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SAFETY ANALYSIS REPORT

Location:

**X17B2 Beamline/Synchrotron Medical Research Facility (SMERF)
National Synchrotron Light Source, BNL**

Associated Project:

Transvenous Coronary Angiography with Synchrotron X-rays

**- an addendum to the Phase II NSLS Safety Analysis Report
BNL #52205, June 1989**

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February 1990

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**NATIONAL SYNCHROTRON LIGHT SOURCE
BROOKHAVEN NATIONAL LABORATORY
ASSOCIATED UNIVERSITIES, INC.**

UPTON, NY 11973

**UNDER CONTRACT NO. DE-AC02-76CH00016 WITH THE
UNITED STATES DEPARTMENT OF ENERGY**

MASTER

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1. Preliminary Statement

This document should be treated as an addendum to the Phase II NSLS Safety Analysis Report (Ref. 1). The reasoning is that the X17B2 facilities and associated research program described herein are an extension of the "High Energy High Power Superconducting Wiggler Beamlines [X17]" already described in Section 4.2 of the Phase II document. As such, many NSLS and X17 related Policy, Building and Experimental Area items are already dealt with in detail and will only be referenced in this document where changes or differences occur pertinent to the X17B2 facility and program. Based on DOE Order 5481.1B (Safety Analysis and Review System), the Synchrotron Medical Research Facility described in this SAR is classified in the Low Risk Hazard Class.

2. Description of the Facility and Research Program

2.1 SMERF Facility

The Synchrotron Medical Research Facility, hereafter called SMERF, was constructed as part of the Phase II NSLS building expansion program. Figure 1 shows the relation of SMERF to the overall NSLS experimental floor. The nine room, 180 m² complex contains the downstream portion of the X17 Superconducting Wiggler beamline, designated as X17B2. Figure 2 shows SMERF in detail. The size of this medical research area is dictated by the fact that it must provide space for a beamline and imaging detector equipment, beamline control and imaging computers, an imaging area, human patient and physician as well as physicist areas. Specifically, the facility consists of the following rooms:

- a) Reception: patients, after having been admitted at the Clinical Research Center (BNL Medical Dept.), will be brought here prior to the imaging procedure.
- b) Toilet: for the convenience of the patients.
- c) Fluoroscopy: devoted to catheterization of patients; location of C-arm fluoroscopy unit, table and monitor.
- d) Dark Room: image processing area for photographic negatives, slides and prints.
- e) Storage: equipment storage area.
- f) Angiography: the room in which the coronary angiography imaging procedure will take place.
- g) Phy: room from which the Responsible Physician will monitor and control the imaging sequences.
- h) Data + Control: room for beamline control, imaging and safety system computers and monitors.
- i) Monochromator: continuation of beam pipe from X17B1 hutch enters this room and directs white SR beam to the X17B2 monochromator.

In addition to the above, SMERF is serviced across the hallway by an elevator large enough to contain a gurney plus attendants. The elevator communicates half a floor level up with an entrance and parking area for incoming and outgoing patients. This means that patients, under normal circumstances, will never see the experimental floor during their visits to the NSLS.

2.2 Research Program

While this SAR is not intended to serve as a review of the merits of the medical research program, a brief description of that program is appropriate here in order to provide the reader with a frame of reference.

The Transvenous Coronary Angiography program had its inception in 1979 due to the combined efforts of researchers at Stanford University, Lawrence Berkeley Laboratory (LBL) and Stanford Synchrotron Radiation Laboratory (SSRL). The equipment and procedures have already been proven on three sets of human patients (a total of six individuals). The research equipment developed and built for the California program is now relocated and installed in SMERF.

Current medical practice for imaging human coronary arteries involves the insertion of a catheter into a leg or arm artery, guiding the catheter tip up the artery (high pressure, against the flow of blood) until it reaches the openings of the coronary arteries located in the proximal end of the aorta. A radio-opaque dye (containing iodine) is injected into the coronary arteries and an x-ray image of the coronary arteries is taken using broad energy spectrum x-rays (10-100 keV).

Our technique is intended to be less invasive and thus reduce the risk to the patient by using the advantages of high flux, tunable synchrotron radiation. In this case, the catheter is inserted into a neck or arm vein (low pressure, with the flow of blood). Visualization of the catheter during the catheterization

procedure is accomplished using a standard C-arm fluoroscopy unit. With the patient positioned in the imaging chair, the dye is injected by a power injector and eventually enters the coronary arteries. The x-ray imaging is done in dual energy digital subtraction mode. Two high intensity narrow energy band x-ray beams, above and below the iodine k-edge (33.169 keV), are produced by a dual crystal monochromator. The beams are directed so as to cross over at the patient's heart and then continue on to a dual 300 element linear detector. The patient is translated through the beam by the vertical motion of a chair. Fast-acting safety shutters open only when the beams are over the heart region. Under typical operating conditions (see Section 5.1 for details) the patient can receive up to a 1.5 rad local skin surface dose per image scan. The low energy image is then digitally subtracted from the high energy image to remove bone and tissue artifacts and the resulting image shows the coronary arteries. Multiple images may be taken with each injection and the patient may undergo a series of images in more than one position to better project various arteries.

While the initial research period will be devoted to angiography, plans are already being made for future programs in computed tomography (CT), cancer radiotherapy and possibly human radiosurgery.

2.3 Beamline Configuration

The X17 beamline including wiggler, front-end components, transport hutches, X17C hutch and X17B1 hutch are described and diagrammed in Figs. 4.5-4.9 of the Phase II NSLS SAR (Ref. 1). The X17B2 portion of the beamline lies immediately downstream of the X17B1 hutch (Fig. 3) and accepts the central 5 mradian portion of the X17 wiggler SR beam. Fig. 4 shows the components as set up for the angiography program. These consist of a dual crystal monochromator which monochromates and divides the white SR beam into two separate beams above and below the k-edge of the radio-opaque dye in use. The beams are defined by vertical slits, pass through dual fast-acting safety shutters, another photon shutter and finally a dual beam monitor. All these items are located in the Monochromator Room. The beams then pass into the Angiography Room where they proceed to the patient chair. There they cross and finally proceed to the dual 300 element linear detector. Shielding configurations will be detailed in Section 4.10.2. Safety systems and interlocks will be described in Section 5.1.

3. Building Systems

3.1 Introduction

The general principles and explanations outlined in Section 3 of the Phase II NSLS SAR also apply to the X17B2/SMERF area. Detailed below are items which differ in some way from the generalized descriptions. The designation of SMERF as an Ambulatory Health Care Facility - see Appendix 1 - has a direct bearing on some of these differences. This Facility complies with the National Electrical Code, Article 517.

3.2 Electrical Power

3.2.1 *Circuit Box*

As a safety precaution, all SMERF outlet, lighting and electrical power wires have been routed to a single circuit panel board located in the Support Room. This limits access and prevents accidental power disruptions. Original sources of regular and emergency power will be yellow tagged to identify wires/circuits dealing with SMERF.

3.2.2 *Wiring*

Type AC (Armor Cable) wiring has been substituted for any existing Type NM (Non-Metallic) wiring.

3.2.3 *Grounds*

All receptacles have insulated ground conductors.

3.2.4 *Ground Fault Interrupter (GFI)*

GFI duplex outlets have been installed where appropriate.

3.2.5 *Receptacles*

Additional duplex outlets mounted in #3000 raceways have been installed in all rooms where beamline equipment is located.

3.2.6 *Emergency Lights*

Two L-100 Exide Electronic 6V central emergency lighting units are mounted on Angiography and Physician Room walls. Remote lamps for five other rooms are wired to these units. Lamps from both systems are located in the Angiography and Fluoroscopy Rooms in case one of the systems fails.

3.2.7 *Emergency Power Outlets*

Emergency power outlets have been installed in the Angiography and Fluoroscopy Rooms. These outlets are also supplied by regular power. The switch-over time to emergency power is approximately 10 seconds.

3.2.8 *Emergency Generator*

The emergency generator is located in the basement of Bldg. 535. It is tested by PE once a month (no load on system) and is serviced once a year. See Appendix 2.

3.3 Structural Modifications

3.3.1 *Steel Column Modification*

A cutout in one flange of support column #36 located in the Angiography Room was required to accommodate the x-ray beams and equipment for the imaging procedure. The column was reinforced and all new structures plus welds passed inspection. See Appendix 3.

3.3.2 *Life Safety*

Due to the existence of a 90' dead end distance created by the construction of the X17 enclosed beamline, a new emergency exit has been constructed through the old x-ray ring walkway wall past the SMERF Fluoroscopy Room. An "Emergency Exit Only" crash-bar door is installed in this exit. See Appendix 4. This is in full compliance with "Life Safety Code", NFPA101, Chapter 28 (Industrial Section) for the beamlines on the X-ray Ring floor, and Chapter 12 (New Health Care; Ambulatory Health Care Facilities) for the various patient areas.

