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27710

Occupational and Environmental Safety Office **BOX 3155**
RADIATION SAFETY DIVISION **TELEPHONE (919) 668-3156**
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Operating and Safety Procedures for

Revision 9/12/2013

Manufacturer: Kratos Analytic Type: Analytical X-ray Photo Spectroscopy Model: Axis Ultra Serial Number: C332438/01 Room 1537	Manufacturer: PANalytical Inc. Type: Analytical X-ray Diffraction Model: PX 3040 PR Serial Number: DY-1669 0233 Room 1537
Manufacturer: Nikon Metrology Type: MicroCT Scanning Model: XT H 225 ST CT Serial Number: JN 2423 Contact: Jimmy Thostenson, room 1545	Manufacturer: Anton PAAR USA Inc Type: Small Angle X-Ray Scattering (SAXS1) Model: SAXSess mc2 Serial Number: 81274529 Identifier: SAXS1 Contact: Michelle Gignac, room 1567
Manufacturer: SAXSLAB ApS Type: Small Angle X-Ray Scattering (SAXS2) Model: GANESHA Serial Number: G09-13-44 Identifier: SAXS2 Contact: Jimmy Thostenson, room 1567	

X-ray Authorized User: Mark D. Walters
Shared Materials Instrumentation Facility (SMIF)
Bldg CIEMAS (engineering west),

I. Introduction

This document is a set of operating and safety procedures unique to each registrant's equipment and facility and is required by the North Carolina Regulations for Protection Against Radiation (NCRFPAR)

Section .0600	X-ray in the Healing Arts
Section .0800	Requirements for Analytical X-ray Equipment
Section .1000	Notices, Instructions, Reports and Inspections
Section .1603	Radiation Protection Programs

These procedures must be posted at a location where employees may view them on their way to and from any particular work location to which the document applies. They may be posted by reference with a notice indicating where they are kept. {Rule .1002(a) & (b)}

II. Responsibilities

A. X-ray Authorized User's (XAU) responsibilities

Each XAU will be responsible for:

1. All operations carried out with the equipment;

2. Providing the Radiation Safety Division with a completed X-ray application form. The Radiation Safety Division will review each proposed installation and operating procedures. Approval from the Radiation Safety Officer must be secured before the X-ray equipment is operated;

3. The safe use of radiation producing machines under his/her permit;

4. Ensuring that all personnel under their supervision receive general training from the Radiation Safety Division in the safe use of X-ray equipment either through direct training or via online course(s);

5. Compliance with the specific recommendations made by the Radiation Safety Division, and also the general equipment and safety requirements;

6. Ensuring that only approved staff will operate the X-ray equipment;

7. Providing specific hands-on training to the approved operators for each X-ray unit and maintaining records of the training;

8. Ensure all operators maintain Radiation Safety online and operational training.

B. Approved Operator's responsibilities

Each Approved Operator of the X-ray equipment will be responsible for:

1. Wearing the assigned personnel monitoring badge(s) as required.

2. Notifying the Radiation Safety Division when:

    a. It is necessary to alter safety devices, such as bypassing interlocks. The exception would be generic bypassing for test purposes that has received prior written authorization by the Radiation Safety Division;
    b. It is known or suspected that a radiation exposure of personnel may have occurred;
    c. An existing unit is moved or beam path is altered;
    d. There are changes in operating parameters such as kV and mA beyond that which were previously approved by the Radiation Safety Division;
    e. There are changes in the approved shielding arrangement;
    f. There is any major service performed on the X-ray unit.
    g. Changes in status of x-ray unit. For example: x-ray unit status changes from active to inactive, inactive to stored, changes in authorization, and changes in location of x-ray unit.

C. Duke University Radiation Safety Office

The Duke University Radiation Safety Office is responsible for:

1. Approving XAU application for each X-ray unit;
2. Registering X-ray equipment with state of North Carolina;
3. Maintaining compliance with state regulations;
4. Conducting radiation surveys and record keeping audits;
5. Providing face-to-face and/ or online training;
6. Providing radiation monitoring (personal and/or environmental dosimetry), as required.

III. Training

A. Training and Qualifications of Personnel

1. The XAU is responsible for the safe use of radiation-producing machines under his/her approved authorization.

2. The XAU shall ensure that personnel authorized to operate radiation-producing machines are trained and qualified in their safe use and are cognizant of accepted radiation protection practices in controlling radiation exposures to themselves and others in the vicinity.

