CRITERIA FOR ACCREDITATION OF AN ULTRASOUND DEPARTMENT

Prepared by: SADCAS Advisory Committee - MIAS	**Approved by**: Chief Executive Officer	**Approval Date**: 2022-03-29 **Effective Date**: 2022-03-29

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1. PURPOSE AND SCOPE

The purpose of this document is to define the SADCAS general, technical and specific requirements to be met by Ultrasound facilities in the field of Medical Imaging requiring accreditation to ISO 15189.

2. ABBREVIATIONS

AIUM: American Institute of Ultrasound in Medicine
CD: Compact Disc
CT: Computed Tomography
DVT: Deep vein thrombosis
EHR: Electronic Health Record
EMR: Electronic Medical Record
FAST: Focused Assessment with Sonography for Trauma
FNA: Fine Needle Aspiration
ID: Identity
MRI: Magnetic Resonance Imaging
OPD: Outpatient Department
PACS: Picture Archiving and Communication System
QA: Quality Assurance
SOP: Standard Operating Procedure
TVS: Transvaginal Sonography
UB: Urinary Bladder
UPS: Uninterrupted Power Supply

3. GENERAL REQUIREMENTS

3.1 Service Provided

3.1.1 The scope of activities of the Ultrasound Services shall indicate which of the following services are provided on site and which are not:

- Abdominal
- Obstetrics
- Pelvis
- Vascular
- Paediatric
- Ultrasound-guided interventional techniques
- Transcranial doppler
- Elastography
- Small parts
  - scrotum
  - Breast

- Ophthalmology
- Cranial-sonography
- Musculoskeletal
- neck
- Thyroid

3.1.2. For the procedures carried out on site the Ultrasound Service shall indicate the extent to which such procedures are carried out:

- Type of procedure
- Instructions
- Standard or limited exam
- Invasive or non-invasive
- Analysis with clinical data
- Doppler studies
- Single study, Follow ups, Serial

3.1.3. Where any procedures are referred to another Ultrasound Service for complete or partial examination, such information shall be provided by the referring imaging facility:

- Identity of patient
- Identity of referrer
- Date of referral
- Reasons for referral
- History of patient

3.2 **Examination Procedures**

3.2.1**. Abdominal**

Preparation; fasting for a minimum of 8 hours or more to ensure empty stomach.

3.2.2**. Breast**

Preparation; No special preparation except removal of artifacts and infection control**.**

3.2.3**. Obstetrics first trimester**

Preparation:

- full bladder on transabdominal
- empty bladder on Transvaginal Sonography(TVS)
- technique for TVS
- use of sheaths (condoms)
- use of chaperon

- consent for procedure
- Wherever possible avoid 3D or 4D or power doppler

3.2.4. **Obstetrics second and third trimester**

Preparation; Empty bladder or minimal fluid in the Urinary Bladder (UB) for cervical assessment.

3.2.5. **Pelvis**

Preparation; Full bladder unless transrectal and transvaginal in which case requires empty bladder. Avoid risk of cervical shock in hysterosonography under pelvis.

3.2.6. **Vascular**

Preparation; No special preparation except in case of active bleeding where infection control measures can be considered

3.2.7. **Ophthalmology**

Preparation; No special preparation .

3.2.8. **Cranial-sonography**

Preparation; No special preparation.

3.2.9. **Musculoskeletal**

Preparation; No special preparation.

3.2.10. **Small parts**

Preparation; No special preparation.

3.2.11. **Paediatric**

Preparation; No special preparation for paediatrics under 2 years although room temperature is required. Those who can cooperate can be prepared as adults.

3.2.12. **Ultrasound-guided interventional techniques**

These procedures will only be done at a secondary or tertiary level of care by qualified Radiologist. Procedure Specific preparations and protocols shall be availed and followed.

There shall be a protocol for

- Fine Needle Aspiration (FNA)
- Biopsy

- Drainage or Aspiration

3.2.13**. FNA**

No special preparation.

3.2.14**.Biopsy and drainages**

Those with required qualifications only will perform the procedures.

Procedure Specific preparations and protocols shall be availed and followed.

4. RISK MANAGEMENT

4.1.1 Each department shall monitor and review the effectiveness of its ultrasound policy and procedures to manage risks.

4.1.2 Each department shall have a risk register to manage and control risks.

4.1.3 To support this, for all procedures each department shall have:

- An incident reporting Policy.
- Health and Safety Policy.
- Data Protection Policy.
- Patient Identification Policy.
- Sonographer/Radiographer Reporting Policy.
- Continuous professional development Policy.

