Standard Operating Procedures

Foodborne Illness Investigation and Food Security Preparedness and Response

City of Newton Health and Human Services Department

The standard operating procedures listed below regarding foodborne illness investigation and surveillance system of complaints and outbreaks are based on the Massachusetts Department of Public Health's *Foodborne Illness Investigation and Control Reference Manual.*

Newton is committed to thoroughly investigate complaints received regarding foodborne illness and injury.

I. Investigation Procedures

a. Designated and qualified individuals

Newton Department of Health and Human Services has designated that the following people are trained in foodborne illness complaints and outbreaks: 4 environmental health specialists, 1 public health nurse. The Commissioner of the Newton Department of Health and Human Services will provide the above individuals with additional support and guidance when necessary.

When a complaint is received the administrative assistant will forward the complaint to any of the environmental health specialists investigating official (environmental health inspector or public health nurse). If the call received relates to a foodborne illness that is *confirmed by a laboratory, the MDPH, and/or the healthcare provider,* the information should be forwarded to one of the *public health nurses*. The public health nurse may also receive this information via MAVEN, the computer system used statewide to monitor communicable diseases. If the call received relates to a foodborne illness that is a *complaint and unconfirmed,* the information should be forwarded to one of the *environmental health specialists.* If the call received relates to a *foodborne injury*, the call shall be forwarded to one of the *environmental health specialists*.

b. Contact Information

If any of the designated personnel above have questions regarding investigating foodborne illness complaints and outbreaks, they are advised to contact the following:

<u>Massachusetts Department of Public Health:</u>

Food Protection Program: 617-983-6700 (fax: 617-983-6770)

Division of Research and Epidemiology: 617-624-5600 (fax: 617-624-5698)

State Laboratory Institute: 617-983-6200 (fax: 617-983-6210)

c. Contract with state epidemiological investigation program

An understood agreement with the Massachusetts state epidemiological investigation program can be found in the MA DPH Foodborne Illness Investigation and Control Reference Manual. This agreement outlines that in the event of a foodborne illness investigation, findings will be reported from the Health Department to the State of Massachusetts and the roles, duties, and responsibilities of each party are identified.

Chapter 6 in the MDPH reference manual indicates the roles, duties, and responsibilities of each party involved in the epidemiological investigation and the steps to take to conduct an investigation.

d. Logs and databases and the intake of information

Logs and databases of foodborne illness complaints are maintained in the City's shared drive and have been kept since 2007. The foodborne illness log contains the following fields: Case number, date received, date of investigation, establishment name, address, type of complaint, confirmed illness, samples submitted, inspector, date of inspection, and result of inspection see Appendix A. Prior to conducting an inspection, the environmental health specialists will call the complainant and fill out a foodborne illness intake form (Appendix B- 105 CMR 590.000) An inspection will take place of the food implicated in the complaint. There is a click-off section at the beginning of the report indicating that the following inspection is a foodborne illness complaint. This record will be tied to the restaurant's electronic file and can be reviewed at any time. The environmental health specialists will also fill out the Foodborne Illness Complaint Worksheet, Summary Report, and complete a HACCP Risk Assessment (Appendix C). The procedures and guidance that is used for collecting information on the suspect foods' preparation, storage, or handling during on-site illness, food injury or outbreak investigations comes from the 2009 FDA Food Code for correct food safety techniques for preventing foodborne illness and the MDPH Foodborne Illness Investigation and Control Reference Manual.

In addition to the logs and databases the environmental health inspectors keep for complaints, the public health nurse maintains a database of all confirmed foodborne illness cases that is connected to the state. The public health nurse receives a case report through the Massachusetts Virtual Epidemiologic Network or MAVEN, or by phone call. She then will answer every question in the question package and will submit the information. If the illness in question is a foodborne illness, the MAVEN system will prompt the public health nurse to send a Foodborne Illness Investigation worksheet (Appendix B) to the state Food Protection Program.

e. Reporting and follow-up requirements

The public health nurse will take certain actions and follow-up in certain ways depending on the confirmed foodborne illness in question. There are a certain set of procedures depending on the person involved (ex: food handler), or disease involved. These distinctions and procedures can be found in the Massachusetts Department of Public Health Guide to Surveillance, Reporting, and Control 2nd Edition (2006).

The results of what the environmental health inspectors find at the restaurant in question will determine the steps they will take to follow up. If they find that the food in question was prepared properly following the correct food safety steps according to the most recent edition of the FDA Food Code, there is no further follow-up necessary. If the person calling requests a call back, the environmental health inspectors will return the call. If the inspectors find that the food in question was in fact prepared incorrectly, employee hygiene practices are questionable, or any other source of potential foodborne illness was not addressed according to the most recent edition of the FDA Food Code, corrective action will be taken with the restaurant depending on the severity of the violation. Foods that are blatantly contaminated will be discarded and foods that pose an imminent health hazard will result in emergency closure or suspension order (several infected food handlers, lack of refrigeration, etc…)

f. Informing appropriate law enforcement agencies

In the case of intentional food contamination, law enforcement authorities would be notified. The public health nurse or the environmental health inspector would be responsible for notifying dispatch at the Newton Police Department 617-796-2100, who would then take over the investigation. The environmental inspectors or public health nurse would provide any applicable documentation to the case and assist in any way they could. In addition to the Newton Police Department, state and federal agencies would also be notified in certain circumstances. If the product was shipped interstate, the state Food Protection Program would be contacted. If the product in question originated outside the agency's jurisdiction or has been shipped interstate, the FDA would be notified. The environmental health inspectors have the authority to embargo any of these products in question according to 105 CMR 590.116.

2. Reporting Procedures

a. Sharing Reports

Possible contributing factors to a foodborne illness, food-related injury, or intentional food contamination are identified in each on-site investigational report. This is true for both confirmed foodborne illnesses, and complaints that yield confirmed poor food safety technique that could directly lead to the unconfirmed foodborne illness complaint. The environmental health inspectors will continue to note the possible contributing factors on their intake form, and on their electronic inspection report of the restaurant. The MDPH Manual recommends that the environmental inspectors use the

HACCP form and their own intake forms when conducting on-site investigation/inspections. This intake form is the normal inspection form that the Environmental Health Specialists use to inspect a restaurant, except "Foodborne Illness Complaint" would be selected in the drop down menu (Appendix D).

According to the MDPH Manual, local boards of health are not required to report a foodborne illness complaint to MDPH. However, local boards of health are required to report any and all suspected foodborne illness outbreaks and one case of botulism, or one case of chemical poisoning to MDPH, the Food Protection Program, and the MDPH Division of Epidemiology within 24 hours.

Reports will be shared with the state epidemiologist and all disease outbreaks will be shared with the state epidemiologist and the CDC.

3. Laboratory Support Documentation

Chapter 6 of the MDPH Manual indicates that the Division of Diagnostic Laboratories and the State Laboratory Institute (SLI) is willing and able to provide analytical support to the jurisdiction's food protection program. It is also indicated in Chapter 6 the type of sample collection and submission of certain contaminants.

In the event that the MDPH State Laboratory is not available to assist Newton with this type of laboratory service, G&L Laboratories located in Quincy, Massachusetts would be contacted.

G&L Laboratory: 617-328-3663 (fax: 617-472-0706)

4. Trace-back procedures

The MDPH Manual outlines the procedure for the trace-back of foods. When conducting a foodborne illness investigation the environmental health staff would also ask for vouchers or invoices from the restaurant in question to determine the origination of the suspect food item. In Appendix E there is a log that outlines the trace back procedure of foods. In the case that the trace-back of foods indicates a foodborne illness from a certain product, Newton will alert the MDPH of this finding, and the MDPH will be responsible for alerting food safety authorities on the federal level.

5. Recalls

Recalling foods in a foodborne illness outbreak; responsibility and verification processes

In the event of an illness, outbreak, or intentional food contamination that a food item needs to be recalled, the environmental staff will notify MDPH Food Protection Program who will notify users on the HHAN (Health and Homeland Alert Network) depending on its severity and take care of all recall procedures. These procedures are similar to 21 CFR Part 7 that indicate (Appendix F). In the case that the food item that

needed recalling originated in Newton, the environmental staff would document that the food item was removed from factory/store shelves via the embargo form (Appendix G). The inspectors can also physically remove the affected foods according to the embargo procedure seen in Appendix H.

6. Media Management

Providing information to the public

Newton has a written Emergency Risk Communication Plan contained in Appendix I that illustrates the media response in the event of a food safety emergency. According to the plan, the Commissioner of Health would be responsible for addressing the media and would cooperate and coordinate with other agencies involved in the investigation.

7. Data Review and Analysis

Newton will conduct a yearly review of the data in the complaint log in order to identify trends and possible contributing factors that are most likely to cause foodborne illness. The review will focus on multiple complaints on the same establishment, complaints on the same establishment type, complaints implicating the same food, complaints associated with similar food preparation processes, number of confirmed foodborne disease outbreaks, number of foodborne disease outbreaks and suspect disease outbreaks, contributing factors most often identified, number of complaints involving real and alleged threats of intentional food contamination, number and complaints involving the same agent and any complaints involving unusual agents when agents are identified.

In the event that Newton has had zero confirmed foodborne illnesses during the twelve months prior to the analysis, a mock investigation will be completed using the above standard operating procedures. The FDA has provided a variety of table top exercises to test our foodborne illness standard operating procedures called FREE-B (Food Related Emergency Exercise Bundle). These exercises are offered on the FDA website (www.fda.gov/ and can be easily printed out and completed in a reasonable amount of time.

Appendix I

Introduction

The Newton Department of Health and Human Services provides health alerts and warnings to the public, as well as health-related public information, during local emergency response. Health alerts and public information may address:

- Protective actions to prevent the spread of disease
- Protective actions in hazardous materials releases
- Health-related effects of exposure to harmful biological, chemical, or radiological agents
- Boil Water Orders, Unsafe Water Alerts, and food safety information
- Isolation/quarantine orders and information

Preparation

1. Meet with the Local or Regional Emergency Management Agency to obtain procedures for requesting activation of the Emergency Alert System (EAS).