3. New personnel are required to receive training from the XAU prior to using radiation-producing machines and satisfy all other appropriate training requirements.

4. Approved operators are required to obtain annual refresher training in the lab- and equipment-specific SOPs and radiation safety.

B. Training Documentation

1. All radiation safety related training or education that employees receive shall be properly documented and maintained on file for review by Radiation Safety. Suggested training topics include:

   a. Radiation Safety online training for nonmedical x-ray equipment: http://www.safety.duke.edu/OnlineTraining/RS118/ and http://www.safety.duke.edu/OnlineTraining/RS115/
   b. Proper use of interlocks, safety features and operating controls
   c. Security requirements for operating controls/unoccupied rooms
   d. Radiation levels in the primary beam and scatter from objects
   e. Knowledge of and supervised experience with experimental protocols

2. Equipment-specific training should be conducted as needed and at least annually by the XAU or designee. Radiation Safety training should be conducted as needed via online training or by Radiation Safety personnel. New employees shall receive complete equipment, lab and radiation safety training prior to operation.

IV. General Equipment and Safety Requirements

These instructions are provided to you so that we can comply with the state rules for radiation control. The North Carolina Division of Radiation Protection, enforces the radiation rules in North Carolina. These rules require that our radiation machines meet specific requirements. The rules also require that certain procedures be followed and that certain records be kept. A copy of these rules is always available for you to read and review. It is entitled the North Carolina Radiation Protection Section and is located at Duke University OESO Radiation Safety Division, 2214 E Elder Street and on the following website: http://www.ncradiation.net/

The intent of this document is to establish procedures to minimize radiation exposure of personnel. You, as an operator, are required to know the procedures and requirements in this document and be able to demonstrate that you can use them properly. After reading this document and demonstrating that you can use the machines safely and correctly, you must sign and date the "Record for Instruction of Individuals in Operating and Safety Procedures" for the Dr. Mark D. Walters lab located at the end of the document (Appendix A). The operators are exempt from this signature in Appendix A provided Dr Walters supervises and maintains a list of operators and their training.

The rules also require that each facility be registered with the state. The Notification of this Registration is located at Duke University OESO Radiation Safety Division, 2214 E Elder Street, Durham, NC 27710. {Rule .1002}

All operators of X-ray machines are responsible for following the radiation safety procedures. Dr. Mark D. Walters has the responsibility and authority for overseeing matters relating to radiation protection. He also confirms all training and serves as the primary contact person with the Duke's Radiation Safety Division unless otherwise noted on the XAU approved application. Duke's Radiation Safety Division maintains the registration of X-ray generating equipment on campus with the North Carolina Department of Health and Human Services, who is responsible for regulating radiation safety. Employees should submit all radiation question or concerns about radiation safety to Dr. Mark D. Walters or Duke's Radiation Safety Officer (RSO), Dr. Terry Yoshizumi.

There shall be posting of the state's "Standards for Protection Against Radiation, Instruction and Reports to Workers, Notices and Inspections" located in areas where the X-ray unit operators and adjacent employees may read it. All areas where radiation may be emitted are to be posted as such, according to the NCRFRAP Section .1002. A "Notice to Employees" form can be obtained from the Radiation Safety Office.

The general requirements for radiation safety and your rights and obligations as a radiation worker are found in NCRFPAR Section .1600.

A. General

1. Do not operate this X-ray equipment without specific authorization from Dr. Mark D. Walters (X-Ray Photo Spectroscopy, X-Ray Diffraction) or Jimmy Thostenson (Micro CT Scanning, SAXS2 (Ganesha system) or Michelle Gignac (SAXS1 (Anton-Paar system))

2. The Fitzpatrick CIEMAS 1537 has been established as the location where the X-Ray Photo Spectroscopy and X-Ray Diffraction units will be operated. The Fitzpatrick CIEMAS 1545 has been established as the location where the MicroCT Scanning unit will be operated. The Fitzpatrick CIEMAS 1567 has been established as the location where the SAXS1 and SAXS2 units will be operated. The restricted area is designated by "Caution – Radiation Area when X-ray Energized" signs.

