

ULTIMATE MEDICAL ACADEMY Standard Operating Procedure SOP-ED-149 Development Date: 9/20/2017 Effective: 9/20/2017 Revised: X/X/XX	Applies to: <ul style="list-style-type: none"> • Clearwater
DENTAL LABORATORY RADIATION SAFETY	

Policy

DAEF program laboratory at Ultimate Medical Academy meets applicable requirements of the US Environmental Protection Agency (EPA), Florida Administrative Code (FAC) Rule 62-730 and related Occupational Safety and Health Administration (OSHA) regulations. This policy describes steps of hazardous chemical waste, while Biomedical Exposure Control Plan (SOP-GEN-177) outlines management of the regulated medical waste.

Purpose

UMA has established a radiation safety program to ensure that work with radioactive materials and radiation machines is conducted in a manner that protects health and minimizes danger to life, property and the environment

Scope

The state's radiation control regulations are found in Chapter 64E-5, Florida Administrative Code (FAC). The State of Florida Department of Health (FDOH) is granted regulatory authority by the U.S. Nuclear Regulatory Commission to oversee the acquisition and use of radioactive materials and radiation producing machines within the state. The Ultimate Medical Academy radiation machines are registered with the Bureau of Radiation Control (BRC) Radiation Machine Program in Jacksonville.

UMA also complies with U.S. Department of Transportation (DOT) regulations governing the shipment of hazardous materials, including radioactive materials, which are found in Title 49, Code of Federal Regulations (49 CFR).

Definitions

Radiation includes alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but such term does not include sound or radio waves, or visible light, or infrared or ultraviolet light.

Personal Protective Equipment (PPE) is equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses.

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Restricted area means any area access to which is controlled by the laboratory management for purposes of protection of individuals from exposure to radiation or radioactive materials.

Dose means the quantity of ionizing radiation absorbed, per unit of mass, by the body or by any portion of the body.

Dosimeter is a personnel monitoring equipment or devices designed to be worn or carried by an individual entering radiography area for the purpose of measuring the dose received.

ALARA Principle is “As Low As Reasonably Achievable” principle compels the dental community to expose patients to as little radiation as possible to achieve the desired diagnosis and treatment

Responsibility

Each department is listed in this section. Place “YES” under “Procedures” for each department that has a role. If a department has no role, “N/A” is placed under “Procedures” for that department.

DEPARTMENT	PROCEDURES
Accreditation	YES
Admissions Department	N/A
Career Services (All Placement and Externship)	N/A
Compliance	YES
Education	YES
Finance	N/A
General—institution-wide policy	YES
Human Resources	N/A
Information Technology	N/A
Learner Services	N/A
Marketing	N/A
Registrar	N/A
Student Finance	N/A

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Procedures

Radiology Laboratory Registration and Licensing Requirements

Radiation-producing machines must be registered with the Florida Department of Health (FDOH) Bureau of Radiation Control (BRC) within 30 days of acquisition, using Form DH-1107.

Within 15 days of assembly/installation of an X-ray machine, a Form DH-1114 (Report of Assembly of Non-Certified X-ray Systems) must be submitted. The form must be signed by a registered radiation machine vendor, certifying that all components were installed in accordance with state requirements and were adjusted and tested per the manufacturer instructions. The BRC must be notified within 15 days of the sale, lease, transfer, relocation, loan, assembly, installation or disposal of an X-ray machine or major component, using DOH Form DH-1114. If the system contains certified components, FDA Form 2579 must be used. The BRC must be notified in writing within 30 days any changes to the information in the Certificate of Registration. Reports are required for a change of address, or receipt, sale, transfer and/or disposal of a machine or major components. Registration is administered by UMA Facilities in collaboration with the DAEF Program Director and Laboratory Compliance/AHA Specialist.

DAEF Program Laboratory at UMA is licensed by the Florida Department of Health licensing requirements in Part II of Chapter 64E-5, FAC. Licensing is managed by the UMA Accreditation and Licensing department in collaboration with the DAEF Program Director and Laboratory Compliance/AHA Specialist.

Roles and Responsibilities in DAEF Laboratory

DAEF Program Director ensures compliance of all terms and conditions of the license, registration and regulations of radiography equipment and procedures; ensures that all personnel are properly trained, read and understand UMA radiation safety, operating and emergency procedures; provides regular guidance on ways to minimize radiation exposures; ensures that radioactive materials and radiation producing machines are used only by personnel authorized by the license/registration, and that they wear dosimetry and other personal protective equipment as required; ensure that radioactive materials and radiation machines are properly secured against unauthorized access or removal; ensure that the sealed sources are leak tested at required intervals and as prescribed by the manufacturer or the license; ensures that radiation survey instruments are calibrated by a licensed and qualified vendor at least annually and following service/repair; conduct annual reviews of the

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radiation safety program's content and implementation; maintain all required records, including those pertaining to training, personnel monitoring, inventories, leak tests, and radioactive material receipt/transfer/disposal.

