

UNIVERSITY of LOUISVILLE

HUMAN USE RADIATION SAFETY MANUAL

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DEPARTMENT OF ENVIRONMENTAL HEALTH AND SAFETY
Office of Radiation Safety
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THE UNIVERSITY OF LOUISVILLE
RADIATION SAFETY PROGRAM

I. INTRODUCTION

The purpose of this manual is to provide clinicians, medical physicists and technologists who administer radioactive material to patients with policy and procedure regarding the safe use and disposal of radioactive material as approved for human use by the University Radiation Safety Committee under the University's Broad Medical License 202-029-22.

The Administration of the University of Louisville has a commitment to providing a safe environment for faculty, staff and patients during the medical use of radioactive material. It is the responsibility of all Deans, Department Chairs and clinicians to implement radiation safety policy and procedure as approved by the University Radiation Safety Committee under the authority delegated by Administration. Oversight of this policy and procedure is carried out by the University Radiation Safety Office under the supervision of the University Radiation Safety Officer.

A specialized part of the University's overall safety program is radiation safety. The elements of our Radiation Safety Program for human use are contained in the following sections and appendices. They have been carefully developed to help all involved individuals conduct their duties in an efficient and safe manner. Radiation health and safety standards are among the best studied and most thoroughly applied in the safety field. While allowable human exposures are set well below the hazardous levels, this university also strongly supports the "As Low As Reasonably Achievable" radiation safety philosophy regarding radiation dose. Appendix A outlines our commitment to this philosophy. It is essential that all staff members know their duties and responsibilities regarding radiation safety, and constantly practice good safety techniques. Study these pages. Know and practice the safety rules.

**CHARTER FOR THE UNIVERSITY RADIATION SAFETY COMMITTEE
UNIVERSITY OF LOUISVILLE**

June 26, 1990

Convening Authority and Composition

The President of the University of Louisville, upon recommendation of the Dean of the Medical School, Vice President for Research, Vice President for Administration and the University Provost, shall appoint a University Radiation Safety committee. The committee shall consist of at least ten (10) members, plus ex-officio representatives. The membership shall, at the minimum, include representatives from University administration, representatives from university administration and nursing service, the University Radiation Safety Officer and University faculty members. The membership requires expertise in the following areas:

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| 1. Research (Non-human) Use Sub-committee (3 members) | Concerned with protection and safety aspects of radioactive materials use in the research environment; including contamination control, ventilation proper waste disposal and safety aspects and training of lab personnel as well as approval of research protocols involving <u>in-vitro</u> radioactive materials use and <u>in-vivo</u> use of radionuclides in animals. |
| 2. Human Use Sub-committee (3 members) | Concerned with protection and safety aspects of radionuclide use in the clinical setting, including all areas of radiation safety for patients and occupationally exposed personnel and approval of authorization applications and human use protocols. |
| 3. Ionizing and non-ionizing radiation producing machines (1 member) | Concerned with protection and safety aspects of machines and instruments that produce ionizing and non-ionizing radiation, including proper shielding of operators and training. |
| 4. U of L hospital administration nursing services (2 members) | Concerned with radiation safety issues of patient care as well as nursing service. |
| 5. University Administration (1 member) | Concerned with radiation safety issues regarding University faculty/staff and students as well as research grant activity. |
| 6. University Radiation Safety Officer | Ex-officio member providing radiation safety expertise to all committee members. |
| 7. Other <u>ex-officio</u> members as deemed necessary by the committee. | Members from other University areas where radioactive material is used or stored who can |

provide assistance to the committee as requested.

The membership of the committee, both voting and ex-officio shall be selected to provide expertise in each of the areas of clinical and research uses of radiation outlined above. Collectively, the members of this committee must have the capability of assessing the safety of research projects, human use involving radionuclides and the use of both ionizing and non-ionizing radiation producing machines. Appointments to the committee will be for a minimum of three (3) years.

General Purpose

The Radiation Safety Committee has two main charges:

1. Ensuring that all individuals who work with or in the vicinity of radioactive materials or radiation have sufficient training and experience to enable them to perform their duties safely and in accordance with Kentucky Cabinet for Human Resources regulations 902KAR:100, conditions of the radioactive material licenses, tenants of the Radiation Safety Manual and good radiation safety practice.
2. Ensuring that all use of radioactive material and radiation is conducted in accordance with Kentucky 902KAR:100 regulations, license conditions, and radiation safety manual policy and procedure.

