

# CHAPTER 1 - ADMINISTRATION

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## 1.1 – Administration Notes

The FDA is a part of the Department of Health and Human Services (HHS). An appointed Commissioner who serves at the discretion of the President heads the agency. The FDA is a team of dedicated professionals working to protect and promote the health of the American people. The FDA's complete organization structures are available on [FDA's Intranet website](#).

The Office of Regulatory Affairs (ORA) is responsible for the operational activities of FDA through the work of its headquarters and field staff across the continental United States and Puerto Rico. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products, and reviews imported products offered for entry into the United States. Resources for ORA employees can be found on the [ORA site](#).

Accessible to all FDA employees, the [InsideFDA](#) and [ORA](#) intranet websites contain information about organizational structures for FDA/ORA. The [ORA Organizational chart](#) provides an overview of current ORA organization; information about specific offices within ORA can be found under the Office Tab on the ORA main SharePoint site. The FDA intranet site also contains the [Employee Resources Hub](#) that provides FDA employees with information such as [new employee orientation](#), employment programs, human resources, facility services, trending topics, occupational safety and health services, and employee trainings. The [Administrative Topic Hub](#) covers resources for topics pertaining to acquisitions and grants, budget and finance, Continuity of Operation Plans (COOPs) and emergency planning, financial services, forms and office templates, furlough guidance, security, workforce management, and travel services.

## 1.2 – ORA Travel

All official travel must be authorized and approved with a valid travel authorization (TA) using FDA's Electronic Government Travel Service, [ConcurGov](#). Typically, the travel authorization should be submitted at least 5 days in advance for review and approval. Travel itineraries listing where and how you can be reached should be provided to your supervisor since situations arise which necessitate contacting you while in travel status.

The FDA uses an Electronic Government Travel Services (ETS) as the Government Travel Service. The ETS is the Government-contracted, end-to-end travel management service that automates and consolidates the Federal travel process in a self-service Web-centric environment, covering all aspects of official travel, including travel planning, authorization, hotel and rental car reservations, ticketing, expense reimbursement, creating authorizations and vouchers (including local travel vouchers) and travel management reporting. In addition, the ETS will interface with the Unified Financial Management System (UFMS) for obligation and payment of travel vouchers. The system incorporates Federal Government travel policies which include the city pair airfare contract program and Federal Travel Regulations and is structured to require justification if you want to deviate from General Services Administration's (GSA) regulations. A policy has been established with the FDA so that your government-issued credit card will be your primary method of billing and payment when you book flights, make hotel reservations, or reserve a rental car.

Additional information can be obtained by contacting your Administrative Staff or visiting [OFM's site](#).

[The Fiscal Management Manual site](#) provides policy, process, procedure, training, and additional materials for the FDA financial community.

Emergency travel can be approved, and the travel order prepared and authorized after the fact. "After the fact" TAs should be utilized on a very limited basis. The preparer should ensure that a detailed justification/explanation is provided and uploaded as an attachment in the TA to facilitate processing.

The [Federal Travel Regulation \(FTR\)](#) contained in 41 CFR 301, the [Department of Health and Human Services \(DHHS\) Travel Manual](#), the FDA supplements to the DHHS 2012 Travel Manual and the [Collective Bargaining Agreement \(CBA\)](#) govern official travel. Article 42 of the National Treasury Employees Union (NTEU) CBA or Article IX of the American Federation of Government Employees (AFGE) CBA (depending on which union the bargaining unit employee is affiliated with) is intended to be read in conjunction with the FTR and the HHS Travel Manual. If there is a conflict between the HHS Travel Manual and the CBA, the CBA governs. Become familiar with these documents.

The [HHS Travel Policy Manual](#) is intended for use by HHS Employees, invitational travelers, consultants, and others authorized to travel on behalf of the Department. Please note that the words "employee" and "traveler" are the same for the purpose of this policy and in alignment with the FTR definition of "employee."

The current HHS Travel Policy Manual provides users with the complete source of the Department's management policies and procedures regarding travel and transportation procedures. Topics addressed in the Manual include, but are not limited to, Temporary Duty (TDY) Travel, Relocation Allowances, Interagency Personnel Agreements (IPAs) Travel and Transportation Expenses connected with the death of certain employees, and Acceptance of Payments of Travel Expenses from Non-Federal Sources (Sponsored Travel). All material contained in the Investigations Operations Manual (IOM) must be used in conjunction with, and subject to, federal travel regulations.

[Job aids and SOPs](#) are provided to guide users in how to prepare for travel with FDA. Additional travel information can be obtained from the [ORA Office of Management's Travel webpages](#), as well as the [Office of Financial Management \(OFM\)](#) Intranet home page.

### 1.2.1 - Government Contractor-Issued Travel Charge Card

The Government Travel Charge Card Program (GTCC) provides travelers with a safe, effective, convenient, and commercially available method to pay for expenses associated with official travel. Refer to the [FDA Staff Manual Guide 2343.1](#) for additional information on policy governing the Agency-wide Travel Card Program and the procedures employees must follow for use of the card while on official travel.

Your Government Travel Card is a tool that assists you in the performance of your duties. The manner in which you use the travel card will reflect directly upon you as an employee and as an individual. With the privilege of a government travel card also come the responsibilities for its proper use. Use of the card does not relieve you of the responsibility to employ prudent travel practices and to observe rules and regulations governing travel for FDA, and as set forth in the FTR.

Travel charge cards are issued to employees to pay for all official travel and travel-related expenses. You must use the card only for authorized expenses incurred in connection with official travel orders, e.g. for

lodging, transportation, baggage fees, parking, meals, etc. unless you have been granted an exemption. Exceptions can include expenses that are either relatively minor or inconvenient for credit card usage such as parking, local transportation, tips, phone calls, and certain expenses for which credit cards are not accepted. For more information on authorized exemptions, see the HHS Travel Manual, Chapter 9-00-10 C and D or go to the HHS Office of Finance web site for additional information on policy governing the Department-wide Travel Card Program and the procedures employees must follow for use of the card while performing official travel.

Personal use of the travel card or using the travel card to pay for someone else's travel expenses is prohibited. The use of the travel card for non-official expenses may result in disciplinary actions. Do not charge office supplies, training, conference registration fees, photocopies, postal services, or equipment on the travel card. Instead, use the purchase card or other acquisition vehicles to procure non-travel related services and products.

The only exception for use of the card not in connection with official travel applies to ATM withdrawals for purchase of samples.

Payments will include direct payment to the credit card company for expenses charged to the individual's official government travel credit card. Typically the M&IE portion of per diem is reimbursed to the personal bank account, not the travel card. The HHS Travel Policy Manual states that the Government Issued travel card must be used for all travel related expenses including Per Diem and including M&IE. Concur defaults to reimbursing M&IE to the personal bank account. However, this can be changed during the TA and/or voucher creation stage to have the M&IE reimbursed to the Travel Card.

ATM cash advance is to be used only to cover anticipated out-of-pocket incidental travel expenses which generally cannot be charged directly to the card. Excessive ATM cash advances not commensurate with travel are Travel Card misuse. Therefore, direct charge of the Travel Card must be utilized in lieu of ATM Cash whenever and wherever possible for approved, travel related expenses. You will use your government-issued credit card to obtain a cash advance from an ATM machine, for official government business only. Ensure your Travel Authorization (TA) contains a statement that you are authorized to use an ATM to obtain cash advances and the maximum total amount authorized for your trip. ATM withdrawal for official travel is authorized based on 80% of your M&IE and estimated out of pocket expenses for the trip. Regardless of amounts indicated on your TA, ATM cash advances also may not exceed the weekly ATM withdrawal limit on your Travel Card account. This limit is established at the time that you apply for the travel card- based on a personal credit worthiness check. There are usually two fees associated with an ATM cash advance. The "Terminal Fee" assessed by the ATM terminal's owner/supplier and the "Cash Advance Fee" assessed by the bank. Currently, there are two formulas to calculate the reimbursable Cash Advance Fee using a 2.5% of the fee or a minimum of \$3.00:

- Percentage – 2.5% multiplied by (Cash advance amount + ATM Terminal Fee).
- Minimum payment - \$3 plus (Cash advance amount + ATM Terminal Fee).

The Cash Advance Fee is described in your credit card agreement. These amounts should be included on the Travel Authorization/Voucher along with receipts before reimbursement is made.

Additionally, there is also an international fee charged if cash advances are taken during foreign travel.

The government reimburses employees for authorized expenses. The employee is responsible for making payment to the bank; the cardholder is solely responsible for the timely payment of travel card bills and that account is delinquent if not paid within 30 days after the first statement date.

Read and understand the “HHS Traveler’s Agreement for Government Contractor-Issued Travel Charge Card Users” before signing.

Immediately report a lost or stolen travel card to the bank and your Agency/Organization Program Coordinator (A/OPC) or travel coordinator.

If you do not have a government travel card and are required to travel, please contact your administrative officer about receiving a travel advance.

### 1.2.2 – U.S. General Services Administration (GSA) and Travel Management

[GSA Federal Travel Regulations \(FTR\)](#) summarizes the travel and relocation policy for all federal civilian employees and others authorized to travel at the government’s expense. Federal employees and agencies may use the FTR as a reference to ensure official travel and relocation is conducted in a responsible and cost-effective manner.

Other important sites include:

- [GSA Domestic Per Diem Lookup](#) to assists travelers with finding Domestic Per Diem Rates.
- [U.S. Department of State Foreign Per Diem Rates by Location](#) to determine Foreign Per Diem Rates per location.
- [GSA Airline City Pairs Search](#) to assist travelers with finding the Airline City Pairs for the Current and Former Fiscal Year. For Domestic Travel, the traveler enters either the Departure City or three letter International Air Transport Association (IATA) code and the Arrival City or IATA code to find the Airline City Pair. For International Travel, the Departure and Arrival cities are required to query the Airline City Pair.

### 1.3 – Travelers’ Health

[Travelers’ Health](#) is a link to CDC’s Travelers Health Section. The CDC/Traveler's Health website is committed to updating the public with current and accurate information regarding vaccines and medicines, along with travel advice/recommendations, notices and resources. Investigators are encouraged to frequently review this site in advance of travel.

[FDA Occupational Health Services](#) has Health Units established for FDA employees to receive occupationally related medical services. Each health unit provides access to on-site first aid and urgent care services; onsite clinical care, referral and follow-up for work related injury and illness; immunizations; health risk appraisals; health screenings; health counseling; and health and wellness education. Services are provided by appointment only. To request OHS services **Outside the National Capital region**, please send an email to [occupationalhealthservices@fda.hhs.gov](mailto:occupationalhealthservices@fda.hhs.gov).

Also reference IOM Chap 5 for more traveler health and safety information.

## 1.4 – Division of Travel Operations

The ORA Office of Management's Division of Travel Operations (DTO) provides overall strategic leadership and guidance to ORA on all aspects of travel in accordance with established guidelines. DTO works to advance the strategic goals and objectives related to travel policies and guidance in ORA and assures compliance with statutes, executive orders, and administrative directives.

To assist ORA travelers and travel preparers, DTO has created the [Travel Resources SharePoint site](#) intended to provide cumulative guidance to facilitate travel. The DTO site has information regarding domestic and foreign travel, gainsharing, travel tips & tricks, conference approvals, travel charge card information and travel processes & SOPs.

### 1.4.1 – Domestic Travel

#### 1.4.1.1 – Domestic Travel Guide

ORA travelers preparing for domestic travel should use the [Domestic Travel Guide](#) to help walk them through the TA process. The Domestic Travel Guide – developed by the DTO Domestic Travel Branch - helps guide the traveler through what information and documents are needed to prepare travel authorizations and vouchers. Included in the guide are potential expenses to include on the TA, such as: Flights, Lodging, Lodging Tax, Hotel—Above Per Diem, First Bag Airline Fee, Taxi, Shuttle, Subway, etc., Tips/Gratuities, POV information, Airport Parking, Rental Car, Gasoline for Rental Vehicles, Tolls, ATM fees, Internet Expense, Conference Attendance and Laundry/Dry Cleaning.

The guide also includes information on payment methods, what and how to add comments for each expense and the supporting documentation needed for both TAs and Vouchers. Required information to include in the TA Trip Details section, how to identify states that are exempt from lodging tax (and what this means) as well as the types of travelers are also covered.

Additional information on domestic travel, including forms, frequently asked questions and tips on using ConcurGov are available on the [DTO Domestic Travel site](#).

#### 1.4.1.2 – Domestic Travel Contacts

DTO Travel Specialists: Travelers can reach out to their respective Travel Specialist (also called a Federal Agency Travel Administrator or FATA) as identified on the [DTO Travel Specialists Contact Sheet](#) with questions or for assistance.

Additional Contacts:

- [OMEGA World Travel](#): 1-855-326-5411
- [Citibank Customer Service](#): 1-800-790-7206
- Both OMEGA and Citibank are available 24 hours a day, 7 days a week. For any travel emergencies and concerns, contact your supervisor and OMEGA World Travel.

### 1.4.2 – Foreign Travel

#### 1.4.2.1 – Foreign Travel Information

International travel is important to achieving Departmental goals. However, such travel is typically very expensive and entails security concerns and other sensitivities. Therefore,

managers must carefully monitor the frequency of the overseas travel performed by their employees and others authorized to travel for HHS. OpDiv/StaffDiv Heads must maintain proper delegations of authority to ensure they approve proposed official international travel only when it effectively and safely serves the goals of the Department.

When assigned to a foreign inspection, employees will be assigned a Trip Coordinator from DTO who will assist with coordinating the logistics of the trip, such as flights and lodging. The Trip Coordinator will provide the traveler with all pertinent information upon assignment on topics such as passports, visas, and immunization/health information. DTO has also captured materials and resources that serve as a supplement to the trip-specific communications that are sent to the foreign traveler on its [Foreign Travel SharePoint site](#). Be sure to visit the: Pre-Travel, During Travel, Post-Travel, Contact Information, as well as the Resources section, to find links to useful information that may assist you through all aspects of the foreign travel process.

All Investigators conducting ORA foreign inspections must take required courses and trainings prior to departure. Investigators should contact their Program Office for information on these courses. See the [DTO Foreign Travel Security Training Requirements](#) site for more information.

DTO has also put together a [timeline of the coordination process](#). While actual time for trip coordination will vary based on each trip's specifics, this timeline gives the traveler a good idea on what to expect during the coordination process. For foreign travel, be aware that there are differences in reporting requirements and reimbursable expenses. See the Guide to International Inspections and Travel, [Chapter 2, Subchapter 215.2](#) – Reimbursable Expenses, for specifics.

#### 1.4.2.2 – Foreign Travel Contacts

Travelers should always contact their DTO Trip Coordinator first. Before departure, travelers will also be provided a list of additional DTO contacts their travel itinerary for any questions they have during travel should their Trip Coordinator be unavailable.

Additional contacts that may be useful during foreign travel:

- [Office of Human and Animal Food Foreign HAF Operations](#)
- [Office of Medical Products and Tobacco Operations Contacts](#)
- [Office of Management Contacts](#)
- [Office of Regulatory Affairs Travel Specialists \(FATA\) Contacts](#)
- [Office of Security and Emergency Management](#)
- [Employee Resource Information Center \(ERIC\)](#)
- [Tricare Overseas Program \(TOP\)](#):1-888 777-8343
- [Concur Government Edition \(CGE\)](#)
- For Mailing Documents to the U.S.: UPS Int'l Service Center: 1-800-782-7892
- [FDA's Computer Security Incident Response Team](#) (Certain designated countries only): Report if you suspect lost, misplaced, or stolen equipment or if you believe there has been a personally identifiable information (PII) breach.
- [Disaster Evacuation Contact System \(DECS\)- Blue Card](#): DECS provides management of the status of FDA personnel and their family members, information crucial in

determining resource allocation for continued FDA mission execution during emergencies/disasters.

- [OMEGA World Travel](#): Always attempt to contact the Trip Coordinator prior to contacting OMEGA at 855-326-5411
- [Citibank CitiManager](#): 1-800-790-7206 or [CCJAXL1HelpDesk@citi.com](mailto:CCJAXL1HelpDesk@citi.com)

### 1.4.3 – Per Diem and Subsistence Allowances

Per Diem is based on the actual cost of lodging, plus a set amount for "Meals and Incidental Expenses" (M&IE), not to exceed the maximum rate for the prescribed city or area. Subsistence is the cost of lodging, meals, tips, and the miscellaneous expenses you incur while in travel status. FDA Approving Officials, as well as FDA travelers, must follow the provisions of the FTR and HHS travel policy guidelines in authorizing, incurring, and approving per diem and subsistence expenses. Current per diem rates can be found on the [General Services Administration's \(GSA\) website](#).

Per Diem commences when you depart your home, office, or other point of departure, and terminates when you return to your home, office, or other point. This applies whether you are traveling by auto or by common carrier. M&IE may apply where there is no overnight lodging. However, M&IE will not be allowed for periods of time less than twelve hours; your work time plus your total commute time must be greater than twelve hours for you to be eligible for M&IE.

The [ConcurGov Program Support Center \(PSC\)](#) has developed training and job aids to assist users with the most common travel processes in the online travel management system, ConcurGov. Each job aid includes simple step-by-step instructions for specific processes within the ConcurGov system. Topics include air travel, travel expense planning, the FedRooms program, booking travel, authorizations and vouchers, receipts, SmartPay and more.

The FTR requires traveling employees to exercise care in incurring expenses which includes claiming a federal exemption from payment of state and/or local taxes on lodging whenever this option is available. Not all states and localities offer tax exemption, and some locations do not specify a particular form. Please view [GSA's tax-exempt state map](#) to determine tax exemption status and forms by state.

For domestic travel if the hotel does not accept the tax-exempt form, report lodging taxes separate from lodging expenses and claim them on your travel voucher. Foreign travel taxes still remain a part of your lodging expenses.

Lodging expenses should be paid using your government-issued credit card, when possible with direct payment to your government issued credit card (split disbursement) indicated on your travel voucher. It is your responsibility to pay the bill on time. The FDA will reimburse late charges on your bill only when you can show the late payment was due to late reimbursement of funds by the FDA.

Accurately record all of your expenditures; see IOM 1A.1.2 for information on recording expenses.

