2023-2026

ACCREDITATION STANDARDS

FOR IVF CENTRES

SASREG

Southern African Society of Reproductive Medicine and Gynaecological Endoscopy

www.sasreg.co.za

Preamble

The South African Society for Reproductive medicine and Gynecological Endoscopy (SASREG) is a society that promotes quality fertility care in South Africa. It aims to serve and protect the interest of the patients undergoing assisted reproductive treatment (ART), specifically through in vitro fertilisation (IVF) treatment. We recognise the multi-disciplinary nature of reproductive science and medicine, which includes andrologists, counsellors, social workers, embryologists, nurses, and reproductive specialists.

These disciplines are all subjected to the Ethical Code of conduct set out by the Health Professions Council of South Africa (HPCSA) and governed by the Regulations of the Health Act. As a society of professional peers, SASREG does not hold any statutory powers.

SASREG appointed a multi-disciplinary task team to draft a South African-specific standards document to be applied for accreditation of ART facilities. Under the guidance of an internationally recognised expert and advisor on accreditation standards, Dr David Mortimer, from an ART-focused consultation company Oozoa Biomedical Inc., the process commenced.

This document aims to provide a framework and set criteria for SASREG accreditation. The most critical perspective of this new accreditation process is that it does not seek to check boxes but rather review the monitoring and control systems that an ART facility has in place to ensure that quality care will be provided at every phase of treatment. Therefore, there are Required Operational Procedures (ROP) that establish a minimum standard and good practice (non-ROP) standards that need certain levels of compliance to achieve accreditation.

SASREG aim to ensure that the surveying process will be carried out independently, non-adversarial, and constructively.

The accreditation process is voluntary.

This document will remain a living document, developing over coming accreditation cycles to ensure that the scheme stays relevant and current as our field advances and our quality services of ART care progress and expand.

Special thanks to the contributors in compiling these standards during 2021, the stakeholders, trial survey clinics and surveyors who provided feedback for refinement during 2022.

SASREG Accreditation Sub-Committee

Chairperson:	Ms Lydia Els-Smit
Vice-Chairperson:	Dr Chris Venter
Members:	Mr Gerhard Boshoff
	Dr Yusuf Dasoo
	Ms Marisa Marais
	Prof Igno Siebert

SASREG Presidency

President:	2020 - 2022
	Dr Sulaiman Heylen
	2022 - current
	Dr Jack Biko
Vice-President:	2020 - 2022
	Dr Jack Biko
	2022 - current
	Dr Chris Venter

** We want to acknowledge Harrilabs for sponsoring the professional editing and layout of this document, and express our gratitude to Ms Lydia Els-Smit and Dr Marie-Lena de Beer for the impressive time they have spent refining and edting the technical wording.*

Aim of the Accreditation Standards

The SASREG Accreditation Standards aim to provide a framework of quality care in fertility units across Southern Africa. The objective of the survey is to assess the systems that a fertility unit implements to ensure quality service to its patients.

The aim of the Accreditation and Standards is not to delve into specific details of the process; instead, it seeks a description of the quality control system with monitoring checks that are in place in the facility and the evidence generated on how it is maintained.

Our colleagues from several ART clinics in South Africa have compiled each section in this document, ensuring that the content is both in line with most international guidelines and according to our country's context. A complete electronic version of all the references (which were not infringing on copyrights) used is available on the SASREG website to provide a reading list to expand knowledge.

Interpretation of the Accreditation Standards

The Standards in this document are grouped into identified functional Departments of an ART organisation, namely:

- Facility Management
- Clinical Services
- Nursing Services
- Laboratory Services
- Psychological Counselling Services

The departments are dedicated according to each specialized health care service while the Facility Management department focus on the overarching aspects of the organisation's directing and management. The Clinical and Nursing departments are subdivided into functional Sections according to the specific type of services that are provided.

The Standards document is sectioned as follows:

- Management
- Clinical Consultations and Treatments
- Procedure room
- Oncofertility
- Nursing and Coordination
- Procedures and Recovery
- Laboratory
- Fertility Counselling

Each of these section's standards is further grouped according to related Areas to address, namely:

- Facility, Planning and Design
- Qualifications and Staff structure
- Equipment and Consumable Management
- Processes and Procedures
- Information, Communication and Feedback
- Risk and Emergency Management

Each section has a tabled index of the Areas and Standards to ease navigation.

Interpretation of the Accreditation Standards

The Standards in this document are compiled into a table template format for consistency, easy reading and understanding. The Standards table includes the Standards' area, name, aim, intention, understanding on a practical level and the compliance points, which are supporting information that will serve as proof of compliance.

Each Standard in the document is laid out into the following headings to describe it:

- Standard table number: Combination of the Section and Standard number
- Department and Section headings
- Standard name: Area and Standard title
- Standard Statement or Goal: The aim/objective of the Standard
- Intent: What the Standard intends to achieve and/or reason for the importance of the Standard
- Interpretation Guidelines: Explanatory details on what the Standard entails, practical aspects, and examples.
- Supporting information as Proof of Compliance: The information that will be needed as proof for achieving the goal of the Standard. Information provided as part of the self-assessment and evidence reviewed during the survey will be used to assess compliance with each Standard, also referred to as Compliance Points.
- ROP "Required Operational Practice": Indication of whether the specific Standard is required and essential or non-essential.

Specific Standards were identified as essential for accreditation and have been marked as ROP, which is either related to governmental regulatory requirements or the health and safety of staff and/or patients. A ROP Standard is indicated as a "Yes" in the ROP indicator of each Standard table and indicated in the table of contents before each section. These ROP Standards will require high compliance to achieve full accreditation status (see Compliance Level below). Non-ROP Standards are solid suggestions for good practice and may become ROP Standard in future accreditation cycles.

The numbering system of each Standard Table consists of a unique number, e.g., A.1. or E.2. generated by the combination of the assigned Section alphanumeric and the Standards number. Each compliance point is also numbered to enable specific reference to it during the survey process, e.g., A.1.i. or B.4.ii.

A list of Informative or Authoritative References that pertain to the compiled Standards document allows the organisation to refer to the guidelines and regulations relevant to each department.

Self-Evaluation and Compliance

Each organization will need to study this document and do a Self-Evaluation of their compliance with each Standard before applying for accreditation. This is an essential preparation for the survey.

As proof of compliance with each of the standards, a combination of visualization of physical aspects, live discussions, and provision of documentation in some form will be expected during the survey. The documentation requirements can be in the form of certificates, records, consents, standard operations protocols, log sheets, minutes of meetings and policies. Some documents are expected to be reviewed at the time of application, as indicated in the application process instructions (see Addendum 1).

The following simplified descriptions can be used to interpret the meaning of the various documents the Standards may refer to:

- **Certificate**: An official document provided as proof that something has happened or has been done or is true.
- **Policy**: Policies represent the global rules and framework laid down by management that govern the organization's operations.
- **Standard Operation Protocol (SOP):** SOP in health care is a written process or set of instructions to be followed to complete a job safely, with no adverse effect on personal health or environment and in a manner that maximizes the probability of a beneficial health outcome in an efficient manner.
- **Consent**: A form that contains the relevant information and is signed by a patient prior to a medical procedure to confirm that they agree to the policy being performed and understand the information given.
- **Form**: A form is a simple formatted document that is either printed or typed and contains blank spaces to insert required or requested information.
- **Record**: A record is a collection of related data contained in one or more files or a database.
- **Log sheet**: An official dated record of specific activities or events used to track patterns or operations or attendance.
- **Meeting minutes**: Meeting minutes are notes that are recorded during a meeting with dates and attendees. They highlight the key issues that are discussed, motions proposed or voted on, and activities to be undertaken.
- **List**: A list is a series or record of short pieces of information, usually arranged one below the other so that they can be read quickly or counted.
- **Index**: An index is a functional type of list that is arranged according to a system (numbering or alphabetical) to retrieve items referring to it.

There are four (4) levels of compliance that can be reached per Standard at assessment. These are as follows with their interpretations:

- **Fully Compliant**: All aspects met according to Supporting Information as Evidence of Compliance assessment.
- **Largely Compliant**: Minor aspects need attention, but no 'must' actions need to be remedied.
- **Partially Compliant**: Requires at least one "must" action recommendation that will need to be dealt with to be accredited.
- **Non-Compliant**: One or more "must" actions are required that must be resolved for accreditation to be considered; if there are too many "non-compliant" items, then accreditation could be withheld.

Compliance Level

The organization must achieve at least ≥90% Fully and Largely compliance ratings to ROP Standards and ≥70% Fully and Largely Compliant ratings for non-ROP Standards for successful full accreditation.

Provisional accreditation will be awarded when full compliance levels are closely met. Full accreditation can be achieved by submitting a few specified items on the survey report.

Non-compliant accreditation status is when most of the compliance points could not be supported with evidence viewed during the survey. A full re-survey will be required after the organization can provide proof of the required amendments made. This should be a rare event since full accreditation should be achieved during the Self-Evaluation process before application.

All departments and sections that correspond to the ART services provided by the organization are compulsory for accreditation and must be included as part of the accreditation. Oncofertility and some standards specifically indicated are optional as applicable to the organization. This must be indicated on the Self-Evaluation document and confirmed during the survey by the surveyors.

Only allowable non-applicable standards, confirmed by the surveyors, can be excluded from the compliance score calculation without a negative impact.

Application and Surveys

The organization can apply for accreditation when they have reached a satisfactory compliance level during its Self-Evaluation process.

The application process will entail submitting the completed Self-Evaluation Excel template, indicated required documents and payment of prescribed accreditation fees to SASREG. For further details, please see Addendum 1.

The survey will be performed by an appointed team of surveyors consisting of a clinician, an embryologist, a counsellor, and a nurse. The survey intends to be a physical site visit with all surveyors on-site at the facility. The Nursing department may be a virtual survey. In case of exceptional circumstances, and upon agreement with the Accreditation committee and surveyor team, one of the other departments may also be a virtual survey. All virtual surveys will include a detailed live video walk-through and screen sharing etc. to enable visual assessment of physical aspects and mimic an on-site survey as closely as possible to ensure it is not inferior.

The survey will take place over at least one full day at the organization, depending on the ease of seeing the supportive information. Virtual surveys may be arranged on a different day than the on-site survey visit.

The organization's staff should be available and have supporting information ready where possible during the survey to facilitate the survey process to enable the surveyor(s) to establish compliance efficiently during the survey visit. Ideally, a large organization with several staff per section should nominate a responsible person per department or section who will assist each surveyor during the survey processes. This can be indicated during the application. The survey team will review the Self-Evaluation and documentation submitted during the application and may discuss these with the organization before the survey visit and/or virtual appointment as part of their preparation.

At the end of the on-site survey, the surveyors may have a feedback session with the organization in the form of an exit meeting to briefly discuss their most important observations. The full accreditation feedback report will follow when all relevant departments have been surveyed, and the outcome has been confirmed.

Accreditation Outcome

The outcome of the accreditation survey will be a result of a process where the survey report is confirmed by the surveyor team, followed by the Accreditation Committee and finally approved by the SASREG Executive Committee. Any members on these Committees that are directly affiliated with the organization being accredited will be excluded from this process to prevent bias. The accreditation certificate will be issued accordingly. Any complaints from the organization regarding the survey should be addressed to the Chair of the Accreditation Committee.

In case of Provisional Accreditation being awarded, the required supporting information and evidence must be submitted on time as per the final survey report to receive full accreditation.

Full accreditation is valid for four years, after which the survey process will be repeated according to an updated Standards document that will apply to the following accreditation term.

All documentation received during the application and survey process will be held securely by Turners Secretariat upon completion of the survey process and not by any of the Surveyors, Accreditation Committee members or Board Members themselves.

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FACILITY MANAGEMENT

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Guidelines: Authoritative / Informative References

1. (South African Government, 2003)
2. (National Department of Health, no date)
3. (South African Department of Health, 2012a)
4. (Legal and Regulatory Affairs, no date)
5. (South African Government, 1965)
6. (South African Health Products Regulatory Authority, no date)
7. (The South African Pharmacy Council, 2019)
8. (South African Government, 1974)
9. (South African Government, 2018)
10. (South African Government, 2006)
11. (South African Government, 1993)
12. (Barnard, 2001)

A. MANAGEMENT

Table 1. Summary of Facility Management Standards

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	**Yes** No No	1. Building plan, structure, and installations compliance. 2. Design for efficient workflow and services. 3. Reception and waiting area(s).
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	4. Human resources.
EQUIPMENT & CONSUMABLE MANAGEMENT	**Yes** **Yes** No	5. Procurement, maintenance, and repairs. 6. Medication control and management. 7. Supply chain vendor contact list.
PROCESSES & PROCEDURES	Yes	8. Quality control of specialized services.
INFORMATION, COMMUNICATION & FEEDBACK	**Yes** No **Yes** **Yes** No	9. Documents and records. 10. General patient communication. 11. Informed consents for treatment and procedures. 12. ART data submission to national registries. 13. Complaints and feedback management.
RISK & EMERGENCY MANAGEMENT	**Yes** **Yes**	14. General Hygiene and Infection control. 15. Risk assessment and disaster plans.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.1.	Standard Name: Facility, planning & design: Building plan, structure, and installations compliance.	ROP: **Yes**
Standard Statement / Goal: The facility must comply to local authority requirements, regulations and have the compliance approvals in place.		
Intent: The facility must be structurally sound and safe for patients and staff and be fit to serve as a health facility to provide health services. The essential basic services must be adequately installed and maintained by authorized service providers.		
Interpretation Guidelines: Building structure standards must prove to be certified as compliant with local authorities' building standards as a healthcare facility. Installations of essential services, i.e., plumbing, electrical, etc., and any additional special items, or services, i.e., air conditioners, gas supply, fire plan, network cabling, etc., must be approved and/or certified by authorized providers or installers as compliant to the appropriate regulatory bodies and proof thereof kept on file. A list and agreements of authorized service providers must be available for technical repairs and/or installations of these items and/or services.		
Supporting Information as Evidence of Compliance: i. Certificate of occupation from local building inspector or authority. ii. Records of safety/compliance for installations by certified installers/providers of basic and additional services and systems. iii. List/Index of contractors for repairs for basic and additional services and installations.		

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.2.	Standard Name: Facility, planning & design: Design for efficient workflow and services.	ROP: No

Standard Statement / Goal:
The facility should be designed to be efficient in its operations when providing the services offered, with specific considerations to provide comfort for patients and occupational health and safety of the personnel.

Intent:
The design and layout of the facility should be favourable to provide the ART services it offers efficiently and effectively while including essential considerations for the comfort of patients and the occupational health of personnel.

Interpretation Guidelines:
The layout of the floor plan should be designed to optimize the flow of patients through the areas of service while providing comfort and privacy where needed. Waiting rooms and hallways should allow for the expected patient load at hectic times.

Occupational health and safety measures should be included in the design of the work areas according to their function and considering the expected daily hours spent in the work area.

Access-controlled areas should be well planned and indicated, not reducing workflow and efficiency. The facility should have clear indications of its entrances and exits for patients, which should also be access controlled for safety. Access control should consider security, confidentiality, quality, and prevailing practices.

Medical information, patient samples and laboratory resources should be safeguarded from unauthorized access.

Supporting Information as Evidence of Compliance:

i. Facility floorplan or layout and considerations for patients and personnel.
ii. Occupational health considerations.
iii. Physical walk through for flow of patients and personnel.
iv. Access control system and/or policies.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.3.	Standard Name: Facility, planning & design: Reception and waiting area(s).	ROP: No

Standard Statement / Goal:
The waiting and reception areas should have a comfortable atmosphere.

Intent:
The reception area should ensure the patient is comfortable and secure while waiting, with sufficient comfortable seating for the number of patients.

Interpretation Guidelines:
The entrance and exit should be clearly marked with appropriate signage.

There should be a visible reception desk with reception staff to attend to patients. The reception staff should have a full view of the reception/waiting area to control the entrance and observe the arrival and departure of each patient. Each receptionist should have relevant signage of the doctor/function they serve/assist, which is in clear view of the entire waiting area.

The reception and waiting area(s) should be calm, comfortable, inviting, and safe.

There should be sufficient seating to accommodate the patient load. Designated areas allocated to accommodate family members can be considered to allow partners and additional people when needed.

The waiting times should be monitored against the National Core Standards for Health Establishments in South Africa.

Supporting Information as Evidence of Compliance:

i. Facility layout to show proper considerations for reception areas where needed.
ii. Summaries of patient satisfaction survey results.
iii. Booking diary to indicate capacity.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.4.	Standard Name: Qualifications & Staff structure: Human resources.	ROP: **Yes**

Standard Statement / Goal:
The organization must have a human resource management system in place.

Intent:
The organization must have a system for managing the personnel they employ or a service contract with an applicable company. The approach must be structured and comprehensive to include records of all relevant qualifications and updated registrations at professional bodies where appropriate. Contracts and agreements with all personnel performing duties and/or providing a service to patients at the facility, including their expected responsibilities and job descriptions, must be in place.

Interpretation Guidelines:
The organization must have a policy in place on the recruitment, hiring and management of appropriate personnel, including the hiring or contracting persons for part-time, locum or specialized services for the required or expected role and responsibility within the organization.

Staff and contractual persons' records must include historical (from inception) up to current information and be updated regularly:

- Qualifications,
- Up-to-date registrations with professional bodies where applicable,
- CVs and service/experience records,
- Job descriptions with expected roles and responsibilities,
- Contract and/or agreements, which include arrangements for backup staff during leave and unforeseen events as applicable,
- Remuneration,
- Individual meetings, appraisals, complaints, and events with resolutions,
- Continuous professional development (CPD).

Records and reviews must be handled confidentially, and access must be controlled by relevant management personnel.

CPD compliance support must be part of the HR system to ensure all relevant personnel are updated to current knowledge pertinent to enhance learning and performance of their duties and responsibilities in the field of ART.

The system must include the management of staff knowledge, training, and competency regarding all disaster plans and health and safety measures within the organization relevant to their roles.

There must be a clear staff structure and appropriate roles and responsibilities for the whole facility.

Team building, organized interactions and regular staff meetings must be part of managing the cooperation, efficiency, and integration of personnel and the organization's functions.

There must be a mental health support system in place for counselling for personnel when needed, i.e., grief, adverse events, trauma, and burnout.