The goal of this committee shall be to facilitate clinical uses of radiation by providing expedient review of the Radiation Safety Program and to address the requirements of any applicable regulatory agencies.

In order to ensure that research and patient care is not hampered by this review, all necessary administrative support will be given to this committee.

Specific Duties

The University Radiation Safety Committee shall:

1. Be familiar with all pertinent regulations, the terms of the license, the radiation safety manual and information submitted in support of the request for amendments to authorizations for the use of radionuclides and radioactive material licenses.
2. Review the training and experience of all individuals who use radioactive material (including clinicians, researchers, physicists and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with Kentucky 902KAR:100 regulations, license conditions and radiation safety manual policy and procedure.
3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive materials (e.g. lab technicians, nursing personnel, physical plant, custodial and security personnel) are properly instructed as required by 902KAR 100:165, Section 2.

4. Review all requests for use of radioactive materials within the University.
5. Approval of research grant proposals that involve the use of radiation in animals.
6. Prescribe special conditions that will be required during a proposed use of radioactive materials such a bioassay, physical examinations of users and special monitoring procedures.
7. Review the entire radiation safety program annually to meet ALARA requirements and determine that all activities are being conducted safely and in accordance with Kentucky 902KAR:100 regulations, license conditions, and radiation safety manual policy and procedure.
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
9. Maintain written records of all committee meetings, actions, recommendations, and decisions.
10. Ensure that the radioactive material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures and personnel as deemed necessary.

Administrative Procedures

1. The new policies and procedures recommended by the committee shall be carried out and monitored by the University Radiation Safety Office and any other individuals or offices designated by Vice President for Administration. The Committee Chairman and University Radiation Safety Officer will sign off on proposals needing institutional review for radiation safety concerns.
2. The Chairman will sign-off on approved grant proposals and new policy and procedure which have been affirmed by committee vote.
3. All members of the University Radiation Safety Committee meet as often as necessary to carry out its duties, but at least each calendar quarter.
4. To establish a quorum, 50 percent of the committee's membership, including the University Radiation Safety Officer and the member from University administration must be present.
5. Approval of motions shall require a majority of those present.

B. Radiation Safety Officer (RSO)

The RSO is responsible for the administration of the radiation safety program and is delegated the necessary authority to carry out his/her responsibilities by the Radiation Safety Committee.

Arrangements may be made as needed for radiation safety consultants to supplement the RSO in conducting surveys, waste management and general radiation safety matters. The authority and responsibility of the RSO shall include, but is not limited to, the following:

1. General supervision of procurement, receipt, storage and record keeping of radioactive material and sources.
2. Instruction of personnel in radiation safety.
3. Conducting investigations of incidents and reporting to the Radiation Safety Committee.
4. Authority to terminate immediately a project or activity which is a threat to health or property.
5. General surveillance over all radiation source activities and consultative radiation safety services.
6. Quarterly review of personnel monitoring records for regulatory compliance and ALARA commitments.
7. Periodic review of radiation safety documentation (i.e. sealed source leak tests and inventories and surveys).

III. CRITERIA FOR EVALUATING USER QUALIFICATIONS FOR THE USE OF RADIOACTIVE MATERIALS

A. HUMAN USE OF RADIOPHARMACEUTICAL DRUG PRODUCTS APPROVED BY FDA FOR ROUTINE PROCEDURES

In order to use radioactive material not exempted by the State of Kentucky, an applicant must be licensed to practice medicine in the Commonwealth of Kentucky, and hold a faculty appointment with the University Of Louisville.

General and specific training and experience requirements for applicants adopted by the committee are those contained in Appendix Q of this manual.

Satisfactory completion of the University of Louisville course, Radiological Physics for Radiology Residents or its equivalent in practical training will serve as evidence of acceptable basic training.