4.1.4 Consent for procedures and policies stating clearly all cases which require verbal consent and were written consent might be required such as:

- Intimate procedures.
- Ultrasound guided Interventional procedures.

4.1.5 Chaperone Policy.

4.1.6 Image storage Policy.

4.1.7 Professional indemnity Policy.

4.1.8 Fire risk and personnel fire training Policy.

4.1.9 Spill and control of slip Policy.

4.1.10 Violence and aggression Policy.

4.1.11 Decontamination of Ultrasound Transducers – Standard Operating Procedure.

4.1.12 Infection control standard precautions shall be guided by level of criticality as indicated.

4.1.13 Specialised sterile procedures where probe contacts sterile tissue or vascular system are used during Ultrasound guided procedures such as:

- Surgery
- Intraoperative procedures
- Drainages
- Biopsies
- Needle guidance
- Transvaginal oocyte retrieval
- Venous catheter placement
- Vascular ablation

4.1.14 High level disinfection or Sterilisation is required for specialised sterile procedures.

4.1.15 Use of sterile sheath/gel is also required for specialised sterile procedures.

4.1.16 Semi sterile procedures were probe contacts mucous membranes and non-intact skin used during wound and intracavitary procedures such as:

- Transvaginal
- Transrectal
- Transoesophageal
- Wound scanning
- Burn graft evaluation
- Surface ultrasound (broken skin)

4.1.17 High level disinfection is required for semi-sterile procedures.

4.1.18 Use of sheath is also required for semi-sterile procedures.

4.1.19 Nonsterile procedures were probe only contacts healthy intact skin such as:

- Transabdominal scan
- Surface ultrasound

4.1.20 Low level disinfection is required.

5. INFRASTRUCTURE AND ENVIRONMENT

5.1.1 Each Ultrasound department in a hospital-based facility for general procedures except specialised procedures shall have at least the following:

- Area for administration, clerk, reception and section supervisors.
- Adequate Communication telephone lines for communication in different rooms
- Close access to a toilet changing area and privacy at Ultrasound room or reception
- Reporting area
- File Cabinet
- Storage for Linens and Equipment
- Counter Top and Sink with hot and cold water

5.1.2 Each Ultrasound room must have the following:

- A minimum room size to accommodate bed, machine, writing desk and stretcher movement.
- Waiting area
- Epoxy or non-slippery floor
- Sub waiting area
- Patient confidentiality in examination rooms for all procedures.
- Overhead Lights Dimmer to avoid glare in all procedures
- Dual Level Lighting (bright and dim)
- Emergency Oxygen
- Suction Line
- Space for Ultrasound system
- Dedicated Power Outlet
- Network Interface
- Optimum Heat Ventilation and Air Circulation (HVAC) system
- Ventilation shall be supported through windows or air conditioning system
- drip stands and disposal skips for the majority of types of clinical waste.
- Stepping stool
- Time services are offered must be displayed
- Information for patients and their clinicians must be provided

5.1.3 Each Ultrasound department in an out of hospital-based facility for general procedures except specialised procedures shall have at least the following:

- Area for reception.
- Communication telephone
- Close access to a toilet changing area and privacy at Ultrasound room or reception
- Reporting area
- File Cabinet
- Storage for Linens and Equipment
- Counter Top and Sink with hot and cold water

- Each Ultrasound room must have the following
- A minimum room size to accommodate bed, machine, writing desk and stretcher movement.
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- Epoxy or non-slippery floor
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- Patient confidentiality in examination rooms for all procedures.
- Overhead Lights Dimmer to avoid glare in all procedures
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6. ULTRASOUND EQUIPMENT, MEDICATION, CONTRASTS AND CONSUMABLES

For all procedures depending on level of care the department shall have documented procedures for handling equipment, medication, contrasts and consumables.

6.1 Equipment

6.1.1 Each department shall ensure that all equipment is operating correctly, effectively decontaminated prior to use and safely and regularly maintained.

