIBILITIES The members of the Quality Assurance Oversight Committee are identified in Attachment A.

   A. Represent the interests of their organizations.

   B. Review proposals for recommended changes in Center's QA program.

   C. Identify the need for new or revised QA policies and procedures.

   D. Report all actions of the Committee to the Office of the Center Director.

MEMBERS - QUALITY ASSURANCE OVERSIGHT COMMITTEE

Deputy Director for Programs

Director, Office of Cosmetics and Colors

Director, Office of Food Labeling

Director, Office of Plant Dairy Foods and Beverages

Director, Office of Premarket Approval

Director, Office of Seafood

Director, Office of Special Nutritionals

Director, Office of Special Research Skills

Director, Office of Scientific Aanalysis and Support

QUALITY ASSURANCE RESPONSIBILITIES

RESEARCH & NONCLINICAL LABORATORY STUDY SELECTION COMMITTEE

1. PURPOSE This Guide provides the duties, responsibilities, and membership of the Research & Nonclinical Laboratory Study Selection Committee.

2. POLICY The Research & Nonclinical Laboratory Study Selection Committee must carry out their responsibilities as identified below to assure that the nonclinical laboratory studies and other reseach undertaken are consistent with Center management priorities.

3. RESPONSIBILITIES The members of the committee are identified in Attachment A. All nonclinical laboratory studies subject to the GLP Regulations as well as other research must be approved by the Research & Nonclinical Laboratory Study Selection Committee Before being initiated.

   A. GLP Studies

      1. Review Agency and Center needs in the areas of toxicity testing.

      2. Review efforts by other organizations in the area of toxicity testing.

      3. Propose specific nonclinical laboratory studies for resource estimate evaluation.

      4. Set priorities for the nonclinical laboratory study proposals.

      5. Select nonclinical laboratory studies to be conducted based upon available resources and Center management priorities.

B. Other Research

1. Review Agency and Center needs for relevant research to support existing programs.

2. Coordinate research efforts in order to minimize duplication and wasted resources.

MEMBERS - RESEARCH AND NONCLINICAL LABORATORY STUDY SELECTION COMMITTEE

1. Deputy Director for Programs
2. Director, Office of Cosmetics & Colors
3. Director, Office of Food Labeling
4. Director, Office of Premarket Approval
5. Director, Office of Seafood
6. Director, Office of Special Research Skills
7. Microbiology Strategic Manager
8. Nutrition Strategic Manager
9. Pesticides & Chemical Contaminant Strategic Manager
10. Risk Assessment/Risk Communication Strategic Manager
11. Research Liason Strategic Manager

QUALITY ASSURANCE RESPONSIBILITIES

FEED AND BEDDING CONTRACTOR, MOD I

1. PURPOSE This Guide describes the quality assurance duties and responsibilities associated with the services provided by the Feed and Bedding Contractor.

2. BACKGROUND The Feed and Bedding Contractor will provide various laboratory services in support of animal studies and barrier activities conducted at the MOD I facility. Additionally, this Contractor has the capability to provide diet and/or dosing solution preparation in support of CFSAN studies upon request of the study director. This contract is monitored by a project officer from the Beltsville Technical Operations Staff.

3. POLICY The Feed and Bedding Contractor must carry out their responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition.

3. RESPONSIBILITIES

A. Order and maintain animal feed and bedding sufficient to meet research requirements.

B. Sterilize feed and bedding materials for transfer to the Animal Care Contractor for use behind the barrier (see CFSAN/QA Laboratory Manual Guide 3002.16).

C. Prepare and transfer diets for specific studies to Animal Care Contractor at times designated in the study protocol.

D. Maintain inventory of dietary ingredients to be used in the preparation of purified, semi-purified or chemically defined diets.

E. Clean and maintain the rooms and equipment used in the diet mixing process.

F. Develop and maintain SOPs outlining duties for areas covered by the Food and Bedding Contract, including the establishment of shelf life for feed and dietary ingredients.

G. Dispose of outdated materials and damaged or vermin infested containers of feed and bedding.

H. Monitor autoclaves and refrigerator/freezer units for proper operation on a daily basis.

I. Calibrate balances prior to use.

J. Participate in pre-study meetings which require interaction with other contract and government study personnel.

QUALITY ASSURANCE RESPONSIBILITIES

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

1. Purpose
2. Background
3. Policy
4. Responsibility
5. References

1. Purpose This guide is to provide information relating to authorities and quality assurance responsibilities under which the Institutional Animal Care and Use Committee performs its duties as concerned with the conduct of animal research for the Center for Food Safety and Applied Nutrition.