3.3.3 *Radiation Shielding*

In order to ensure the safety of Non-Radiation Workers from SR and fluoroscope x-ray scatter in the SMERF area, a 1/16" layer of lead was added to the walls of the Angiography, Fluoroscopy and Monochromator Rooms (covered by 1/2" gypsum wallboard). The lead goes to a 7' height except behind the detector where it reaches a 12' height. Details are covered by PE Spec. 7471, available upon request.

3.4 Building Access and Egress

This topic has been dealt with in Section 3.3 of the Phase II NSLS SAR (Ref. 1) and in Sections 2.1 (SMERF Facility) and 3.3.2 (Life Safety) above. It is important to note, however, that an Adverse Reaction Plan will be developed by the Responsible Physician for the SMERF patients. Included in this plan will be a well established procedure for evacuating stabilized patients from the building via the nearby elevator or either of the x-ray floor roll-up doors. The plan will include coordination with emergency services (police, fire, ambulance) and will be drawn up in conjunction with the BNL Clinical Research Center (CRC) Emergency Plans and Safety Committee.

4. Hazards

4.1 Fire Hazard and Control

Fire protection is being extended from the existing building system. Smoke detection is provided in the various suites. Photo-electric Type detection is alternated with Ionization Type for best coverage. Twenty-five percent of the manufacturer's maximum recommended spacing is used to provide prompt detection. The system complies with NFPA 72E on the placement of fire protection devices.

Sprinkler protection is being extended from the existing wet pipe system. The occupancy is classified as an ordinary hazard Group II area as per NFPA 13, "Installation of Sprinkler Systems". Standard 165°F temperature rated sprinkler heads have been installed. The system complies with NFPA 13's installation rules for sprinkler systems.

New research related equipment will be added. This will increase the loss potential for the area. Major component values are \$140,000. (detector), \$50,000. (patient chair), \$100,000. (fluoroscopy equipment), \$60,000. (computers), \$100,000. (electronic equipment), \$250,000. (beamline equipment). Assuming total loss during a fire the loss potential is within limits of a sprinklered and smoke detector protected facility (DOE Order 5480.7). Replacement of components, should they be completely destroyed by fire, would take about 12 months. A version of the detector which could be used as a spare is being developed by colleagues at Lawrence Berkeley Laboratory, CA. It is possible that a spare fluoroscopy set-up could be borrowed from colleagues at North Shore University Hospital. It is also possible that spare computer components could be borrowed from other projects on the BNL site.

4.2 Toxic Hazards

None anticipated.

4.3 Laser Hazards

None anticipated.

4.4 High Pressure Systems

A 60 psi "house air" system services the beamline. Standard DOT compressed gas cylinders of helium and argon will be located outside the Monochromator Room. These cylinders will be appropriately secured in the Data/Control Room and the gasses piped into the Monochromator Room. The helium will provide the atmosphere inside the monochromator box and the argon will provide the dual beam monitor atmosphere.

4.5 Chemical Storage

Emergency medical supplies will be kept in the Angiography Room in a crash cart locked with break-away locks. Drugs, IV solutions, radio-opaque dyes, and other medical supplies will be stored in medical cabinets in the Angiography or Fluoroscopy Rooms. Supplies will be monitored by BNL Medical Department personnel (nurses and pharmacist).

Small quantities of standard chemicals (eg. solvents) will be kept in cabinets in the Data/Control Room or in the Storage Room.

Photo processing chemicals will be kept in the Dark Room.

4.6 Ozone Production

None anticipated. The white SR beam will be contained within either evacuated beam pipes or in a

helium filled monochromator box. The monochromatic beams which pass through air for imaging purposes are not anticipated to generate significant quantities of ozone.

4.7 Cryogenic Hazards

The linear detector located in the Angiography Room is the only piece of equipment utilizing liquid nitrogen. A dewar containing 25 liters is used to cool a cryogenic vacuum pumping system. LN is resupplied manually every 2-3 days during use of the detector. Flash evaporation of the 25 liters of LN would result in displacement of approximately 8% of the room volume. This would result in a decrease of atmospheric oxygen from 20.9% to 19.3%. While 19.3% is slightly below the OSHA low value of 19.5% (Ref. 2), the slightly deficient oxygen condition would exist instantaneously only upon the flash evaporation of the entire 25 liters of LN. Due to rapid dissipation, a substantial hazard would not exist even under this worst case scenario.

4.8 Magnetic Field Hazards

None anticipated.

4.9 Hazardous Wastes (Environmental Hazards)

4.9.1 Photographic Wastes

The Dark Room will house an automated photo processing unit for generating negatives, slides and prints of the angiographic x-ray images. A silver recovery system will be employed. All developer and fixer liquid wastes will be bottled, labelled and placed in the building's Waste Collection Area for proper disposal.

4.9.2 Medical Wastes

The angiographic imaging procedure involves the insertion of a catheter into a human patient, the use of IV solutions, the injection of imaging dyes and the removal of the catheter. Associated with this procedure will be the release of various human body fluids and the necessary use of various materials to clean up the fluids. Thus, the procedure generates liquid, solid and "sharps" wastes which should be viewed as potentially infectious. The Medical Department has defined strict protocols for the handling and disposal of such wastes (see Appendix 5 and 6) by the medical personnel associated with the research project (such as physicians, nurses and matrons). NSLS personnel will not be involved in the procedures. Custodians assigned to Bldg. 725 will, however, be involved in the day-to-day cleanliness of the SMERF rooms. These custodians will undergo a documented training course given by the Infection Control staff of the BNL Medical Department. Custodial supervisors will inform the Infection Control staff when a new, untrained custodian begins work so that this new person may also be trained.

4.10 Radiation Hazards

- all radiation shielding and procedures conform with the ALARA philosophy (Ref. 3).

4.10.1 Comments

Shielding against radiation due to SR beam scatter is one of the most important hazards to be controlled in the SMERF area. A 5 mradian wide, high energy spectrum white SR beam ($E_e \leq 22.2$ keV) is directed to the X17B2 Monochromator Room where two monochromatic beams are created. These beams then proceed into the Angiography Room for human imaging purposes. Their power is eventually deposited in a lead beam stop downstream of the imaging detector. Radiation shielding is necessary to protect the medical and NSLS personnel both within the immediate vicinity of the Angiography and Monochromator Rooms and in the offices located above these rooms.

All radiation scatter, shielding and dose calculations have been done using the software program PHOTON developed by Dean Chapman (Ref. 4). The accuracy of PHOTON calculations was

determined by Elke Bräuer and William Thomlinson (Ref. 5) by empirical measurements for a variety of configurations on bending magnet beamlines ($E = 5$ keV). PHOTON was always found to be slightly conservative in its calculations i.e. calculating slightly higher photon flux transmission, scatter or dose than were actually measured.

4.10.2 Radiation Shielding

Our shielding decisions have been governed by the dose limits for Non-Radiation Workers as set forth in DOE Order 5480.11 i.e. ≤ 100 mrem/yr. These limits resulted in the following shielding configuration:

a) Angiography Room

The existing walls consist of three layers of 5/8" gypsum wallboard. The entire wall surface of this room is covered to a height of 7' with 1/16" lead sheet. The two walls extending from the corner behind the detector are covered to a height of 12' for a width of 8'. The doors each have a 1/8" steel thickness which is sufficient shielding thickness. Windows in the doors are covered with 1/8" lead equivalency glass. A physician's window in the wall between the Angiography and Physician Rooms consists of 1/8" lead equivalency clear plastic. The ceiling is at a height of 16' and consists of 18 gauge (0.048") steel deck and at least 3" cement. This serves as excellent shielding for personnel in the offices above. A lead beam stop is located downstream of the detector.

b) Monochromator Room

The existing walls consist of three layers of 5/8" gypsum wallboard. The wall surfaces are covered with 1/16" lead sheet to a 7' height except for the wall shared with the Angiography Room (already shielded) and the wall shared with the x-ray ring floor (12"-18" thick high-density concrete). The 1/4" thick stainless steel monochromator box is contained within a "cave" consisting of 1/8" steel + 1/4" lead + 1/8" steel plates. This will adequately contain the white SR beam scatter. A lead bremsstrahlung shield is located downstream from the monochromator. The Monochromator Room steel door and ceiling provide adequate existing shielding.

c) Fluoroscopy Room

In addition to the above sources of white and monochromatic SR beam scatter, the Fluoroscopy Room will contain a mobile C-arm fluoroscopy unit (see Section 5.4 for maintenance information). The question of shielding the Fluoroscopy Room against the scattered x-ray radiation of this unit was presented to Dr. Salvatore Vacirca (see Appendix 7), Radiation Safety Officer for North Shore University Hospital, Manhasset, NY. For typical cardiac (arterial) catheterization procedures at North Shore, his calculations showed scattered radiation of 24 mR/wk. This dose value is based on fluoroscope output of 2 Roentgen/min., scattered radiation at 0.1% of primary at 1 meter, 4 patients/wk. at 3 minutes each. His opinion was that the existing gypsum walls would be sufficient shielding for such cumulative scatter, but that if the patient load were increased, 1 mm of lead sheet to a height of 7' should be installed in the walls. It should be noted, however, that our venous technique will take an average 6 second fluoroscopic run time/patient (see Section 5.2), therefore our weekly cumulative scatter will be much less. Therefore, the 1.588 mm (1/16") lead sheet we have installed will provide a more than adequate margin of radiation protection.

