UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة و وقاية المجتمع

Oncology Center Regulations

Empowerment And Health Compliance Department

Ministry Of Health And Prevention

(2018)

Table of Contents

Acknowledgment

Ministry of health and prevention (MOHAP) is pleased to present the "Regulation for Oncology Services", which represents a milestone towards fulfilling the MOHAP strategic objective to "Improve quality standards in healthcare facilities".

This regulation places an emphasis on facility design and services criteria with a focus on quality of services and safety of patients and healthcare professionals based on the international standards of best practices in this domain, while taking into consideration the local and federal laws. Therefore, this document provides a base for the empowerment and health compliance department to assess the oncology services provided for all Emirates, to ensure a safe and competent delivery of services and to develop the quality management systems.

Ministry of health and prevention (MOHAP) would like to thankfully acknowledge these professionals and thank them for their dedication to quality in health and their commitment in undertaking such a complex task.

Scope:

This document applies to oncology services provided in Ministry of health and prevention (MOHAP) licensed health facilities, which includes semi-governmental and private health facilities operating. MOHAP may amend this document as and when there may be a need to do so. The latest version of the regulation shall be published on the MOHAP website www.moh.gov.ae.

Purpose:

The regulations which developed through by Ministry of health and preventions should ensure the provision of the highest level of safety and quality of patient care at every time.

CHAPTER ONE:

ONCOLOGY SERVICES

REQUIRMENT

1. Introduction

1.1. The oncology services are classified as:

1.1.1. Medical oncology

1.1.2. Radiation oncology

1.1.3. Surgical oncology

1.2. Oncology services can be provided in one of the following facility categories:

1.2.1. A hospital or in a unit attached to a hospital.

1.2.2. Day surgical center.

1.2.3. Cancer Treatment Center

1.3. All health facilities providing oncology services shall ensure that patients have access to services required to diagnose, treat, rehabilitate and support patients with cancer and their families.

1.4. As a part of comprehensive treatment, palliative care should be part of the care plan provided by the health facility.

1.5. Application procedure

1.5.1. Preliminary approval: To provide oncology services in the emirates, the applicant shall submit a proposal to the empowerment and health compliance department with the following:

1.5.1.1. Comprehensive study of the intended service and category of diseases that the oncology treatment is proposed for.

1.5.1.2. List of diagnostic and radiotherapy equipment (if applicable) with manufacturers' specifications/ installation manuals. Facility Schematic design drawings are not required at this stage.

1.5.1.3. Detailed feasibility study of the proposed project

including the cost of the equipment and the financial resources of the project.

1.5.1.4. Resumes, qualifications and experience of all healthcare professionals who are involved in providing the oncology service in the facility.

1.5.1.5. Employ or contract with accredited radiation physics firm or a radiation physicist to design the facility layout or a contract with an internationally accredited body to design the oncology facility.

1.5.2. Based on the documents submitted, empowerment and health compliance development will review the submitted material to determine compliance and suitability for further processing and issue a Preliminary Approval. In case the application is rejected, a detailed report of rejection reasons will be provided.

1.5.3. The applicant shall submit a detailed facility schematic design drawings in AutoCAD format within three (3) months of the Preliminary Approval.

1.5.4. Official Initial Approval

The applicant must submit an application through the online licensing system to the empowerment and health compliance department along with all necessary documents, which are as follows:

1.5.4.1. If the oncology service is provided in a stand-alone facility, the applicant must submit a copy of the Land Registration Certificate showing the land plot number issued by Emirates Municipalities.. For existing licensed health facilities these documents are not required.

1.5.4.2. Schematic design drawings in AutoCAD format showing the proposed floor layout with

measurement for each room/area and labeled as per services provided with detailed shielding precautions wherever applicable.

1.5.4.3. The detailed feasibility study/ list of equipment, etc.

1.5.4.4. Passport photocopy with residency visa for non-locals.

1.5.4.5. UAE identity card.

1.5.5 Once the application is approved, an initial approval letter with defined activities will be issued. This letter will be required to obtain licensing by the Emirates Economic Department or equivalent licensing bodies if the facility is a stand-alone facility.

1.5.6. Final inspection (Pre-operation assessment):

1.5.6.1. The applicant shall submit an online request for final inspection, upon which empowerment and health compliance department shall conduct an onsite pre-operational assessment.

1.5.6.2. To obtain the MOHAP license, the applicant must meet the following:

1.5.6.2.1. Appoint a Medical Director (in case of a stand-alone oncology facility) or a Physician in-charge for oncology services in a Hospital or Day Surgical Center with other services and specialities.

1.5.6.2.2. Employ and license the qualified healthcare professionals as per the Preliminary Approval submission to satisfy the facilities proposed functional program and to meet patient needs for all services/

procedures provided.