6.1.2 There shall be a circuit Breaker protected and easily accessible for equipment protection.

6.1.3 There shall be an uninterrupted power supply (UPS) to the ultrasound system.

6.1.4 There shall be protocols or SOPs for:

- Selection of equipment
- Procurement of equipment
- Equipment set-up and applications training
- User Acceptance and Testing Certification
- Maintenance and repair
- Equipment modifications
- Replacement plan

- Hired equipment
- Quality Assurance (QA) procedures
- Image quality
- Reporting of equipment faults and adverse events
- Availability of Service level agreements and schedules for maintenance of equipment
- Arrangement with medical physicist for other QA procedures
- Have an equipment inventory record
- An equipment management program shall be also available for Ancillary equipment such as PPEs, Printers, resuscitation equipment and consumables.
- Emergency equipment must be nearby and easily available

6.2 Medication

6.2.1 Each department shall have protocols and Standard Operating Procedures (SOPs) which must be followed.

6.2.2 Each department shall ensure practitioners get the relevant history of the patient for any allergies before administration of any medication (prophylaxis) and sedation in preparation for any procedure particularly in Interventional ultrasound techniques such as:

- Biopsies.
- Drainage and aspirations.
- Fine Needle Aspiration (FNA).

6.2.3 Each department must have an emergency drug trolley in the event of an emergency.

6.2.4 Basic equipment for first aid according to the level of care shall be available.

6.2.5 Each department must have preparatory procedure with instructions on medication use ensuring there is:

- No medication errors that arise
- By making patients sign consent forms
- Patient indicate Drug allergies
- Record of drug used and amount used
- No or minimal adverse effects
- Proper storage
- Expiry date verification

6.2.6 Each department shall ensure drugs are administered by qualified personnel such as:

- a radiologist
- a registered nurse
- a competent Practitioner trained to administer drugs

6.2.7 Each department shall have proper guidance and instructions on route of administration such as:

- intravascular
- intramuscular
- orally
- per rectum

6.2.8 There shall be a policy and communication from the suppliers on the use of expired medication.

6.3 Contrasts

6.3.1. For departments that conduct contrast enhanced ultrasound such as hysterosonography.

6.3.2. The procedures where contrast enhanced ultrasound is done shall be listed.

6.3.3. Support from a lead medical practitioner shall be available.

6.3.4. Appropriate training shall be provided to avoid associated risks.

6.3.5. Professional indemnity Insurance shall be a requisite.

6.3.6. Quality assurance and audit programs shall be followed.

6.3.7. Consent procedures and acceptance that a sonographer is the person who shall obtain this.

6.3.8. Protocols shall be available for each individual type of procedure that the sonographer will undertake.

6.4 Consumables

6.4.1. The department shall have a stock management processes to ensure there are no stock outs.

6.4.2. The department must have in place:

- Sterile packs and appropriate equipment needed for various interventional procedures done in the department;
- Examination gloves.

6.4.3. The department must have procedures to store ultrasound gel ensuring that the gel bottles are clean

7. PRE-EXAMINATION PROCESS

7.1 The department shall have protocols to:

- Capture patient records;
- Schedule examinations taking into account turnaround time for each procedure and infectious control in case of infectious diseases such as tuberculosis;
- Cater for non-ambulatory patients, patient escorted by ambulance and senior citizens;
- Assess the completeness and accuracy of a request form with the following minimum requirements according to IAUM;
  - Patient information i.e., patient names, date of birth, address, contact details such as hospital ward or phone number and pregnancy status:
  - Examination information i.e., study requested, clinical indication and date of request: and
  - Referrer information i.e., referring practitioners' signature, name and contact details.
- Identify patient positively with any form of approved identity particulars such as National Identity (ID), driving licence or any other form of recognised patient identity;
- Ensure triaging and emergency recognition of conditions such as Focused Assessment with Sonography for Trauma FNA(FAST), infectious diseases, ambulant patients on Oxygen, RIF pai(Appendicitis), ectopic pregnancy, threatening miscarriage, Deep Vein Thrombosis, Torsion, placenta abruption, aortic dissection or leaking aneurysm etc.;

7.2 Introduce yourself and then:

- Take relevant clinical information;
- Explain procedure to patient with reassurance;
- Evaluate appropriateness of examination on presented clinical context for each case;
- Get written informed consent form the patient for interventional procedures;
- Review prior tests (clinical, labs, prior imaging);
- Properly instruct patients prior to procedure;
- Conduct quality assurance assessments to ensure:
  - There is no equipment damage;
  - The machine is clean and disinfected to avoid risk of infecting patients;
  - Cables are kept clean;
  - probes are kept clean;
  - probe holders are kept clean;
  - visuals inspections are conducted regularly;
  - There is optimum screen resolution; and
  - The room is clean and adequately prepared.

