

DATE: February 27, 2014 (original date of issuance)
May 14, 2014 (amended)

FROM: Annette Tyree Debisette, PhD, RN
Captain, USPHS
Training Officer, Division of Human Resource Development (HFC-60)

SUBJECT: COURSE ANNOUNCEMENT:

Inspection of Laser Manufacturers, RH301

ORA U

11919 Rockville Pike

Rockville, MD

Room 116

Begin: Tuesday, June 24, 2014 at 8:00 AM

End: Thursday, June 26, 2014 at 5:00 PM

Please note correction to reflect corrected FY14 hotel per diem rate of \$224.

AUTHORIZED TRAVEL DATES:

Arrival: Monday, June 23, 2014

Departure: Friday, June 27, 2014

Everyone is expected to return on the departure date unless there are extenuating circumstances. ([See Accounting & Admin Info.](#))

POINTS OF CONTACT:

Participants seeking information or assistance with this training course should contact, in the following order:

- 1) Immediate Supervisor (first source of information and assistance)
- 2) New Hire Training Coordinators (for "new hire" related questions)
- 3) District Administrative Officer (AO) (Gov Trip, travel, and accounting code information)
- 4) Regional Training Officer (RTO) (cancellation, substitutions, hotel issues, pre-requisite waivers, special requests for additional overnight stay)
- 5) CAPT Annette Debisette, PhD, RN Training Officer (final POC if the RTO is unavailable)
FDA/Division of Human Resource Development
301-796-4542 Fax 301-827-8708 e-mail: annette.debisette@fda.hhs.gov

COURSE DESCRIPTION / OBJECTIVES:

Inspection of Laser Manufacturers, RH301

This course trains field investigators and engineers to perform inspections of both medical and non-medical laser manufacturers. Participants will learn how to evaluate compliance with both medical device and electronic product radiation control (EPRC) requirements.

Objectives: Upon completion of this course, participants will be able to:

1. Interpret EPRC and medical device requirements, how they are related and how they apply to medical and non-medical laser manufacturers.
2. Conduct inspections independently by applying EPRC and if applicable, quality system inspectional techniques appropriately.
3. Document inspectional observations that are supportable and actionable.
4. Recommend appropriate actions for field and or CDRH follow-up.

Target Audience: Primary audience: Consumer Safety Officers, Engineers, and Compliance Officers. Supervisory Consumer Safety Officers and Center reviewers will be admitted on a space available basis.

CEU: Application Pending.

PREREQUISITES:

Prior to attending, nominees must:

1. Completed new hire training curriculum, including audit (FDA: Level I). State employees should have completed their new hire program and have experience working in the program area.
2. Successfully completed the Basic Radiological Health course (RH201).

COURSE COMPLETION REQUIREMENTS:

To successfully complete this course and receive a course certificate with Continuing Education Units* (CEUs), each participant will be required to:

1. Bring laptop computer.
2. Review the FD&C Act, Chapter V, Drugs and Devices, Subchapter C; Electronic Product Radiation Control (sections 531-542) prior to coming.
3. Review 21 CFR Code of Federal Regulations Parts 800-1200 prior to coming.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>
4. Be on time and attend the entire course.
5. Participate in class discussions, exercises, workshops and presentations.
6. Pass the course assessment(s).

Course Assessments/Exam Policy*

As an authorized provider of Continuing Education Units accredited through the International Association for Continuing Education and Training (IACET), DHRD courses are required to have an assessment(s) component (knowledge & application) to evaluate the effectiveness of the training presented and the participant's grasp of the material covered. Each participant must pass all course assessments and activities.

SLOT ALLOCATIONS:

RTOs will allocate slots to the Districts utilizing the ORA Survey Data:

- NER- 3
- CER- 3
- SER- 3
- SWR- 3
- PAR- 3
- HQ-1
- CDRH- 2
- States- 2*
- International- 2 (IA)

***NOTE:** At least 10% of the slots are reserved for State participants. Please refer all State inquiries to:

FDA/ORA Regional Training Officer (RTO)

Regional and/or District Offices will refer any States contacting them about this training course to the Regional Training Officer. Regions and Districts can not assign slots for these courses to a specific State without the approval of the Training Officer and concurrence of the RTO and/or DFSR (Wendy Campbell and Nikki Wilson). Funding for State employees to attend this course is to be provided by their State agency.