Figure 5 gives a diagrammatic presentation of the PHOTON calculations for shielding and resulting skin surface doses. Doses are given in mrad/hr. A white SR beam scatter source exists at the silicon crystal within the monochromator. Monochromatic SR beam scatter sources exist within both the Monochromator and Angiography Rooms. A worst case analysis of scatter was assumed for the Monochromator Room using ICRU4 tissue. The patient is the source of scatter in the Angiography Room and is also represented by ICRU4 unit density artificial tissue. Doses are calculated after the scatter has been absorbed by various shielding configurations: monochromator box + cave, Monochromator and Angiography Room 1/16" leaded walls (incl. 1.9" CaSO_4), steel doors, and an 18 gauge steel deck + 3" concrete ceilings located 16' above floor level.

4.10.3 Radiation Monitoring

A reasonable point of view is that the results of the PHOTON calculations should be used for guidance only and should not be treated as the final word. To that end, the commissioning of the X17B2 beamline and SMERF facility will be a real-time process utilizing the expertise of beamline as well as S&EP personnel. The NSLS Safety Officer and Operations Coordinators will assist in rigorous radiation monitoring surveys of all areas surrounding the white and monochromatic SR beams, including the offices above the beamline. S&EP will be asked to establish longer term surveys (TLDs) for the area. Any radiation leakage found will be dealt with immediately to the satisfaction of the safety personnel concerned.

The dose received by the patient will be the sum of the amount calculated from the dual beam monitor flux measurements and the amount estimated from the fluoroscopy procedure. A program for calibrating the above instruments for accurate dose measurements will be developed with the assistance of S&EP and the Medical Department. The total dose allowable for any patient will be determined by the Responsible Physician.

5. Safety

5.1 Operations (Safety Interlock Systems)

The safety system employed on the X17B2 beamline, Monochromator Room and Angiography Room will combine the properties of the standard NSLS safety interlock system and the Angiography Personnel Protection Interlock (APPI) system. The NSLS interlock system has been in use since 1982 and is detailed in Appendix VI of the NSLS Safety Analysis Report (Ref. 6). A complete, documented interlock system test is performed by the NSLS Safety Officer every six months. The purpose of the NSLS interlock system is to provide a safe environment for researchers and exclude them from areas of radiation. The APPI system was developed by Robert Hettel and staff at SSRL for their coronary angiography program. This system's capabilities have been tested and used in numerous phantom, animal and human patient runs at SSRL. The APPI system is now an integral part of the X17B2 beamline. Its purpose is to protect the patient being imaged from excessive radiation dose. The APPI system will undergo a review by the NSLS Safety Review Committee. Committee members will be assisted by Safety and Environmental Protection Division staff. No human research shall occur until the NSLS Safety Committee has given written and signed approval of the APPI system. The APPI system will not be enabled for human studies by an NSLS Safety Officer until a) the NSLS Safety Committee approves the APPI system, b) this Safety Analysis Report is approved by the BNL Assistant Director for Reactor, Safety and Security and c) the human studies research program is approved by the Human Studies Review Committee.

Operation of the X17B2 beamline must be done in sequence with the X17B1 beamline (see Figure 2). In order to allow the SR beam into the B2 Monochromator Room, the B1 plus transport hutches must be searched and interlocked.

Standard operations will have a transport pipe installed the length of the B1 hutch. This pipe is not part of the interlock system and is in place to eliminate air scatter in the B1 hutch. The white SR beam passes through the evacuated B1 transport pipe into the B2 monochromator box.

The Monochromator Room is treated in exactly the same fashion as a standard white beam hutch. The door into this room forms part of the interlock chain. Entry is allowed only after closure of the front end safety shutter. A lead beam stop, which ensures that the white beam does not reach the patient, is located just downstream of the monochromator box. The monochromatic beam photon shutters are located in the Monochromator Room downstream from the monochromator. A photon shutter similar in design to standard NSLS photon shutters, but consisting of a 0.75" thick lead shutter instead of a 5/8" thick copper shutter, is used for allowing entry (other than patients) into the Angiography Room. This shutter allows the Angiography Room to function as a normal monochromatic hutch. The angiography fast-acting safety shutter assembly is also located in the Monochromator Room and is composed of redundant shutters, each shutter consisting of two steel/lead blades activated by rotary solenoids (fail closed), and is capable of closure in <50 msec. The two shutters are operated simultaneously via two separate logic chains. The fast-acting safety shutters control the x-ray exposure for the imaging. Loss of electrical power to the fast-acting safety shutters results in closure of the rotary solenoids thereby blocking monochromatic beam entry into the Angiography Room.

The bounds of operation are that the ring current shall not exceed 250 mA and the wiggler critical energy (E_c) shall not exceed 22.2 keV (Ref. 1, p. 37). The patient is exposed to monochromatic beams (and their harmonics) above and below 33.17 keV. In a standard thoracic image, exit skin surface dose due to 33 keV photons is down by a factor of about a 1000, compared to entrance skin surface dose, due to attenuation (Ref. 7). If the chair stops, the patient will receive a 360 rads/sec skin dose rate over an area of 0.92 cm² (actually 0.5 mmV x 184.5 mmH dictated by beam focusing in the vertical and 5 mradH beam at 36.9 m from the source). Since the fast-acting safety shutters close in less than 50 msec based on recent tests at the NSLS, this would result in a maximum additional local skin dose of less than 18 rads.

The presence of the fast-acting safety shutters in the beamline is the most significant difference between X17B2 and all other NSLS beamlines. Since the shutters close in less than 50 msec, the Kirk-key lock on the normal entry door from the Physician Room into the Angiography Room will not be used during the patient imaging experiments. The door will be redundantly sensed to be in a closed position. This feature allows immediate entry in the event that a patient has a problem.

The Angiography Room is operated in two different modes. The selection of the proper interlock configuration is made by the NSLS Safety Officer by unique key control.

5.1.1 Set-Up Mode

This is a non-patient mode in which the dual monochromatic x-ray beams are allowed into the Angiography Room. White beam is on the B2 monochromator. The X17 Transport Hutch, B1 Hutch and B2 Monochromator Room are interlocked. The Angiography Room undergoes a standard search with two timed search buttons and accompanying sound/light alarms. The Kirk key and microswitch interlocks on the three doors are functional. The photon shutter opening occurs by pressing the physician scan switch. Closure occurs upon pressing the photon shutter closed button. The fast-acting safety shutters, allowing the beams into the Angiography Room, are controlled from the computer by beamline personnel and open only when all interlocks are satisfied. Tripping any door interlock closes the fast-acting safety shutters and photon shutter.

5.1.2 Patient Mode

This mode is used only when imaging patients. White beam is on the B2 monochromator and the interlock chain is complete for the X17 Transport Hutch, B1 Hutch, B2 Monochromator Room and the three doors into the Angiography Room. The Physician or a person designated by the NSLS Safety Officer is in charge of a search of the Angiography Room (no sound/light alarms) and ensures that only the patient, if any, is in the room during operation of the imaging sequence. No timed search buttons are used. The door to the Reception and Fluoroscopy Rooms are locked from the outside but are passable from the Angiography side. The door to the Physician Room is unlocked. This mode requires action by two special keys. The first key, held only by NSLS safety personnel, is used to switch the APPI interlock circuits from Set Up Mode to Patient Mode. The second key, held by either the Physician or a person designated by the NSLS Safety Officer, is used to enable the scan sequence. This ensures that it is only the Physician or designated person who can start a scan after searching the Angiography Room. The Physician or designated person then presses and holds the scan switch button to initiate the scan sequence. The sequence automatically opens the photon shutter. The timing of the patient chair movements and fast-acting safety shutter activation are controlled by the computer imaging program. A scan fault is detected if the scan switch button is released at any time during the scan sequence. Any fault detected by the APPI system causes the fast-acting safety shutter and photon shutter to close and latch out. The NSLS Safety Officer must re-enable the system before operations can resume. Additional conditions causing a fault include:

- a) the patient chair translating up and down at a slower than preset speed while fast-acting safety shutters are open,
- b) failure of either or both fast shutters to be closed when the patient is not within correct imaging positions or when scan sequence is over,
- c) exceeding the total scan time preset by the physician,
- d) entry into the Angiography Room doors by personnel,
- e) conflict in hardware logic, and
- f) incorrect voltage on shutter power supplies.