Applicants should support their training and experience history with a preceptor statement from their training institution. The preceptor statement should be signed by the chairman of the institution's radioisotope committee. Certification by the American Board of Radiology or the American Board of Nuclear Medicine may be accepted by the Committee as sufficient evidence of satisfaction for all training and experience requirements.

B. GUIDELINES FOR THE HUMAN USE OF RADIONUCLIDES IN NON-ROUTINE OR INVESTIGATIONAL PROCEDURES

An applicant must already be authorized for Human use. In addition, review and approval guidelines of applications for experimental and non-routine medical uses of radioactive material adopted by the Committee are those contained in Appendix R of this manual. It should be emphasized that

approval of the University Human Studies Committee is also mandatory prior to performing these procedures.

When non-routine or investigational medical use proposals fall under the authority of U.S. Food and Drug Administration (FDA) regulations, the investigator shall satisfy all FDA requirements, including the filing of an Investigative New Drug (IND) application or become approved as an investigator under a sponsor's IND. The Committee will accept as adequate evidence for approval of the study, copies of the forms material, protocols and reports required to satisfy FDA requirements.

In general, non-routine or investigational medical procedures will be preceded by animal and/or in vitro data. Animals may be used to document or determine (1) Pharmacology (pharmacodynamics, endocrinology, metabolism, ect.). (2) Toxicity and Pathology (acute toxicity studies, sub-acute and chronic toxicity studies, reproduction and teratology studies, miscellaneous studies, ect.). (3) Dose range studies.

Animal studies will have been conducted in a manner to give proper consideration and attention to the condition of the use such as to whether the radioactive compound is for short or long term use, or whether for infants, children, pregnant women or fertile women.

IV. PROCUREMENT OF RADIOACTIVE MATERIALS FOR HUMAN USE

A. Ordering of Routinely Used Material

The immediate approval of a purchase order for radioactive material is delegated by the Nuclear Medicine Physician to the Nuclear Medicine Technologist or by the Radiation Oncologist to the Medical Physicist or Dosimetrist. The Nuclear Medicine Physician or Radiation Oncologist must be authorized by the University Radiation Safety Committee to use radiopharmaceuticals for human use and such uses must be reviewed by the Radiation Safety Officer (RSO). The Nuclear Medicine Technologist, medical physicist or dosimetrist is responsible for the inventory of all radioactive material used routinely. Radioactive materials will be procured from NRC or Agreement State licensed suppliers.

B. Quality Management (e.g., Therapeutic Uses or I-131, I-125 >30 uCi):

1. A written directive will be obtained from the physician who will perform or oversee the procedure. The written directive will contain the isotope, total prescribed dose and signature and date of authorized user.
2. Persons ordering the material will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, patients name, etc.
3. The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
4. It is essential that written records be maintained for all ordering and receipt procedures.
5. Appendix C will serve as a model for ordering and receiving radioactive material.

C. Receipts, Transfers, Unpacking and Storage Radioactive materials are normally delivered to the Nuclear Medicine Hot Laboratory during working hours. On off-duty hours, the packages are received as per Appendix C-2.

All personnel involved with the receipt of radioactive material shipments must be instructed in the proper procedures and precautions. Appendix C-2 is a model for written instructions for this purpose. A copy of these instructions is to be given to all involved individuals.

Unpacking of radioactive material receipts must be done in accordance with the established safety procedures described on Appendix D. A copy of these procedures must be kept posted in the nuclear medicine area.

When a written package radiation survey is needed (or required by 902 KAR 100.019 Section 28, an entry should be made in a receipt log as described in Appendix D.

D. Records

Each clinical area is responsible for maintaining the master record file or log of all radioactive material ordered, received, transferred, used and disposed. The Nuclear Medicine Technologist, Medical physicist or Dosimetrist will maintain these records under the supervision of the Radiation Safety Officer. Records of radiation surveys, incident reports, personnel dosimetry results, leak tests, and survey instrument calibration shall also be maintained in each clinical area.

The following records must be kept and are to be available for inspection at any time by the Radiation Safety Office and authorized regulatory agency representatives.

1. Type and amount of radionuclides on hand.
2. Results of radiation surveys.
3. Sealed source leak tests and inventories, dose calibrator quality control testing, and survey meter calibrations control testing, and survey meter calibrations.

