Drug Chemistry Section
Drug Chemistry Procedure Manual
Effective Date: March 23, 1998

Modification of J-1
Prepared By: Aaron Joncich
Approved By: I. L. Allcox
Supercedes: September 1, 1996

Name of Procedure:

Toxicology
Operating and Safety Procedures for Use With The Seifert: Isovolt 320 DS-1 Industrial X-ray Unit

Suggested Uses:

This document addresses the rules and regulations applying to the Non-Healing Arts Application of irradiating bio-hazardous materials for the purpose of sterilization.

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 Regulations for Protection Against Radiation (NCRFPAR) and is located with the Radiation Safety Officer.

Items Needed to Perform Procedure:

Seifert: Isovolt 320 DS-1 Industrial X-ray Unit
Paste P8 (Identification # 9 018 32)
Water, 68 degrees Celsius or less.
Haskris Water Chiller / Recirculator
Radiation meter capable of measuring mR/hour

Instrument Maintenance:

1. Replace paste on the four voltage connector cones every three months as described in manual.

2. Change water as needed, or take necessary steps to prevent bacterial growth.

3. Perform annual radiation surveys and document results.

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Application of Procedure on Evidence:

The following procedure has been registered with the North Carolina Division of Radiation Protection. To maintain the registration, the format of the submitted procedure has not been modified.

Literature References:

Operation Manual and Description - Fully Stabilized Industrial X-Ray Equipment - Isovolt 160/225/320/420/450 with control DS-1, Seifert and Co., 9/85.

North Carolina Regulations for Protection Against Radiation - 15A NCAC 11, NCDEHNR, July 1993.

"Inactivation of HIV by Ionizing Radiation in Body Fluids and Serological Evidence", **Journal of Forensic Sciences**, November 1989.

NORTH CAROLINA STATE BUREAU OF INVESTIGATION DRUG CHEMISTRY LAB: IRRADIATION OF BIO-HAZARDOUS MATERIALS

OPERATING AND SAFETY PROCEDURES FOR USE WITH THE SEIFERT: ISOVOLT 320 DS-1 INDUSTRIAL X-RAY UNIT

PURPOSE: This document addresses the rules and regulations applying to the Non-Healing Arts Application of irradiating bio-hazardous materials for the purpose of sterilization.

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 employees to read and review. It is entitled the North Carolina Regulations for Protection Against Radiation (NCRFPAR) and is located with the Radiation Safety Officer.

The rules require that each X-ray facility be registered with the state. The Notification of Registration is located with the Radiation Safety Officer.

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 manual and be able to demonstrate that you can use them properly. After reading this document and demonstrating that you can use the machine safely and correctly, you must sign and date the "Record for Individuals in Operating and Safety Procedure" located at the end of this document. The attached, "Safety and Procedural Guidelines in Industrial Applications", should be read by all x-ray unit operators.

All operators of x-ray machines are responsible for following the radiation safety procedures. Aaron Joncich is the radiation safety officer (RSO) for the North Carolina State Bureau of Investigation and has the responsibility and authority for overseeing matters relating to radiation protection. The RSO also confirms all training and serves as the contact person with the North Carolina Department of Environment, Health, And Natural Resources, which is responsible for regulating radiation safety. Employees should submit all radiation questions or concerns about radiation safety to the RSO.

There shall be posting of the State's "Standards for Protection Against Radiation Notices, Instruction and Reports to Workers, 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 NCRFPAR section .0411.

A copy of the operating procedures is to be posted near the x-ray equipment. A copy of the units most recent survey is to kept on the premises.

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

I. Emergency Procedure

If there is a need to turn off the unit in an emergency: TURN 'OFF' THE CIRCUIT BREAKER ON THE WEST WALL.

II. Excessive Exposure

If you suspect there has been an excessive exposure or a radiation incident, immediately notify Aaron Joncich, the RSO. The RSO will then notify the Division of Radiation Protection. The address is: Division of Radiation Protection, P.O. Box 27687, Raleigh, North Carolina, 27611-7687. The telephone number is 919-571-4141. The RSO will also notify the Assistant Director of the NCSBI Laboratory Section of the incident, in writing.

III. Personnel Monitoring

[Refer to the attached Regulatory Guide,"Appropriate Personnel Monitoring" for more information on personnel monitoring in the workplace.]

Always wear the personnel monitoring badge on your chest or collar when you are working with radiation producing equipment, and make sure it is the badge assigned to you.

When not in use, store badges in a low radiation area. The control badge shall also be stored in a radiation free area.
The RSO is responsible for the exposure records and exchanging the badges on a regular basis.