5.2 Fluoroscopy Procedure

The introduction of a contrast agent for the imaging procedure requires the insertion of a catheter into the venous system of the patient. Visualization of the catheter position is done using a fluoroscope. The catheter tip will be placed at the junction of the superior vena cava and the right atrium utilizing the brachial vein. Unlike cardiac (arterial) catheterization, venous catheterization is a very fast and uncomplicated procedure. Fluoroscopic run times for this procedure are 3-9 seconds. For the average patient, the fluoroscopic run time will be 6 seconds during which the patient will receive a total skin surface dose of 180 millirads (based on 2 Roentgen/min. fluoroscope output) over a 9" diameter viewing area. During the catheterization procedure and the operation of the fluoroscope, "Do Not Enter" signs will be lit on the two doors leading into the Fluoroscopy Room.

The nurse and physician in the Fluoroscopy Room will wear standard catheterization lab lead aprons. No radiation will penetrate these aprons. The estimated dose to exposed areas of the primary physician (individual closest to the patient during fluoroscopic procedure) will be approximately 20 mrem/procedure (pers. comm. Dr. Salvatore Vacirca, Medical Physicist, North Shore University Hospital). Attendant staff will receive less dose. Routine BNL film badges will be worn by fluoroscopy personnel.

5.3 Personnel Training

5.3.1 Beamline Operation

All personnel coming to do research at the SMERF facility will be required to view the NSLS safety video tape which provides an introduction to NSLS experimental hutch entry systems, a description of radiation safety, fire alarms and evacuation procedures. Users will also attend the required BNL safety orientations or new NSLS orientation programs currently under development.

It is the responsibility of the Principal Investigator to train and document the training (see Appendix 8) of new SMERF personnel regarding beamline operation and safety systems as well as the facility safety responsibilities of the Responsible Physician. During Set-Up and Patient Modes it is the responsibility of the NSLS physicists to operate the beamline. The Principal Investigator is responsible for overall safety and quality assurance. Prior to each imaging sequence, a checklist of beamline and scan parameters is completed and signed by a physicist and the Responsible Physician (see Appendix 9).

Medical research studies will be conducted according to the policies established by the Governing Body of the CRC. Individual protocols must be approved by the BNL Human Studies Review Committee. The CRC Patient Care, Quality Assurance and Safety Committees ensure the proper implementation of the studies. While on the BNL site, the patients are always under the supervision of a physician and/or a nurse. During Patient Mode it is the Responsible Physician who ensures the safety of the patients. The Responsible Physician is also in charge of the Angiography Room and ensures that the patient is the only person in the Angiography Room during actual imaging.

5.3.2 Medical Staff

Clinical Research Center (BNL) registered nurses, acting as clinical liaison with visiting hospital personnel, will be responsible for clinical quality assurance activities and provide support to the angiography nurses during angiographic procedures.

Full-time cardiologists from accredited hospitals will place the venous line for the x-ray contrast injection. These physicians are Board certified cardiologists who perform many elective cardiac catheterizations annually. These cardiologists will be assisted by cardiac research nurses who are trained in cardiac angiography, CCU/ICU care, and certified in ACLS (Advanced Cardiac Life Support).

Physician and nurse competency and training for all medical aspects of this project will be determined by the Executive Committee of the BNL Medical Department when granting clinical privileges at BNL.

5.3.3 Custodial Staff

As stated in Section 4.9.2, Building 725 custodians will undergo a training course given by Medical Department Infection Control staff. This course will address the specific needs of human research area cleanliness in SMERF.

5.4 Equipment Calibration

All beamline equipment inspection, maintenance and calibration will be the responsibility of the NSLS X17 beamline staff (physicists and technicians). Oversight will be done routinely by NSLS Safety Officer and safety coordinator inspections.

Inspection, maintenance and calibration of all medical equipment will be done on a scheduled basis by the Medical Equipment Maintenance Shop staff in the BNL Medical Department according to the requirements of the Joint Commission for Accreditation of Health Organizations (JCAHO) and using the computerized program already in place at the CRC (see Appendix 10). This includes an annual mechanical and electrical safety check, and verification that the fluoroscope meets the manufacturer's design specifications. Standard operation and maintenance of the fluoroscopy unit will follow the guidelines set forth in NCRP Report No. 102 (Ref. 8). Staff members of the Shop may exercise the right to train and assign specific X17B2 beamline or medical personnel to do various medical equipment inspection, maintenance and calibration jobs. Complete records of all work will be kept.

5.5 Additional Oversight of Patient and Equipment Safety

The coronary angiography/SMERF project, because of its human patient involvement in the research protocol, is overseen by many committees. A brief review of the committees is a useful exercise to demonstrate the breadth of issues concerned.

5.5.1 Laboratory Safety Committee

A BNL committee which reviews Safety Analysis Reports and recommends for approval to the BNL Assistant Director for Reactor, Safety and Security.

5.5.2 Human Studies Review Committee

A BNL committee which reviews the medical, ethical, scientific and legal aspects of research protocols and patient safeguards.

5.5.3 NSLS Safety Committee

Reviews beamline and research safety issues peculiar to the NSLS facility.

5.5.4 NSLS Beamline Review Committee

Reviews construction, vacuum and shielding configurations on new beamlines.

5.5.5 Clinical Research Center (CRC) Quality Assurance Committee

Reviews quality and appropriateness of patient care as well as improvement of patient care.

5.5.6 CRC Patient Care Committee

Monitors inspection control, medical record review, physician competence and determination of breach of research protocol.

5.5.7 CRC Emergency Plans and Safety Committee

Reviews and audits all aspects of patient and staff related safety at the facility.

5.5.8 North Shore University Hospital-Cornell University Medical College Human Studies Review Committee

Because patients and physicians from North Shore University Hospital are involved in this research, the research protocols were reviewed and approved by this Committee on March 12, 1989. This Committee requires a Progress Report every 12 months (N.I.H. Assurance of Compliance No. M-1302).

5.5.9 Stanford University Administrative Panel on Human Subjects in Human Research

Because personnel from the Stanford Synchrotron angiography group are involved in this research, the research protocols were reviewed and approved by this committee on June 6, 1989. The research projects must be reviewed and re-approved annually by this panel (N.I.H. Assurance No. M-1272).

6. Risk Assessment

6.1 Introduction

The NSLS Phase II SAR (Ref. 1) has already covered the major safety features and assessed the various risks for the Phase II NSLS facility as a whole. Only those risks directly related to SMERF and coronary angiography will be dealt with below. Risk categories are taken from the DOE Risk Assessment Course (Fig. 6).

6.2 Equipment Loss

While malfunctioning equipment might result in a radiation risk (described below), actual damage to equipment (detector, patient chair, fast-acting safety shutters, monochromator crystals, etc.) would result in the expense of repairs and delay of the research program. The risks assessed are as high as Critical (II) for the detector but Marginal (III) for the other equipment, with a Remote (D) as a probability for any loss. Equipment Loss During a Fire has been analyzed in paragraph 3.5. It is within the limits of DOE Order 5480.7.

6.3 Radiation

As described in Section 5.1.2 above, there is a risk to the patient of over-exposure to the dual x-ray imaging beams due to either slower than preset chair speed, chair stoppage during the fast-acting safety shutter imaging period, or a failure of the fast-acting safety shutters to close when commanded by the computer imaging programs. In those cases, fault conditions would arise immediately calling for the closure of the B2 fast-acting safety shutters and photon shutter. The risk to the patient is assessed as Marginal (III) resulting in an x-ray dose of 18 rads/50 msec (see Section 5.1 above) and is considered Remote (D). While exposure to the white SR beam would certainly be Critical (II) and result in a skin surface dose rate of about $6.9\text{E}+06$ rads/sec over an area of $5.0\text{ mmV} \times 184.5\text{ mmH}$ (Ref. 4), the probability is Extremely Improbable (E) because of the positioning of the 0.25" thick stainless steel monochromator box, the 8" thick bremsstrahlung shield, the 0.25" steel/0.25" lead monochromator cave and the 1/16" lead wall shielding in the B2 Monochromator Room.