1.5.6.2.3. Install and operate equipment required for provision of the proposed services in accordance with manufacturer specifications.

1.5.6.2.4. Develop policy and procedure documents for the following:

1.5.6.2.4.1. Infection control measures and hazardous waste management

1.5.6.2.4.2. Medication management

1.5.6.2.4.3. Patient health record

1.5.6.2.4.4. Medical emergency action plan

1.5.6.2.4.5. Patient discharge/ transfer plan

1.5.6.2.4.6. Radiation safety policies

1.5.6.2.4.7. Patient transfer and emergency action plan

1.5.6.2.4.8. Staff documentation and job description

1.5.6.2.4.9. Incident Reporting

1.5.6.2.4.10 Disaster Management/ Emergency preparedness plan.

1.5.6.2.4.11.Informed Consent

1.5.6.2.4.12. Safety measures against biohazards and radioactive medical waste.

1.5.6.2.4.13. Full disclosure of information to patients about Confidentiality and release of information

1.5.6.2.4.14 Safe administration of systemic therapy

1.5.6.2.4.15. Timely referral to palliative and hospice care.

1.5.6.2.5. Maintain Charter of Patients' rights and responsibilities noticeably posted on the facility premises at least in two languages (Arabic and English).

1.5.6.2.6. Provide evidence of FANR license to use the Ionizing Radiology equipment in the facility.

1.5.6.2.7. Maintain adequate lighting and utilities, including temperature controls, water taps, sinks and drains, electrical outlets and telecommunication systems.

1.5.6.2.8. Keep floors, work surfaces, and other areas clean and neat.

1.5.6.2.9. Clearly, display signage and direction for different services provided in at least in two languages (Arabic and English).

1.5.6.2.10. Clearly displayed hazardous signs aimed to restrict access for the safety of patients, visitors and staff.

1.5.6.2.11. Designate secured areas for the collection of medical waste, radioactive waste, general storage facilities for supplies and equipment and storing area for hazardous materials.

1.5.6.2.12. Ensure accessibility for handicapped and disabled individuals.

1.5.6.2.13. The facility safety plan, design and equipment shall comply with the fire safety requirements by the Civil Defence Department.

1.5.6.3. Based on the result of the onsite pre-operational assessment and after meeting the MOHAP requirements, the facility management shall transfer/add the Medical Director and other healthcare professionals to the facility. Upon which the MOHAP

license will be issued by the empowerment and health compliance department.

1.2.6.4. However, in case of non-compliance or any modification recommendations an online report will be issued (within five working days). The facility management is required to act accordingly and schedule another pre- operational assessment visit.

1.2.6.5. Licensing department shall issue a license for the stand-alone facility or approve the addition of oncology service(s) for an existing licensed health facility.

1.2.6.6. For the stand-alone facility, the license shall state the name and address, the license number, the period of licensure validity, the specific service(s) that the facility is licensed to deliver.

2. General Design Consideration

2.1. The facility shall be located in an area, which is accessible and convenient to population using either public transportation or vehicles.

2.2. Radiation oncology services shall not be located in a commercial buildings or malls.

2.3. Provide parking area in the facility premises to satisfy the needs of patients.

2.4. In case the oncology services are part of a hospital, preferably a discreet entry shall be provided for patients.

2.5. The facility shall be accessible by ambulance.

2.6. Each facility design shall ensure appropriate levels of patient acoustical and visual privacy and dignity throughout the care process, consistent with needs established in the functional program.

2.7. Natural light shall be provided as much as possible in public spaces,

waiting areas and those treatment areas that patients and staff occupy for long periods.

2.8. The facility shall be air-conditioned and with special emphasis on shielding the HVAC ducts in radioactive areas from the rest of the facility, and ensuring that negative air pressure is provided in isolation rooms.

2.9. Public corridors shall have a minimum width of 1.5 meters.

2.10. Items such as provisions for drinking water, vending machines, etc., shall not restrict corridor traffic or reduce the corridor width below the required minimum.

2.11. The minimum door opening width for patient use shall be 0.85 meters. In areas where the facility serves patients confined to wheelchairs, the minimum width of door openings shall be one meter.

2.12. Door swings shall be oriented to provide patient privacy.

2.13. The minimum distance from the floor to the structural ceiling height shall be three meters.

2.14. Color contrast between walls, floors and doors shall be considered as it may reduce falling risk of blurred vision patients.

2.15. Selected flooring surfaces shall be easy to maintain, easy to disinfect, readily cleanable, impervious and appropriately wear-resistant for the location.

2.16. Slip-resistant flooring products shall be considered for flooring surfaces in wet areas (e.g. ramps, shower and bath areas) and areas that include water for patient services as well as stairways.