Supporting Information as Evidence of Compliance:

i. Staff structure organogram of whole facility.
ii. Policy on hiring appropriate personnel and filing system of personnel records.
iii. Backup staff agreement(s) where applicable.
iv. Written evidence/Minutes of staff meetings and staff feedback.
v. Educational/Training system or policy.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.5.	Standard Name: Equipment & Consumable management: Procurement, maintenance, and repairs.	ROP: **Yes**

Standard Statement / Goal:
Proper management of all the equipment and consumables used within the facility to ensure optimal functioning.

Intent:
An ART facility relies highly on properly functioning equipment and consumables to provide quality patient care and health services.

There must be a system for managing and servicing all the essential equipment, sterile contact materials, consumables, and accessory items.

At a minimum, manufacturer's schedules, instructions, or both must be used. The system must include policies regarding the procurement of appropriate items, acceptance of deliveries, service and maintenance requirements, validations before clinical use and the repair and 'out of service' processes.

Current instruction on the use, safety and maintenance of equipment, including manuals and directions for the use of the equipment, must be readily available.

Interpretation Guidelines:
Policy on the procurement, ordering and management of appropriate equipment and consumables.

The system must include a stock control system of all contact materials, accessories, replacement parts and consumables used for providing essential services.

The system must indicate responsible persons in the various departments and processes involved in the chain, including but not limited to acceptance at delivery, validation before clinical use where needed, reporting of faulty functions or defects, backup items, suppliers, and contacts for emergencies, etc.

Equipment records must include historical (from procurement) up to current information and must be updated regularly:

- Manufacturer and instruction manual with troubleshooting,
- Service schedule, services record history, with result or report where applicable,
- Faults and repairs with a report where applicable,
- Service and repair contractor and technical call-out in case of an emergency where applicable,
- Back-up unit/item where applicable.

Agreements and clear lines of communication must be in place with suppliers and/or distributors to enhance supply chain management and contingency plans for emergencies, disaster situations, discontinuation of products and reporting of faulty or defective items.

Supporting Information as Evidence of Compliance:

i. Policy on equipment management, with service schedules and technical repair providers.
ii. Policy on consumable and contact material stock control and management.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.6.	Standard Name: Equipment & Consumable management: Medication control and management.	ROP: **Yes**

Standard Statement / Goal:
Medicines within the facility must be managed and controlled according to national regulations and the manufacturers' instructions.

Intent:
All pharmaceuticals and medications must be controlled and managed according to Government regulations. Pharmaceuticals and medications must be suitably stored to maintain shelf-life and ensure adequate efficacy when used correctly. There must be a stock control system for the medicine and medicinal supplies, including measures to ensure the availability of the medication and medicinal supplies for the delivery of services according to demand.

Interpretation Guidelines:
The organization must comply with the provisions of the Pharmacy Act of 1974 and the Medicines and Related Substances Act of 1965. All pharmaceuticals and medications (Schedule 0-7) must be stored correctly to ensure contained efficacy when utilized. Appropriate access control (a locked cupboard with keys to designated responsible persons) and movement register implemented for Schedule 5, 6 & 7 drugs, to ensure both patient and practitioner safety must be in place. These medications must be made available/provided by an appropriately licensed pharmacy/dispensary, and proof of the responsible, qualified pharmacist must be available. A clear structure and list must be available indicating designated responsible persons with appropriate authority and qualifications to manage the medications.

All medications must be stored and handled according to the manufacturer's instructions, and inserts must be available for reference.

Records of all prescribed drugs supplied or administered to patients by the ART clinic must be in place. Expired medication must be disposed of in line with the applicable legislation on pharmaceutical waste.

A system or process must be in place for reporting or feedback from patients and staff regarding adverse events or functions due to or possible result of medication and use thereof, to be followed up by management. Additional preventive measures must be in place to correctly use medications, e.g., SOP for similar medications or slight name changes.

There must be dedicated pharmaceutical fridge(s) for the storage of cold chain medications, which must have clear signage to indicate its designation to staff. Clear signage must indicate appropriate use, e.g., "No food or other items to be kept in this fridge". The cold chain must be maintained as per manufacturer instructions, and fridge(s) must be monitored via an independent thermometer (no mercury thermometers to be used) and regular temperature checks. SOP for temperature checks must be in place, and the log sheets of temperature readings must be kept on record for control and future reference.

Agreements and clear lines of communication must be in place with suppliers and/or distributors to enhance supply chain management, and contingency plans must be in place for emergencies, disaster situations, discontinuation of products and reporting defective items.

Supporting Information as Evidence of Compliance:

i. Up-to-date drug register book.
ii. SOP and manufacturer's instructions for storage and use of medications, including reporting and feedback of adverse outcomes.
iii. Log sheets for temperature monitoring.
iv. Soundalike vs lookalike SOP.
v. Policy and designated responsible persons for medication management and access in the facility.
vi. Qualified responsible pharmacist for high-scheduled drugs (where applicable).

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.7.	Standard Name: Equipment & Consumable management: Supply chain vendor contact list.	ROP: No

Standard Statement / Goal:
The supply chain vendors for equipment, consumables, and medication should be available to support the stock control system to ensure continuous patient care services.

Intent:
The supply chain vendors for all equipment, consumables and medication should be listed and available to support the stock control system for troubleshooting stock shortages or faulty items and ensuring patient care is uninterrupted.

Interpretation Guidelines:

- There should be a list of supply chain vendors available for designated staff.
- The list should include all consumables, equipment, and medications in use.
- The supply vendor list should be comprehensive and contain all the necessary contact information for the equipment and contact material items.
- There should be a process and chain of communication and action in case of supply issues and equipment changes, equipment services, consumables, and medication.

Supporting Information as Evidence of Compliance:

i. Supply chain vendors list available to designated staff.
ii. Procedure for supply chain problems and changes.
iii. Supplier contracts should be in place, and backup suppliers, where essential.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.8.	Standard Name: Processes & Procedures: Quality control of specialized services.	ROP: **Yes**

Standard Statement / Goal:
The specialized services and sterile supplies external service providers provide must be appropriately certified, validated and monitored for quality.

Intent:
The organization requires specialized services from external providers as a supplement to the provision of ART services. The specialized services that may affect the quality of ART services, especially those that may cause harm or risk to patients or staff, the integrity of critical equipment, samples, or the facility itself, must be provided by appropriately certified companies/organizations. The necessary agreements must be in place to ensure that the quality of their service is controlled and reliable.

Interpretation Guidelines:
If the facility does not have the capacity and the required certification to provide the following specialized services in-house, a certified external provider/supplier must be in place:

- Medical/Biohazardous waste removal,
- Liquid nitrogen, medical gases and laboratory gases,
- Sterilized surgical packs,
- Sterile contact materials,
- Disinfectants for cleaning and hand washing,
- Air quality and ventilation maintenance services and testing,
- Electrical service and/or electrician(s) for power backup system(s), e.g., generator and/or uninterrupted power supply system
- Plumbing service and/or plumber(s) for specific equipment if applicable,
- Refrigeration services,
- Critical and sensitive medical and laboratory equipment maintenance services and repairs.

The agreements with the external provider and, where applicable, the certification of the technicians working on-site or on the equipment item must be up to date and on record.

All certificates providing proof of the quality of the service and/or product supplied must be on kept record.

A monitoring process must be in place to assess the quality of service provided: These include, but are not limited to:

- In the case of receiving sterile supplies, there must be a process to check that the batch or items have the appropriate labels to confirm the sterility and inspect for any defects.
- Each occasion of service delivery must have a paper trail for traceability and accountability to assure the quality of the service delivered for reference in case of an event, failure, or fault. The paper trail must include but not be limited to a log or job card with time & date, type of service, the technician/provider, notes on any issues or suggestions, and signatures of persons involved (technician/delivery and facility's designated responsible person).

Supporting Information as Evidence of Compliance:

i. List of certified specialized services, including their certificates, individual certification of technicians (where applicable) and service provision agreements.
ii. Records of services delivered (paper trail) and certificates received.
iii. Staff monitoring process to confirm and report the quality of service/products.

FACILITY MANAGEMENT

DEPARTMENT: Management		Section: General
A.9.	Standard Name: Information, Communication & Feedback: Documents and records.	ROP: **Yes**

Standard Statement / Goal:
The organization must have an administrative system of managing all documents to ensure on-hand availability to relevant staff and the proper use, filing, and storage of patient records and documents while providing ART services.

Intent:
ART services involve various types of important documents and records. A system must be in place to ensure the proper use of relevant forms, SOPs and consents; with current versions available at suitable locations, regular reviews and updates must be done. Completed patient documents and records must be safely filed and appropriately stored.

Interpretation Guidelines:
An administrative system of all the organization's documents and records must be in place. Documents must be easily identifiable (e.g., logo on letterhead), readable, and clear to understand for both staff and users.

The documents must include, but not be limited to:

- Information sheets and leaflets,
- Consents to procedures and treatments,
- Policies and SOPs,
- Forms,
- Reports and letter templates,
- Patient scripts, records, and results,
- Financial and billing documents.

An index policy document must depict a list of policies in effect at the facility.

There must be a process to ensure documents are regularly reviewed, updated, implemented for use, and outdated documents archived.

Document protection may be needed to prevent unauthorized editing.

The system must ensure that the relevant documents are available to the appropriate staff for proper use.

An automated backup system must be in place, e.g., cloud service, server, and external drive set-up. Hard copies must be available in case the electronic version is unavailable.

Medical files and patient records must have confidential but efficient organizational processes in place to ensure the required confidentiality, proper filing, and storage, yet so ordered that efficient access and use by relevant personnel, where needed during the provision of ART services, is in place.

Electronic systems for patient records and results - including sharing via electronic devices on messaging groups - must have a policy in place to ensure patient records remain confidential.

Supporting Information as Evidence of Compliance:

i. Outline the document control management system/policy with the review process.
ii. Accessibility control of current documentation.
iii. Backup system for documents.
iv. A policy on electronic patient records and sharing on devices or groups.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.10.	Standard Name: Information, Communication & Feedback: Documents and records.	ROP: No

Standard Statement / Goal:
To ensure that all patients understand their treatment, regardless of a language barrier or disability.

Intent:
Effective communication with the patient is the foundation of effective treatment and coordination.

Interpretation Guidelines:
Information leaflets regarding procedures should be available in various languages according to the local population and include simplified images and/or visual aids to improve understanding.

An interpreter service should be on file when needed for a translation into the patient's language or sign language.

When communicating electronically, the staff member should be able to use programs such as Google Translate to ensure that the patient understands what is communicated.

Supporting Information as Evidence of Compliance:

i. Policy on communication with patients with language barriers.
ii. Translations of information sheets.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.11.	Standard Name: Information, Communication & Feedback: Informed consents for treatment and procedures.	ROP: **Yes**

Standard Statement / Goal:
There must be a consent form for all treatments and procedures the patient will undergo to ensure patients are fully informed and consent and prevent litigation.

Intent:
Patients must give and sign appropriate and relevant consent forms in advance of receiving ART treatment.

Interpretation Guidelines:
There must be consent forms for all types of ART treatments and procedures as medically required, including agreements regarding the use and storage of gametes and embryos.

Consents and agreements must be based on current legal frameworks and/or guidelines (e.g., SASA guidelines for sedation) and/or legal advice (e.g., SASREG consent forms) and updated and revised appropriately.

All relevant parties must sign the applicable consent forms before having treatment.

Consent forms must be given to patients before their treatment for them to read, consider and ask questions.

The contents of every consent form must be explained to the patient, so they are fully informed before signing. The signed copies must be kept on file and be accessible to the appropriate healthcare professional performing the treatment and/or procedure for confirmation of informed consent.

Electronically received signed consents must be checked for legitimacy by phone call or confirmation from patients' email addresses.

The designated and authorized staff member must receive the relevant consent forms.

Consent forms must have a translated version according to local population demands and/or be provided by an interpreter.

Surrogacy High Court Approval documentation must be in place for appropriate treatment.

Supporting Information as Evidence of Compliance:

i. Consent documents for procedures and treatments.
ii. Policy for receiving consents (can request record at random, de-identified).
iii. Information and consent revisions.
iv. Example of Surrogacy case with High Court Approval and treatment plan (de-identified, if applicable).

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.12.	Standard Name: Information, Communication & Feedback: ART data submission to national registries.	ROP: **Yes**

Standard Statement / Goal:
The organization must have a process to ensure that ART services' data are submitted to operational national data registries, including SARA/ANARA.

Intent:
ART services involve various treatments, and outcomes should be recorded and submitted to active national ART data registries.

Interpretation Guidelines:
A policy or SOP must be in place to submit the ART data from the organization to the current active national registries, including the SARA/ANARA registry.

The organization should be registered with SARA/ANARA via the online submission website.

Data entry into the registries must be up to date and done on time and to a current yearly deadline.

All treatments related to ART and fertility preservation that the organization performs must be submitted.

All the outcomes of the treatments must be submitted as far as the knowledge of the organization permits.

Submission of intra-uterine insemination data entry is optional.

Supporting Information as Evidence of Compliance:

i. Policy or SOP on data entry into current data registries.
ii. Registration of organization on SARA/ANARA data capturing website.
iii. Evidence of current, up-to-date data submission to SARA/ANARA.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.13.	Standard Name: Information, Communication & Feedback: Complaints and feedback management.	ROP: No

Standard Statement / Goal:
The organization should have a system to receive, report and act on complaints and feedback from patients and personnel to improve the quality of their services.

Intent:
ART treatments involve a complex integration of several services and interactions between patients, personnel, suppliers, products, services and processes within the facility. Receiving and acting on feedback and complaints is an integral part of monitoring the quality of care and improvement where the opportunity arises.

Interpretation Guidelines:
A policy of handling feedback, complaints and suggestions from patients and staff should be in place. This policy should include anonymous feedback options.

The system should include processes for the following, but not limited to:
Requesting and receiving feedback via a structured approach, e.g., questionnaires or polls, and open processes, e.g., suggestion box.

- Processing the feedback received through designated channels,
- Reviews and discussion for action on the feedback,
- Implementation of changes/actions,
- Replying/Answering feedback and complaints received of actions taken.

The system should be adapted and applied to all services provided by the organization..

Public reviews on social media platforms should also have a handling process to ensure proper public engagement.

The feedback, suggestions, review and action implementation should have a positive and improvement effect on the functioning of the organization, performance of personnel, quality of care of patients and ART services. In addition, it should also reduce the chances of reoccurrence and provide additional support to assist.

There should be a mechanism to show how complaints logs/registers were resolved or addressed.

The agenda for meetings to include a feedback and complaints section.

Supporting Information as Evidence of Compliance:

i. Policy on complaints and feedback system.
ii. Meeting minutes to include feedback and action.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.14.	Standard Name: Risk Management & Emergency Plans: Hygiene and infection control.	ROP: **Yes**

Standard Statement / Goal:
Cleaning and infection control measures are in place and monitored for a hygienic environment.

Intent:
The facility, laboratories and office areas must be clean and neat to provide healthy and safe spaces where patients and staff are accommodated. There must be a proper system of managing the cleaning for all the various types of areas and items and providing hand washing facilities where needed. General and medical waste must be managed appropriately.

Interpretation Guidelines:
All areas, including working spaces, offices, communal areas, ablution facilities, kitchens, etc., must be cleaned regularly according to a schedule. In high-risk areas (e.g., ablution, sluice), the system must include cleaning logs and have audit checks to ensure appropriate cleaning procedures and timetables are followed.

Cleaning must be done with appropriate soaps, disinfectants and cleaning equipment. Cleaning chemicals and disinfectants must be appropriately stored.

Hand washing facilities with running water, appropriate soap, hand drying, and sanitation must be available where needed.

General and medical waste must have appropriate handling processes (protection equipment included), and regular removal schedules must be in place. Ablution facilities must consist of proper separate disposal containers for female sanitary wear.

There must be training for all personnel in the handling processes of the types of waste.

An infection prevention program must be in place to reduce the infection rate, e.g., instruction posters at basins on how to wash hands and medical waste instruction signage for proper disposal.

The organization must ensure that all incidents involving infectious material, body substances and hazardous waste are reported and managed appropriately. Such incidents must be recorded, cause examined, and reviewed to prevent reoccurrences.

An informative system must be in place and updated according to current world affairs that affect their roles, e.g., pandemic response plan.

Particular infection control policies must be updated and implemented according to governmental notices and speciality professional body guidelines in cases of disease outbreaks, e.g., COVID-19 infection control SOPs.

Supporting Information as Evidence of Compliance:

i. Cleaning schedules, equipment, and storage.
ii. Cleaning logs and audits on hygiene and infection control.
iii. Staff and patient feedback and feedback surveys.
iv. Special infection control policy according to governmental notices when applicable.
v. General and medical waste management plan with infection prevention.

FACILITY MANAGEMENT

DEPARTMENT: Facility Management		Section: Management
A.15.	Standard Name: Risk Management & Emergency Plans: Risk assessment and disaster plans.	ROP: **Yes**

Standard Statement / Goal:
Disaster and emergency plans based on risk assessments must be in place for the safety of personnel and patients and the reduction of detrimental effects to samples and critical and sensitive equipment.

Intent:
A risk assessment of probable local disasters and applicable emergency action plans must be in place for appropriate measures to be taken in emergencies. In addition to local authorities' required emergency plans, additional risk assessment and emergency plans need to be in place according to the location and layout of the facility and the ART services it provides. All staff must be trained and knowledgeable of the emergency plans and measures for proper execution.

Interpretation Guidelines:
The risk assessment must identify local disaster possibilities, natural, building, services and civil related, that would place patients, staff, the continuation of service and the integrity of samples at risk. Emergency, preventative and contingency plans must be drawn up to provide clear on-hand instructions, appropriate reactions and actions during such disaster situations.

A Fire and evacuation Plan approved by the local Fire Department or authority, including annual inspection and service certification of fire alarms and extinguishers, must be in place.

The emergency plans must include the necessary emergency contact SOP and numbers specific to each identified disaster situation. Quick reference emergency contact lists must be available at all workstations and areas of the facility.

Patient alarm bells, where required for patient safety (e.g., at recovery beds, disabled ablution facilities, etc.), must be in place.

There must be a generator that supplies emergency electrical power sufficient for all the critical equipment and other essential identified items (e.g., lights) within the facility. The emergency power supply must be integrated with the facility's electrical supply to provide emergency power supply sockets in the various medically necessary areas where required.