7. References

1. Stefan, P. June 1989. Phase II Safety Analysis Report National Synchrotron Light Source. National Synchrotron Light Source, Brookhaven National Laboratory, Upton, NY. BNL #52205. 131 pp.
2. American National Standard Institute, Inc. 1980. Practices for Respiratory Protection. Volume Z88.2-1980. p. 14.
3. U.S. Nuclear Regulatory Commission. October 1982 (Rev. 1). Regulatory Guide 8.18: Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be as Low as Reasonably Achievable. 14 pp.
4. Chapman, D. January 1988. PHOTON: A User's Manual. National Synchrotron Light Source, Brookhaven National Laboratory, Upton, NY. BNL Informal Report #40822. 61 pp.
5. Bräuer, E. and W. Thomlinson. 1988. Experimental Verification of PHOTON: A Program for Use in X-Ray Shielding Calculations. Nucl. Instr. and Meth. A266: 195-198.
6. Batchelor, K. (ed.). July 1982. National Synchrotron Light Source Safety Analysis Report. National Synchrotron Light Source, Brookhaven National Laboratory, Upton, NY. BNL #51584. 121 pp.
7. Nordstrom, E., N. Gmür, D. Chapman, M. Collins and W. Thomlinson. November 1989. Dose Rate to Human Organs from Monochromatic Synchrotron Beams. National Synchrotron Light Source, Brookhaven National Laboratory, Upton, NY. BNL Informal Report 43433. 11 pp.
8. National Council on Radiation Protection and Measurements. June 30, 1989. NCRP Report No. 102: Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use). 139 pp.

8. FIGURES

SMERF

Figure 1: NSLS experimental floor with Synchrotron Medical Research Facility (SMERF) highlighted.

Figure 2: Synchrotron Medical Research Facility (SMERF) in detail.

Figure 3: X17B1 hutch leading to downstream X17B2 (SMERF) area.

Figure 4: Plan and elevation views of X17B2 (SMERF) beamline components in Monochromator and Angiography Rooms.

SYNCHROTRON MEDICAL RESEARCH FACILITY

Figure 5: Shielding for X17B2 (SMERF) Angiography and Monochromator Rooms and beamline with resulting PHOTON calculated dose values.

- RISK ASSESMENT -

		POTENTIAL CONSEQUENCES				PROBABILITY*						
HAZARD SEVERITY	Category	Descriptive Word	Personnel Illness/Injury	Equipment Loss (\$)	Test Unit Downtime	Data Compromise	A Frequent	B Reasonably Probable	C Occasional	D Remote	E Extremely Improbable	F Impossible
	I	Catastrophic	Death	> 800,000	> 4 Months	Data never recoverable or primary program objectives lost		① *				
	II	Critical	Severe injury or severe occupational illness	100,000 to 800,000	2 Weeks to 4 Months	Repeat of test program.			② *			
	III	Marginal	Minor injury or minor occupational illness	1000 to 100,000	1 Day to 2 weeks	Repeat of test period.				③ *		
	IV	Negligible	No injury or illness	< 1000	< 1 Day	Repeat data point, or data requires minor manipulation or computer rerun.						

HAZARD SEVERITY		
Category	Descriptive Word	Potential Consequences
I	Catastrophic	May cause death or system loss
II	Critical	May cause severe injury, severe occupational illness, or major system damage
III	Marginal	May cause minor injury, minor occupational illness, or minor system damage
IV	Negligible	Will not result in injury, occupational illness, or system damage

PROBABILITY*		
Level	Descriptive Word	Definition
A	Frequent	Likely to occur repeatedly during life cycle of system (test/activity/operation)
B	Reasonably Probable	Likely to occur several times in life cycle of system
C	Occasional	Likely to occur sometime in life cycle of system
D	Remote	Not likely to occur in life cycle of system, but possible
E	Extremely Improbable	Probability of occurrence cannot be distinguished from zero
F	Impossible	Physically impossible to occur

RISK PRIORITY	
*Code	Contractor Action Required
①	Imperative to suppress risk to lower level before operation
②	Operation may require written, time limited waiver endorsed by Contractor Management
③	Operation Permissible
AF Action Required	
①	High Risk Imperative to lower risk if possible AEDC CC approval required
②	Medium Risk AEDC DO v DE approval required as applicable
③	Lower Risk AEDC DOP, DOF, DOT or DEV DEM approval required as applicable

* Probability that the potential consequence occurs.

Figure 6: Risk categories from the DOE Risk Assessment Course.

9. APPENDICES

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: June 5, 1989
TO: Distribution
FROM: J. DiNicola *J.D.*
SUBJECT: Angiography Room 1-137

A review the National Electrical Code Article 517 was made by J. Levesque and the writer concerning the subject area. Under the general definition of Health Care Facility the application of ambulatory health care facility was found applicable in defining this area.

Therefore, the following sections of Article 517 are applicable with a summary of the some immediate implications:

Part B. Wiring

1. All receptacles shall have an insulated ground conductor.

Part C. Health Care Facilities Not Covered Under Parts D & E.

Part F. Patient Care Areas

1. Area is a General Care area.
2. Romex is not a suitable wiring method.
3. Two branch circuits should serve receptacles in this area.

Part H. Communications Systems & Fire Alarm

89064/jd

Distribution
Electrical Engineering
J. Carroll
K. Batchelor
T. Dickinson
N. Gmur
J. Levesque
T. McEvaddy
J. Sanchez

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: 2-15-89
TO: Nicholas F. Gmur
FROM: C.F. Johnson C.F.J. (x7626)
SUBJECT: Preventive Maintenance on 725 Emergency
Generator - PE Equipment # 535GR-26668

As per your request in phone conversation and subsequent memo, I have prepared a summary of PM activity performed by Plant Engineering on the generator in question.

Attached please find:

1. Equipment Information - This is the nameplate data of this generator as recorded in our PM database.
2. PM Tasks by Equipment Report - This represents the PM tasks presently assigned and pertinent information concerning frequency and type.
3. PM Specifications - The highlighted specifications apply to this generator. These specifications are applied as the tasks mentioned in item 2.

At the present time, Plant Engineering does not perform actual load or transfer tests on this generator. We agree that this type of test should be performed, but this would require a simulated power failure in the building on a routine basis, at least to the emergency bus. Due to the various user requirements and conflicting operating schedules, a test of this nature is difficult to perform. What this means is that the electrical transfer and distribution system (emergency) was tested and proven when installed, but is not routinely tested as part of the PM schedule. If this or any other portion of this PM plan needs further discussion please feel free to contact me at ext. 7626.

BROOKHAVEN NATIONAL LABORATORY
PLANT ENGINEERING DIVISION
EQUIPMENT INFORMATION

Equipment Number	535GR-26668	Name	GENERATOR
Serial Number	4A-1322818		
Department	EF	Group	HEM
Manufacturer	GENERAL MOTORS		
Model Number	4151-E	Class	GE
Original Cost	3736	Replacement Cost	0
Location	BLDG-535 BASEMENT	Purchase Date	05/78
Track Spares	Y		
Meter Reading	138	Meter Units HR	Usage per Day 0.00
Service Status	IN	Charge Number	M35202

Engineering Notes

BNL #86733,DIESEL,TANK CAPACITY 6,000,GAL PER HR 10,75KW,12V
Supplies emergency power to 725.

BROOKHAVEN NATIONAL LABORATORY
PLANT ENGINEERING DIVISION
PM SPECIFICATION CATALOG

Spec No.	Name	Procedures	Craft	Planned Hours	St PI
GR-001	EMERGENCY GENERATOR TEST 1x/mo.	1. Notify Building Rep of test 2. Check block heaters 3. Check water level 4. Check belts for wear or cracks 5. Check and clean battery posts and connections 6. Start Engine 7. Verify normal run conditions on gages and thermometers 8. Test run for 1 hour Contact supervisor with any operational problems. If additional maintenance is required, have repair work order issued to cover the work	581	2.00	
LOG THE FOLLOWING INFORMATION					
Engine hours _____ Start time _____ Stop time _____					
GR-002	EMERGENCY GENERATOR SERVICE	Every 200 hours runtime or once a year: 1. Change belts 2. Change oil and filters 3. Change coolant solution	581	4.00	
HE-001	WINTERIZE HEAVY EQUIPMENT	1. Check and correct antifreeze concentration in all equipment	581	80.00	
HY-001	HYDRANT SERVICE CHECK LIST	HYD. TAG., IF TAG IS COVERED WITH PAINT, INSTALL NEW TAG. ALL CHAINS SHOULD BE FASTENED. NOZZLES SHOULD BE TIGHT, TIGHTEN & CAULK IF NECESSARY. LUBE NOZZLE WITH SOAP. WITH NOZZLE CAPS TIGHT, TURN ON WATER & CHECK FOR LEAKS, LOG ON HYD. FORM. HYD. SHOULD OPEN & CLOSE EASILY. MUELLER HYDS. FILL RESERVIOR WITH HYD. OIL.	321	0.25	

