

**MEMORANDUM OF UNDERSTANDING (MOU)
BETWEEN
THE FOOD AND DRUG ADMINISTRATION (FDA)
AND
THE NATIONAL TREASURY EMPLOYEES UNION (NTEU)
REGARDING
MANDATORY FOREIGN INSPECTION ASSIGNMENTS**

FDA and NTEU agree that they are committed to treating domestic and foreign inspection assignments equally and that foreign inspections are part of the overall Agency work plan. Accordingly, the Parties agree to the following:

- 1) The FDA will rotate inspections fairly and equitably among similarly qualified employees.
- 2) In order to encourage volunteers for foreign inspections, the FDA will announce a call for volunteers on a semi-annual basis to participate on international inspections. This national volunteer list will identify traveler, area of expertise, and country and time preferences for travel. This list will be the first consideration for identifying employees to conduct foreign inspections.

If management does not select a volunteer for an inspection from the national survey, inspection assignments will be issued on a regional basis at which time the region will work to identify a qualified volunteer by disclosing the assignment request to all qualified employees within the region.

If no volunteers who apply for the inspections are selected or if no volunteers apply, then FDA will make every reasonable effort to assign the inspections on the regional/district level using the following assignment process:

- a) To any qualified GS-13 employee;
- b) To any qualified GS-12 employee;
- c) To any another qualified employee.

All assignments listed above will be made on the basis of regional inverse seniority based upon HHS Entry On Duty date (EOD). Once an employee is chosen for (and performs) the inspection, the employee's name then goes to the bottom of the inverse seniority list based on grade.

In the event that the Agency adopts a PD containing a specific percentage of time to be spent in the international arena, qualified employees on this PD will be considered by management prior to a), above.

- 3) From October 1, 2003 to September 30, 2004, qualified employees GS-12 or below will not be assigned to perform a foreign inspection trip more than once per year.
- 4) All volunteers and assigned employees may switch their scheduled foreign inspection assignment with an appropriately qualified counterpart within their region, contingent upon management approval.
- 5) Hardship Exemptions: If an employee who is assigned to perform a foreign inspection is unable to accomplish the work assignment due to an emergency or unforeseen circumstance, they should notify both District management and DFI immediately. Employees may be excused from foreign inspection assignments by management upon a showing that they have valid extenuating circumstances present that would not allow them to perform the assignment. Valid extenuating circumstances are, primarily, conditions outside the control of the employee which would preclude them from being able to travel abroad without some economic or personal harm otherwise occurring. The request for an exemption should be made in writing within five (5) workdays of receipt of the foreign inspection assignment. The circumstances surrounding an employee's inability to conduct the foreign inspection will be reviewed on a case-by-case basis and management will make the final decision on the employee's work assignment. Any management denials of such requests will be provided in writing to the employee within five (5) workdays of the request. All denials are grievable through the negotiated grievance procedure.
- 6) From October 1, 2003 to September 30, 2004, for qualified employees GS-12 or below who did not volunteer for the inspection assignment, foreign inspections will normally be limited to a period of no more than two weeks.
- 7) Employees will always be provided with contact information for an alternate or back-up trip coordinator to handle any necessary travel or inspection changes when the primary coordinator cannot be reached. However, in the absence of access to a travel planner, employees may make their own travel arrangements.
- 8) Employees that are required to take numerous short legs of a trip once they have arrived in the country where the foreign inspection is to occur may advise the travel planner as to their preferred mode of transportation for those legs of the trip.
- 9) The FDA will provide non-volunteers assigned to conduct foreign inspections as much advance notice as possible, but normally no less than eight (8) weeks prior to the assignment.