The generator must have a reliable engagement system (e.g., Auto-start, or designated trained and responsible persons to start the generator manually). Reliable refuelling with an SOP for regular monitoring indicating designated accountable persons must be in place. Alarms of electrical supply failure must be in place, mainly if manual engagement or override SOPs are used to indicate faults. Regular testing of the generator and supply must be done. The technical support for the generator and electrical supply must be available to responsible persons and at the main distribution board/box.

Emergency and disaster management plans specific to various areas of services must be in place (as per this document in sections) and included in the safety manual where appropriate.

Staff and designated responsible persons must be well trained in the emergency plans, knowledgeable in their responsibilities and competent to execute them. Staff training in emergency plans related to life-threatening situations, e.g., medical emergencies, must result in proof of competency, e.g., a CPR certificate.

Supporting Information as Evidence of Compliance:

i. Approved Fire and evacuation plan (written and specified roles and responsibilities) with good service and inspection certificates.
ii. Risk assessment report and resulting emergency plans, including electrical backup system.
iii. Logs of staff training in emergency plans, including formal competency certificates where applicable.

CLINICAL SERVICES

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Guidelines: Authoritative / Informative References

1. (Roelofse and Jansen van Rensburg, 2020)
2. (Barnard, 2001)
3. (SASREG Guidelines Sub-committee, 2018)
4. (South African Department of Health, 2020)
5. (South African Government, 2012)
6. (Practice Committee of the American Society for Reproductive Medicine, 2014)
7. (The Practice Committee of the American Society for Reproductive Medicine, 2013)
8. (Anderson et al., 2020)
9. (ESHRE guideline: Female Fertility Preservation, 2020)
10. (Lambertini et al., 2020)
11. (Nisolle et al., 2000)
12. (Anderson, Wallace and Telfer, 2017)
13. (Committee of the American Society for Reproductive Medicine, 2019)
14. (ASRM, Committee Guidelines)
15. (Cobo et al., 2010)
16. (ESHRE guideline: medically assisted reproduction in patients with a viral infection/disease†, 2021)

B. CLINICAL CONSULTATIONS AND TREATMENTS

Table 2. Content summary of Standards for Clinical Consultations and Treatments.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	No	1. Sonar examination and consultation rooms.
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	2. Required qualifications and registration.
EQUIPMENT & CONSUMABLE MANAGEMENT	No	3. Equipment and consumables for gynecological examinations.
PROCESSES & PROCEDURES	**Yes** No	4. Treatment SOPs and guidelines. 5. Consultation efficiency and records.
INFORMATION, COMMUNICATION & FEEDBACK	No	6. Patient consent, information, and feedback.
RISK & EMERGENCY MANAGEMENT		

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Clinical Consultations and Treatments
B.1.	Standard Name: Facility, Planning & Design: Sonar examination and consultation rooms.	ROP: No

Standard Statement / Goal:
The consultation and examination room should ensure the patient's privacy and have the appropriate facilities to perform the required gynaecological consultation and examinations.

Intent:
The consultation and examination room should ensure patients' privacy and keep consultations confidential. The consultation room should ensure the patient is comfortable and safe for the duration of the consultation. The examination facilities should be clean and hygienic for the safety of patients and staff.

Interpretation Guidelines:
The rooms for consultation and examinations should be structurally sound.

The consultation and examination rooms should be appropriately designed and adequately enclosed with a door to ensure privacy with adequate space to accommodate the patients and partner(s).

The rooms should be adequately ventilated with controllable lighting, overhead as needed for examinations.

Supporting Information as Evidence of Compliance:

i. Design and layout to show appropriate considerations for consultation and examination rooms to serve the purpose.

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Clinical Consultations and Treatments
B.2.	Standard Name: Qualifications & Staff structure: Required qualifications and registration.	ROP: **Yes**
Standard Statement / Goal: Optimizing patient safety during assisted reproductive treatments and procedures.		
Intent: The withdrawal of gametes from a person must only be performed by a reproductive specialist as defined by the Regulations of the National Health Act. In the case of sperm, a qualified urologist is alternatively allowed to perform the withdrawal procedure.		
Interpretation Guidelines: As per current regulations, only qualified physicians are allowed to: • withdraw a gamete or cause a gamete to be withdrawn from a female, • do an embryo transfer procedure. The reproductive specialist qualification requirement is MB, BCh, MMed O&G / FCOG or similar, Fellowship / Grandfather in Reproductive Medicine and current active HPCSA registration status.		
Supporting Information as Evidence of Compliance: i. Copies of qualifications and HPCSA registrations with current active status and BHF registration of clinicians performing reproductive medicine treatments.		

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Clinical Consultations and Treatments
B.3.	Standard Name: Equipment & Consumable Management: Equipment and consumables for gynecological examinations.	ROP: No

Standard Statement / Goal:
Adequate equipment and instrumentation standards should be available for conducting a gynaecological examination, including the necessary consumables.

Intent:
The organization should ensure the availability of an ultrasound machine with a vaginal probe capable of adequately and accurately visualizing the appropriate pelvic structures.

Adequate examination beds and equipment necessary for gynaecological examination are required. All essential consumables needed to perform a gynaecological examination should be easily accessible.

Interpretation Guidelines:
There should be an appropriate working ultrasound with vaginal and abdominal probes validated fit for purpose.

There should be a suitable examination bed for conducting ultrasound and gynaecological examinations.

There should be adequate equipment and accessories for conducting a gynaecological examination, including light control.

The necessary consumables and instruments for conducting a gynaecological examination should be readily available, and a process should be in place to manage the replacement between patients. Clean and sufficient equipment, instruments, and consumables, regularly checked waste bins replaced as required should be in place.

An appropriate covering or a gown should be provided to the patient for physical examination.

Appropriate cleaning should take place in the examination room between patients.

Supporting Information as Evidence of Compliance:

i. Working ultrasound with vaginal and abdominal probes.
ii. Suitable examination bed(s).
iii. Equipment and accessories for conducting a gynaecological examination, including light control.
iv. Appropriate covering or gown provided to the patient for physical examination.
v. Cleaning schedule/policy of the examination room between patients.

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Clinical Consultations and Treatments
B.4.	Standard Name: Processes and Procedures: Treatment SOPs and guidelines.	ROP: **Yes**
Standard Statement / Goal: Fertility treatment procedures and diagnostic processes must be led by SOPs and guidelines for patient risk management.		
Intent: Specific risk reduction and management guidelines must be used as the foundation for infertility treatment procedures and referral processes.		
Interpretation Guidelines: Clinical policies based on recognized guidelines must be followed for treatment procedures to reduce patient risk regarding the following, but not limited to: • Hyperstimulation syndrome. • Multiple pregnancies. • Prevention of viral disease transmissions during ART. Recognized guidelines must be followed for diagnostic and referral processes, which include the following but are not limited to: • Infertility diagnoses, e.g., endometriosis, recurrent miscarriages, etc., • Referring to appropriate supporting health practitioners as required.		
Supporting Information as Evidence of Compliance: i. Clinical policies regarding reducing risks for hyperstimulation and multiple pregnancies and viral disease transmissions.. ii. Recognized guidelines used as the basis for clinical policies. iii. Referral network and processes. iv. Information leaflets on the above conditions. v. Statistics on adverse events and multiple pregnancy rates of the year preceding the survey.		

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Clinical Consultations and Treatments
B.5.	Standard Name: Processes and Procedures: Consultation efficiency and records.	ROP: No
Standard Statement / Goal: To define processes and procedures to ensure that consultation and examinations are conducted safely and efficiently, and findings are recorded sufficiently.		
Intent: The consultation should be scheduled for a sufficient time to address the patient's needs. This should allow for a thorough history and clinical examination when indicated. Information collected from the consultation should be kept in a filing system or electronically. Clinical and sonar examinations should be conducted appropriately, with adequate attention to necessary hygiene practices.		
Interpretation Guidelines: There should be a scheduled time for consultation and examinations. Patient consent to examination and treatment should be received before any consultation or examination. Notes regarding the consultation and finding of examinations should be recorded and filed, either written or electronically.		
Supporting Information as Evidence of Compliance: i. Supporting evidence of adequate consultation time to address the need of patients. ii. Notes regarding the consultation should be structured. iii. Clinical notes recorded either written or electronically.		

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Clinical Consultations and Treatments
B.6.	Standard Name: Information, Communication and Feedback: Patient consent, information and feedback.	ROP: No

Standard Statement / Goal:
The patient should have adequate access to information and timeous feedback on results and treatment planning, with clear channels to address complaints when they arise.

Intent:
All relevant information should be shared freely with the patient.

The patient should engage in a manner or at a level of scientific complexity that ensures that they understand their diagnosis, treatment plan and prognosis.

Informed consent should be confirmed to be received before treatment commences and as treatment may change.

Results of special investigations should be communicated in a timeous and appropriate fashion.

Clear channels for the patient to raise further questions or complaints should be available.

Feedback from the patients on their experience at the organization should be sought to identify any problem areas.

Interpretation Guidelines:
All information and results should be available to patients.

There should be communication with patients in a language that they can understand.

There should be visuals and other aids available to enhance understanding.

There should be scheduled or other feedback on the results of special investigations.

Supporting Information as Evidence of Compliance:

i. Standard operating procedures to document and facilitate communications.
ii. Visual aids to enhance understanding and knowledge.
iii. Complaint file and actions taken.
iv. Patient Satisfaction Questionnaire.
v. Quality control meeting minutes.

CLINICAL SERVICES

C. PROCEDURE ROOM

Table 3. Content summary of Standards for the Procedure room.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	**Yes**	1. Procedure room design and layout.
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	2. Qualifications, training and staff levels procedures under sedation.
EQUIPMENT & CONSUMABLE MANAGEMENT	**Yes** **Yes**	3. Equipment and consumables for safe sedation practice. 4. Equipment and consumables for retrieval and transfer procedures.
PROCESSES & PROCEDURES		
INFORMATION, COMMUNICATION & FEEDBACK	**Yes**	5. Identification, records and informed consent.
RISK & EMERGENCY MANAGEMENT	**Yes**	6. Optimal hygiene standards and infection control.

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Procedure room
C.1.	Standard Name: Facility, Planning & Design: Procedure room design and layout.	ROP: **Yes**

Standard Statement / Goal:
The procedure room must have the appropriate facilities to perform required gamete retrievals and embryo transfers, with access to a recovery area and must provide patient privacy during operation.

Intent:
The organization must provide dedicated procedure room(s) for gamete retrievals and embryo transfer and all the necessary designs and facilities to perform the procedures adequately. The design must ensure that patient privacy is secure during operation and that adequate change and scrubbing facilities are available.

Interpretation Guidelines:

- The procedure room must be fit and validated for oocyte retrievals and embryo transfers. It can also be used for uterine inseminations.
- The procedure room must comply with safe sedation practice guidelines and local health authority guidelines and be licensed where required (e.g., procedure rooms within Western Cape Province require licensing by the provincial health authority).
- The procedure room must be access controlled to ensure that only authorized personnel and the patients undergoing procedures enter and exit it.
- An adequately sized procedure room to allow personnel movement and the equipment around the patient must be in place.
- The procedure room must provide easy access for the patient's movement on the bed from and to the recovery area. It must give patients privacy with proper doors.
- A sluice room to dispose of and decontaminate (deep clean) equipment and consumables must be present.
- There must be an appropriate change room area for staff to dress in proper attire for procedures.
- A scrub basin must be available in the vicinity of the procedure room and/or change area, preferably at the staff entrance and en route from the changing area to the procedure room.
- There must be adequate lighting with the additional light control of positioning and dimming.
- The procedure room must have sufficient ventilation and temperature control. The temperature within the procedure and recovery must be temperature controlled to reduce bacterial growth and ensure patient comfort.
- If the laboratory is adjacent to the procedure room, the positive pressure must be set lower than the laboratory to prevent air movement into the laboratory.
- There must be the required number of electrical and emergency backup sockets. The power supply to the critical equipment must be uninterrupted to prevent damage and supply sufficient long-term supply to essential and emergency equipment.
- There must be adequate oxygen, air, and vacuum outlets installed and in working order.

Supporting Information as Evidence of Compliance:

i. Design and plans to show proper installations and facility layout for the procedure room, change area and scrub basin.
ii. Temperature control.
iii. Access control measures.
iv. Validation and certification of air quality and positive pressure testing in the procedure room.
v. Validation/Approval letter from the sedation practitioner confirming the suitability of facilities for sedation practice or DOH license where required.

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Procedure room
C.2.	Standard Name: Qualifications & Staff structure: Qualifications, training and staff levels procedures under sedation.	ROP: **Yes**

Standard Statement / Goal:
The physician and nurse(s) must be adequately trained in performing gamete retrievals and embryo transfers, and the staff level must be sufficient to support the sedation process.

Intent:
Sedation procedures must be done by qualified registered sedation practitioner(s) and supported by adequately trained nursing staff during assisted reproductive procedures.

Interpretation Guidelines:
Only qualified and experienced doctors must perform the aspiration and transfer procedures for the ART treatment cycle.

The nursing assistant must be adequately trained and experienced in fertility procedures and able to assist in the sedation process. Nursing assistance must include safe and hygienic collection and transport of the biological material and monitoring during recovery after the procedure.

The sedation practitioner must have a medical qualification and registration with the HPCSA. The sedation practitioner must have training in sedation techniques or demonstrate equivalent experience with audit records and comply with SASA recommendations for inducing sedation.

Aspirations are usually performed under conscious sedation called PSA (procedural sedation and analgesia). The guidelines stipulated by SASA must be followed:

- Only ASA class1 and 2 patients
- Sedation for aspirations is usually considered moderate sedation and under 30 minutes.

Staff levels for assisted reproductive procedures under sedation:

Optimal 3-person model:

- Fertility physician,
- Sedation Practitioner,
- Nursing Assistant.

A dedicated SP (sedation practitioner) must be present if the procedure is complex or when a combination of drugs is used in obese patients and those with co-morbidities or for prolonged sedation over 30 minutes.

Minimal under exceptional circumstances, a 2-person model:

- Fertility physician,
- Nursing assistant as a dedicated observer.
- An operator and an appropriately trained and dedicated observer are performing the procedure.

The operator provides the sedation for the procedure (i.e., single operator-sedation practitioner). The observer is responsible for monitoring the patient under sedation and assisting the operator in case of an adverse event. The observer must be a nurse trained and able to monitor vital signs and airway and able to assist with ventilation if necessary. The procedure must be less than 30 minutes.

Supporting Information as Evidence of Compliance:

i. List all staff present during sedation procedures with qualifications, registrations and training/ audit records.
ii. Policy on staff level and responsibilities during sedation procedures according to the procedure, sedation patient class and sedation level.
iii. 3-person model vs 2-person model – Proof of documentation.

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Procedure room
C.3.	Standard Name: Equipment & Consumable Management: Equipment and consumables for safe sedation practice.	ROP: **Yes**

Standard Statement / Goal:
To ensure patient safety, the appropriate sedation and monitoring equipment, medication, and consumables is available and confirmed to be sufficiently supplied in the procedure room by either the appointed sedation practitioner(s) or a Department of Health (DOH) license.

Intent:
Equipment, medication, and consumables required for safe sedation must be confirmed to be available and sufficient by the sedation practitioner inducing sedation for retrieval and transfer procedures.

Interpretation Guidelines:
The procedure room must comply with the necessities for safe sedation practice according to the sedation level as outlined by current recognized guidelines.

ART facilities have varying set-ups and must accordingly ensure their procedures are performed in an appropriately validated procedure room or theatre as required:

The procedure room is a recognized theatre:
The appropriate DOH license must be in place as validation.

The procedure room is separate from a recognized theatre:
The sedation practitioner(s) inducing the sedation for the procedures must confirm that the procedure room contains the required equipment and consumables to perform safe sedation according to the level of sedation necessary for the relevant procedures for assisted reproduction (gamete retrievals and embryo transfers).

In cases where any gamete retrieval or embryo transfer requires advanced anaesthesia in a theatre facility, a DOH license must be in place at the facility where such procedures are done.

Supporting Information as Evidence of Compliance:

i. Validation letter from the sedation practitioner (confirming the appropriate facilities for sedation practice is in place) or DOH license of procedure room where applicable (provincial regulations).
ii. The DOH license of the theatre facility is used when required (separate procedure room set-up).

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Procedure room
C.4.	Standard Name: Equipment & Consumable Management: Equipment and consumables for retrieval and transfer procedures.	ROP: **Yes**
Standard Statement / Goal: An adequate standard of equipment and instrumentation for conducting a gamete retrievals and embryo transfers including the necessary consumables.		
Intent: To ensure the availability and use of specialized equipment for gamete retrievals and embryo transfers, including the appropriate consumables.		
Interpretation Guidelines: There must be a proper working ultrasound with vaginal and abdominal probes validated fit for purpose, e.g., to enable adequate visualization of follicles, uterus, endometrium, transvaginal and abdominal. There must be a suitable bed with lithotomy positioning for conducting the procedures. Trendelenburg positioning is optional. There must be the required clean instruments, accessories, and consumables for conducting gamete retrievals and embryo transfer. Sterile and preferably disposable consumables must be used to enable safe and adequate oocyte collection, embryo, and sperm transfer. Re-used instruments must undergo appropriate disinfection before use, including a clean rinsing process to remove any residual disinfectant that may affect gametes or embryos. Appropriate cleaning and re-stocking required sterile consumables and disinfected instruments must occur between patients.		
Supporting Information as Evidence of Compliance: i. Sonar equipment and accessory list with validation records, user manuals for instructions of use and maintenance schedule with history logs. ii. List of consumables and instruments used during these procedures.		

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Procedure room
C.5.	Standard Name: Information, Communication & Feedback: Identification, records, and informed consent.	ROP: **Yes**
Standard Statement / Goal: Adequate and accurate identification, data collection and informed consent.		
Intent: Accurate identification of patient and tissue sample is essential. Informed consent must be obtained in advance of the procedure commencing.		
Interpretation Guidelines: Patient and sample identification SOPs must be in place to ensure double checks. This includes the transfer or transport of reproductive fluids and tissues between the procedure room, the laboratory, and independent laboratories for tissue analysis (histology) where appropriate. The procedure must be fully explained to the patient, including side effects, complications, and consent forms to be read and signed. Consent for sedation must be following recognized sedation guidelines. Procedure notes and if any incident notes must be recorded.		
Supporting Information as Evidence of Compliance: i. SOPs on patient and sample identification. ii. Procedural notes and sedation records. iii. Sedation consent forms. iv. Procedure and monitoring forms.		