BROOKHAVEN NATIONAL LABORATORY
PLANT ENGINEERING DIVISION
PM TASKS BY EQUIPMENT

02/14/89

Page 1

Equipment No.: 5356R-26668

Name: GENERATOR

Group: HEM

Location: BLOS-535 /BASEMENT

Current Meter: 138 HR

Usage per Day: 0

Number of Tasks: 2

In Service: IN

Task	Type	Spec	Name	Cycle Qty	Cycle Unit	Cycle Type	Plan. Craft	Hours	Next Due	Next Meter	Auto Force	Last Service	Serv. YTD	Serv. LTD	Group
1	S	GR-001	EMERGENCY GENERATOR TEST	1	M	F	581	2.00	03/01/89	0	Y	/ /	0	0	HEM
2	S	GR-002	EMERGENCY GENERATOR SERVICE	0	A	V	581	4.00	/ /	~~300~~	Y	/ /	0	0	HEM

* M = Monthly

A = Annually

End of Report

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: May 31, 1989
TO: Mr. K. Batchelor, NSLS
FROM: I. Ludwig, Plant Engineering (x. 7874)
SUBJECT: (ILR 254596) Steel Column Modification (Col. #36)

Pursuant to your request for information re. the above noted subject and for implementing this information into the FSAR the following applies:

To accommodate the proposed beam line equipment a cutout from one flange of existing column #36 is required. Engineering calculations which address maximum loading conditions indicate that reinforcement of the column is required so that the structural integrity of the column is not impaired. Steel plates welded to the column in a specific configuration will be utilized to provide that reinforcement as well as a 4:1 Factor of Safety. If you have any questions you can contact me on extension 7874.

IL-148:hlm
cc: T. Timko
J. Levesque
B. Patel

BROOKHAVEN NATIONAL LABORATORY
M E M O R A N D U M

DATE: April 6, 1989
TO: K. Batchelor
FROM: J. Levesque *J.L.*
SUBJECT: X-17 Beamline Dead End Distance

The following documents the resolution of the excessive dead end travel distance created by Beamline X-17's extension through the perimeter aisle.

Concern

With the construction of Beamline X-17's shielded enclosure, a dead end distance over 90 ft. was created. This was in violation of the Life Safety Code (NFPA 101-89, Par. 28-2.5.2). The maximum allowable distance is 50 ft.

Resolution

After reviewing the area with T. Dickinson, C. Weilandica, R. Zantopp, D. Chapman, and N. Gmur a second exit through the Recovery Rm. was decided on.

By providing a new exit as shown on the attached diagram, the dead end distance will be 50 ft.

The shaded area between the X-17 transport hutch and X-18 Beamline is not considered a normally occupied area. The shaded area is solely for equipment access. The clear width of this region is less than 3 ft. wide.

Summary

The proposed arrangement will improve the level of safety and comply with DOE Orders.

JL/sc

attachment

cc: J. Deitz

F: x17beam.

1.2

BROOKHAVEN NATIONAL LABORATORY
M E M O R A N D U M

DATE: March 24, 1989
TO: Medical Department Staff
FROM: H. Susskind, Safety Coordinator
SUBJECT: Guidelines for Infectious Waste Disposal

Please follow the attached guidelines for disposing of infectious wastes.

HS:dm

I. DEFINITION

Infectious waste shall mean and include the following:

1. Containers with discarded sera that have not been autoclaved.
2. Biological waste which contains discarded excretions, exudates and secretions.
3. Discarded laboratory waste which has come into contact with pathogenic organisms.
4. Blood and body fluids containing visible blood.
5. Animal carcasses exposed to pathogens in research.
6. Sharp items (disposable syringes, needles, scalpels, etc.) that have had contact with the above items.

II. COLLECTION**A. Solid Infectious Waste**

Solid infectious waste (items I. 1-3) is to be collected in plastic lined ice-cream containers (ICC), available from the stockroom. These containers should be sealed by the user with tape and labeled "POTENTIALLY INFECTIOUS". Special tape is available in the Clinical Laboratory. Infectious waste that is also radioactive should be so labeled. Foot operated waste cans should be used for all radioactive ICCs.

B. Liquid Infectious Waste

1. Blood samples are usually present in disposable centrifuge tubes, vials or syringes. These will be collected in ICCs or puncture resistant, red colored disposable sharps collectors (PRC), as appropriate, for disposal. These containers are available from the stockroom. They should be sealed by the user with tape and labeled "POTENTIALLY INFECTIOUS". Special tape is available in the Clinical Laboratory. Infectious waste that is also radioactive should be so labeled. Foot operated waste cans should be used for all radioactive ICCs.
2. Urine samples are to be collected and the containers should be sealed by the user with tape and labeled "POTENTIALLY INFECTIOUS". Special tape is available in the Clinical Laboratory. Infectious waste that is also radioactive should be so labeled. Foot operated waste cans should be used for all radioactive ICCs.

C. Animal Carcasses:**1. Non-Radioactive**

Carcasses are to be properly packaged by the user and placed in the Veterinary Services freezer (Room 9-433-0).

2. Radioactive

Carcasses are to be properly packaged and labeled by the user and placed in the designated S & EP freezer located in the Medical Department basement.

D. Sharps

Sharp items are to be collected in PRCs for disposal. Containers holding radioactive waste should be so labeled.

III. PROCESSING AND DISPOSAL

A. Solid Infectious Waste

1. Non-Radioactive

The sealed containers are to be delivered to Veterinary Services for incineration. The ash will be disposed of in accordance with BNL policy.

2. Radioactive

The containers are to be brought to S & EP and the appropriate form filled out (BNL F-2544). S & EP will have it autoclaved in Veterinary Services, after which it will be sent to Waste Management for disposal.

B. Liquid Infectious Waste

1. Non-Radioactive

Non-radioactive blood waste is to be autoclaved or incinerated with solid waste prior to disposal because the residual liquid volume in centrifuge tubes, syringes, etc. is too small to be handled separately.

2. Radioactive

Radioactive blood waste containers are to be brought to S & EP and the appropriate form filled out (BNL F-2544). S & EP will have it autoclaved in Veterinary Services, after which it will be sent to Waste Management for disposal.

3. Urine

Urine is to be disposed of in the Sanitary system. For special problems or presence of radioactivity, see S & EP.

C. Animal Carcasses

1. Non-Radioactive

These carcasses are to be incinerated by Veterinary Services. The ash will be disposed of in accordance with BNL policy.

2. Radioactive

Proper disposal will be handled by Waste Management.

D. Sharps

1. Non-Radioactive

The containers are to be brought to the S & EP office and the appropriate form filled out (BNL F-2568). S & EP will have it autoclaved in Veterinary Services, after which it will be sent to Waste Management for disposal.

2. Radioactive

The containers are to be brought to the S & EP office and the appropriate form filled out (BNL F-2544). S & EP will have it autoclaved in Veterinary Services, after which it will be sent to Waste Management for disposal.

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: December 15, 1987

TO: Staff, Clinical Research Center; A. D. Chanana, M.D.,
Chairman, Medical Department

FROM: William H. Adams, M.D. *WHA*

SUBJECT: Prevention of HIV transmission

The Clinical Research Center is currently following the August, 1987, guidelines recommended by the Centers for Disease Control for prevention of HIV transmission, including the protection of health care workers. I have received the recommendations of the Ad Hoc Committee selected by Dr. Chanana to review the CDC guidelines. After consulting further with CDC personnel, I wish to formally institute the recommendations made by the Ad Hoc Committee, with the exception that handwashing is not required between patients undergoing routine phlebotomy unless there is a tear in a glove permitting skin contamination with blood or unless there is visible contamination of the glove with blood. In these situations, the hands should be washed before regloving. Phlebotomy personnel will, however, continue to change gloves between patients.

PREVENTION OF HIV TRANSMISSION

1. Gloves should be worn when performing venous or arterial punctures. These should be changed after contact with each patient or employee which involves bloodletting. In addition, if there is a tear in a glove permitting skin contamination with blood or if there is visible contamination of the glove with blood, the hands should be washed before regloving.
2. Needles should not be recapped, bent, or broken. After use, sharps should be placed in puncture-resistant containers.
3. Gloves should be worn when processing blood and body fluids. Masks and protective eyewear should be worn if aerosols are likely.
4. The outside of specimen containers should not be contaminated. If this happens the exposed surface should be decontaminated with gauze soaked in 1:10 Chlorox solution or its equivalent.
5. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting should not be done.

6. Laboratory work surfaces should be decontaminated with an appropriate germicide such as 1:10 Chlorox solution after a blood/body fluid spill and when activities are completed. Refer to blood spill procedure in the CRC infection control guidelines.
7. Hands should be washed after completing lab activities. Lab coats should be removed before leaving the lab area.
8. For appropriate disposal of infectious waste and sharps, refer to the Waste Disposal Section in the CRC infection control guidelines.

