



TITLE:

FMD-142: Technical Assistance

ORIGINAL EFFECTIVE DATE:
[SEPTEMBER, 1 1995]

Sections included in this document

1. Purpose..... 1

2. Scope..... 1

3. Responsibility 1

4. Background..... 1

5. References..... 2

6. Procedure 2

 6.1 Technical Assistance Opportunities 2

 6.2 Requesting Technical Assistance 3

7. Glossary/ Definitions 5

8. Records..... 6

9. Supporting Documents..... 6

10. Document History..... 6

11. Change History 6

12. Attachments 6

1. Purpose

To provide ORA field management with procedures for obtaining technical expertise or assistance for inspections, investigations and training operations.

2. Scope

This document applies to the Office of Regulatory Affairs, both Headquarters and Field Operations.

3. Responsibility

It is the responsibility of the field offices to request technical assistance for inspections, investigations, training, etc. as needed following the process described herein. It is the responsibility of the appropriate headquarters unit to respond to field requests following this procedure.

4. Background

The need for specialized technical expertise and assistance in FDA becomes more evident as technological innovations are increasingly adopted by FDA regulated industry. Meeting the



TITLE:

FMD-142: Technical Assistance

ORIGINAL EFFECTIVE DATE:
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demands presented by a complex industry is a shared responsibility throughout FDA and may be met by reaching out for specific expertise from ORA and Center subject matter experts.

When used, technical assistance during inspections and investigations has shown significant advantages. These advantages include: the ability to provide efficient, in-depth technical coverage; less chance for misinterpretation or erroneous observation; expediting center reviews; and on-the-job training (OJT) for field staff.

Additionally, training performed by technical experts increases the knowledge of the field staff, allowing for the dissemination of specialized knowledge obtained by technical experts such as National Experts (NEs), Program Experts (PEs) and Center Experts. These interactions also allow for developmental growth of field, HQ and Center staff further bolstering succession plans of the agency.

5. References

N/A

6. Procedure

6.1 Technical Assistance Opportunities

ORA field managers and operating personnel should be alert for instances where significant benefits may result from local use of specialized technical resources. This includes both inspectional/investigational assistance and training provided locally by NEs, PEs and Center Experts when specific knowledge is required. When potential benefits are not clear but possibilities exist, the pending situation should be reviewed in terms of desired outcomes, to assist in making decisions.

With our emphasis on excellence in inspectional work and increasingly complex, novel and/or sensitive in nature inspections and investigations, field managers are encouraged to utilize the technical expertise available in the Agency to an even greater extent.



TITLE:

FMD-142: Technical Assistance

ORIGINAL EFFECTIVE DATE:
[SEPTEMBER, 1 1995]

Such expertise is available from ORA Office of Operations (OO) through the Office of Food and Feed Operations (OFFO)/Division of Food and Feed Program Operations and Inspections (DFFPOI)/Food and Feed Program Operations Branch (FFPOB) and Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO)/Medical Products and Tobacco Operations Branch (MPTPOB) national experts, program experts, as well as Center engineers, commodity specialists and scientists.

The expertise of these individuals fall into many areas of science and product processing including, but not limited, to the following state of the art technology: firms with non-compliant histories, specialized training, course instructors, technical review, special investigations, manufacture of complex sterile drugs and medical devices, low acid canned food processing, large and small volume parenteral manufacturing, epidemiology, mechanical, electrical, chemical and bioengineering, quality engineering, quality assurance, good manufacturing practices, computer processing, good laboratory practices, blood and biologic products, veterinary drugs, produce, etc..

While a list of national experts and their area(s) of expertise would probably be of some value because of the all-encompassing nature of the expertise available to us, such a list is impossible to prepare without missing someone. We therefore suggest that you keep the above in mind and follow the procedures below to obtain needed expertise to conduct joint inspections or request of specialized training. Technical assistance is available for all program areas, products and situations.

6.2 Requesting Technical Assistance

6.2.1 Contacting Headquarters

6.2.1.1 When specialized knowledge and skills are needed and not available locally, or within the Region, assistance should be requested from OO through the appropriate branch, FFPOB or MPTPOB. To initiate the process, the individual district (DD, DIB, etc.) should contact one of the following individuals, identified in Table 1, for their specific commodity need.



TITLE:

FMD-142: Technical Assistance

ORIGINAL EFFECTIVE DATE:
[SEPTEMBER, 1 1995]

6.2.1.2 The initial request should be by telephone. This should be confirmed with a written request which includes the following information:

- a. Nature of assistance required (Inspection/Investigation/Training/Audits)
- b. National expert, program expert or other individual desired to provide assistance (Assistance will be provided by HQs to ensure the correct resource is used)
- c. Dates assistance required/desired
- d. If an inspection; firm name, address, background, lead district investigator
- e. If an investigation, information regarding the background of the case
- f. If for training; areas to be covered, number of participants, nature of audience, location, formal or on-the-job, etc.

6.2.1.3 FFPOB/MPTPOB will contact the requester to discuss their ability to meet the request. Alternate suggestions will be discussed at this time. FFPOB/MPTPOB will provide written confirmation of arrangements made to provide the requested assistance. Headquarters will normally fund the travel for the assistance. There are times, depending on the nature of the request; the requesting office may be requested to provide funding. This will be discussed with the requesting organization.

6.2.1.4 When subject matter expertise is required from a Center office, the appropriate ORA HQ Branch Chief will work with the applicable Center program office to identify that expertise and arrange for the assistance to be provided.

Table 1-Commodity Specific Contacts

Medical Products and Tobacco			
Monica Caphart	Chief, Medical Product and Tobacco Operations Branch	301-796-5406	Commodities: Drug, Computer and BIMO
Kevin A. Gonzalez	Chief, Medical Product and Tobacco Operations Branch	240-402-0550	Commodities: Medical Device, Biologics and Tobacco



TITLE:

FMD-142: Technical Assistance

ORIGINAL EFFECTIVE DATE:
[SEPTEMBER, 1 1995]

Food and Feeds

Eric Pittman	Chief, Food and Feed Program Operations Branch	312-596-4259	Foods: LACF/AF, Seafood, Produce, Nut Butters, Infant Formula, Dietary Supplements, etc. Feeds: BSE, Medicated Feeds, Tissue Residue, Animal Husbandry, Non-Medicated Feeds, etc.
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7. Glossary/ Definitions

DDFPOI: Division of Food and Feed Program Operations and Inspections

DMPTPO: Division of Medical Products and Tobacco Program Operations

FFPOB: Food and Feed Program Operations Branch

HQ: Headquarters

MPTPOB: Medical Products and Tobacco Program Operations Branch

NE: National Expert

OFFO: Office of Food and Feed Operations

OMPTO: Office of Medical Products and Tobacco Operations

OO: Office of Operations

PE: Program Expert



TITLE:

FMD-142: Technical Assistance

ORIGINAL EFFECTIVE DATE:
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8. Records

Email request from District Office

9. Supporting Documents

N/A

10. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
2.0	R	10/16/2014	ERIC S. PITTMAN, CHIEF, FFPOB KEVIN A. GONZALEZ, CHIEF MPTPOB	Ellen Morrison, Deputy Associate Commissioner for Regulatory Affairs (Operations)

* - D: Draft, I: Initial, R: Revision, C: Cancel

11. Change History

Version	Change
2.0	Updated organizational data and contact information
	Modified name from Technical Inspection Assistance to Technical Assistance
	Added PEs to the document

12. Attachments

N/A