



Office of Regulatory Affairs

**Office of Training Education and
Development
Student Handbook**

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MISSION

The Office of Training Education and Development (OTED) provides high quality learning opportunities through timely, cost-effective learning products that support FDA's mission and strategic goals and meets current training and development needs of ORA personnel, state and local regulatory officials, and other stakeholders.

VISION

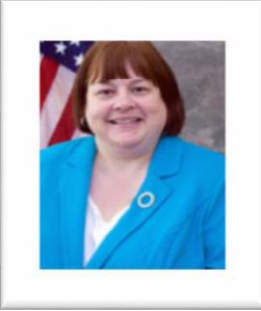
Developing and delivering collaborative FDA training products by leveraging our staff strengths to assist public health regulatory officials in excelling in their job performances and improving public health safety for all.

COMMITMENT TO QUALITY



OTED is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET continuing education unit CEU. As an IACET Accredited Provider, OTED offers CEUs for its programs that qualify under the American National Standards Institute (ANSI) IACET Standard.

WELCOME FROM THE DIRECTOR



Welcome to the Office of Education Training and Development (OTED) located in the Office of Regulatory Affairs (ORA)! We are very excited to share the importance of the work we do. Our work supports the mission of the U.S. Food and Drug Administration (FDA), to protect the public and global health. Simply put, we are ORA's training organization. We help people realize their full potential by offering engaging and dynamic training, educational and developmental programs.

Here at OTED, our goal is to provide the best training and certification events possible to enable you to **learn** critical job-related information, **grow** in your professional development and **thrive** in your career path. As you read this handbook, please keep that goal of learning, growing and thriving in mind.

One interesting fact to I'd to share with you: Many past OTED students have now come back to leave their legacy by participating as a presenter, course advisory group member or giving back knowledge in other areas that support OTED. We are grateful to all individuals within the FDA community that enhance and support our training environment.

As a stakeholder in OTED, you have an immense impact on ORA because you are the regulatory workforce to protect and promote public health. My personal goal for you is to have a positive experience learning and growing in order to support our shared FDA Mission.

Thank you for what you do each day to help protect our consumers, family and friends.

Please let us know how we're doing, we'd like to hear from you! Send your feedback to OTED@fda.hhs.gov

Welcome to the Office of Training Education and Development!

A handwritten signature in black ink that reads "Patricia L. Alcock". The signature is fluid and cursive.

Patricia L. Alcock
Director, Office of Training Education and Development

INTRODUCTION

This Student Handbook is intended as a reference to guide you while you are attending an OTED course or program. Please read this handbook closely because it will provide you with useful information which will assist you throughout your professional development. The handbook provides information about the course catalog, registration process, logistics, and general guidance about OTED's education, development and personnel certification procedures and practices. This document was developed to assist in consistency, uniformity and transparency on OTED's procedures and expectations while you are attending ORA national training courses. OTED programs and services are periodically reviewed and the Office therefore reserves the right to make changes at any time without notice.

ORGANIZATION STRUCTURE AND CHARTS

WHO WE ARE AND WHAT WE DO

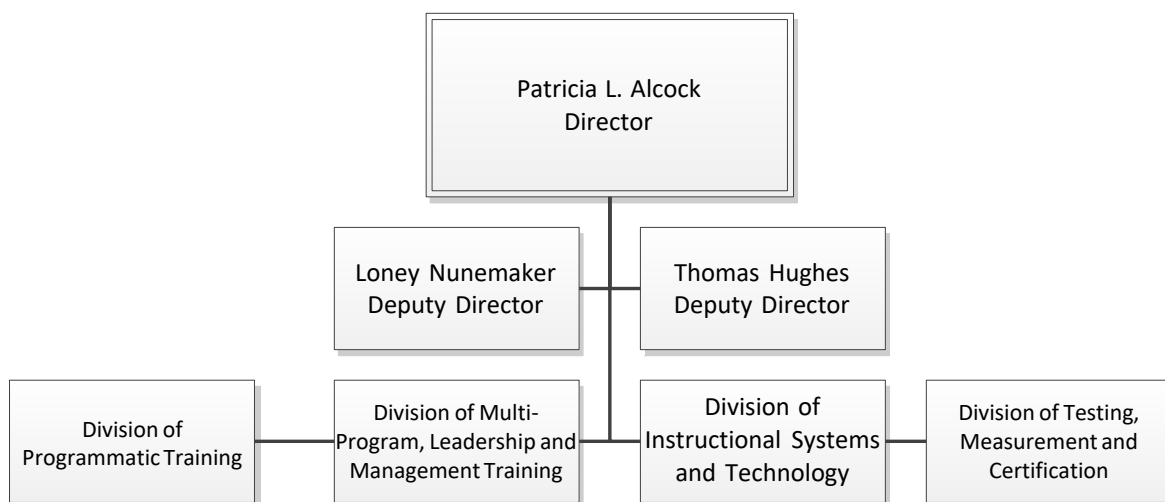
OTED provides education, development, and personnel certification programs for employees of the Office of Regulatory Affairs (ORA) in support of the FDA and ORA mission. OTED maintains ORA and related State and local training data, approves ORA certification programs and associated standards for regulatory staff, and provides oversight of OTED's accreditation commitments.

