EMPLOYEE MANAGEMENT

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EMPLOYEE MANAGEMENT

DISCIPLINARY ACTIONS - NON-COMPLIANCE WITH CENTER FOR FOOD SAFETY AND APPLIED NUTRITION QUALITY ASSURANCE POLICIES AND PROCEDURES

1. PURPOSE This Guide directs Center personnel to the Agency's personnel procedures for disciplinary action. It is intended to highlight these procedures so that:

   A. Managers and supervisors are fully aware of the options available to them for dealing with employees who fail to comply with quality assurance policy and procedures.

   B. Operating personnel are fully aware of the actions they are subject to, should they fail to comply with the quality assurance policy and procedures.

   C. Operating personnel are aware of appeal procedures.

2. POLICY As in all other performance related problems, non-compliance with Center for Food Safety and Applied Nutrition laboratory QA polices and procedures will be dealt with according to prescribed agency personnel procedures.

3. GENERAL The quality of the laboratory work conducted by the Center for Food Safety and Applied Nutrition, and for the CFSAN under contact, is critical to the regulatory decision for which it is used. There is nothing more critical to the reputation of the Center than the quality of its work. For this reason, the policies and procedures established must be adhered to and supported by all Center personnel. Failure to comply is a serious offense, especially if the non-compliance could in any way compromise the results of the laboratory work.

4. MANAGEMENT RESPONSIBILITY The available forms of disciplinary action are:

* Admonishment
* Reprimand
* Suspension
* Demotion
* Removal

These more formalized actions should only be contemplated after sound management techniques are used to correct the given performance deficiency. The first course of action is simply to assure that management's expectations are clearly communicated to the employee. Should the employee fail to comply with the policies and procedures, it becomes management's responsibility to intervene to correct the situation. Corrective action will, of course, have to be tailored to the situation.

The performance appraisal systems for the Senior Executive Service and the Employee Personnel Management System for supervisors and the operating laboratory personnel all provide an excellent vehicle to communicate general expectations related to quality assurance from the supervisor to the subordinate. More specific expectations are communicated through a variety of ways including the contents of the Laboratory Quality Assurance Manual, standard operating procedures, Division quality assurance plans, protocols, and other written directives, as well as through the normal direction provided by supervision.

Non-compliance with the Center's policies and procedures will be identified through various sources:

__ management observation
__ Quality Assurance Staff inspections
__ Regulatory Inspections by FDA Field offices

Non-compliance should, of course, be reflected in the appropriate employee appraisal system in which the employee is rated.

When a supervisor believes the circumstances warrant the application of some form of disciplinary action, he/she should contact the appropriate DPM employee relations specialist for the Center. It is important that the procedures identified in OPM, DHHS, and FDA regulations and procedures are followed and that the action taken is applied fairly throughout the organization.

5. EMPLOYEE APPEAL Should an employee feel that disciplinary action is unfair, review of the action taken is available through the grievance or appeal procedures. The specific form of that review will depend on the nature of the disciplinary action. The Division of Administrative Services and Personnel office are available for assistance and advice in dealing with appeal procedures.

6. ASSISTANCE AND ADVICE Copies of the applicable regulations for personnel actions are maintained by the Division of Administrative Services as well as in the Division of Personnel Management. Likewise, the Administrative officer and the employee relations specialists assigned to the various organizational components are available to provide advice and assistance in processing disciplinary actions for non-compliance with QA requirements. Pleases note that the following FDA Staff Manual Guides contain the cited requirements for consulting the Division of Personnel Management prior to taking certain adverse or disciplinary actions:

SMG 1431.12 Adverse Action Authority

"CONSULTATION WITH SERVICING PERSONNEL OFFICERS. Officials delegated authority herein will consult with their servicing personnel office before issuing a letter proposing a suspension of adverse action or a letter of decision on these actions."

SMG 3116.4 Official Reprimands

"SERVICING PERSONNEL OFFICERS. Servicing personnel officers are responsible for providing advice and assistance to supervisory and management officials authorized to propose and to make original decisions on official reprimands. Servicing personnel officers shall require and assure that letters proposing to reprimand and letters of decision to reprimand are prepared by or reviewed by a person who is technically competent in official reprimand procedures, processes, and requirements. Servicing personnel officers are also responsible for advising all employee, including supervisors and managers, of the requirements of official reprimand procedures amt regulations."

SUMMARIES OF TRAINING AND EXPERIENCE AND JOB DESCRIPTIONS - NONCLINICAL LABORATORY STUDIES

1. PURPOSE This Guide describes the policy and procedures for the preparation and use of summaries of training and experience and job descriptions.

