

1. INTRODUCTION

The Minimum Service Delivery Standards came into existence pursuant to the promulgation of the Punjab Healthcare Commission (PHC) Act 2010, which heralds the beginning of a new paradigm of healthcare service delivery framework in Punjab. The PHC has disseminated the MSDS amongst all the key stakeholders and will employ teams of trained surveyors, comprising of health experts and subject specialists, to survey Health Care Establishments (HCEs) using a standard monitoring approach (MSDS Implementation Toolkit) at various stages from the issuance of provisional to a regular license. The PHC has developed the "MSDS Reference Manual for Hospitals" to facilitate and guide HCEs in the implementation of MSDS.

1.1. Target Users

This is a reference manual for all MSDS implementers including Policy Makers, HCE Owners, Health Managers, Healthcare Providers, Support Staff and Surveyors.

1.2. Theme

The basic theme of this manual remains explanations and references to policies and procedures/SOPs to be adopted by the implementers to address the demands of the Minimum Standards required to be reached. Numerous explanations and SOPs have been developed/adopted for better understanding of Quality Improvement Program in various settings.

1.3. Methodology

The experts at the PHC, with the assistance of a consultant provided by TRF, drafted the MSDS Reference Manual and presented it to a pool of Public and Private sector experts, including the Technical Advisory Committee (TAC) members, who extensively reviewed the draft individually and then collectively in a consultative workshop to make it suitable for all Hospitals providing services in multispecialty and single specialty settings. Their recommendations were subsequently incorporated and got confirmed by the relevant specialists before finalization at the PHC. The Draft Manual has finally been approved by the PHC Board of Commissioners.

1.4. How to use this manual

Providing healthcare that complies with the minimally required standards, and ensuring appropriate documentation of all processes undertaken in the provision of healthcare services, is the principle for MSDS implementation. It is to be remembered that care not documented, is considered care not provided. The users are expected to carefully read and understand the requirement of each standard and then go to the relevant indicator (Reproduced in the Reference Manual from the MSDS). Explanations under the indicators will then be easily understood for implementation actions, documentations and notifications.

HCEs may modify the Guidelines/SOPs to match their needs in producing better results.

2.1

Access, Assessment, and Continuity of Care (AAC)

2. STANDARDS

2.1 Access, Assessment, and Continuity of Care (AAC)

A healthcare organization should consider the care it provides as part of an integrated system of services, healthcare practitioners and professionals, and levels of care, which make up a continuum of care. The goal is to correctly match the patient's healthcare needs with the services available, to coordinate the services provided to the patient in the organization, and then to plan for discharge and follow-up. The result is improved patient care outcomes and more efficient use of available resources.

The laboratory must provide useful clinical data. Data must be legible, accurate, reported in clearly designated units of measurement, and promptly reported to persons authorized by law to receive and use medical information. Reference intervals (normal ranges) must be readily available to clinicians, preferably on the test report itself.

Similarly, radiology is now the key diagnostic tool for many diseases and has an important role in monitoring treatment and predicting outcome. It has a number of imaging modalities in its armamentarium which have differing physical principles of varying complexity. Radiologists have been strongly involved in technological developments and have been responsible for much of the evaluation of the strengths and weaknesses of different investigations. They have developed the knowledge of the appropriate integrated imaging algorithms to maximize clinical effectiveness. The standards described here deal with the implementation of these developments into the clinical setting and for ensuring the best use of assets and healthcare resources.

STANDARD-1. AAC-1: LABORATORY SERVICES ARE PROVIDED AS PER THE REQUIREMENTS OF PATIENTS

IND.1 SCOPE OF THE LABORATORY SERVICES IS COMMENSURATE TO THE CLINICAL SERVICES PROVIDED BY THE ORGANIZATION

Scope of Laboratory Services

- i. The hospital shall have a well-organized, adequately supervised laboratory with adequate space, facilities and optimum temperature for equipment to perform **services commensurate** with the hospital's needs for its patients.

Basic clinical laboratory services necessary for routine examinations shall be available regardless of the size, scope and nature of the hospital. Provision shall be made to carry out adequate clinical laboratory examinations including Chemistry, Microbiology, Haematology, Serology, and Clinical Microscopy.

Laboratory facilities and services shall be available for emergency tests at all times.

- ii. Some services may be provided through arrangements (Contacts/TORs) with other Licensed Hospitals and Laboratories/Diagnostic Centres in the Public/Private Sector which have the appropriate facilities.

The Healthcare Establishment (HCE) should ensure the availability of laboratory services commensurate to the healthcare services provided by it during hospital working hours, either by in house or outsource arrangement, however the emergency tests directly affecting the patient's emergent care should be available in house for example RBS, ABG, Cardiac Enzymes etc.

IND.2 ADEQUATELY QUALIFIED AND TRAINED PERSONNEL PERFORM AND/OR SUPERVISE THE INVESTIGATIONS

Staff Authorized to Perform or Supervise

The HCE identifies the laboratory staff members performing tests, including those who are approved to perform point of care screening tests at the bedside, and those who direct or supervise staff performing tests. Supervisory and technical staff should have appropriate and adequate qualifications (Histopathology, Microbiology, Immunology, Haematology and Chemical Pathology etc.), training, experience, skills and are oriented to their work. The technical staff is given work assignments consistent with their qualification, training and experience. In addition, the HCE shall ensure that there is a sufficient number of staff to perform tests promptly and to provide necessary laboratory services during all hours of operation and for emergencies. Staff

with proper qualifications, appropriate training and experience shall interpret tests and write reports.

Clinical laboratory services are under the direction of an individual who is qualified by virtue of documented training, expertise, and experience. This individual assumes professional responsibility for the laboratory facility and the services provided in the laboratory, as well as tests performed outside the laboratory such as the testing performed at bedside (point of care testing). The oversight of services outside of the laboratory includes ensuring consistent organization wide policies and practices, such as training, supply management etc., but not daily supervision of those activities. Daily supervision remains the responsibility of the leaders of the department or unit in which the testing is conducted.

- i. A Laboratory Manager/Director with the following qualifications may be positioned at a hospital:
 - a. A medical graduate qualified in any discipline of pathology. He/she may be a PhD, FCPS, MRCPATH, M.Phil or some equivalent degree, OR
 - b. A person with diploma in clinical pathology (DCP)

The Manager/Director is responsible for testing, Quality Assurance, personnel training, equipment and inventory.

- ii. Other required staff are given below:
 - a. Technicians and Technologists, with a Diploma in Lab Technology/BSC/MSC who are responsible for conducting testing.
 - b. Support Staff
 1. Phlebotomists: They should be given in-house training on the Sample Collection Manual
 2. Typist/Administrative staff
 3. Cleaning staff

IND.3 POLICIES AND PROCEDURES GUIDE THE: 1. COLLECTION, 2. IDENTIFICATION, 3. HANDLING, 4. SAFE TRANSPORTATION, 5. PROCESSING AND 6. DISPOSAL OF SPECIMENS

SOPs for Handling of Specimens

i. Sample Collection

Specimen collection is the first phase of interaction between the patient and the laboratory. Appropriate counseling should be done before specimen collection, and consent taken whenever needed. Attention should be paid to the patient's sensibilities during the entire process. Any error in specimen collection can lead to erroneous results. It is therefore

considered an important step of good clinical laboratory practice and is referred to as "**pre-analytic control**".

A phlebotomist/laboratory technician will be responsible for collecting the sample.

- a. Specimen collection can be done at the patient's bedside, in the laboratory or in the field.
- b. Trained manpower should be employed for specimen collection.
- c. A Laboratory should have a "Primary Specimen Collection Manual", containing information on patient preparation before specimen collection (if any), and the exact methodology of specimen collection, labelling, handling, transportation and storage of the specimens. In addition, the laboratory should provide adequate and appropriate information/instructions to patients wherever necessary. All pre-analytical factors that may influence the test results should be identified. This manual should be available for reference and should be used for the training of staff engaged in specimen collection.

Guidelines for obtaining/collecting specimens;

1. Collect the material from the site in which the etiologic agent will most likely be found.
2. Collect the specimen at the optimum time (e.g., early morning sputum for acid-fast bacillus (AFB).
3. Obtain cultures prior to administration of antibiotics whenever possible.
4. Collect adequate volume of material. Inadequate amounts of specimen may yield false negative results.
5. Collect the specimen in a manner that minimizes or eliminates contamination from indigenous flora as much as possible, to ensure that the sample will be representative of the infected site.
6. Use appropriate collection devices, transport media and sterile, leak proof containers.
7. Use sterile equipment and aseptic technique to collect the specimen, to prevent introduction of microorganisms during invasive procedures.
8. Clearly label the specimen including specific information regarding the site of collection (e.g., blood obtained via blue lumen of right subclavia central catheter) and complete the ordering process.
9. Identify the specimen source and/or specific site correctly so that proper processing methods and culture media will be selected by the laboratory personnel.