4. Method and amount of disposal, including radiation survey results for material held for decay.
5. Patient dose records, including patient's name dose prescribed, dose assayed, type of procedure, and date. Records will be retained for review by the licensing body for the periods specified below.

Indefinitely:

Personnel Monitoring and Bioassay Records

Radiation Accident Investigation Results

Radiation Safety Committee Minutes

10 Years:

Misadministration Reports

5 Years:

Sealed Source Leak Test and Inventory Results

3 Years:

Patient Dose Records

Survey Results, Including Area Surveys and Hold For Decay Surveys

Mo-99 Breakthrough Results

Survey Meter Calibration and Dose Calibrator QC Test Results

V. NUCLEAR MEDICINE QUALITY CONTROL

A. Radiopharmaceuticals

Radionuclides, radiopharmaceuticals, and product labeling kits must be either procured from an NRC or Agreement State licensed radiopharmaceutical vendor or proposal by a nuclear pharmacist or physician authorized user, and meet appropriate standards of purity and sterility. Kits must be prepared and used in accordance with approved instructions furnished by the manufacturer and accompanying each reagent kit. Records of use of unit and multi-dose will be kept as specified in Appendix F. For Tc-99m doses, the Nuclear Medicine Technologist will either perform a Moly breakthrough test as per Appendix P or review the results of the Moly breakthrough assay performed by the supplier of the radiopharmaceutical. No dose will be used when, at the time of administration, there is more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m. For all gamma emitting doses whose prescribed activity is > 10 uCi, the dose shall be assayed in the dose calibrator to an accuracy of $\pm 10\%$ prior to being administered to patients. No dose > 10 uCi shall be administered to a patient if it exceeds the prescribed activity by $\pm 10\%$.

B. Misadministrations

Potential misadministrations should be reported immediately and investigated by the RSO.

Misadministrations as defined in 902 KAR 100 regulations, should be reported as per applicable sections of that document.

C. Radiation Detection Equipment

Calibration and quality control of equipment utilized to measure, detect and assay radioactive material will be performed as per Appendix G.

VI. THE RADIATION SAFETY PROGRAM

A. Training

Individuals working in or frequenting restricted areas in the university must be informed of radioactive material presence, storage and use and radiation levels present. Nursing, housekeeping, security and other personnel frequenting areas where radioactive material is utilized or stored will be given radiation safety instructions at least annually.

Personnel who utilize radioactive material will be instructed on applicable provisions of applicable 902 KAR 100 regulations and license conditions, including incident reporting responsibilities, and the right to know their exposure/bioassay results; before commencing work, after significant program changes, and annually thereafter. A copy of, or the location of the regulations, radioactive material license, guides, laboratory rules, procedures, survey results and personnel monitoring records will be available to these individuals and they will be instructed in appropriate portions (Appendices H, I and J). Training records will be retained for review.

Radiation Workers will be trained on good radiation safety practices. Uniforms or lab coats are worn during duty hours and gloves donned when handling liquid radioactive material or potentially contaminated articles. Absorbent material will be laid down prior to mixing or preparing unsealed sources of radioactive material. Syringe and vial shields and handling devices (tongs, forceps, etc.) are available and are to be used to minimize extremity and whole body dose.

B. Airborne Contamination

Individuals wishing to be authorized for gases (ie Xe-133) should contact the Radiation Safety Office. The RSO will evaluate each proposed use as per Appendix M of

" A Guide for the Preparation of Radioactive Material License Applications for Medical Programs"
(Areas where radioactive gases are utilized must have air flow measurements performed semi-annually).
Aerosolized radionuclides are administered within a closed, shielded system that provides for collection and disposal of the aerosol. Trap filters are not reusable. They will be properly shielded and held for decay as per Appendix L.

C. Personnel Monitoring

All personnel who directly handle gamma or high energy Beta emitting radioactive material shall be provided with, and wear, a whole body personnel monitoring device, such as a film badge or thermo luminescent dosimeter (TLD). These monitoring devices will be procured from a NLVAP certified dosimetry service and will be changed at least bi-monthly. Individuals who are occupationally exposed on an occasional basis (ie nurses caring for therapy patients) shall be issued a whole body monitor during the period of potential exposure. The monitoring device is to be worn in a manner such that the dose it receives can be expected to approximate the maximum radiation dose to the head and/or trunk of the wearer. Individuals wearing lead aprons should wear two film badges, one on the trunk of the body, under the apron and the other on the collar outside the apron.