2. Prepare pre-scripted EAS messages for health and medical emergency response public information, alert, and warning. Maintain pre-scripted EAS and public information on computer hard drives with backup versions on CD-ROMs.

3. Prepare pre-scripted fact sheets and public information/education for bioterrorism-related events, isolation/quarantine, and mass prophylaxis.

4. Prepare pre-scripted Boil Water Orders, Unsafe Water Alerts, and Food Safety Alerts.

5. Identify translation needs for the community and translate pre-scripted EAS and public information, as needed.

6. Contact local news media to provide information on the Newton Department of Health and Human Services emergency response and to prepare a Media Plan with input from local media representatives.

Pre-Event Planning for Risk Communication[1]

[1] The Risk Communication Response Action Checklist and Instructions are excerpted from the MDHP Risk Communication Plan Template for Local Boards of Health, June 2004.

PRE-EVENT PLANNING CHECKLIST	INSTRUCTIONS
☐ Meet with fire, police, emergency management and hospital representatives to determine risk communication responsibilities for your community. ☐ Determine in advance who is responsible for signing and approving health alerts, warnings, and press releases. ☐ Determine in advance who is responsible for announcing health alerts, warnings, or press releases. ☐ Designate official spokespersons to provide the following types of information: ▪ Warnings to the public on unsafe areas, areas to be evacuated. Evacuation instructions or in-place-protection instructions. ▪ Warnings to the public on unsafe food, water or other consumables. ▪ Instructions to avoid health risk. ▪ Public Information on where to seek medical assistance. ▪ Instructions for worried well to avoid overloading medical providers. ▪ Instructions on self decontamination. ▪ Information on health effects of the current agent or pathogen of concern. ▪ Animal disease outbreak. ▪ Events with mass casualties.	Refer to the Newton Risk Communication Plan for additional information.

PRE-EVENT PLANNING CHECKLIST	INSTRUCTIONS
IDENTIFY RISK COMMUNICATION STAFF ☐ Spokesperson for the Department of Health and Human Services ☐ Staff to prepare FAQs and message development ☐ Media relations staff (outgoing information to media, and incoming requests for information and briefings) ☐ Staff to monitor media for rumors and situations which need correction.	Designated Health Spokesperson: Interim Commissioner of Health and Human Services, Linda Walsh Message, and content development**::** Interim Commissioner of Health and Human Services, Linda Walsh Media Relations: Director of Policy and Communications, Jeremy Solomon Media and Helpline Monitors:
IDENTIFY EXPERTS TO ASSIST ☐ Identify experts in the community to give advice on health effects of radiation, chemical agents, and unusual diseases. ☐ Identify experts ahead of time for assistance with zoonotic diseases and vector borne diseases.	Radiation experts: 617-242-3035 & 617-242-3453 *Monday-Friday 9-5* **Any other time:** 617-242-3453 (*Rings through to MA State Police*); 508-820-2121 (*MA State Police direct line*); or,508-820-2000 (*MA Emergency Management Agency*) Chemical experts: would this just be a poison control center Unusual disease experts: Veterinarians: Animal Inspectors, Dr. Elizabeth Shepherd Dr. Jeff Giles 781-433-0467 Vector control:
ASSEMBLE COMMUNICATION AIDS	

PRE-EVENT PLANNING CHECKLIST	INSTRUCTIONS
COORDINATE WITH NEIGHBORING JURISDICTIONS ☐ Establish contact with counterparts in neighboring jurisdictions; decide on a procedure for maintaining uniformity of information in public information releases during an event which crosses boundaries.	Neighboring jurisdiction contacts: See Contacts in Neighboring Communities TAB A, above
COMMUNICATIONS SYSTEMS ☐ Identify alert and information communication systems available in the community to address the public and the means of activation and/or contact. ☐ Identify alert and warning systems in the community to reach clinicians, veterinarians and other medical care providers.	Emergency Alert System (EAS): *(Contact method: telephone #, radio call sign, etc.)* Approval for releases/alerts on the EAS is required from: Interim Commissioner of Health and Human Services, Linda Walsh Automatic telephone dialing systems *(Contact method: telephone #, radio call sign, etc.)* Approval for releases /alerts on the automatic dialing system is required from: Interim Commissioner of Health and Human Services, Linda Walsh Broadcast fax to medical providers: *(Contact method: telephone #, radio call sign, etc.)* Approval for releases /alerts on the Broadcast Fax is required from: Interim Commissioner of Health and Human Services, Linda Walsh

PRE-EVENT PLANNING CHECKLIST	INSTRUCTIONS
HELP-LINE COMMUNICATIONS ☐ Identify staff or volunteers to work in any helpline center in public health (or at an EOC). ☐ Identify staff and volunteers who can communicate in languages other than English (if necessary for the area). ☐ Review or establish content approval authorities and procedures for HelpLine staff. ☐ Review content approval requirements for the Department of Health and Human Services web site.	*Insert contact information (name, phone) for HelpLine staff and volunteers. (See below)* Helpline staff: Help Line content approval is required from: Interim Commissioner of Health and Human Services, Linda Walsh Website content approval is required from: Interim Commissioner of Health and Human Services, Linda Walsh

Response Actions for Risk Communication

RESPONSE ACTION CHECKLIST	INSTRUCTIONS
CRISIS RESPONSE	
☐ Receive information regarding a public health emergency. ☐ Verify information ☐ Report to incident scene and Incident Commander. Request a briefing. ☐ Or, report to a designated Emergency Operations Center (EOC) Incident Commander/EOC Director. Request a briefing. ☐ OR assist IC with health alerts from office. ☐ Assist the IC with immediate protective action alerts to the public	The Newton Department of Health and Human Services may become aware of a public health emergency when information is received from: ▪ Hospitals, clinics, or physicians ▪ On-scene incident command ▪ Data from on-going or increased surveillance ▪ Information from Massachusetts Department of Public Health, the CDC or other government agency.
<u>If the situation is unfolding slowly and there is time:</u> ☐ Obtain copies of current situation reports from the ICS Plans Section, if applicable. ☐ At the request of the Commissioner of Health and Human Services, prepare draft health information releases for the public and the media. ☐ Establish and maintain contact, as appropriate, with other public information personnel in other departments, jurisdictions, on-scene, and at the EOC to determine what public information has already been disseminated. ☐ Determine single point of information release. ☐ Determine and observe constraints on the release of information imposed by the IC, or the EOC Director. ☐ Determine staffing needs for the PIO. ☐ Arrange for assistance from designated	Newton Emergency Operations Center Public Information Officer (PIO): Director of Policy and Communication, Jeremy Solomon MA Department of Public Health PIO: Neighboring jurisdiction Department of Health PIO: Health alerts, warnings, medical statements releases and instructions are approved by: Interim Commissioner of Health and Human Services, Linda Walsh

RESPONSE ACTION CHECKLIST	INSTRUCTIONS
staff or identified experts to communicate medical and technical information. ☐ Forward draft health /medical statements, warnings, releases or instructions for approval. **MEDIA RELATIONS TASKS** ☐ Disseminate releases to the media after approval. ☐ Arrange for meetings between the media and Department of Health and Human Services incident personnel. ☐ Provide escort service to the media and VIPs. ☐ Maintain documentation of public information and news media releases. ☐ Maintain documentation of response costs, including equipment; overtime labor hours, and mileage. ☐ At a shift change, provide a detailed status report and all written materials to replacement staff. **MESSAGE LINE AND HELP LINE TASKS** ☐ Coordinate set-up of a HelpLine call center for the general public. Obtain required approval for content of HelpLine messages. .Prepare pre-recorded messages for the telephone line. ☐ As necessary, identify staff to assist with Help Line call center.	

TABLE 1 – DETERMINATION OF RESPONSIBILITY FOR RELEASE OF PUBLIC INFORMATION			
Circumstance	**Agency Preparing Public Information**	**Approval required by (or not applicable –NA)**	**Contact: work / home/ cell/ pager**
Unsafe areas - health	Department of Health and Human Services	Interim Commissioner of Health and Human Services, Linda Walsh	617-796-1420 (w) 978-263-5893 (h) 617-504-8190 (c)
Evacuation or in-place sheltering	Police Department	**????**	
Unsafe consumables	Department of Health and Human Services	Interim Commissioner of Health and Human Services, Linda Walsh	617-796-1420 (w) 978-263-5893 (h) 617-504-8190 (c)
Health precautions	Department of Health and Human Services	Interim Commissioner of Health and Human Services, Linda Walsh	617-796-1420 (w) 978-263-5893 (h) 617-504-8190 (c)
Medical assistance	????		
Worried well	Department of Health and Human Services	Interim Commissioner of Health and Human Services, Linda Walsh	617-796-1420 (w) 978-263-5893 (h) 617-504-8190 (c)
Self Decontamination	Police Department		
Health effects	Department of Health and Human Services	Interim Commissioner of Health and Human Services, Linda Walsh	617-796-1420 (w) 978-263-5893 (h) 617-504-8190 (c)
Outbreak in animal population	Department of Health and Human Services	Interim Commissioner of Health and Human Services, Linda Walsh	617-796-1420 (w) 978-263-5893 (h) 617-504-8190 (c)
Mass casualty events	Police Department		

APPENDIX A

FOODBORNE ILLNESS, FOOD-RELATED INJURY FOOD CONTAMINATION / TAMPERING LOG

CASE NUMBER	DATE RECEIVED	DATE OF INVESTIGATION	NAME OF ESTABLISHMENT	ADDRESS	TYPE OF COMPLAINT
2014-1					

FOODBORNE ILLNESS, FOOD-RELATED INJURY FOOD CONTAMINATION / TAMPERING LOG

CONFIRMED CASE?	TYPE OF CONTAMINATION	NOTIFIED LAW ENFORCEMENT	SAMPLES SUBMITTED?	INSPECTOR

FOODBORNE ILLNESS, FOOD-RELATED INJURY FOOD CONTAMINATION / TAMPERING LOG

FINAL DISPOSTION	FOLLOW-UP REQUIRED?	NOTIFIED

Massachusetts Department of Public Health
FOODBORNE ILLNESS COMPLAINT WORKSHEET

Date: ___/___/___
#: _____

Please Complete and Send or Fax to:
MDPH Food Protection Program
305 South Street, Jamaica Plain, MA 02130
Fax: (617) 983-6770