10. If the specimen is collected through intact skin, cleanse the skin first with 70% alcohol followed by an iodine solution (e.g. povidone-iodine) or chlorxidine/alcohol combination. If iodine is used, remove excess iodine after the specimen has been collected.
11. Provide clear instructions to patients if they are collecting their own specimen (e.g., clean catch urine, or stool) in order to obtain the best quality specimen and allay their fears.
12. Deliver the specimen promptly to the laboratory. Delay in transport may compromise the specimen.
13. As with all patient contact episodes, consistent attention must be given to hand hygiene and use of appropriate personal protective equipment (PPE).
14. Use appropriate safety devices to minimize risk of accidental needle stick, cut or puncture. It is advisable to make sure the user is knowledgeable about how the safety device works prior to its use.

Every laboratory should make a LAB Safety Manual according to the following guidelines;

Laboratory Safety Procedures

A. GENERAL

- I. Work carefully and cautiously in the laboratory, using common sense and good judgment at all times.
- II. EATING, DRINKING AND SMOKING ARE PROHIBITED in the laboratory and in the laboratory space of a combined lecture/laboratory room.
- III. Long hair must be tied back during laboratory sessions.
- IV. Open toed shoes are prohibited.
- V. No sleeveless tops are permitted. Thighs and midriffs must be covered with protective clothing while working in the laboratory. Lab coats must be worn when directed by the instructor.
- VI. Identify the location of all exits from the laboratory and from the building.
- VII. Be familiar with the location and proper use of fire extinguishers, fire blankets, first aid kits, spill response kits and eye wash stations in each laboratory.
- VIII. Note the location of the red phones (if available) that provide direct access to the Office of Management. In the event of an emergency, pick up the red receiver and state the

location and the nature of the emergency. Identify the location of the nearest desk phones.

- IX. Report all injuries, spills, breakage of glass or other items, unsafe conditions, and accidents of any kind, no matter how minor, to the instructor immediately.
- X. Keep sinks free of paper or any debris that could interfere with drainage.
- XI. Lab tables must be clear of all items that are not necessary for the lab exercise.
- XII. Wash hands and the lab tables with the appropriate cleaning agents before and after every laboratory session.

B. OPEN FLAMES - FIRE HAZARD

- I. Identify and be familiar with the use of dry chemical fire extinguishers that are located in the hallways and laboratory rooms.
- II. Flames are only to be used under the supervision of the instructor.

C. SHARP OBJECTS AND BROKEN GLASS

- I. Pointed dissection probes, scalpels, razor blades, scissors, and microtome knives must be used with great care, and placed in a safe position when not in use.
- II. Containers designated for the disposal of sharps (scalpel blades, razor blades, needles, dissection pins, etc.) and containers designated for broken glass are present in each laboratory. Never dispose of any sharp object in the regular trash containers.
- III. Report all cuts, no matter how minor, to the senior.
- IV. All labs and the preparation room house a first aid kit containing antiseptics, bandages, Band-Aids and gloves to care for minor cuts.
- V. Do not touch broken glass with bare hands. Put on gloves and use a broom and dustpan to clean up glass. Dispose of ALL broken glass in the specific container marked for glass. Do not place broken glass in the regular trash.
- VI. When cutting with a scalpel or other sharp instrument, forceps may be used to help hold the specimen. Never use fingers to hold a part of the specimen while cutting.
- VII. Scalpels and other sharp instruments are only to be used to make cuts in the specimen, never as a probe or a pointer.

D. NOXIOUS CHEMICALS

- I. Material Safety Data Sheets should be available in a yellow binder mounted on the door of the laboratory. In case of a spill, an accident or a safety question, staff can find chemical safety information in the Data Sheets.
- II. The lab should be equipped with a portable safety exhaust hood for the handling of noxious fumes.
- III. Chemical spill clean-up kits are available in every lab.

E. INSTRUMENTS AND EQUIPMENT

Care must be used when handling any equipment in the laboratory. The staff is responsible for being familiar with and following correct safety practices for all instruments and equipment used in the laboratory.

I. *Microscope Handling*

- a) Microscopes must be carried upright, with one hand supporting the arm of the microscope and the other hand supporting the base. Nothing else should be carried at the same time.
- b) Microscopes must be positioned safely on the table, NOT near the edge.
- c) After plugging the microscope into the electrical outlet, the cord should be draped carefully up onto the table and never allowed to dangle dangerously to the floor.
- d) The coarse adjustment must NEVER be used to focus a specimen when the 40x or oil immersion lens is in place.
- e) When finished with the microscope, the cord should be carefully wrapped around the microscope before returning it to the cabinet.
- f) The microscope must be placed upright and in the appropriate numbered slot in the cabinet.
- g) All prepared microscope glass slides are to be returned to their appropriate slide trays; wet mount preparations are to be disposed of properly.
- h) Malfunctioning microscopes should be reported to the instructor.

II. *Hot Plates and Water Baths*

- a) The instructor will regulate the temperature of hot plates and water baths with a thermometer.
- b) This equipment must be placed in a safe place.

- c) Use insulated gloves or tongs to move beakers or test tubes in and out of the water baths.
- d) Use care when working near hot plates and water baths, as they may still be hot even after being turned off.

F. PRESERVED SPECIMENS

- I. Gloves (latex and non-latex) are provided to handle preserved specimens.
- II. When larger specimens are being dissected, the part of the specimen that is not being dissected should be kept enclosed in the plastic bag.
- III. When dissecting smaller specimens, seal the bag after removing the specimen, so as to confine the preservative in the specimen bag.
- IV. Notify the instructor if there is a spill of preservative.
- V. Body parts or scraps of the specimen are NOT to be disposed of in the sink.
- VI. Dispose of dissecting pins or other sharp objects in the red sharps containers, NOT in the regular trash.
- VII. Specimens are to be clearly labelled and stored in designated containers or cabinets when not in use.
- VIII. Follow the directions of the instructor concerning the proper disposal of preserved specimens after they are finished being used

G. BODY FLUIDS

Special precautions are to be followed in all laboratories using any body fluids, such as blood, saliva, and urine, because of the potential to transmit disease-causing organisms.

- I. Follow all instructions carefully.
- II. Use gloves and goggles in all laboratory experiments that involve the use of body fluids.
- III. All contaminated material, such as slides, cover slips, toothpicks, lancets, alcohol swabs, etc., must be placed in a biohazard bag for proper disposal and should never be reused.
- IV. No samples of body fluids are to be brought into the laboratory from outside sources.

HISTOLOGY & CYTOLOGY LABORATORY SAFETY PROCEDURES

The following laboratory safety guidelines for Histology and Cytology are in addition to the laboratory safety procedures to be followed for all sorts of laboratories:

- i) Students are only permitted to work on the preparation of histology slides (including infiltration and embedding, sectioning, and staining) during the scheduled class time and under the guidance of the instructor.
- ii) Staff should wear protective gloves when handling fixatives, embedding solutions, and staining solutions.
- iii) Only water is to be poured down the sinks; all chemical solutions should be collected in labelled waste containers.
- iv) Xylene must be used under the hood.
- v) Any spills should be reported immediately to the instructor or laboratory technician.
- vi) Staff must use forceps to transfer slides from one coplin jar to the next.
- vii) All lids on the coplin jars must be secured except when transferring slides from one jar to the next.
- viii) All sharp instruments (e.g., razor blades and microtome blades) must be handled with extreme care and disposed of in designated sharps containers.
- ix) Before removing a paraffin block from the microtome, the microtome wheel must be locked in position and the microtome blade must be removed from the blade holder.
- x) All scraps of paraffin must be swept from the floor and the microtome table, using a dustpan and brush.
- xi) Microtomes must be covered when not in use.
- xii) The specimen should be secured properly so that there is no leakage, spillage or contamination. A Biohazard symbol should be used on the containers during transportation. Appropriate specimen transportation kits (such as use of dry ice, etc.) should be used wherever required. The specimen should be sent to the laboratory along with the requisition form.

Figure No. 1



ii. Identification and Labelling

A properly labelled sample is essential so that the results of the test match the patient. The key elements in labeling are:

- a. Patient's surname, first and middle.
- b. Patient's ID number.

NOTE: Both of the above MUST match the same on the requisition form.

- c. Date, time and initials of the sample collector must be on the label of EACH tube.
- d. Automated systems may include labels with bar codes.