Distribution:

A. D. Chanana

V. Brooks

D. Fabian

N. Netusil

J. Matkovich

T. Johnson

L. Schlichtercroll

W. Scott

P. Heotis

J. Cizinsky

D. N. Slatkin

Clinical Laboratory ✓

Radiology

D. Christman

NORTH SHORE UNIVERSITY HOSPITAL

A TEACHING CENTER OF
CORNELL UNIVERSITY MEDICAL COLLEGE

Department of Medicine
Division of Cardiology

(516) 562-4763/4100

July 15, 1988

Appendix 7

Nicholas F. Gmur
Brookhaven National Laboratory
National Synchrotron Light Source
Building 510E
Upton, LI, NY 11973

Dear Nick:

Enclosed are comments from Dr. Vacirca concerning the fluoroscope.

Sincerely,

John Morrison, M.D.

JM:hb
encl.

300 Community Drive, Manhasset, New York 11030

A VOLUNTARY NON-PROFIT HOSPITAL

* R = Roentgens

12 JULY 88

Scattered Radiation

24 mR/week at 1 meter

based on Fluoro output of 2 R/min*

Scattered radiation 0.1% of primary at 1 meter.

4 pts per week at 3 minutes each

EXAM ROOM

At position A - say 1 meter (EXAM ROOM)

24 mR/week

with 47.6 man plaster sheet rock = 2 HVL

$$24 \text{ mR/week} \times \left(\frac{1}{2}\right)^2 = 6 \text{ mR/week}$$

EXAM ROOM OCCUPANCY FACTOR $\approx \frac{1}{4}$

$$6 \text{ mR/week} \times \frac{1}{4} \approx 1.5 \text{ mR/week}$$

RECEPTION AREA

Position B about 2 meters

$$\text{Dose rate } 24 \text{ mR/week} \times \left(\frac{1}{2}\right)^2 = 6 \text{ mR/week}$$

with 2 HVL of sheet rock $\approx$

$$6 \text{ mR/week} \times \left(\frac{1}{2}\right)^2 = 1.5 \text{ mR/week}$$

Occ Factor $\approx \frac{1}{4}$

$$1.5 \text{ mR/week} \times \frac{1}{4} \approx 0.4 \text{ mR/week}$$

S.J. Vaccaro, PhD

NOTE:

12 JULY 88

BASED ON 4 PATIENTS PER WEEK
AND 3 min. OF FLUORO EACH.
THE SHIELDING PROVIDED BY THE
4.8 CM OF GYPSUM WALLS IS
SUFFICIENT.

IF YOU INCREASE THE PATIENT LOAD
BY 2 OR GREATER, A 1 mm Pb
THICKNESS TO A HEIGHT OF 7' ABOVE
IS RECOMMENDED ON EXAMINATION
135 AND RECEPTION AREA (139) INCLUDING
DOOR AND GLASS.

S.T. Vaccaro, PhD

SYNCHROTRON MEDICAL RESEARCH FACILITY

DOCUMENTATION OF TRAINING

The following topics will be covered in training sessions prior to approval by the Principle Investigator, Dr. William Thomlinson, for any person to participate in a medical research program on the NSLS Beamline X17B2 involving human studies:

1. BNL and NSLS Safety Orientation
2. Film Badge Orientation
3. X17 Beamline Operations
4. X17 and SMERF Safety Systems
5. Emergency Procedures
6. Human Study Protocols
7. Safety Analysis Report
8. Responsibilities of Personnel

In addition, medical personnel must also have the following:

9. Active Guest Appointment to the Staff of the Clinical Research Center
10. Instruction in their responsibilities during Patient Mode operation of the Angiography Room

Signature of Staff Member: _____ Date: _____

Signature of Principle Investigator: _____ Date: _____

DRAFT

Appendix 9

EXPERIMENTAL LOG for PATIENT STUDY

Date _____ Time _____

Machine

- _____ GeV and _____ mA
- wiggler field _____ kgauss
- lifetime _____ hours
- physician display of current _____

Monochromator

- stepping motor = _____ steps
- piezo voltage _____ volts
- table position _____ steps
- water flow ON _____

Slit - position settings: 1- _____ 2- _____ 3- _____ 4- _____

Shutters operational _____

Ionization Chamber

- gas flowing at _____ scfh
- high voltage ON and voltage _____ volts
- electrometer gains (x10=
1- _____ 2- _____
3- _____ 4- _____

Chair

- chair zero position correct _____
- phantom scan in correct position _____
- position alignment system OK _____

Detector

- thermoelectric cooler ON _____
- vacuum OK _____
- high voltage ON and voltage _____ volts

Power Injector

- Computer interface OK _____
- Renografin 76 loaded _____

ECG Machine Operational _____

Crash Cart Available _____

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CALIBRATION SCAN PROTOCOL

Calibration Scans done in Diagnostic Mode

- Scan Speed _____ cm/sec
- I (angi) gain _____
- NO absorber Gain _____ Scan # 1- _____ 2- _____
- Attenuator 1 Gain _____ Scan # 1- _____ 2- _____
- Attenuator 1+2 Gain _____ Scan # 1- _____ 2- _____
- Attenuator 1+2+3 Gain _____ Scan # 1- _____ 2- _____
- Position Scan Absb Gain _____ Scan # 1- _____ 2- _____
- Position + 1 Gain _____ Scan # 1- _____ 2- _____
- Position + 1+2 Gain _____ Scan # 1- _____ 2- _____

Phantom Scan

- phantom heart position X= _____
Y= _____
- Interlocks operational _____
- gain of detector _____
- manual scalars reset _____
- Absorber IN/OUT _____
- scan speed _____ cm/sec
- Scan number _____

ring scan

- Keithley voltages Vu (Upper) _____ volts
Vl (Lower) _____ volts

After scan

Time _____

Manual scalars N1= _____ N2= _____ N3= _____

Dose(rad) from Voltages = $0.218 (Vu + Vl) F =$ _____ Rads
-6

Dose(rad) = $1.96 \times 10^{-6} (N1 + N2)$ _____ Rads

Total Accumulated Dose _____ Rads

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PATIENT POSITIONING SCAN

Description

- Previous exposure dose received _____ Rads
- Safety system in PATIENT mode _____
- ECG heart rate _____ beats/min
- Manual scalars reset _____
- Interlock check _____
  - Safety interlocks all GREEN _____
  - hutch stoppers OPEN _____
- Scanning parameter check _____
  - gain of detector electronics _____
  - scan speed _____ cm/sec
- number of frames F= _____
- starting frame number _____
- starting position X= _____ mm
Y= _____ mm
- Scan number _____
- Electron current _____ mA
- Absorber IN _____
- Chair position correct _____
- Patient positioned in chair OK _____
- Lead apron on patient _____
- Injector Armed (Y/N) _____
  - If YES _____
    - Renografin loaded _____
    - tubing connected (Y/N) _____
- Injection parameters _____ ml at _____ ml/sec
- Door Interlock OK _____

READY for SCAN APPROVAL _____ and _____

- Patient moved to starting position _____
- Computer ready for scan command _____
- Beam ON _____

During scan

- Keithley voltages Vu (Upper) _____ volts
Vl (Lower) _____ volts

After scan

Time _____

Manual scalars N1= _____ N2= _____ N3= _____

Dose(rad) from Voltages = $0.218 (Vu + Vl) F =$ _____ Rads

Dose(rad) = $1.96 \times 10^{-6} (N1 + N2)$ _____ Rads

Total Accumulated Dose _____ Rads

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PATIENT ANGIOGRAPHY SCAN

Description of scan _____

- Previous exposure dose received _____ Rads
- Safety system in PATIENT mode _____
- ECG heart rate _____ beats/min
- Integrated flux display reset _____
- Manual scalars reset _____
- Interlock check
  - Safety interlocks all GREEN _____
  - hutch stoppers OPEN _____
- Scanning parameter check
  - gain of detector electronics _____
  - scan speed _____ cm/sec
- number of frames F= _____
- starting frame number _____
- starting position X= _____ mm
Y= _____ mm
- Scan number _____
- Electron current _____ mA
- Absorber OUT _____
- Chair position correct _____
- Patient positioned in chair OK _____
- Lead apron on patient _____
- Renografin loaded _____
- Tubing connected (Y/N) _____
- Injector parameters _____ ml at _____ ml/sec
- Injector ARMED _____
- Door Interlock OK _____

READY for SCAN APPROVAL

- Patient moved to starting position _____
- Computer ready for scan command _____
- Beam ON _____

During scan

- Keithley voltages V (upper) _____ volts
V (lower) _____ volts

After scan

Time _____

Manual scalars N1= _____ N2= _____ N3= _____

Dose(rad) from Voltages = $0.218 (V_u + V_l) F$ _____ Rads

Dose(rad) = $1.96 \times 10^{-6} (N1 + N2)$ _____ Rads

Total Accumulated Dose _____ Rads

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Final Calibration Scans After Patient Has Left