- 10) The FDA will normally provide non-volunteers assigned to conduct foreign inspections with advance notice of ten (10) calendar days of their full travel schedule, including information regarding any dangerous conditions in-country as defined by the State Department.
- 11) All affected employees will be given the opportunity to attend the FDA/ORA International Inspections Course, preferably prior to performing their first foreign inspection.
- 12) The FDA will provide all employees that perform foreign inspections with travel services, medical insurance coverage, and/or emergency transportation/evacuation insurance coverage.
- 13) The FDA will authorize business class travel in accordance with 41 CFR 301-10.124(i) of the Federal Travel Regulations, and other applicable laws and regulations.
- 14) Up to fifteen (15) hours of overtime or compensatory time per week will be authorized in advance for workdays in excess of eight hours for all trips involving transoceanic travel. For all other trips (e.g., Canada and Mexico) employees will be authorized up to ten (10) hours per week for workdays in excess of eight (8) hours. All overtime must be requested and approved in advance.
- 15) Employees will be expected to complete the write-up of reports normally not later than thirty (30) calendar days after they return from conducting the foreign inspection.
- 16) In order to guarantee the safety of FDA employees and consistent with existing FDA policy, two (2) employees will normally be assigned as a team on any foreign inspection trips to countries given travel advisories or warnings by the State Department and other countries as determined by management. The team will include at least one (1) employee who has prior experience in foreign inspections.
- 17) Translators will be provided for employees while performing inspections abroad whenever there is no designated English-speaking company representative available at the firm being inspected.
- 18) As a resource, the FDA will provide, upon request, the name(s) and contact information of employee(s) who have conducted foreign inspection(s) in a particular country of interest.
- 19) Cell phones that connect internationally will be provided to all employee teams performing a foreign inspection for the duration of their time abroad. In the event that

a cell phone is unavailable that is compatible with the country in which the foreign inspection is being performed, an international calling card will be provided to the inspection team.

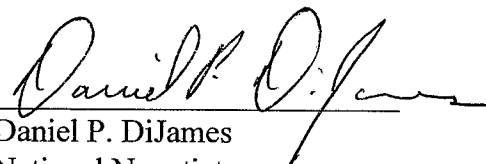
- 20) The FDA will request that the firms being inspected in countries given travel advisories or warnings by the State Department and other countries as determined by management, provide a driver and/or a company contact for employee(s) assigned to inspect the firm. Management will continue to make reasonable efforts to ensure that strict security practices are adopted for all employees in these types of countries, including providing a contact that may be reached at all times in case of emergencies.
- 21) In accordance with government rule and regulation, employees will be allowed to process ATM transactions on their expense vouchers in order for them to avoid carrying massive amounts of traveler checks or cash at any one time. This authorization will be stated on all foreign travel orders.
- 22) DFI does not routinely schedule inspections in countries that have an associated State Department warning. The State Department warning is used as a signal that such requests for inspection need to be further evaluated on a case-by-case basis. During this assessment, FDA weighs concerns about the safety of its investigators against the public health benefits to US citizens of having access to the product being inspected. For routine inspections, FDA has historically made decisions on the side of caution for the safety of its investigators. For products that are innovative breakthrough products or are considered medically necessary, FDA generally errs on the side of public health benefit and requests volunteers to conduct the inspections. FDA has applied this policy uniformly to avoid establishing precedents for one country that could not be consistently fulfilled in other countries for which we have similar concerns about travel. The Agency will normally only use volunteers to conduct inspections in countries that have an associated State Department warning.
- 23) A lack of experience with foreign inspections will be considered when the performance of any employee on such inspections is evaluated.
- 24) Management will hold formal 7114 meetings with all affected FDA employees regarding the changes to the foreign inspection program and this MOU. A representative from each appropriate NTEU chapter will be notified in advance of the meetings and afforded the opportunity to attend.
- 25) This MOU will become effective upon the signature by both parties. The MOU will expire upon the expiration of the current FDA/NTEU collective bargaining agreement (CBA), or on the effective date of its successor, whichever occurs first. The Parties recognize that this MOU will remain in effect during the interim between the expiration of the current CBA and the effective date of any successor agreement.

For the FDA:



Diana Kolaitis
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RFDD, Northeast Region
Chief Negotiator

For the NTEU:



Daniel P. DiJames
Daniel P. DiJames
National Negotiator

Execution Date: June 11, 2003