OTED also develops the strategic training, education and development plan for ORA personnel and, where appropriate, state and local regulatory partners, in line with ORA's mission, program priorities and core values. Finally, under the leadership of the Office Director, OTED also provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other ORA senior leaders on ORA national training, education, development and personnel certification policies, programs, and procedures.

Office of Training Education and Development (OTED)

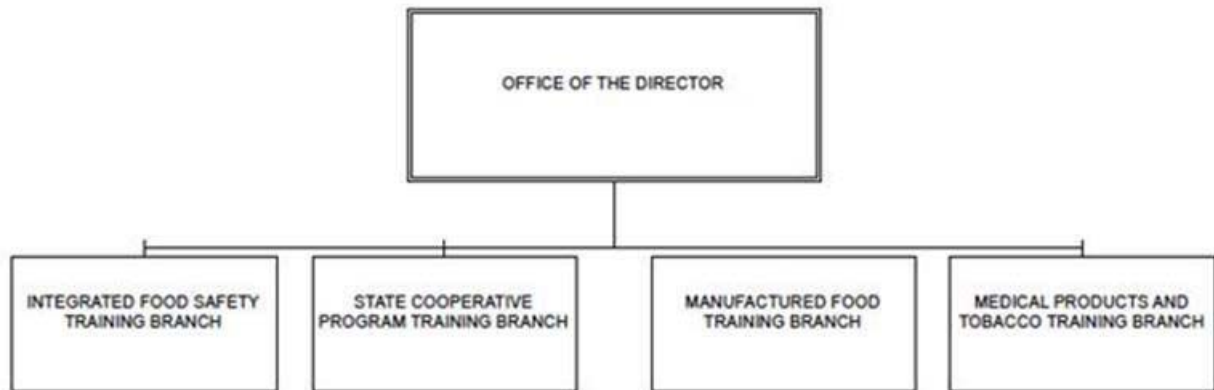
The Immediate Office provides oversight and guidance to OTED's four divisions: Division of Programmatic Training (DPT), Division of Multi-Program Leadership and Management Training (DMPLMP), Division of Instructional Systems and Technology (DIST), and the Division of Testing, Measurement and Certification (DTMC). The office structure is illustrated (below).

Office of Training Education and Development



DIVISION OF PROGRAMMATIC TRAINING (DPT)

DPT has four Branches – the Integrated Food Safety Branch, State Cooperative Program Training Branch, Manufactured Food Training Branch, and Medical Products and Tobacco Training Branch. The Division’s primary responsibility is designing, developing, and delivering training and educational programs for the Office of Regulatory Affairs (ORA) staff and other regulatory partners in the program areas of Human and Animal Food, Pharmaceutical Quality, Biologics, Bioresearch Monitoring, Medical Device and Radiological Health, and Tobacco.



DIVISION OF MULTI-PROGRAM, LEADERSHIP AND MANAGEMENT TRAINING (DMPLMP)

DMPLMT has two Branches – the Multi-Program Training Branch and the Leadership, Management and Administrative Training Branch. The Division’s primary responsibility is designing, developing, and delivering training and educational programs for Office of Regulatory Affairs (ORA) staff and other regulatory partners in the program areas of Compliance, Imports, Laboratory, ORA Information Technology (IT) Systems, Administration, Leadership, Management and Basic Investigator programs.

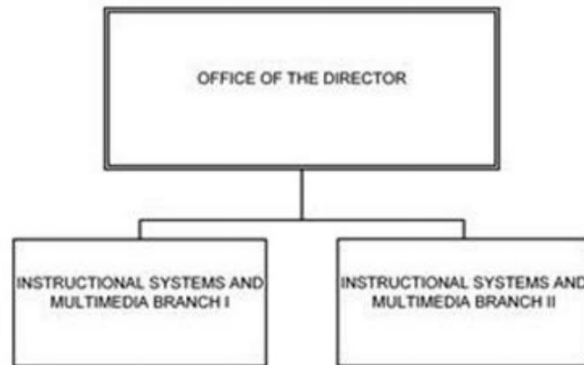
**OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT
DIVISION OF MULTI-PROGRAM, LEADERSHIP AND MANAGEMENT TRAINING**



DIVISION OF INSTRUCTIONAL SYSTEMS TECHNOLOGY (DIST)

DIST has two Branches – the Instructional Systems and Multi-Media Branch I and the Instructional Systems and Multi-Media Branch II. Both Branches function to guide the design and development of training following best practices in the training industry.

**OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT
DIVISION OF INSTRUCTIONAL SYSTEMS AND TECHNOLOGY**



DIVISION OF TESTING, MEASUREMENT AND CERTIFICATION (DTMC)

DTMC has two Branches – the Test and Measurement Branch and the Certification Branch. The Division directs planning, design, development, implementation and evaluation of assessment strategies and surveys; and establishes Office of Regulatory Affairs (ORA) certification programs which determine competency standards that qualify regulatory staff through fair and reliable assessment practices

**OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT
DIVISION OF TESTING, MEASUREMENT AND CERTIFICATION**



PROFESSIONAL DEVELOPMENT

PROFESSIONAL DEVELOPMENT COURSES, PROGRAMS AND RESOURCES

Your career growth and professional development is important to us! At OTED, we have developed numerous programs, courses and resources to help you begin this exciting journey including:

- Commodity specific education and training programs
- Personnel Certification
- Professional Development Resources
- Management and Supervisory Programs
- Mentoring Program and Resources
- Remote Manager and Employee Resources
- New Employee Resources
- Program Support and Developmental Resources
- Leadership Resources
- And many more!

COURSE CATALOG AND SCHEDULES

OTED's course catalog and class schedule are available through OTED's Learning Management System (LMS). The LMS is frequently referred to by the vendor name, Pathlore. The LMS, or Pathlore, can be accessed at this link: <https://orauportal.fda.gov/stc/ORA/>.

The course catalog describes all OTED courses, including online courses. The OTED Instructor led classes link provides additional information. Instructions for performing most user tasks are discussed in the Pathlore Job Aid available at this link: <https://orauportal.fda.gov/stc/ORA/PathloreUserJobAids.pdf>.

INDIVIDUAL DEVELOPMENT PLAN (IDP) (FOR FDA/ORA STUDENTS ONLY)

As you determine what opportunities will meet your needs or career requirements, OTED recommends that you begin your journey with creating your Individual Development Plan (IDP). An IDP is an optional tool that you can use to individually document, your career development. An IDP does the following:

What an IDP is...	What an IDP is not...
Serves as a career development tool	An appraisal or performance management instrument
Helps employees recognize how their work creates a roadmap for their career growth	A performance improvement plan
Attract and retain a high-performing workforce	Only to be completed annually
	A document which is set in stone

IDP BENEFITS

You are in charge of your career path! ORA is an exciting organization with many opportunities for growth and development. Below are some of the benefits as to why developing an IDP is critical to your success. This also helps OTED, along with our Training Needs Survey, to determine what training offerings to include each fiscal year that are most pertinent to you, the student. It is an excellent discussion to have with your supervisor during or prior to your PMAP.

WHAT'S IN IT FOR ME (WIIFM)?	
Confidently explore career development	Collaborative dialogue about a mutual career path (supervisor & employee)
Supervisors gain better understanding of employees' goals & development needs	Supervisors can align staff development with organizational goals and necessary competencies

IDP ROADMAP: 5 SIMPLE STEPS

- 1. Planning:** employee self-assessment (employee checklist of needs/goals/skills)
- 2. Employee/Supervisor Meeting:** discuss employee assessment (i.e.-strengths, areas for improvement, interests, goals, and organizational requirements-strengths assessment.)
- 3. Create IDP:** employee, in consultation with supervisor, completes the plan for individual development. (As a reminder, this is a fluid document, any changes or modifications can be made at any time with supervisory concurrence.)
- 4. Implement plan:** employee pursues training and development identified in plan
- 5. Evaluate outcomes:** supervisor/employee evaluate usefulness of training and development experiences

You can access the fillable form on OTED's website at:

<http://inside.fda.gov:9003/downloads/EmployeeResources/Training/OTEDCourses/UCM480297.pdf>

CERTIFICATION (FOR FDA/ORR STUDENTS ONLY)

When thinking about your IDP you should consider adding courses related to the (ORR) Investigator and Analyst Certification Programs. Rather than explicitly focusing on a training curriculum, OTED's certification programs have been developed to assess FDA's field investigators' and analysts' knowledge, skills and abilities needed to carry out their regulatory responsibilities consistently. Below is a list of current ORR Certification Programs:

- Level 1 Investigator
- Level 1 Analyst
- Level 2 Cooperative Programs (voluntary)
- Milk
- Retail
- Shellfish
- Bioresearch Monitoring
- Clinical BIMO Investigator
- Pharmaceutical Quality
- Drug Investigator
- Biological Products
- Blood Bank/Plasma Center Investigator
- Medical Devices and Radiological Health
- Medical Device Investigator
- Human and Animal Food
- LACF/AF Investigator
- Seafood Investigator
- Enforcement and Import
- Import Investigator

Details about how to be part of OTED's certification programs can be found at:

<http://inside.fda.gov:9003/EmployeeResources/Training/OTED/ucm608231.htm>

COURSE SCHEDULE, ANNOUNCEMENTS, AND CLASS REGISTRATION

COURSE SCHEDULE

OTED Course schedule is finalized and posted by September 30th for the upcoming fiscal year. The schedule can be found in our Learning Management System (LMS) - Pathlore and on our OTED Website under the Course Calendar.

COURSE ANNOUNCEMENTS

OTED training courses are formally announced to the ORA field staff through course announcements. Course announcements provide a description of the course and information regarding course dates, locations and target audience, points of contact, continuing education credits, prerequisites and logistics. In general, announcements are issued 8-12 weeks in advance of the course.

COURSE PREREQUISITES

All students must complete course prerequisites prior to registering for each course. Prerequisites are listed in the course catalogue and in the course announcement. Prospective ORA students, you should plan ahead by identifying prerequisites for specific courses you intend to take as early as possible and incorporate them into your IDP or similar individual training plans. Other prospective students should discuss the prerequisites with their management in order to have enough time to complete the prerequisites before they are due.

STUDENT NOMINATION (FOR FDA/OR A STUDENTS ONLY)

Using responses from the training needs survey, Program Training Officers (PTOs) work with OTED Training Officers and Program Management to allocate seats to each District. Districts nominate prospective students through the PTO. If you are nominated, please make sure you have met all course prerequisites.

REGISTRATION PROCESS

As a prospective student employed by the FDA, you can self-nominate for classes using the [ORA Pathlore Learning Management System \(Pathlore\)](#). All FDA ORA personnel automatically have an account in Pathlore. Designated Program Training Officers (PTOs) will provide the final approval for each student based on procedures defined by their Program Area. Students will receive additional logistical information (e.g., funding memos) from the OTED Training Officer prior to the course.

Other prospective students must work through their management to self-nominate for classes. This is done outside of Pathlore. The prospective student's management will work with their FDA contacts to submit registrations for courses. The OTED training officer will have those students registered in Pathlore.

TRANSCRIPTS

Please see the following links for information on how to access your personal training transcript from OTED:

- For web-based courses and learning requirements delivered through the **ComplianceWire learning portal**, please log into [ComplianceWire](#) and click "history."
- For courses and learning requirements delivered through the **HHS Learning Portal**, log into [HHS Learning Portal](#) and click "learning."

- For classroom courses and learning requirements delivered by **OTED**, [please log into the ORA Pathlore Learning Center and click on the 'Training Transcript' link.](#)

LOGISTICS

LOCATION

OTED is located in the FDA Washington DC metro area, at FDA Building Montrose Metro 2 (MM2) in Rockville, MD.

Our physical address is:
11919 Rockville Pike
Rockville, MD 20852
301-796-4550
FAX 301-827-8708



TRAVELING TO OTED

BY AIR

The Washington DC metro area is accessible by 3 airports:

- Ronald Reagan Washington National Airport (DCA)
- Baltimore Washington International Thurgood Marshall Airport (BWI)
- Washington Dulles International Airport (IAD)

BY PUBLIC TRANSIT

DC Metro: <http://www.wmata.com/rail/> will provide you with information on schedules, fares and maps and other transit information, including operation during inclement weather.

Directions from White Flint Metro Stop to the OTED facility:

Exit the RED Line at the White Flint Metro Station and turn right. Follow MD Route 355 North (Rockville Pike) 2 city blocks. The Montrose Metro 2 Building (MM2) will be located on your right at 11919 Rockville Pike. (The Pike and Rose Shopping Center is located across the Street, you will be able to see REI directly across the intersection from the Montrose Metro 2 Building.)

BY CAR/TAXI/SHUTTLES

Airport/local area shuttles and taxi services (need 24 hours' notice):

The following is a non-exclusive list of local shuttles and taxi services.

Disclaimer: Please note that this list is for your convenience only and does not represent an endorsement of any kind.

- Burki Limo 1-877-665-3292
- Super Shuttle 1-800-258-3826
- Barwood Taxi 301 984-1900

Rental Cars

Rental cars are **NOT authorized unless specifically stated on the course announcement.**

Parking at Montrose Metro 2 (MM2):

Local students and instructors are strongly encouraged to use the Metro, carpools, or other public transit systems since parking at the Montrose Metro 2 Building is limited.