#### 1.4.3.1 Per Diem Rates, Actual Expense Reimbursement, and Lodging

Section 5.1 of the [HHS Travel Policy Manual](#) provides guidance for HHS civilian employees, invitational travelers, and OpDiv/StaffDivs regarding allowable per diem and subsistence expenses for TDY travel. HHS employees are expected to travel on a lodgings-plus per diem basis. Under the lodgings-plus per diem method, a maximum per diem rate is established for lodging, plus M&IE, at a specific location.

Travelers or designated personnel must make lodging reservations using the ETS and/or contracted TMC. First consideration must be given to establishments that are contracted by GSA under the [FedRooms](#) program to ensure that travelers stay in fire-safe accommodations at a rate that is at or below per diem.

For Mandatory Statements Required on Travel Vouchers - See IOM Exhibit 1-1 Allowable Expenses Chart for allowable expenses, receipts required, etc.

### 1.4.3.2 Miscellaneous Expenses

Section 5.2 of the [HHS Travel Policy Manual](#) provides guidance for HHS employees and invitational travelers on reimbursable miscellaneous expenses incurred during official travel. Each type of miscellaneous expense will be reported as a separate line item on the travel voucher, indicating the amount and dates when incurred. Unless otherwise specified, receipts are required only when the individual expense is greater than \$75.

Miscellaneous Expenses per the HHS Travel Policy Manual include:

- Hotel taxes: GSA does not include hotel taxes in the lodging rates that are issued as part of the per diem rates for the continental U.S. Hotel taxes are a miscellaneous expense item. Travelers are required to request exemption from state and local taxes where applicable. When the tax exempt option is available and used, the completed form is required to be attached to the traveler's voucher. Lodging taxes should not be claimed when the tax exemption form is used.
- Business and Personal Telephone Calls: Refer to [Staff Manual Guide 2343.2](#) to determine the maximum allowable reimbursement for telephone calls home. Also addresses Pre-Paid phone cards, Employee-Owned Personal Communication Devices, Internet Fees, Wireless access (internet fees), Airport/airplane internet fees.
- Laundry, Dry Cleaning, and Pressing of Clothing
- Baggage Fees
- ATM Fees/International Transaction fees for foreign withdrawals
- Trusted Traveler Programs and PreCheck (TM) Custom's and Border Protection's (CBP) Trusted Traveler Programs
- Emergency and Other Authorized Miscellaneous Expenses

### 1.4.3.3 - Special Travel Situations

See [HHS Travel Policy Manual](#) section 5.4 for guidance regarding special travel situations including the use of annual and compensatory leave.

## 1.4.4- [Transportation Allowances/Expenses](#)

### 1.4.4.1- Transportation Expenses

Section 4.1 of the [HHS Travel Policy Manual](#) provides guidance for FDA/HHS employees, invitational travelers, and OpDiv/StaffDivs regarding allowable transportation expenses for TDY travel. General Transportation Expenses topics include:

- Transportation Method and Routing

- Transportation Gratuities: Limited to 15% of the charge for service. If there is no service charge, the limit for tips is \$5.
- Procuring Common Carrier Transportation
- Mandatory Use of Contract Fares and When Contract Fares May Not Be Used. Refer to Federal Travel Regulation (FTR) [301-10.107](#) and [301-10.108](#) for additional information.
- Use of Privately Owned Vehicles (POVs), Rental Cars, and Other Special Conveyances

#### 1.4.4.2 -Authorization Of A Per Diem Allowance At The Official Station Or Within The Local Transportation (Formerly Local Travel) Area

Section 4.2 of the [HHS Travel Policy Manual](#) provides guidance regarding the authorization of a per diem allowance in conjunction with official business that takes place at the employee's official station or within the HHS defined local transportation (formerly local travel) area. It also applies to officers of the Commissioned Corps U.S. Public Health Service. Local transportation expenses do not require a no-cost travel order. Topics include:

- Criteria for Determining Allowable Local Travel Transportation Expenses
- Non-Reimbursable Local Travel Transportation Expenses
- Reimbursable Local Travel Transportation Expenses

### 1.4.5 - FURLOUGH GUIDANCE

#### 1.4.5.1 - Ethics Rules During a Shutdown

As federal employees--furloughed or not—you are still governed by the provisions set forth in the Standards of Ethical Conduct as well as the Hatch Act and other federal laws.

Things to Know:

- When seeking outside employment, no prior approval is required if not intending to work for a prohibited source. If you're seeking outside employment with a prohibited source, you must receive prior written approval.
- If you are substantially involved in the acquisition/disposal of real estate at GSA, please see GSA Supplemental Standards of Ethical Conduct (5 C.F.R. 6701.104).
- You cannot receive compensation for teaching, speaking, or writing that relates to your official duties.
- You cannot represent another person before any federal agency, department or court except for yourself, spouse, parents and children (18 U.S.C. 205).
- You cannot receive compensation from anyone else for their representational services before any federal agency, department, or court that is provided by another, including an employer (18 U.S.C. 203).
- You cannot use your official title to imply the government sanctions or endorses your personal activity.
- All gift rules still apply.
- The Hatch Act rules still apply. Visit the Hatch Act Update GSA InSite page for an overview and more information regarding the Hatch Act.

- Standards of Ethical Conduct for Employees of the Executive Branch, GSA Supplemental Standards of Ethical Conduct, as well as the conflict of interest statutes still apply.
- All media inquiries regarding your professional capacity, or GSA business, including speaking engagements, must be referred to the GSA Media Affairs team by emailing [press@gsa.gov](mailto:press@gsa.gov) or your Regional Public Affairs Officer if you're located in a regional office.

If you have any questions about your ethical obligations during the government shutdown, please contact GSA Ethics Law Staff at 202-501-0765 or your Regional Counsel. Find general furlough information in the [OPM's Pay & Leave Furlough Guidance](#).

#### 1.4.5.2 – Travel During A Lapse In Appropriations

Section 13 of the [HHS Travel Policy Manual](#) provides instructions and information concerning transportation and other expenses incident to travel in the event of a Lapse in Appropriations for HHS.

Travel in the event of a Lapse in Appropriations often involves unique or extraordinary travel scenarios for Federal employees and those traveling on behalf of HHS. However, all travel must be conducted in accordance with the FTR.

The policy guidance FAQs are intended to address those scenarios that occur most often, but it does not address every possible scenario.

Due to the fluid nature of a lapse in appropriations, visit [the PCS website](#) for the most recent information related to travel in the event of a lapse in appropriations.

During a lapse in appropriations, the Federal government may enact an Emergency Furlough. During an Emergency Furlough, the Office of Personnel Management (OPM) may issue guidance related to travel for employees impacted by an administrative furlough.

FDA Shutdown FAQs are contained in Exhibit 1-2; additional guidance may be found on [OPM's Shutdown Furlough Guidance](#) webpage.

### 1.5 – Vehicle Accidents

Immediate Action –

- Render first aid. If you are injured, obtain emergency treatment.
- Contact police.
- Report the accident to your supervisor as soon as possible.

#### 1.5.1 – Government-Owned Vehicle (GOV)

Each GOV used for district operations should be furnished with a GSA Fleet Vehicle Packet (Exhibit 1-3) with a [Fleet Vehicle Accident Kit-GSA 1627](#) (Exhibit 1-4). The US Government is self-insured and additional information can be found on the Fleet Vehicle Accident Kit.

##### 1.5.1.1 – Information to be Obtained

- Description of vehicles involved, including license numbers
- Name, address and other pertinent information about drivers and owners of other vehicles; exchange state driver license information if possible

- Names, addresses and signed statements of witnesses
- Names, official affiliation of investigating police officers
- Photographs of the scene and the damage
- Make no statements as to responsibility for the accident, except to your supervisor or investigating official.

### 1.5.1.2 – Reporting

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor and the chief of the motor pool from which the vehicle is assigned, unless your supervisor advises you the district will handle it. Report the accident to the GSA Accident Management Control Center ([Accident Management Center \(AMC\) | GSA](#)) Call (866) 400-0411, and select option 2.

- Complete the following forms and submit as required:
  - "[Motor Vehicle Accident \(Crash\) Report](#)" (SF-91) (A blank copy of this form should be kept in the glove compartment)
  - Copy of a traffic regulation or ordinance which was violated
  - Results of any trial or disposition of summons if any arrests were made or charges referred.
  - "[Claim for Damage, Injury, or Death](#)" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.) To be completed by claimant or non-government employee.
  - Investigation Reports and Policy Reports
  - "[Statement of Witness](#)" (SF-94)
  - Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
  - Statement listing date of purchase, purchase price and salvage value where repair is not economical
  - Photographs of damage and/or scene of accident if available
- File reports to comply with all local and state laws dealing with accident reporting. Keep copies of all reports made and attach them to the federal accident report.
- Check with your personal insurance carrier for their requirements.
- Immediately submit to your supervisor any notice, summons, legal paper or claim, which may subsequently arise from the accident.
- Check with your supervisor or administrative staff to determine if additional reports or information are needed.
- Submit completed claims package electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) e-mailbox or by inter-office mail or by the U.S. Post Office to the FDA Fleet Manager, Logistics and Transportation Management Branch, 10903 New Hampshire Ave, Bldg. 71, Room 2132, Silver Spring, MD 20993.

Tort claims must contain the completed SF-91 (Motor Vehicle Accident Report) and the -SF-95 (Claim for Damage, Injury, or Death). Notify the ORA Fleet Operations Manager of the accident via email at [ORAFleetManager@fda.hhs.gov](mailto:ORAFleetManager@fda.hhs.gov).

See also: [FDA Fleet Vehicle Risk Management: Motor Vehicle Accidents/Incidents](#) for additional information.

### 1.5.1.3 – Liability

[The Federal Drivers Act \(28 U.S.C. 2679\(a\)-\(e\)\)](#) was enacted to protect government drivers from personal liability while driving within the scope of their employment. This means you must be on official business to be covered. It relieves you from the burden of acquiring private automobile liability insurance for driving while on the job. The government's exclusive liability provided by this Act is predicated on its status as employer, without regard to whether the vehicle involved is government owned or privately owned.

[The Military Personnel and Civilian Employees' Claim Act of 1964](#) allows for claims against FDA by employees, provided the loss or damage was within the scope of their employment and the employee (claimant) is free of negligence regarding those losses (See IOM 1.5.1.3.1). [The Federal Tort Claims Act](#) provides for claims generally coming from outside the Agency where the activities of the Agency or specific individual employees are negligent and cause death, injuries, or property loss or damage (See IOM 1.5.1.3.2).

Claims should be submitted through your Administrative Office electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) email box via the Outlook mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management Branch, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132, Silver Spring, MD. 20993. The claim will be reviewed and forwarded to the Office of the General Counsel, (OGC) for determination. The claimant will be notified by the OGC.

#### *1.5.1.3.1 – Military Personnel and Civilian Employees' Claim Act of 1964*

Documentation and information are to be submitted as follows for military personnel and civilian employees' claims under the [Military Personnel and Civilian Employees' Claim Act of 1964](#).

#### *1.5.1.3.2 – Tort Claims*

Tort Claims can be filed by any individual who states that they have suffered personal injury or property damage or loss resulting from the action of an FDA employee or Commissioned Officer who was acting within the scope of employment.

##### **1.5.1.3.2.1 – Property Damage or Personal Injury**

"[Claim for Damage, Injury, or Death](#)" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.)

- Investigation Reports and Policy Reports

- [“Statement of Witness”](#) (SF-94)
- Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
- Statement listing date of purchase, purchase price and salvage value where repair is not economical
- Photographs of damage and/or scene of accident if available

## 1.5.2 – Privately Owned Vehicle (POV)

The [Federal Employees’ Compensation Act](#) (Workmen’s Compensation) protects employees against losses due to personal injuries received while operating POVs on official business.

Under the Federal Driver’s Act [28 U.S.C. 2679(a)-(e)], you are immune from any civil liability to other parties for property damage, personal injury, or death resulting from operation of a vehicle within the scope of your employment. This immunity applies whether the vehicle involved is a GOV or POV. The government would defend any such claim or suit and would pay any damage award to the injured party.

If an accident was caused by your negligent operation of a vehicle, and your vehicle is damaged, the cost of repairing your vehicle will not be paid for by the government. **You should look to your own private insurance carrier for reimbursement, payable under the terms of your own automobile insurance policy.** You are protected from liability by the Federal Drivers Act. See IOM 1.5.1.3 for further information on this.

If the accident is determined not to have been caused by your negligence, the provisions of the [Military Personnel and Civilian Employees’ Claim Act of 1964](#) (31 U.S.C. 240-243) would be applicable. **Under this Act, you would be reimbursed for the deductible portion of the repair not covered by your own automobile insurance policy, up to a maximum of \$250.00 deductible.** (You may also collect from the other party’s insurance.) Form HHS-481, [Employee Claim for Loss or Damage to Personal Property](#), should be obtained, completed, and submitted electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) Outlook e-mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132 Silver Spring, MD 20993 with evidence establishing that the use of a POV was authorized for official purposes and that the accident was not caused by your negligence.

Liability - see IOM 1.5.1.3.

Reporting - Report vehicle accidents as instructed in IOM 1.5.1.

## 1.5.3 – Rental Vehicle

### 1.5.3.1 – Reporting

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor as soon as possible. Follow IOM 1.5.1.1 to obtain the necessary information (e.g. description of vehicles involved, license plate numbers, pertinent information about drivers and owners of other vehicles, etc.)

Contact the car rental company to report the accident. Even if the damage to the rental vehicle appears to be minor, do **NOT** drive the rental vehicle from the scene unless you have contacted the rental car company and have obtained permission to do so.

- If the rental car company, other driver(s) involved, or other parties inquire about the requirements for filing a tort claim or personal property claim, provide them the "[Claim for Damage, Injury, or Death](#)" (SF-95). Provide the SF-95 to all customers (e.g. other drivers, their insurance company, rental car company) by following the Example Email Communication to Claimant Regarding Form SF-95 Submission (Exhibit 1-5). All claimants will return their SF-95 forms to you for submission with the tort claims package.
  - If possible, capture the date SF-95 forms are returned to you. If the form is returned via email, save a copy of the email and submit a copy of the email with the claims package.
- In addition to SF-95 forms, the following documents (as applicable) must be included in the claims package:
  - "[Motor Vehicle Accident \(Crash\) Report](#)" (SF-91)
    - Note: Since the accident did not involve a GSA fleet vehicle, sections X1 through XIII will not be completed.
    - SF-91 must be reviewed and signed by your supervisor.
  - "[Statement of Witness](#)" (SF-94), if any, or equivalent written statement.
  - Two repair estimates for claimant's vehicle
  - Copy of claimant's receipts
  - Police Report
    - If you do not have a police report, you must explain why.
  - Pictures of damages to rental vehicle
  - Pictures of damages to claimant's vehicle
- Submit completed claims package electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) e-mailbox or by inter-office mail or by the U.S. Post Office:  
FDA Fleet Manager, Logistics and Transportation Management Branch  
10903 New Hampshire Ave, Bldg. 71, Room 2132  
Silver Spring, MD 20993.

You will submit the claims package as described above even if you do not have SF-95 forms returned to you by the applicable claimants. Do not delay submission of the tort claims package. Explain which documents are not being submitted and why at the time the claims package is submitted to the Tort Claims Office. Missing documentation can be submitted as they become available (e.g. SF-95, police report)

Tort claims must contain the completed SF-91 (Motor Vehicle Accident Report) and the SF-95 (Claim for Damage, Injury, or Death). Notify the ORA Fleet Operations Manager of the accident via email at [ORAFleetManager@fda.hhs.gov](mailto:ORAFleetManager@fda.hhs.gov).

## 1.6 – Transportation

Section 4.2.5 of the [HHS Travel Policy Manual](#) provides guidance for FDA/HHS employees, invitational travelers, and OpDiv/StaffDivs regarding modes of travel- public, private, government and rental.

Your agency must select the method most advantageous to the Government, when cost and other factors are considered. Under [5 U.S.C. 5733](#), travel must be by the most expeditious means of transportation practicable and commensurate with the nature and purpose of your duties. In addition, your agency must consider energy conservation, total cost to the Government (including costs of per diem, overtime, lost work time, and actual transportation costs), total distance traveled, number of points visited, and number of travelers”.

### 1.6.1 – ORA Government-Owned Vehicle (GOV)

GOVs for district operations are furnished by the regional GSA motor pool office. GOV users should follow the district operating procedures in effect for the appropriate GSA motor pool. Each district has an assigned Fleet Operations Representative that can answer general GOV questions as needed.

Vehicle Operation - You are required to have a valid state, District of Columbia, or commonwealth operator's permit for the type of vehicle to be operated, and a valid DHHS identification document (i.e., Agency ID card, credentials, building pass, etc.).

Each district has working arrangements for the repair and maintenance of vehicles, either with GSA contractors or the GSA Fleet. It is your responsibility to adhere to those safety and maintenance checks. Do not operate cars known to be mechanically unsafe. Handle emergency repairs in travel status in accordance with your district and GSA motor pool procedures.

Purchase fuel and oil for your GOV with GSA Wright Express (WEX) Credit Cards. GSA WEX Credit Card receipts are to be turned into the GSA regional motor pool servicing your location. Follow your district procedure for submitting GSA WEX Credit Card receipts. Make emergency purchases with cash only when the GSA WEX Credit Card is refused. You also have the option to contact [GSA's Maintenance and Control Center \(MCC\)](#) which provides GSA Fleet customers and vendors with one-stop service for mechanical repairs. The MCC provides authorization for repairs and services over \$100, or for any tire and battery replacement, regardless of cost. Please consult your local Fleet Operations Representative and/or Fleet Vehicle Custodian and supervisor for specific instructions and guidance.

To contact the MCC, call 1-866-400-0411, and follow the menu options. The GSA Fleet Vehicle Assistance Card can be printed and carried with you for reference (Exhibit 1-6).

You are responsible for all traffic violations, including parking fines, you incur during the use and operation of a GOV. See [Staff Manual Guide \(SMG\) 2173.1](#), Section Attachment D 1.H.

While traveling on official business, you may be reimbursed for parking fees or overnight storage charges. Provide for the safe and proper overnight storage of GOVs while you are in travel status and put the charges on your travel voucher. Receipts are required when available.

Bridge, ferry and road tolls may be paid in cash. Put these charges on your travel voucher. Receipts are only required for amounts over \$75.00.