DEADLINES / SPECIAL NOTICES:

Regional Training Officers, Training Contacts:

1. Please provide a copy of this announcement to each participant as soon as they are identified.
2. **By COB Friday, May 23, 2014** forward all participant names and registration information via e-mail to CAPT Annette Debisette.

Course Participants:

1. **Hotel Reservations by COB Friday, May 30, 2014**, participants and instructors that will be in travel status must confirm their reservation at the Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852 (301) 822-9200 Room block: **“FDA: Radiological Health Training Programs** (See LODGING INFORMATION below for additional information.)
2. **By COB Friday, May 23, 2014** complete the “Attachment “A” for Participant Registration Information” at the end of the document and forward it via e-mail, **as a Word attachment** (Word Doc) to:

FDA: your Regional Training Officer (RTO).

FDA/Centers: Your Center Training Contact.

State: Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts can not assign slots for these courses to a specific state without the approval of the Training Officer and concurrence of the Regional Training Officer and/or DFSR (Wendy Campbell or Nikki Wilson). Funding for the state employee to attend the RAST course would be provided by their State agency.

TRANSPORTATION:

- Travelers must select an airport and flight that is most cost effective to the Government, in accordance with the Federal Travel Regulations.
 - Reagan Washington National (DCA)
 - Baltimore Washington International (BWI)
 - Dulles International Airport (IAD)
- Rental cars are **NOT authorized**.
- DC Metro: <http://www.wmata.com/rail/>
- Shuttles (need 24 hours notice):
 - Super Shuttle (800) 258-3826 <http://www.supershuttle.com/>
 - Federal Airport Shuttle (301) 528-2929 <http://www.federalairportshuttle.net/>
 - Barwood Taxi (301) 984-1900 <http://barwoodtaxi.com/>

LODGING INFORMATION:

Lodging: **\$224+** 13% lodging tax

M&IE: \$71

Marriott Bethesda North Hotel and Conference Center, FEMA ID: **5114**
5701 Marinelli Road
Rockville, MD 20852
(301) 822-9200

Reservations By: Friday, May 30, 2014

Check-in time: 4:00 PM Checkout: Noon

Room Block: FDA: Radiological Health Training Programs

Hotel Cancellation Policy: No later than 24 hours prior to your intended arrival date to avoid cancellation charges. If you cancel, please obtain a cancellation number from the hotel.

Internet Fee for Official Duties:

OFS requires preapproval for Internet Fee and must be included in the traveler’s Travel Authorization (TA). Internet Fee no longer can be claimed thru a local voucher.

DHRD will **not** reimburse Internet Fee for those travelers required to perform official duties for their office while attending a DHRD Training. The traveler's office is responsible for this expense. A second line of accounting codes must be entered into the TA using the traveler's office funding.

COURSE LOCATION:

ORA U
11919 Rockville Pike
Room 116
Rockville, MD 20852
(301) 796-4550

Metro directions to the hotel: Take the Red Line train toward White Flint Metro. This train will be marked "Red Line to Shady Grove." Get off at the White Flint Metro station and take escalator up to the street level. The hotel is located directly across the street from the White Flint Metro station.

Walking directions to ORA U: ORA U is located approximately 2 city blocks from the hotel. Walk north on Rockville Pike and the training center will be on your right after you pass the intersection of Rockville Pike and Old Georgetown Road.

Parking at ORA U: Local participants and instructors are strongly encouraged to ride Metro, carpool, or use public transit since parking at ORA U is limited. Those commuting locally need to voucher parking expenses with their office (local voucher) except for ORA staff.

Instructors, CAG (Course Advisory Group) members, and employees who car pool (two or more) to ORA U may be granted permission to park at ORA U on a case-by-case basis pending availability. Arrangements must be made two weeks in advance with the DHRD course training officer. Please contact the training officer two weeks in advance to confirm arrangements and receive further instructions for parking.

Possible parking options for local participants and instructors who must drive to ORA U:

1. White Flint Metro station and use the pay-to-park lot. Reference the following links for more information; <http://www.wmata.com/default.cfm> :
[http://www.wmata.com/riding/hours_fares.cfm#Metrorail Fares](http://www.wmata.com/riding/hours_fares.cfm#Metrorail_Fares)
2. Metrorail daily parking is available at the parking lot east of Rockville Pike on Marinelli Road.