CLINICAL SERVICES

DEPARTMENT: Clinical Services		Section: Procedure room
C.6.	Standard Name: Risk & Emergency Management: Infection incidents, power back-up and emergency trolley.	ROP: **Yes**

Standard Statement / Goal:
There must be appropriate SOPs to handle infection incidents, and medical emergencies, including power backup to emergency equipment, are available.

Intent:
It is required that the procedures and recovery process provide a safe environment for staff and patients.

The proper infection control measures and emergency SOPs must be in place. Power backup must supply critical and emergency equipment.

Interpretation Guidelines:
The organization must ensure there is a risk reduction and emergency plans in place for the following, but not limited to:

- Use of sterile or properly disinfected instrumentation and accessories.
- Use of personal protective equipment such as surgical gowns, aprons, gloves and goggles,
- Infection control and incident management, i.e., disinfection and cleaning SOPs, medical waste management,
- Emergency Trolley for medical emergencies,
- Power backup for critical theatre equipment,
- Appropriate hand disinfection at the scrubbing basin.

The organization must ensure that all incidents involving infectious material, body substances and hazardous waste are reported, managed appropriately, recorded, cause examined, and reviewed to prevent reoccurrences.

The organization ensures that an Emergency Trolley and policy are in place, stocked, checked, and recorded daily, and nurses are confident in using them as needed.

Training must be provided for nurses to know how to manage the failure of utilities (UPS), and a call system must be in place for remote monitoring of essential equipment.

Supporting Information as Evidence of Compliance:

i. Training and monitoring logs of power backup and functioning emergency and critical equipment for the procedure room while on power backup.
ii. Records of emergency trolley supplies and monitoring.
iii. SOPs for disinfection, cleaning and handling of biohazardous waste in the procedure room.

ONCOFERTILITY

D. ONCOFERTILITY

This section is applicable to organizations performing female fertility preservation for oncological reasons.

Table 4. Content summary of Standards for Oncofertility.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	No	1. Oncofertility services.
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	2. Oncofertility knowledge.
EQUIPMENT & CONSUMABLE MANAGEMENT		
PROCESSES & PROCEDURES	**Yes** No No	3. Cryopreservation competency. 4. Scheduling of Oncofertility patient referrals. 5. Financial support.
INFORMATION, COMMUNICATION & FEEDBACK	No **Yes**	6. Multi-disciplinary Oncofertility patient care. 7. Informed consent.
RISK & EMERGENCY MANAGEMENT		

ONCOFERTILITY

DEPARTMENT: Clinical Services		Section: Oncofertility
D.1.	Standard Name: Facility, Planning & Design: Oncofertility Services.	ROP: No

Standard Statement / Goal:
An Oncofertility facility should be able to indicate the range of fertility preservation treatment options available to their oncology patients.

Intent:
The organization should indicate the various fertility preservation treatments offered. Treatment should be individualized after considering all the relevant clinical factors.

Interpretation Guidelines:
The treatment option for an Oncofertility patient is highly case-specific.

The fertility preservation treatments should consider the type of cancer, egg reserve, chemotherapeutic regime/radiation, the prognosis of the patient, costs, and time available. The final decision should include the approval of the treating oncologist.

Should a specific option not be available at the facility, the patient should be referred to a facility where the treatment is available.

The appropriate stimulation SOPs for Oncofertility should be followed.

The welfare and future fertility of the patient should supersede all other interests.

Supporting Information as Evidence of Compliance:

i. SOPs of Oncofertility treatment options offered.
ii. A contingency plan, as who they refer to should the full spectrum of options not be available or if the clinician is on leave.

DEPARTMENT: Clinical Services		Section: Oncofertility
D.2.	Standard Name: Qualifications & Staff Structure: Oncofertility knowledge.	ROP: **Yes**

Standard Statement / Goal:
The fertility specialist must understand the basic principles in fertility preservation specifically related to cancer diagnoses.

Intent:
Multiple clinical factors determine the intended Fertility preservation option. A basic understanding of cancer treatment and its effect on future fertility is paramount in understanding and treating these patients. Treatment must be individualized after considering all the relevant clinical factors.

Interpretation Guidelines:
The fertility specialist must provide documentation of courses/workshops completed to improve knowledge in this field.

The American Society of Reproductive medicine (ASRM), as well as the European Society of Human Reproduction and Endocrinology (ESHRE) online courses in Basic Oncofertility care or similar workshops/courses, must be completed.

Supporting Information as Evidence of Compliance:

i. Evidence of Oncofertility workshops and/or courses attended.

ONCOFERTILITY

DEPARTMENT: Clinical Services		Section: Oncofertility
D.3.	Standard Name: Processes & Procedures: Cryopreservation competency.	ROP: **Yes**
Standard Statement / Goal: The procedure of cryopreservation is an essential step in the preservation of a patient's fertility potential.		
Intent: Optimization of future clinical outcomes. Competency in cryopreservation techniques is essential to optimize the chances of achieving a future live birth.		
Interpretation Guidelines: Cryopreservation is a proven modality in preserving future fertility. Data on cryopreservation outcomes of techniques performed should be recorded, and competency statistics calculated and monitored for efficacy.		
Supporting Information as Evidence of Compliance: i. Records of data and statistics on cryo-survival rates and pregnancy outcomes in cryopreservation treatment cycles.		

DEPARTMENT: Clinical Services		Section: Oncofertility
D.4.	Standard Name: Processes & Procedures: Scheduling of Oncofertility patient referrals.	ROP: No
Standard Statement / Goal: Rapid access to fertility preservation consultation should be provided to Oncofertility referred patients.		
Intent: To prevent delaying time-sensitive oncology treatment, potentially impacting the patient's long-term prognosis.		
Interpretation Guidelines: Accessible contact numbers for referring physicians should be provided. Oncofertility patients should be seen as a medical emergency and be scheduled within a short period, not exceeding a few days from referral.		
Supporting Information as Evidence of Compliance: i. Policy and SOP of Oncofertility patient scheduling. ii. Referral network for effective Oncofertility patient management.		

ONCOFERTILITY

DEPARTMENT: Clinical Services		Section: Oncofertility
D.5.	Standard Name: Processes & Procedures: Financial support.	ROP: No
Standard Statement / Goal: Oncofertility care may contribute further to the financial burden on the oncology patient.		
Intent: Financial support and counselling should be offered to the oncology patient requiring fertility preservation.		
Interpretation Guidelines: Oncology treatment, in general, is expensive. Medical aids do not always cover the total costs of oncology care, leaving the patient to cover the rest out of pocket. Oncofertility care may add to the financial burden of the patient. Fertility preservation remains a very emotional decision, which may contribute to feelings of guilt should it be deferred. Private fertility facilities should actively assist in reducing the financial burden by including significantly discounted fees and a transparent financial assistance policy for these patients. This may involve nonprofit organizations for financial assistance.		
Supporting Information as Evidence of Compliance: i. Policy of financial considerations must be provided (private organizations only).		

DEPARTMENT: Clinical Services		Section: Oncofertility
D.6.	Standard Name: Information, Communication & Feedback: Multi-disciplinary Oncofertility patient care.	ROP: No
Standard Statement / Goal: Clinical records highlight the multi-disciplinary care involved in decision-making for Oncofertility treatments.		
Intent: Clinical records, a multi-disciplinary approach policy and individualised care for Oncofertility treatments should be in place.		
Interpretation Guidelines: A policy of multi-disciplinary care and/or collaborative network of Oncofertility patients, should be in place. Clinical notes should record aspects as follows, but not limited to: • Type and stage of Cancer, • Planned oncology treatment, • Patient's current fertility reserve, • Gonadotoxic risk of planned treatment (low/moderate/high), • Fertility preservation strategy, • Alternatives to fertility preservation, • Limitations of fertility preservation techniques, • Patient's decision and wishes.		
Supporting Information as Evidence of Compliance: i. A policy of multi-disciplinary care and/or collaborative network for Oncofertility treatments.		

ONCOFERTILITY

DEPARTMENT: Clinical Services		Section: Oncofertility
D.7.	Standard Name: Information, Communication & Feedback: Informed consent.	ROP: **Yes**

Standard Statement / Goal:
Consent forms are essential in all Oncofertility procedures and the storage of specimens.

Intent:
Clinicians treating Oncofertility patients are responsible for ensuring they clearly understand their treatment options and the advantages and limitations thereof.

Interpretation Guidelines:
Oncofertility services must ensure that consent documents explain the procedure and its related risks. There are many unknowns in Oncofertility, and patients must be counselled accordingly.

The consent document must explain the need for additional future consent for the use of stored material.

Directives are required for the stored gametes, embryos, or tissue as to what should be done with the stored samples if the patient becomes deceased, unavailable, abandoned, or fails to pay storage fees.

These directive options must include discard, donate, use for experimental purposes or posthumous usage by the partner.

Oncology patients are case specific with different circumstances for each of them. Therefore, individualized gamete disposition forms must be encouraged.

It is strongly recommended that a fertility lawyer is involved in drafting consent forms in cases where minors are involved.

Consent in the case of experimental procedures must be accompanied by an Institutional Review Board (IRB) approval documentation or ethical approval from a recognized ethical committee. An IRB must consist of at least three persons, which can include the treating oncologist, surgeon, reproductive medicine specialist or social worker.

Supporting Information as Evidence of Compliance:

i. Consent forms for fertility preservation, usage, and postmortem disposition.
ii. Approval documentation as appropriate for experimental procedures.

NURSING SERVICES

Contributors

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Guidelines: Authoritative / Informative References

1. (International Health Facility Guidelines, 2017)
2. (South African Nursing Council, National Department of Health, 2005)
3. (South African Government, 2018)

E. NURSING AND COORDINATION

Table 5. Content summary of Standards for Nursing and Coordination.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	No	1. Coordination station/office.
QUALIFICATIONS & STAFF STRUCTURE	**Yes** No No **Yes**	2. Qualifications and training of nursing staff. 3. Nursing staff levels. 4. Training and competency in third party coordination. 5. Training and management of medications for ART.
EQUIPMENT & CONSUMABLE MANAGEMENT	No No	6. Equipment for nursing and coordination. 7. Stock control of consumables, contact materials and medications at nursing stations.
PROCESSES & PROCEDURES	No No No	8. Demonstration of medication use. 9. Management of donors and donor treatments. 10. Management of surrogacy treatments.
INFORMATION, COMMUNICATION & FEEDBACK	No No	11. General patient communication. 12. Reporting of results.
RISK & EMERGENCY MANAGEMENT	**Yes** No	13. Infection control and medical emergency SOPs. 14. Disaster planning and power back-up.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.1.	Standard Name: Facility, Design & Planning: Coordination station/office.	ROP: No
Standard Statement / Goal: The IVF coordinator or nurse's consultation room should ensure the patient's privacy, be sufficient for patient load and have a comfortable and informative atmosphere.		
Intent: The consultation room/station/office should provide safety, privacy and adequate comfort and space to provide a room favourable to coordination discussions. Ensure sufficient nurses' rooms, stations, and offices for the patient load.		
Interpretation Guidelines: The coordination room/station/office should be enclosed with a door and sound-reducing walls to ensure the patient's privacy and confidentiality. There should be adequate ventilation, light, and temperature control within closed consultation areas. There should be sufficient and comfortable space and seating to ensure patients are satisfied and can focus on understanding the information given to them. This should include adequate space to demonstrate medication use to the patients. There should be a limit threshold to booking these rooms to accommodate the busiest times. There should be easy access to patients' files and relevant information, physically or digitally. There should be enough nurses' stations to efficiently serve the expected patient load.		
Supporting Information as Evidence of Compliance: i. Facility design, layout, and floorplan to show proper considerations for coordination and nurses' stations where needed. ii. Summaries of patient satisfaction survey results.		

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.2.	Standard Name: Qualifications & Staff Structure: Qualifications and training of nursing staff.	ROP: **Yes**

Standard Statement / Goal:
Nurses performing the ART coordination functions and roles to assist in clinical services for patient care throughout treatment to be appropriately qualified and trained.

Intent:
The organization must ensure nurses assisting in clinical services during ART treatment receive quality care by appropriately qualified, trained, and registered nursing staff to manage the specific nursing role with appropriate authority, accountability, and responsibility.

Interpretation Guidelines:
The IVF coordination nurse must be registered and have minimum qualifications as stipulated by SANC.

There must be records of all nursing staff's annual registration with the South African Nursing Council (SANC), including updated records of annual licensure, credentialing and certification of all nursing staff as prescribed by SANC.

There must be a clear organogram describing lines of communication and functions.

There must be an orientation program for new IVF nursing staff with all essential components of nursing services to be provided, including recorded experience (records) of in-house training.

The organization must have a system to ensure nursing staff attends workshops and lectures appropriate to ART.

The organization must ensure that the nursing duties are developed in partnership with multi-disciplinary collaboration (regular meetings with all role players in the various specialist fields) within the facility, and patients must be holistically given care and ensure the effective continuation of support.

Supporting Information as Evidence of Compliance:

i. Facility organogram about nursing roles.
ii. Records of nursing qualifications and registrations concerning responsibilities.
iii. Attendance certificates of ART-related workshops/presentations.
iv. Meeting minutes for multi-disciplinary collaboration.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.3.	Standard Name: Qualifications & Staff Structure: Nursing staff levels.	ROP: No

Standard Statement / Goal:
Sufficient nursing staff should be employed according to the patient load, type and complexity of treatments to be coordinated, number of clinicians, range of services provided and level of training of nurses in the team.

Intent:
The nursing staff level should be sufficient to provide the expected quality care for the workload considering the patient load, treatment services, number of clinicians, coordination responsibilities and complexity of ART cycles.

Interpretation Guidelines:
The organization should ensure that the number of nurses and their responsibilities are sufficient to provide quality and efficient coordination care to the patient and workload.

The number of patients, the number of clinicians, and the type and complexity of cycles should be considered.
The responsibilities and the level of nursing staff training and qualifications should also be considered.

There should be clear communication between levels of staff and responsibilities for efficient care and coordination integration between patients, clinicians and treatment services.

Regular meetings should be held to ensure all staff questions are addressed and prevent possible burnout.

Supporting Information as Evidence of Compliance:
i. Organogram indicating communication, functions and integration model.
ii. Records/Minutes of nursing staff meetings.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.4.	Standard Name: Qualifications & Staff Structure: Training and competency in third-party coordination.	ROP: No
Standard Statement / Goal: Nursing staff should be appropriately trained and competent in the care and coordination of third-party ART treatments.		
Intent: ART cycles and treatments are more complex when a third party is involved, i.e., a donor and/or surrogate. Therefore, additional training and competency levels should be in place for the nursing staff coordinating third-party treatments.		
Interpretation Guidelines: The organization should ensure that only competent registered nurses manage clients/patients who need liaising with donor banks/ surrogacy cycles. The IVF coordination nurse should be competent in donor bank guidelines set out by accepted practice guidelines. The IVF coordination nurse should have competencies in working with surrogacy cycles, and the organization should have a process to ensure such. SASREG Guidelines should be followed for donor and surrogacy cycle management.		
Supporting Information as Evidence of Compliance: i. Policy on training for nursing staff new to third party coordination and expected competency levels.		

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.5.	Standard Name: Qualifications & Staff Structure: Training and management of medications for ART.	ROP: **Yes**

Standard Statement / Goal:
Nursing staff must be appropriately trained and competent in managing and administering medications involved during ART.

Intent:
The nursing staff must be adequately trained and competent in administering and managing the medications used for ART, including stimulation drugs and specialized drugs related to sedation procedures.

Interpretation Guidelines:
The training and competency in medications must include, but not be limited to, according to organization operations and staff responsibilities:

- Stimulation drugs as used by clinical services,
- Intravenous (IVI) Medications,
- Anaesthetic medications used for on-site sedation procedures,
- Schedule (5 – 7) medications where applicable.

A policy must be in place to ensure that all nurses have good knowledge of pharmacotherapy for all medication prescribed in ART, correct dosages needed and skilful administration as well as expected health care user response.

Competencies must be reviewed in annual appraisals or records of attendance at informative talks.

Continual education programs are in place, ensuring all nurses are kept informed as ART treatment cycles are adapted/ changed, as well as different treatment options, SOPs and potential risks.

Policies/procedures must be in place to document the nurse medicine management responsibilities concerning each stage of medicine management.

A process must be implemented to identify, record, and communicate medication-related allergies. The nurse must be fully knowledgeable in responding to such allergic reactions appropriately, including a similar process applied in clinical services.

Policies must be in place to ensure medication identification is made with the healthcare user to prevent “mix up” with sound-alike/look-alike medications.

Supporting Information as Evidence of Compliance:

i. Policies and SOPs for medication administration and management and training.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.6.	Standard Name: Equipment & Consumable Management: Equipment for nursing care and coordination.	ROP: No

Standard Statement / Goal:
The necessary patient care and cold storage equipment are available, sufficient, and working correctly at nursing stations.

Intent:
Nursing needs specific equipment to perform patient care, communicate and monitor, and keep cold chain medications under required storage conditions to ensure patients receive the care to support quality ART treatment. The necessary equipment should work correctly and sufficiently, readily available to the nursing staff at their stations according to the service provided.

Interpretation Guidelines:
Nursing stations should be equipped with items for the following, but not limited to:

- Communication channels, i.e., PC, telephone, etc.,
- Basic health and body monitoring, i.e., blood pressure, weight, height, etc.,
- Cold storage fridge where needed for cold chain medications,
- Fetal heart monitoring, if applicable.

The required equipment may vary according to the function of the nursing station. Relevant equipment should be readily available to provide comprehensive and efficient patient care.

A laptop/tablet/desktop computer should be available to access patient communication emails and pathology lab results in portals.

Each consultation room/station/office should have the required teaching and explanation aids available.

All the equipment should be working as expected and checked regularly for function, mainly electronic and patient monitoring equipment and cold storage fridges for medication.

There should be a service log for all serviceable equipment ensuring all items are updated with their service interval.

Clinical and cold storage equipment should have an instruction manual, troubleshooting, and expected functionality. Validation should be done when new equipment is introduced and after a repair or service before clinical use to confirm anticipated functionality.