Questions? Call:
Food Protection Program: (617) 983-6712
Division of Epidemiology: (617) 983-6800
Enterics Laboratory: (617) 983-6609

PERSON COMPLETING INFORMATION

Name: _____ ☎: ( ) _____ - _____

Affiliation: ☐ Local BOH *(town)*: _____ ☐ State DPH *(division)*: _____ ☐ Other: _____

REPORTER / COMPLAINANT

Name: _____ ☎: ( ) _____ - _____

Affiliation: ☐ Consumer ☐ Laboratory ☐ Local BOH ☐ Medical Provider ☐ State DPH ☐ Other

specify: → division, *facility*, address, *town, etc.* _____ _____ _____

ILLNESS INFORMATION

Persons ill: ☐

Symptoms: *(mark if reported for anyone):*

☐ Diarrhea ☐ Vomiting ☐ Nausea ☐ Abdominal cramps
☐ Fever ☐ Bloody stool ☐ Headache ☐ Muscle aches
☐ Chills ☐ Loss of appetite ☐ Fatigue ☐ Dizziness
☐ Burning in mouth ☐ Other symptoms: _____

Onset: →
Earliest Date: ___/___/___ Time: ___:___ ☐AM ☐PM
Latest (if > 2 ill) Date: ___/___/___ Time: ___:___ ☐AM ☐PM

Duration: ☐ Less than 24 Hours ☐ 24-48 Hours ☐ More than 48 Hours ☐ Ongoing ☐ Unknown

Ill Persons:

	Name	Address/Town	☎	Age (yrs)	Occupation	Med. Provider/☎
1	☐ same as reporter (above)					
2						
3						
4						

Medical attention received *(by anyone)*? ☐ Yes ☐ No ☐ Unknown → *If Yes, specify above:* ↑

Stool specimens submitted *(by anyone)*? ☐ Yes ☐ No ☐ Unknown → To SLI [1]? ☐ Yes ☐ No ☐ Unknown

Medical diagnosis reported?

FOOD HISTORY

→ Obtain history back 72 hours prior to symptoms, or if organism identified, between min / max incubation periods (p.2)

→ If > 2 ill, follow above time frame for common meals (foods) only

Date & Time[2]	# Exp[3]	Food(s) consumed	Restaurant / store where purchased (name, town)	Place consumed
☐ B ☐ L ☐ D				☐ Same *(as left)* ☐ Home ☐ Other *(specify)*:

1 State Laboratory Institute, 305 South St., Jamaica Plain, MA, 02130 - (617) 522-3700
2 Always record Time if possible; otherwise, choose B=breakfast, L=lunch, D=dinner

FOOD HISTORY *(continued)*

Date & Time[2]	# Exp[3]	Food(s) consumed	Restaurant / store where purchased (name, town)	Place consumed
☐ B ☐ L ☐ D				☐ Same *(as left)* ☐ Home ☐ Other *(specify)*:
☐ B ☐ L ☐ D				☐ Same *(as left)* ☐ Home ☐ Other *(specify)*:
☐ B ☐ L ☐ D				☐ Same *(as left)* ☐ Home ☐ Other *(specify)*:
☐ B ☐ L ☐ D				☐ Same *(as left)* ☐ Home ☐ Other *(specify)*:
☐ B ☐ L ☐ D				☐ Same *(as left)* ☐ Home ☐ Other *(specify)*:

NOTES

FOOD TESTING

Food(s) available for testing? ☐ Yes ☐ No ☐ Unknown → Sent to SLI [1]? ☐ Yes ☐ No ☐ Unknown

→ *If Yes, specify food(s) & sources*:

Product and Manufacturer Information for Commercially-Processed Food(s)

Product name: _____ Code/lot # _____

Expiration date: ____/____/____ Package size/type: _____

Manufacturer: _____

Address: _____ ☎: ( ) ____ - ____

Incubation Periods for Selected Organisms

	Min	Max		Min	Max		Min	Max
B. cereus (short)	1 hr	6 hrs	E. coli O157:H7	3 days	8 days	Staph. aureus	30 min	8
B. cereus (long)	6 hrs	24 hrs	Hepatitis A	15 days	50 days	Shigella	12 hrs	96 hrs
Campylobacter	1 day	10 days	Salmonella (non-typhi)	6 hrs	72 hrs	Vibrio cholerae	few hrs	5 days
Cyclospora	1 day	14 days	Salmonella typhi	1 wk	3 wks	Viral GI	12 hrs	48 hrs
C. perfringens	6 hrs	24 hrs	Shellfish poisoning	minutes	few hrs	Yersinia	3 days	7 days

1 State Laboratory Institute, 305 South St., Jamaica Plain, MA, 02130 - (617) 522-3700

2 Always record Time if possible; otherwise, choose B=breakfast, L=lunch, D=dinner

APPENDIX C

Foodborne Illness Complaint
Environmental Investigation Summary Report

Fax or Mail to: MA Department of Public Health
305 South St.
Jamaica Plain, MA 02130
Att: Foodborne Illness Response Coord.
Tel: 617-983-6712 Fax: 617-983-6770

Establishment	**Type of Operations**
Address City/Town	☐ Food Service
Date Complaint Received	☐ Retail
Date(s) Investigated	☐ Residential Kitchens
Implicated Food(s)	☐ Mobile
Implicated Pathogen: No. of Persons ill:	☐ Temporary
	☐ Caterer
	☐ Bed & Breakfast

Were any food employees ill in the two weeks prior to the suspect event?	YES	NO
Did any food employee become ill* after the suspect event?	YES	NO
Were any food employees tested?	YES	NO

Food Samples Collected From: ☐ CONSUMER ☐ FOOD ESTABLISHMENT ☐ WHOLESALE MANUFACTURER / DIST.

** diarrhea, vomiting, fever, sore throat with fever, infected cuts or lesions, jaundice*

A. Recent Compliance History

1) Date of Most Recent Inspection Prior to Complaint:

Attach copy of most recent inspection report issued prior to complaint.

B. Risk Assessment of Suspect Food *(Required)*

Attach your HACCP based risk assessment of the suspect food(s) or process(es). Include food source, volume prepared, preparation steps (who, how, where, when), monitoring procedures used, identification of critical control points and any corrective actions that were taken if necessary to correct inadequate monitoring procedures.

If you need assistance with your risk assessment, please call the MDPH Food Protection Program at 617-983-6712.

C. Level of Regulatory Compliance Noted During On-site Investigation(s)

Attach copy of inspection report form, if issued.

IN (In Compliance) **OUT** (Out of Compliance) **NA** (Not Applicable) **NO** (Not Observed)

Management and Personnel

1. PIC assignment, knowledge, duties and responsibilities	IN	OUT		
2. Food employees aware of employee health reporting requirements	IN	OUT		
3. Handwashing frequency and procedures adequate	IN	OUT		
4. Handwashing sinks accessible and supplied with water, soap and towels	IN	OUT		
5. No bare-hand contact with ready-to-eat foods	IN	OUT	NA	NO
6. If gloves used, procedures are adequate	IN	OUT	NA	NO

C. Level of Compliance Noted During On-site Investigation(s) *(Continued)*

Other Risk Factors and Major Interventions

1. Food and water from approved sources	IN	OUT		
2. Cooking PHFs	IN	OUT	NA	NO
3. Reheating of PHFs	IN	OUT	NA	NO
4. Cooling of PHFs	IN	OUT	NA	NO
5. Hot and cold holding of PHFs	IN	OUT	NA	NO
6. Calibrated food thermometer available	IN	OUT		
7. Prevention of cross-contamination of RTE foods with raw ingredients	IN	OUT	NA	NO
8. Protection of food/ food contact surfaces	IN	OUT		
9. Cleaning and sanitization of food contact surfaces	IN	OUT		
10. Storage and use of toxic chemicals	IN	OUT		
11. Mandatory HACCP and risk control plans	IN	OUT	NA	NO
12. Highly susceptible populations (HSP) requirements	IN	OUT	NA	NO
13. Consumer advisory requirements	IN	OUT	NA	NO

D. Corrective and Enforcement Actions

Please check the type(s) of corrective or enforcement actions that were taken in response to this complaint.