Laboratory Compliance/AHA Specialist administratively supports DAEF Program Director with following: assists DAEF Program Director with updates to policy for the radiation safety program; conducts periodic or discretionary reviews or evaluations of the radiation safety program; recommends special conditions, as may be necessary, such as additional training and/or instructions, designated or limited areas of use, disposal methods, etc.; review occupational radiation safety exposures and incidences to propose to DAEF Program Director cause and corrective action; review all reports/ maintenance logs for accuracy and timely completion by DAEF Program Director, DAEF Faculty and qualified DAEF Laboratory Assistants.

DAEF Faculty is permitted to use radioactive material, operate radiation generating equipment and conduct student education activities if they meet the requirements for training/licensure in accordance with Rule Chapter 64B5-16.005(2)(i) Florida Administrative Code (F.A.C.) requirements.

DAEF Students may work radiography machine under direct supervision of the UMA DAEF qualified faculty. Direct supervision means that the faculty must work closely with the individual, physically demonstrate the procedures, and give instruction on the hazards of the experiment. The supervisor should be physically present during radiography operation. The DAEF student should make trial runs, when necessary, using non-radioactive materials until he/she can safely conduct or assist in conducting the radioactive experiments.

Maintenance personnel who are required to work in labs where possible radiation hazards exist must be informed of the hazards and be supervised when necessary. Laboratory Compliance/AHA Specialist and DAEF Program Director should be notified by the Facilities before the maintenance work begins, so that proper oversight and safety measures are provided as necessary. The following are examples of projects that should be reported before work is begun:

- Work on drains or sinks that have been used for disposal of radioactive materials.
- Work on lab equipment that is likely to be contaminated with radioactive material.

Janitorial personnel must be advised of any radiation hazards present and as to the meaning of warning signs and labels. Laboratory Compliance/AHA Specialist provides such instructions on an as-needed basis and during annual training for all personnel entering DAEF laboratory.

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ALARA Principle

Section 64E-5.303, FAC requires use (to the extent practical) of procedures and engineering controls based on sound radiation protection principles to achieve occupational and public doses that are as low as reasonably achievable (ALARA).

Authorized users and radiation workers at UMA are instructed to apply ALARA principles and good work practices to minimize their radiation exposures, and to strictly adhere to UMA radiation safety policies and procedures in order to keep their exposures as low as practical.

DAEF Program Director annually reviews all reasonable modifications to be made to procedures, equipment and facilities to reduce exposures.

Radiation Safety Training Program

Handling and use of radioactive material and ionizing radiation-producing equipment at Ultimate Medical Academy DAEF program laboratory is restricted to trained personnel. The UMA’s radiation safety training program has two components: initial and refresher training. Initial training covers the two training requirements specified in Florida radiation control regulations: radiation awareness training (instructions to maintenance, janitorial, faculty, other staff and students in DA1140 DAEF course) described in section 64E-5.902, Florida Administrative Code (FAC) and authorized user training for students as a part of curriculum described in section 64E-5.1307, FAC.

Radiation Awareness Training conducted annually covers information on the storage, transfer, and use of radiation sources; principles and fundamentals of radiation protection and safety practices, including ALARA principles; precautions and procedures for minimizing radiation exposures; biological effects of radiation exposure, including internal and external radiation hazards; radiation detection, measurement and monitoring techniques; applicable provisions of Florida radiation control regulations and the UMA radioactive materials license, machine registration and radiation safety program; personnel monitoring, occupational and public dose limits, and occupational radiation exposure reporting requirements; laboratory policies and procedures, including workers’ responsibility to report any unsafe conditions in the workplace; requirements for shipping and receipt of radioactive materials; radioactive waste processing and disposal; procedures for responding to radiological incidents and emergencies.

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Authorized User Training in the DAEF course DA1140 Radiology and OSHA in addition to radiation awareness training module, requires review of radiation device manual, supervised hands-on instruction on the instrument's use prior to being allowed to operate it independently.