Personnel who directly handle millicurie amounts of radioactive material shall also be provided with finger film or TLD badges. Other personnel will be assigned appropriate personnel monitoring devices as deemed appropriate by the RSO.

Individuals may only wear personnel monitoring devices which have been directly assigned to them. Personnel monitoring devices shall not be exchanged with other individuals. The RSO will assign temporary devices in the event of loss, accident or emergency. Any dose recorded by the temporary device will be incorporated into the assigned individual's permanent dose record.

The personnel monitoring records, including the name, sex, social security number, date of birth and work station of each participant, will be kept on file in Nuclear Medicine and Radiation Oncology. A duplicate copy will be kept in Radiation Safety. The RSO will review these records quarterly to determine which individuals may be receiving significant exposures. Film badges should be ordered using the "Personnel Monitoring Badge Action Form", Appendix E.

Investigations of overexposures, serious accidents and spills of radioactive material should be impartially conducted by the RSO to permit correction of any conditions that could have lead to the event. Such investigations are important since they may discover defects in previously accepted procedures or equipment. Positive corrective action can then be taken immediately. A written report should be prepared so that others may benefit from the experience.

The various lead brick and other radiation shields in the Hot Lab are to be used to best advantage in reducing exposure rates from sources such as Mo-99/Tc-99m generators, and stored product inventory. Spent generators shall be stored in their lead shipping shields until disposal or returned to the vendor.

Restricted areas shall be under surveillance by personnel as a security measure. When unattended, stored radioactive material must be secured by lock and key. Key control is maintained through the RSO, Radiology Supervisors, Nuclear Medicine Technologists and security staff.

Radioactive material will be transported to patient areas only as absolutely necessary and then while properly posted, labeled and shielded.

Radiation safety surveys will be conducted as per Appendix K.

The State of Kentucky Radiation Control Branch will be notified whenever overexposures exceed regulatory limits. a) Whole body Total effective dose equivalent greater than 5.0 rem/year b) extremity dose greater than 50 rem/year.

Bioassay will be performed on every individual that either prepares or administers volatile radioactive material (i.e. >30 mCi of I-131 sodium iodine). Bioassay will be performed within three (3) days, of administration or preparation, as per Appendix O.

The University of Louisville has instituted a policy regarding exposure to the fetus of the “Declared” pregnant worker. This policy has been approved by the Radiation Safety Committee and the Administration of the University of Louisville. Any occupationally exposed workers wishing to declare their pregnancy should follow the policy outlined in Appendix EE.

D. Sealed Sources

All radioactive sources requiring periodic leak tests will be tested according to 902 KAR 100.060 regulations by University Radiation Safety Personnel, using the procedures in Appendix N. Sealed sources for medical use and dose calibrator sources above the exempt quantities listed 902KAR100:080 will be inventoried quarterly and records showing quantities and kinds of radioactive material, location of sources, date of inventory and survey of storage location, shall be maintained for review.

E. Waste Disposal

1. Solid Waste.

Solid waste will be held for decay or disposed as de minimus as per 902 KAR 100:021 (Appendix L), or transferred to an NRC or Agreement State or NRC licensed disposal service. All material transferred to another licensee will be shipped in accordance with applicable state or U.S. DOT regulations. Records of such transfers will be kept.

2. Liquids

No liquid radioactive waste will be released via the sanitary sewerage system except human excreta from Nuclear Medicine procedures.

F. Radiation safety procedures and instructions for the handling of patients containing therapeutic amounts of radioactive material

1. Hospital Routine

For patients requiring hospitalization, the RSO shall be notified in advance when a patient is to be given a therapeutic amount of radioactive material and informed of the radionuclide, planned dosage and when it is to be administered. The RSO will then make special radiation safety arrangements, including radiation measurements (1) at bedside, (2) one meter above the patient to establish presence of thirty millicuries or greater gamma emitting radiopharmaceutical and (3) the surrounding uncontrolled areas, placement of necessary caution signs on the bed or room, and (4) posting a Nursing Care instructions. See Appendices M, for more detailed instructions. Rubber or plastic gloves shall be available and worn whenever contamination is suspected. Surveys shall be conducted anytime contamination is suspected.