[FDA Fleet Vehicle Operator Training: Prerequisite for GOV operation](#)

## [FDA Fleet Vehicle Operation: Use and Care of Government Vehicles](#)

### [GSAFleet2Go](#)

GSAFleet2Go is a mobile app for General Services Administration Fleet drivers to supply maintenance and repair, Fleets Service Representatives, preventive maintenance and recall reminders, accident reporting, and other relevant Fleet info.

#### *1.6.1.1.1 – Care and Custody of U.S. Vehicles*

GSA has issued instructions on the use and protection of U.S. Government vehicles, [GSA WEX Credit Card](#), and car keys. The parts of these instructions applicable to you while the car is in your custody are:

- The car should be locked when parked in public areas, in private lots, or in open government parking areas.
- The vehicle operator is responsible for the keys and WEX card. They should be returned to the Fleet Operations Representative and/ or Fleet Vehicle Custodian's office or KeyTrak system (if installed) and secured in a locked environment daily/nightly. These items should be kept in a safe place in the office if the vehicle is stored at a location other than assigned FDA GOV storage.
- It is permissible to turn over a GOV to either parking lot attendants or valet parking attendants who must park the vehicles at locations where the drivers/operators are not permitted to park the vehicles themselves when no self-parking options are available. You must remove the WEX credit card from the GOV, keep it secure when handing the vehicle off to the valet or parking attendant, and keep it with you in a safe place.
- The credit card may only be used to purchase fuel and vehicle lubricants or other vehicle appropriate items listed on the back of the card for the vehicle identified, and not used for other vehicles.
- Before signing a service ticket, check for accuracy. Be sure the imprinted address is legible and write the vehicle mileage (odometer reading) on the ticket. Submit a copy or original to the Fleet Operations Representative or Fleet Vehicle Custodian for your appropriate district for monthly reporting requirements.
- Odometer readings can also be reported by using Get Odometer Reading at the Pump (GORP) when time to refuel a vehicle.
- Filling the government-owned vehicle with fuel is the responsibility of the authorized driver. Follow district guidelines for submitting fuel receipts.
- The use of tobacco products is prohibited in government-owned or commercial leased vehicles.
- In accordance with [Executive Order 13513](#), "No Texting While Driving", federal employees shall not engage in text messaging (a) when driving GOV, or when driving POV while on official government business, or (b) when using electronic equipment supplied by the government.

Refer to the HHS Program Support Center [Fleet Management Resources](#) website for more information.

#### *1.6.1.1.2 – Use of a GOV between Your Residence and Place of Employment*

No FDA/ORA employee shall use a GOV for transportation between their home and place of employment without the expressed written approval of the Secretary of Health and Human Services. Requests for Home-To-Work Authority must be submitted in writing by the supervisor of requesting individual to the ORA Fleet Operations Manager. See also: [Staff Manual Guide 2173.1](#) and [FDA Fleet Vehicle Operation: Home-to-Work Policy for Use of Government Vehicles](#).

Vehicles assigned to or purchased or leased by FDA are intended for official business as authorized by [Federal Management Regulation 102-34.220](#). FDA motor vehicles are not provided for the convenience of FDA employees.

Official business shall be interpreted strictly and shall not be construed to encompass the mingling of official business with non-official business. Official business is defined as those activities conducted during duty hours, which are considered an official part of the employee's assigned duties. Non-official business for which the use of Government owned or commercially leased/rented vehicles is illegal includes, but is not limited to such activities as:

- Attending to personal business
- Attendance at luncheons or other social engagements
- Pleasure trips; etc.

Any employee of the Federal Government who willfully uses or authorizes the use of any Government-owned or commercially leased/rented vehicle for other than official purposes shall be suspended from duty by the office concerned, without compensation for not less than 30 days and shall be suspended for a longer period or summarily removed from office if circumstances warrant.

Government vehicles should only be used when it is: (1) the least costly method of transportation available (considering the value of employee time and actual transportation costs) or (2) when no other practical method of transportation is available considering the mission to be performed; the location; and any equipment needed to be transported to support the mission.

The Daily Log of Government Vehicle ([Form FDA-3369](#)) must be maintained by all approved persons using a GOV, assuring that all items indicated on the form are completed for each trip. The DHHS now requires that each approved person taking a GOV home, must indicate the location of their residence in Column 10 on the FDA-3369.

The Daily Log must be kept for at least a period of three years and must be available for audit purposes. Please work with your Fleet Operations Representative and/or Fleet Vehicle Custodian to get the completed FDA-3369 forms uploaded to the appropriated vehicle on the [Fleet Management Program \(FMP\)](#) SharePoint site. If you need access to the site for uploading the form, please email the ORA Fleet Operations manager at: [ORAFleetManager@fda.hhs.gov](mailto:ORAFleetManager@fda.hhs.gov).

### 1.6.1.1.3 – Roadside Assistance for U. S. Vehicles

For situations that may require emergency towing, changing flat tires, or lock-out service, the following options are available:

- For roadside assistance from Monday through Friday from 7:00 AM to 8:00 PM ET, contact GSA Fleet MCC at 866-400-0411, choose option 1.
- For roadside assistance outside of the timeframe listed above, roadside assistance is offered by the manufacturers for vehicles under warranty. The contact for specific manufacturers can be found at [GSA Roadside Assistance](#).

## 1.6.2 – Privately Owned Vehicle (POV), Rental Vehicle, and Other Special Conveyances

See [HHS Travel Policy Manual](#) section 4.1.10.

### 1.6.2.1 – Privately Owned Vehicle (POV)

On official business, you may use your POV instead of a GOV, if authorized. However, reimbursement for mileage will not exceed the cost of using a GOV. Mileage is payable to only one employee when two or more employees travel in the same vehicle on the same trip. The employee claiming reimbursement will list on the voucher the names of other passengers accompanying him or her. See current [POV Mileage Reimbursement Rates](#).

You should carry a set of government accident reporting forms whenever you use your POV for official business. See IOM 1.5 for accident reporting requirements.

In general, the mileage allowance is in lieu of all expenses of operating your POV, except tolls. Unless otherwise authorized, reimbursement is limited to the cost of travel by common carrier. Standard highway guide mileage may be used in lieu of odometer readings for direct travel from one town to another. Explain any extra mileage on your travel voucher.

According to [HHS Logistics Management Manual](#), HHS employees and contractors may use their POVs for official purposes when it is considered to be advantageous to HHS. Employees and contractors authorized to use POVs for official duties are entitled to reimbursement, per miles driven, based on GSA's annual rates.

**Please Note - HHS employees and contractors who use POVs should inform their insurance companies that their vehicles are being used for official purposes. An HHS employee or contractor assumes full financial liability when using a POV for official purposes.**

### 1.6.2.2 – Rental Vehicle

GSA and the Department of Defense (DOD) both provide employees with a nationwide commercial auto rental program. Agency policy dictates leasing the least expensive auto to satisfy the transportation requirements. If a rental vehicle is determined to be the most advantageous mode for travel, there must be specific written authorization or prior approval to obtain this service. See your Administrative Officer for additional information and necessary form to be uploaded into ETS.

When an employee is authorized in advance to hire a rental vehicle for official travel, the employee may use the rental vehicle for official purposes while at the TDY station, including travel to and from restaurants near the work site or hotel. Employees should be aware that the Government will deny liability for any loss or damage to a vehicle rented for official business purposes using a government travel charge card if that loss/damage arises from activities outside the scope of official business travel. Refer to the [HHS Travel Policy Manual](#) section 4.1.10.2 (Rental Vehicles) for more information rental car fuel, usage, default rental car size, responsibility for violations, etc.

Optional Collision Damage Insurance, known as CDW, will not be reimbursed for domestic travel. Participating rental companies have agreed to settle any claim for damages with the FDA. CDW is required for foreign travel and will be reimbursed. The government will not pay or reimburse you for Personal Accident Insurance (PAI) for domestic or foreign travel.

Travelers are required to adhere to the same rules and regulations covering government owned vehicles when using a rental car while on official business.

### 1.6.2.3 – Public Transportation

Public transport (also known as public transportation, public transit, or mass transit) is a system of transport for passengers by group travel systems available for use by the general public unlike private transport, typically managed on a schedule, operated on established routes, and charge a fee for each trip. Examples of public transport include city buses, trolleybuses, trams (or light rail) and passenger trains, rapid transit (metro/subway/underground, etc.) and ferries. Public transport between cities is mostly conducted by airlines, coaches, and intercity rail.

Public transportation should be used when practical between points where official business is being conducted and employees may be reimbursed for use of public transportation when using to conduct official government business.

### 1.6.2.4 – Bus

There are no government-preferred providers for bus service. If a traveler wishes to use bus as a means of common carrier transportation, it requires pre-authorization by the AO. Refer to the [HHS Travel Policy Manual](#) section 4.1.10.3 (Buses) for more information.

Shuttles/buses are an optional mode of transportation between sites when on TDY travel (e.g., between residence and carrier terminal, place of lodging and temporary work site, carrier terminal and place of lodging). Reimbursements for use of shuttles/buses in these instances will only be allowed when authorized on your TA. Use of a shuttle or bus for domestic local travel between sites (examples above) does not require supporting documentation to be uploaded in your TA. These transportation costs must be broken down into daily expenses. Receipts are mandatory if cost is over \$75.00.

Per the [HHS Travel Policy Manual](#) section 4.1.3 (Transportation Gratuities), tips to a taxi, shuttle service, or courtesy transportation driver are limited to 15% of the charge for service. If there is no service charge, the limit for tips is \$5. Employees are expected to make maximum use of courtesy transportation (e.g., free airport/hotel shuttle service) in lieu of incurring charges for the same

transportation. Transportation Gratuities should be listed as a miscellaneous expense on the Travel Voucher.

### 1.6.2.5 – Other and Special Conveyances for Transportation

Refer to the [HHS Travel Policy Manual](#) section 4.1.10.4 for more information on other types of conveyances such as public transportation (e.g. subway, train, ferry). TA and receipt requirements for public transportation between sites when on TDY travel are the same as described above for shuttles/buses (IOM 1.2.2.3).

### 1.6.2.6 – Authorization of and Reimbursement for the Use of Transportation Network Companies

In practice, employees shall consider courtesy shuttles, public transportation, multiple party transportation, and taxicabs before using a Transportation Network Company (TNC). Some fees particular to TNCs such as "surge" or "peak hour" fees shall not be reimbursed.

Refer to the [HHS Travel Policy Manual](#) section 4.1.10.5 and [Understanding Transportation Network Companies](#) for more information.

TA and receipt requirements for TNCs between sites when on TDY travel are the same as described above for shuttles/buses (IOM 1.2.2.3). See IOM 1.2.2.3 for more information on allowable transportation gratuities/tips.

### 1.6.2.7 – Taxi

Reimbursements for the use of taxicabs will only be allowed when authorized on your TA. Allowable tips are 15% of the reimbursable fare. Receipts are required for fares over \$75.00.

You will be reimbursed for the usual cab and/or airport limousine fares plus tip from your home/office to the common carrier terminal on the day you depart on an official overnight trip, and upon your return. In lieu of cab, you may use your personal car at a mileage rate not to exceed the cab fare plus tip. See your administrative personnel for current mileage rates, the maximum allowable taxicab fares, and other pertinent details.

## 1.7 - Media Interactions During Inspections

The inspectional and investigational activities of the FDA receive extensive coverage in online/social, electronic, broadcast and print media. ORA field inspectional staff are occasionally requested by the media to comment or provide information on their individual inspectional activities. Such requests can include being interviewed and filmed during inspections, investigations and sample collections. If media representatives contact you, be courteous and helpful, but refer all requests for information, interviews and personal appearances to your supervisor. Those requests must be approved in advance and should be referred to [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov) for coordination with FDA's Office of Media Affairs.

Remember that you are always on the record, even during your initial contact with a reporter. Never tell a reporter you have to obtain clearance first; instead, obtain contact information, topic/questions and response timeframe for follow-up with the ORA Press Team. A request for information and a request for

an interview should be treated the same way. When fielding a question(s) in person at an event or via the telephone if the person asking questions does not first identify themselves as a member of the news media, it is ok for you to ask if they are a member of the news media. If they are not a member of the news media then follow existing protocol to direct people to the appropriate location at the FDA's website, [www.fda.gov](http://www.fda.gov) for the most up to date information on any topic.

The reason you should ask if the person is a member of the media is to ensure that any message shared with the public via a news organization is the latest vetted messages that have undergone close coordination with our scientific and policy experts at FDA headquarters.

Do not solicit media interviews or on-camera appearances. There may be occasions when management of a firm you are inspecting invites representatives from the news media to observe the inspectional process. Please see IOM 5.1.4.3 for instructions on how to appropriately handle such events.

### 1.7.1 – Media Resources

- [ORA Media Engagement](#)
- [Mobile Support Instructions pdf](#) (Exhibit 1-7)
- [ORA Media Fact Sheet](#)
- [Media Tip Card](#) (Exhibit 1-8)
- [Media Preparedness Training](#)
- [ORA Media SharePoint Links](#)
- Contact: [ORApres@fda.hhs.gov](mailto:ORApres@fda.hhs.gov)
- [Office of Media Affairs Contacts](#)
- [ORA Media Engagement Communications Toolbox](#)

## 1.8 - Equipment

You are responsible for the proper acceptance, use, protection, and surrender of any Government property assigned to your custody or control; you may be held liable for violations of such responsibility when they result in losses to the Government. The [Personal Property Management Program \(PPMP\)](#) oversees the integrity, proper use, and safe guarding of equipment.

Per PPMP policy:

- Accept property only when properly assigned to you and do not remove any property without consent.
- Do not use, or permit any other person to use, FDA property for any purpose other than official use.
- Coordinate the disposition of all property through the PPMP or the [Center/Office Accountable Property Officer \(APO\)](#).
- An employee leaving any jurisdiction shall return any property or account for all personal property and other items for which personally responsible.
- Assure proper care of property entrusted to you (safe parking for vehicles, keeping inspectional and investigational equipment securely locked in the trunk of the car, not leaving valuable equipment in the car's trunk while the car is in for servicing, not leaving electronic

equipment/computers in the trunk of the car for extended periods in extreme hot or cold weather conditions, storing all property in safe, secure areas...)

All FDA property related questions should be directed to your supervision who will then reach out to the Property Custodial Officer or the [Center/Office's APO](#).

For lost or stolen equipment, immediately contact your supervisor, the FDA IT Security Operations Center and your foreign travel trip planner as applicable if you suspect lost, misplaced or stolen equipment (e.g., Blackberry, laptop, Ironkey, cell phone, etc.) that contains personally identifiable information (PII) such as a person's home address or social security number, or other sensitive non-public information. Using the [IT Security Incident Checklist](#) (Exhibit 1-10) as a guide, immediately contact the FDA Systems Management Center at:

- Email: [FDA\\_Systems\\_Management\\_Center@fda.hhs.gov](mailto:FDA_Systems_Management_Center@fda.hhs.gov)
- Toll Free Number: 855-5FDA-SMC (855-533-2762)

Additionally, a memorandum should be prepared detailing

- the circumstances surrounding the loss
- a full description of the article including FDA barcode/tag/serial number as available
- the comprehensive steps you took to recover the item(s)

In the case of theft, obtain a police report and provide a copy of the report within two days of the incident.

Follow your District procedures for any additional requirements.

Responsibilities for government property in your custody are also outlined in the [Staff Manual Guide 2280.5](#).

### 1.8.1 - EQUIPMENT CARE/CALIBRATION

First-line maintenance rests with you as the custodian of the items entrusted to you. Generally, common sense and handling the equipment as if it belonged to you, should suffice, such as in equipment that requires little or no maintenance as such, other than dusting, replacing batteries and bulbs, making minor adjustments, properly packing in carrying cases, and proper protection as necessary.

Needed repairs, defects, or inoperative equipment, should be immediately reported to your supervisor. When in travel status, necessary minor repairs to equipment may be obtained locally, if possible, and reimbursement claimed on your travel voucher. Major repairs should be cleared through your supervisor.

You are responsible to assure equipment assigned to you is calibrated for accuracy prior to using in inspectional activities. This includes thermometers, pyrometers, balances, scales, stopwatches, etc.

Thermometers are used for evidence development during inspectional activities to enforce the Federal Food Drug and Cosmetic Act and other statutes in the specific ORA programs. Refer to [SOP-000735 Thermometer Maintenance Procedure](#), in the Quality Management Information System (QMIS), for details.

Stopwatches may be calibrated using the atomic clock at [the U.S. Naval Observatory](#) in Washington D.C., using the commercial numbers at (202) 762-1401 or (202) 762-1069. Calibrate stopwatches at several different time intervals within the expected parameters of use. At least three runs should be made at each interval, then averaged for each interval and the correction factor, if any, entered on the record of calibration maintained with the watch. Calibration of your computer's internal clock can be obtained from the same source. Information and software is also available on the U.S. Naval Observatory's Website. For more detailed stopwatch/timing devices calibration instructions, see the National Institute of Standards and Technology (NIST) procedure [SOP 24](#).

## 1.8.2 – INFORMATION TECHNOLOGY (IT) DEVICES/EQUIPMENT

[FDA's IT Hub](#) provides FDA employees with the latest IT news, updates, and informational resources about technology services, programs, systems and applications used agency wide.

### 1.8.2.1 - [FDA Information Systems Security and Privacy Guide](#)

Documents FDA control parameters and consolidates and aligns FDA IT Security Policies with requirements and standards. This document is an addendum to the Staff Manual Guide 3251.12 and establishes comprehensive IT security and privacy requirements for the FDA IT security program and information systems.

### 1.8.2.2 - [FAQs](#)

Refer to this site for information on telework, lost/stolen IT equipment, virtual meetings, etc...

### 1.8.2.3 - [Mobile Devices Security Awareness](#)

At FDA, a "Mobile Device" is an interactive mobile computing device, such as BlackBerry devices, laptops, and mobile phones with text capabilities. These devices can be used remotely and used both in and out of the Agency. If you have a mobile device for work or personal use, make sure to protect both the machine and the information it contains.