The critical items should have a backup in good working order with similar checks and services where applicable.

Supporting Information as Evidence of Compliance:

i. List of relevant equipment at stations.
ii. Equipment manuals and service logs with calibration/validation logs where applicable.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.7.	Standard Name: Equipment & Consumable Management: Stock control of consumables, contact materials and medications at nursing stations.	ROP: No

Standard Statement / Goal:
An adequate stock control system is effectively managed to ensure traceability and a sufficient supply of patient care consumables at nursing stations.

Intent:
Nursing stations are usually stocked with various patient consumables and medication for proper patient care. An adequate stock control system should ensure that careful attention is paid to the order, using, and billing of patient consumables.

Interpretation Guidelines:
A proper stock control system should be in place for managing consumables and medical stock, including medications. The system should be adequate to ensure sufficient and appropriate stock is available at the relevant nursing stations.

The stock control system should address the following aspects, but not limited to:

- Minimum stock levels,
- Ordering,
- Acceptance of new batches, including if the cold chain was adhered to if required,
- Checking for defects, faults, and expirations before use,
- Refilling,
- Rotation for use (first in, first out principle to avoid redundancy),
- Traceability of contact materials,
- Introduction of new stock, including changes in the brand, name, type, version, method of application, etc.,
- Stock taking and monitoring of levels,
- Stand-in person if the responsible person is absent.

Contact materials should be traceable from the manufacturer through to the end user and receiver in case of a recall, adverse reactions or faults and defects. The system should include a process for the management of defective contact materials.

Storage of consumables, medical contact materials and medications should be appropriate and according to the manufacturer's instructions. Manufacturer's instructions and inserts should be available for all stock items as reference.

Fridges for cold storage medical items and medication should be appropriately marked as such with no food or drinks therein and monitored to ensure required storage temperatures are maintained.

Supporting Information as Evidence of Compliance:

i. Stock control system organogram with responsible persons and roles.
ii. Traceability system of contact materials.
iii. Monitoring and checking lists.
iv. Necessary SOPs and manufacturer's inserts/instructions.
v. Documentation of all standing orders and rotating stock agreements.
vi. Storage locations and cold chain storage monitoring.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.8.	Standard Name: Process & Procedures: Demonstration of medication use.	ROP: No

Standard Statement / Goal:
Ensure that the use of medication is demonstrated in such a way that the patient can comfortably and effectively self-administer their stimulation medication.

Intent:
Patients may need to administer their stimulation medication at home between monitoring sonar examinations to reduce the need for daily visits to the facility. Nursing staff need to be able and have the necessary aids to provide sufficient demonstration and communication to instruct patients to perform the self-administration effectively.

Interpretation Guidelines:
Medication administration should be demonstrated by adequately trained and designated staff, usually a nurse.

The nurse should confirm with the clinician and the patient which medication needs to be demonstrated.

There should be a designated, private area that can be used to demonstrate the use of the medication, and the privacy of the patient should be protected. The designated area/room should be calm and well-lit.

The medication should be identified quickly, and additional marking and instructions made on the medication if needed.

Teaching materials (syringes, needles, diagrams) should be used to demonstrate medication administration as close to reality as possible. If needed, additional teaching materials should be available or requested from the supplier/manufacturer to assist.

There should not be any language barriers. If there are, an interpreter should be present.

The patient should be able to demonstrate that they understand through “show and tell”. Active administration by the staff/nurse should also be done as part of the demonstration.

The patient should be instructed accurately and timeously to understand fully. The patient should be capable and comfortable administering medication at the end of the demonstration session.

Supporting Information as Evidence of Compliance:
i. Policy and SOPs of demonstrating and explaining medication administration to patients.
ii. Patient satisfaction surveys or feedback.

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.9.	Standard Name: Process & Procedures: Management of donors and donor treatments.	ROP: No
Standard Statement / Goal: Ensure donors and donor cycles are managed appropriately to provide quality care for donors and recipients.		
Intent: Donors and donor treatment cycles require additional care measures during coordination and SOPs to protect donor identity throughout treatment.		
Interpretation Guidelines: A system should be in place for the recruitment of donors if applicable. If donors are obtained from agencies, these agencies should be recognized by SASREG. A system should be in place that prevents identifying information from being passed between donors and recipients. Donor anonymity, where applicable, should be maintained (before, during and after treatment). Correct processes and procedures should be in place to ensure that the suitable donor is always matched with the right recipient throughout the treatment cycle.		
Supporting Information as Evidence of Compliance: i. Policy and SOPs of donor treatments and management. ii. SOPs in place to ensure all relevant information(results) are recorded (e.g., family history, medical history, physical examination, blood tests.)		

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.10.	Standard Name: Process & Procedures: Management of surrogacy treatments.	ROP: No
Standard Statement / Goal: Ensure that surrogates and commissioning parents are well informed of the entire process before and during treatment.		
Intent: Surrogates and surrogacy treatment cycles require additional care measures during coordination to ensure that surrogates and commissioning parents are adequately informed regarding their treatment.		
Interpretation Guidelines: Commissioning parents should have received an information package detailing all aspects of surrogacy. The organization should have processes to ensure that the commissioning parents are fully informed of the surrogacy process. The commissioning parents should receive adequate counselling.		
Supporting Information as Evidence of Compliance: i. Policy on surrogacy cycle management. ii. Information sheets and documentation of information discussions. iii. Relevant results/documentation on file (e.g., tests performed on the intended parents and surrogates.)		

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.11.	Standard Name: Information, Communication & Feedback: Information relay of medical procedures.	ROP: No
Standard Statement / Goal: Ensure the patient receives accurate information regarding the process/procedure they will undertake.		
Intent: It is essential to communicate and explain the stimulation processes and medical procedures to patients in advance of and during their treatment.		
Interpretation Guidelines: Processes should be in place to ensure that all information regarding medical procedures is communicated accurately and consistently from the treating doctor through to the nursing staff and the patient. All procedures and different treatments should be communicated clearly to patients to ensure their understanding. There should be an information trail of communication to patients regarding medical procedures. Information regarding medical procedures should be accessible to relevant staff involved in the patient's care. The patient should receive sufficient information to understand the different clinical investigations and interventions.		
Supporting Information as Evidence of Compliance: i. Policy and/or SOP of information relay from treating doctor to nurse to patient. ii. Information sheets, leaflets and documentation are used to explain all the different procedures and processes.		

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.12.	Standard Name: Information, Communication & Feedback: Reporting of patient results.	ROP: No
Standard Statement / Goal: Ensure patient results are being conveyed promptly, to enhance coordination, treatment, and communication with the patient.		
Intent: Timeous and effective communication with the patient is a core function of coordination during ART treatment. Patient results and the implication thereof on their treatment are essential.		
Interpretation Guidelines: The turnaround time for communicating results should be consistent. The nurse should inform patients of the results and the implications thereof if the treating doctor has delegated the responsibility. A qualified person should give results. When patients are being informed of results over the telephone, a record should be kept of proof that the patient was contacted and results were relayed. Additional processes of results reporting should be in place to report in case of special patient requirements, e.g., minors, hearing disabilities, language barriers, etc. A copy of the results and communication thereof should be kept on file.		
Supporting Information as Evidence of Compliance: i. Policy and/or SOP of patient results reporting and documentation of communication.		

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.13.	Standard Name: Risk & Emergency Management: Infection control and medical emergency SOPs.	ROP: **Yes**

Standard Statement / Goal:
The appropriate infection control measures and safety SOPs must be in place at nursing stations, and the nursing staff is well-trained in the emergency SOPs.

Intent:
Nursing staff must have essential roles in the SOPs and measures for infection control and health emergency procedures. All nurses must be adequately trained and have easy access to the safety manual at their stations.

Interpretation Guidelines:
The Safety manual must address the following, but not limited to:

- Needle prick,
- Patient unwell (CPR),
- Infection control,
- Hazardous waste.

All nurses' Cardiopulmonary resuscitation (CPR) training must be regularly updated.

The organization must have a process to verify that nurses are aware of their responsibilities during emergency SOPs and can perform their role when needed.

The nursing stations and procedure rooms must be managed by nurses according to the facility's infection control policies on sharps management, as well as always ensuring cleanliness with records of duties for such doing.

The organization must ensure that protective equipment and clothing appropriate to the risk involved in handling hazardous waste are provided and correctly used by all nurses.

Supporting Information as Evidence of Compliance:

i. Safety manual and location for nursing.
ii. Hazardous waste and Infection control policy about nursing, including information update process.
iii. Training logs and updated emergency course completion (CPR, etc.).

NURSING SERVICES

DEPARTMENT: Nursing Services		Section: Nursing and Coordination
E.14.	Standard Name: Risk & Emergency Management: Disaster planning and power back-up and monitoring.	ROP: No
Standard Statement / Goal: Critical and sensitive equipment is located in nursing stations on the backup power supply for medical emergencies.		
Intent: The critical, medical emergency and sensitive equipment at nursing stations should be on battery power backup to ensure continuous availability.		
Interpretation Guidelines: The organization should have batteries or an uninterrupted power supply (UPS) system for critical nursing equipment, which is regularly monitored for proper functionality and the length of the power supply to be sufficient.		
Supporting Information as Evidence of Compliance: i. Monitoring logs of battery or UPS supply to critical, medical emergency and sensitive equipment at nursing stations.		

PROCEDURES AND RECOVERY

F. PROCEDURES AND RECOVERY

Table 6. Content summary of Standards for Procedures and Recovery.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	No No	1. Recovery area design, equipment and access control. 2. Sluice or dirty utility area.
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	3. Training for nurses in ART sedation procedures and recovery.
EQUIPMENT & CONSUMABLE MANAGEMENT		
PROCESSES & PROCEDURES	**Yes**	4. Patient identification for admission & discharge.
INFORMATION, COMMUNICATION & FEEDBACK	**Yes**	5. Consents and documentation for procedures and recovery.
RISK & EMERGENCY MANAGEMENT	No **Yes**	6. Cleaning and infection control in recovery. 7. Power back-up and emergency trolley.

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.1.	Standard Name: Facility, Design & Planning: Recovery area design, equipment and access control.	ROP: No

Standard Statement / Goal:
The recovery area should be a restricted access area and provide a safe, calm, and private space to provide quality recovery processes.

Intent:
The procedure room and recovery area should be favourable for all the recovery processes before and after ART procedures after sedation. It should be so planned and equipped that control can be exercised over all persons and materials that enter it.

Interpretation Guidelines:
The recovery area should be in proximity with easy access to the procedure room, including providing sufficient space for beds, transfer of patients on beds and instrument trolleys.

There should be practical and suitable lighting within the recovery area.

Sufficient ablution and handwashing facilities should be available for patients in recovery and appropriately located.

There should be the necessary number of electrical and emergency backup sockets and gas/air/vacuum outlets.

All equipment for recovery processes should be validated as fit for purpose and sufficient for patient load and located adequately for use.

There should be easy and quick access to the emergency trolley from the recovery area.

The ventilation and air temperature within the recovery area should be controlled according to the patient load.

The recovery should be access controlled to ensure that only authorized personnel and the patients undergoing procedures enter and exit in a meticulous manner. A policy regarding managing the number of patient relatives or persons that may accompany the patient, including keeping the areas calm and without disturbances, e.g., no children or phone calls, should be in place to ensure proper patient care.

There should be allocated storage space for patient valuables and belongings.

Supporting Information as Evidence of Compliance:

i. Facility design and/or layout to show proper considerations for procedure room and recovery area
ii. Access control measures.
iii. Recovery monitoring equipment, including number and locations.
iv. Temperature and ventilation control.

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.2.	Standard Name: Facility, Design & Planning: Sluice or dirty utility area.	ROP: No

Standard Statement / Goal:
A well-kept sluice/dirty utility area or sterilization station should be available.

Intent:
The Sluice/dirty utility area should allow all soiled linen and instruments to be discarded or cleaned. This is to ensure that adequate infection control is always maintained. This area requires a defined unidirectional workflow for instruments from dirty to clean or sterile and then to the clean/sterile store.

Interpretation Guidelines:
There should be a designated central sterile services department (CSSD) and/or Sluice/dirty utility area to disinfection instruments and clearing soiled linen. This area should have adequate space to enable its full functionality.

A flushable sink is advisable in the Sluice/dirty utility area, with documentation stating: 'No handwashing'.

There should be a clean area to place an autoclave and/or sterilizing container. The sterilizing/cleaning solutions used should be embryo-safe, or disinfectants should be flushed with sterile water before use to ensure residues are removed.

No cardboard boxes should be permitted to enter the clean area.

The sterile stock should not be stored in this area to avoid the potential for mixing unsterilized instrument sets with sterile sets. A door should seal the dirty and clean areas.

There can be a 3rd party agreement with an outsourced service contractor with an appropriate laundry service and a sterile pack service provider where required. Linen should be of material with low lint shedding, and laundry washed with low volatile organic compounds (VOCs) release (no perfumes) appropriate for ART.

If an autoclave is used/present:
The size of the autoclave should be sufficient to enable a correct load of packs/items to be sterilized according to the healthcare establishments' needs.

The autoclave should be serviced at the correct intervals, as per the manufacturer's instructions.

Sterile indicators should be used to make sure that items coming out of the autoclave have been effectively sterilized.

Autoclave run logs should be maintained noting the following: Date, Time, Packs/items, Temperature, Pressure, Sterilizing time, and drying time. Routine and regular tests should be run on the autoclave to ensure the items are adequately sterilized (i.e., Bowie Dick tests).

Appropriate staff should receive training on working the autoclave and troubleshooting any problems.

Supporting Information as Evidence of Compliance:

i. Facility design and layout to show proper considerations for sterilization and sluice/dirty utility areas as needed.
ii. Evidence of up-to-date service certificate of the autoclave (if present and in use).
iii. Evidence of the quality control logs for the autoclave – testing kits, run logs (indicating temperature and pressure for each run) (if present and in use).
iv. Copy of 3rd party agreements (service contractor) for sterile services where applicable.

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.3.	Standard Name: Qualifications & Staff Structure: Training for nurses in ART sedation procedures and recovery.	ROP: **Yes**
Standard Statement / Goal: The nursing staff who perform duties during sedation procedures and recovery processes on-site must have the appropriate training, competency, and experience.		
Intent: Nursing staff to assist in sedation procedures and recovery must have the proper training and knowledge to perform their functions and provide the expected quality patient care during these services.		
Interpretation Guidelines: The nursing staff providing nursing services during sedation and recovery must have completed appropriate training as required by SANC and be competent to do so or work under the direct supervision of the sedation practitioner. The training of the nurses must include appropriate understanding and use of the relevant medical devices and clinical equipment authoritatively to ensure patient health and safety. Specific policies/ procedures must be in place for training, supervision and competency recording when nurses must work outside the scope of practice, e.g., diagnostic ultrasound, pregnancy testing or sperm preparation for insemination.		
Supporting Information as Evidence of Compliance: i. The policy of nurse training for sedation and recovery procedures, including any additional procedures outside the scope of practice where applicable.		

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.4.	Standard Name: Processes & Procedures: Patient identification for admission & discharge.	ROP: **Yes**

Standard Statement / Goal:
All patients admitted for the on-site procedures must be identified with their recognised information.

Intent:
Positive identification of patients before procedures is essential, including during recovery and discharge processes.

Interpretation Guidelines:
The patient must have a unique folder number.

The patient's details must be visible where the procedure is done for their identity and correct procedure to be confirmed.

There must be two sets of identifying information used for each patient, namely:
- an identity bracelet on the patient's arm to identify him/her,
- the patient must actively inform staff what their name and surname is to confirm detail on the bracelet.

Active checks must be performed to confirm the identity of a patient.

Supporting Information as Evidence of Compliance:
i. Identification SOPs for admissions and discharges for procedures.

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.5.	Standard Name: Information, Communication & Feedback: Consents and documentation for procedures and recovery.	ROP: **Yes**
Standard Statement / Goal: The patient must have informed consent and medical documentation completed for all procedures performed.		
Intent: Patients must give and sign appropriate medical consent forms before undergoing procedures in the procedure room, and all the relevant medical documentation regarding admission, procedures, recovery and discharge processes must be completed for all patients and procedures.		
Interpretation Guidelines: There must be appropriate consent forms and medical documentation for the type of procedures done in the procedure room. The consent forms must be signed and received by an authorized staff member (doctor/nurse) before the procedure. The relevant medical documentation for recording medical information for the procedures and recovery processes must be in place, completed and filed for future reference.		
Supporting Information as Evidence of Compliance: i. Consent and medical documentation forms for procedures, including random patient record (de-identified).		

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.6.	Standard Name: Risk and Emergency Management: Cleaning and infection control in recovery.	ROP: No

Standard Statement / Goal:
Optimal hygiene standards and infection control in the recovery area surrounding the procedure room.

Intent:
To provide adequate hygienic and clean conditions in the recovery area and hallways surrounding the procedure room to prevent infections, including active cleaning and linen and consumable replacement measures between changing patients.

Interpretation Guidelines:
Cleaning, consumable replacement and disinfection SOPs between patients and monitoring before and after admission and discharge processes should be in place.

Linen and laundry management for replacing, cleaning, storage and supplying the recovery area and procedure beds should be in place.

Supply and management of clean attire, including clean gowns and single-use covers (e.g., caps, shoe/foot covers, etc.) for patients before entering the procedure room as required should be in place. Prompt response and management of incidental fluid spills (i.e., blood, vomit, etc.) within recovery and ablution facilities of the recovery areas should be in place.

The presence and use of regular and medical waste bins for appropriate disposal with appropriate signage for patients to understand should be in place.

Supporting Information as Evidence of Compliance:

i. Cleaning, consumable replacement and disinfection policy for the recovery room.
ii. Linen and patient attire management.
iii. Waste management and signage for the recovery area, including in the ablution facility.

PROCEDURES AND RECOVERY

DEPARTMENT: Nursing Services		Section: Procedures and Recovery
F.7.	Standard Name: Risk & Emergency Management: Power back-up and emergency trolley.	ROP: **Yes**

Standard Statement / Goal:
Appropriate SOPs and equipment must be in place to handle medical emergencies, including power backup to critical equipment supplied and monitored.

Intent:
It is essential to provide the recovery area with the necessary emergency equipment for proper emergency care, and power backup must be supplied to the critical and emergency equipment.