3. Only authorized personnel shall be in the vicinity when x-ray equipment is being operated.

4. Bypassing interlocks is strongly discouraged, but it is recognized that there may be times when bypassing interlocks is necessary for maintenance. Written approval from the Radiation Safety Office is required before bypassing the interlocks. Explicit steps must be taken to inform all Operators of the machine or device that the interlock is inoperable, and a sign with the individual's name, expiration date

and time of the bypass approval, and a description of the status of the interlock must be placed on the equipment and control panel.

5. Equipment whose primary purpose is the production of radiation should not be left operating unattended unless there are suitable indicators present to show that the equipment is switched on.

B. Open Beam Configuration – NOT Applicable

1. The useful direct beam shall be collimated to the area of interest.

2. Staff shall stand at least six (6) feet away from the useful beam and the irradiated subject during exposures, or other distances recommended by the Radiation Safety Office.

3. Align the beam and film cassette by _____(insert procedure).

4. Use the technique provided by _____ (XAU's name) at the control panel to adjust the X-ray machine technique factors (mAs, mA, time and kVp) according to sample size.

5. Always use a sturdy tripod or stand for holding portable X-ray units. The portable X-ray unit shall never be held by staff while unit is being operated.

6. Staff shall use mechanical holding devices if a sample must be held.

7. Open beam equipment should never be left unattended during operation without adequate safeguards.

C. Closed Beam Configuration – Kratos Analytical Axis Ultra (SN C332538/01) and Panalytical X'Pert Pro MRD (SN DY-1669 0233) and Nikon XT H 225 ST CT (SN JN 2423) and Anton-Paar SAXSess MC2 (SN 81274529) and SAXSLAB ApS GANESHA (SN G09-13-44)

1. The sample chamber closure will be interlocked by a fail-safe method. The X-ray tube high voltage supply or a shutter in the primary beam will operate so that no X-ray beam can be consciously and deliberately defeated and conspicuously posted. (See Section A 4.)

V. Protective Equipment

A. Shielding Protective Equipment (Lead Aprons, Lead Gloves, Protective Eyewear) – NOT Applicable

1. Lead aprons will be stored in _____ (indicate location). Radiation Safety Division maintains a lead apron annual inspection database.

2. Care should be taken in storing lead aprons and gloves carefully so as not to crack the shielding material inside.

3. Be sure to wear an apron and gloves that fit appropriately to provide complete coverage yet does not affect the efficiency of your work.

B. Lead Integrity Inventory and Inspection

All articles of shielding protection shall be visually inspected for damage no less frequently than once per year or whenever the integrity of the equipment is suspect. A record of this inspection should be kept on file and via on-line at the Radiation Safety Shielding PPE website: www.safety.duke.edu/RadSafety/aprons/default.asp.

VI. Personnel Monitoring – Not Applicable

1. If one is assigned, always wear a personnel monitoring badge when you are working with the X-ray unit.

2. Wear your individual monitoring device (dosimeter) outside the lead apron, between the waist and neck level.
3. The badge shall be worn only by the person to whom it is issued.

4. Dosimeters should be protected against damage from heat, moisture, and pressure.

5. Dosimeters must not be worn during non-occupational exposure, such as during medical or dental x-rays, nuclear medicine procedures, or brachytherapy procedures.

6. When not in use, personnel dosimeters should be stored in a low radiation area. The control badge shall be stored in a radiation-free area and returned with personnel badges for evaluation. The Radiation Safety Division is responsible for evaluating the exposure records and exchanging the badges on a routine basis.

If you suspect there has been an excessive exposure or a radiation incident, immediately notify Dr. Terry Yoshizumi, RSO at 668-3188. The RSO will then notify the NC Radiation Protection Section, if required.

VII. Facilities

All areas where x-ray units are located must be posted as follows:

1. Entrances to all rooms containing radiation producing machines must be posted with a sign bearing the words, *Caution-Radiation Area when X-Ray Energized* or similar wording.

2. A label bearing the words, *Caution Radiation, This Equipment Produces Radiation When Energized* or *Caution-High Intensity X-ray Beam* must be placed near the energizing switch.

Machines must be provided with a visual indicator located on or near the tube head which indicates when x-rays are being produced.

A. Shielding and Access Control

The utilization of shielding and access control will depend on the unit type.

Each x-ray tube housing shall be so constructed that when all shutters are closed the leakage radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour.

Interlocking devices and shutter mechanisms should not be bypassed and should be inspected at frequent intervals to insure proper operation.