Examples of mobile devices include:

- Laptops, tablets, and iPads
- iPods and MP3 players
- Global Positioning System (GPS) satellite receivers
- BlackBerry devices
- Cell and smart phones
- PIV Card Readers
- Small (pocket-size) USB and FireWire (IEEE1394) hard drives
- USB flash drives (also known as thumb drives) and other removable memory devices (flash memory, SD cards)

Risks and Concerns with Mobile Devices:

- Mobile devices often have removable memory cards that create the potential for data leaks or loss.
- USB flash drives can be an immense source of data leakage. Thumb drives are easy to keep hidden because they are small. An employee with bad motives can easily slip one in and out of a facility, stealing Gigabytes of data.
- Centralized systems are not able to easily manage portable devices.
- Putting adequate safeguards in place to check what data is coming and going can be difficult.

- Mobile device breaches are often more difficult to detect than non-mobile breaches because users may not know about the loss for days or weeks.
- Social media applications and other applications can pull more information than intended. Personal information including your location, phone number, and address can be revealed. Be cautious and check the permissions of an application before it is installed.

Reporting an Incident: Report an incident to the FDA IT Security Operations Center if you suspect lost, misplaced, or stolen equipment (e.g., cell phones, laptops, badges, documents/paperwork, etc.) or if you believe there has been a Personally Identifiable Information (PII) Breach. Consult the [FDA Reporting a Security Incident page](#) for more information.

- Do NOT put FDA information on your personally owned mobile and portable devices.
- Keep an eye on your equipment at all times and report lost or stolen equipment by Reporting an Incident to the FDA Cybersecurity Operations Center immediately.
- Use FDA-approved mobile devices and media with encryption on FDA systems.
- Do not use personal flash drives or thumb drives in FDA equipment.
- FDA now offers a secure flash drive, called the IronKey.
- Do not place non-FDA-owned or authorized portable devices on FDA networks or sync to FDA PCs without prior written authorization from the FDA CISO. "It is against FDA Policy to connect any personal IT equipment (including laptops, printers, etc) to the FDA network or to FDA equipment."

Only Agency approved mobile devices will be used with FDA data or the FDA network. All mobile devices shall be marked with appropriate FDA property tags.

Encryption is a process that transforms plain text or data using a mathematical formula/algorithm and a "key" making it unreadable to an outside party. Only those that have the "key" can decrypt the data. The more extensive the key, the harder it is to solve the encryption. Encrypt all sensitive information including the following:

- FDA information or data that is accessed remotely
- Messages containing sensitive information that are sent outside of FDA's network

The following MUST be encrypted:

- Laptops or other mobile devices with sensitive information
- Equipment that is transported and/or stored offsite

#### 1.8.2.4 - Risks of Connecting Personal Devices to the FDA Network

Any personal or contractor-owned device that is connected to the network that is not authorized or does not meet government security standards is not allowed. Many types of personal devices could contain a vulnerability that could put the network at risk. Follow FDA/HHS policies and the HHS Rules of Behavior to help protect the FDA network. If you believe you may have accidentally connected a device to the network and/or feel malware has infected your computer, contact ERIC immediately. Note that if your office purchases a USB drive or other device that is not on the Master Approved Technologies (MAT) list, you should not connect this device to the network. You can locate the MAT list of approved software, hardware and devices at [Request-IT](#).

## 1.8.2.5 - Traveling outside of the US with Government Furnished Equipment

### 1.8.2.5.1 - Use of Government Furnished Equipment (GFE) During Foreign Travel

Before you bring FDA technology assets on international travel on behalf of the FDA, remember:

- If you do not need a laptop or iPhone, do not take it. This also applies to personal travel.
- Carrying portable devices is discouraged, but not prohibited. Consult with [IT-ForeignTravelSecurity@fda.hhs.gov](mailto:IT-ForeignTravelSecurity@fda.hhs.gov) if you plan to take portable devices on personal international travel.
- Do not leave IT equipment unattended.
- Do not connect unauthorized IT equipment to your laptop or iPhone (i.e. thumb drives, hard drives, etc).
- USB thumb drives are prone to malware infections. Rewritable discs (i.e. CD-RW, DVD-RW) and IronKeys are an excellent substitute to thumb drives.
- Loaner laptops and iPhones issued solely for international travel should NEVER be connected to the FDA network upon return.
- Return all FDA loaner IT equipment the next business day upon arriving back to the office.
- Contact [IT-ForeignTravelSecurity@fda.hhs.gov](mailto:IT-ForeignTravelSecurity@fda.hhs.gov) for loaner equipment requests or questions.

Effective October 2017, all FDA Federal Employees and contractors traveling or planning to travel to China and its territories (i.e., Hong Kong) on official business must attend a counterintelligence awareness briefing prior to making travel arrangements. The U.S. Embassy will not approve an eCC until this requirement is met. This eCC represents official approval from the U.S. Embassy for U.S. government employees to enter the country. This briefing should be at the level of your security clearance (unclassified for Public Trust holders or classified for SECRET or TOP SECRET clearance holders). The briefing is good for one year.

Remember that you have no expectation of online privacy in most countries. For that reason, you should be aware of the following items, whether you are traveling for business or pleasure.

- Expect that transmission of information is being intercepted and read at any location where networks are controlled by another government. Foreign network providers can disable mobile device encryption and then turn it back on after information is intercepted. How to protect the data: Do not process or transmit sensitive information. Do not take FDA or personal technology assets (laptop, iPhone, cell phone, etc) if you do not need them or connect to the FDA network via the virtual private network (VPN) or access FDA email (i.e. webmail or Outlook). Click here to view the FDA Information Systems Security & Privacy Guide (SMG 3251.12a) [Appendix U: Mobile Equipment for Overseas Travel to Designated Countries](#).
- When overseas, foreign communication networks can intercept wireless device signals. Assume that all forms of communication with wireless devices are monitored and subject to compromise. Hacker software can be used to locate and connect to vulnerable Bluetooth-enabled cell phones, allowing address book information, photos, calendars, and SIM card details to be downloaded. Unauthorized long-distance phone calls could also be made using the hacked device. How to protect the data: Power off mobile devices when not in use and only use the Bluetooth function if absolutely necessary. (Do not use the Bluetooth function if traveling for business). Remove the battery from your mobile device and store it separately from the device.

- Anywhere facilities (i.e. hotel) are controlled by another government, you should expect tampering with unattended electronic devices. Hotel rooms and safes are accessible by hotel staff and possibly local authorities. How to protect the data: Avoid leaving electronic devices unattended in a hotel room. If that is not possible, remove the battery, and hard drive as accessible, and store separately from the device.
- Be aware that public Internet kiosks and cafes are breeding grounds for malicious software that can capture private information (passwords, bank account or credit card numbers, phone numbers, names, etc). How to protect the data: Avoid connecting to public Wi-Fi hot spots and always use FDA provided systems and solutions using the Virtual Private Network (VPN) for remote access. Click here to view the FDA Information Systems Security & Privacy Guide (3251.12a) [Appendix M: Remote Access](#).
- When passing through airport security, watch your laptop and other equipment until it enters airport scanners.
- Do not check a laptop with your baggage.

Immediately report any suspected tampering, unauthorized use, loss or theft of any FDA asset to the SMC/Cybersecurity Operations at [FDA\\_Systems\\_Management\\_Center@fda.hhs.gov](mailto:FDA_Systems_Management_Center@fda.hhs.gov) or 855-533-2762 (24x7).

#### 1.8.2.5.2 Foreign Travel FAQs

- [Foreign Travel FAQs \(pdf\)](#)

### 1.8.2.6 - Reporting an IT Security Incident

#### 1.8.2.6.1 – Reporting IT Security Incident Checklist

- [Reporting IT Security Incident Checklist](#) (Exhibit 1-9)

##### 1.8.2.6.1.1 Immediately contact

- Email: [SMC@fda.hhs.gov](mailto:SMC@fda.hhs.gov)
- Toll Free Number: 855-5FDA-SMC (855-533-2762)

### 1.8.2.7 - Employee Resource & Information Center (ERIC)

- Online: Submit your own ERIC ticket via the [FDA Service Portal](#).
- By phone: 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742)
- By email: [ITCallCenter@fda.hhs.gov](mailto:ITCallCenter@fda.hhs.gov) for IT-related issues OR [ERIC@fda.hhs.gov](mailto:ERIC@fda.hhs.gov) for all other issues.

## 1.9 - OFFICIAL IDENTIFICATION

### 1.9.1 - Credentials/Badges

[Guide 2280.3](#) provides instructions for the issuance and control of FDA Credentials and Badges including expiration, renewal, transfer, separation and retirement. Contact your supervision and [FDA-ORACredentials@fda.hhs.gov](mailto:FDA-ORACredentials@fda.hhs.gov) for additional information and questions.

#### 1.9.1.1 - Policy, Authority

Official credentials are for issuance to investigators and inspectors who are regularly engaged in investigational and inspectional activities; however, on occasion they may also be issued to other FDA personnel when it is necessary for these employees to engage in inspectional activities which

would require credentials. By virtue of their position, credentialed employees are recognized as authorized to perform the duties assigned.

Badges may only be issued to holders of FDA credentials to facilitate performance of their duties when it is determined that the possession of a badge would be advantageous. **Investigator badges shall not be used in routine operations.** They shall be used only in those situations where display of a badge is essential for rapid identification to indicate authoritative presence in order to facilitate FDA operations. Division Staff Manual Guide, FDA 2280.3, 5b, outlines situations in which use of the badge may be appropriate.

FDA official credentials and badges shall be used for OFFICIAL business only. They shall not be used as a means of personal identification or for personal purposes. Show your credentials to appropriate firm personnel during all non-undercover investigations, inspections, sample collections, recall effectiveness checks, etc.

Precautions against photocopying your credentials: although firm management may examine your credentials and record the number and your name, do not permit your credentials to be photocopied. Federal Law ([Title 18, U.S.C. 701](#)) prohibits photographing, counterfeiting, or misuse of official credentials. Credentials must not be shown over video during remote activities, such as a remote regulatory assessment. Do not permit a firm to take your fingerprints. Contact your SCSO for more information as necessary.

To apply for official credentials, you must complete FDA 2115 and submit it to ORA [FDA-ORACredentials@fda.hhs.gov](mailto:FDA-ORACredentials@fda.hhs.gov) for processing. Please see your Administrative Officer for additional information.

#### 1.9.1.2 - Renewal/expiration

Though issuing officials will notify credential and badge holders no later than 30 days prior to the expiration date that their credentials/badge will expire, check your credentials periodically, prior to performance of duties, to ensure they are not expired.

#### 1.9.1.3 - Care of Credentials, Badges

FDA Official Credentials confer extensive inspectional authority on you. Exercise the utmost care of your badge and credentials. Carry them in a manner that will assure positive protection against loss. Do not carry them in the upper pockets of your clothing where they may fall out if you bend over. Carrying your credentials and badge in the glove compartment of your car or leaving them in the pocket of an unattended coat or jacket are invitations to loss or theft.

#### 1.9.1.4 - Lost or Stolen Credentials, Badges

The procedure for reporting loss or theft of credentials and/or badge is in the [Staff Manual Guide \(SMG\) 2280.3](#). Notify your supervisor immediately. Report the loss or theft to local law enforcement authorities (police department) and request a copy of the report including the police report identification number. Also report the loss or theft to the [local \(state\) FBI field office](#) so that the number of the credentials/badge can be entered into the National Crime Information Center (NCIC) system.

A written report containing the police report number and a statement that the local FBI field office was notified must be submitted to your supervisor and the issuing official. Replacement credentials will be issued at the discretion of the authorizing official.

## 1.9.2 - PIV

The FDA identification badge (PIV) is a multi-purpose badge that includes a magnetic strip (for card access) and a barcode (for employee identification programs). The purpose of your FDA PIV badge is to ensure that only authorized personnel gain access to FDA facilities. The badges are encoded to limit an individual's access to designated security areas. The FDA Badging [PIV Card FAQs](#) discusses PIV issues such as login, PIV pins, signing a document, remote networking, lost PIV and how to get PIV assistance.

## 1.10 - Business Cards

Business Cards are defined as cards of introduction bearing the name, address, phone number, fax number and e-mail address of active agency representatives. The distribution of business cards facilitates prompt and efficient communications by the persons and organizations with whom the Agency transacts business. The purpose of the business card is to further the Agency's statutory mission and therefore, the purchase constitutes a proper expenditure. Due to certain restrictions pertaining to the purchase of business cards, employees should consult with local management prior to purchasing such items, to ensure adherence to agency policy and procedures.

Resources:

[ORA Memorandum on Ordering Business Cards](#)

[ORA Visual Identity Resource Center](#)

## 1.11 - Ethics and Integrity

The Food and Drug Administration's ethics program is structured to provide advice and assistance to current and former employees in order to help ensure that decisions they make, and actions they take, are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity of the Federal government. The [FDA ethics program](#), including prohibited financial interests, political activity, laws and regulations, gifts, conduct and outside activities, is available publicly at FDA.gov and internally through the [ORA Office of Management Ethics and Integrity](#) SharePoint site.

### 1.11.1 - Expected Conduct

As you work to advance the health and welfare of the public, seek to maintain the highest standards of ethical conduct. You are responsible for complying with the regulations, obtaining advice from your supervisor, personnel or local administrative staff, and when required, obtaining advanced approval for certain outside activities.

FDA employees must be persons of unrivalled integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibility, its personnel must carry on the agency's business effectively, objectively, and without even the appearance of impropriety. Their actions must be unquestionable, and free of suspicion.

The [Principles of Ethical Conduct](#) were established by Executive Order 12674, modified by Executive Order 12731, as basic principles regarding the conduct of federal employees. It is important that federal employees observe these principles in order to promote confidence in the integrity of the federal government.

[United States Code, Title 18](#) contains the criminal conflict of interest statutes applicable to employees in the executive branch of the government. Included in Title 18 is a prohibition against solicitation or receipt of bribes; a prohibition against acting as an agent or attorney before the government; post-employment restrictions; a prohibition against participating in matters affecting personal financial interest; and a prohibition against receiving supplementation of salary as compensation for government service.

#### [Standards of Ethical Conduct for Employees of the Executive Branch](#)

The Standards were developed by the Office of Government Ethics and set forth the basic obligation of public service. The standards contain regulations regarding matters such as conflicting financial interests, impartiality in performing official duties, and misuse of position.

#### [HHS Supplemental Standards of Ethical Conduct](#)

On February 3, 2005, The Department of Health and Human Services (HHS) amended the Supplemental Standards of Ethical Conduct ([5 CFR 5501](#)) and Supplemental Financial Disclosure Requirements section ([5 CFR 5502](#)), both effective on that date. On August 31, 2005, HHS published the Final Rule for both sections.

#### [Department of Health and Human Services--Standards of Conduct](#)

These regulations were superseded in 1992 by the Office of Government Ethics "Standards of Ethical Conduct for Employees of the Executive Branch." However, certain portions of the HHS Standards of Conduct remain applicable. This link contains the remaining relevant portions of 45 CFR Part 73.

You are the eyes and ears of FDA, and to most of the public you are their only contact with FDA. Your actions may be the basis upon which they judge the entire FDA. The public expects exemplary behavior and conduct from the government employee. This responsibility applies to both on the job and off the job activities. As you inspect or appraise individuals, you are, in turn, being evaluated. Both the industries FDA regulates and the public-at-large are keenly aware of, and are quick to report, what they consider improper actions by government employees.

You are expected to conduct yourself in a prudent manner, so that the work of the Agency is effectively accomplished. Your job is to gather and present the facts. Accuracy and objective observation are essential.

As a government official, your actions are under constant scrutiny. You must comply with the statutes and regulations listed above and epitomize integrity more broadly noting:

- Cameras/video/audio recording are everywhere
- Integrity means doing the right thing even if no one is watching.
- In dealing with management and the public, your approach must be mature, dignified, authoritative and cordial.
- As a law enforcement officer, you must employ authority with discretion.
- Depend on tact, diplomacy and persuasion to obtain the desired information.
- Be courteous and frank when calling attention to potentially violative practices and conditions.
- Be fair and responsive.
- Do not assume the role of a consultant.
- Do not be argumentative.

- Avoid replies that are likely to appear arbitrary or bureaucratic.
- Never recommend the products or services of a particular firm.
- Keep information obtained during inspections and investigations confidential.
- Avoid situations that may be or appear to be a conflict of interest.
- Your reports should be complete, concise, accurate and objective.
- Your personal habits must be above reproach.
- Look professional and effective in dress, grooming, and demeanor.
- Take pride in your work.
- Never use Government equipment/supplies for personal use.
- Never use public office for private gain.
- Never give preferential treatment to any person or organization.
- Never impede Government efficiency or economy.
- Maintain independence from outside influences and impartiality in performance of duties.
- Never make a Government decision outside of official channels.
- Never undermine the confidence of the public in the integrity of the Government

### 1.11.2 - Gifts

Gift means anything of monetary value (gratuity, favor, discount, entertainment, hospitality, loan, forbearance; includes services, training, transportation, local travel, lodging, meals). It DOES NOT include:

- modest items of food and non-alcoholic refreshments such as soft drinks, coffee and donuts offered other than for a meal
- greeting cards and items of little intrinsic value, such as plaques, certificates and trophies, meant primarily for presentation
- loans and discount opportunities from financial institutions that are available to the general public
- rewards and prizes given to competitors in contests or events, including random drawings open to the public, unless the employee's entry into the contest is required as part of his official duties (e.g., attending a conference where attendees are all entered into a drawing)
- anything for which the Government pays, e.g., items purchased with Government funds
- any gift accepted by the Government, e.g., sponsored travel
- anything for which the employee pays market value; and
- Free attendance at an event provided by the sponsor of the event to an employee who is assigned to present information on behalf of the FDA, or an employee whose presence is deemed essential by the FDA to the presenting employee's participation, on any day when the employee is presenting

For additional information, [click here](#).

Notwithstanding any of the exceptions provided above, an employee shall not:

- Accept a gift in return for being influenced
- Solicit or coerce the offering of a gift
- Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using his/her public office for private gain.

### 1.11.2.1 - Gifts Between Federal Employees

In general, FDA employees may not:

- Give a gift to an official superior (an employee, including but not limited to an immediate supervisor, whose official responsibilities include directing or evaluating the performance of the employee's official duties or those of any other official superior of the employee). This includes making a contribution toward a gift.
- Solicit a contribution from another employee for a gift to an official superior of either employee
- Accept a gift from subordinates in the employee's chain of command
- Accept a gift from a lower-paid, non-subordinate employee, unless there is a personal relationship that justifies the gift.