- ☐ Order for Correction Issued to correct violations relating to:
  - ☐ Risk factors and major interventions ☐ Good retail practices
- ☐ Food Employee / Food Handling Procedures & Policies Modified
- ☐ Embargo
- ☐ Voluntary Disposal
- ☐ Food Employee Restriction/Exclusion
- ☐ Emergency Suspension or Closure
- ☐ Food Employee/ PIC Training
- ☐ Press Release/ News Alert
- ☐ Equipment /Physical & Sanitary Facilities Modified /Upgraded
- ☐ None
- ☐ Other: (Describe Below)

Completed By: _____ **Title:** _____

Agency: _____ **Date** _____

REMINDER: ***Please submit the following documents along with this form to the MA Department of Public Health***

A Copy of Most Recent Inspection Report Issued Prior to Complaint

B. HACCP Risk Assessment and Related Environmental Data

C Inspection Report Form(s) and Related Enforcement Documents

Mail or Fax To: **MDPH Food Protection Program**
305 South Street
Jamaica Plain, MA 02130
Attention: Foodborne Illness Response Coordinator

Tel. Number: (617)983-6712
Fax Number: (617)983-6770

On the F Drive Template

HACCP RISK ASSESSMENT

City/Town of:_____

Product/ Process:		ESTABLISHMENT NAME
INGREDIENTS	Source	ADDRESS
		PERSON IN CHARGE
		INFORMATION FOR THIS RISK ASSESSMENT WAS OBTAINED BY: ☐ Observation Of Suspect Food/Process ☐ Observation Of General Food Handling and Sanitation Practices ☐ Interview With Food Employee Responsible For Preparing Implicated Food. ☐ Interview With Person-In-Charge Or Other Employee
Weight/Volume of Suspect Food Prepared or Served:		Dates of Investigation:

PLEASE PRINT CLEARLY

	Describe Product Flow (Preparation Steps) Who, What, Where, When	Describe Environmental Data Collected to Verify Control or Lack of Control of Hazards	HAZARDS Contamination Survival Proliferation	Describe Corrective and Preventive Measures Initiated (Include changes in food handling procedures, orders for correction, embargoes/disposals, food employee restrictions, food safety training, emergency suspensions and closures, etc.)	Date Verified
☐CCP					
☐CCP					
☐CCP					
☐CCP					

Page No.___ Of ____

HACCP RISK ASSESSMENT

City/Town of: _____ _____

Product/ Process:		ESTABLISHMENT NAME
INGREDIENTS	Source	ADDRESS
		PERSON IN CHARGE
		INFORMATION FOR THIS RISK ASSESSMENT WAS OBTAINED BY: ☐ Observation Of Suspect Food/Process ☐ Observation Of General Food Handling and Sanitation Practices ☐ Interview With Food Employee Responsible For Preparing Implicated Food. ☐ Interview With Person-In-Charge Or Other Employee
Weight/Volume of Suspect Food Prepared or Served:		Dates of Investigation:

PLEASE PRINT CLEARLY

	Describe Product Flow (Preparation Steps) Who, What, Where, When	Describe Environmental Data Collected to Verify Control or Lack of Control of Hazards	HAZARDS Contamination Survival Proliferation	Describe Corrective and Preventive Measures Initiated (Include changes in food handling procedures, orders for correction, embargoes/disposals, food employee restrictions, food safety training, emergency suspensions and closures, etc.)	Date Verified
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Page No.___ Of ____

Food Analysis

Water Testing

Pet Product Analysis

Air Quality Testing

Environmental Analysis

Fuel Testing

Consumer Product Testing

Cosmetics Product Analysis

Medical Device Testing

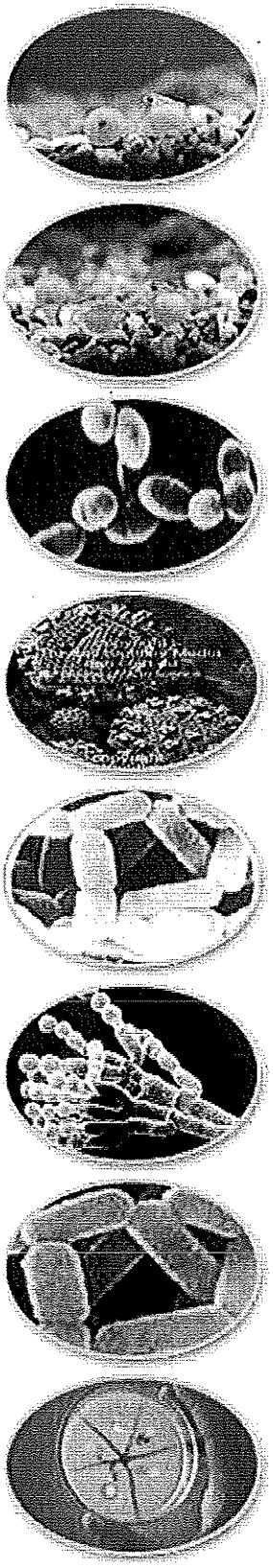
Pharmaceutical Testing

Soil Testing

Microbiology Testing

We offer a full range of quantitative microbiology testing services for wide varieting objects. We can perform the following tests:

Acetophiles	Listeria Momocytogenes
Acid Tolerant Bacteria	Listeria Momocytogenes
Aerobic Plate Count	Minimum Inhibitory Concentration
Aflatoxin	Mold Identification
Anaerobic Plate Count	Osmophilic Bacteria
Aeromonas	Proteolytics
Bacillus Cereus Presumptive	Psychrophiles
Bacillus Cereus Confirmation	Pseudomonas
Bacillus Thuringensis Confirmation	Spores
Bacterial ID Verification	Salmonella
Bifido Bacterium	Shigella
Comp lobacter jejuni complete	Staphylococcus
Clostridium botulinum presumptive	Staph. aureus
Coliform, total	Strep. faecium
E. Coli	Sulfite Bacteria
Fecal coliform	Thermophiles
Flat Sours	Thermodurics
Lactic Acid Bacteria	Total Gram/Negatives
Lacto Bacillus	Yeast and Mold
Lipolytic Bacteria	Yersinia
Listeria Presumptive	Vibrio
Listeria Genus	



Genetically Modified Organisms (GMO)

GMO Presence / absence (to 0.1%) by PCR

GMO quantitative (real time) by PCR

Polymerase Chain Reaction (PCR)

Campy lobacter jejuni

E. Coli

Listeria genus

Listeria momocyto genes

Salmonella genus

Staph.aureus

Tel: (617) 328-3663 Fax: (617) 472-0706
Address: 246 Arlington St., Quincy, MA 02170
Email: info@gllab.com

Food Analysis

Water Testing

Pet Product Analysis

Air Quality Testing

Environmental Analysis

Fuel Testing

Consumer Product Testing

Cosmetics Product Analysis

Medical Device Testing

Pharmaceutical Testing

Soil Testing

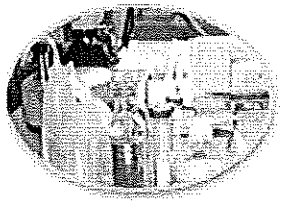
Chemical Analysis

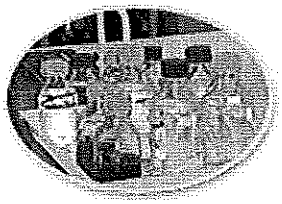
Aristolochic Acid
Amino Acids
Tryptophan
Cystine
Glutamic Acid
Acid Value
Alcohols
BHA & BHT
Bromate
Colors
Chlorophyll
Caffeine
Density
Isoflavones
Domoic Acid
Egg Solids
Formaldehyde
Free Fatty Acids
Histamine
Idole
Idoline
Light Filth
Lute in
Net Weight
Nitrate
Nitrite
Organic Acids
Pectinase Activity
Peroxidase
Peroxide Value
pH
Pigments
Salt Content
Chloride
Added Salt
Water Phase Salt
Sorbic Acids & Benzoic Acid
Sieve Test
Specific Gravity
Succinic Acid
Starch Damage
Sulfites
Strychnine
Viscosity

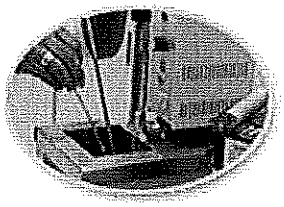
Volatiles Organics

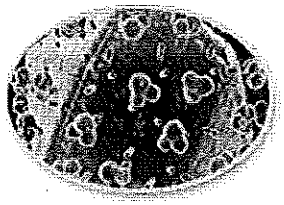
Volatile Oil

Inorganics









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APPENDIX F

CHAPTER 7 - RECALL ACTIVITIES

CONTENTS

SUBCHAPTER 7.1 - RECALLS

7.1.1 - DEFINITIONS

7.1.1.1 - Recall

A Recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers, and against which the Agency would initiate legal action (e.g., seizure). Recall does not include a market withdrawal or a stock recovery. See the Agency recall policy outlined in 21 CFR 7.1/7.59 - Enforcement Policy - General Provisions, Recalls (Including Product Corrections) - Guidance on Policy, Procedures and Industry Responsibilities.

7.1.1.2 - Recall Classification

Recall Classification is the numerical designation, i.e., I, II, or III, assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

7.1.1.2.1 - CLASS I RECALL

Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

7.1.1.2.2 - CLASS II RECALL

Class II Recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

7.1.1.2.3 - CLASS III RECALL

Class III Recall is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

7.1.1.3 - Recall Type

Recall type is a designation based on whether the recall is Voluntary, FDA Requested (at the request of the Commissioner or his/her designee), or ordered under section 518(e) of the FD & C Act [21 U.S.C 360h (e)].

7.1.1.4 - Recall Strategy

Recall strategy is a planned specific course of action to be taken in conducting a specific recall, which addresses the

depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

7.1.1.5 - Depth of Recall

Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, i.e., wholesaler, retailer, user/consumer, which is known as the depth of recall.

7.1.1.6 - Recall Number

The recall number is the number assigned, by a responsible Center, for each recalled product they initiate. This number consists first of a letter designating the responsible Center (see letter Codes below), a 3 or 4 digit sequential number indicating the number of recalls initiated by that Center during the fiscal year, and a 4-digit number (the Center for Devices and Radiological Health (CDRH) uses 2-digit numbers) indicating the fiscal year the recall was initiated. For example: F-100-2011 identifies the 100th recall initiated by the Center for Food Safety and Applied Nutrition (CFSAN) in FY-2011. The following letters are used to identify the Centers.

Letter Center/Office

F Foods - CFSAN

D Drugs - Center for Drug Evaluation and Research (CDER)

Z Medical Devices & Radiological Health - CDRH

V Veterinary Medicine - Center for Veterinary Medicine (CVM)

B Biologics - Center for Biologics Evaluation and Research (CBER)

N Medical Devices (Voluntary Safety Alerts and Notifications)

A Audit Numbers issued by the District performing the recall, the Centers, Office of Enforcement (Division of Compliance Management and Operations [DCMO], or the Division of Domestic Field Investigations (DFI) to monitor recalls requiring audit checks.