VIII. Operation and Safety Procedures

A. Operating Procedures

The operating procedures and training checklist for the Kratos Axis Ultra X-Ray Spectroscopy system (XPS1) can be found on the SMIF web site at https://smif.lab.duke.edu/Description.asp?ID=2.

The operating procedures and training checklist for the Panalytical X'Pert Pro X-Ray Diffraction system (XDIF1) can be found on the SMIF web site at https://smif.lab.duke.edu/Description.asp?ID=1.

The operating procedures and training checklist for the Nikon MicroCT system (MICROCT1) can be found on the SMIF web site at https://smif.lab.duke.edu/Description.asp?ID=88.

The operating procedures and training checklist for the Anton-Paar SAXSess MC2 system (SAXS1) can be found on the SMIF web site at https://smif.lab.duke.edu/Description.asp?ID=91

The operating procedures and training checklist for the SAXSLAB ApS GANESHA system (SAXS2) can be found on the SMIF web site at https://smif.lab.duke.edu/Description.asp?ID=92

B. Emergency Procedures

The general emergency procedures that govern the SMIF facility are adequate for the labs (Rooms 1537, 1545, and 1567) where the X-Ray units are located. These emergency procedures can be found in the SMIF Lab Safety and Procedures manual found on the SMIF web site at https://smif.lab.duke.edu/pdf/SMIF_LabSafetyManual.pdf. Furthermore, all users of the SMIF facility, including users of the X-Ray units, must attend a "SMIF General Safety and Procedures" class before access to SMIF is granted and training is begun.

C. Quality Control (if applicable)

Performance checks of the XPS1 and XDIF1 systems are conducted monthly, and results are posted and maintained in notebooks located at the workstation of each system.

The procedure for the XPS1 monthly performance check is:

a. Load Silver standard sample
b. Sputter clean for 10 minutes using 5kV large spot settings and no raster
c. Optimize Z height using Ag 3d peak
d. Run Performance Scans
    i. Load PerformanceRun.dset flowchart (located in Data/Walters/Monthly_performance folder)
    ii. Change data filename to indicate today's date
    iii. Click submit to run
e. Use processing zone to process data
    i. Use display window to find peak positions and peak counts (not CPS) for O1s, C1s and Ag MNN
    ii. Load all Ag 3d plots into processing and choose Quantify
    iii. Enter Ag 3d region and set start = 371eV and end = 365 eV
    iv. Press "apply", go to History and press "Apply" again
    v. Read position, FWHM, and counts (not CPS) for each plot

The procedure for the XDIF1 monthly performance check is:

1. Load the Tungsten standard sample
2. Use the procedure for Phase Analysis measurements found on the SMIF web site at https://smif.lab.duke.edu/pdf/XDIF1%20Phase%20Analysis%20Rev8b.pdf
    i. Perform detector and sample alignments
    ii. Run the Monthly Performace program
3. Measure and record the three peak heights, FWHM, and counts

The procedure for the MICROCT, SAXS1 and SAXS2 monthly performance check is TBD

Appendix A

Record for Instruction of Individuals in Operative and Safety Procedures

In accordance with NCRFPAR, these procedures have been made available to each individual who operates the X-ray equipment. I certify that each of the individuals listed has demonstrated to me, on the date indicated, that he/she is competent in these operative and safety procedures and can operate the X-ray equipment in a safety manner. This was demonstrated by an evaluation of the operator's knowledge of the equipment and safety procedures by the RSO.

THIS DOCUMENT CAN NOT BE ACCEPTED WITHOUT SIGNATURES.

9/17/2013

_____ _____

Mark D. Walters, Ph.D., Director of SMIF Date

9/17/2013

_____ _____

Terry Yoshizumi, Ph.D., RSO Date

Each operator is required to receive training from Mark Walters, Jimmy Thostenson, or Michelle Gignac as applicable. Following successful completion of the training, the operator and Mark Walters, Jimmy Thostenson, or Michelle Gignac sign off on the Certification Checklist (see Section 8A) before unsupervised access is granted. Hard copies of the signed checklists are kept in the individual SMIF user files.

Operator Statement: I have read these procedures and agree to abide by them. – NOT Applicable

_____ _____

Signature of Operator Date

_____ _____

Signature of Operator Date

_____ _____

Signature of Operator Date