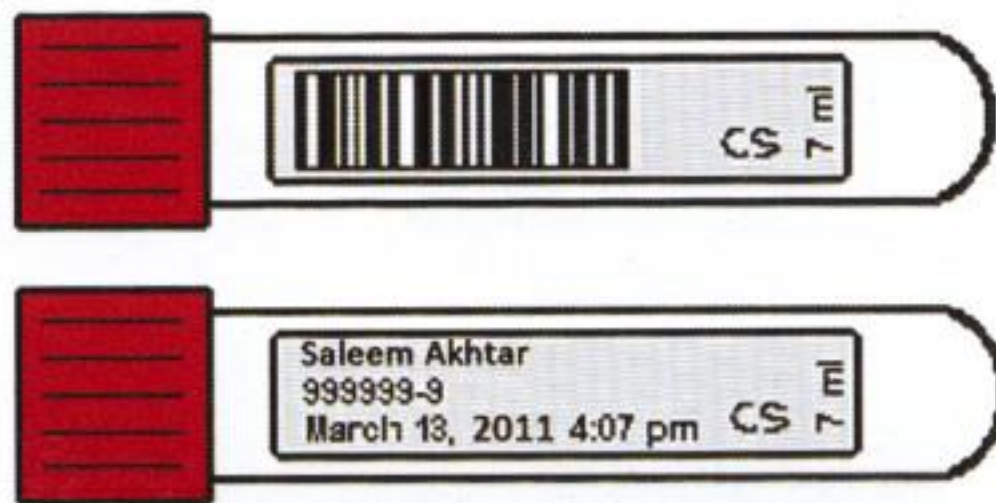
The date and signature/initials of the collector must be recorded after the specimen has been collected and after verifying that the patient's name and ID on the label agrees with that on the test requisition. This is the single most important factor in preventing errors in a patient's specimen identification. **Use of a request form wrapped around the container is not acceptable as a specimen label.** Specimens will not be accepted if the information on the specimen label does not match the information on the accompanying requisition.

Figure No. 2



Examples of labelled collection tubes are shown below:

Figure No. 3



iii. Handling

There is clearly a difference between the hazards posed by packages sent to a specialist or reference laboratory and those to a routine diagnostic laboratory. The former are likely to contain cultures or concentrates of infectious agents whereas the bulk of the latter is not particularly infectious. It is advisable that cultures and such specialized materials are unpacked in the laboratory by professional staff. There is concern over the use of clerical staff for receiving and documenting specimens. It is not unusual to see food and drink being consumed by clerical staff near the specimens. The disturbingly large numbers of untrained staff who acquire infections in the laboratory undoubtedly include clerical and reception staff. Therefore, **it is essential that clerical staff handling specimens should be given some form of training in the safe handling of specimens.** Any specimen in a plastic bag which carries a "Danger of Infection" label should not be removed from that bag. The **accession number** can be put on the outside of that bag. Leaking or broken specimens should not be touched. Provision should be made for a member of the professional staff to deal with such samples. These specimens should not be allowed to be moved to other parts of the room.

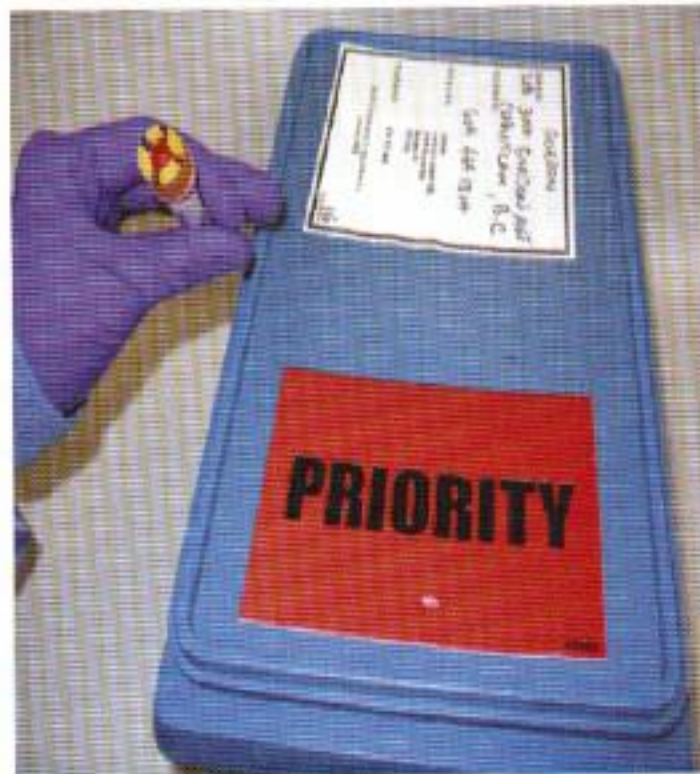
Figure No. 4



Note: Handle all samples as if infectious.

iv. Safe Transportation

Figure No. 5



Transport within hospitals and to referral labs.

All employees are required to take reasonable care of their own health and safety as well as that of all other persons who may be affected by their acts or omissions at work. Responsibility for the safe collection and packaging of clinical samples shall rest entirely upon the sender, it is

therefore imperative that all areas where clinical materials are generated remain conversant with up to date safety codes of practice.

All laboratory specimens are potentially hazardous.

It is important that care is taken when collecting and handling clinical samples to ensure that the risk of infection to staff is kept to an absolute minimum. These rules must be observed at all times and never allowed to lapse at busy periods or because of a failure to maintain adequate supplies of bags or containers. Members of staff employed within the laboratory must not be put at risk because of ignorance, negligence or bad technique.

Note: Never leave samples unattended in a public area.

Transport of Samples using Courier Services

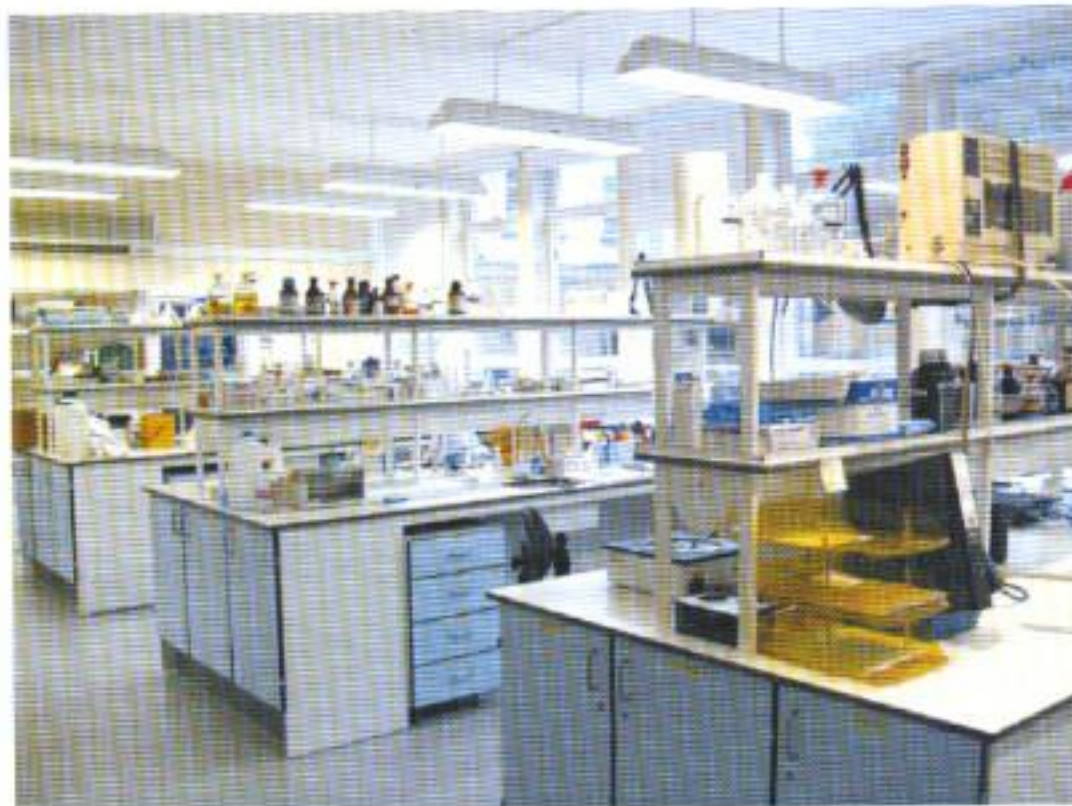
- a. Samples must always be carried in closed boxes, which are clearly marked as **Biological Substance**.
- b. Samples must be individually bagged, placed in a secondary bag containing absorbent material, sealed and carefully placed in the transport container.
- c. Two storage boxes will be provided for each surgery or clinic, one for holding bloodspecimens and one for non-blood specimens.
- d. On collection by the couriers, the samples will be transferred by the couriers into two separate transport boxes, one for blood, and one for non-blood, lined with a clear plastic bag containing absorbent material and which can be secured with a cable tie when full.
 1. Where a patient's pathology request requires both blood and non-blood samples, these should be placed in the non-blood containers.
 2. Blood and tissue slides should be regarded as sharps and placed in an appropriate plastic slide transport box before packaging.
 3. Handle specimen containers gently at all times.
 4. Samples must never be carried unprotected in the open hand or given to other members of staff in this way.
 5. Samples must not be left unattended when not secured in the van.
- e. The patient's confidentiality must be preserved at all times.
- f. In the event of a vehicle breakdown or a road traffic accident, do not allow persons other than courier or laboratory staff to handle specimens.
 1. Any spillage must be reported immediately to a designated senior member of the department concerned.