2. Release or Discharge from the hospital of patients containing radioactive material. Patients containing or receiving radioactive material shall remain hospitalized until the sources are removed or their content of radioactivity is reduced to an acceptable level (Appendix S). After release of the patient, an exit survey shall be performed to assure absence of radioactive contamination. For residual activities, established guidelines will be followed (Appendix T).

3. Emergency Surgery or death of a patient containing radioactive material.

- a. Contact Radiation Safety (852-5231) if Emergency Survey is required. Scheduled surgery, as a planned follow-up to the administration of radionuclides should be delayed until after a 24 hour period.
- b. The surgeon or pathologist who may be called upon to work with the patient or body containing radioactive material should be fully informed that he is dealing with radioactive material and be monitored during the procedure.
- c. If a radioactive patient dies in the hospital, the physician who pronounced the patient dead shall contact the physician in charge of the case and the RSO shall be notified at once.
- d. Autopsies may be carried out only after consultation with the RSO.
- e. The funeral director will be notified and instructed in special precautions as deemed necessary by the RSO (See Appendix U).

G. Radiation Emergencies

Relatively large quantities of radioactive material are available in a nuclear medicine department. Much of the total quantity is in a liquid form, normally contained by glass or plastic. Should a container be broken, all the avenues of exposure are then available -- direct exposure, surface contamination, airborne contamination, and ingestion. Radiation workers must be alert to prevent conditions, which might lead to an emergency situation, and to respond appropriately should an emergency arise.

The most probable radiation emergencies are considered to be:

1. Radioactive Material Spills

Spills present a hazard to personnel through direct exposure and contamination. The best protection is through effective preventive, containment, and cleanup efforts. Specific

spill procedures have been developed (Appendix H) and are posted at appropriate locations.

Thorough familiarity with these procedures is important to assure proper immediate response.

2. Fire

Fire is an emergency in itself that may be compounded when radioactive material is involved. Heat may destroy glass and plastic containers of radioactive liquid or melt lead radiation shielding.

Combustible materials should be kept to an absolute minimum in areas where radioactive materials are utilized or stored. Know the fire response procedures; how to turn in an alarm and how to contact the local fire department. Notify the fire department of the presence of radioactive materials and brief its staff on special precautions to be taken when entering a restricted area.

3. Decontamination

Contamination precautions and decontamination procedures are maintained for the protection of the people administering radioactive substance. Rigid techniques help control contamination. It is an unwritten law for personnel working with radionuclides that they decontaminate their own "spills" and area, under the supervision of the Radiation Safety Officer.

a. Procedure to Follow

- i. Put on disposable gloves (also boots if necessary) before entering the room or area.
- ii. Prevent liquid from spreading (contain by placing any absorbent material over the spilled liquid).

- iii. Monitor the spill, equipment, or people involved to determine the amount of radiation being emitted.
- iv. All persons not involved and not contaminated should remove themselves from the area immediately.
- v. Contaminated clothing, including shoes, should be removed before the individual leaves the area. Thorough washing should be accomplished immediately.
- vi. Monitor personnel after washing. Repeat washing as necessary. Excessive scrubbing of the body should be avoided. Use of hot water should be avoided because it increases circulation to the contaminated area of the body and enhances the absorption of radioactivity into the circulating blood. Warm water and mild soap is recommended.
- vii. Radioactive particles are more easily removed from hard surfaces, such as stainless steel basins, than from more porous materials.
- viii. Minor cuts should be encouraged to bleed, thereby reducing absorption capabilities. The treatment of major cuts should be considered before contamination.
- ix. Brushes are not good for applying friction to a surface. The bristles cause splattering and spreading of contamination.
- x. Place all trash and waste in moisture-proof containers for removal from the area.

- xi. Wash and monitor yourself thoroughly; this is essential.

Contamination under the fingernails becomes the major problem in the decontamination of hands.

- xii. Report the incident as required by procedures.