- In Diagnostic Mode	_____				
- Scan Speed	_____	cm/sec			
- Position + 1+2	Gain	_____	Scan #	1- _____	2- _____
- Position + 1	Gain	_____	Scan #	1- _____	2- _____
- Position Att	Gain	_____	Scan #	1- _____	2- _____
- Attenuator 1+2+3	Gain	_____	Scan #	1- _____	2- _____
- Attenuator 1+2	Gain	_____	Scan #	1- _____	2- _____
- Attenuator 1	Gain	_____	Scan #	1- _____	2- _____
- NO absorber	Gain	_____	Scan #	1- _____	2- _____

Phantom Scan

- phantom position	X= _____	Y= _____
- gain of detector	_____	
- manual scalars reset	_____	
- Absorber IN/OUT	_____	
- scan speed	_____	cm/sec

Scan number _____

During scan

- Keithley voltages	V (upper)	_____	volts
	V (lower)	_____	volts

After scan

Time _____

Manual scalars N1= _____ N2= _____ N3= _____

Dose(rad) from Voltages = $0.218 (V_u + V_l) F =$ _____ Rads

Dose(rad) = $1.96 \times 10^{-6} (N1 + N2)$ _____ Rads

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Medical Equipment Maintenance Shop
SOP #1

STANDING OPERATING PROCEDURE

Biomedical Equipment Repair Shop

1. PURPOSE: This SOP has been prepared to outline current policies, procedures and responsibilities governing the efficient operation of the Biomedical Equipment Repair Shop.
2. SCOPE: This SOP applies to the internal operation and the maintenance of all medical, veterinary, laboratory and x-ray equipment supported at this clinical research center and designated satellite activities. It is applicable to all personnel assigned to the Biomedical Equipment Repair Shop.
3. RESPONSIBILITY: The Biomedical Equipment Repair Shop is responsible for installation, repair, preventive maintenance and electrical safety testing necessary to insure proper functioning of all medical equipment within the highest standards possible. Additional responsibilities are listed in the Appendix.
4. STANDARDS OF BIOMEDICAL MAINTENANCE: Biomedical equipment maintenance must BE OF THE HIGHEST STANDARDS POSSIBLE. Equipment used by medical personnel is most important since its purpose is to save lives and prevent suffering of sick patients. With this purpose as the ultimate objective, the highest standards of maintenance are mandatory.
5. RECOMMENDATIONS AND SUGGESTIONS: Recommendations and suggestions for improving this SOP by individual users are encouraged and should be brought to the attention of the Biomedical Equipment Repair Shop staff.
6. GENERAL: Procedures have been written and attached in APPENDIX format for simplification. Each Appendix provides a reference for detailed information when required. Consult Appendix listing for the appropriate title, paragraph and page number.

APPENDIX A

PREVENTIVE MAINTENANCE (PM) PROGRAM

1. DEFINITIONS.

- a. Preventive Maintenance: The systematic care, servicing, and inspection of equipment for the purpose of maintaining it in a serviceable condition and detecting and correcting incipient failures before they develop into major defects. PM includes lubrication, minor adjustments, replacement of common hardware or bench stock items, etc.
- b. Critical Safety Factors: Deficiencies that if not corrected can result in injury or death to the patient or operator.
- c. Deficiency: A malfunction or defect in equipment which causes it to be inoperative, inaccurate, or unsafe to operate in its present condition.
- d. Shortcomings: A malfunction or defect in equipment which reduces its effectiveness or capabilities.

2. TECHNIQUES.

- a. PM will be conducted in accordance with AAMI Vol 8 No 4, manufacturer's literature, and other technical directives, such as the G-29, Veterans Administration services pamphlets. All equipment will be inspected using the shop PM schedule.
- b. Nontechnical medical equipment will be given a visual inspection and if at all possible, an operational checkout. Technical medical equipment will be given a more complete inspection as described below.

3. PERFORMANCE OF PM. PM will be more than performing an inspection. It is the act of servicing as well as inspecting. Proper PM cannot be accomplished with a clipboard and pen. Personnel assigned to perform PM should be prepared to handle the following tasks:

- a. Cleaning. Cleaning in areas not normally accessible to the operator.
- b. Lubrication. Unusual lubrication requirements should be accomplished by the MFG or MFG Field Rep.
- c. Calibration. Calibration should be regularly performed on items of equipment where accuracy of output is essential.
- d. Inspection of Critical Safety Factors. Any item not meeting prescribed safety standards should be reported to on duty orderly, removed from service and turned in for repair.
- e. Operational Test. All phases of equipment operation should be checked for normal output or responses.
- f. Adjustments, Parts Replacement. Minor adjustments, replacement of common hardware (nuts, bolts, and screws, etc) should be done whenever necessary.

4. PM MANHOUR REQUIREMENTS. Individuals assigned to perform PM will accomplish services to technical items prior to servicing nontechnical equipment. Items that have an MMCN number maintained are considered technical equipment and will be serviced before nontechnical items. The time allotted to each activity for PM will include some time to perform PM on technical equipment first and if additional time is available, to service nontechnical items. The PM team will not spend more than 1/10th hour per item, or 10 items per hour, servicing nontechnical items. In addition, the PM team is expected to accomplish required PM tasks on technical items within the time published for each item. As individuals become familiar with each item, it is expected that PM tasks will be accomplished at a faster rate.

5. PM RECORDS KEEPING. Repairmen are expected to maintain records properly and turn in required worksheets at the conclusion of each inspection. The PM team will accomplish the following tasks:

a. The Biomedical Equipment Repairman will complete Form Nov. 1976 (Sample attached) and have person of the sector being inspected sign for the second copy. Indicate and items or problems encountered and instruct individuals to initiate a work request. The Biomedical Repairman will return to the shop, inform the Shop Foreman of overall outcome of preventive maintenance inspections and turn in the inspection sheets and work request for the respective areas.

b. Ensure Form Nov. 1976 is properly filled out and the activity supervisor's signature has been secured. One copy of this form will be given to the activity supervisor at the conclusion of the PM visit. One copy will also be turned in to the shop supervisor with all other paperwork.

c. The work order clerk will ensure that all PM actions are inputted into the VAX to ensure PM data is placed on the Automated Maintenance Record.

APPENDIX B

RESPONSIBILITIES AND DUTIES OF BIOMEDICAL EQUIPMENT REPAIRMEN

1. Works under the general supervision of their Shop Foreman.
2. Answer telephone and personal inquiries regarding the adjustment, repair or overhaul of medical equipment and various other electrical and mechanical appliances and devices.
3. Determines the extent of repairs and/or adjustments required, whether it falls within his capability or should be repaired by outside contractor or depot. Repairs and checks for proper operation of equipment assigned him for repair.
4. Prepares the necessary administrative paperwork involved with the repair or the paperwork for referral to contractors or depot for repair if beyond their capability.
5. Brings to the attention the the Shop Supervisor or Maintenance Engineer all equipment considered uneconomically repairable.
6. Provides lists of parts required to repair an item when parts are not in stock.
7. Assists in performing preventive maintenance inspections, floor conductivity tests, line receptacle and leakage current tests.
8. Monitors the repair or maintenance of equipment on service contracts.
9. Performs other duties as assigned by the Maintenance Supervisor.
10. Records all completed repairs, calibrations or preventive maintenance services in accordance with established policy.

APPENDIX C

POLICIES AND PROCEDURES (GENERAL)

1. DUTY HOURS. The normal duty hours are from 0830 hours to 1700 hours Monday through Friday. Lunch break starts at 1200 hours and ends at 1230 hours. Branch personnel will not deviate from this schedule without the permission of the Hospital Administrator.
2. OVERTIME. All overtime will be kept at a minimum level and must be authorized in advance by the branch chief. Personnel will be given compensatory time in accordance with the needs and requirements of the activity.
3. EMERGENCY CALL DUTY. After hours - Shop Supervisor can be called at his home after 1800.
4. COMPLAINTS. This branch will maintain an "open door policy" and will be available at all times to hear complaints and/or problems. Personnel are advised to seek assistance through the chain of command.
5. NEWLY ASSIGNED PERSONNEL. The Shop Supervisor will insure these personnel have completed inprocessing procedures and are oriented toward shop procedures before shop duties are assigned. This orientation will include a complete review of this procedure.
6. MAINTENANCE OF PRIVATELY OWNED EQUIPMENT. Repair of privately owned equipment will not be accomplished using government owned tools, test equipment, parts, or facilities. The term repair is to include service, calibration, and cleaning.
7. SHOP CLEANLINESS. All personnel are responsible for maintaining the shop area, office areas, parts room and storage areas in a high state of cleanliness at all times.