2. Decontamination materials shall be carried in each vehicle to enable small spillages to be contained. In the event of major contamination, the Pathology Support Services must be contacted before any material is touched.
- g. The response by the Pathology laboratory staff will depend upon the size and extent of the spillage and upon the level of contamination.
- h. All decontamination shall be in accordance with the Pathology Safety Policy which should be available as SOPs. Always wash hands thoroughly before rest breaks and at the end of a work period.

v. Sample Processing

- A. Collect the required amount of specimen. While small amounts of blood are now used for many automated tests, there are minimum requirements. Optimum collection volumes allow for the test to be repeated and verified if necessary.
- B. Minimum volumes are to be used for patients where unnecessary blood loss may affect patient status.
- C. When difficulties are encountered with blood volumes, consult the laboratory. Avoid haemolysis, which can elevate certain analytes (e.g., LDH, K, AST).
- D. Follow specific specimen processing instructions. The laboratory should develop its SOPs in this regard.
- E. A Quality Control manual should be developed by each laboratory.
- F. Instrument and method of testing for each test should be defined.
- G. Periodic calibration of equipment as per laboratory/manufacturer guidelines should be conducted and records should be documented.
- H. Never decant or aliquot the specimen from one type of container to another.
- I. Unusual specimens (lipemic, icteric, hemolyzed) may require a repeat specimen.
- J. When using tubes with anticoagulants, especially for coagulation tests, a sufficient fill volume is required to ensure the appropriate specimen dilution.
- K. Use the proper container and mix all specimens containing anticoagulant or preservative by gentle inversion 8 to 10 times.
- L. Reference ranges and critical values should be defined for each test.

Figure No. 6



vi. Sample Disposal

Make an inventory of toxic compounds in the laboratory and prepare a protocol for their collection and disposal.

Waste sample remains should never be disposed of by washing down a drain. Use proper receptacles for this purpose. Nevertheless, sinks and gullies should be fitted with removable SILT TRAPS which should be emptied regularly. In certain cases, heavily polluted samples may have to be treated as toxic chemical waste.

Figure No. 7



General guidelines for hazardous materials disposal are given on the following page.

1. INFECTIOUS WASTE

A. GENERAL

- I. Infectious waste must be disposed of in a carefully controlled manner in accordance with National Guidelines on Hospital Management.
- II. Infectious waste has been defined to include biological waste, cultures and stocks, pathological waste, and sharps.
- III. Infectious waste must either be incinerated or treated prior to disposal.
- IV. The term infectious waste is synonymous with biohazard; it **does NOT include** chemical agents, such as carcinogens, which affect living organisms through chemical means.

B. DEFINITIONS

I. *Biological Waste*

- a) Includes blood and blood products, excretions, exudates, secretions, suction and other body fluids that cannot be directly discarded into the municipal sewer system.
- b) **EXCLUDES** articles contaminated with fully absorbed or dried blood.
- c) Biological waste must either be incinerated or sterilized with steam in a dedicated autoclave.
- d) After treatment, biological waste may be treated as normal refuse.

II. *Cultures and Stocks*

- a) Includes etiologic agents and associated biologicals, including specimen cultures and dishes and devices used to transfer, inoculate and mix cultures.
- b) Includes wastes from the production of biologicals, serums, and discarded live or attenuated vaccines.
- c) Cultures and stocks must be treated in the same way as biological waste.

III. *Pathological Waste*

- a) Includes biopsy materials, all human tissues and anatomical parts from surgery and other procedures.
- b) Includes carcasses and bedding from animals exposed to pathogens in research, but does NOT include teeth or preservative agents such as formaldehyde.
- c) Pathological waste must be incinerated.

IV. *Sharps*

- a) Includes needles, scalpel blades, lancets and syringes that have been removed from their original sterile containers.
- b) Sharps must be incinerated.
- c) The definition **DOES NOT EXEMPT** needles or syringes used for non-infectious materials, such as transferring chemical solutions.

C. DISPOSAL

- I. Waste which is to be incinerated must be collected and taken to an infectious waste incinerator.
- II. Waste which may be disposed in the ordinary trash should be clearly marked "NON-INFECTIOUS" or "STERILE" and put inside outer packaging which is **NOT** red or orange in color.
- III. Autoclaves used for infectious waste treatment must be designated and tested.
- IV. Autoclave users must develop written operating procedures to keep records with detailed parameters for treatment, methods for monitoring, methods for indicating adequate sterilization conditions during each treatment, and monthly tests of sterilization conditions using a specified biological indicator.

D. STORAGE

- I. Infectious waste should be segregated from other wastes by putting it in separate containers at the point of generation.
- II. Locate containers to minimize access by unauthorized persons and clearly identify as containing infectious waste.
- III. Except for sharps, store infectious waste in red plastic bags OR containers made of other materials impervious to moisture and strong enough to prevent tearing under normal use conditions.
- IV. Pathological, biological and culture/stock wastes should be treated or disposed within 7 days of generation, or within 30 days if refrigerated or frozen.
- V. If a generator (laboratory or department) produces less than 50 pounds of waste in a calendar month, the 7 day storage limitation does not apply.
- VI. Sharps should be contained in leak proof, rigid, puncture resistant RED containers which have tight lids or are taped closed.
- VII. There is no limit on the length of storage for sharps.

2. CHEMICAL WASTE

GENERAL

- I. Prior to disposal of any chemical waste, a designated person must perform an **official hazardous waste determination** to see if the waste is hazardous.
- II. A short list of non-hazardous chemicals can be notified; all others should be considered hazardous until the determination has been made.
- III. Hazardous waste is incinerated, at off-site locations, whenever possible. Departments are encouraged to employ waste reduction procedures to limit costs. Use these guidelines to prepare and request disposal of hazardous chemical waste.

Hazardous chemical waste refers to any material substance that is

- i) CORROSIVE (pH<2 or pH>12)
- ii) REACTIVE (oxidizers, water reactive)
- iii) FLAMMABLE (flash point <140 F)
- iv) TOXIC

Containers

- i) All waste must be in appropriate **NON-LEAKING** containers with **lids that are non-leaking, tight fitting** and are **not cracked, broken, or chemically damaged**.
- ii) The container size should match the amount of waste.
- iii) Containers must be compatible with the waste contained.
- iv) Liquid containers must be less than 5 gallons and weigh less than 45 pounds.
- v) Paper or cardboard primary containers should be put into sealed plastic bags.
- vi) Except for common solvents which can be bulked together, waste disposal charges are related to container volume rather than solely a weight basis; a partially full container may cost the same as a full one.

Labels

- i) All unused chemicals in original non-leaking containers with the manufacturer's label will be accepted as it is.
- ii) All other waste requires a hazardous waste label. The labels must be completed and attached to each waste container, except for very small containers.
- iii) Labels should be affixed in a manner that does not cover existing labels or markings.

- iv) Solvent labels should preferably be put onto string tags attached to containers.
- v) Complete the LOWER part of the label with your name, building, room number, department, and identification of contents. Include total weight or volume and percent ranges for all constituents.

Packing

- i) Generators should find cardboard boxes and make them available to the designated staff at the time of waste removal.
- ii) **DO NOT pack waste in boxes**, since waste containers will be examined by visual inspection.
- iii) Sanitary staff will pack waste in boxes according to compatibility.
- iv) Boxes should be sealable when necessary, and sturdy enough to transport the material.
- v) Boxes exceeding 45 pounds or 18 inches on a side cannot be safely handled by one person, and will not be picked up.