### 1.11.2.2 - Gifts From Outside Sources

If an FDA employee solicits or accepts a gift from an outside source that does business with or seeks official action from the employee or the employee's agency (a "prohibited source"), the public may be concerned that the donor will receive favored treatment as a result of the gift. Even if a gift is from a person or organization that has no official dealings with the employee's agency, accepting a gift offered because of the employee's official position may create an appearance of using public office for private gain. FDA employees may not solicit or accept gifts from a "prohibited source" or given because of the employee's official position, unless an exception applies, or the item is excluded from the definition of a gift.

### 1.11.2.3 - Gifts From Foreign Governments or International Organizations

As a Federal Government employee, you may not accept gifts from foreign governments or international organizations except as permitted under the [Foreign Gifts and Decorations Act \(FGDA\), 5 U.S.C. 7342](#). The FGDA allows an employee to accept a gift with a market value of less than \$415 from a foreign government or an international organization so long as the gift is intended as a souvenir or mark of courtesy. An international organization in this context refers to one which the US is not a member, such as the European Union (to clarify, a state-owned or operated company is NOT a foreign government for purposes of this statute). This statutory restriction extends to the spouse and dependents of the employee.

In the HHS General Administration Manual Chapter 20-25, Foreign Gifts and Decorations, the section on Gifts of Minimal Value states that, with specific exceptions, "an employee may not accept a gift of more than minimal value unless it appears that to refuse the gift would likely cause offense or embarrassment or otherwise adversely affect the foreign relations of the United States. If an employee accepts a tangible gift of more than minimal value, such a gift is deemed to have been accepted on behalf of the United States and, upon acceptance, becomes the property of the United States."

Procedures for appropriate disposition of such gifts are also included in the HHS Chapter. If you accept a gift from a foreign government or international organization on behalf of the U.S. Government, you must immediately contact an Ethics Specialist at the Ethics Hotline (240) 402-1111 or email [FDAethics\\_Advice@fda.hhs.gov](mailto:FDAethics_Advice@fda.hhs.gov) when you return to the office.

### 1.11.3 - Attempted Bribery

Bribery is the practice of offering or soliciting something, such as money or a favor, to a person in a position of trust to influence that person's views or conduct. Occasionally, FDA employees experience bribery attempts.

Bribery or attempted bribery of a Federal Officer is a crime ([18 U.S.C. 201](#)). If you are offered money or anything else of value, pursue the following course of action:

- Attempt to obtain a clarification of the offer (e.g., Ask questions like, "What is this for?").
- Do not accept or refuse the offer. Appear to vacillate, and keep the door open for future contact.
- Calmly terminate the exchange.
- As soon as possible, prepare detailed notes concerning what transpired.
- Contact your supervisor as soon as possible. The Division should notify OCI/OIA immediately.

### 1.12 - QMiS

Quality Management Information System (QMiS) is the repository for ORA's internal procedural documents and quality reports. Standard operating procedures, work instructions, templates, checklists, transmittal notifications, and reports are organized by component and document type.

### 1.13- ORA Time Reporting

#### 1.13.1 - eNSpect (also known as MARCS Field Client)

eNSpect is the first phase of the modernization of the FDA Field Accomplishments and Compliance Tracking System (FACTS) network. FACTS is still available and slowly over time more and more functionality will move into eNSpect. Currently, eNSpect supports multiple roles, components and functions and can be used online or offline. The bulk of the Investigator's work is performed in the Field Client.

#### 1.13.2 - ORA Insight Time Reporting (ITR)

Insight Time Reporting (ITR) is an activity-based time reporting system that will enable ORA to report the work we do and identify the resources we need before we need them.

#### 1.13.3 - ORA Activity Code structure

Insight Time Reporting (ITR) activity code structure which includes the activities and definitions that were specifically developed for ORA.

#### 1.13.4- Field Accomplishments and Compliance Tracking System (FACTS)

An agency-wide information system that provides automated support for the daily activities conducted by the FDA ORA headquarters and field offices. FACTS provides a central data repository for workload management, sample collections, investigative operations, and compliance operations through inspections, reporting, and tracking.

## Exhibits

### 1–1 Allowable Expenses Table

This Table lists allowable expense items and the requirements that must be met to assure reimbursement. Unless indicated, there are no special requirements for reimbursement. Please see your administrative staff or supervisor for additional information.

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
<b>BAGGAGE</b>	Yes	Yes	
1. All fees pertaining to the first checked bag			
2. Additional charges relating to the second and subsequent bags may be reimbursed when the Agency determines those expenses are necessary and in the interest of the Government (See <a href="#">FTR 301-70.300</a> )	Yes	Yes	Yes
3. Excess Baggage Charges for government property	Yes	Yes	Yes <sup>1</sup>
4. Service Charge for checking baggage by checking agent where such charges for checking baggage in baggage rooms, or station or air terminal	Yes	Yes	Yes
5. Storage Charges (e.g., when traveler stores baggage or equipment when such charges are result of official business.)	Yes	Yes	Yes <sup>2</sup>
6. Transfer Charges - when necessary for official travel (e.g., when changing between stations where free transportation is not issued by common carrier.) CAUTION: Where the traveler's plans are changed, he/she shall make sure that baggage has been checked beyond the point where he/she leaves the train is stopped or transferred. If baggage cannot be intercepted or transferred and is carried to original destination on unused portion of ticket, the traveler shall give full explanation of facts when submitting unused portion of ticket. Failure to do so will result in any excess cost being charged to traveler.	Yes	Yes	Yes
<b>FEES OR TIPS</b>	Yes	Yes	
1. Tips – Allowable tips are 15% of the reimbursable fare.		(over \$75)	
2. Parking Fees - charges for parking automobiles	Yes	(over \$75)	
3. Porter - allowable only at transportation terminals for handling Government property carried by travelers. NOTE: Porter fees for personal property, briefcases, etc. are not allowed.			Yes <sup>3</sup>
4. Traveler Checks	Yes	Yes	
Money Orders	Yes	Yes	
Certified Checks	Yes	Yes	
Transaction Fees for use of Automated Teller Machines (ATMs) – Government contractor issued travel card	Yes	Yes	

<p>5. Registration Fees – Attendance at local non-government sponsored meetings</p> <p>a. Payment of registration fee should be made via the Citibank government Purchase Card if the organization(s) will accept credit cards.</p> <p>b. Citibank Convenience Checks</p> <p>c. If the credit card cannot be used, and the organization accepts the purchase order, HHS-99 or SF-182 the organization may bill FDA directly</p> <p>Please see your Administrative Officer for additional information and guidance when requesting payment of registration fees.</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p>
<p>6. Exchange of Currency</p> <p>a. Allowed during foreign travel</p>	<p>Yes</p>	<p>Yes</p>	
<p>i. Fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries</p> <p>ii. Commissions for conversion of currency in foreign countries</p> <p>iii. Costs of traveler's checks, money orders, certified checks purchased in connection with official travel. Costs may not exceed amount needed to cover reimbursable expenses.</p> <p>b. Not allowed: exchange fees for cashing checks or drafts issued in payment of salary.</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>Yes<sup>4</sup></p> <p>Yes</p> <p>Yes</p>	
<p>7. Special Expenses for Foreign Travel - Passports, visa fees, costs of photographs for passports and visas, costs of certificates of birth, health, identity, and of affidavits, and charges for inoculations not obtainable through a federal dispensary</p>	<p>Yes</p>	<p>Yes</p>	
<p><b>HIRE OF ROOM</b></p> <p>1. Allowed when necessary to engage a room in a hotel or other place to transact official business</p>	<p>Yes</p>	<p>Yes</p>	<p>Yes<sup>6</sup></p>
<p>2. Not allowed for personal use (cost included in subsistence allowance).</p>			
<p><b>PERSONAL SERVICES</b></p> <p>Stenographic and typing services, guides, interpreters, drivers of vehicles, etc.</p>	<p>Yes</p>	<p>Yes</p>	<p>Yes<sup>5</sup></p>
<p><b>POSTAGE</b></p> <p>Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.</p>	<p>Yes</p>	<p>Yes</p>	<p>Yes<sup>7</sup></p>
<p><b>POST OFFICE BOX RENTAL</b></p> <p>Where necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.</p>	<p>Yes</p>	<p>Yes</p>	<p>Yes</p>
<p><b>PUBLIC TRANSPORTATION WHILE IN TRAVEL STATUS</b></p> <p>Public transportation fares are allowed from (or to) common carrier, or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business.</p>	<p>Yes</p>	<p>Yes (over \$75)</p>	<p>Yes<sup>8</sup></p>
<p>Public transportation fares between places where meals are taken, and places of business or places of lodging <b>are not</b> allowed, except where nature and location of work at temporary duty station is such that suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.</p>			
<p><b>TAXICABS WHEN USED LOCALLY WHILE IN TRAVEL STATUS</b></p> <p>Taxicabs are allowed from (or to) common carrier or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business where cheaper mode of transportation is not available or is impracticable to use.</p>	<p>Yes</p>	<p>Yes (over \$75)</p>	<p>Yes<sup>8</sup></p>

Taxicabs are not allowed between places where meals are taken and places of business, except where nature and location of suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.	Yes	Yes (over \$75)	Yes <sup>8</sup>
Limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point	Yes	Yes (over \$75)	
<b>TELEPHONE CALLS / INTERNET CHARGES</b>		Yes <sup>9, 10</sup>	
1. Official Business – Charges for local and long-distance calls are allowed when made on official business			
2. Personal Calls – Employee traveling overnight within CONUS may be reimbursed for one brief telephone call per day to her/his residence in accordance with government-wide rules and regulations. Reimbursement is limited to actual expenses, not to exceed \$5.00 times the number of consecutive nights of travel on official business; applicable only when the employee is authorized to be on travel for one or more consecutive nights; and conditioned upon the unavailability of government-provided long distance telephone systems and services (including government-issued telephone calling cards) during each day of travel on which expenses are incurred.		Yes	
a. OCONUS Travel may be reimbursed only for telephone call(s) home from a foreign country which have been authorized prior to the beginning of travel and are shown on the travel authorization. Permitted frequency and cost must be stated on the travel authorization and adhered to by the employee.			
3. Internet Charges – (Federal and Departmental policy requires specific written or electronic authorization when the use of internet services is required for official business.)	Yes	Yes (over \$75)	
<b>RECORDS</b> Charges for copies of records furnished by State officials, such as Clerks of Courts, etc., when necessary for performance of official business		Yes	Yes <sup>5</sup>
<b>SHIPMENTS (FREIGHT OR EXPRESS) - see IOM 4.5.5</b>		Yes	Yes <sup>12</sup>
<b>MISCELLANEOUS EXPENSES</b>			
1. Cash used in lieu of transportation request for passenger transportation and accommodations.	Yes	Yes	Yes <sup>5</sup>
2. Purchase of emergency supplies.	Yes	Yes	
3. Any other miscellaneous expenditure incurred by traveler in performance of official business, such as samples of drugs, cosmetics, etc., purchased by FDA inspectors and investigators.	Yes	Yes	
<b>LAUNDRY EXPENSES</b> Employees will be reimbursed for laundry, cleaning, and pressing expenses equal to the number of travel days multiplied by \$5.		Yes	
a. For CONUS travel, employees must be on travel for four or more nights.			
b. Employees on OCONUS travel are not permitted to claim separate laundry expenses			

FOOTNOTES:

- <sup>1</sup> Voucher must show weight of baggage and points between which moved.
- <sup>2</sup> State that storage is solely on account of official business.
- <sup>3</sup> State that porter fee was for handling Government property carried by traveler.
- <sup>4</sup> Voucher shall show rate of conversion and commission charges.

- <sup>5</sup> Voucher shall show date of service, quantity, unit, and unit price.
- <sup>6</sup> In addition to information required in footnote #5, state necessity for hire of room.
- <sup>7</sup> State that postage was used for official mail.
- <sup>8</sup> State necessity for daily travel.
- <sup>9</sup> For telegrams, faxes, cablegrams, and long-distance telephone calls, show points between which service was rendered, date, amount paid on each and "official business".
- <sup>10</sup> For local telephone, calls show number of calls, rate per call, total amount expended each day, and "official business".
- <sup>11</sup> When government Bill of Lading is not used, explain circumstances.
- <sup>12</sup> Continental United States (CONUS) is defined as the 48 contiguous states and the District of Columbia.

## 1–2 FDA Furlough Shutdown FAQs

<p><b>“What if I am on travel during a Lapse in Appropriations?”</b></p>	<p>If you are identified as a non-expected employee who is to be placed in a furloughed status due to a lapse in appropriations while you are on TDY, you will need to arrange to return home within the next 24 hours or the first available flight. However, if your OpDiv/StaffDiv has identified you as an excepted employee, you may be eligible to stay in a TDY status. Please contact the TMC to make any necessary travel arrangements. Once Congress passes and the President signs a new appropriation or continuing resolution, accommodations for a return to TDY will be addressed on a case-by-case basis. HHS will only pay expenses for the time that it takes you to return to your official duty station. After that, you will be in a furloughed status and the agency will not pay for any additional expenses.</p>
<p><b>“Must agencies cover travel expenses during a furlough day, if an employee’s travel status requires a stay that includes a furlough day?”</b></p>	<p>Yes, agencies must provide per diem or actual expenses to excepted employees whose travel status requires a stay that includes a furlough day. If you are identified as a non-expected employee, you will need to arrange to return home with the next 24 hours or the first available flight. If excepted employees are authorized Per Diem (Lodging, Meals &amp; Incidental Expenses) they are entitled to the full amount of Meals and Incidental Expenses or 75% on a travel day. If an excepted employee is on actual expenses, they can be placed on Actual Expenses for: up to 300% of Lodging, only up to 300% of M&amp;IE, only up to 300% of both Lodging and M&amp;IE. If an employee is on actual expenses, the employee is required to provide a receipt for all items, including meals. Without a valid receipt, the OpDiv/StaffDiv would not be responsible for reimbursement. It should be clearly stated that they are on actual expenses and that receipts are required for all expenses, even those that fall below the \$75 threshold.</p>
<p><b>“Can I still use my Government Travel Card?”</b></p>	<p>The Government travel charge card may remain active during a lapse in appropriations, but only excepted employees should use them. You should contact the travel charge card vendor’s customer service at the number on the back of the card should you experience problems with your card. In addition, you will not be able to submit your voucher until the Federal Government reopens for business. The Government will not reimburse you while there is a lapse in appropriations (more commonly referred to as a "shutdown"). As always, all charges on your government issued travel card are your responsibility.</p>
<p><b>“Can I stay at my TDY location while in a furloughed status?”</b></p>	<p>In general, the Department cannot obligate funds for TDY expenses or accept voluntary services in the absence of appropriations for non-expected activities. By remaining on TDY, you are acting in an official capacity. Therefore, the general rule state above pertains: if you are identified as a non-expected employee who is to be placed in a furloughed status due to a lapse in appropriations while you are on TDY, you will need to arrange to return home with the next 24 hours or the first available flight. If you are not an excepted employee that is currently on TDY, long term or not, and elect to stay at the TDY location, you need to be aware of the following: 1. Once you are furloughed you will no longer be covered under the Federal Employee’s Compensation Act for workers compensation insurance; 2. You will not be reimbursed for per diem, including lodging, meals and incidental expenses (M&amp;IE); you will be responsible for all costs incurred once you are in a furlough status; 3. If you are currently in long-term housing under a lease</p>

	<p>arrangement, your situation will be reviewed on a case-by-case basis, depending on when the next lease payment is due; and 4. During the furlough, no work is allowed to be performed as agencies may not permit voluntary performance of non- excepted services as covered in 31 U.S.C. 1342. a. These restrictions are enforced by criminal penalties. An officer or employee of the United States who knowingly and willfully violates the restrictions shall be fined not more than \$5,000, imprisoned for not more than 2 years, or both. 31 U.S.C. 1350.</p>
<b>“Can I use the ETS?”</b>	<p>No, since you will not be on official Government travel, you cannot use the ETS; you will also not be able to: 1. Use the ETS to make travel authorizations or submit vouchers; 2. Use City Pair Fares for flights; 3. Use the Government Car Rental Agreement managed by the Defense Management Travel Office (DTMO); and 4. Use the FedRooms program; Hotels may choose to offer you a “government rate” but that is at the hotel’s discretion.</p>
<b>“Can an employee use personal funds by travelers to complete the Agency’s mission by attending an already planned conference?”</b>	<p>No. In attending a conference on behalf of the Department, you are acting in an official capacity. The Department cannot accept voluntary services in the absence of appropriations for non-excepted activities.</p>
<b>“Do relocation benefits stop during a Government shutdown?”</b>	<p>No, the monies for relocation come from already approved money and must be obligated up front for a relocation move, also referred to as a Permanent Change of Station (PCS). Each agency should have a plan in motion for those who may need assistance to include extensions to Temporary Quarters Subsistence Expenses (TQSE), etc.</p>
<b>“Do people who are in Temporary Quarters still receive benefits?”</b>	<p>As TQSE is reimbursed at the new PDS, there is no "old" PDS to recall the employee to. Since no permanent residence has been purchased yet, TQSE is the employee's only option. There is no case law that covers this issue; however, based upon the reasoning above, GSA legal is of the opinion that the expenses can still be incurred, particularly if the relocation monies have been obligated prior to beginning the move, but reimbursement cannot be made until the lapsed funds can be accessed again.</p>
<b>“Can the employee accept an offer during the shutdown period and therefore bind the government to the fee? Can contractors continue to order appraisals and inspections during the period the government has no money?”</b>	<p>First, there is no case law on this point. Thus, it is GSA legal’s contention that if the fair market value of the home was obligated when the contract with the Relocation Service Provider (RSP) was executed, and the amount is from a revolving fund or a fund that does not lapse under a furlough situation, then the offer can be accepted. However, if the fair market value of the home was not obligated, then there are no funds available to bind the Government, and the employee must wait until the applicable appropriation is passed to accept an offer. General rules regarding continuation of contractual arrangements should be followed. As for appraisals and inspections, these need to wait until the applicable appropriation is passed if the transactions are not covered by a revolving fund or a fund that does not lapse under a furlough situation.</p>
<b>“Can I proceed to start my enroute travel to an OCONUS foreign post during a government shut down?”</b>	<p>Per the State Department Regulation, staff policy office: “This is not to be treated any differently than a domestic move. All monies spent on relocation are monies already approved and pre obligated. In addition, the employee may present their credentials to the foreign country with no problems.”</p>

<p><b>“What about other types of relocation allowances such as pre-departure, temporary quarters, and Household Goods (HHG)? Are these considered entitlements that should be obligated and expenses incurred, or should these future relocation expenses be stopped and not obligated?”</b></p>	<p>If relocation has been approved and obligated prior to the shutdown, it may move forward. If it has not been approved and obligated prior to the shutdown, it cannot be started until after the budget is resolved. However, even if the funds have been obligated for a relocation, an agency should confirm with Human Resources if an employee should perform a House Hunting Trip (HHT) during the furloughed timeframe since an employee is normally in a “pay status” while on an HHT. It also applies for an enroute travel – they are in a pay status for the authorized number of days. Questions that may come in to play include “are the employees covered (insurance/disability) during those days if they travel and also furloughed.” Check with your HR office for further guidance.</p>
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# 1-3 GSA Fleet Vehicle Packet

## Maintenance and Accident Instructions:

**GSA Fleet – Vehicle Assistance Centers Call 1 (866) 400-0411**

Press 1 - Maintenance Control Center (MCC) – mechanical or tire problems  
 Press 2 - Accident Management Center (AMC) – accident body damage and glass  
 Press 3 - Fleet Service Card acceptance problem  
 Press 4 - Vendor with a payment problem

**Fueling Instructions:**

1. Using your Fleet Service Card, select Credit at the pump
2. Enter 6 Digit PIN
3. Enter odometer reading
4. Choose proper fuel. Use of mid-grade, premium or full-service fuel is prohibited.