Instructors, CAG (Course Advisory Group) members, and employees who carpool (two or more) to the Montrose Metro 2 Building may be granted permission to park in the ORA U building garage on a case-by-case basis pending availability and providing arrangements are made two weeks in advance with the OTED course Training Officer. Please also make sure to confirm arrangements prior to arrival and receive further instructions for parking.

Additional parking options for local students and instructors:

- White Flint Metro station and use the pay-to-park lot. Reference the following link for more information <https://www.wmata.com/fares/index.cfm>.
- Metrorail daily parking is available at the parking lot east of Rockville Pike on Marinelli Road.

LODGING

LODGING INFORMATION

Training Course Announcements have details about the lodging locations for training. All students should follow your agency procedures to schedule flights and complete your travel paperwork promptly. FDA students, when you are notified that you have been selected to attend a training course you will be issued a funding memo from OTED. The OTED funding memo will be sent approximately 30 days prior to the course via separate email. Upload OTED's funding memo under "Expenses & Receipts" tab in your travel authorization. The Training Officer will send a Travel Authorization Memo to ORA students and FDA instructors with the respective accounting codes.

ROOM BLOCK

All students should make their room reservations in advance of the room block deadline stated on the course announcement. When the hotel room block expires students may not be able to get a sleeping room at the selected hotel at the negotiated government per diem rate.

For FDA Students: When an OTED rooming block is used, you need to contact the hotel directly to make room reservations. Be sure to reference the rooming block specified in the course announcement and to request the prevailing government per-diem rate. There is no need to go through CGE for a rooming block. You must indicate in the "Document Detail" section of the Travel Authorization that there is a "Hotel Reservation made through a room block detailed within the OTED Course Announcement." Please make every effort to stay at the designated hotel with the negotiated room block. If, for any reason, you do not use the room block, you must go through CGE to book lodging.

Keep in mind that added lodging costs may be your ,your district office's or Agency's responsibility. Approval requests should be routed through the Program Training Officer to the OTED Training Officer for a case-by-case review by OTED management. Tardiness to our programs/courses due to staying at another hotel will not be tolerated, and any additional transportation costs to/from another hotel to the course location will be at your own expense or your Agency's responsibility.

HOTEL CANCELLATION

Check the specific hotel cancellation policies. You should make any cancellations no later than 72 hours prior to the intended arrival date to avoid cancellation charges. If you should need to cancel your

lodging reservation, request a cancellation number from the hotel for your records. Check your credit card statement to make sure you did not incur any cancellation charges.

FDA students, any additional lodging fees accrued as a result of missed deadlines for hotel reservations must be paid by your Division, unless your Division obtained prior approval from OTED.

LOCAL HOTEL INFORMATION (Rockville site only)

You should always follow the lodging information listed in the course announcement. However, in certain instances, you may need to make different lodging arrangements. The following is a non-exclusive list of local hotels.

Disclaimer: Please note that this list is for your convenience only and does not represent an endorsement of any kind.

Hotel	Address
<u>Bethesda Marriott</u>	5151 Pooks Hill Road Bethesda, MD 20814 301-897-9400 Nearest Metro: Navy Medical Center; 1.2 mi; Red Line ORAU: 2.9 mi from hotel Shuttle: Complimentary (only to metro)
<u>Double Tree Washington-Bethesda</u>	8120 Wisconsin Avenue Bethesda, MD 20814 301-652-2000 Nearest Metro: Bethesda & Navy Medical Center Station, 0.6 mi, Red Line ORAU: 4.5 mi from hotel Shuttle: Only to NIH
<u>SpringHill Suites</u>	9715 Washingtonian Blvd Gaithersburg, MD 20878 301-987-0900 Nearest Metro: Shady Grove; 4 mi; Red Line ORAU: 6.9 mi from hotel Shuttle: No shuttle service
<u>Hilton Washington DC/Rockville Hotel & Executive Meeting Center</u>	1750 Rockville Pike Rockville, MD 20852 301-468-1100 Nearest Metro: Twinbrook; 0.2 mi; Red Line ORAU: 0.8 mi from hotel Shuttle: Complimentary to ORAU
<u>Marriott Bethesda North Hotel & Conference Center</u>	5701 Marinelli Road North Bethesda, MD 20852 301-822-9200 Nearest Metro: White Flint Metro Station; .2 mi; Red Line ORAU: .5 mi from hotel Shuttle: N/A

Best Western Plus Rockville	1251 West Montgomery Avenue Rockville, MD 20850 301-424-4940
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INCLEMENT WEATHER INFORMATION

Because courses are held at various locations throughout the year, you may encounter different weather-related challenges at your training location. Please contact your Training Officer to inquire about the local inclement weather procedures. The following is the inclement weather procedure for Montrose Metro 2 (MM2).