3. EMERGENCIES

- A. **HAZARDOUS MATERIAL SPILLS** are an inevitable part of most work environments. To effectively combat spills, it is necessary to prepare for them beforehand. Whenever employees work with a substance, they should be aware of its characteristics, and should have formulated plans of what to do in case of a spill, including what steps to take, who to call for assistance, what PPE is necessary, and what material is appropriate to contend with a spill, and where to find appropriate spill-response equipment. Departments are encouraged to have spill response kits at strategic locations.
- B. **GENERAL GUIDELINES** The first step in dealing with any chemical spill is to assess the magnitude of spilled material and the associated level of hazard. No one should attempt to deal with a spill until properly equipped with adequate PPE and spill treatment materials. Risk assessment is successful only if personnel are familiar with the hazardous properties of the material they are handling and have developed methods to follow in the event of a spill.
- C. **PROCEDURES** If the risk assessment suggests you can safely and properly clean up the spill :
 - I. **Get personal protective equipment.** Do not attempt spill response until you have put on PPE appropriate for the situation. Available equipment may include respiratory protection, goggles, gloves, impervious shoes/boots, and body protection. All equipment will not be necessary for every situation, but should be

available. If you are unsure about your ability to control a spill, get assistance. Any spill for which respiratory protection is needed must not be conducted without backup personnel equipped in the same manner.

- II. **Get spill control equipment** from your department's spill kit. Spill control materials are sold in two general forms: loose materials (vermiculite, cat litter) and spill control pillows, which are produced in various shapes and contain different types of absorbents. Spill control pillows are preferred because they are much easier to pick up when finished. Also available are materials designed for specific types of chemical spills such as acids or solvents. In general, spilled liquids present more danger than solids, and quick response is therefore critical. For flammable liquids, special attention should be paid to potential ignition sources in the vicinity.
- III. **Absorb** the spill. If there is danger the spill may spread, dike the perimeter with absorbent, then absorb. "Floor chemistry" should not be attempted. If you desire to perform simple neutralization/treatment schemes, first absorb and contain the material.
- IV. **Collect** the contaminated absorbent and put into a sturdy leak proof container. Close the container if there are volatile substances which may continue to pose a threat.
- V. **Dispose** of the contaminated absorbent in the same manner you would dispose of the substance that was spilled. If the spilled chemical is hazardous, do not put the cleanup residue in the dumpster. If hazardous, contact professionals to dispose.

4. EMPTY CONTAINERS AND GLASS

A. EMPTY CONTAINERS

- I. Containers that have held hazardous substances are empty by definition when one of two following conditions is met. For one group of materials, a container is empty when all contents have been removed by techniques ordinarily used for that type of material (e.g., pouring for liquids), and the container has less than 3% of the original contents. For another group, a container is only empty when it has been triple rinsed with a solvent capable of removing the remaining contents. Contact the manufacturer for specific discussions of which group a material falls into.
- II. In all cases, remove as much of the contents as possible before disposal (including recycling). For liquids, this would be turning the container upside down and letting it drain until no more drops will come out. For low viscosity liquids such as aqueous solutions, let drip no less than 60 seconds.

B. NON-HAZARDOUS CHEMICALS

- I. A designated person must perform an official hazardous waste determination for disposal of all chemicals.
- II. Collect solids in disposable, non-leaking containers, labelled with contents, clearly marked as non-hazardous, and prepared for disposal.
- III. Solutions containing only non-hazardous, water miscible liquid materials, with pH between 6 and 9.5, can be disposed through the sewer system.
- IV. Remember: **"hazardous" includes flammable liquids even if water soluble.**

The items listed below are considered NON hazardous:

- a) Acetates: Ca, K, Na, K, Mg, NH₄
- b) Naturally occurring amino acids and salts
- c) Citric acid and salts of Na, K, Mg, NH₄, Ca
- d) Bicarbonates: Na, K
- e) Borates: Na, K, Mg, Ca
- f) Bromides: Na, K, NH₄
- g) Carbonates: Na, K, Mg, Ca, NH₄
- h) Chlorides: Na, K, Mg, Ca, NH₄
- i) Formates: Na, K, Mg, Ca, NH₄
- j) Lactic acid and salts of Na, K, Mg, NH₄, Ca
- k) Sugars and sugar alcohols
- l) Starch
- m) Iodides: Na, K, Ca
- n) Oxides: B, Mg, Ca, Al, Si, Fe, Zn
- o) Phosphates: Na, K, Mg, Ca, NH₄
- p) Silicates: Na, K, Mg, Ca
- q) Sulfates: Na, K, Mg, Ca, NH₄

Caution: Chemicals and chemical products should not be given or sold to the general public or offered as surplus property. Commercial chemical products may be offered as surplus property if reasonable cautions are followed.

C. TREATMENT

- I. Elementary neutralization can be performed on wastes which are hazardous only because they are corrosive (acids, bases).
- II. A neutralized solution should have a final pH value between 6 and 9. Corrosive waste should not be discharged through the sewer system.
- III. Treatment of other materials to lessen the hazard or amount of waste can be included as part of the SOPs in laboratories.
- IV. Such procedures should be written and made a part of specific experimental protocol.

5. RADIOACTIVE WASTE DISPOSAL

A. GENERAL PROCEDURES

- I. Only containers available from authorized departments shall be used.
- II. Each radioactive waste container must have a record of materials in the container which is kept up-to-date.
- III. Mark each container with a "Caution-Radioactive Material" label.
- IV. Package the waste according to the instructions given for each waste type below.
- V. Segregate waste according to half-life:
 - a. less than 91 days = short-lived
 - b. greater than 90 days = long-lived
- VI. When the container is full, complete a *Radioactive Waste Disposal* tag. Instructions are on the back of the tag.
- VII. Attach the tag to the outer surface of the container.

B. SOLIDS

- I. Segregate by half-life.
- II. Place dry waste in drums, marked "Dry Radioactive Waste Only."
- III. Place all solid radioactive waste (filter papers, gloves, bottle caps, **empty** scintillation vials, etc.) into the innermost plastic liner.
- IV. When full, tape the plastic liner shut; do not overfill.
- V. Do not put unabsorbed liquid in dry waste drums.

- VI. Do not put contaminated equipment or radioactive powders in dry waste drums.
- VII. Contain sharps in a separate rigid red plastic container to prevent puncture injuries.

C. LIQUIDS

I. Aqueous wastes

- a) Segregate aqueous waste by half-life.
- b) Must be placed in carboys with secure screw tops.
- c) Must have a "Caution - Radioactive Material" label attached.
- d) Keep containers closed during storage.
- e) Supply secondary containment able to contain the liquid in case of breakage.
- f) Segregate LSC fluid, aqueous, and other liquids.

II. Scintillation vials with counting fluid

- a) Must be placed in a container supplied by the duly authorized firm.
- b) Mark container "Scintillation Vials Only".
- c) Carefully place UNOPENED vials into the inner plastic liner. When full, tape the plastic liner shut; do not overfill.
- d) Dispose of bulk liquid scintillation counting fluid by emptying into properly labelled liquid waste jugs and treating as liquid waste.
- e) Segregate scintillation fluid from other liquid wastes.
- f) Empty scintillation vials may be washed and reused, or may be disposed as dry waste if they contain NO residual scintillation fluid.

D. MIXED WASTE

Mixed waste is any waste material, other than LSC fluid, that contains radioisotopes and possesses other hazardous properties; i.e. the waste is:

- I. Flammable or explosive
- II. Toxic
- III. Corrosive (pH greater than 12.5 or less than 2)
- IV. Reactive
- V. Persistent (halogenated hydrocarbons and polycyclic aromatic hydrocarbons with more than three and less than seven rings)

- VI. Carcinogenic
- VII. Mixed waste must be characterized for isotope as well as hazardous components and concentrations (% by weight or volume)
- VIII. Common examples of mixed waste include:
 - a) Radio-labelled carcinogens
 - b) Solvents containing radioisotopes
 - c) Contaminated lead
- IX. There is a disposal option for liquid scintillation cocktail containing radioisotopes.

E. WASTE STORAGE

The storage of hazardous materials must be in compliance with National Guidelines on Hospital Management. Your methods of handling waste are subject to unannounced inspections by regulatory inspectors.

- I. All containers need to have a **label** at all times indicating the contents. For waste materials, this could be a simple label such as "WASTE SOLVENT" or "USED ACETONE".
- II. Put the label on the container **BEFORE ADDING WASTE**.
- III. All containers need a lid at all times when not actively adding or removing waste. Evaporation in a hood is **not** a legal disposal method. **Funnels do not count as lids.**
- IV. Secondary containment is advised for liquid containers.
- V. Storage limits and locations are the same for waste as for new materials. For example, storage of flammable liquids in excess of 10 gallons requires a flammable liquid storage cabinet. Glass bottles may **not** be stored on the floor because they can easily be broken by accidental kicking.