**These Require Prior MCC Approval**

- Repairs over \$100
- Replacement of:
  - Tires
  - Glass
  - Batteries



www.gsa.gov  
March 2019  
05-19-00532

**Involved in an accident? See Accident Reporting Kit inside.**



U.S. General Services Administration

## GSA Fleet Vehicle Packet

**Zone 1**

Hartford, CT: (860) 240-3314  
 Baltimore, MD: (410) 406-2201  
 Hooksett, NH: (603) 666-7957  
 Buffalo, NY: (716) 551-4596  
 New York Metro Area: (732) 906-5605  
 Harrisburg, PA: (717) 770-4575  
 Philadelphia, PA: (215) 446-4832  
 Pittsburgh, PA: (412) 294-4001  
 San Juan, PR: (787) 749-4440  
 Franconia, VA: (703) 605-9350  
 Richmond, VA: (804) 279-6807  
 Chesapeake, VA: (757) 424-2389  
 Huntington, WV: (304) 529-5584

**Zone 2**

Alabama/Mississippi/  
 NW Florida: (850) 581-2036  
 Montgomery, AL: (334) 450-0796  
 Florida: (321) 213-6052  
 Georgia: (770) 435-7806  
 Fort Gordon, GA: (404) 215-8625  
 Chicago, IL: (630) 655-3464  
 Southern IL: (618) 622-5807  
 Indianapolis, IN: (312) 350-2286  
 Kentucky/Tennessee: (502) 909-3895  
 Livonia, MI: (313) 226-2391  
 Twin Cities, MN: (612) 725-4002  
 Jackson, MS: (601) 965-4192  
 North/South Carolina: (910) 436-2649  
 Camp Lejeune, NC: (910) 451-2698  
 Cleveland, OH: (330) 342-0272  
 Dayton, OH: (937) 427-5639  
 Charleston, SC: (843) 727-4043  
 Fort Jackson, SC: (803) 751-7603  
 Nashville, TN: (615) 907-6208  
 Milwaukee, WI: (414) 769-5644

**Zone 3**

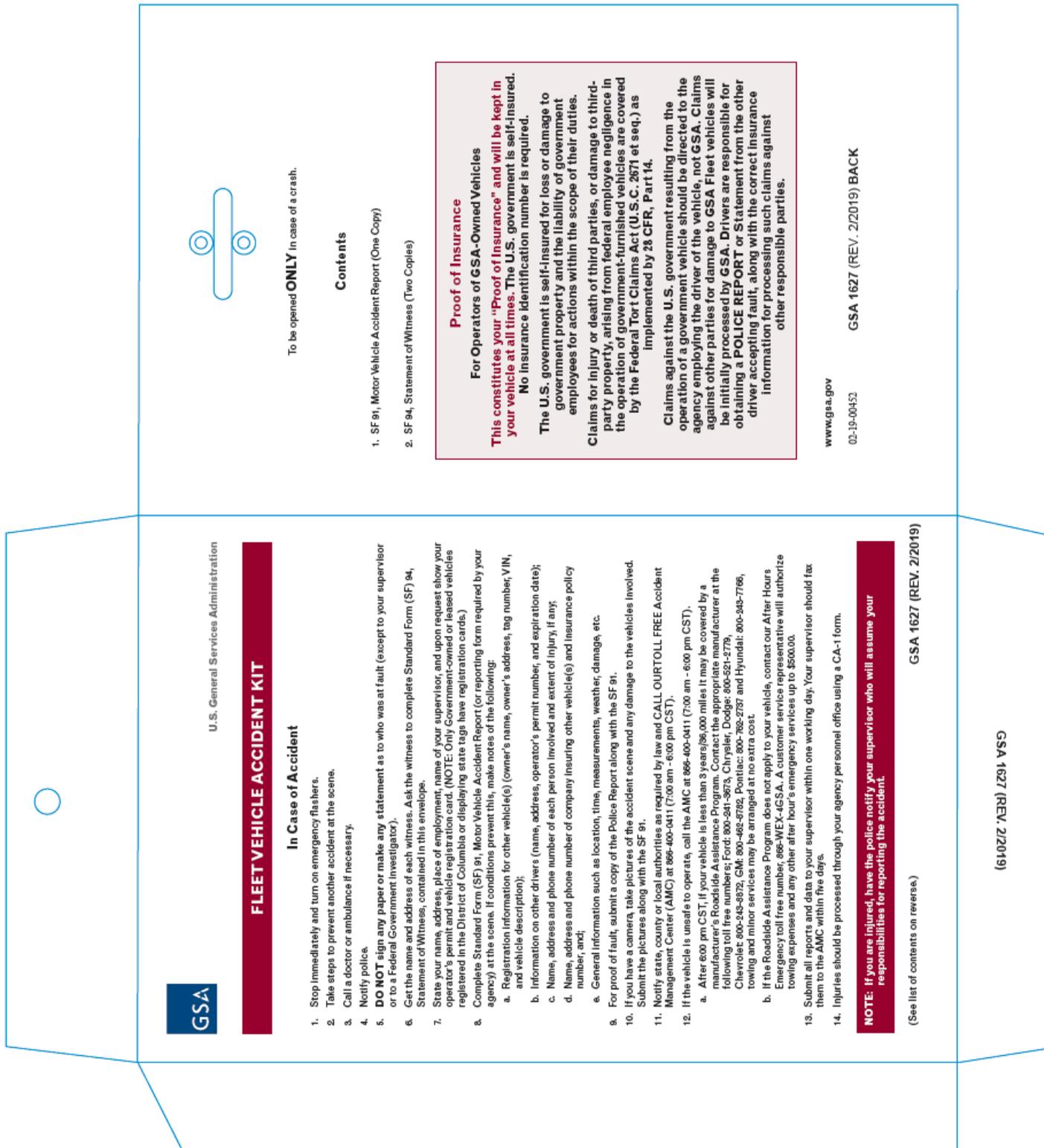
Little Rock, AR: (501) 324-5514  
 Denver, CO: (303) 236-7221  
 Baton Rouge, LA: (225) 757-7635  
 Kansas City, MO: (816) 823-3620  
 St. Louis, MO: (314) 263-3023  
 Helena, MT: (406) 449-5265  
 Bismarck, ND: (701) 250-4318  
 Albuquerque, NM: (505) 248-7347  
 Gallup, NM: (505) 863-9324  
 Los Alamos, NM: (505) 346-8601  
 Oklahoma City, OK: (405) 231-4436  
 Rapid City, SD: (605) 341-3842  
 El Paso, TX: (915) 772-1165  
 Houston, TX: (832) 397-8415  
 San Antonio, TX: (210) 306-2342  
 Dallas/Ft. Worth/  
 Ft. Hood, TX: (817) 850-8248  
 Utah: (801) 625-5020

**Zone 4: (415) 522-2858**

Phoenix, AZ  
 Los Angeles, CA  
 San Diego, CA  
 San Francisco, CA  
 Honolulu, HI  
 Auburn, WA  
 Vancouver, WA

Visit [www.gsa.gov/gsafleetfms](http://www.gsa.gov/gsafleetfms) for the most up to date contact information  
 Ask your FSR for information on the GSAFleet2Go App  
 Download the App on the Apple App Store or on Android's Google Play

# 1-4 Fleet Vehicle Accident Kit-GSA 1627



To be opened **ONLY** in case of a crash.

**Contents**

1. SF 91, Motor Vehicle Accident Report (One Copy)
2. SF 94, Statement of Witness (Two Copies)

**Proof of Insurance**

**For Operators of GSA-Owned Vehicles**

**This constitutes your "Proof of Insurance" and will be kept in your vehicle at all times. The U.S. government is self-insured. No insurance identification number is required.**

The U.S. government is self-insured for loss or damage to government property and the liability of government employees for actions within the scope of their duties.

Claims for injury or death of third parties, or damage to third-party property, arising from federal employee negligence in the operation of government-furnished vehicles are covered by the Federal Tort Claims Act (U.S.C. 2671 et seq.) as implemented by 28 CFR, Part 14.

Claims against the U.S. government resulting from the operation of a government vehicle should be directed to the agency employing the driver of the vehicle, not GSA. Claims against other parties for damage to GSA Fleet vehicles will be initially processed by GSA. Drivers are responsible for obtaining a POLICE REPORT or Statement from the other driver accepting fault, along with the correct insurance information for processing such claims against other responsible parties.

www.gsa.gov

02-19-00452

GSA 1627 (REV. 2/2019) BACK

## 1-5 Example Email Communication to Claimant Regarding Form SF95 Submission



Return Address

Date of Communication

Address of Recipient

Good Day,

Per our conversation, attached is a copy of the **SF-95 form**. This form is used to file a claim against the government for damage, injury, or death. As a result of the incident that occurred on XX/XX/XXXX, I am required to notify you of your right to file, if you should desire. If you chose to file a claim, complete the form and please return the completed form to me via email for initial review and submission to the FDA Claims Liaison.

If you need additional information, please let me know.

Space for signature

Name and title of communication author

## 1-6 Fleet Vehicle Assistance Card



U.S. General Services Administration

## GSA Fleet Vehicle Assistance Centers

**Call 1 (866) 400-0411**

**Press 1** – Maintenance Control Center (MCC)–  
mechanical and tire problems

**Press 2** – Accident Management Center (AMC)–  
accident body damage

**Press 3** – Fleet Service Card acceptance problem

**Press 4** – Vendor with a payment problem

(3/10)

(over)



U.S. General Services Administration

## GSA Fleet Vehicle Assistance Centers

**Mechanical and Tire Procedures:** Inspect vehicle to verify operator's complaint. All repairs that exceed \$100 require MCC approval. Call for purchase order before initiating repairs. MCC approval is required for all tire and battery purchases, regardless of price. Repairs under \$100 are authorized using the Fleet Services Card. For after-hours emergency repairs, call (866) 400-0411. Do not submit invoices for charge card purchases.

**Accident Body Damage Procedures:** Inspect vehicle to verify operator's complaint. All repairs that exceed \$100 require AMC approval. Call for purchase order before initiating repairs. Fax all accident reports, estimates and correspondence to: (678) 827-8395 for Eastern and Central Time Zones (except: KS, MO, NE, and IA) or (816) 823-3634 for all other locations. For more info refer to: Accident Reporting Kit and "A Guide to Your GSA Fleet Vehicle," located in the glove box of your vehicle.

5-10-00341

## 1-7 ORA Mobile Media Support



### MOBILE MEDIA SUPPORT

- + Thank them for their interest!
- + State that you would be more than happy to speak with them, but you need to refer them to the ORA Press Team
- + Email address: [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov)
- + **DO** send a “Heads Up” email with the reporters **name, organization, nature of their inquiry & location of contact** to [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov)
- + **DON'T** say, “No Comment”
- + **DO** refer them [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov)
- + **REMINDER:** not sure what to do re: a press or media inquiry? Contact [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov)

# 1-8 Media Tip Card

Office of Regulatory Affairs

## CAN WE TALK? A Guide to Dealing with the Media



The Division of Communications is here to assist you!

### WHEN YOU ARE CONTACTED BY A REPORTER....



#### By phone or email:

forward the message to [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov).

#### At a conference or speaking event:

provide them with [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov) for follow-up.

- We will work with the reporter to find out the deadline and focus of the request.
- When an interview is requested, we will coordinate with you and the Office of Media Affairs to set up the terms and scope of the interview.
- We will help prepare you for the interview by identifying key points you want to make during the interview and secure all required clearances.



**NOTE:** Never tell a reporter you have to obtain clearance first.

#### Suggested Response:

*Let me get your contact information, your topic or questions, and deadline. I will have a member of the ORA Press Team follow-up with you to schedule time for us to talk.*

### WHEN YOU TAKE AN ACTION THAT MAY ATTRACT MEDIA ATTENTION

(e.g., establish guidance, exercise an enforcement)...

- We will work with you to determine whether a press announcement is appropriate and feasible.
- Please contact us as early as possible via email to [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov).

### SOME HELPFUL TIPS



#### Before the interview

- Decide on the **3 or 4 most important aspects** of the action or topic and **make them the focus** of your comments.
- **Make your message concise** and easy to understand.
- **Use data or analogies**, when appropriate.



#### During the interview

- **Place** your topline messages and supporting points in front of you.
- If you are being filmed while seated, **sit up straight and lean slightly forward**. Avoid wearing white or clothing with busy prints or oversized jewelry that might distract the viewer.



#### Do's and Don'ts during the interview

- **DO** restate your primary message in several different ways during the interview. End with your most important point.
- **DO** mention our website [www.fda.gov](http://www.fda.gov). Newspapers and other media organizations are increasingly interested in using graphics and referring readers to online content.
- **DO** take a moment if you feel you need time to think.
- **DO** redirect the conversation with a positive response if a reporter poses a question with a negative slant. For example, use phrases like: "On the contrary..." or "Not so; we strive..."
- **DO** avoid using jargon and acronyms. For example, refer to the "Office of Regulatory Affairs," not "ORA."
- **DON'T** say "no comment." If you don't know or can't provide an answer, explain why. Direct the reporter back to ORA Press for help in providing follow-up information or resources.
- **DON'T** speculate if a reporter asks "What if...?" questions. One possible response is something like, "More work is needed within the scope of the FDA's mission."

## 1-9 Reporting IT Security Incident Checklist

**Please include the following pieces of information, so that we can quickly and efficiently respond:**

Customer Information:

- Your full name
- Your FDA email address
- Your best immediate phone number contact
- A brief explanation of the circumstances
- When did the incident occur (Date, Time)?
- Location of the incident
- What country were/are you in?

Device Information:

- Type of device stolen (e.g., Laptop/Desktop/Iron Key/Storage Drive/RSA Token/Blackberry)
- FDA Asset Tag or Serial#
- Brand/Series/Model
- Encryption Type
- Sensitive Information or PII

Important:

- To request new equipment [click here](#). The FDA SMC does not handle "IT Acquisition" requests.
- Please notify your center Property Custodial Officer (PCO) and/or Accountable Property Officer (APO) of this theft as soon as possible for a replacement. You can determine your center's PCO/APO by searching on <http://inside.fda.gov>.
- To learn how to report a suspected PII loss, [click here](#).

**Note:** Security personnel will receive your email and respond to you immediately. **DO NOT** try to handle the security incident yourself; wait for a member of the security team to contact you and direct you.

**Tips for Protecting FDA Equipment and Information:**

- Lock your equipment at all times and do not leave your equipment unattended when outside of FDA facilities (e.g. car, metro).
- Be alert and aware of your work environment. If you notice unknown individuals not wearing a badge, offer to escort them or report it to the FDA Security Command Center at (301) 796-2409.

## 1-10 – Previous Chapter 1 SUBCHAPTER 1.5 - Safety

### SUBCHAPTER 1.5 - SAFETY

Safety is a responsibility of FDA employees, their supervisors, and the Agency's management. These responsibilities include:

1. The reporting of any hazards or suspected hazards;
2. Taking the necessary safeguards to minimize the opportunity for safety problems.

The Agency cannot permit employees or supervisors to disregard established or otherwise reasonable safety precautions and thereby place themselves and/or their fellow employees and/or the Agency's facilities at risk. Refer to IOM 5.2.1.2 - Personal Safety for additional inspectional safety concerns.

Be alert for problems associated with defective or misused equipment or supplies and their possible impact on patients and/or users. Contact your supervisor and/or the headquarters contacts listed in the applicable compliance program as necessary for assessment. The home district of the manufacturer should be notified of product misuse, so it may be brought to the manufacturer's attention for consideration of precautionary labeling or redesign of the product. Fully document these problems, to include the hazard and/or defect observed and whether user actions could be a contributing factor. Documentation should present sufficient data, such as photos and diagrams, to supplement a narrative describing the situation as well as the collection of samples.

When conducting an inspection or collecting a sample in a facility which requires donning personal protective equipment, guidance should be provided by the firm's management as follows:

1. Information about the specific hazards that may be encountered
2. The potential concentrations of these hazards
3. The personnel protective equipment determined to protect against these hazards

The firm's management should be able to provide you with documentation showing how these hazards were determined, what the expected exposures are and how they relate to the Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL). It should also offer information about the personal protective equipment that will protect you against a hazardous exposure. If you have any doubts about the hazards or the equipment recommended or provided to protect against them, do not enter these areas. The Safety Liaison for your Program or District or the ORA Safety Office will be able to help you evaluate the information provided to you, or furnish information regarding the hazard and the recommended personal protective equipment.