RAIN

In spring/summer months the Rockville, MD area may experience intense rain storms. Remember to bring appropriate weather gear. In the event of an intense rain storm, taxi-sharing to and from the building can be vouchered. You are still expected to arrive on time for class.

SNOW

The Rockville, MD area experiences cold, snowy winters. If you are traveling to the Montrose Metro 2 location from warmer climates you may want to bring a warm coat or dress in layers. In the event of snow, please monitor the OPM website for opening status in the Washington DC Metro area at: <https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/current-status/>

WHAT SHOULD YOU DO IF THE FEDERAL GOVERNMENT (OPM) ANNOUNCES AN "UNSCHEDULED LEAVE POLICY" DUE TO ADVERSE WEATHER CONDITIONS?

Generally, OTED follows the Washington DC Metro area dismissal and closure procedures. Based on the local circumstances and the specific training requirements, Training Officers will determine how to proceed to ensure that your course attendance requirements are fulfilled. Please remember to notify your supervisor(s) of your situation.

**** PLEASE NOTE:** – FDA students, taking leave in travel status affects your travel voucher. You will need to request leave from your supervisor and you will **not** receive per Diem for that day.

WHAT IF THE FEDERAL GOVERNMENT HAS A DELAYED OPENING?

The course will be delayed/begin as scheduled, depending on the local situation. Arrive as soon as possible and be prepared to plan to cover any materials you have missed. Contact the Training Officer of your course for additional guidance. Training Officers will advise students about how the remainder of the course will proceed and what will be required to make up any missed materials.

DOES OPM GUIDANCE STILL APPLY IF THE COURSE TAKES PLACE OUTSIDE OF THE ROCKVILLE TRAINING SITE (AT YOUR HOTEL)?

If the training takes place at the hotel you have a block room reservation, you are expected to be in class on time. For all other situations, consult your Training Officer.

THE FEDERAL GOVERNMENT IS CLOSED?

Class will be cancelled that day. OTED Management will decide on a case by case basis whether to hold the course over another day or condense training time. Contact the Training Officer of your course for additional guidance.

SAFETY

FIRE SAFETY

You should locate the closest exits when entering any building structure and familiarize yourself with the appropriate evacuation routes. Do not try to fight a fire. If a fire alarm sounds, you should evacuate immediately.

AUTOMATED EXTERNAL DEFIBRILLATORS (AEDS)

AEDs are typically located near elevators and restrooms. When you open the AED cabinet door, a local alarm will sound.

EMERGENCY

As a general rule, in case of emergency follow the instructions from your Training Officer and/or emergency personnel. To contact Police, Fire Department or Rescue Squad from OTED press 9 + 911 from in house phones. If you are not at the MM2 building dial 911 from your cell phone and be sure to provide your exact location. Report all emergencies to your OTED Training Officer.

USE OF BUSINESS OFFICE/EQUIPMENT

OTED does have several Information Technology (IT) systems and resources available, including copiers are provided for official government use only. These systems include but are not limited to desktop and laptop computers, portable electronic devices (PED), applications, network services and telephone systems. Using the OTED systems and resources does not give any right to, or expectation of privacy while using these resources, including Internet and email services.

You must adhere to standards of behavior that are expected of any government employee while using these IT systems or resources. Use of the OTED systems to generate, access, transmit, or store information of a criminal, offensive, or sexually explicit nature is prohibited. All information on the OTED IT systems or resources is subject to monitoring and may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes. Your use of the OTED systems and resources express consent to such monitoring, recording, and auditing. Violations will be reported to the appropriate agency point of contact. Accidental violations such as access to internet sites that contain offensive materials must be immediately reported to the Training Officer.

GENERAL OTED COURSE INFORMATION

IACET

OTED is an authorized provider of continuing education credits or CEUs by the International Association of Continuing Education and Training (IACET). As an accredited education and training institution, OTED learning events are required to follow strict standards of development and delivery that require OTED to establish and publish training requirements including training course prerequisites, participation, assessment, completion, and evaluation.

COURSE COMPLETION REQUIREMENTS FOR ALL STUDENTS

OTED course completion requirements for all students include completing any course pre-work, attending the entire course, participating in the course discussions, exercises, and presentation, and passing the course assessments. Please contact the Training Officer for the course for additional questions about course prerequisites and completion requirements.

COURSE ATTENDANCE

All students are required to attend all scheduled classes and training sessions per OTED policy and IACET CEU requirements. If you will miss a portion of a course, you may not be permitted to continue to participate and should attend another session. Any student who is habitually late for class without a compelling reason may be asked to leave the course.