Interpretation Guidelines:
The organization must ensure there is a plan in place for the following, but not limited to:

- Sufficient and properly located power backup supply for critical emergency equipment,
- Emergency Trolley for medical emergencies or easy and quick access if shared with the procedure room.

The power supply to the critical equipment must be uninterrupted power supply to prevent damage and supply sufficient long-term supply to critical and emergency equipment.

Training must be provided for nurses to know how to manage the failure of utilities (UPS), and a call system must be in place for remote monitoring of essential equipment under the care of a specifically designated nurse as needed.

The organization must ensure that an Emergency Trolley is in place or is located in such proximity to the recovery area that personnel have quick and easy access.

Supporting Information as Evidence of Compliance:

i. Location, training and monitoring logs of power backup and emergency and critical equipment functioning in recovery while on power backup.

LABORATORY SERVICES

Contributors

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Guidelines: Authoritative / Informative References

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2. (Magli et al., 2008)
3. (De Los Santos et al., 2016)
4. (Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology, 2008)
5. (Mortimer and Mortimer, 2005)
6. (Hammond and Morbeck, 2019b)
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8. (Morbeck, 2015)
9. (Esteves and Bento, 2013)
10. (Agarwal et al., 2017)
11. (World Health Organization, 2021)
12. ('Association of Biomedical Andrologists – Laboratory Andrology Guidelines for Good Practice Version 3 – 2012', 2012)
13. (Practice Committees of the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, 2021)
14. (Pfeifer et al., 2016)
15. ('BSI Standards Publication Medical laboratories — Requirements for quality and competence (ISO 15189 : 2012)', 2012)
16. (Alpha Scientists in Reproductive Medicine, 2012)
17. (South African Department of Health, 2012b)
18. (ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine, 2017)
19. (Practice Committees of the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, Committee of the Society for Assisted Reproductive Technology and Committee of the Society of Reproductive Biologists, 2014)
20. (CFAS ART Laboratory Special Interest Group, 2016)
21. (Loskutoff et al., 2013)

LABORATORY SERVICES

G. LABORATORY SERVICES

Table 7. Content summary of Standards for Laboratory Services.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	No	1. Workspace, design, and accessibility of laboratories.
	No	2. Cleanrooms and workstations for therapeutic procedures.
	No	3. Storage facilities and accessibility for laboratory supplies.
	No	4. Cryostorage dewar location(s).
	No	5. Semen collection room.
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	6. Required qualifications and registrations.
	No	7. Staff structure and levels.
	No	8. Training and credentials.
EQUIPMENT & CONSUMABLE MANAGEMENT	No	9. Laboratory equipment management and maintenance.
	No	10. Consumables for diagnostic and therapeutic procedures.
	No	11. Cryostorage dewars.
PROCESSES & PROCEDURES	No	12. Policies and standard operating procedure management system.
	No	13. Quality management systems for embryology and cryopreservation procedures.
	Yes	14. Traceability and identification of patient samples.
INFORMATION, COMMUNICATION & FEEDBACK	**Yes**	15. Patient information and consent.
	No	16. Documentation and reporting of laboratory procedures.
	No	17. Documents, reports, and consent control.
RISK & EMERGENCY MANAGEMENT	**Yes**	18. Infection and contamination control in laboratories.
	Yes	19. Emergency back-up power supply to critical laboratory equipment.
	Yes	20. Access control and liquid nitrogen safety.
	Yes	21. Adverse events, emergency, and disaster planning.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.1.	Standard Name: Facility, planning & design: Workspace, design, and accessibility of laboratories.	ROP: No

Standard Statement / Goal:
Laboratory areas should be constructed using appropriate materials and should have sufficient ventilation and light. Design should provide adequate space with designated administrative areas and clean rooms for therapeutic processing, including consideration for operator comfort, efficiency, and safety of the gametes and embryos.

Intent:
Ergonomic emphasis should be placed on the laboratory space design and workflow to ensure efficiency and minimize the risk of accidents whilst optimizing the protection of the biological samples and achieving optimal embryo culture outcomes. The space should be sufficient for the number of procedures and comfortable for staff. Areas, where liquid nitrogen (LN) is used should be fit for purpose. Access control for authorized personnel should be considered.

Interpretation Guidelines:
The laboratories should be constructed with materials appropriate for the type of laboratory and service provided; therefore, materials used in the construction of different work areas should be fit for purpose according to designated use (chemicals, stains, samples). It must include consideration to minimize bacterial growth and regular disinfection requirements.

There should be adequately covered floor and wall surfaces which are unfavourable for bacterial growth and non-absorbent to fluids.

Laboratories and work areas should have air control supplying adequate ventilation, temperature control and light control for visibility. The use of controlled lighting and minimal sun or UV exposure in the laboratory should be in place.

Procedures requiring aseptic techniques should be physically separated from other activities, including separated designated areas for sample processing/procedures and record keeping, data entry and administrative duties.

Adequate space and work efficiency consideration should be provided for each designated area according to the laboratory services and workload, and specific considerations where physical workspaces are shared for different laboratory activities.

The risk of accidents while handling or carrying containers with gamete or embryos should be considered and minimized.

Laboratory access should be restricted to authorized personnel only.

Clear distinctions between hand washing and laboratory/chemical washing should be indicated.

Supporting Information as Evidence of Compliance:

i. Evidence/Visual inspection of design and floor plan to demarcate the layout of the lab and working ergonomics.
ii. Identify different workspaces and facilities allocated according to the type of procedure, i.e., chemical workspaces, diagnostics, admin, therapeutic etc.
iii. Evidence/Visual inspection of access control method.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.2.	Standard Name: Facility, Planning & Design: Cleanrooms and workstations for therapeutic procedures.	ROP: No

Standard Statement / Goal:
Laboratory areas for therapeutic procedures should be a stable cleanroom environment with specific attention to Volatile Organic Compound (VOC) release and stringent air quality control and temperature control that is appropriate for handling gametes, embryo culture and manipulation techniques.

Intent:
Various environmental factors and temperatures affect the quality of gametes and embryos. Therefore, samples should be safeguarded against these external influences. A stable cleanroom environment with materials with low VOC release that adheres to stringent air quality and temperature control measures is required to optimize gamete and embryo handling and aseptic techniques. Workstations for therapeutic procedures should achieve good air flow and filtering capacity levels.

Interpretation Guidelines:
The cleanroom(s) should be constructed with materials appropriate for laboratories and clean rooms, with specific additional consideration of minimizing particles and VOCs being released by materials.

The cleanroom setup should be conducive to gamete and embryo culturing, allowing temperature control, light control, low VOC release and aseptic techniques. Although VOCs measurement or monitoring is not required, special consideration should be taken of the type of materials used during setup to minimize the presence of VOCs (paints, glues, steel, laminated wood etc.).

Surfaces, benches, cupboards, and furniture materials should be of materials with low VOC release.

All surfaces and furniture should be conducive to regular cleaning with appropriate disinfectants.

The air filtration handling unit should be able to provide the embryology laboratory with positive pressure over all adjacent areas/laboratories. It should be separated with closed doors to maintain positive pressure during operations. Positive pressure should be monitored.

In air handling units or setups that recycle air to optimize laboratory air filtration, the fresh air should be sufficient for personnel and shown to be calculated and checked by the air handling unit technician.

Air quality in laboratories and workstations should be regularly monitored, at least annually, by certified measurements that include particle counts and air changes per hour.

Appropriate workstations with extraction (Fume hood) should be used when working with fixatives, VOCs, or other toxic agents.

Cleanroom access should be restricted to authorized personnel only.

Low lint shedding laboratory attire should be provided to be used in clean room areas, and a designated change room area should be available in the proximity of cleanroom entrances.

Supporting Information as Evidence of Compliance:

i. Floorplan and physical inspection for identification of different workspaces and facilities allocated according to the type of procedure, i.e., chemical workspaces, diagnostics, and therapeutics.
ii. Evidence of Air handling unit/Positive pressure unit and HEPA filtration.
iii. Validation and certification of filtration and positive pressure unit.
iv. Evidence and visual inspection of cleanroom laboratory attire and changing rooms.
v. Access control to cleanroom areas.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.3.	Standard Name: Facility, planning & design: Storage facilities and accessibility for laboratory supplies.	ROP: No

Standard Statement / Goal:
Laboratory supplies and consumables should be stored appropriately, and media and chemicals according to manufacturers' instructions. Designated storage should facilitate use and stock control.

Intent:
The quality of laboratory supplies may be affected by improper storage, and manufacturers' instructions should be followed for proper storage. Designated storage facilities should be accessible for operators and stock control processes.

Interpretation Guidelines:
The laboratory should have designated and appropriate storage facilities for supplies and consumables to facilitate stock control processes, maintain product integrity and be accessible to areas of use.

Media and chemicals should be stored according to manufacturers' instructions to maintain the quality of the product.

Supporting Information as Evidence of Compliance:

i. Evidence/Visual inspection of storage areas indicating designated storage facilities by the type of consumables, media, or chemicals being stored (Chemical cabinet, fridges, storerooms etc.).
ii. Accessibility of storage areas.
iii. Evidence of a stock control system.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.4.	Standard Name: Facility, planning & design: Cryostorage dewar location(s).	ROP: No

Standard Statement / Goal:
Cryostorage dewars and liquid nitrogen (LN) reservoirs should be in well-ventilated spaces and accessible to trained staff.

Intent:
Nitrogen is an asphyxiant which displaces breathable oxygen. The design of the allocated space(s) where storage dewars and reservoirs are kept should ensure sufficient ventilation and only be accessible to adequately trained staff. Accessibility should also ensure safe movement between the cryopreservation workspace and storage.

Interpretation Guidelines:
The storage dewars and LN reservoir should be located in designated space(s) that have been designed to provide sufficient ventilation to dissipate LN vapour.

Surfaces and materials which usually can come in direct contact with LN during cryopreservation procedures should be fit for purpose and resistant to explosion or cracking.

The storage area should have sufficient space for staff to access dewars, decant LN from reservoirs and safely move from the storage area to the cryopreservation workspace as required during cryopreservation and cryobanking procedures.
Space for all storage dewars of cryopreserved material should comfortably accommodate all the storage dewars and allow easy access to each dewar as required.

Any equipment required to use (open or close or access) any storage dewar or access LN (decant or pump) should be available, properly stored and accessible in the storage area, and instructions should be available for safe use.

Supporting Information as Evidence of Compliance:

i. Evidence/Visual inspection of cryostorage area(s) of dewars with location, design and/or layout with indication of ventilation, LN contact materials, and movement between workspaces and storage area(s) for access.
ii. Equipment related to storage dewars and LN reservoir use including their location and instructions.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.5.	Standard Name: Facility, planning & design: Semen collection room.	ROP: No

Standard Statement / Goal:
Semen samples should be collected in a private room near the laboratory to limit the exposure of the semen to environmental fluctuations and to control the time between collection and analysis.

Intent:
A suitable semen collection room (SCR) is essential to quality care for Andrology. The SCR should be located near the laboratories to control environmental effects. Washing facilities for before and after collection should be available in the SCR.

Interpretation Guidelines:
Instructions for producing a semen sample should be posted in the SCR.

The room should be designed and equipped with careful consideration for the following:

- Clutter free and safe decontamination
- Comfort, privacy, security, and hygiene
- Access for disabled patients
- Requirements for couples

A bathroom should be available close by if a toilet is not located in the room. If a semen collection room is not present at the laboratory, clear instructions should be available for off-site production.

Supporting Information as Evidence of Compliance:

i. Evidence/Visual inspection of semen production rooms and available facilities (toilet, basin, etc.).
ii. Instruction leaflets on producing a semen sample using the various acceptable methods (masturbation, special condom etc.).
iii. If a semen collection room is not present on-site, evidence of alternative options is available, and instructions for semen collection off-site.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.6.	Standard Name: Qualifications & staff structure: Required qualifications and registrations.	ROP: **Yes**

Standard Statement / Goal:
All ART laboratory services may only be performed by qualified embryologists (Clinical Technologists and/or Medical Biological Scientists in Reproductive Biology) with relevant HPCSA registration.

Intent:
All embryology and andrology procedures must be done by laboratory staff that hold the relevant reproductive biology qualifications and who is registered as such with the HPCSA.

Interpretation Guidelines:
Only qualified embryologists must perform embryology and andrology procedures for assisted reproduction with current, active HPCSA registration as embryologists.

Fully qualified embryologists must be registered with the HPCSA with Independent Practice status as either of the following:

- Clinical Technologist in Reproductive Biology; or
- Medical Biological Scientist in Reproductive Biology.

Supervision under a fully qualified embryologist (as above) for performing ART procedures is required for HPCSA registrations with Supervised Practice:

- Clinical Technologist (Reproductive Biology) with a national diploma; or
- Clinical Technologist or Medical Biological Scientist Interns in an accredited training institute.

The laboratory service must have at least two embryologists, of which the primary one must be a fully qualified embryologist with independent practice.

A secondary embryologist that is an off-site backup must also be fully qualified.

The laboratory management must support employed laboratory staff to achieve the required Continuous Professional Development (CPD) points to uphold HPCSA registration. All laboratory staff must maintain their professional development with accredited activities and earn the required annual CPD points.

Training of intern embryologists must be conducted in accordance with HPCSA training institution accreditation.

Supporting Information as Evidence of Compliance:

i. Copies of qualifications and HPCSA current registrations of all laboratory staff.
ii. Staffing list and organogram.
iii. Training institution accreditation if applicable.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.7.	Standard Name: Qualifications & staff structure: Staff structure and levels.	ROP: No
Standard Statement / Goal: Laboratory staff should be structured according to responsibilities. Staff levels should be sufficient to provide services and accommodate supervision during therapeutic procedures.		
Intent: Laboratory staff should be clearly and appropriately structured according to the level of responsibility. Sufficient staff should be available according to the laboratory procedures provided. The team structure should provide supervision where training is done and witness all critical steps.		
Interpretation Guidelines: Staff should be structured according to the laboratory services provided, and the number of staff should be sufficient to handle the patient/sample loads. The number and complexity of treatment cycles/cases and diagnostic/analytical services, including student training where applicable, should be considered. Where training is done, the team structure should supervise the trainee with trained personnel as required during all laboratory procedures.		
Supporting Information as Evidence of Compliance: i. Presentation of Laboratory staff structure with responsibility levels, including supervision for training and supervised practice during therapeutic procedures as applicable. ii. Evidence of Rotation schedule indicating staff rotation (i.e., weekly planner, weekend work) responsibilities and according to patient/procedure loads.		

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.8.	Standard Name: Qualifications & staff structure: Training and credentials.	ROP: No

Standard Statement / Goal:
Personnel with appropriate training and credentials should perform all diagnostic and therapeutic laboratory procedures to ensure competency. Relevant competency benchmarks should be continuously monitored should be implemented.

Intent:
Proper handling, analyses and processing of reproductive fluids, gametes or embryos is essential to quality service in assisted reproduction. The execution of procedures should be done by or under the supervision of adequately trained personnel. The laboratory should have a KPI monitoring system and a competency benchmark system to confirm competency per operator in place.

Interpretation Guidelines:
Laboratory staff should be adequately trained in the procedures and SOPs they are expected to perform and the proper use of equipment and instruments, including safety and risk management protocols.

Procedural outcome data of processes and operators should be analyzed for performance KPIs, and competency benchmarks should be in place.

Regular reviews by team leaders for proficiency and competencies are advised for re-training consideration accordingly.

Competency and training of relevant staff should entail attending appropriate workshops and educational material or related discussions.

Supporting Information as Evidence of Compliance:

i. Evidence of staff training and records of the workshop and educational activity attendance.
ii. Policies on training expectations for performing therapeutic and diagnostic ART procedures by staff in the laboratory.
iii. Policies on KPIs and benchmarks for monitoring procedures that also includes operator competency.
iv. Evidence of KPI reviews and discussions regarding competency and recommendations made.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.9.	Standard Name: Equipment & consumable management: Laboratory equipment management and maintenance.	ROP: No

Standard Statement / Goal:
Laboratories should have and maintain equipment that is fit for purpose. Equipment should be in working condition and sufficient to perform the diagnostic and therapeutic procedures offered by the laboratory.

Intent:
The laboratory should contain the appropriate equipment for the optimal handling and culturing of gametes and embryos. Laboratory equipment should be maintained according to prescribed service intervals, validated to be fit for purpose before diagnostic and clinical use, and continuously monitored to ensure proper function.

Interpretation Guidelines:
Equipment manuals should be available with user instructions and service requirements, including troubleshooting, safe handling, transport, and storage to prevent deterioration.

Only trained personnel should operate laboratory equipment.

The service and calibration schedule for all equipment should be in line with the manufacturer's recommendation and supported by relevant documentation.

Support technician contact details for all equipment should be in place.

All laboratory equipment should have logs of continuous performance monitoring by relevant systems or personnel.

A protocol should be in place for the management of defective equipment. This should include measures to prevent the use thereof and ensure that a backup is available that can be used so that laboratory services can safely continue.

Supporting Information as Evidence of Compliance:

i. Evidence of manufacturer's manual with user instructions available for all equipment (electronic or hard copies).
ii. Evidence of equipment service providers list and schedule.
iii. Evidence of monitoring of critical equipment.
iv. Evidence of service records of critical equipment.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.10.	Standard Name: Equipment & consumable management: Consumables for diagnostic and therapeutic procedures.	ROP: No

Standard Statement / Goal:
All procedures involving handling gametes and embryos should be done using the appropriate consumables and media.

Intent:
Processing and handling reproductive fluids, gametes or embryos should be performed using appropriate consumables and mediums specifically manufactured for purposes that have not expired.

Therapeutic processes should include sterile contact consumables with additional safety analyses and media manufactured explicitly for the procedures.

Interpretation Guidelines:
Consumables and media used for laboratory procedures should be fit for purpose according to the process or procedure.

Consumables and media should preferably be supplied by reputable commercial manufacturers and not contain any material of animal origin.

Any consumable or medium in contact with patient samples, especially for therapeutic processing, should be sterile and have additional analyses or confirmation of safety for the sample type (Mouse embryo assay, human sperm survival assay etc.) and should not have reached expiration.

Protocols describing the proper use, handling and storage of consumables and media should be available. Where storage at a defined temperature is specified, ongoing records of the storage temperature should be recorded.