If you do not have the specific personal protective equipment recommended by the firm's management, have your District furnish what you need. In some cases, the firm may be willing to provide the necessary personal protective equipment, however if respiratory protection is required, you should comply with ORA's Respiratory Protection Program. You should only use respirators provided by FDA, unless your District's IH or the National Safety Office has approved the use of other devices. See IOM 1.5.1. It is ultimately your responsibility to ensure that you do not expose yourself to any hazard.

Disaster conditions present inherently dangerous situations. See IOM 8.5.

Operations in the radiological area also pose special dangers. See IOM 1.5.4.2.4. Obtain advice on protective measures from the ORA Radiation Safety Officer whose contact information is listed in the FAQs (#12) on the ORA Safety webpage.

## 1.5.1 - PROTECTIVE EQUIPMENT

### 1.5.1.1 - Eye Protection

Wear safety glasses during all inspectional activities in which there is a potential for physical or chemical injury to the eye. These glasses should at a minimum meet the American National Standards Institute standard z87.1 for impact resistance. Guidance should be provided by the management of the facility being inspected as to additional eye protection required. Indirectly vented or unvented goggles should be worn whenever there is the potential for a chemical splash or irritating mists. Additional eye protection may be required in facilities that use exposed high intensity UV lights for bacteriostatic purposes, tanning booth establishment inspections (EIs), etc. Follow the manufacturer's recommendation regarding eye protection for any instrumentation generating light in the UV or higher energy wavelength range. You may contact the ORA Safety for assistance in selecting eye protection against physical or chemical injury. You may contact the ORA Laser Safety Officer or ORA Radiation Safety Officer for guidance on protective eye wear when working near radiation-emitting devices.

### 1.5.1.2 - Hearing Protection

You should wear hearing protection in noisy areas. The OSHA PEL for employees exposed to noise ranges from 90 decibels for an 8-hour time-weighted average to 115 decibels for 15 or fewer minutes per day. However, risk factors for hearing loss include personal susceptibility, noise intensity, noise frequency, distance from the noise source, etc. The noise reduction rating is provided by the manufacturer of various earplugs and muffs, but also depends on the appropriate fit. The efficiency of muff type protectors is reduced when they are worn over the frames for eye-protective devices.

### 1.5.1.3 - Protective Clothing

1. Wear safety shoes on inspections, as required.
2. Wear hard hats in hard hat designated areas.
3. Use appropriate gloves to avoid slivers and/or splinters when handling rough wooden cases or similar items. Use protective gloves when handling hot items or working around steam pipes, and when handling frozen products or working in freezers. Use protective gloves when handling lead pigs containing radioactive materials to avoid hand contamination. If you are handling solvents, wear gloves that are impermeable to the solvent. Your regional Industrial Hygienist or the ORA National Safety Officer can provide guidance in the type of gloves to use for a particular solvent.
4. Plan ahead for the clothing that may be required for a particular location or situation. Such clothing includes coveralls, lab coats, freezer coats, rubber or vinyl aprons, and disposable paper-like coveralls.

### 1.5.1.4 - Respiratory Protection

If it is possible to perform an inspection without entering areas in which respiratory protection is mandated or recommended, do not enter these areas. If you determine it is necessary to enter an area in which you must wear a respirator, you must have documented evidence showing the requirements of the District Respiratory Protection Program have been met prior to wearing your respirator. Your District shall have a written Respiratory Protection Program, as delineated in IOM 1.5.1.4.1.

#### 1.5.1.4.1 - PROGRAM PROVISIONS

In any workplace where respirators are necessary to protect the health of the employee, or whenever respirators are required by the employer, OSHA requires the employer to establish and implement a written respiratory protection program with worksite specific procedures according to the requirements in [29 CFR 1910.134](#). The program must include the following provisions:

1. Procedures for selecting respirators for use in the workplace, and annual fit testing of each employee wearing the selected respirator(s).
2. Medical evaluation of employees required to use a respirator prior to the employee's use of a respirator, and repeated as specified in the Respiratory Protection Program. A medical evaluation can be obtained by contacting your local Industrial Hygienist.
3. Procedures for using respirators in routine and reasonably foreseeable emergency situations.
4. Procedures for maintaining respirators.
5. Training of employees in the hazards to which they are potentially exposed during routine and emergency situations, and in the proper use of respirators including limitations of their use and fit checking procedures each time the respirator is donned.
6. Procedures for regularly evaluating the effectiveness of the program. OSHA requires each employer perform an evaluation of any workplace which may contain respiratory hazards. If these respiratory hazards cannot be removed through engineering controls, the employer must provide respirator protection. Do not enter any area you suspect may contain an unevaluated respiratory hazard. Your training should include a determination of the minimum respiratory protection for each type of inspection you may perform. Your regional Industrial Hygienist or the ORA Safety and Occupational Health Manager may be consulted for guidance in the type of respirator, type of cartridge or filter, and the useful life of the cartridge or filter.

#### **1.5.1.4.2 - FIRMS WITH POTENTIAL RESPIRATORY HAZARDS**

The following list includes situations, which have been identified as having the potential for respiratory hazards:

1. Feed, drug or tobacco plants where there is a possible inhalation hazard due to airborne particulates.
2. Fumigation or storage facilities where treated grain or produce is encountered, including trucks, vessels, railroad cars, fumigation chambers.
  - a. Do not enter any structure or conveyance or sample any product that is being treated with the fumigants Methyl Bromide, Phosphine or Sulfuryl Fluoride. If a sampling area is suspected of having been fumigated with methyl bromide, phosphine, or Sulfuryl Fluoride and has not been cleared according to the EPA requirements, contact your local industrial hygienist for guidance as to how to ensure that the area is safe to enter. Do not enter the area until it is appropriately aerated and tested. If entry is required using personal protective equipment, your local industrial hygienist can provide guidance to ensure you are using the appropriate respirator and cartridge, and any other protective equipment necessary based upon the fumigant concentration. See IOM 1.5.3.4, Asphyxiation Hazards, and IOM 1.5.4 Inspections, for additional cautions related to fumigants.
  - b. Areas and/or products being treated with fumigants are required by Environmental Protection Agency (EPA) to be placarded, and the placards not removed until the treatment is complete (usually 12 hours to 4 or more days) and the areas and/or products are clear of fumigant gases (phosphine <0.3 ppm and methyl bromide <1 ppm).
  - c. Self-contained breathing apparatus (SCBA) is generally the only respiratory protection gear approved for use in areas being fumigated. It is necessary to follow many other precautions when working around fumigants. See Note on Methyl Bromide and Phosphine at the end of this section for additional information.
3. Facilities using ozone, or where ozone is produced as a by-product of the manufacturing operation.
4. Facilities where sterilizers utilize ethylene oxide gas (EO) - See IOM 1.5.4.2 Factory Inspection.
5. Grain elevators or other grain storage facilities, which may present asphyxiation hazards, toxic decomposition gases, or biological toxins such as aflatoxin. See IOM 1.5.3.3.2.
6. Grain elevators or other grain storage facilities that potentially contain aflatoxin in the dust.
7. Spice grinders and repackers that potentially produce airborne respiratory irritants such as pepper.
8. Any rodent-infested area. - See IOM 1.5.5.4 Hantavirus Associated Diseases.
9. Poultry Houses – exposure to particulates, chemicals and possible infectious agents.

### 1.5.1.5 - Health and Hygiene

Inoculations - FDA provides operating field personnel with various inoculations for protection from infection or injury on the job.

The following schedules of shots are recommended:

1. Domestic Work:
  - a. Tetanus: Permanent immunity through the Tetanus Toxoid series followed by a booster dose every ten years;
  - b. Typhoid: No longer required even if working in a contaminated environment. Booster dose may be given every three years if desired and requested by employee;
  - c. Smallpox: No longer required in the U.S.;
  - d. Other: As required by your specific job.
  - e. Hepatitis B Vaccine: a synthetic vaccine has been developed and is available to those employees that may be exposed to the virus during the normal course of official duties. Contact your AO to arrange for this vaccination. Keep in mind a vaccination is not to be considered a substitute for good laboratory/field safety practices. This vaccine is specific for Hepatitis B virus (HBV) only, and not for other blood pathogens.
2. Foreign Travel - Check with your supervisor well in advance of planned foreign travel as to specific requirements of the countries to be visited.
  - a. Typhoid: recommended for travel to areas where typhoid fever is endemic.
  - b. Cholera: a primary vaccination or a booster within six months is required for traveling to India and Korea. May also be required occasionally for other nations.
  - c. Other: as required for specific country.

Physical Examinations - There is no requirement for periodic physical examinations. Even so, it is your responsibility to adhere to good personal hygiene and health practices.

If any firm management demands evidence of recent physical examination before permitting inspection, consult your supervisor. A mere request to examine your hands for sores, etc., is not unreasonable. However, do not accede to a physical examination.

### 1.5.2 - AUTOMOBILE SAFETY

Prior to operating a motor vehicle that is owned, leased, or rented by HHS/FDA, any federal employee or contractor authorized to do so must self-certify that their driver's license is valid, recertify that their license is valid every two years, complete the training titled **Driver's Overview and Fleet Card Use** (accessible via the HHS Learning Portal

<http://inside.fda.gov:9003/EmployeeResources/FacilityServices/FleetServices/ucm503525.htm>) and ensure that the use of any government vehicle is for official business only.

Individuals authorized to use a vehicle for official business must:

1. Operate the motor vehicle with due regard for public safety.
2. Operate, park, store and lock as appropriate to prevent theft or damage.
3. Obey all applicable Federal Executive Orders, state and local traffic laws.
4. Use all safety devices (including seat belts).
5. Pay any parking fees and fines.

Prior to driving, check the following:

1. Tires, check for tread wear, etc.
2. Mirrors, for proper adjustment
3. Brakes
4. Windshield
5. Lights, headlight, turn signals and brake

6. Gasoline and oil gauges
7. Spare, jack, lug wrench, first aid kit, flares, etc.
8. Fire extinguishers are no longer required in vehicles
9. Seat belts must be used

When transporting materials of trade or items that when shipped commercially would be regulated as hazardous materials/dangerous goods, adherence to US DOT Regulations may not always be required, but is always highly recommended.

For example:

Ensure all volatile solvents, either in the sample collection kit or contained in a sampled material, are properly packaged and sealed to prevent spills or leakage. Be especially aware of the hazards associated with transporting dry ice. The concentration of carbon dioxide gas can cause a dangerous over-pressurization if sealed improperly or displace oxygen which can cause drowsiness, or even an asphyxiation hazard, if the dry ice is carried in an unventilated vehicle. See IOM 1.5.3.4

### 1.5.3 - SAMPLING

When you are collecting samples, always be alert for possible dangerous conditions (e.g., poisonous materials or fumes, flammable or caustic chemicals, high places, etc.)

#### Opioid Sampling

Opioids are substances derived from the opioid poppy or manufactured synthetic analogues. When conducting opioid sampling adequate safety precautions must be observed during the sampling process. Do not handle opioids including fentanyl and fentanyl analogues without appropriate Personal Protective Equipment (PPE) which may include nitrile gloves, coveralls, goggles and a respirator depending on the situation and exposure risk. Possible routes of opioid exposure may include inhalation, ingestion and dermal contact. Opioids have the potential to be inhaled in situations where drug samples are disturbed, and particles become airborne. Avoid tasks that may aerosolize fentanyl or other opioids. Change gloves if they become contaminated. Avoid contact with eyes, mouth, nose or unprotected skin with contaminated gloves. Wash hands with soap and water immediately after sampling or as soon as feasible. Do not use alcohol-based hand sanitizers to clean contaminated skin as this could increase the drug absorption.

Opioid overdose symptoms include respiratory distress with slow shallow breathing, small constricted “pinpoint” pupils, confusion, drowsiness, nausea and vomiting and loss of consciousness. The opioid antidote medication Naloxone (Narcan) nasal spray can reverse the effects of opioid overdose and restore normal breathing. Naloxone (Narcan) training is available for individuals at risk for exposure to opioids. Contact a supervisor or industrial hygienist for training information.

Sources:

<https://www.cdc.gov/niosh/topics/fentanyl/healthcareprevention.html>

[https://www.cdc.gov/niosh/ershdb/emergencyresponsecard\\_29750022.html](https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750022.html)

#### 1.5.3.1 - Sample Fumigation and Preservation

Follow safety precautions when fumigating and/or preserving samples. Guidance is as follows:

1. Whenever possible, freeze the sample. If freezing is not practical, contact your servicing laboratory for alternative fumigants and preservatives.
2. When fumigants or preservatives are used, exercise care to limit your exposure to these chemicals. Contact your ORA Safety for the appropriate precautions necessary with these chemicals.
3. Safety Data Sheets (SDS) for each of these chemicals must be available at each duty site (e.g.,

District office, resident posts), and can be obtained from the chemical manufacturer. These sheets list the hazards involved with these chemicals and precautions to take for use. You must read and follow the instructions in the SDS prior to using the chemical. If a measured amount of chemical fumigant or preservative is present at the time of shipping, follow the guidance and properly ship the item as indicated if the substance is a regulated hazardous material. Again, if you have any questions regarding safety or shipping concerns contact ORA Safety.

### **1.5.3.2 - Electrical Hazards**

Many samples are collected in poorly lighted areas, or in older poorly wired buildings. Be alert for low hanging wires, bare, exposed, or worn wires, and broken or cracked electrical outlets.

When you are using portable power tools, etc., be extra cautious of the shock hazard. See Inspectors Technical Guide # 22 regarding Ground Fault Circuit Interrupters, and use one if feasible.

### **1.5.3.3 - Physical Hazards**

Be alert for dangerous conditions on all sampling operations. If it is necessary to use a flame to sterilize sampling equipment, use extreme care. All flammable liquids in your sampling kits must be in metal safety cans. See IOM 4.3.6.1.2

Care must be taken when handling sharp objects, e.g., knives, syringes with needles, glass, etc. If it is necessary to sample such objects, take care in packing the sample to avoid injuring anyone who handles the sample later. Place them in a rigid container, e.g. glass jar, plastic box, etc. In addition, state in the Remarks or Flag Section of the Collection Report (C/R) (FDA-464) that a syringe and needle were collected as part of your sample.

#### **1.5.3.3.1 - RAIL SAFETY**

Railyards:

Railyards are dangerous areas. If there is a Safety Office at the yard, inquire about specific information concerning current hazards.

Maintain a safe distance from equipment in motion and cross tracks at right angles whenever possible without stepping on rails. Be aware of the pressure-wave created as a train (or any moving vehicle) passes. The force can knock people down and into the path of subsequent cars.

Railcars:

1. When sampling, make sure doors are propped open to avoid accidental closing if the car is bumped while you are in it.
2. Display a warning flag or similar device to alert others you are in the car. Always have a railroad yardman or another FDA investigator present.
3. When entering the car, make sure the ladder is secure.
4. On hot days, or after a car has been fumigated, it should be aired out prior to entering, preferably by opening both doors.
5. Observe "No Smoking" in rail cars.
6. Don't crawl under railcars - go around them.
7. Avoid any cables between the railroad tracks. These are often used to move cars on sidings. A cable snapping taut can kill or maim.

#### **1.5.3.3.2 - GRAIN HANDLING FACILITIES**

Grain storage structures, such as grain elevators and feed mills, can present life-threatening hazards. It is always preferable to inspect them or collect samples from the outside. If it is not possible to collect the

samples from the outside, consult your supervisor prior to collection. Before entering a grain storage structure:

- Meet with the facility's operator to discuss hazards that may be present in the storage structure, including entrapment or engulfment in grain, asphyxiation, or the presence of toxic or flammable atmospheres, as well as procedures to be followed in the event of an emergency.
  - Confirm that the operator will lock out any moving equipment within the storage structure such as conveyors and augers, and will conduct atmospheric tests for oxygen, combustible gases and toxic gases. Contact your Supervisor for any questions.
1. Refer to IOM 1.5.4.1 Man Lifts and Ladders for guidance. Do not use Man Lift without supervisor approval.
  2. Make sure cross-rungs on ladders are safe.
  3. When stepping off ladders or man lifts, be sure the floor is actually a floor and not a bin covered with canvas, cardboard, or other temporary non-supportive cover.
  4. Never stand or walk across the surface of the material stored in a silo. The surface may only be a "thin crust" over a hollow space in the silo. Breakthrough the crust often causes death by engulfment of the material and subsequent asphyxiation.
  5. Make sure walkways between bins are sturdy.
  6. Use caution when sampling from high bins or tanks. Wet or icy conditions may prevail, so check these conditions.
  7. When brass grain bombs are used to collect bin samples, do not drop the bomb to the surface of the grain. This could cause sparks if it hits the bottom or side of a bin. Lower the bomb gently to the grain surface, then raise it four to five feet and let it fall to the grain surface to collect the sample. Do not use steel grain bombs; use only brass bombs for sampling.
  8. Do not use flash units in dusty areas because of the possibility of explosion hazard. Any electrical devices (flashlights, cell phones, communication radios, etc.) used should be explosion-proof. See IOM 5.3.4 for additional information.
  9. Do not enter a grain storage structure without appropriate personal protective equipment or if any grain is frozen or caked to the walls. Wear PPE during inspection and sampling including bump caps.

### 1.5.3.3.3 - CLOTHING

Clothing:

1. Do not wear loose fitting clothes when collecting samples or conducting inspections, the clothes could catch on equipment or conveyor belts and lead to injuries.
2. Do not carry notebooks, credentials, etc., in the outer pockets of your inspectional uniform because they could fall into the equipment.
3. Steel mesh gloves should be worn when cutting portions from frozen products such as fish, etc.

### 1.5.3.3.4 - TRUCKS

Make sure any truck you enter during sampling and/or inspection will remain stationary while you are in it.

### 1.5.3.4 - Asphyxiation Hazards and Confined Spaces

This hazard is not exclusive to any program or inspection/sampling site. Many firms can have areas or operations that may present hazards associated with confined spaces, permitted confined spaces, or oxygen deficient atmospheres. OSHA's permit-required confined spaces standard defines "confined space" and "permit-required confined space (permit space)" at 1910.146(b). OSHA defines a confined space as meeting the following criteria: **Is large enough for an employee to bodily enter and work; Has limited or restricted means of entry and exit.** There are specific OSHA requirements for training that may be required when conducting inspection/sampling activities. If there are no additional instructions provided by

SOP's, safety requirements listed in the sampling assignment or local work instructions that provide this additional guidance, contact ORA Safety.