2. Background Authorization for the formation and utilization of an animal care and use committee is mandated by the provision of the Animal Welfare Act (P.L. 99-198; Food Security Act of 1985). This mandate was followed by the enactment of Title 9 Chapter 1, Subchapter A (Animal Welfare) by the Animal and Plant Health Inspection Service, USDA, which describes the procedures and administrative activities which must be followed to document the proper functioning of the animal care and use committee.

   The Institutional Animal Care and Use Committee (IACUC) shall be appointed by the Center Director. The members of the IACUC shall have sufficient experience and expertise that would enable them to oversee the institution's animal program, facilities and procedures. The IACUC shall consist of not less than five members and shall include at least one doctor of veterinary medicine, one practicing scientist experienced in animal research, one nonscientific member and one individual not affiliated with or related to a person affiliated with the center. An individual who meets the requirements of more than one category may fulfill more than one requirement.

   The Center Director shall develop and execute the Assurance Document that shall detail how the Center will operate to provide conformance with the provisions of the Animal Welfare Act and the Public Health Service Guidelines.

3. Policy The CFSAN Institutional Animal Care and Use Committee shall execute its responsibility as identified below to assure that the animals utilized in Center research are humanely treated with minimization of pain and discomfort.

4. Responsibility

A. Review the Center's animal research program at least once every 6 months using the USDA regulations and the Guide for the Care and Use of Laboratory Animals as a basis and to prepare reports of the status to the Center Director.

B. Inspect all animal facilities including animal study areas and satellite facilities at least once every 6 months.

C. Prepare reports of IACUC evaluations and submit the reports to the Center Director.

D. Review and investigate legitimate concerns involving the care and use of animals at the Center's research facilities resulting from public complaints or from reports of non-compliance received from facility personnel.

E. Make recommendations to the Center Director regarding any aspect of the Center's Animal program, animal facilities or personnel training.

F. Review and approve proposed activities related to the care an use of animals included in the protocol,protocol amendments and standard operating procedures.

G. Suspend any activity involving animals when necessary if approval procedures are not followed.

5. References In response to the requirements for implementation of the Animal Welfare Act and for the functioning of the IACUC, the Public Health Service published the policies which govern the conduct of animal research within or funded by PHS agencies. The PHS policies are contained in:

A. Public Health Service Policy on Humane Care and Use of Laboratory Animals

B. Institutional Animal Care and Use Handbook

C. Institutional Administrator's Manual for Laboratory Animal care and Use

D. Guide for the Care and Use of Laboratory Animals

QUALITY ASSURANCE RESPONSIBILITIES

ANIMAL HUSBANDRY CONTRACTOR, MOD I

1. Purpose This Guide describes the quality assurance duties and responsibilities associated with the services provided by the Animal Husbandry Contractor.

2. Background The Animal Husbandry Contractor will provide animal husbandry services in support of animal studies in a barrier sustained environment at the MOD I facility. Additionally, this Contractor has the capability to provide technical support (ie. oral intubation, injections, bleeding, tissue excision, etc) to animal studies conducted in CFSAN upon the request of the study director. This contract is monitored by a project officer from the Beltville Technical Operations Staff.

3. Policy The Animal Husbandry Contractor must carry out his responsibilities as identified below to assure the quality and integrity of the animal studies conducted in the Center for Food Safety and Applied Nutrition.

4. Responsibilities

   A. Provide all personnel, equipment, tools, materials, supervision and other items necessary to perform animal husbandry services.

   B. Provide technical support to the Veterinary Medical Officer in quarantine services and procedure.

   C. Perform daily observations to assess condition of animals housed in the barrier area.

   D. Monitor and record the environmental condition (temperature and humidity) of all animals rooms as well as collect water samples from each room.

E. Sanitize and prepare the loading area to receive animal shipments into the facility and verify accompanying documents.

F. Provide sufficient personnel to assure that fresh feed and water are available to laboratory animals.

G. Operate tunnel and rack washers to provide clean cages, water bottles, litter pans, etc in support of animal studies.

H. Provide support for surgical procedures, injections and dosing upon request of study director/principal investigator.

I. Decontaminate, sanitize and maintain all animal rooms and barrier passageways in a manner that assures the proper environment for conducting animal studies and that meet the requirements of the barrier procedures at the MOD I facility.