ACCOUNTING AND ADMINISTRATIVE INFORMATION

- When a participant fails to confirm a hotel reservation by the deadline and cannot obtain lodging at the negotiated rate, any additional cost must be paid by the nominee's district, unless the district obtains prior approval from DHRD. Approval requests should be forwarded to the Training Officer for a case by case review by DHRD management.
- Employees should stay at the designated hotel with the negotiated room block. Travelers must indicate in the "Trip Detail" section of the Travel Authorization that there is a "Hotel Reservation made thru a Room Block detailed within the ORAU Course Announcement". If the employee chooses to stay at a different hotel, the employee will be responsible for any costs incurred above and beyond what the expenses would have been if the employee stayed at the hotel with the negotiated room block. Reimbursement will be made at the negotiated rate. If the employee does not use the room block, the employee must use GovTrip to book the hotel.
- When accounting codes are released approximately 4 weeks prior to the course, the training officer will send a Travel Authorization Memo to ORA participants and FDA instructors.
- Rental cars are not authorized
- Civilian dress is business casual as defined by your district.
- Commissioned Corps Officers are required to be in uniform while attending training.

- Prior to attending the course, the commissioned officer should contact CAPT Diann Shaffer (ORA Commissioned Corps Liaison) if unsure which uniform to wear on a scheduled plant tour.
- Bring your FDA or other official government issued identification for identity verification.
- **Please note: Due to budget constraints, DHRD will no longer pay for UPS return shipment of student manuals, etc.**
- **Request & justification to stay an additional night** (if applicable): Requests need to be **submitted to your Regional Training Officer (RTO)** in advance via email **by the student's supervisor**. One request can be provided for all students listed from the same District/Lab. Approval must be granted **prior** to the student traveling to the course. DHRD is unable to assist in reimbursement for "after the fact". The RTO will forward requests to the DHRD Training Officer for review/approval.

The request is to include:

1. Reason/justification for request to address factors such as:
 - District policy indicating what is an "unreasonable hour" for travel (if citing undue hardship to the employee)
 - Available flight times (contract and non-contract)
 - Airports researched (if more than one in the area)
 - Any related cost comparison (non-contract fare vs. staying the extra night)
 2. Statement of supervisory concurrence
- If approved, your voucher needs to include a copy of the e-mail granting approval to stay the extra night.
- After the course, FDA participants should report their actual course time in the "Miscellaneous Operations Accomplishment Hours" screen in FACTS following all applicable guidance. The data entered should include the appropriate Operation Code and PAC.
 - Op 83 – Training Given (for use by FDA course instructors)
Op 84 – Training Received (for use by FDA participants)
82R800 – Medical Device courses

SPECIAL NEEDS:

FDA provides reasonable accommodations to employees with disabilities. If you need a reasonable accommodation for any part of the training process - due to medical conditions, physical limitations or particular learning challenges - please notify the Training Officer prior to the course. Reasonable accommodations will be granted on a case-by-case basis. For Voice TTY or other interpreting needs, please contact Interpreting Services at the following e-mail address: interpreting.services@oc.fda.gov.

/s/
CAPT Annette Tyree Debisette
Training Officer, DHRD
(301) 796-4542

Attachment A

Attachment for Participant Registration Information

Please submit the information as listed in the format and order below as a Word attachment (Word Doc) no later than COB **Friday, May 23, 2014** via e-mail to:

FDA: Your Regional Training Officer (RTO).

FDA/Centers: Your Center Training Contact. Center Training Contact will forward information to the DHRD Training Officer.

FDA/ORA Regional Training Officer (RTO)

State: Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and districts can not assign slots for these courses to a specific state without the approval of the Training Officer and concurrence of the Regional Training Officer and/or DFSS (Wendy Campbell and Nikki Wilson). Funding for the state employees to attend the RAST course would be provided by their State agency."

List State/Local Agency: _____

Inspection of Laser Manufacturers RH301
ORA U
11919 Rockville Pike, Room 116
Rockville, MD
 June 24-26, 2014

Participant Registration Information
Participant's Legal Name:
Position/Title:
GS Series and Grade:
Agency/Organization/Division:
Duty Station (Complete Address with Mail Code):
Business Phone Number and Extension:
Fax Number:
E-mail address:
Supervisor's Name:
Supervisor's Phone Number:
Arrangements needed to accommodate special needs (if any):
Name and Phone Number to contact in case of emergency (optional):
Course Prerequisites: (write in completion dates on the appropriate line) 1. Completed new hire training curriculum (including the audit FDA: Level I) date _____. State employees should have completed their new hire program and have experience working in the program area.
2. Completed RH201 Basic Radiological Health Course date _____