2. POLICY Individuals engaged in or supervising the conduct of nonclinical laboratory study shall have current summaries of training and experience and job descriptions on file with the unit to which they re assigned. This is required by the Good Laboratory Practice Regulations (21 CFR Part 58).

3. GENERAL GUIDANCE

   A. Laboratory management shall assure that current summaries of training and experience and job descriptions are prepared and are on file. This should include those engaged in or supervising the conduct of nonclinical laboratory work (including support) as specified in the study protocol.

   B. The summary of training and experience and job descriptions shall be updated as required. Management shall review the files annually to insure their current status.

   C. The summaries of training and experience and job description will be maintained on file with the Quality Assurance Staff.

   D. The summaries of training and experience and job descriptions shall be available for inspection by study directors in determining the suitability of personnel for a particular study.

   E. The summary of training and experience will take the form of a Curriculum Vitae. It should include information pertaining to education and experience. (Since the SF-171, Personal Qualifications Statement, contains personal information and is protected by the privacy act Title 5 of the Code of Federal Regulations, the SF-171 should not be used for this purpose).

EMPLOYEE MANAGEMENT

LABORATORY QUALITY ASSURANCE TRAINING

1. Purpose
2. Policy
3. Procedures

1. PURPOSE This guide describes the policy and procedures with respect to laboratory quality assurance training.

2. POLICY Management shall assure that laboratory personnel receive quality assurance training consistent with their duties and responsibilities.

3. PROCEDURES

   A. Laboratory supervisors shall review with new laboratory personnel the policies and procedures contained in the CFSAN Quality Assurance Manual and specific instruction in the Division laboratory quality assurance plans. The Management Analysis and Employee Development Branch (HFS-656) is available to provide additional aids.

   B. Laboratory management shall assess the quality assurance needs of their personnel and provide on the job or formalized training as available and necessary.

   C. Study Directors and management shall assure that personnel engaged in or supervising the conduct of a nonclinical laboratory study receive specific Good Laboratory Practices training. This training is available through the Management Analysis and Employee Development Branch (HFS-656).

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DIVISION LABORATORY QUALITY ASSURANCE PLANS

1. PURPOSE This Guide describes the policy and procedures associated with the development and maintenance of Division Laboratory Quality Assurance Plans.

2. POLICY All Divisions conducting laboratory work shall develop and maintain a specific quality assurance plan relevant to their laboratory function.

3. PROCEDURES

   A. Contents Division Quality Assurance Plans shall contain requirements pertaining to planning, environment, materials, instruments and equipment and documentation applicable to the Division laboratory operations and a system to implement these requirements, monitor their effectiveness and take corrective actions when needed. The plans shall contain a quality assurance checklist as given in Attachment F revised and/or supplemented as necessary to meet the quality assurance needs of the Division.

Division Quality Assurance Plans must adopt as a minimum the specific (applicable) requirements as set forth in Attachments A-E. Divisions that are responsible for conducting highly specialized laboratory work shall supplement these requirements with additional elements reflective of their specialized functions. Division Quality Assurance Plans must also include a means of monitoring their plans internally. This must include a supervisory review of the laboratory and employee adherence to principles of quality assurance as it applies to employee laboratory work. Any type of internal monitoring must include a means of recording and correcting deviations.

B. Approval Division Quality Assurance Plans should be submitted through appropriate channels to the Center for Food Safety and Applied Nutrition, Quality Assurance Staff (CFSAN/QAS) for approval. Any changes in the approved plans must be submitted to the CFSAN/QAS for approval prior to distribution.

C. Distribution and Filing Approved changes should be distributed to all affected employees. A distribution list (to include the QAS) should be included as part of the plan. The plans should be filed in Chapter 11 of this manual.

D. Monitoring Branch Chiefs and 1st line supervisors should utilize the Division Quality Assurance Plans to monitor their personnel. Specifically, the Division QA Checklist will be used during these inspections. The CFSAN/QAS will also utilize the Division QA Checklist for monitoring adherence to the Division QA Plans.

Division Quality Assurance Plan - Planning Requirements

Division Quality Assurance Plans must contain a section on planning requirements. The items below should be considered for inclusion in this section.

1. A means for establishing work priorities based on program needs, investigator capability and availability of equipment and other resources.

2. An approved tactical pan available for all laboratory work.

3. A protocol prepared and approved for all laboratory work that clearly defines the research objective, experimental approach and the procedures to be utilized to accomplish the stated objective.