An appropriate stock management system should be available for all consumables, media and reagents (records of batches, usage and suppliers with details). Records should be kept by laboratories to trace defects or recalls.

The stock control system should ensure proper rotational use and levels for consumables and media, including steps to be taken when consumables or media do not conform to product inserts or operator expectations.

Supporting Information as Evidence of Compliance:

i. Evidence and descriptions of consumables and media required/used in the laboratory (in SOPs).
ii. Evidence of a list of suppliers and contact details.
iii. Evidence of stock management systems of mediums and consumables, including records of levels, batches, dates used and expiration dates.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.11.	Standard Name: Equipment & consumable management: Cryostorage dewars.	ROP: No

Standard Statement / Goal:
Cryostorage dewars in use should be sufficient, operational, and monitored.

Intent:
ART cryopreserved material is stored in dewars using either LN or nitrogen vapour. These storage dewars and the LN reservoir should be in good working condition to maintain the temperatures needed for cryopreservation storage. Regular monitoring for stability and operation is required.

Interpretation Guidelines:
All cryostorage containers/dewars used for cryopreservation should be regularly checked for leaks, level of liquid nitrogen, storage space remaining, and clarity of key identifiers used.

A guideline or protocol should be in place describing the checking of liquid nitrogen levels, with scheduled confirmation of changes over time to check for leaks and visual inspection of ice build-up, the integrity of the neck, wheels, and general storage room (alarm/monitoring system for LN2 levels or other accessories or monitoring equipment). Minimum container levels should be known and clearly indicate where the checks are being performed.

An SOP should be in place to validate new dewars before storage for samples.

Sufficient storage containers should be available according to the number of samples being processed and cryopreserved, with separate containers being advised for different types of cryopreserved samples.

Separate containers for material from patients with blood-borne viruses are also advised.

There should be reserve spaces or a reserve dewar to accommodate the movement of canisters or stored samples in case of dewar failure.

Supporting Information as Evidence of Compliance:

i. Evidence of quality control SOPs for cryostorage dewars.
ii. Evidence of logbook of LN2 levels measuring etc.
iii. SOP and/or Policy on the management of cryostorage dewars.
iv. Evidence of inspections and validations (service records).

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.12.	Standard Name: Processes & procedures: Policies and standard operating procedure management system.	ROP: No

Standard Statement / Goal:
Laboratories should have current versions of the SOPs and policy documents on all the services offered.

Intent:
SOPs and policies should describe and guide all laboratory procedures' significant decisions, actions, and principles. SOPs should assure reproducibility and competence in performing all services, including quality control processes.

Interpretation Guidelines:
A system of laboratory policies and SOPs should be in place.

The policies should be updated and maintained, with current versions available in the laboratory where required. Policy manuals and SOPs should be reviewed and revised annually and be aligned with updated internationally accepted standards.

The policies and SOPs for all procedures offered and/or performed by the laboratory should describe in sufficient detail to assure reproducibility and competence in performing the laboratory services, including quality control processes.

SOPs should address the handling of each sample & be written and available (paper &/or electronically) to all the staff for executing the processes to refer to it.

Short and graphic protocols that match the complete SOPs can be used as a quick reference for staff to ensure consistency at specific workstations. Compounded procedures can be described in a single SOP, if applicable.

SOPs should include the specimen chain of custody within the facility and have specimen witnessing at all critical steps as identified by laboratory management.

Protocols should be comprehensive and include preparation processes, sample handling methods, devices, and equipment.

The staff that are appropriately trained and listed to perform specific procedures should be outlined in the SOPs.

The quality management system should be integrated to allow actionable changes to occur according to reviews, mainly when sub-optimal outcomes are recorded.

All manuals or SOPs should be updated, reviewed, and revised annually or when changes are made.

A backup of all SOPs should be kept off-site or in a cloud, and older versions should be archived when no longer in use - but be available for reference.

Supporting Information as Evidence of Compliance:

i. Evidence of the outline/index of Policies and SOPs relating to laboratory procedures offered.
ii. Evidence of current Policies and SOPs (hardcopy or electronic) and the backup in place.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.13.	Standard Name: Processes & Procedures: Quality management systems for embryology and cryopreservation procedures.	ROP: No

Standard Statement / Goal:
Laboratory processes should be managed to optimize outcomes, and performance indicators should be monitored to support quality assurance processes. The results of ART cycles should be monitored by key performance indicators (KPIs) to evaluate efficacies continuously.

Intent:
Quality management is the integration of activities, which include quality control, quality assurance and quality improvements. A quality management system should be in place to provide a statistical monitoring system that can detect culture condition shifts in embryology procedures and monitor and optimize cycle outcomes. Key performance indicators (KPIs) should be calculated, compared to accepted benchmarks, and regularly reviewed for adjustments.

Interpretation Guidelines:
Relevant outcome data from all procedures provided should be captured in a database for KPI analysis, regularly ensuring current results.

The laboratory should maintain a series of KPIs to monitor laboratory processes and outcomes. The laboratory management should define the parameters, KPI calculations and expected benchmarks to be achieved internally and include quality indicators as provided in internationally accepted consensus publications.

Policies/ SOPs reflecting the KPI outcome and possible actions required (if any) if the KPIs fall outside the set max and min parameters.

Documentation of KPIs and outcomes should be appropriately filed and archived for future reference.

Supporting Information as Evidence of Compliance:

i. Presentation of the laboratory database for capturing and analysis for KPI calculations with comparisons to own defined and published competency and/or benchmark values.
ii. Evidence of a schedule of KPIs reviews and discussions.
iii. Presentation and/or guidelines for troubleshooting and corrective actions when KPIs fall below expected values (e.g., root cause analysis).

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.14.	Standard Name: Processes & Procedures: Traceability & Identification of samples.	ROP: **Yes**

Standard Statement / Goal:
A system must be in place to ensure accurate traceability of patient samples with their identifiers throughout the laboratory service provided to control critical steps and avoid possible misidentification.

Intent:
It is a requirement for a laboratory to ensure accurate and precise identification of patient samples at the time of handling to trace, retrieve and process the correct patient sample(s) quickly and accurately. At a minimum, two unique identifiers are required for all samples to ensure positive identification.

Interpretation Guidelines:
All SOPs relating to patient traceability and witnessing must be clear, consistent, and implemented to ensure accurate traceability throughout the laboratory procedures.

Verification and witnessing of corresponding patient details, containers, and documents must be done at critical steps. The identity of the individual providing the witnessing must be adequately recorded on laboratory forms and be available for future reference or in case of inquiry.

Critical steps include, but are not limited to:
- Retrieval of gametes from the patient,
- Insemination of oocytes with spermatozoa,
- Loading of the embryo transfer catheter before the transfer procedure,
- All steps of cryopreservation,
- Semen processing.

Unique patient identifiers must be generated consisting of numeric or alphanumeric codes and/or combinations of patient details, treatment date and sample details. The unique identifiers must be generated consistently to ensure easy, reliable recognition by all staff.

Labelling must be permanent, clear, legible, and easily visible within the laboratory and/or incubator environments.

Supporting Information as Evidence of Compliance:
i. Evidence of SOPs and/or policy addressing the witnessing chain and identification at critical steps.
ii. Evidence of SOPs for patient identification and generation of unique identifiers.
iii. Evidence of labelling system including cryostorage.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.15.	Standard Name: Information, communication & Feedback: Patient information and consent.	ROP: **Yes**

Standard Statement / Goal:
To receive informed consent for procedures before treatments and follow appropriate information and explanations to the patient(s).

Intent:
The patient must give informed consent before performing any procedure. Information and the contents of the consent regarding the planned procedures must be relayed and be available to patients to provide proper informed consent for the appropriate processing of their samples. Consent must be filed and kept for future reference.

Patients requiring transport of their specimens should be well informed of the potential risks and liabilities and recommended shippers or modes of transport and available couriers.

Interpretation Guidelines:
Consent must be in place for all diagnostic and therapeutic procedures performed by the laboratory.

Patient information regarding the various diagnostic and therapeutic procedures/manipulation techniques must be available to assist in informative discussions and for patient use.

Patient consent (either verbal or signed) must be in place before procedures are performed.

Consent must be in advance, with enough time for the patient to understand the procedure and ask questions. Withdrawal of consent must be respected and documented.

The laboratory must verify that appropriate informed consent is obtained before performing the treatment.

Adapted consent and communication procedures must be in place for patients with additional requirements, e.g., persons with a physical or mental disability or language barrier.

Patients must be given sufficient information on transportation procedures before any transportation process of fresh or cryopreserved sample material. The information must include details regarding the potential risk of specimen loss during transportation, packing processes, handling at the various stages during shipping, thawing procedures and liability in case of failure.

Supporting Information as Evidence of Compliance:
i. Evidence/list of consent forms available for procedures performed by the laboratory.
ii. Policy on consent from patients with additional requirements.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.16.	Standard Name: Information, communication & Feedback: Documentation and reporting of laboratory procedures.	ROP: No

Standard Statement / Goal:
To accurately document the relevant outcomes for communication to both other healthcare professionals and patients. All processes and/or procedures should be well written, including results and all relevant information.

Intent:
Reporting should be transparent with internationally accepted reference values where applicable.

Insightful interpretative comments and summary of results are essential according to the clinical interpreter, i.e., expert fertility clinicians may require a low level of commentary. Still, a higher level may be required for other healthcare providers.

Laboratory processes should be adequately recorded, with outcomes and relevant information communicated to the treating physician and appropriate departments to ensure quality reproductive care. It should promote information sharing, patient feedback and patient communication.

Interpretation Guidelines:
Proper and sufficient documentation of all diagnostic and therapeutic procedures should be in place.

Documentation should include labelling of consumables, method & techniques for sample handling, a device used, date & time manipulation, operators at handling intervals or procedures performed, witnesses, sample quality and grading, stage of development and incubator placement.

Relevant information regarding the outcome/result should be provided to the treating physician. Reporting should include patient identification details, date of treatment, sample type, quality and stage of development, and procedures performed.

All information should be available for reporting and feedback to the patient when requested.

Documentation of procedures and outcomes, including all correspondence between staff, patients, and referring colleagues, should be appropriately filed and/or recorded in the patient medical record for future reference.

Supporting Information as Evidence of Compliance:

i. Evidence of a policy on reporting results.
ii. Example of the report and interpretive commentary.
iii. Presentation of laboratory procedures for documentation, recording, filing, and reporting of all procedures performed, outcomes, and sample types involved (show blank or anonymized examples), including the different types of manipulation.
iv. List/Index of available forms used for diagnostic and therapeutic procedures, i.e., semen evaluation form, Embryology culture report/summary, Cryopreservation report.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.17.	Standard Name: Information, communication & Feedback: Documents, reports, and consent control.	ROP: No

Standard Statement / Goal:
The laboratory should have an organizational document control system to ensure proper documentation for all laboratory services.

Intent:
Laboratory services involve several types of the necessary documentation. A system should be in place to ensure the proper use of appropriate documents; current versions are used, regular updates are done, the documents about the laboratory service are available to responsible staff where required, and a backup is in place.

Interpretation Guidelines:
An organizational system for laboratory documentation should be in place.

The documents include, but are not limited to:

- Information leaflets,
- Record keeping of processes and/or tests,
- Reports,
- Consents.

Documentation should be updated and maintained, with current versions available in the laboratory where required. The system should ensure reviews and updates at least annually.

Signed informed consent should be checked as received and should be on record before commencing procedures and treatments.

The laboratory documentation system should have an automated regular backup system, e.g., cloud service and external drive set-up.

Medical files and information should be handled confidentially and be appropriately stored and organized for reference during laboratory operations.

Supporting Information as Evidence of Compliance:

i. Document control management system/policy with the review process.
ii. Consents and laboratory records management.
iii. Accessibility control of current documentation.
iv. A backup setup for the laboratory document system.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.18.	Standard Name: Risk Management & Emergency Plans: Infection and contamination control in laboratories.	ROP: **Yes**

Standard Statement / Goal:
All laboratory procedures and protocols must include measures to be taken to reduce the risk of cross-contamination and promote staff safety. A safety manual must be readily available, and all personnel must be familiar with safety and protective measures.

Intent:
All laboratory procedures entail handling potentially infectious biological material and fluids, posing the potential hazard of transmitting diseases to personnel and contamination other biological samples, consumables, and equipment. Medical waste must be managed appropriately. Safety processes must be in place for staff safety and reduce the risk of cross-contamination.

Interpretation Guidelines:
Laboratory SOPs must include safety measures and aseptic techniques for handling procedures of samples, specimens, equipment, medium and consumables. The Laboratory Safety manual must address the criteria for achieving a safe and healthy working environment.

Laboratory policies and manuals on lab safety must be reviewed and revised annually.

Protocols must aim to reduce contamination risks during the handling and processing of specimens, including seropositive samples during gamete processing, culture, cryopreservation, and storage. For example, samples from different patients must not be handled or processed simultaneously in the same workstation, or a specifically dedicated work area must be identified.

Disinfection must be done when any form of spilling or like occurs. Protocols must be available to safely and effectively clean and disinfect equipment and work areas.

Hand washing facilities must be in or close to laboratory areas, especially and preferably at entrances to cleanrooms (no basins within cleanrooms).

Only disinfectants with proven ART laboratory compatibility and efficacy must be used at or in the proximity of therapeutic processing stations.

All bodily fluids must be handled as biohazardous material. Adequate facilities and containers must be available for the safe disposal of hazardous or biological waste. A recognized biological waste company must be used to manage medical waste. Medical waste and any used consumables in contact with biological materials must be disposed of as prescribed.

Vaccinations and appropriate personal protective equipment must be offered and/or available for staff safety to handle biological material.

Staff must be informed of viral screening information and seropositive/infected patients before processing such samples to ensure appropriate protocols are followed. Specific preventative protocols must be in place for processing seropositive samples.

Supporting Information as Evidence of Compliance:

i. Policies and SOPs of aseptic techniques and contamination reduction (need to be specific within general SOPs).
ii. SOPs for handling processes (fluids, gametes, culture, cryopreservation, storage) of seropositive patient samples, including additional protective and contamination reduction measures.
iii. Disinfectants with corresponding compatibility and efficacy labelling or similar as applicable.
iv. Evidence of protection and disinfection procedures at workstations.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.19.	Standard Name: Risk Management & Emergency Plans: Emergency back-up power supply to critical laboratory equipment.	ROP: **Yes**

Standard Statement / Goal:
A regulated backup power supply must be available for and connected to all critical and sensitive laboratory equipment to prevent detrimental effects of power failures, interruptions of optimal embryo culture conditions and damage to sensitive instruments.

Intent:
There must be an uninterrupted backup power supply to provide and regulate electrical power to all critical equipment related to sample processing, cold storage, incubation, and visibility (light) to prevent interruptions, ensure the continuation of laboratory services, and protect embryo culture conditions and sensitive instrumentation. The backup power supply must be checked and monitored to be in working order.

Interpretation Guidelines:
An uninterrupted backup power system in place for essential and critical equipment used explicitly for sample processing, incubation/culture and visibility (light).

Cold storage equipment for media used for sample processing and incubation must also be connected to the backup power supply to prevent loss or chemical changes that may reduce its efficacy.

The backup power supply must, at minimum, be able to sustain critical items like incubation for several hours (>2 hours) and at least allow sample processing procedures to be completed.

The backup power must be continuous and connected in line with the equipment (i.e., UPS) to prevent any sudden interruptions during operations and the necessity of manually changing plugs or laying extension cords during power failure.

The backup power supply or electrical system must control electricity fluctuations to protect sensitive instrumentation from damage and failure during power interruptions.

Extra emergency plug points must be available in the laboratories as additional backup.

Alarm/Notification systems for power supply connections to incubators used for embryo culture must be in place.

The emergency power supply must be regularly tested and monitored for sufficiency and longevity of supply and function.

The backup power supply must have a management plan with instructions for operations, regular checks, and available technicians or technical support.

Supporting Information as Evidence of Compliance:

i. System and set-up of backup power supply within laboratories, including provided supply length.
ii. Equipment and critical items identified to be connected to the backup power supply.
iii. Alarm/Notification system for power supply connections to incubators used for embryo culture.
iv. Additional emergency power supply points.
v. Logs of monitoring checks and service records.
vi. SOPs and management plan of the backup power supply system with technical support details.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.20.	Standard Name: Risk Management & Emergency Plans: Access control and liquid nitrogen safety.	ROP: **Yes**

Standard Statement / Goal:
The safety of personnel during cryopreservation and cryopreservation storage and workspaces.

Intent:
Large volumes of liquid nitrogen can displace breathable oxygen rapidly when transitioning to the vapour phase, which can cause life-threatening asphyxiation. The design of the cryopreservation areas must have controlled access to only trained personnel, and appropriate safety measures to prevent health risks must be in place.

Interpretation Guidelines:
The cryopreservation area must have controlled access, preventing unauthorized entry by persons without relevant knowledge of liquid nitrogen and its use.

Where large quantities of liquid nitrogen are being stored, ventilation must be adequate to dissipate nitrogen and reduce the chances of build-up in the event of a leak.

A system must be in place to warn operators of potentially faulty equipment or nitrogen leakage when the storage area is enclosed without active ventilation of fresh air, e.g., an oxygen sensor or similar means of confirming room air safety (regarding the percentage of O2) before entering the storage space.

Supporting Information as Evidence of Compliance:

i. Visual inspection or evidence of a warning system for nitrogen leakage and/or build-up in the enclosed storage area(s) or sufficient active fresh air ventilation into the storage area.
ii. Evidence of an emergency plan when a nitrogen leak has been identified.
iii. Evidence of protective gear provided.
iv. Evidence of SOP for the use and accessibility of liquid nitrogen.

LABORATORY SERVICES

DEPARTMENT: Laboratory Services		Section: Laboratory Services
G.21.	Standard Name: Risk Management & Emergency Plans: Adverse events, emergency, and disaster planning.	ROP: **Yes**

Standard Statement / Goal:
The laboratory must have a risk assessment plan with protocols to manage adverse events, emergencies and possible disasters that may put the laboratory services, staff, and samples at risk of failure. An emergency plan must be in place to ensure that reasonable efforts are made to safeguard the gametes, embryos, and records during disaster situations while preserving staff safety.