FDA & ORA students, you will not be granted annual leave while attending training, unless extenuating circumstances apply. If unforeseen circumstances arise, a leave request must be coordinated through both the Training Officer and your supervisor. Unavoidable delays in travel or for emergency situations (e.g., death in the family, illness, hospitalization, court appearance, etc.) will be reviewed and decided upon on a case by case basis.

FDA & ORA students, sick leave may be authorized when you are absent from class for incapacitation due to an illness or injury. Sick leave is coordinated through the Training Officer and your Supervisor. You will also be required to use leave when you are more than 15 minutes late or away from the classroom for more than 15 minutes.

Note: The Training Officer will make every effort to find a student if he/she is more than 30 minutes late and has not contacted the Training Officer. If the Training Officer cannot find the student, the Training Officer will contact OTED management, the individual's supervisor and/or emergency contacts.

CODE OF CONDUCT

STANDARDS OF CONDUCT

All FDA and ORA staff are expected to comply with HHS Standards of Conduct while at the OTED Training Facility at MM2 or attending any of our courses linked here:

<https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm071768.htm>.

You are expected to conduct yourself in a manner befitting a government employee. Executive Order 11222 (18 U.S.C. 201) states the basic philosophy of conduct for those who carry out the public business: "Where government is based on the consent of the governed, every citizen is entitled to have complete

confidence in the integrity of his government. Each individual officer, employee or advisor of government must help earn and must honor that trust by his own integrity and conduct in all official actions.”

You are expected to adhere to these principles and to standards of behavior that will reflect credit upon the Government. Additionally, you are reminded that the Office of Personnel Management regulations state that Federal employees shall not engage in criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct, or other conduct prejudicial to the Government. Included in the Government Code of Conduct is a statement regarding the responsibility to protect and conserve all Federal property.

You must be constantly aware that your behavior both at the training event and in the local community is reflective not only of yourself, but also of the Federal Government and the FDA. Model conduct is particularly important in hotels and training facilities, where the rights of others to an environment conducive to work, study and rest are paramount. Misconduct on or off the training site, at any time, is grounds for disciplinary action, to include dismissal from training.

OTED’s TRAINING ETHICS GUIDLINES

FDA employees, contractors and partners are expected to exhibit the highest levels of personal conduct and integrity in training. OTED requires that all individual work assignments submitted by any student be the sole product of the student. For group activities, everyone in the group is required to participate and contribute to the work. With that in mind, the following are considered to be violations of the OTED Training Ethics Guidelines as it applies to individual assignments:

- Copying from another student’s work
- Soliciting, giving, and/or receiving unauthorized aid
- Duplicating or replicating of any part of a graded examination or exercise
- Exchanging and/or transmitting examination questions/materials or study aides from one class to another
- Use of or possession of duplicated or replicated examination questions/materials
- Using unauthorized aids

Violation of the OTED Ethics Policy may result in dismissal from training. If you have any ethics concerns related to an OTED class, please contact the Training Officer.

CLASSROOM CONDUCT

To maximize the learning experience for you and your class mates, you should actively participate in the creation of an environment conducive to learning. Get plenty of sleep so you are alert and able to participate in all activities. Focus on learning and avoid distractions, such as viewing non-training (e.g. newspapers, magazines) related material during class time. Sleeping, eating and the use of tobacco products are strictly prohibited during class.

USE OF ELECTRONIC DEVICES DURING TRAINING

Make sure your business and personal phone are always set on silent during class time. Similarly, the use of text messaging and/or use personally owned electronic devices is only allowed during breaks. Do not answer business emails and make every effort to schedule business calls outside of class time. If you are unable to reschedule an important phone call, please notify the Training Officer prior to the classroom lecture. Then quietly exit the classroom so other students are not disturbed. You can use unoccupied breakout rooms available or go outside to make phone calls.

Once a lecture begins and/or resumes, all electronic devices must be completely turned off and stored out of view, unless being used for academic purpose, such as viewing course material, completing activities and taking notes. Do not use earbuds in class unless you are attending virtually.

These recommendations are meant to help enable students to get the most from their training experience and show respect to instructors and fellow peers.

FOOD AND BEVERAGES

Non-alcoholic drinks may be permitted in the classroom, provided the beverage containers have a lid. Certain training locations, such as computers labs, may prohibit beverages. Generally, food is not allowed in the training facilities.

FRATERNIZATION

The students and staff have the right to expect that training, education, development and certification decisions and evaluations are based upon proficiency, impartiality and professionalism. Such an environment encourages mutual professional respect, as the fundamental basis for student and staff relationships at OTED and contributes to the continued effective performance of the duties and responsibilities.