4. A mechanism for the handling and analysis of regulatory samples.

5. A definition of management and scientific personnel responsibilities.

6. A system for monitoring all quality assurance aspects of laboratory work.

Division Quality Assurance Plan - Environment Requirements

Division Quality Assurance Plans must contain a section on environmental requirements. The items listed below should be considered for inclusion in this section.

1. A procedure for identifying unneeded equipment and supplies that should be stored, surplused or discarded.

2. A routine schedule for cleaning laboratories.

3. A check to determine that instruments, and equipment are installed according to the manufacture's recommendations and suggestions.

4. A requirement that all outdated chemicals and reagents are disposed of properly.

5. A requirement that eating and drinking in laboratories will be restricted to areas that will not affect analytical results.

6. A mechanism for properly reporting, and documenting any source of environmental contamination beyond laboratory control.

Division of Quality Assurance Plan - Material Requirements

Division Quality Assurance Plans must contain a section on requirements for materials. The items listed below should be considered for inclusion in this section.

1. A requirement that chemicals and reagents of suitable purity are used.

2. A requirement that purity of chemicals and reagents are determined prior to use particularly if the purity of the chemical is critical in a procedure.

3. A requirement that chemicals and reagents are dated when received and initialed and dated when opened.

4. A requirement that laboratory prepared solutions are labeled with identity, concentration, date of preparation, name of the preparer, date of expiration, storage requirement and warning of hazard.

5. A requirement that when solutions are prepared, standardized (or restandardized), the date, analyst, weight(s), volume(s), temperature and calculations are recorded.

6. A check sample program tailored to fit the laboratory function is detailed.

7. A requirement that reagent blanks and/or recovery experiments are conducted as part of each applicable analysis.

8. A requirement that all reference materials meet established specifications, are of known composition stable under test conditions, well characterized, and in the same quality state as the test substance being compared.

9. A requirement that all reagents and chemicals bear proper labeling.

10. A requirement that chipped or excessively scratched (etched) glassware is discarded.

11. A requirement that all pipettes, burets, graduated cylinders, etc., are adequately calibrated for the measurement being made.

12. A requirement that contaminated glassware is not used.

Division Quality Assurance Plan - Instrument and Equipment Requirements

Division Quality Assurance Plans must contain a section on instrument and equipment requirements. The items listed below should be considered for inclusion in this section.

1. A requirement that instruments, including balances are calibrated and/or standardized prior to and during use.

2. A requirement that manufacturer's recommendations or established alternate procedures are followed when operating instruments and equipment.

3. A requirement that routine preventive maintenance and repair are provided and documented.

4. A requirement that an individual(s) is identified as principal user or monitor for every major piece of equipment.

5. A requirement that instruments and equipment manuals are kept in a location accessible to laboratory personnel and a label placed on the instrument containing this information.

Division Quality Assurance Plan - Documentation Requirements

Division Quality Assurance Plans must contain a section on documentation requirements. The items below should be considered for inclusion in this section.

1. A requirement that records of equipment maintenance and repair are maintained.

2. A requirement that records of instrument/equipment calibration are maintained.

3. A requirement that all data are recorded in properly identified bound notebooks or on data forms.

4. A requirement that laboratory notebooks are maintained as identified in CFSAN/QA Guide 3009.01, Laboratory Notebooks.

Division:_____

Branch :_____

LABORATORY QUALITY ASSURANCE CHECKLIST (NON-GLP)

ENVIRONMENT

1. Work environment (plumbing, heating, lighting ventilation, etc.) is routinely checked and monitored by laboratory personnel for adequacy to work being conducted.

   A. Housekeeping is satisfactory.

   ( ) yes ( ) no

   (1) Decontamination systems are adequate for the type of work conducted (microbiology).

   ( ) yes ( ) no

   COMMENTS:

2. Potential environmental contaminants or cross contaminants are considered and eliminated whenever possible.

   ( ) yes ( ) no

   A. Policy is established concerning eating, and drinking in the laboratories.

   ( ) yes ( ) no

   (1) Areas are designated or defined.

   ( ) yes ( ) no

(2) Eating, and drinking policy includes consideration of the environment and sample integrity.

( ) yes ( ) no

COMMENTS:

3. All pieces of equipment are located in an appropriate environment (e.g., temperature, humidity, etc.) to assure proper functioning.

( ) yes ( ) no

COMMENTS:

PLANNING

4. Tactical Plans and protocols have been developed and approved for laboratory projects and objectives are defined.

( ) yes ( ) no ( ) NA

A. Responsibilities are spelled out.

( ) yes ( ) no ( ) NA

B. The experimental designs (approaches to meet the objectives) are established.

( ) yes ( ) no ( ) NA

COMMENTS:

5. All laboratory employees have received orientation in the Division quality assurance plan. Current laboratory employees are kept apprised of changes in laboratory procedures.