Figure No. 8



vii. Storage of Specimens and Blood in the Wards, Labs and in other Departments

It is the responsibility of the laboratory staff that:

- a. Specimens should be stored in wards or labs, for a limited time period, and arrangements should be made for processing or disposal as early as feasible.
- b. Proper storage facility should be provided in the wards and labs (storage cabinets, freezers etc.).
- c. Ensure the appropriate labelling of the specimen container and the pathology request form if the patient is known or suspected of having a disease considered "high risk".
- d. Ensure that the specimen is packaged and stored in a suitable and safe manner.
- e. Routine Histology specimens must be placed directly into formalin and can be stored at room temperature until transported to the Histology Laboratory.
- f. Frozen Section specimens must be sent dry, directly to the Histology Laboratory.
- g. FNA slides for Cytology Referral should be stored at room temperature until transported to the Histology Laboratory.

Some of the Histology slide boxes are as given below:

Figure No. 9



Figure No. 10



IND.4 LABORATORY RESULTS ARE AVAILABLE WITHIN A DEFINED TIME FRAME

Timely Reporting of Laboratory Results

- i. The organization defines the time period for reporting laboratory test results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergency tests and after-hours and weekend testing needs are included. Results from urgent tests, such as those from the Emergency Department, Operating Theatres, and Intensive Care Units, are given special attention in the planning and monitoring process. In addition, when laboratory services are by contract with an outside organization, the reports must also be timely as set forth by organizational policy or the contract.
- ii. Turnaround time is defined as the period of time from receipt of the specimen in the laboratory to release of the result. Results of routine tests drawn are generally available,

- the following day. In some cases, owing to the complexity of the test or when the test is not performed on a daily basis, a longer turnaround time may be indicated.
- iii. The head of the laboratory must establish a liaison with the clinical administration requesting for a test to ensure that specimens are delivered promptly to the laboratory and that there is no delay between dispatches of the reports from the laboratory until they reach their destination. Any delays that have occurred must be investigated and steps must be taken to solve the problems and avoid the problems in future. The HCE/Laboratory shall ensure availability of adequate staff, material and equipment to make the laboratory results available within a defined time line.

IND.5 CRITICAL RESULTS ARE REPORTED IMMEDIATELY TO THE CONCERNED PERSONNEL

SOPs for Reporting Critical Laboratory Results

- i. Critical test results are defined as any values/interpretations for which delays in reporting can result in serious adverse outcomes for patient care. These values should be defined by the laboratory director, in consultation with the concerned clinicians. The scope includes laboratory, cardiology, radiology, and other diagnostic tests in the inpatient, emergency, and ambulatory settings¹.
- ii. All critical reports are verbally informed to the concerned consultant immediately by the pathologist. The laboratory should have procedures for immediate notification of a physician, or other clinical personnel responsible for patient care, when results of certain tests fall within established "alert" or "critical" ranges.
- iii. As soon as the technical validity of the results has been established by a senior technician/technologist, the requesting doctor must be contacted without delay. If the identity of the requesting doctor is not obvious from the request form, his/her identity must be ascertained from the ward. If this fails, urgent results can be phoned to the ward or clinic sister or the most senior nurse on duty.
- iv. When results are transmitted verbally, in all cases the request form must be signed to indicate when and to whom and by whom the results are communicated. This must always be followed by a written report.
- v. Such results will be telephoned to any patient-care unit lacking a computer terminal. A written record of test results telephoned to patient care areas must be made by the physician, nurse or other individual who receives the report.
- vi. The process developed by the organization for managing the critical results of diagnostic tests must include a definition of critical tests and critical values for each type of test, by

¹Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards.

whom and to whom the critical test results are reported, the established time frames for reporting and follow-up and an established method for monitoring compliance.

- vii. Advanced technologies and innovations may be used for prompt reporting/communication of results to the requesting clinicians.

Note: Blood Group results must never be given by telephone.

IND.6 LABORATORY TESTS NOT AVAILABLE IN THE ORGANIZATION ARE OUTSOURCED TO ORGANIZATION(S) BASED ON THEIR QUALITY ASSURANCE SYSTEM AND INDEPENDENT ACCREDITATION

Outsourcing Specialized Tests

Specialized tests not performed in the hospital are referred to external laboratories. The laboratory director shall select the reference laboratory. Specimens for referral laboratories are dispatched from the Pathology Department. When results are received from the referral laboratory, the original report is always forwarded to the requesting clinician. A list of the referral laboratories currently being used should be displayed.

Laboratory management, with the advice of users where appropriate, shall establish a procedure(s) for the referral of specimens to other laboratories and to consultants who are to provide second opinions, which includes:

- i. Evaluating and selecting referral laboratories and consultants in terms of competence to perform the requested examinations and ensuring that there are no conflicts of interest.
- ii. Maintaining a record of all referral laboratories.
- iii. Maintaining a record of all specimens referred.
- iv. Recording of dispatch dates.
- v. Maintaining a record of reports.
- vi. Monitoring the return of reports from the referral laboratory or referral consultant.
- vii. Defining the respective responsibilities for the interpretation and reporting of referred examinations.
- viii. Periodically reviewing the arrangements with referral laboratories to ensure that requirements including terms of EQA performance and turnaround times continue to be met.

Note: Referral laboratories should, where possible, be accredited by some accreditation body or meet the requirements of the sender's quality management system.

STANDARD-2. AAC-2: IMAGING SERVICES ARE PROVIDED AS PER THE CLINICAL REQUIREMENTS OF THE PATIENTS

IND.7 IMAGING SERVICES COMPLY WITH LEGAL AND OTHER REQUIREMENTS

Compliance with Statutes

A request for a Radiological Examination/Diagnostic Imaging will be regarded as a request from a Clinician or Health Professional to the Radiology Department for an opinion based upon a radiological examination, to assist in the management of a clinical problem.

- i. Diagnostic Imaging or radiological procedures will only be performed upon a written request signed by a Registered Medical or Dental Practitioner.
- ii. Signed referrals (request form or letter) must precede or accompany the patient. Signed faxes are also accepted. Only doctors are permitted to sign, not nurses or other paramedical staff. There should be an appropriate use of the PMDC ID i.e. the Registration Number.
- iii. All requests must carry sufficient information to identify the patient. This normally consists of the first name, middle name if any, and family name, date of birth and address.
- iv. All requests must carry sufficient clinical information to enable the requested examination to be justified. The referral forms should contain adequate information to justify the procedure requested. The radiologist is responsible for justifying the procedure.
 - a. All requests shall clearly state the examination requested.
 - b. All requests must include the contact details of the Referring Clinician, including the address and telephone number.
 - c. All requests for X-ray examinations (between the diaphragm and the knees) for all fertile females must state the date of the first day of the patient's menstrual period.
 - d. The organization shall have a system for providing radiology and diagnostic imaging services required by its patient population, clinical services offered and Health Care Provider(HCP) needs.
 - e. Radiology and diagnostic imaging services, including those required for emergencies, may be provided within the HCE, by agreement with another organization, or both. Radiology and diagnostic imaging services are available after normal working hours for emergencies.
 - f. Outside sources are convenient for the patient to access, and reports are received in a timely way that supports continuity of care. The HCE selects outside sources based on the recommendation of the director or other individual responsible for radiology and diagnostic imaging services. Radiology and

diagnostic imaging services, in house as well as outside sources, must meet applicable laws and regulations (enforcement of PNRA regulations and other statutory requirement) and have an acceptable record of accurate and timely services. Patients are informed when an outside source of services is owned by the referring physician.

- g. Every HCE should have SOPs for outsourcing (from the request to the assessment of service provider and turnaround time of the report).
- h. All the statutory requirements e.g. clearance from Pakistan Nuclear Regulatory Authority (PNRA), use of dosimeters, lead sheets, lead aprons, signage, display as per relevant regulations are to be met with.

IND.8

SCOPE OF THE IMAGING SERVICES IS COMMENSURATE TO THE CLINICAL SERVICES PROVIDED BY THE ORGANIZATION

Scope of Imaging Services

The Radiological/Diagnostic Imaging Services shall aim at providing safe, efficient, and quality services as required for good patient care. Specific radiological and diagnostic imaging services provided shall depend upon the size and scope of the facility (to be enlisted by the HCE). Staff strength shall be commensurate with the number of beds, patient load and investigations performed.

A full complement of imaging services (to be enlisted by the HCE) should also be provided to cater to emergency situations arising from the services delivered by the HCE. Adequate support* service must be available at places where invasive imaging services are provided, to meet with an event of emergency. This involves resuscitation and in some cases emergency surgery/CABG when cardiac procedures e.g., angioplasty etc. are involved.