Fraternization and other inappropriate student/staff relationships violate the high standards needed to maintain the effective performance of duties and maintenance of public trust. The definition of “staff” is interpreted broadly; to include OTED Training Officers, CAG members, instructors, OTED support personnel, FDA staff and contract personnel who have direct contact with students. It does not matter that the instructor or staff member is not assigned to your class or program care and consideration must be given to rule out the perception of impartiality.

ATTIRE

BUSINESS CASUAL

Your personal appearance should always reflect a positive image upon the FDA. Therefore, you should observe high standards of appearance at all times, including during training courses. In general, business casual attire can be worn during training courses. Examples of business casual dress include sport coats, cotton trousers, slacks, polo shirts, button down shirts without a tie, sweaters, loafers, dresses, blouses, dress heels, boots, and flats.

Casual attire such as tank tops, cut-off shorts, swimsuits, athletic gear, ball caps, flip flops and clothing with profane, obscene or offensive statements or scenes should not be worn to training courses.

UNIFORMS

Commissioned Corps Officers are required to be in uniform while attending training. If the course has a component taking place outside the classroom (e.g., plant tour) uniform instructions will be provided as part of the course announcement.

If you are unsure which uniform to wear, Commissioned Officers may contact ORA Commissioned Corps Affairs, at oracc@fda.hhs.gov prior to attending the course.

DISPLAY OF IDENTIFICATION (ID) BADGES

You are required to prominently display your FDA badge or visitor badge, above the waist, at all times while attending training in a FDA facility.

STUDENTS RIGHTS

EQUAL EMPLOYMENT OPPORTUNITY (EEO)

OTED has a zero-tolerance policy regarding EEO discrimination. The EEO Program encompasses the special emphasis programs as well as the discrimination complaint process. This program was established to ensure the equitable treatment of all individuals in employment, promotion, training, and other personnel management actions without regard to their race, color, religion, sex, age, national origin, retaliation, disability, or genetics. This includes sexual harassment. You are also protected against discrimination based on your sexual orientation.

If you are the victim of harassment, or if you observe harassment at an OTED training, you should notify your Training Officer immediately. FDA policy states to contact the EEO office within 45 calendar days of the alleged matter. You may also contact the Office of Inspector General directly.

REASONABLE ACCOMMODATION PROCESS

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.

UNACCEPTABLE BEHAVIOR

OTED is committed to Occupational Safety and Health. To ensure a safe work environment, you are encouraged to:

- Take responsibility for following all safety procedures
- Stay aware of your environment
- Recognize dangerous or unsafe conditions
- Report possible hazards immediately to your class instructor or training officer

WEAPONS

Unless required by your position, you are prohibited from bringing weapons, personal or government-issued, into the facility.

USE OF TOBACCO

OTED as part of FDA and HHS is a tobacco-free environment. Use of cigarettes, vaping, e-cigarettes and smokeless tobacco is not permitted within 50 feet of OTED owned and rented facilities.

ALCOHOLIC BEVERAGES

Alcohol use is not permitted during OTED training. During non-training hours, your use of alcohol becomes a personal choice, but that choice cannot, in any way, interfere with your training or place

others at risk. Irresponsible alcohol use will result in disciplinary action and possibly removal from the training program. Be responsible with your alcohol consumption and always use a designated driver.

DRUG-FREE ENVIRONMENT

OTED is a Drug-Free Federal Workplace per Executive Order 12564, establishing that Federal employees refrain from using illegal drugs on or off-duty.

USE OF GOVERNMENT VEHICLES

As provided by law, the use of OTED government vehicles are restricted to official purposes only. Federally owned or rented vehicles should be operated by federal personnel only. You must have a valid driver's license to operate an OTED government vehicle; you are responsible for its proper use and protection. Any accidents, regardless of cause and severity, must be reported to your Training Officer. The use of tobacco products (including smokeless and vapor) is strictly prohibited in government vehicles. Unless specifically authorized by an instructor, food and drink are also prohibited in OTED government vehicles. Students using the OTED vehicles must have the statement required on their approved travel orders and have attended the required GSA training.

A Last Few Words of Advice for Students

Here is some advice for you from former students and best practices we have from the adult learning community:

- You get out of training what you put into it, be ready to actively participate and make the most of this opportunity.
- Take advantage of meeting all the new people at this training course. Network, network, network – it is a great way to make friends and working relationships that will last your entire career.
- Suspend judgment – a negative tone can feed on itself and ruin the experience for you and others.
- Bring your best practices and share them with fellow students. We can all learn from each other.
- ASK QUESTIONS – you may not have the opportunity again. Our instructors and SMEs are here to help you.

Thank You!

Thanks so much for your interest and participation in our courses. We value your feedback on this handbook and our programs. OTED strives to continue to provide quality training to our stakeholders and we look forward to meeting all of you.