( ) yes ( ) no

COMMENTS:

MATERIALS

6. Chemicals and reagents are dated when received, initialed and dated when opened. Laboratory prepared reagents are labeled to indicate identity, date of preparation, the concentration, the preparer's name/initials, and any special requirements (stor-age conditions, expiration dates, etc.).

( ) yes ( ) no

A. Purity of chemicals and/or reagents is known, prior to use

( ) yes ( ) no

COMMENTS:

7. When solutions are prepared, standardized, (or restandardized), the date, analyst, weight(s), volume(s), temperature, and calculations are recorded.

( ) yes ( ) no

COMMENTS:

8. All reference materials meet the following established performance specifications: they are (a) well characterized, (b) in the same quality state as the test substance being compared, (c) of known stability, and (d) properly labeled.

( ) yes ( ) no ( ) NA

COMMENTS:

9. Reagent blanks and/or recovery experiments are utilized as part of the analyses.

( ) yes ( ) no ( ) NA

COMMENTS:

10. All pipettes, burets, and volumetric flask (not certified as pre-calibrated) are calibrated on a routine and/or periodic basis.

( ) yes ( ) no

A. Glassware is clean prior to use.

( ) yes ( ) no

B. Chipped or excessively scratched (etched) glassware is discarded.

( ) yes ( ) no

COMMENTS:

INSTRUMENTS AND EQUIPMENT

11. Instruments (including balances) are calibrated/standardized prior to use and as needed during use.

( ) yes ( ) no

A. This is recorded.

( ) yes ( ) no

COMMENTS:

12. The laboratory has a program of preventive maintenance for instruments and equipment that can be maintained by laboratory personnel.

( ) yes ( ) no

A. This information is recorded.

( ) yes ( ) no

B. Individual(s) is identified as principal user(s) or monitor(s) for instruments and equipment.

( ) yes ( ) no

C. Instrument and equipment manuals are kept in a location readily accessible to laboratory personnel.

( ) yes ( ) no

D. Personnel are familiar with procedures for obtaining instrument/equipment repair.

( ) yes ( ) no

COMMENTS:

DOCUMENTATION (NON-REGULATORY)

13. Original data are properly and completely recorded in the official FDA bound notebooks (except the cross referenced and other data mentioned in 13 (a)).

( ) yes ( ) no

A. Integrity of data which cannot be recorded in the laboratory notebooks is maintained (e.g., cross reference computer data, tapes, graphs, charts, etc.).

( ) yes ( ) no

COMMENTS:

B. Above are identified with name, date, BFQ number, etc.

( ) yes ( ) no

COMMENTS:

14. Manuscripts and laboratory reports on completed work are reviewed by appropriate supervisors.

( ) yes ( ) no

COMMENTS:

15. A means of recording receipt and accountability of non-regulatory samples is established.

3005.04

( ) yes ( ) no

COMMENTS:

DOCUMENTATION (REGULATORY AND NON-REGULATORY)

16. System for accountability of reference standards is established.

( ) yes ( ) no ( ) NA

A. The system defines the standards specifications.

( ) yes ( ) no

B. It includes a repository (or repositories).

( ) yes ( ) no ( ) NA

C. The system requires documentation of purity, use, individual using standard, and other data which establish standard authenticity.

( ) yes ( ) no

COMMENTS:

DOCUMENTATION (REGULATORY)

17. A means of identifying regulatory samples is established.

( ) yes ( ) no

A. An individual(s) is designated as responsible for making this identification.

( ) yes ( ) no

B. A sample accountability record is always used.

( ) yes ( ) no

COMMENTS:

18. All laboratory personnel and supervisors who work on regulatory samples are familiar with the information found in Chapters 1 - 4and 12 of the Laboratory Pracedures Manual.

( ) yes ( ) no ( ) NA

A. Copies of the pertinent portions of this manual are on hand or readily available.

( ) yes ( ) no

B. Regulatory samples analyses are conducted in accordance with this manual to insure sample integrity and accountability throughout receipt, storage, handling, preparation and analyses.

( ) yes ( ) no ( ) NA

COMMENTS:

19. There is a checking system in place to insure that analysts worksheets are properly filled out and utilized in accordance with LPM procedures.

( ) yes ( ) no ( ) NA

COMMENTS:

20. Check analyses are run on violative samples by the same method or another official method, if possible.

( ) yes ( ) no ( ) NA

COMMENTS:

EMPLOYEE MANAGEMENT

STANDARD OPERATING PROCEDURES

1. Purpose
2. Definition
3. Policy
4. Procedures

1. PURPOSE This Guide defines and establishes requirements and procedures for the preparation and maintenance of laboratory standard operating procedures.