Radiography Signs

A restricted area is defined as any UMA laboratory space where radioactive materials are used or stored. Laboratory doors posted with a "Caution – Radioactive Material(s)" sign signify a restricted area. Only trained and approved workers are permitted to work in restricted areas. DAEF program lab must be posted with:

- DAEF Laboratory License
- UMA Radiation Safety Rules & Emergency Posting
- FDOH BRC "Notice to Employees" form, Information Notice 7 and 17
- Chart with a Specific Procedure used in Laboratory in accordance with FDOH BRC Notice 21

Personnel Monitoring Requirements (PM)

Dosimeter badges are required for personal monitoring (PM). Personnel monitoring (PM) badges provide a legal record of a person's occupational external radiation exposures. A PM badge is assigned to an individual using or assisting in the use of radiation sources in accordance with requirements specified in 64E-5.315 and 64E- 5.1310, FAC.

Instructions for proper use of PM badges are as follows:

- PM badges are individually assigned and cannot be shared. If a replacement badge is used, it must be marked with the name, initials and/or identification number of the individual designated to wear it.
- PM badges should only be worn on site and in restricted areas.
- Badges are to be protected at all times from moisture, chemicals, intense heat or light. A badge is not to be left in close proximity to a source of radiation. When not in use, badges are to be stored by DA1140 course instructor of record.

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- A spare badge may be assigned to a new employee until the badge vendor issues a badge bearing the worker's name for the next monitoring period. Such badges must be imprinted with the worker's name or initials. The dose recorded by the badge will be added to their occupational dose record.
- Students are responsible for turning in their badges to the DA1140 course instructor of record at the end of the monitoring period to ensure rapid processing.
- The DA1140 course instructor of record must notify immediately the Laboratory Compliance/AHA Specialist if a PM badge is lost or damaged. In such cases, an estimate of the worker's dose for the period covered by the badge must be provided to the badge vendor and kept on file. If a replacement badge is used for the remainder of the monitoring period, the dose recorded on the badge must be added to the estimated dose to obtain the worker's total occupational dose for the monitoring period.
- Monitored students may request a report of the occupational dose history at any time. UMA issues an annual dose report to all badged students. In addition, a report may be issued upon student's request.
- The DAEF Program Director reviews dosimetry reports within 30 days of receipt to determine if unnecessary exposures are being received. She will sign or initial, and date each report and will investigate within 30 days the cause of any exposure considered to be excessive. If warranted, the DAEF Program Director will take corrective actions to prevent recurrence. A report of each investigation and the actions taken, if any, will be documented and maintained for inspection purposes.

Female students and declared pregnancies

Prior to working with ionizing radiation, female students/faculty are provided instructions concerning the potential risks involved for pregnant women exposed to radiation and a copy of U.S. NRC Regulatory Guide 8. Students/faculty that have declared themselves pregnant will be instructed to wear their assigned PM badge at waist level to estimate the embryo/fetus dose. Such workers will sign a Declaration of Pregnancy Form that includes the estimated date of conception, and documents receipt of instructions on monitoring requirements during pregnancies. The objective is to keep the fetal dose as low as possible, not to exceed 500 mrem from occupational radiation exposures during the pregnancy, and to follow the FDOH BRC recommendation that an embryo/fetus not receive more than 50 mrem in any one month. In the event of a declared pregnancy, the badge vendor will be notified to order a fetal badge and request the fetal monitoring reporting option to track exposure of the declared pregnant student/faculty and the embryo/fetus. This reporting option shows the dose to the

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mother's badge and the fetal badge; each month a summary report shows estimated dose from conception to declaration, rolling exposure history by month for both mother and child, and accumulated fetal totals for the gestation period. Pregnancy monitoring records will be retained with the dose records of the mother.

Storage and Labeling of Radioisotopes

All items that store, use, or are contaminated must be labeled with a radioactive warning label. Use "Radioactive" tape for items that are contaminated. All radioactive material and waste containers must be properly labeled to identify the radioisotopes and estimated activity being stored. UMA uses labels or tape that bears the radiation symbol and states "Caution – Radioactive Material(s)". The Laboratory Compliance/AHA Specialist and DAEF Program Director must be notified by faculty and/or authorized staff when potentially contaminated equipment is moved to a new location, disposed of, or otherwise withdrawn from use.

Contamination Control

Ultimate Medical Academy follows basic principles which can be applied to the control of radioactive contamination:

1. Minimize the amount of activity being handled.
2. Make sure there is appropriate containment of radioactive material.
3. Follow the correct procedures regarding protective clothing, washing, monitoring and decontamination.
4. Maintain the laboratory area in a clean and neat fashion in order to reduce the potential for cross-contamination.

Radiography waste management is further addressed in the UMA Dental Laboratory Waste Management Policy

End of Procedure

Procedures are maintained by the Campus Directors (ground) and Business Unit Owners (online) and reviewed with department managers to ensure proper implementation. Departmental managers are responsible for implementing and monitoring the procedures that pertain to their department and are responsible for training their staff.