J. Develop and maintain SOPs outlining the duties for areas covered by the Animal Care Contract.

K. Participate in pre-study meetings which require interaction with other contract and government study personnel.

QUALITY ASSURANCE RESPONSIBILITIES

NECROPSY AND PATHOLOGY SUPPORT SERVICES

1. PURPOSE This Guide describes the quality assurance duties and responsibilities of the Pathology Branch, Division of General Scientific Support.

2. BACKGROUND The Pathology Branch, Division of General Scientific Support has the responsibility of providing when requested, necropsy and pathology support to scientific studies conducted in the Center for Food Safety and Applied Nutrition. A Staff Pathologist has been assigned on-site at the MOD I facility on a part-time basis for the purpose of administering to the necropsy/pathology needs of studies conducted in the facility. The remaining Pathology Staff, located at FB-8,.is also available to assist with necropsy and subsequent histopathological evaluation when the need arises. In addition, the Branch Chief of the Pathology Branch has the authority to contract to an outside source the necropsy, tissue preparation and microscopic evaluation of tissues from studies that require this support when contract funds are available. Study Directors/Principal Investigators requiring this support shall secure it by contacting the Branch Chief, Pathology Branch, HFS-716 during the planning stages of the research (See QA Laboratory Manual Guide 3003.01 - Planning and Conducting Laboratory Studies).

3. POLICY The Pathology Branch supervisors and staff shall carry out their duties and responsibilities as described below to assure the quality and integrity of the research conducted in the Center for Food Safety and Applied Nutrition.

4. RESPONSIBILITIES The Branch Chief of Pathology Branch has the responsibility for deciding if the support required by a study is to be done by staff personnel or by the pathology support contract. The decision should be made at the time the study director/principal investigator secures his/her written commitment for pathology services in support of his/her research. In addition, the Pathology Branch shall:

A. Prepare a support protocol in a timely fashion for those studies that require necropsy/pathology services.

B. Assure that standard operating procedures are prepared, approved and followed for all procedures used.

C. Assign staff pathologist who must be available to perform unscheduled necropsies on animals that die or are found in moribund condition.

D. Assure that the specimens collected and the records maintained are appropriately identified with BFQ number, animal number, sex, dose level, date collected, etc.

E. Assure that any change or addition made to the support protocol is approved by the study director.

F. Assure that the pathology contractor, when used, is aware that the Good Laboratory Practice regulations must be adhered to if support is for a nonclinical laboratory study.

G. Prepare a report of the results and submit if to the study director/principal investigator in a timely fashion.

QUALITY ASSURANCE RESPONSIBILITIES

CHEMICAL SUPPORT SERVICES, MOD I

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

1. PURPOSE This Guide describes the quality assurance duties and responsibilities associated with services provided by the Chemical Support Contractor.

2. BACKGROUND The Chemical Support Contractor will provide on a routine basis specified analytical determination for nutrient and contaminant profiles in feed and diets, a contaminant profile for water, and chemical analysis of test and control articles and test vehicles; and for homogeneity, stability, and concentration of the test/control article in the test vehicle. In addition, support chemical analysis of requested analytes specified in research studies will be performed after the contractor has performed satisfactory method validations per analyte requested . This contract is monitored by a project officer from the Beltsville Technical Operations Staff. Researchers who wish to utilize the chemistry support services must contact the chemistry Quality Control Officer, BTOS for information.

3. POLICY The Chemical Support Contractor must carry out their responsibilities as identified below to assure the quality and integrity of the laboratory work conducted by the Center for Food Safety and Applied Nutrition.

4. RESPONSIBILITIES

A. Contractor will provide the facility and all personnel, equipment, tools, materials and other items and services necessary to perform the requested chemical analysis.

B. The process of Contractor chemical support sample analysis will be initiated through written request (electronic mail or fax) by the Project Officer.

C. Prior to initiation of each task the contractor will demonstrate their capability of validating the methods required for analysis of the specified requested analytes.

D. Contractor will receive samples only after satisfactory demonstration of analysis capability and will document chain of sample custody.

E. Contractor will provide timely and accurate chemical analyses of specified requested analytes and documentation of strict adherence to quality assurance standards and GLP regulations requirements.

F. Contractor will perform analyses which characterize test articles, test vehicles, feed/diet, water and specified analytes deposited in various animal tissue and/or biological fluids.

G. Contractor will prepare reports and tables to summarize the results of the analysis and provide the original raw data of the requested analysis.

H. Contractor's work assignments will undergo an internal QA audit prior to final submission of reports and data.

I. Contractor will prepare and maintain SOP's outlining duties for areas covered by the Chemical Support contract such as methods of analyses, instrumentation operations, sample preparation, documentation and calibrations procedures required to adhere to the GLP regulations.