IV. Operation of the X-Ray Unit

The room in which the x-ray unit is located (Room #S430 at 121 East Tryon Rd, Raleigh, NC) is a restricted area at all times. Only authorized operators of the x-ray unit are allowed access to room # S430. Exceptions to the area restriction for maintenance, or other reasons, are to be authorized by the RSO. No pregnant women shall be allowed in Rm. S430.

Under no circumstances is anyone allowed to be in the shielded inner room inside Room S430 while the x-ray unit is in operation. No unauthorized operators shall be in the area of the instrument control panel at any time unless authorized by the RSO.
IMPORTANT: The x-ray unit is to be operated with the x-ray tube's circular window directed vertically down. Operation of the unit in any other direction may cause a radiation exposure risk.

Try to keep radiation exposure as low as possible. Never allow the lead shielded door to be open or any lead panels to be removed when operating the x-ray unit.

The x-ray equipment in this facility was installed following the manufacturer's specifications. Do not alter, tamper with, or remove any of the filters or collimator, shielding, or in any way cause needless radiation exposure.

V. Irradiation Procedures

Every activity involving the use of the x-ray unit will be logged in the activity log book for the x-ray unit. The log will include the date, time, operators initials, items irradiated, and system parameters used.

The following parameters have been determined to be effective for inactivation of the HIV virus, and will be used for the irradiation of contaminated materials.(Reference: Bigbee, et al., JFS, Nov. 1989)

RAD 25,000
Voltage 300 kV
Amperage 10 mA
Time 33 minutes
Distance 25.7 cm*

***This is the minimum distance a sample may be placed from the source of the**

x-rays. Increasing the distance two fold requires a four fold increase in the run time (e.g. at 51.4 cm the run time would be 132 minutes).

Here are the calculations used to determine x-ray to sample distance and the time required to achieve the needed dose (based on measurements of the beam shape).

d = diameter (cm) of the top of the sample to be irradiated.
h = height (cm) of the sample.
X = distance (cm) from the x-ray focal point to the bottom of the sample. This is based on the approximate 20^{o} angle, from the normal, beam projection. (Subtract 12.2 cm to get the distance from the lens face to the bottom of the sample).

$$X = (d / 0.744) + h$$

T = Time (minutes) required to irradiate the sample with the correct dose.

$$T = X^2 / 25.7^2 * 33$$

A. Place evidence to be irradiated under the x-ray tube.
B. Exit room and close the door completely.
C. Turn on the water chiller / recirculator.
D. Turn on the unit's power.
   1. Turn on the power at the circuit breaker.
   2. Turn on the unit's power controller by turning the red knob on the front of the cabinet.
   3. Turn on the control unit using the on/off key-switch to the on position.
E. Select the warm up procedure according to the length of time the unit has been off: day
F. Enter the maximum kV to be used (i.e. 300kV).
G. Press start button to begin warm-up (monthly warm-up takes 30 minutes).
H. After the warm-up, use the keys to the right of the display (kV, mA, min) to enter the corresponding values.
I. Press the start button to begin the irradiation.

VI. System Security

The room that houses the system (Room S430) will be locked at all times. Access to Room S430 will be possessed by only those authorized to operate the x-ray unit and the Supervisor of the Drug Chemistry Section. Keys to the control box of the x-ray unit will be available to only those authorized to operate it. The door of the inner chamber is connected to a fail-safe switch, which will not allow the operation of the unit if the inner door is open. There is a emergency-off button in the x-ray chamber. There is an audible alarm and a flashing light in the inner room, which are activated 10 seconds prior to the activation of the x-ray unit. There is an "x-ray on"

light on the outside of the x-ray chamber.

VII. Inspections

Surveys of the x-ray unit's area must be performed annually, and after any maintenance that may affect the x-ray output or room shielding.

Appendix A

RECORD FOR INSTRUCTION OF INDIVIDUALS IN OPERATING AND SAFETY PROCEDURES FOR THE OPERATION OF THE SEIFERT: ISOVOLT 320 DS-1 INDUSTRIAL X-RAY UNIT

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 operating and safety procedures and can operate the x-ray equipment in a safe manner. This was demonstrated by operating the x-ray unit under my supervision.

_____
RSO signature - Aaron Joncich date

Operator Statement:

I have read these procedures and agree to abide by them.

signature	date	RSO
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

CERTIFYING STATEMENT

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These procedures have been developed to ensure safe radiological working conditions. Everyone must adhere to these procedures. Prior approval must be obtained for any deviation from these procedures.

In accordance with Rule .1603(c), the registrant shall annually review the radiation protection program content and implementation.

signature of registrant	date
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____