7.1.1.7 - Medical Device Notification Order

A medical device notification order is an order issued by FDA requiring notification under section 518(a) of the FD & C Act [21 U.S.C. 360h (a)]. The directive issues when FDA determines a device in commercial distribution, and intended for human use, presents an unreasonable risk of substantial harm to the public health. The notification is necessary to eliminate the unreasonable risk of such harm, and no more practicable means is available under the provisions of the Act to eliminate such risk.

7.1.1.8 - Medical Device Notification

A medical device notification is a communication issued by the manufacturer, distributor, or other responsible person in compliance with a Notification Order. It notifies health professionals and other appropriate persons of an unreasonable risk of substantial harm to the public health presented by a device in commercial distribution.

7.1.1.9 - Medical Device Safety Alert

A medical device safety alert is a communication voluntarily issued by a manufacturer, distributor, or other responsible person (including FDA). It informs health professionals and other appropriate persons of a situation which may present an unreasonable risk to the public health by a device in commercial distribution.

NOTE: Medical Device Notifications and Safety Alerts as described in IOM 7.1.1.7, 7.1.1.8, and 7.1.1.9 are to be handled by the Districts as recalls. They will go through the stages of alert, recommendation, classification, field notification, firm notification letter, firm effectiveness checks and status reports, FDA audit checks and termination recommendations.

SUBCHAPTER 7.2 - RECALL NOTIFICATION / INSPECTION

If FDA learns of a potentially violative product which may lead/has lead to a class I or significant class II recall, an inspection should be made to determine the root cause(s) of the problem(s). If the firm has failed to take appropriate corrective and preventive action, violations should be documented for possible regulatory action.

NOTE: In all discussions of violative or potentially violative products with the responsible firm, make it clear FDA is not requesting recall action. FDA requested recalls are authorized only by ORA, or by delegation of authority such as Drug Efficacy Study Implementation (DESI) recall requests.

When an investigation determines there is no evidence of manufacturing or distribution problems, but a firm has removed products from the market as a result of actual or alleged tampering with individual units, the action will be considered a Market Withdrawal. In addition, product that has been reported by a firm to be stolen and is being removed by the market by the firm will also be considered a market withdrawal. A market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments, repairs, theft, etc.

7.2.1 - INSPECTION PROCEDURES

An important part of your job is to identify the root cause for the recall and assure the firm has implemented procedures to prevent it from recurring. In some cases,

management will have conducted its own analysis and reached conclusions about the problem and its cause. The initial judgments about the problem are not always correct nor discriminating enough to identify the underlying causes. You need to verify the steps taken were sufficient in depth and scope and reflect the correct conclusions about both the problem and correction.

Determine if the firm conducted a failure analysis using techniques such as fault tree analysis or failure mode analyses. Did it consider things such as the length of time the product has been manufactured and sold, complaints or returns for the same or similar problems, any reworking of product prior to release or distribution which may have been due to the same or similar problems and, process or personnel changes which occurred about the time the problem appeared?

For all recall inspections, in addition to verifying the identification of the root cause:

1. Issue a Notice of Inspection (FDA 482);
2. Discuss the suspected problem with management and review the firm's complaint file;
3. Investigate all areas, control points and/or circumstances which may have a bearing on the product's deficiency;
4. Fully develop individual responsibility for the problem;
5. Review batch records, processing logs and/or other types of records for violative lots and associated lots;
6. Review and obtain copies of the firm's quality control/analytical data;
7. Determine any actions the firm has taken, is taking, or has planned to take to prevent similar occurrences. If corrective action is not underway, determine the firm's timetable for achieving correction; and
8. Determine what action the firm has taken or plans to take, and the time frames involved, regarding questionable product(s) remaining in commerce.

7.2.1.1 - Recall Decision Follow-up

If the firm has decided to recall, do the following:

1. Request that management obtain their FDA District's review of recall correspondence and any press releases before they are issued to prevent misunderstandings between the firm, its customers, and the FDA. This suggestion is voluntary on the part of the firm and is not required;
2. If the firm requests guidance in preparing recall communications, provide it in accordance with your District policy. See Chapter 7 of the RPM and IOM Exhibit 7-1 for an example of recall communications;
3. See RPM Chapter 7-10, Attachment B "Recommendation for Recall Classification" and 21 CFR 7.46a(1)-(9) for information to be obtained;
4. Obtain an Official Sample of the recalled product. (See IOM 7.2.6 for the collection of samples for electronic products or medical devices.);
5. Obtain a complete distribution list of all shipments of the suspect lot(s), including foreign distribution;
6. Obtain specimens or copies of all labels and labeling associated with the recalled product;
7. Obtain complete copies of all recall communications issued or planned including the text of phone conversations, and submit them to your District's recall coordinator. Look in the Blue Pages for a list of District Recall Coordinators;
8. Advise the firm on how the returned products should be handled. FDA must witness or otherwise verify the reconditioning or destruction of the products returned under the recall; and
9. Take any other steps necessary in your judgment, or that your District requires.

NOTE: At this early stage there usually has not been a recall evaluation by the appropriate Center. In the absence of such an evaluation, avoid suggesting the firm extend its recall efforts.

7.2.2 - FOOD RECALLS

Experience with food recalls dictates specific information be obtained from firms which have used recalled material in the production of another product. This is necessary to decide if the recall must be extended to a new product(s). In those instances, the following are some areas to be covered:

1. Incoming ingredient quality control procedures;
2. Quality control over ingredients at the time of use, and the products in which the ingredients are used;
3. A detailed description of the methods used in preparation and packaging of the processed product;
4. How the finished product is stored and shipped;
5. Labeling of product, and any cooking instructions for consumer or purchaser;
6. Quality control testing of the finished product. Detail any test(s) performed by firm; and
7. For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient? Did USDA determine what testing was done by the firm?

This information must be evaluated by CFSAN (HFS-607) prior to the initiation of any sub-recall.

7.2.2.1 - Interstate Milk Shippers

The FDA will not ordinarily be involved in the classification and auditing of Interstate Milk Shippers (IMS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the State(s). However, the FDA District office in which the recalling firm is located must be assured that all States involved in an IMS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, States issue warnings to protect the public health.

In the event that FDA determines that the States are unable to effect the recall actions necessary, the Agency will classify, publish, and audit the recall, including issuance of a public warning when indicated.

7.2.3 - MEDICAL DEVICE RECALLS

Medical device recalls may result from manufacturing defects, labeling deficiencies, failure to meet premarketing requirements [PMA, 510(k)], packaging defects or other nonconformance problems. How firms identify the causes of medical device recalls and corrective action activities is essential to the analysis of medical device failures and the determination of the effectiveness of the medical device GMP program. It is also useful in evaluating the medical device program, and for directing attention to problem areas during inspections. 21 CFR Part 806.1 requires device manufacturers and importers to report certain actions concerning device corrections and removals. They must also maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA. (See 21 CFR Part 806.20). Failure to report as required by 21 CFR 806.10 is a violation and should be listed on the FDA-483, "Inspectional Observations." This may be included in a direct reference Warning Letter.

Each device manufacturer or importer must submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer, if one was initiated:

1. To reduce a risk to health posed by the device; or
2. To remedy a violation of the Act caused by the device which may present a risk to health, unless the information has been provided according to 21 CFR 806.10 (f), or the correction or removal action is exempt from the reporting requirements under 21 CFR 806.1(b).

Collection of complaint, PMA and 510(k) related information is necessary to determine compliance with the GMP requirements. During recall follow-up inspections, answers should be obtained to the questions below, in addition to routine recall information. For firms where it has been established a manufacturing defect led to the recall, conduct a complete GMP evaluation of the manufacturing operations. Report such inspections into FACTS as "qualifying" GMP inspections.

7.2.3.1 - Problem Identification

1. How did the firm identify the nonconformance which led to the recall (e.g., complaint, in-house data, etc.)?
2. If the recall was due to a device defect, did the firm conduct a documented failure analysis of the device, using such techniques as fault tree or failure mode analyses? If so, report whether these results were provided for review.
   a. Did the firm determine the failure mechanism (e.g., shorted component, incomplete weld, etc.)?
   b. If not, how did firm determine the cause of the nonconformance?
   c. If not, what rationale does the firm have for not conducting a failure analysis?
3. Did the firm determine at what phase of the device life cycle the nonconformance occurred (i.e., design, manufacturing, storage, use, etc.) and the actual cause of the nonconformance (i.e., software design error, process out of specifications, employee error, user misuse, etc.)? What evidence does the firm have to support the determination?
4. Did the firm determine if the nonconformance resulted in an injury or death?
5. If a component was responsible for the defect, determine if the same component was used in other devices manufactured by the firm. If so, has the firm conducted an analysis to assure the defect in the component will not have a deleterious effect on the operation of the other device(s)?
6. If a component was responsible for the device defect, what other device manufacturers use the same component (and especially the same lot number of the component)? Has the manufacturer of the recalled device notified the component manufacturer? Has the component manufacturer contacted its other customers about the problem?
7. Why was the component defective? Did the manufacturer of the component change the specifications without notifying the finished device manufacturer? Did the component fail to meet its release specifications?
   NOTE: A visit to the component manufacturer may be needed to adequately answer questions 5, 6 and 7. Before doing so, confirm with CDRH and your supervisor that the matter is egregious enough to warrant this "next step."
8. Did the finished device manufacturer have an incoming component/raw material sampling and testing procedure? If not, why not?
9. If the manufacturer recalled the device because the labeling was inaccurate, or the wrong labeling was applied to the device (label mix-up) determine the following:
   a. What quality system procedures should have been established to prevent the problem?
   b. If the label or instructions for use were inaccurate, was the inaccuracy introduced in the design stage, or was it due to a printing problem?
10. If the device has been on the market for a year or more, and the manufacturer claims the problem is the result of design:
    a. Why is the problem just now showing up? How many reports concerning the problem did the firm receive before deciding a recall was necessary? Does the firm have a procedure established for determining if a recall is necessary, and if so, did it follow the procedure? Obtain a copy of the procedure.
    b. If the firm doesn't provide rational answers to the above questions, determine if they explored other possible causes for the problem.
    c. Was the design feature which caused the problem included in the design of the device that was the subject of a premarket submission?
    d. If the design feature which caused the problem is part of the original design, did the manufacturer recall all products manufactured since the device was introduced to the market? If not, why not?
    e. If the problem was introduced via a design change, did the manufacturer follow established design change or change control procedures? If yes, are the procedures adequate? Was the nature of the

problem such that it should have been anticipated, and the design verification/ validation study fashioned to detect the problem?

f. Has the manufacturer recalled all products distributed since the design change was introduced? If not, why not?