2. DEFINITION A Standard Operating Procedure (SOP) is defined as: written instruction which sets forth policy or procedures associated with a routine laboratory function.

3. POLICY Laboratory management should insure that standard Operating Procedures (SOP's) are developed which will be useful in organizing and controlling their laboratory operation.

   A. Specifically, those laboratories involved in the conduct of a nonclinical laboratory study must prepare SOP's as required by the Good Laboratory Practice (GLP) Regulations, 21 CFR Part 58. Procedures involving the care of the live animal are required to be prepared by the Animal Husbandry Contractor at the MOD I facility. However, the GLP regulations require at a minimum the development of the following SOP's.

      1. Receipt, identification, storage, handling, preparation and method of sampling the test and control articles

      2. Collection, identification and transfer of specimens

      3. Laboratory tests

      4. Data handling, storage and retrieval

      5. Analysis of test and control articles in mixture

      6. Maintenance and calibration of equipment

B. Other SOP's defining routine or repetitive laboratory task should be developed as necessary.

C. All SOP's should be filed and distributed in a manner in which all necessary personnel have access. A historical file of SOP's and all revisions shall be maintained.

D. SOP's developed by the those units not engaged in non-clinical laboratory (GLP) studies shall be included with the division quality assurance plan (CFSAN/QA Laboratory Manual Guide 3005.04).

4. PROCEDURES

A. Preparation of SOP's. Each SOP shall:

1. Be written clearly and concisely

2. Be written in a language easily understood by the user

3. Contain a Title to indicate the purpose, an SOP identification number, a date of issue or revision, number of pages, name and dated signature of preparer and approver

4. Contain all necessary instructions in a logical, sequential fashion and, if possible, provide a statement giving any desired or expected results for comparison

5. Contain a step by step description of the experimental procedure

6. Describe all reagents needed including their preparation, frequency of preparation and use.

7. Indicate the equipment/instruments required. Give their settings, calibration/standardization checks, maintenance check and corrective actions.

8. Give the frequency and sequence of the sample analysis. Explain any calculation, safety precautions, data recording requirements and reporting procedures.

B. Maintenance and Distribution

The maintenance of SOP's to assure compliance with the above Center policy is the responsibility of Division Director and/or Branch Chiefs (for SOP's developed as a part of the unit QA plans) and Study Directors (for SOP's required by 21 CFR part 58 for nonclinical laboratory [GLP] studies). Suggested below are ways in which the respons-ible individual may wish to establish necessary control over maintenance and distribution of SOP's.

1. Maintain SOP's in a suitable binder, provide Table of Contents

2. Limit distribution to only those individuals required to have the information

3. Maintain record of a distribution

4. Develop a unique, numbering system for identifying SOP's to assure accountability

5. Maintain current and effective SOP's by periodic review and revision

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LABORATORY HOUSEKEEPING

1. PURPOSE This Guide describes the quality assurance policy and procedures pertaining to laboratory housekeeping.

2. POLICY All Center for Food Safety and Applied Nutrition (CFSAN) laboratories shall be maintained in a clean and orderly fashion to assure the quality and integrity of the data generated.

3. RESPONSIBILITIES

   A. Laboratory personnel - Laboratory personnel shall be held accountable for maintaining a neat, clean and uncluttered work area. This shall include taking steps to insure that benches, cabinets, ceilings, walls and floors are kept clean and free of clutter and that any unused or nonfunctional equipment is promptly and properly stored and/or surplused.

   B. Laboratory supervisors - Supervisors shall be responsible for assuring that personnel properly maintain neat and clean working areas. Branch Chiefs shall also insure that quality assurance plans contain appropriate directives and/or SOP's necessary for proper housekeeping in the areas supervised.

   C. Study Directors - All Study Directors shall assure that all units involved in the nonclinical laboratory study have proper housekeeping procedures to help assure the quality and integrity of study data. Study Directors will discuss any deficiencies with unit management. Unit supervisors are responsible for insuring deficiencies are corrected.

4. PROCEDURES

   A. Laboratory - Specific procedures necessary to maintain laboratory areas shall be incorporated as part of the Division quality assurance plans and/or nonclinical laboratory study SOP's.

C. Facilities - For areas pertaining specifically to the FB-8 facility, i.e., floors, walls, ceiling, etc., personnel should contact the Washington Facilities Section, Building Operations Branch, HFA-260 for assistance.

At MOD I, personnel should contact the Beltsville Research Facilities Section, HFA-265.