IND.9

ADEQUATELY QUALIFIED AND TRAINED PERSONNEL PERFORM, SUPERVISE AND INTERPRET THE INVESTIGATION

Authorization to Perform, Supervise and Interpret

Radiology and diagnostic imaging services, provided at any location in the organization, are under the direction of an individual who is qualified by documented training, expertise and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the radiology and diagnostic imaging facility and the services provided. When this individual provides clinical consultation or medical opinion, he/she is a qualified/authorized radiologist.

The radiology and diagnostic imaging director's responsibilities include;

- i. Developing, implementing, and maintaining policies and procedures.
- ii. Administrative oversight.
- iii. Maintaining any necessary quality control program.
- iv. Recommending outside sources of radiology and diagnostic imaging services.
- v. Monitoring and reviewing all radiology and diagnostic imaging services.

The organization identifies which radiology and diagnostic imaging staff members perform diagnostic and imaging studies, those who are approved to perform point of care tests at the bedside, those who are qualified to interpret the results or verify and report results, as well as those who direct or supervise the processes. Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their work. Technical staff members are given work assignments consistent with their training and experience. In addition, there is a sufficient number of staff to perform, interpret and report studies promptly and provide necessary staffing during all hours of operation and for emergencies.

Human Resource for Diagnostic Radiological and Imaging Services:

- i. The radiologist in charge of the diagnostic imaging services may be available full-time or part-time depending on the size and complexity of the department.
- ii. The authority and accountabilities (e.g. Error report, Audit report) of the person in charge are clearly delineated.
- iii. The diagnostic imaging services shall be staffed with a qualified radiologist, qualified radiographers, nursing, clerical and administrative staff.
- iv. Sufficient numbers of qualified personnel and support staff are employed to enable the services to meet the documented purposes.
- v. A qualified radiologist and radiographer shall be on duty or be available on-call after normal working hours.
- vi. There is evidence of a staff development plan, which provides the knowledge and skills required for staff to maintain competency in their current positions as the demands on the positions evolve. There is evidence of competency assessment.
- vii. There is a structured orientation programme where new staff is briefed on their services and relevant aspects of the facility to prepare them for their roles and responsibilities.
- viii. There are continuing education activities for staff to pursue professional interests and to prepare for current and future changes in practice. There is evidence that staff education and development needs have been appraised and identified.

- ix. Staff receive written evaluations of their performance at the completion of the probationary period and annually thereafter, or as defined by the facility.
- x. Proper instructions are provided and safety precautions are implemented for the protection of patients and staff who are exposed to the hazardous equipment.
- xi. In a teaching hospital, the diagnostic imaging services, subject to requirements of safety and comfort, provide for the relevant educational needs of under-graduates and post-graduates.
- xii. In facilities which have teaching and research responsibilities, the staff of the diagnostic imaging services gives their cooperation or participate in the teaching and research programmes related to the field of diagnostic imaging².
- xiii. A radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is **not** considered a treating physician.

A physician should supervise diagnostic tests. Supervision may be of following type:

General Supervision: This means the procedure is performed under the physician's overall direction and control, but the physician's presence during the performance of the procedure is not required. Under general supervision, training of the non-physician personnel who actually performs the diagnostic procedure, and maintenance of necessary equipment and supplies are the continuing responsibility of the physician.

Direct Supervision: This means a physician must be in attendance in the room during the performance of the procedure and be available to furnish immediate assistance and direction throughout the performance of the procedure.

Interpretation of results is an important component of the service provided by the Radiology and Diagnostic Imaging Department.

The frequency of such comments may vary between specialties;

- a. The management of the Laboratory/Radiology Department shall ensure that advice on examinations and the interpretation of results is available to meet the needs and requirements of users.
- b. Interpretive comments on reports shall be clear, succinct and unambiguous.
- c. Clinical advice and interpretive comments shall only be provided by authorized personnel with appropriate training.

²Malaysian Society for Quality in Health. (2008). *Hospital Accreditation Standards 3rd Edition*.

- d. There shall be systematic communication between Laboratory/Radiology and clinical staff to promote effective utilization of services and to consult on scientific and logistic matters. Where appropriate, a record of such meetings shall be kept.

IND.10**POLICIES AND PROCEDURES GUIDE IDENTIFICATION AND SAFE TRANSPORTATION OF PATIENTS TO IMAGING SERVICES****Identification and Safe Transportation of Patients****i. Identification**

Identification of a patient is done by asking the patient/relatives and comparing the particulars on a Request Form which is on a standard format and contains:

- a. Client's/Patient's name
- b. Identification number
- c. Computerized National identity card (CNIC) number
- d. Address
- e. Date of birth (if not available, then age)
- f. Examination requested
- g. Previous examinations
- h. Clinical diagnosis/indications/relevant history
- i. Information relating to the gestational status in women of childbearing age
- j. Identity of the requesting physician
- k. History of allergy, in red ink
- l. The Radiologist is responsible for the justification of any radiological investigation
- m. He/She will also have to communicate with the primary referring physician and obtain optimum clinical information to perform the investigation.
- n. For medico legal cases(MLC), a mark of identification of the client/patient and name of the police official bringing the client/patient.
- o. Fee to be charged/not to be charged.

ii. Safe Transportation

- a. Some radiology tasks demand the usage of some push or pull force that radiographers must exert when moving patients from one area to another. Exertion of an excessive force may increase the risk of injury to the back, legs, shoulders or any other part. Fragile bodies of older patients/already injured are more prone to further trauma or harm.
- b. For the safety of the human resource, use mechanical power assisted devices whenever heavy patients or large equipment are required to be moved for longer distances. Ensure that a sufficient number of employees are available to move heavy patients. Employee/s should not exert excessive force at any point during the transportation/shifting.
- c. For example, radiographers should be trained to use correct body mechanics when moving patients during procedures, including interalia the following;:
 1. Push instead of pull. Lean slightly into the load to let your body weight assist with force exertion.
 2. Push at about chest height.
 3. Push smoothly and slowly to start.
 4. Do not bend or twist while exerting force.
 5. Keep wrists straight.
 6. Keep elbows close to the body.

Transferring Patients to and from the Exam Table

- A. Radiographers may need considerable support and assistance to move patients to or from examination tables.
- B. Use mechanical powered transfer devices such as lifts or hoists to move patients, especially non-ambulatory, from wheelchairs, beds, or stretchers.
- C. When appropriate, use multi-use devices such as chairs that can open up into beds. These allow patients to move from a sitting position to a prone position, without transfer.
- D. Additional employees should assist in moving and transferring equipment or patients if:
 - I. A mechanical powered device is not available.
 - II. Awkward postures are forced to be used.
 - III. Excessive push force or lifting or supporting a heavy weight is required³.

³United States Department of Labor, Hospital e-Tool, Transporting Patients and Equipment.

IND.11 IMAGING RESULTS ARE AVAILABLE WITHIN A DEFINED TIME FRAME**Timely Reporting of Radiology Results**

The organization defines the time period for reporting diagnostic radiology and diagnostic imaging study results. Results are reported within a time frame based on patient needs, services offered, and the clinical staff's needs. Emergency tests, after-hours and weekend testing needs are included. Results from urgent radiology and diagnostic imaging studies, such as those from the Emergency Department, Operating Theatres, and Intensive Care Units, are given special attention in the planning and monitoring process. Radiology and diagnostic imaging studies performed by outside contractors of services are reported according to organizational policy or contract requirement.

Radiology Turnaround Time (RTAT) means the time from the examinations until the reports are completed;

- i. It would be feasible to have all the inpatient reports within 24 hours and all the outpatient report within 48 hours.
- ii. The referring physician should formally communicate with the radiologist for all emergency procedures (RTAT should be one hour).
- iii. All verbal communications have to be followed by written documentation. Use of PACS/EMR/ICT should be encouraged.
- iv. Reports can be amended only by adding addendums (timed and signed).

The implementation of a Radiology Information System (RIS) and a Picture Archiving and Communication System (PACS), and the integration of these systems with the Electronic Medical Record (EMR), may improve the use of diagnostic imaging in clinical practice. This Information and Communication Technology (ICT) can reduce the radiologists' reporting time, and make the reports and images instantly available to clinicians hospital-wide.

Before the ICT introduction, radiologists used to read images on film and clinicians had to walk to the Radiology Department to look at these images. Reports were printed and distributed on paper. For emergency ultrasound cases, handwritten summaries accompanied the patients returning to the wards. After the ICT introduction, images are immediately (within five minutes) available hospital-wide to clinicians with legal access to the patient's record. All radiology reports are entered directly into the EMR as soon as they are finished (also within five minutes). The reports are issued in two versions: a preliminary version after one radiologist's examination of the images, and a final version once a specialist in radiology had verified the conclusion⁴.