7.2.3.2 - Corrective Action

1. Describe the corrective action taken to correct the immediate problem, e.g., redesign, modify SOP, process validation, etc.
2. Did the firm qualify/validate the corrective action?
3. Did the firm establish responsibility to assure that the corrective action would be implemented and satisfactorily completed?
4. What action did the firm take to prevent recurrence of the nonconformance, e.g., training, increased process monitoring, etc.?
5. Was the nonconformance information provided to those responsible for the areas in which the nonconformance occurred?
6. Did the firm determine if the nonconformance extended to other devices?
7. Did the firm determine if changes were needed in procedures and, if so, did it validate and implement the changes?
8. Has the manufacturer taken appropriate corrective action?

7.2.3.3 - Complaint and Medical Device Reporting (MDR) Reporting

Determine if adequate complaint investigations were performed as required by 21 CFR 820.198(b). Also, determine if the investigation verified the complaint was a failure of the device to meet any or all of its specifications.

For complaints related to the recall, the firm should have made a determination whether the events are MDR reportable. Any event associated with a death or serious injury must be reported under MDR. Malfunctions likely to cause or contribute to a death or a serious injury are also reportable under MDR. Document the firm's explanations for the events they believe are nonreportable. Failure to submit required MDR reports are violations, and should be listed on the FDA-483 at the completion of the inspection.

Provide adequate documentation with the EIR to cross-reference complaints with associated MDRs.

Device Information - Obtain the 510(k) or PMA number for each device under recall. If there is no 510(k) or PMA, determine if the device is a pre-enactment device (i.e., in commercial distribution prior to May 26, 1976). If multiple devices are being recalled, obtain this information for each device model or catalog number under recall.

7.2.4 - DRUG RECALLS

7.2.4.1 - Recalls of Human Drug Products

If the recalled product is covered by a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), determine if the defective product involves the type of problems shown under CFR 314.81(b)(1)(i) and (ii). Also note whether or not the firm reported the problem to the FDA district office that is responsible for the firm within 3 working days of its receipt of the information, as required by that section.

7.2.4.2 - Recalls of Veterinary Drug Products

Veterinary Drug Products Recalls are classified by and health hazard evaluations are obtained through CVM's Division of Compliance (HFV-230), Eric Nelson, Director. To inquire about specific veterinary drug product recalls or to obtain information on how to proceed, contact the Division at 240-276-9200 or contact Kathy Hemming-Thompson at 240-276-9216.

7.2.5 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE BASED PRODUCTS (HCT/Ps) FOR IMPLANTATION, TRANSPLANTATION, INFUSION, OR TRANSFER

The agency may consider an order of retention, recall, destruction, or cessation of manufacturing when any of the conditions specified in 21 CFR 1271.440(a)(1) to (3) exist. The conditions include an agency finding that:

1. The HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or
2. An establishment is in violation of the regulations in this part and, therefore does not provide adequate protections against the risks of communicable disease transmission.

In addition to the conditions noted above, the agency may issue an order of cessation of manufacturing until compliance with the regulations has been achieved, as stated in 21 CFR 1271.440(a)(3), when the FDA determines there are reasonable grounds to believe there is a danger to health. An order to cease manufacturing would be issued where violations create an urgent situation involving a communicable disease, because an establishment is in violation of the regulations in Part 1271 and, therefore, does not provide adequate protections against the risks of communicable disease transmission. An order to cease manufacturing is a remedial action taken to put important protections in place to prevent communicable disease transmission.

NOTE: FDA will not issue an order for the destruction of reproductive HCT/Ps, nor will FDA carry out such destruction itself (21 CFR 1271.440(f)).

7.2.6 – TOBACCO PRODUCT RECALLS

"To inquire about tobacco product recalls or to obtain information on how to proceed, contact the Center for Tobacco, Office of Compliance and Enforcement, Enforcement and Manufacturing Group. See CTP's intranet site for contact information."
http://inside.fda.gov:9003/CTP/ucm249908.htm

7.2.7 - SAMPLE COLLECTION

Collection of samples for regulatory consideration is at the discretion of District management. Consult your supervisor and/or compliance branch for guidance. If a sample is indicated, only collect documentary samples for electronic products or medical devices, unless otherwise instructed.

If, after consulting with the Centers, it is determined that a product must be examined physically for health hazard evaluation, ship an appropriate sample to the designated Center office by the most expeditious and practical means available. Notify the Center of the time and method you sent the product and its estimated time of arrival.

7.2.8 - RECALL ALERT

When a District learns of or confirms a recall situation exists or is planned, they will give the appropriate Center Recall Office and OE/DCMO (HFC-210) a twenty-four hour alert through the Recall Enterprise System (RES). See RPM Chapter 7-10, Attachment A, "Recall Alert Information."

7.2.9 - RECOMMENDATION FOR RECALL NUMBER

A memorandum should be prepared as soon as the recall number is available, and transmitted to your District's R&E Coordinator through your Supervisor. Do not wait for writing, typing and submission of the EIR. A copy of the memo may be attached to your EIR so the information need not be repeated in the body of the report. From the time the recall alert is sent to the appropriate Center, the district has five days to submit the Recall Recommendation (ten days if the recall is completed). See RPM Chapter 7-10, Attachment B "Recommendation for Recall Classification."

7.2.9.1 - Product

For each recalled product, provide: its name; type (e.g. tablet, sugar coated); strength; sizes; form; route of administration; shipping or unit package; and a brief description of the product and its use. If it is a drug product, indicate whether it is a prescription (Rx) or Over-the-Counter (OTC) product. If product labeling does not indicate how the product is to be used, and the health hazard is dependent on use, consult the firm's catalog, the Red Book, or similar sources for that information.

For each recalled product also provide: the brand name; name, address, and type of responsible firm on label; number and description of private labels. Complete copy of all labeling (including product inserts or information sheets). These must be sent to the appropriate Center by an expeditious method.

7.2.9.2 - Code

List all lot and/or serial numbers, catalog numbers, product numbers, packer or manufacturer numbers, etc., which appears on the product or its labeling.

7.2.9.3 - Recalling Firm/Manufacturer

Provide complete name and address of the recalling firm, and identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor. Provide complete name and address of the manufacturer, if different from the recalling firm. Also identify firms which processed or handled the product, or supplied components which might have been responsible for the problem. Indicate which firm(s) appear(s) responsible for the violation.

7.2.9.4 - Reason for Recall Recommendation

Provide detailed information as to how the product is defective and violates the FD&C Act or related statutes.

1. Include any analytical findings in qualitative and/or quantitative terms, whether from the firm or FDA analysis, and which laboratory was involved;
2. Provide inspectional (e.g., GMP) or other evidence, where appropriate; and
3. List in chronological order any complaints, injuries, or associated problems with the product. Include any MDRs that have been submitted.

If firm management was advised of FDA findings, and the problem was discussed with them, report their reactions and plans. If the firm advised FDA of the problem, report and explain firm's own analytical results and how it learned of the need for a recall.

Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.

For DESI related recalls, use the following terminology: "Federal Register Publication (date), Drug Efficacy Study Implementation."

In cases where a veterinary drug product is recalled due to subpotency prior to labeled expiration date provide the following information:

1. The firm's stability testing plan (including the analytical methodology) which established the labeled expiration date;
2. Specific batch numbers in the stability studies, and assay values that are the basis of the firm's recall.
3. Potency specifications which the firm uses for recall purposes; and

4. Final assay values for the active ingredients which were the basis of the initial release of the batch.

Note if information regarding stability data on file with the firm, and the Quality Control (QC) procedures used by the firm to determine the potency of the active ingredients, is available in the EIR.

7.2.9.5 - Volume of Product in Commerce

Provide total volume of product(s) distributed. Provide estimate of amount and availability of stocks remaining on market, at all levels. (Indicate whether this is the firm's or FDA's estimates.) Include product expiration dates or shelf life expectancy.

NOTE: If recommendation is for an FDA Requested Recall, assure there is, in fact, product remaining in commerce.

7.2.9.6 - Distribution Pattern

Report the areas of distribution, the number of direct accounts, the approximate percentage of each type consignee, and the percentage of product sent to each type of consignee. List foreign countries and U.S. Government military and/or civil units/agencies to which product(s) were distributed. If various labels are involved, describe any differences in distribution pattern.

Where there were any Defense Personnel Support Center (DPSC), Department of Veterans Affairs (DVA), or other government agency sales/distribution, the consignee list should be submitted separately through your District's R&E Coordinator to OE/DCMO. Show if these were direct or contract sales. If contract sales, report the contract number, contract date, and implementation date.

7.2.9.7 - Firm's Recall Strategy

Describe the firm's planned recall strategy. Comment on the adequacy of this strategy from your District's viewpoint, and evaluate the firm's ability to accomplish an effective recall. See Sections 7.42 and 7.46 of 21 CFR, Part 7, which set forth information to be obtained from the firm which will be evaluated by the Center. The firm's strategy should include the intended course of action when an account which distributed the recalled product is found out of business. Include the date the recall was initiated, if already underway.

7.2.9.8 - Firm Official

Report the name, title, location, and telephone number of the firm official who should be contacted concerning the recall. In case of potential Class I or FDA requested recalls, also provide this information for the firm's most responsible person.

7.2.9.9 - District Audit Program

Report what actions have already been taken (FDA inspections, sample collections, etc.). Provide specific recommendations for the appropriate Center's action, where appropriate.