8. EXAMINATION PROCESSES

8.1. Protocols should be in place to outline the responsibilities of the practitioner such as to check:

- Request form authenticity;
- Billing and payment confirmation;
- Patient identification;
- Patient clinical information;
- Previous examinations and other clinical data;

- For availability of resources

8.2. SOPs shall be available for:

- Deciding on appropriate technique and views to be used for each case;
- Preparing the patient for procedure in the room;
- Deciding on the need for any person to assist or hold patient;
- Achieving optimization of adaptive techniques and image quality to produce accurate diagnosis;
- Critically analysing acquired images and deciding on the need for further interrogation;
- Monitoring the patient;
- Evaluating quality of diagnostic images;
- Communication of findings and advice on further management;
- Dismissing patients; and
- Preparing room for next patient.

9. POST EXAMINATION PROCEDURES

9.1. There shall be a system of eliciting feedback from patient such as:

- In person
- Or suggestion box

9.2. The department shall have protocols for archiving and delivery of results (Email, Compact Disc (CD), films) Delivery of image reports

9.3. The department shall have protocols for back up of results and reports.

10. ENSURING QUALITY OF EXAMINATIONS

10.1 Each department offering ultrasound services must ensure that:

- Every practitioner shall meet a certain level of training before they can do ultrasound scanning
- Every practitioner shall be registered to practice in their field of expertise
- Every practitioner shall have a portfolio of their continuous professional development and learning
- A record of all examinations shall be kept for regular audits (weekly, monthly)
- A second opinion to be sought in difficult cases

10.2 The department shall also have protocols to:

- verify coherence between produced images and written report
- check veracity of results
- conduct peer reviews
- proof read and sign reports
- monitor patient results delivery

- follow up on patients with referrers
- multidisciplinary teams reviewing ultrasound study reports
- verify turnaround times

11. REPORTING

11.1. An Ultrasound report shall be written and signed off by a Radiologist, Sonographer or Radiographer. Their name and signature must be appended.

11.2. Each report shall include:

- The title
- Patient identification
- Demographics
- Date
- Recipients
- Clinical history
- Clinical observations made by the Practitioner
- Comparison with previous studies, if available and pertinent information recorded.
- Statement of scope of examination (targeted or survey) and technique used
- Analysis of the significant lesion(s) or finding(s)
- Correlation with physical, mammographic Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) finding(s)
- Overall assessment or impression
- Management recommendations

11.3. Every department must have a protocol to address who the report is given.

11.4. Report shall be given to the patient except:

- Where provisions to deliver the report to the Clinician are available.
- The patient is incapacitated
- Where there is Electronic Medical Record (EMR) and/or Electronic Health Record (EHR)

11.5. Reporting times shall be specified by international guidelines.

- Routine results
- Urgent results
- Critical results

11.6. For those conditions triaged as emergency or found as critical must be communicated within an hour. Urgent results must be communicated within 24 hours. Routine results must be communicated as soon as they are ready.

11.7. Retention times for reports before they are destroyed shall be as specified by international standards and local regulatory requirements

12. PERSONNEL AND STAFFING

12.1. The staffing levels of a general Ultrasound department should be according to the number of equipment, working hours, patient volume and scope of services.

12.2. Each department offering Ultrasound services must ensure that;

- Every staff meet a certain level of competency/proficiency before undertaking examinations;
- Every staff is registered to practice in their field of expertise;
- Every staff has a portfolio of their continuous professional development and learning;
- A record of all examinations is kept for regular audits (weekly, monthly); and
- A second opinion is sought in difficult cases.

13. INFORMATION MANAGEMENT SYSTEM

13.1. Every institution must have an Information Management System which:

- Allows capturing of patient identification data;
- Handles Billing and Coding;
- Supports storage and transfer of patient Imaging data such as Picture Archiving and Communication System (PACS); and
- Monitors turnaround times;

13.2. The network bandwidth where PACS is used shall allow smooth transfer and movement of images as required by the system.

13.3. The systems shall be able support teleultrasound as it may improve clinical outcomes.

14. REFERENCES

- ISO 15189 Medical Laboratories - Requirements for Quality and Competence.
- AIUM, 2020. AIUM Practice Parameter for Documentation of an Ultrasound Examination. *J ULtrasound Med,* Volume 39, pp. E1-E4.
- Nyhsen, C. M. et al., 2017. Infection prevention and control in ultrasound - best practice recommendations from the European Society of Radiology Ultrasound Working Group. *Insights into Imaging*, 27 November, pp. 523-535.

APPENDIX - AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Subclause	Description of Change		
Issue 1	-	-		SADCAS CEO	2022-03-29