⁴BMC Health Services Research. (2010). Retrieved from <http://www.biomedcentral.com/>

IND.12 CRITICAL RESULTS ARE INTIMATED IMMEDIATELY TO THE CONCERNED PERSONNEL**SOPs for Reporting Critical Laboratory Results**

Critical results **MUST** be communicated in a timely manner, within one hour. Communication of these results to the physician has to be ensured using any one or a combination of forms of communication e.g. Telephone/fax/email - PACS/EMR/ICT.

- i. Appropriate people for communication:
 - a. **MUST** be a trained HCP responsible for the patient.
 - b. The patient/next of kin if the HCP is not accessible.
- ii. Not acceptable for communication:

A Nurse or physician or an employee of the unit with no responsibility for the patient.
- iii. When communication is verbal it **MUST** be documented, including:
 - a. Person communicating and person to whom the communication is made.
 - b. Time and date of communication.

List of Radiology Critical Results

- i. **General:** Retained sponge or other clinically significant foreign body, new/unexpected and clinically significant mass/tumour or arterial dissection/occlusion.
- ii. **Acute Abdomen:** Life-threatening obstruction; previously undiagnosed abscess, acute thrombotic or embolic event, including DVT; unexpected or previously undiagnosed free air or active leakage; previously undiagnosed, clinically significant haemorrhage or vascular disruption, ectopic pregnancy and intestinal ischemia.
- iii. **Acute Head:** Unexpected and clinically significant intracranial haemorrhage, new midline shift, aneurysm, abscess and meningoencephalitis; clinically significant herniation; new/unexpected cerebral infarction.
- iv. **Acute Neck:** Acute airway compromise, new, clinically significant, unexpected abscess, discitis and unexplained haemorrhage.
- v. **Acute Spine:** New, unexpected, clinically significant discitis, abscess, cord compression or transection and acute cord haemorrhage or infarct.
- vi. **Acute Chest:** New, unexpected, clinically significant collapse of lung, pneumothorax and pulmonary artery embolus.
- vii. **Acute Skeletal:** Impending pathologic fracture and new, unexpected, clinically significant fracture.

- viii. **Nuclear Medicine:** Newly diagnosed absent perfusion in a postoperative kidney, brain death (transplant team waiting for results) and new high probability ventilation/perfusion (V/Q) lung scan⁵.

IND.13 QUALITY ASSURANCE ACTIVITIES ARE EVIDENT IN THE IMAGING DEPARTMENT

Quality Assurance (QA) Program

- i. A QA Program is designed by the management to assure the quality of a product or service. Such a program can have wide-ranging aspects including client feedback, employee empowerment and Quality Control (QC).
- ii. QC involves specific actions designed to keep measurable aspects of the process involved in manufacturing a product or providing a service within specified limits. These actions typically involve measurement of a process variable, checking the measured value against a limit and performing corrective action if the limit is exceeded.
- iii. All medical facilities using X-ray equipment, from a simple intraoral dental unit to an image intensified special procedures system, will benefit from adopting a QA program. An established program will monitor the imaging process from start to finish and reveal potential problems that may otherwise go unrecognized. QA in medical imaging is a rapidly evolving concept and each facility is encouraged to continually pursue ways to improve and expand its program.
- iv. It is essential that one person at a given facility, the QA Coordinator, be in charge of maintaining the QA program and be allotted the time, equipment and space necessary to carry out required duties.
- v. The QC program is based on planning and purchasing the proper equipment, then establishing a high standard of quality and maintaining it. The information provided should enable the Coordinator to set up and monitor the entire program. If a facility protocol is not available for a specific type of equipment (e.g., digital imaging systems), the manufacturer's recommendations should be followed. Establishing an open line of communication with representatives from the PNRA and other technical experts, will make it much easier to set a standard.
- vi. The following equipment may be used for a QC program.
 - a. Sensitometer (21 Step)
 - b. Densitometer
 - c. Box of film (clinically used)
 - d. Aluminium step wedge

⁵UAB School of Medicine, Department of Radiology. Retrieved from <http://medicine.uab.edu/radiology/8349>

- e. Brass or copper mesh screens (1/8 inch or 3 mm spacing) large enough to cover largest cassette in use at facility
- f. Measuring tape
- g. Non-mercury thermometer
- h. Cleaning equipment for screens, cassettes and darkroom
- i. Fluoroscopic test tool

Once you have become proficient at performing the tests the time spent will be minimal. Daily tests should take about 5 minutes to perform and should be done prior to the first patient image of the day. Monthly tests will add an additional 10 minutes to the daily tests. Quarterly tests will take about 45 minutes to perform. The semiannual test for darkroom fog should take no more than 5 minutes to perform and analyze. The annual tests will probably take 1 to 2 hours to perform.

Quality Control Manual

A QC Manual should be created and reviewed at least annually. The manual should include the facility's objectives, QC instructions, QC results, and personnel responsibility. Daily/monthly/quarterly/annual audit should be performed and recorded. SOPs for QA should be clearly defined in the manual.

These can be the following:

- i. Patient related (satisfaction/complaints/RTAT)
- ii. Service related (HR/Equipment/Work space etc.)
- iii. Confidentiality of patients and their reports

The following should also be included in a QC Manual:

- i. A list of the tests to be performed and the frequency for each test, including acceptable test limits, test procedures, maintenance and service records.
- ii. A list of equipment to be used for testing.
- iii. Policy and procedures for QC tests as well as for the facility.
- iv. Sample forms.

Questions asked during a review might include:

- a. Is image quality maintained at the desired level?
- b. Is the X-ray technique chart up-to-date?
- c. Is the screen-film combination used still the best suited for our facility?
- d. Do all personnel meet the required or established qualifications?
- e. Does any equipment need to be replaced?
- f. Do any QC procedures need to be changed or updated?
- g. Are personnel adequately performing assigned tasks?

- h. Is patient and personnel radiation exposure as low as reasonably achievable?
- i. Are all documents up-to-date and accurate?⁶

QA is done with monitoring the following:

1. Tracking Turnaround time and waiting times-
 - A. Methodology: Turnaround time is tracked by manually tracking the in and out time of the patient for each modality in the department.
 - B. A suitable sample (7 days) will be taken for this study.
2. Grading of X-ray films is done by the radiologist-
 - A. Grading of X-ray films is done on the following criteria

I.Positioning	-	1
II.Artifacts	-	1
III.Exposure factors	-	1
 - B. Grading - scores
 - I.Total score of 3 for each Patient to be documented for X-rays.
 - II.In case the quality is graded 1, the X-ray is to be repeated on the radiologist's opinion and more care is to be taken during repeat X-ray.
 - III.Grading score should not be less than 90%.
 - IV.If below 90%, the reason should be evaluated and discussed with the radiologist and rectified immediately.
3. Reject rates for films:
 - It should be less than 3% of the Monthly consumption.
4. Confidentiality of Reports: Confidentiality of patients and their test reports are ensured through the following:
 - A. In the course of performing work responsibilities all information with regard to the patient, their family, their physician and/or the hospital is kept confidential.
 - B. All staff of the department is cautioned not to discuss any such information with others.

⁶Quality Control Recommendations for Diagnostic Radiography, Vol. 3. (July 2001). *Radiographic and Fluoroscopic Machines*. Published by Conference of Radiation Control Program Directors, Inc.

- C. The radiologist is the only person authorized to inform reports to the doctors.
- D. Sound QC systems are essential for providing excellent radiology and diagnostic imaging services.

In summary there is a QC program for the radiology and diagnostic imaging services and it comprises of following:

- i) Validating test methods.
- ii) Daily surveillance of imaging results.
- iii) Rapid correction when a deficiency is identified.
- iv) Testing reagents and solutions.
- v) Documenting results and corrective actions.

IND.14

IMAGING TESTS NOT AVAILABLE IN THE ORGANIZATION ARE OUTSOURCED TO ORGANIZATION(S) BASED ON THEIR QUALITY ASSURANCE SYSTEM AND COMPLIANCE WITH APPLICABLE LAWS AND REGULATIONS

Outsourcing of Radiological Tests

When the organization uses outside sources of radiology and diagnostic imaging services, it should regularly receive and review the QC results of that outside source through qualified individuals. When diagnostic imaging QC of outside sources is difficult to obtain, the manager develops an alternative approach for quality oversight.

Mechanism/SOPs have to be developed e.g., who will approve/call/respond and what would the turnaround time of the service be.

Outside sources are convenient for the patient to access, and reports are received in a timely way that supports continuity of care. Outside sources of radiology and diagnostic imaging services should meet applicable laws and regulations (as specified by PNRA) and should have an acceptable record of accurate and timely services.

Note: *Referral Radiology and Diagnostic Imaging Services should where possible, be accredited by some accreditation body or meet the requirements of the sender's Quality Management system.*