Provide details of any publicity issued or planned by FDA, the firm, the State, or local government.

Provide your District's proposed program for monitoring the recall. Include time table for reviewing the recall status and the level and type of audit checks which will verify the recall's effectiveness.

7.2.9.10 - Recommending Official

Name and title of your District's recommending official.

SUBCHAPTER 7.3 - MONITORING RECALLS

7.3.1 - INSPECTIONS TO MONITOR RECALL PROGRESS

It may be necessary to re-inspect the firm between the initiation and closeout of a recall to monitor its progress and verify the recalled product's disposition. These visits are limited inspections; issue an FDA-482, Notice of Inspection, at each one. Request recalling firms submit periodic status reports to FDA. See 21 CFR 7.53.

7.3.2 - FDA RECALL AUDIT CHECKS

7.3.2.1 - Definition

A recall audit check is a personal visit, telephone call, letter, or a combination thereof, to a consignee of a recalling firm, or a user or consumer in the chain of distribution. It is made to verify all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

7.3.2.2 - Level of Audit Checks

Level A - 100% of the total number of consignees to be contacted.

Level B - Greater than 10% but less than 100% of the total number of consignees to be contacted.

Level C - 10% of the total number of consignees to be contacted.

Level D - 2% of the total number of consignees to be contacted.

Level E - No effectiveness checks.

NOTE: A statistical audit plan may be directed by the Center involved.

7.3.2.3 - Sub-Account Checks

If a recall strategy includes sub-recall by a firm's direct accounts, sub-recall checks will be made following the above levels, as instructed by the Center and your supervisor.

7.3.2.4 - Conducting the Check

Your assignment contains the necessary details of the recall, recall strategy, and a list of accounts to be checked. The Center will indicate how checks will be made, i.e., visit, phone calls, record checks, etc. Obtain at least the following information, plus any additional information requested by the monitoring district or your home District:

1. Name and title of person interviewed;
2. Was notification received, understood, and followed?;
3. Date and method of notification;
4. Amount of recalled product on hand at time of notification;
5. Amount returned and the method of return;
6. Amount destroyed and method of destruction;
7. Amount presently on hand and its status (held for sale, awaiting return, etc.);
8. Date of anticipated return or destruction, and planned method (if applicable);
9. Was sub-recall conducted? (If so, obtain a list of consignees from which to select your sub-recall check locations); and
10. Have injury reports or complaints been received? If so, report details.

When you conduct an audit check by visit, you should visit the storage sites for the recalled product and check the shelf stock to ensure all recalled product has been identified, removed from areas of use and properly quarantined. In firms where products are stored in multiple locations, a sufficient number should be checked to verify the consignee properly found and removed all product subject to the recall. This is especially important in Class I recalls and you should check each storage site.

7.3.2.5 - Audit Check Reporting

The narrative results of your audit check should be reported on an FDA 3177, "Recall Audit Check Report" form. See IOM Exhibit 7-2. Districts have the option of using computer generated audit check forms or hard copies. The FDA 3177 is a three-part form, which is basically self-explanatory. If necessary, instructions for completing it may be found in RPM, Chapter 7, Exhibit 7-12. It is distributed as follows:

Original - Monitoring district.
CC - Accomplishing district files.
CC - District Use

Version 2 of FACTS allows you to enter the amount of time and other data information. When you complete Recall Audits, you should report your time using the "Miscellaneous Operations Accomplishment Hours" screen. You do not need to report the information on the 3177 unless your District SOP requires this. Until some other reporting procedure is developed, continue to report audit checks using the FDA 3177 form or memorandum.

7.3.2.6 - Ineffective Recalls

If your audit check discloses recalled product being held for sale, or a requested sub-recall has not been initiated, document the responsibility for failure to follow recall instructions. This is particularly important if the account received the recall notice and ignored it. An Official Sample should be collected from these remaining products. If in doubt, contact your supervisor or R&E Coordinator. Encourage the consignee to follow the recalling firm's instructions. If a sub-recall is justified, obtain a commitment and details of the firm's sub-recall effort. Get distribution information for follow-up sub-account audit checks.

7.3.3 - RECALL TERMINATED/RECALL COMPLETED

7.3.3.1 - Definitions

Recall Terminated - A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate District office to the recalling firm.

Recall Completed - For monitoring purposes, the FDA classifies a recall action "Completed" when all outstanding product, which could reasonably be expected is recovered, impounded, or corrected.

7.3.3.2 - Closeout Inspection

The final monitoring step is a limited inspection made to verify recall closeout by the recalling firm. A memorandum or limited EIR should be prepared. See RPM Chapter 7, Attachments B1, "Recommendation for Recall Classification and Termination" and Attachment C, "Recall Termination or Recommendation for Termination" for the format. Portions of this format (i.e., Section II and certain items in Section III) will be completed by your supervisor, R&E Coordinator, or compliance officer, depending upon your District's policy.

During the closeout inspection, you should witness destruction or reconditioning of the recalled product when possible. If you are unable to witness the destruction or reconditioning, obtain written documentation from the firm and/or any state or local government agencies which may have witnessed or otherwise verified product disposition.

The disposal of large amounts of contaminated or hazardous items may require the firm to file an Environmental Impact Statement (EIS), or pre-disposal processing to render the goods harmless. Do not agree to witness destruction without resolution of these issues. Obtain a "Letter of Voluntary Destruction" from the firm whenever you witness this operation. See IOM 2.6.4.1.

SUBCHAPTER 7.4 - SPECIAL RECALL SITUATIONS

7.4.1 - General

There are several special recall situations which may require you to deviate from the normal recall procedures. Seek your supervisor's or R&E Coordinator's guidance on these. Examples include:

1. Products in the possession of U.S. Defense Installations;
2. NDA and NADA withdrawals;
3. National Academy of Science (NAS)/Nuclear Regulatory Commission (NRC) (DESI) recalls of drugs judged ineffective; and
4. Recalls involving jurisdiction of more than one Federal Agency (e.g., FDA/EPA, FDA/Consumer Product Safety Commission (CPSC), etc.).

MODEL DRUG RECALL LETTER

John Doe Laboratories
Somewhere, U.S.A. 12345

Control Division
Date _____

(red print) --URGENT: DRUG RECALL -- Nonsterile injectable

Re: List 1234, Cyanocobalamin Injection Lot No. 4321

Recent tests showed that the above lot number of this product is not sterile and therefore, represents a potential public health hazard. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot 4321 on hand. If so, discontinue dispensing the lot and promptly return via parcel post, to our New York City Plant; ATENTION RETURNED GOODS.

(NOTE: If a sub-recall is indicated in a particular situation, the following paragraph should be added:)

> "If you have distributed any of lot 4321, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above."

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. The FDA has classified this recall as class _____ (if classified).

We appreciate your assistance.

John Doe
President

PLEASE FILL OUT AND RETURN

We do not have any stock of List 1234, Cyanocobalamin

Injection Lot No. 4321 on hand

We have requested our accounts to return their stocks of this merchandise to us.

We are returning _____ bottles of List 1234, Lot No. 4321

Name _____

Address _____

First Class
Permit No. 2

BUSINESS REPLY MAIL

No Postage Stamp Necessary if mailed in U.S.A.

Postage will be paid by:

JOHN DOE LABORATORIES
Somewhere, U.S.A. 12345-0909

Henry Doe

JOHN DOE LABORATORIES *FIRST CLASS MAIL*

A. B. C. Pharmacy
Anywhere U. S. A.

(red print) URGENT DRUG RECALL

1. RECALL INFORMATION

a. RES/RECALL NUMBER(S)	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)

2. PROGRAM DATA

a. HOME DISTRICT	b. FEI NUMBER OF RECALLING FIRM

c. PAC CODE	d. HOURS

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY)
PHONE NO.:	PHONE NO.:

c. SUB-ACCOUNT (TERTIARY)	PHONE NO.

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☐ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other: _____

c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?

☐ Yes ☐ No

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED?
(If "No", skip to item 6c.)

☐ Yes ☐ No ☐ Cannot be determined

(If answer is other than "No", explain in remarks.)

b. RECALL NOTIFICATION RECEIVED FROM

☐ Recalling Firm ☐ Other *(Specify below)*
☐ Direct Account
☐ Sub-Account

c. DATE NOTIFIED *(mm/dd/yyyy)*

d. TYPE OF NOTICE RECEIVED *(e.g., letter, phone)*

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? *(If "No", discuss in "Remarks" action taken upon FDA contact.)* ☐ Yes ☐ No

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ None on Hand
☐ Corrected ☐ Was Still Held for Sale/Use*
☐ Destroyed ☐ Held for Return/Correction*

* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED? *Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.)* ☐ Yes ☐ No

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

☐ Injury ☐ Complaint
☐ Illness ☐ None

If answer is other than "None", report details in a separate memo to monitoring district and copy to OEO (HFA-615).

10. REMARKS *(Include action taken if product was still available for sale or use.)*

CHECK		ENDORSEMENT
INVESTIGATOR		SCSO OR R&E COORDINATOR
Signature		Signature
Printed Name		Printed Name
Date of Check *(mm/dd/yyyy)*	District	Date of Endorsement *(mm/dd/yyyy)*

☐ **Effective** ☐ **Does Not Carry Product**
☐ **Ineffective** *(Indicate level)* ☐ **Out of Business**
☐ *Recalling Firm*
☐ *Consignee*
☐ **Other** *(Specify)*: _____

FORM FDA 3177 (2/10) **RECALL AUDIT CHECK REPORT** FSC Graphics (301) 443-1090 EF

City of Newton

Setti D. Warren
Mayor

HEALTH AND HUMAN SERVICES DEPARTMENT
Linda Walsh, Interim Commissioner
1000 Commonwealth Avenue
Newton, MA 02459-1544

Telephone 617.796.1420 Fax 617.552.7063
TDD/TTY 617.796.1089

PublicHealth
Prevent. Promote. Protect.

EMBARGO NOTICE

Date: Click here to enter text. Embargo Number: Click here to enter text.