Intent:
The safety of all personnel, patients and samples must be ensured by an up-to-date system of laboratory risk management with emergency SOPs in case of adverse events and probable disasters. This system must be described in a risk management or safety manual that is readily available even in disaster situations. Regular training of staff in emergency procedures must be done and documented. Local highly probable natural and other disasters should be identified, and an emergency plan should be put in place to minimize the loss of biological material while ensuring staff safety during these situations.

Interpretation Guidelines:
The Laboratory Risk management/Safety manual must address measures for achieving a safe and healthy working environment, including adverse event management, emergency protocols and disaster preventative plans together with contingency plans in place.

Policies must be in place which addresses adverse events, including the documentation, reporting process, resolution taken (corrective action) and preventative measures put in place to minimize reoccurrences.

The most critical emergency SOPs must have quick reference/short versions and be easily accessible throughout the laboratories, with clear instructions and the location of the full version.

The relevant emergency contact lists and numbers must be easily visible and readily available throughout the laboratories.

Laboratory staff must be regularly trained and familiar with all safety and emergency protocols.

Training sessions must be well documented, indicating the instructor, training details and attendees.

Laboratory risk management and emergency policies and manuals on laboratory safety must be reviewed and revised annually and when appropriate (any changes affecting protocols or contacts).

Supporting Information as Evidence of Compliance:

i. Evidence of a safety manual and/or SOPs.
ii. List/Index of emergency contacts.
iii. Evidence of an emergency plan relating to the cryobank.
iv. Evidence of training concerning safety and emergency protocols.

PSYCHOLOGY AND COUNSELLING SERVICES

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The relevant standards of this section will apply to the organisation according to the location or affiliation of the counsellor (on-site or off-site counselling services). The information the organisation provides regarding fertility counselling services will be relevant in all instances.

Guidelines: Authoritative / Informative References

1. (Pearson and Wilson, 2012)
2. (How to Create a Good Counselling Environment ·[Podcast for Counsellors], no date)
3. (Mortimer and Mortimer, 2005)
4. (Psychological Association, 2020)
5. (Boivin, Takefman and Braverman, 2011)
6. (Yee, 2009)
7. (Babaii, Mohammadi and Sadooghiasl, 2021)
8. (Kirkman-Brown et al., 2022)
9. (Gameiro et al., 2015)
10. (Gameiro, Boivin and Domar, 2013)
11. (Streisfield et al., 2015)
12. (Meyers and Domar, 2021)
13. (Pedro et al., 2013)
14. (Royal College of Nursing, no date)
15. (Tulay and Atılan, 2019)
16. (Thaldar, 2020)
17. (Thaldar, 2019)
18. (South African Government, 2006)
19. (Kelvin, Kroon and Ogle, 2012)
20. (Speller et al., 2019)
21. (Boivin, 2001)

H. FERTILITY COUNSELLING

Table 8. Content summary of Standards for Fertility Counselling.

AREA	ROP	STANDARDS
FACILITY, PLANNING & DESIGN	**Yes**	1. Counselling room(s).
QUALIFICATIONS & STAFF STRUCTURE	**Yes**	2. Counselling qualifications.
EQUIPMENT & CONSUMABLE MANAGEMENT	No	3. Assessment tools.
PROCESSES & PROCEDURES	No **Yes** **Yes** No	4. General ART patients. 5. Donors and recipients. 6. Surrogacy. 7. Fertility preservation and Oncofertility.
INFORMATION, COMMUNICATION & FEEDBACK	No	8. Documentation and reporting.
RISK & EMERGENCY MANAGEMENT	No No	9. Emergency numbers and network for referral. 10. Patient file security and back-up.

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.1.	Standard Name: Facility, planning & design: Counselling room(s).	ROP: **Yes**
Standard Statement / Goal: If the organization provides a counselling service, it must be in a safe, private, comfortable, and dedicated counselling space.		
Intent: For on-site counselling, the counselling space must be suitable for this purpose and provide privacy and confidentiality.		
Interpretation Guidelines: There is a dedicated area or office for counselling which provides privacy and confidentiality. Confidentiality must be ensured where conversations are inaudible to those outside the consulting room. The privacy of the room must be tested. There is comfortable seating for the patient(s), including to allow sufficient space for third-party consultations. The inside of the counselling room must not be visible to passing patients, staff or outsiders when in use.		
Supporting Information as Evidence of Compliance: i. Plan of the facility showing counselling room(s). ii. Includes being a room for staff giving results or discussions of a sensitive nature.		

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.2.	Standard Name: Qualifications & Staff structure: Counselling qualifications.	ROP: **Yes**
Standard Statement / Goal: An appropriately qualified and registered practitioner must provide counselling.		
Intent: To deliver a professional counselling and assessment service and be held accountable for that service.		
Interpretation Guidelines: A master's degree (MA) in Clinical or Counselling Psychology and/ or a relevant degree in Social Work is required. The counsellor must have current official registration with either: • the Health Professions Council (HPCSA) as a Counselling or clinical psychologist, or • the South African Council for Social Service Professions (SACSSP) as a social worker. An independent counsellor must have a practice number with the Board of Health Care Founders (BHF). In the event of a referral to an external counselling service provider, the organization must ensure that the service provider is qualified and registered to offer fertility counselling. Information regarding appropriate counselling for fertility must be provided to patients undergoing treatment.		
Supporting Information as Evidence of Compliance: i. Current registration with either HPCSA or SACSSP as applicable. ii. BHF registration number. iii. The agreement or letter of arrangement or memorandum of understanding between the organization and the on-site counsellor. iv. Information on psychologists/counsellors/social workers with the applicable qualifications/ registrations.		

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.3.	Standard Name: Equipment & Consumable Management: Assessment tools.	ROP: No
Standard Statement / Goal: Counsellors use assessment tools to provide better patient prognosis and counselling, dependent on the stage of treatment. These can include information, brochures, and articles relevant to providing a standard or foundation from which to work.		
Intent: There should be evidence of some psychometric testing conducted on patients to ascertain the patient's state of mind and whether referral is necessary to other mental health professionals.		
Interpretation Guidelines: Psychometric tools and assessment sheets should be set up and used by the counsellor to measure or ascertain patients' state of mind and to guide when referral to other mental health professionals (i.e., either psychologist or psychiatrist) is necessary. Tools and assessments should be based on recognized assessments and accepted guidelines. Any assessment tools and questionnaires used should be appropriate and standardized.		
Supporting Information as Evidence of Compliance: i. Baseline psychometric testing tools in use. ii. Patients are informed about counselling options, upon entry to the clinic, during and after treatment.		

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.4.	Standard Name: Processes & Procedures: General ART patients.	ROP: No

Standard Statement / Goal:
The organization provides access to counselling for patients undergoing ART. The purpose is to explore, understand, and resolve issues related to infertility and fertility treatment and to clarify ways of dealing with the fertility-related aspects more effectively.

Intent:
It is crucial to consider the needs of the patient and the couple undergoing fertility treatment, as well as any other person who might be affected by the ART treatment process, including the decisions that have to be made.

Interpretation Guidelines:
To provide counselling, psychosocial services, and support to individuals and couples experiencing fertility challenges.

To educate patients about the implications of fertility treatments on their psychosocial well-being and relationships.

To explore treatment options, improve coping skills, and provide relevant information and resources.

The organization should have processes to ensure all fertility patients are referred or given the option to access fertility counselling services and psychological support before, during, and upon receiving treatment.

Supporting Information as Evidence of Compliance:

i. Information on fertility counselling and supportive resources available.
ii. Access of counsellors visible on website/ brochures/ pamphlets.
iii. A means to monitor the satisfaction of, and access to, counselling services via a patient satisfaction questionnaire.
iv. Evidence with regards to assessing patients at risk.

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.5.	Standard Name: Processes & Procedures: Donors and recipients.	ROP: **Yes**

Standard Statement / Goal:
Counselling services concerning donor gametes are available to recipients, and donors are psychologically screened.

Intent:
Counselling services concerning donor gametes must be available to patients donating or receiving donor gametes or embryos. There must be informed knowledge of the psychological implications and decisions to use donor gametes, either anonymous or known to the recipients and partners. Donors must be psychologically screened to obtain their readiness to donate and to ensure they are aware of the risks.

Interpretation Guidelines:
To ensure recipient patients and partners are thoroughly counselled on the implications of using donors and donors regarding donating gametes or embryos.

Anonymous donors must be psychologically screened.

Donors and recipients of known donations must be psychologically screened and referred to an attorney for consultation regarding the parental rights of the future child.

The recipient(s) must be psychosocially counselled to discuss the following but not limited to:
- their willingness to both make use of donor gamete (s),
- disclosure.

Psychological screening of donors must exclude the following but not be limited to:
- psychopathology in the donor,
- establish commitment and compliance,
- be free of unhealthy substances and
- know the potential risks of the donation.

Supporting Information as Evidence of Compliance:
i. Patient information, including psychological services and parental rights, in a known donation.
ii. Information on donor agencies.
iii. Information on legal services for known gamete donation agreements.
iv. Policy on psychological screening for donors and known donation recipients (generic sample report of known donor assessments).
v. Supporting information of counselling done and/or offered (to be available to the surveyor anonymized to protect patient confidentiality.

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.6.	Standard Name: Processes & Procedures: Surrogacy.	ROP: **Yes**

Standard Statement / Goal:
Information and referral to experienced and appropriately qualified professionals for surrogacy applications before ART treatment commences.

Intent:
Patients requiring surrogacy treatment and willing surrogate mothers must be counselled and adequately informed regarding the processes involved. Information to include referral must include professionals known to the organization as experienced and appropriately qualified for High Court application of Surrogacy Agreements.

Interpretation Guidelines:
Information regarding surrogacy treatment, including the application process and required professionals, must be given and explained to patients that require such treatment.

The organization must be able to refer or provide some indications of experienced and qualified professionals for the High Court application; however, patients must have their own choice in professionals they ultimately use for services as required by the court.

The information must be available, and counselling given to potential surrogate mothers to ensure a complete understanding of the processes involved.

Supporting Information as Evidence of Compliance:

i. Policy on information, explanation and counselling services for patients and potential surrogate mothers.
ii. Information on legal services for surrogacy.
iii. Supporting information of counselling done and/or offered (to be available to the surveyor anonymized to protect patient confidentiality.)

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.7.	Standard Name: Processes & Procedures: Fertility preservation and Oncofertility.	ROP: No
Standard Statement / Goal: Counselling services are provided for patients considering or requiring fertility preservation, and such services are available on short notice for Oncofertility patients.		
Intent: There should be a process for counselling patients according to fertility preservation and the benefits and risks. Counselling services should be readily available to Oncofertility patients on a limited schedule due to urgent medical treatments.		
Interpretation Guidelines: Ensure all patients requiring fertility preservation procedures are fully educated and counselled about their expectations. Oncofertility patients should have a priority scheduling for counselling services whenever there is a time constraint for urgent medical treatment, including fertility preservation procedures. If the patient is a minor, family counselling should be considered.		
Supporting Information as Evidence of Compliance: i. Policy regarding counselling before, during and after fertility preservation procedures, including specific processes for Oncofertility. ii. Provides a checklist indicating that women seeking fertility preservation have been offered counselling before embarking on fertility preservation.		

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.8.	Standard Name: Information, communication & Feedback: Documentation and reporting.	ROP: No
Standard Statement / Goal: Comprehensive written reports on counselling services provided to organizations should be submitted promptly, especially for third-party ART.		
Intent: There should be a process of timeous reporting regarding counselling for patients and specifically for donor gametes and surrogacy treatments.		
Interpretation Guidelines: Reporting should provide necessary information that satisfies the requirements of reports for professionals and organizations.		
Supporting Information as Evidence of Compliance: iii. Policy on assessment reports and supporting information of counselling and reporting. iv. A de-identified sample report.		

PSYCHOLOGY AND COUNSELLING SERVICES

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.9.	Standard Name: Risk Management & Emergency Plans: Emergency numbers and network for referral.	ROP: No
Standard Statement / Goal: The organization should provide emotional support to patients in the event of the unavailability of a counsellor.		
Intent: There should be contact details of one or more additional therapists available on the website or patient brochures in the event of an after-hours emergency or unavailability of the on-site counsellor.		
Interpretation Guidelines: There should be a process for referring patients, and a list of preferred service providers should be available.		
Supporting Information as Evidence of Compliance: i. Policy for psychological referral. ii. A checklist of patients referred and an emergency number, support groups or local emergency room contact details.		

DEPARTMENT: Psychology and Counselling Services		Section: Fertility Counselling
H.10.	Standard Name: Risk Management & Emergency Plans: Patient file security and back-up (on-site counsellor).	ROP: No
Standard Statement / Goal: Counsellors and/or organizations should maintain patient psychological records and reports securely and confidentially, including backups in case of loss of data or premises.		
Intent: Psychological reports should be kept confidential and securely backed up in a disaster.		
Interpretation Guidelines: Files should be kept in a locked cabinet. All reports should be kept on a computer with a backup system.		
Supporting Information as Evidence of Compliance: i. Policy and evidence of files and report management to ensure confidentiality, including a backup system.		

GUIDELINES AND REFERENCES

Guidelines, Authoritative and Informative References

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SASREG ACCREDITATION APPLICATION 2023-2026

Addendum 1 - Application

Private and Confidential

Date of Application: _____

Organization Name: _____

Director(s): _____

_____

_____

Physical Address: _____

_____

Main Phone No.: _____

General Email: _____

Director(s) Email: _____

_____

Accreditation Liaison: _____

Liaison Designation: _____

Liaison Email: _____

I/We hereby declare that all information in this form is to the best of my knowledge correct.

Director Signature: _____ Director Signature: _____

Director Signature: _____

Please indicate:

- ☐ New Application / First Application (no previous accreditation)
- ☐ Renewal of previously Accredited Clinic
- ☐ Application for update survey from Provisional/Non-Compliant Status to Full Accreditation Status

Application Documents

Attach the application and the following documents to the Self-Evaluation MS Excel workbook.

The documents must be compliant before the physical survey visit.

- Approval of the facility safety by the local authority, as applicable:
  - Occupation Certificate for consultation, office and laboratory areas, and
  - Letter by sedation practitioner for procedure room, or
  - Department of Health license as a Health Facility.
- Full staff list with positions.
- List of all clinical personnel with certified copies of highest qualifications and professional body registrations (e.g., HPCSA, SANC, SACSSP).
- Completed Self-Evaluation workbook with specified documentation as indicated therein.
- Proof of Payment of Accreditation Survey fees.

For all applications for a revision to full Accreditation Status, attach all supporting evidence documents as requested by surveyors and as indicated in your previous Survey report. Additionally, attach any of the above documents that may have changed since your previous application and survey, e.g., new staff.

The electronic version of the application submitted documents and Self-evaluation excel workbook would be forwarded to the Surveyors and Accreditation Committee and kept on file by Turners Secretariat.

Self-Evaluation Details

Date of Self-Evaluation: _____

Management Evaluator: _____ Sign: _____

Clinical Evaluator: _____ Sign: _____

Laboratory Evaluator: _____ Sign: _____

Nursing Evaluator: _____ Sign: _____

Counselling Evaluator: _____ Sign: _____

The assigned evaluators of each department should be available during the survey to discuss the Self-Evaluation and the compliance supporting evidence of the Standards and Survey outcomes.

Completing the Self-Evaluation Checklist

The Self-Evaluation Checklist is provided in an MS Excel workbook template, which forms part of the Survey workbook. This will also be used by the Surveyors to complete the survey. It will finally become the Survey Report of the accreditation process of the organization.

The organisation and the assigned evaluators of each department must complete this. The workbook can be saved with the clinic name and date for reference in the application.

The organisation name, evaluators and the “X” marks should be inserted in the appropriate columns, and rows indicated according to your evaluated compliance score. Each compliance point should be given a compliance score, and then the average score should be indicated next to the “Outcome:” of the Standard name in the row.

The Survey workbook contains formulae to calculate the compliance scores and copy any comments made per Standard row into the Survey Summary Report. Please do not change any of the formulae.

If you have difficulty completing the Self-Evaluation in the MS Excel workbook, please contact us via Turners Secretariat before submitting your application.

Evidence of Compliance

The Evidence of Compliance (compliance points) indicated in the Standards needs to be shown by the organization as proof of complying with that Standard and thus is the specific aspects that will need to be shown to the surveyors during the survey visit.

Full Accreditation means that the organization must achieve ≥90% Fully and Largely compliance ratings to ROP Standards and ≥70% Fully and Largely Compliant ratings for non-ROPs.

Although Non-ROP Standards are considered recommendations for implementation in future, these Standards will be assessed as they will allow organizations to identify areas to improve the quality of their ART service. It also aims to prepare your organization for future surveys when some of these might be changed to ROP Standards.

All applicable sections will contribute to the compliance score. If a section is not relevant, e.g., Oncofertility, this section is excluded and will not impact the compliance score. Please indicate a non-applicable area by entering "N/A" in the Self-Evaluation Excel next to the section name.

Compliance Evaluation Interpretation

Fully compliant: All aspects met according to Supporting Information as Evidence of Compliance and surveyor evaluation.

Largely Compliant: Minor aspects need attention, but no 'must' actions need to be remedied.

Partially Compliant: There is at least one "must" action recommendation that needs to be dealt with to be accredited.

Non-Compliant: One or more "must" actions are required that must be resolved promptly before accreditation can be considered; if there are too many "non-compliant" items, then accreditation could be withheld.

Comments/Notes

Notes or comments can be made by the assessing staff and can be inserted in this dedicated section.

It is preferred that details are given here on the supporting evidence that the facility has to provide for the survey as proof of their compliance. Only short-hand informative notes by evaluators are expected and will assist surveyors in preparing for the survey.

Self-Evaluation Compliance Summary

The compliance summary will be tallied in the provided Self-Evaluation MS Excel workbook template, which will indicate your compliance status according to the set levels.

Application Submission

Please submit the application and all required supporting documents to Turners Secretariat via email at **info@sasreg.co.za**

Application Procedure

STEP 1

The Application and Self-Evaluation workbook must be completed.

STEP 2

The required documents, and completed Self-Evaluation, as indicated must accompany the application to be considered for the survey process.

STEP 3

The fees for the first year must be paid in full and proof sent with the application.

STEP 4

The application and all accompanying documentation must be sent through to **info@sasreg.co.za**

SASREG
Southern African Society of Reproductive Medicine and Gynaecological Endoscopy

NOTES

info@sasreg.co.za

www.sasreg.co.za

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2023-01-10