In addition to items 1-6 listed below, the following is a partial list of examples work areas that could require additional OSHA required training:

- Ship cargo holds
  - Walk in freezers
  - Walk in refrigerators
  - Walk in autoclaves
1. Prior to entering closed areas, ascertain if they have been fumigated and, if so, air them out prior to entering.
  2. When sampling or inspecting at rendering plants or fishmeal plants, be alert to possible hydrogen sulfide accumulations in dump pits and other areas. These fumes can be deadly.
  3. Be alert and take proper safety precautions in plants, silos, bins, pits, and any closed areas where semi-solid buttermilk or other liquid dairy products, silage, or other bulk products are stored. If not properly stored, improperly handled, or decomposing, certain products can produce dangerous amounts of carbon dioxide, or other gases, or may deplete the oxygen supply in these areas.
  4. When transporting dry ice or packages containing dry ice in your car, have some external ventilation (See IOM 1.5.4.2.2 and 4.5.3.5 for additional dry ice cautions).
  5. When sampling from the top of a grain elevator, do not jump down, stand on, or walk across the top of grain. There may be a cavity caused by crusted grain which could break and result in you being buried in grain, or being in an atmosphere of fumigating gas.
  6. Be alert when entering storage areas having controlled atmospheres, e.g., where oxygen has been replaced by carbon dioxide to prolong fruit storage, added sulfur dioxide for preservation purposes, etc. These areas must be aerated and deemed safe by the firm prior to entering.

Contact ORA Safety if you require guidance to determine what hazards or DOT regulations may be applicable to a substance when being transported.

### **1.5.3.5 - Radioactive Product Sampling**

Sampling of potentially contaminated FDA-regulated products from all FDA programs could result in potential internal and external exposures to ionizing radiation. Safety equipment required include a radiation dosimeter and radiation pager. Sampling of volatile or powdery material containing radioactive particles requires special training. Air monitor or use of a respirator may also be required. DOT and IATA regulations pertain to shipping these samples. Contact ORA RSO for details.

### **1.5.3.6 – Incident Command System**

How to safely conduct work activities in an ICS structure:

You may be assigned to collect samples of FDA regulated products at the scene of an incident, where an ICS structure has been implemented. These scenes may involve chemicals that pose a threat to human health or the environment. Examples incidents that can be expected have an active ICS structure include chemical spills or hazardous waste sites. In such instances, unprotected personnel are not permitted into hazardous zones. You shall follow the Incident Command System (ICS) at the field level. The Incident Management Team (IMT) will be responsible for tactical operations (i.e., perform investigations/inspections,

collect samples, and or/or detain or destroy contaminated product) in accordance with the Incident Action Plan (IAP) it develops.

### **1.5.3.7 - Carbadox Sampling**

If there is no labeling and /or a dealer refuses to identify any yellow powder, inform the dealer of the hazards of Carbadox. Contact your supervisor and consult with ORA Safety Officer before collecting any samples of suspected Carbadox. If instructed to collect a sample, follow the directions provided by ORA Safety Officer and notify the laboratory about the suspect product before shipping. Copy the ORA Safety Officer on any message to the laboratory.

## **1.5.4 - INSPECTIONS**

Many firms pose safety hazards or problems. Some include:

1. Flying glass in bottling plants
2. Explosion hazards from dust
3. Man-lifts which do not operate properly
4. Asphyxiation problems in rendering plants, fish meal plants, fumigated bins in elevators, fumigation chambers and any closed bins or areas
5. Forklifts and other power equipment operated in the plant. Be alert for their presence and avoid being hit.

### **1.5.4.1 - Man Lifts, Aerial Work Platforms, Scaffolding and Ladders**

#### **Man Lifts**

Do not ride on a rotating belt man lift style elevator at any time.

#### **Aerial Work Platforms**

Many firms have aerial work platforms, mobile aerial devices or bucket trucks to provide temporary access to elevated areas at a facility. Do not operate or ride in firm aerial work platforms. Specific operational and safety training is required to utilize the equipment.

#### **Non-Permanent Scaffolding**

Do not stand on non-permanent scaffolding at any time.

#### **Ladder Safety**

Read and follow any labels or markings on the ladder including maximum load rating. Prior to using ladders always inspect them. Do not use ladders that are damaged or in disrepair. Do not use makeshift ladders or ladders that are positioned on top of boxes or unstable bases. Always maintain a 3-point contact with the ladder when climbing. Do not carry supplies or materials in your hand while climbing the ladder. Do not stand on the top rung unless it is designed for that purpose. If using a portable extension ladder, follow a 4:1 ratio for maintaining the proper angle of a ladder (for every 4 feet of ladder height up to where the ladder rests on a surface, position the ladder base 1 foot away from the wall with 3 feet extending beyond the upper landing surface). Do not overextend the ladder. If possible, have the ladder held by someone while you are using it. When collecting samples from a ladder extreme care should be taken to not overreach or lean too far beyond the center of the ladder and increase the risk of falling.

### **1.5.4.2 - Factory Inspection**

#### **1.5.4.2.1 - RETORTS**

Inspections of retorts require extra safety precautions. Be alert for live steam and other potentially dangerous heat sources. Do not enter a retort if your safety cannot be assured. When it is necessary to enter a retort, inform plant management. The firm must have a confined space policy in place. If the firm is

not aware of the OSHA confined space requirements or does not have a confined space program, DO NOT ENTER THE RETORT.

Contact your Program Liaison Industrial Hygienist for additional information/training about confined space, which includes lock-out/tag-out procedures.

### **1.5.4.2.2 - THERMAL**

The Occupational Safety and Health Act (OSH Act) requires employers to comply with hazard-specific safety and health standards. In addition, pursuant to Section 5(a)(1) of the OSH Act, employers must provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm. In some circumstances heat or cold stress could be considered conditions that require training and other mitigation actions be implemented. ORA Safety can be contacted if you have concerns regarding heat or cold stress.

### **1.5.4.2.3 - CHEMICAL**

When conducting inspections of firm's using chemicals, pesticides, etc., ask to review the MSDS for the products involved to determine what, if any, safety precautions you must take. This could include the use of respirators or other safety equipment.

Ethylene Oxide (EO) - EO is a colorless gas or volatile liquid with a characteristic ether-like odor above 500 ppm. Unmonitored and inadequate ventilation will allow EO buildup of extremely high concentrations, especially in facilities utilizing malfunctioning or leaking equipment. Door gaskets, valves, and threaded fittings are typical areas where leaks have been observed. Additionally, exhaust vents from the sterilizer and the sterilizer room should not be located near air conditioning intake vents, or vented directly into work areas. If the odor of EO is detected, ventilation and containment are inadequate. Leave the area and report the situation to your supervisor for further inspectional guidance. Special EO monitoring equipment is available upon request from the Office of Regulatory Science's National Safety Officer for investigators' safety monitoring of inspectional site.

OSHA standard regulating employee exposure to EO is presently 1 ppm over an 8-hour day. You should avoid all unnecessary and preventable exposure to it. This gas has toxic (including possible cancer and reproductive hazards), flammable and explosive properties, and must be used and handled with caution. Adhere to any procedures the firm has established for protection of personnel from over-exposure to EO. Where improper venting procedures or defective equipment are observed, take adequate precautions, i.e., do not enter potentially hazardous areas, and/or wear protective clothing and a respirator. Refer to IOM 1.5.1. [29 CFR 1910.134](#) contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

### **1.5.4.2.4 - IONIZING RADIATION**

Each investigator who visits a manufacturer of radioactive products or tests ionizing radiation emitting products (e.g., diagnostic x-ray tests) must wear a Thermoluminescent Dosimeter (TLD) to estimate external exposure. These are available in each district; personal alarm dosimeters are also available. These can alert the investigator to high exposure areas during visits to manufacturing firms. Make an estimate of the time spent in areas where radiation is present and estimate exposure during this time from your personal dosimeter. The estimate can be compared to the results from the TLD badges, which would be processed by Winchester Engineering and Analytical Center (WEAC). Contact WEAC for additional information concerning TLD badges.

Experience has shown there is a potential for internal exposure from inhalation of radioactive material, especially in the case of iodine isotopes. Ingestion of radioactive material from contaminated notebooks, workpads, etc. is also possible.

When you are inspecting radiation-emitting devices and substances, take every precaution to avoid undue exposure or contamination. Time, distance, and shielding are important when working around radioactive materials. Adhere to the firm's established safety procedures and precautions. Where employees are required to wear protective apparel, eyeglasses, or monitoring equipment, follow those procedures. Use protective gloves to avoid hand contamination when handling the lead pigs containing radioactive materials.

Monitoring devices must be used whenever exposure is possible. Monitoring equipment must be calibrated periodically in order to be accurate. There are a variety of meters that can be utilized for radiation protection. Film badges are usually used to determine accumulated amounts of radiation, and unless these are analyzed the exposure dosage is unknown. This will be done by WEAC. Dosimeters will provide a reading at the time of exposure.

Investigators conducting inspections of facilities operating positron emission tomography (PET) scanners must receive radiation safety training from the ORA Radiation Safety Officer or complete RH 102 Radiation Safety course to the inspection. Investigators are also required to wear a personal alarm pager and a dosimeter when performing inspection in a PET facility. Intrinsically safe batteries should be installed in Powered Air Purifying Respirators (PAPR) when being worn where there is a potentially explosive condition.

## **1.5.5 - MICROBIOLOGICAL HAZARDS**

When processes involve potential for microbiological contamination, normal controls and procedures should contain or protect against any possible hazards. The procedures may include routine use of protective clothing and equipment. Precautions mentioned below concerning gowning, masks, gloves, etc., in this section, are also important in the event that accidents, spills or unexpected, uncontrolled contamination occurs while you are in work areas. If contamination is known in advance to be uncontrolled or you must handle contaminated materials, do not enter an area or handle these materials without first consulting with your supervisor or ORA safety before entering known contaminated areas. ORA safety is available for consultant on specific topics.

### **1.5.5.1 - Animal Origin Products**

Caution: It may be necessary to wear gowns, masks, rubber gloves, etc., when inspecting some of these work areas. Be guided by how the firm's employees dress for their work areas, and dress accordingly. Consult with the firm's management and your supervisor regarding dress and precautions to follow.

When inspecting manufacturers, or collecting samples of animal origin products, be alert for possible routes of contamination that could lead to your injury or illness. Some possible vectors of disease exist in firms that process products which use animal origin products as raw materials. They include:

1. Anthrax - Care must be taken during inspections of processors of bone meal, dicalcium phosphate and gelatin.
2. Tularemia - Use caution when inspecting rabbit processors. Be careful of scratches from bone splinters. Use gloves for protection.

### **1.5.5.2 - Viral and Other Biological Products**

Take proper precautions to protect yourself. If necessary, consult your supervisor and/or Division microbiological personnel. NOTE: Inspection of vaccine manufacturers may require inoculation in advance of the inspection to adequately protect the investigator. Contact ORA Safety for guidance

Methods of transmission include aerosols, which may be created by manufacturing operations (e.g., centrifugation, filling, etc.) or spills. Transmission may occur through inhalation; contact with contaminated objects, including equipment, animals, waste materials, reagents, file cabinets and doorknobs. Transmission can occur through ingestion, inhalation, or through broken skin.

### **1.5.5.2.1 - PROTECTIVE AND PREVENTIVE MEASURES**

Protective and preventive measures include:

1. Precautions listed in IOM 1.5.5.1 and 1.5.5.3
2. Do not touch. This means equipment, materials, reagents, animals, etc.
3. Wear protective clothing. Evaluate the needs for gowns, caps, masks, gloves, and shoe coverings, and wear them where necessary. Protective clothing worn in a work area where a virus or spore bearing microorganism is handled must not be worn into a work area for another product. Leave all used protective clothing at the firm for proper disposal.
4. Wash hands thoroughly after leaving each work area.
5. Determine if the firm has established safety precautions and procedures, and follow them if adequate.
6. If the firm is processing viruses or other potentially infectious biological agents during the inspection, determine if it is advisable to enter the work areas. Chances of infection through aerosols are reduced when there is no active processing.
7. Females of childbearing age are advised not to inspect areas where the Rubella virus is actively processed unless immunity has been established. Infection during pregnancy may result in congenital abnormalities.
8. Vaccines are available for your protection against some organisms (e.g., Rubella). For information on inoculations and physical examinations, refer to IOM 1.5.1.5.

### **1.5.5.2.2 - VIRAL HEPATITIS AND HUMAN IMMUNODEFICIENCY VIRUS**

Precaution - Blood and Plasma Inspections - Viral Hepatitis and Human Immunodeficiency Virus (HIV) - the virus that causes Acquired Immune Deficiency Syndrome (AIDS). Be alert around blood banks or blood processing operations to the possible dangers of these and other infectious agents.

Keep in mind the following warnings:

1. Do not touch. This means do not handle lab instruments, blood samples, containers or reagents in blood bank labs unless absolutely necessary. Wear lab coats with long sleeves. Disposable lab coats that are impervious to blood are best. These should be left in the laboratory area.
2. Do not smoke, drink, eat or have meetings in the blood banks or in the testing areas for Hepatitis B Surface Antigen (HBsAg), HIV, or any other infectious agents.
3. Consider blood samples, the antigen and antigen testing kits and other associated HIV, HBsAg, and other test reagents as potentially infectious.
4. Consider the possibility of aerosol contamination if there is spilling or splashing of test reagents or blood samples.
5. Use care when placing inspectional or personal equipment in lab areas. Wash hands thoroughly after these inspections. Hepatitis can be transmitted by hand to mouth.
6. Use disposable gloves. Spills may be wiped with a 5% sodium hypochlorite solution and/or solutions such as Wescodyne or Betadine. Autoclaving is the preferred method (121 degrees C for 60 minutes) for sterilizing reagents, samples and equipment.  
Note: When accidental spills, etc. occur in your presence, you are not required to participate in cleaning or disposing of materials. This is the firm's responsibility.
7. Use scrupulous Adhere to Standard/universal personal hygiene at all times in the blood bank and in the testing areas for HBsAg, HIV, and other infectious agents.

### 1.5.5.2.3 - PRECAUTIONS FOR NON-CLINICAL LABORATORY INSPECTIONS

Precaution - Non-Clinical Laboratory Inspections - During inspections/investigations of sub-human primate facilities (e.g., Good Laboratory Practices (GLPs), non-clinical laboratory testing facilities, animal holding facilities, etc.) do not enter rooms housing sub-human primates. Monkeys normally housed in these facilities can carry "Herpes-B Virus", "Simian B Virus", or "monkey-virus". During inspections of this type, use the following guidance:

1. Investigators shall not enter any rooms which hold or house subhuman primates. Bioresearch monitoring (BIMO) inspectional information should be derived from personnel interviews and record examinations conducted outside of the primate areas.
2. All study records usually found in the monkey rooms (Standard Operating Procedures (SOPs); protocols; animal housing, feeding, handling, and care records; animal isolation and health records, room environmental records; dosing and animal I.D. records; animal daily observation records; equipment and room cleaning records, et al.) should be reviewed outside of the rooms.
3. Although contact with subhuman primates in the course of an inspection is prohibited, information on animal room activities may be obtained through personnel interviews.

### 1.5.5.3 - Bacteriological Problems

Take proper precautions to protect yourself. If necessary consult with your supervisor and/or ORA Safety for referral to the ORA National Bio-Safety officer. Possible routes of salmonellosis include dust inhalation in dried milk and dried yeast plants. Thyroid processing plants may also be a source of this problem.

In no case should you taste any item implicated or suspect of causing injuries or illnesses (e.g., consumer complaint samples, etc.). Handle these with extra care since even minute portions of certain items may cause serious illness or even death.

### 1.5.5.4 - Hantavirus Associated Diseases

Rodents and other small mammals have been identified as the primary hosts for recognized Hantaviruses. Infected rodents shed the virus in saliva, urine and feces. The time of this virus' survival in the environment is unknown.

Human infection may occur when contact is made with infected saliva or excreta, through inhalation of aerosol produced when the animals sneeze, or contaminated dust particles are stirred up. In addition, infection can also occur when dried contaminated materials are disturbed and directly introduced into broken skin or onto the conjunctivae.

Hantaviruses can present some or all of the following symptoms: fever, headache, muscle aches, nausea and vomiting, chills, dry cough, and shortness of breath.

Investigators/Inspectors may be subject to an increased risk of infection because of unpredictable or incidental contact with rodents or their habitations, i.e., entering various buildings, crawl spaces and other sites that may be rodent infested.

When encountering or suspecting rodent infested areas, the following protective and preventive measures are recommended:

1. First and foremost, DO NOT HANDLE RODENTS - DEAD OR ALIVE.
2. Be careful when moving items around, excessive dust may increase the risk.
3. To prevent eye contamination, wear goggles or a full-face respirator.
4. High-Efficiency Particulate Air (HEPA) filter masks or respirator cartridges are recommended to avoid inhalation of aerosols.

5. Wear coveralls, and handle and dispose of as infected material.
6. Wear disposable latex or rubber gloves. Be careful to avoid hand contamination when removing gloves. Wash hands thoroughly after removal.
7. In addition to these measures, follow any guidance issued by state health departments.

### **1.5.6 - WIRELESS DEVICES**

The following information is provided regarding the use of wireless devices:

1. If you carry a blackberry, cell phone, or other wireless device, always enquire about a firm's policy with regard to their operation within the establishment as they may pose a safety hazard.
2. An Executive Order, signed by President Barack Obama and issued by the White House on October 1, 2009 prohibits federal employees from engaging in text messaging while driving GOVs, or POVs while on official business, or using government provided electronic equipment, e.g. blackberry, while driving.
3. FDA policy prohibits the use of hand held wireless phones or other wireless devices while operating government, commercially leased/rented vehicles. Drivers who use cell phones within their scope of work are required to use hands-free cell phones and other hands-free devices.

### **1.5.7 - REPORTING**

Automobile Accidents - See IOM 1.2.2.2 - Accidents, for procedures.

Injuries - If you are injured during the performance of official duties, report immediately to your supervisor. If medical aid is required, obtain it as soon as possible. Check with your supervisor on what accident report forms are required and procedures to be followed.

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