Name of Establishment: Click here to enter text.

Address: Click here to enter text. Newton, MA 024 Choose an item.

The following articles of food(s) are hereby EMBARGOED for TEN (10) DAYS as authorized by Chapter 94, Section 189A, as inserted by Chapter 598, Acts of 1948 of the General Laws.

Foods(s): Click here to enter text.

Whoever removes or disposes of the above described articles without permission from the Newton Health and Human Services Department shall be punished by a fine of not less than one hundred ($100.00) and not more than five hundred dollars ($500.00) or by imprisonment for not more than six (6) months.

Signature of Owner or Person-In-Charge: Click here to enter text.

Print: Click here to enter text. Title: Click here to enter text.

Inspector Signature: Click here to enter text.

Print: Choose an item.

Email: Choose an item.

Email: lwalsh@newtonma.gov

590.016: Examination and Embargo of Food

(A) Examination and Sampling. Food may be examined or sampled by the board of health pursuant to M.G.L. c. 94, §§ 146 and 189 for the purpose of determining compliance with 105 CMR 590.000.
(B) Embargo Notice. The board of health may place an embargo on any food, which it knows, or has probable cause to believe is adulterated or misbranded provided that:
(1) A written notice is issued to the holder of the permit to operate the food establishment or to the person in charge; and
(2) The notice specifies in detail the reason(s) for the embargo order.
(C) Embargo Tag. The board of health shall tag, label, or otherwise identify any food subject to the embargo order. The tag or label shall state that the food:
(1) Is believed to be adulterated or misbranded;
(2) Has been embargoed for ten days; and
(3) Cannot be removed, used, sold or disposed of without permission of the board of health.
(D) Storage or Destruction of Embargoed Food. The board of health shall permit storage of food under conditions specified in the embargo order, unless storage is not possible without risk to the public health, in which case immediate destruction shall be ordered and accomplished.
(E) Condemnation, Disposal or Reconditioning. If the food subject to embargo is found to be adulterated or misbranded, the board of health shall take such steps as are necessary, pursuant to M.G.L. c. 94, §§ 146 or 189A, to effect the condemnation and disposal or reconditioning of the food.
(F) Embargo Release. If the food subject to embargo is not found to be adulterated or misbranded it shall be released.

City of Newton

Setti D. Warren
Mayor

HEALTH AND HUMAN SERVICES DEPARTMENT
Linda Walsh, Interim Commissioner
1000 Commonwealth Avenue
Newton, MA 02459-1544

Telephone 617.796.1420 Fax 617.552.7063
TDD/TTY 617.796.1089

Public Health
Prevent. Promote. Protect.

APPENDIX J

TRACEBACK WORKSHEET

PRODUCT NAME	CODE NUMBER(S)	SELL BY DATES	EXPIRATION DATES	SIZE OF PACKAGE	TYPE OF PACKAGING	NAME OF WHOLESALER(S)	NAME OF DISTRIBUTOR(S)	DISTRIBUTOR(S) ADDRESS	DATE(S) RECEIVED

ANNEX 3-1

Risk Control Plan

Establishment Name:			Type of Facility:
Physical Address:			Person in Charge:
City:	State:	Zip:	County:
Inspection Time In:	Inspection Time Out:	Date:	Inspector's Name:
Agency:			

Specific observation noted during inspection:

Applicable code violation(s): - (Optional)

Risk factor to be controlled:

Hazard (most common, significant):

What must be achieved to gain compliance in the future:

How will active managerial control be achieved:

(Who is responsible for the control, what monitoring and record keeping is required, who is responsible for monitoring and completing records, what corrective actions should be taken when deviations are noted, how long is the plan to continue)

How will the results of implementing the RCP be communicated back to the inspector:

As the person in charge of the _____ located at _____,
I have voluntarily developed this risk control plan, in consultation with
_____ and understand the provisions of this plan.

_____ _____

(Establishment Manager) (Date)

_____ _____

(Regulatory Official) (Date)

illness complaint. Establish through an interview with the manager, if food handlers have been ill and if the establishment has received any other similar complaints.

Often complainants will call their LBOH implicating food prepared outside of the LBOH jurisdiction. Immediately refer complaints involving food prepared in another jurisdiction to the appropriate local board of health or, if outside Massachusetts, to the MDPH Division of Food and Drugs. The Division of Food and Drugs will investigate foods manufactured in Massachusetts and will forward complaints implicating foods manufactured out of state to the appropriate state or federal regulatory agency.

Another situation in which a follow-up investigation may not be necessary is when repeated complaints are made by the same individual(s) and prior investigation revealed no significant findings. Invalid complaints may be generated by disgruntled employees, competitors, unfriendly neighbors and dissatisfied customers. Whatever the situation, always briefly summarize for the file your reasons why an investigation was not conducted.

NOTE: If uncertain of whether or not to proceed with an investigation, contact the Massachusetts Division of Food and Drugs (617-983- 6712) or the Division of Epidemiology and Immunization (617-983-6800).

4) Expanding the Investigation

If the complaint appears valid, an environmental and/or epidemiological investigation should be initiated within 24-48 hours. The LBOH should have coverage for weekends and holidays in emergency situations.

The Environmental Investigation. This is not a routine inspection but a foodborne illness investigation. The sanitarian or investigator gathers and assimilates facts to find the cause and contributing factors to illness.

Sanitarians play a key role in proving that a food is responsible for illness by making observations and measurements that relate to contamination, survival and growth of the etiologic agent. The environmental investigation should focus on the preparation and service of the implicated food to determine the risk of contamination and temperature abuse. Foods found to be at risk for contamination because of an infected food handler, poor food handling practices or procedures, or an unapproved source (i.e., clams illegally harvested from contaminated beds) should be embargoed. When contamination is blatant, foods should be discarded. An emergency closure or suspension order may be issued by the LBOH when an imminent health hazard exists, such as several infected food handlers or the lack of adequate refrigeration.

NOTE: See Chapter 7 for detailed information on environmental inspections and enforcement procedures.

The Epidemiologic Investigation. Epidemiologic investigations are usually conducted in outbreak situations. The purpose of the investigation is to identify a problem, collect data, formulate and test hypotheses. It involves the collection and analysis of more facts or data to determine the cause of illness and to implement control measures to prevent additional illness. A questionnaire is often solicited to assist the investigator in developing better hypotheses about the etiologic agent's identity, source and transmission. The investigators interview ill and well persons, and calculate and compare incidence rates of both groups. They make time, place, and person associations and calculate the probability that a food was the responsible vehicle.

The investigator incorporates results from epidemiological associations and the environmental and laboratory investigations, and uses these data in forming and testing hypotheses. Careful development of epidemiologic inferences coupled with persuasive clinical and laboratory evidence will almost always provide convincing evidence of the source and mode of spread of a disease. In situations where food and stool testing are negative, the cause of an outbreak is implicated by epidemiological association.

NOTE: See Chapter 6 for detailed information on the steps in an epidemiologic investigation.

Foodborne Illness in Private Homes. Suspect foods prepared in private homes are sometimes the causative factor in reported illnesses. While it is not within the board of health's authority to conduct an on-site inspection of private homes, the LBOH should try to conduct a HACCP risk assessment based on an interview with the food preparer to identify possible sources of contamination. Often, friends and family are hesitant to participate in an interview or epidemiology questionnaire studies. Encourage participation in an investigation and offer assistance with food and stool specimen testing. Offer advice or educational materials on safe food handling practices and advocate the prevention of further illnesses by ensuring that sick individuals seek medical attention. Additionally, they should be informed of work restrictions associated with certain diseases transmissible through food.

If it appears that a commercially processed food prepared in the home may have been contaminated when the consumer purchased it, obtain product information (e.g., manufacturer name and address, package size and type, code or lot number, expiration dates) and immediately notify the MA Division of Food and Drugs. Try to obtain the suspect food itself, if there are leftovers (see Section 7 of this chapter for more information on collecting leftover food samples).

NOTE: Individuals collecting case information and completing *case report forms* must ensure that they use the most recent forms available from the MDPH Bureau of Communicable Disease Control. If questions arise about the most recent forms or in completing the forms, investigators should contact the Bureau of Communicable Disease Control, Surveillance Program at (617) 983-6801..

NOTE: If during the completion of a *Bacterial/Parasitic Gastroenteritis Case Report Form* or other *case report form*, it appears possible or likely that food was the source of infection, a *Foodborne Illness Complaint Worksheet* (Section 4-A of this chapter) should be started and the appropriate investigations should be initiated (Chapters 5-7) as with any other foodborne illness complaint.

5) Reporting Issues: Timeliness, Priorities, and Confidentiality

A. Timeliness

Report as soon as possible. As presented in Section 4-B of this chapter, all cases of reportable disease must be reported using a *case report form*. Because the process of obtaining information for a *case report form* can take time, you should initially phone in a report, or send a brief written notification via mail or fax to the Surveillance Program within 24 hours. (See telephone numbers in Box 4.4 below.) Later, one can follow-up with an official *case report form.* As long as the LBOH is notifying the MDPH of cases within 24 hours via mail or fax, most *case report forms* can be sent in on a monthly basis. See the attached *Diseases Reportable By Healthcare Providers* at the end of the chapter for further clarification.

The MDPH Bureau of Communicable Disease Control has an epidemiologist on duty daily to answer your questions. An epidemiologist is also available via beeper during non-work hours for **emergency situations** (e.g., if you receive several complaints and are concerned about a potential foodborne illness outbreak). All calls are returned promptly.

The importance of timely reporting can not be overemphasized. If data are reported or collected sporadically, it will be difficult, if not impossible, to actually mount a reasonable and timely public health response. For example, if a local health authority saves up all its reports of salmonella and only submits them once every three years, the data could be interpreted incorrectly. One might think that there had been no salmonella for several years, and that there was suddenly an outbreak situation. Likewise, potential outbreaks among neighboring towns might be missed because no data were received from the local health authority in this particular town until it was too late.