2.17. Highly polished flooring, walling or finishes that create glare shall be avoided.

2.18. Carpet or wooden flooring shall not be used in examination and treatment rooms. But can be used in waiting areas and corridors. Carpet if used shall be glued or stretched tight and free of loose edges or wrinkles.

2.19. Wall finishes shall be easy to disinfect, washable, moisture-resistant and smooth.

2.20. Wall finish treatments shall not create ledges or crevices that can harbor dust and dirt.

2.21. Joints for floor openings for pipes and ducts shall be tightly sealed.

2.22. Equipment, furniture, fittings and the facility itself shall be designed and constructed to ensure that users are not exposed to avoidable risks or injury.

2.23. Ensure emergency exits in the facility with proper signs directing towards them.

2.24. Nurse call and emergency call facilities shall be provided in all patient areas (e.g. bed/chair spaces, toilets and bathrooms) and clinical areas in order for patients and staff to request for urgent assistance.

2.25. Maintain an Uninterrupted Power Supply (UPS) for backup, the power supply of, which shall be able to support all functions of the equipment in the oncology center during treatment.

2.26. The facility should provide the below effective te/ communications services for efficient operation of the oncology service:

2.26.1. Bar coding for supplies, x-rays and records

2.26.2. Access to picture archiving communications systems (PACS)

2.26.3. Paging systems

2.26.4. Electronic medical records and medical record storage systems

2.26.5. Point of clinical care

2.26.6. Patient Administration System (PAS)

2.26.7. Building management system (BMS)

2.26.8. Videoconferencing/ teleconferencing

2.26.9. Wireless technology considerations duress alarm systems fixed and mobile units

2.26.10. Communications room and server requirements.

3. Oncology Service Requirement:

3.1. A comprehensive Oncology service shall consist of the following:

3.2. Reception and Waiting Areas

3.3. Consultation and Examination Rooms

3.4. Diagnostic Imaging Services

3.5. Radiotherapy Services

3.6. Chemotherapy Services

3.7. Surgical care

3.8. Support areas for Oncology care

3.9. Intensive Care Unit (ICU)

3.10. Inpatient rooms

3.11. Outpatient holding area

3.12. Clinical Laboratory and Blood services

3.13. Staff areas including staff station, staff changes areas, etc.

3.14. Meeting room

3.2. Reception and waiting area

3.2.1. The reception should be located at the entrance which able them to have visual control of patient and visitors.

3.2.2. The information counter shall provide access to patient files and records.

3.2.3. The waiting area shall accommodate enough seating and provide wheelchairs accessibility to fulfil the functional requirement of the services.

3.2.4. Sanitizer dispensers shall be available.

3.2.5. In case the oncology service is part of a hospital, male and female waiting areas should be provided or shared with other adjacent departments. But of this Oncology services for pediatric so they should provide area for pediatric patient.

3.2.6. Provide a sufficient number of toilets for patients, their families, and staff with a hand-washing station. Dedicated toilets should be provided for disabled individuals as per the standards and guidelines.

3.3. Consultation and Examination Rooms

Room space requirements shall depend on the services provided, but at least shall meet the following:

3.3.1. The minimum floor area for Consultation and examination room(s) is 12 square meters.

3.3.2. The minimum clearance of examination table, bed or chair should be 0.91m on at least three sides.

3.3.3. The exam table should be designed to accommodate the diagnostic position of all oncology ailments.

3.3.4. A counter space for working should be provided.

3.3.5. A hand-washing station with a hands-free operating tap and disposable liquid or foam soap dispensers shall be provided in all examination rooms.

3.3.6. Hand sanitation dispensers shall be provided in addition to hand-washing stations.

3.3.7. Provisions for hand drying shall be available at all hand-washing stations.

3.3.8. The area below the hand washing station shall be free of clutter at all times.

3.4. Diagnostic Imaging services

Imaging is a major component of the diagnosis and staging of cancer. To ensure continuity of patient care Oncology services shall have an access to diagnostic imaging services in the facility premises or outsourced.

3.4.1. The diagnostic imaging services may include the following:

3.4.1.1. Conventional Radiography (X ray unit) with changing room and controlling room.

3.4.1.2. Ultrasound with toilet.

3.4.1.3. MRI with control room and changing room.

3.4.1.4. Digital Mammography

3.4.1.5. Sonography

3.4.1.6. CT

3.4.1.7. PET CT imaging

3.4.1.8. SPECT/CT

3.4.2. PET CT imaging

3.4.2.1. The major considerations are space, power, floor loading concerns and radiation shielding.

3.4.2.2. The PET CT imaging area shall have the following areas:

3.4.2.2.1. Patient preparation/ Injection room (At least one)

3.4.2.2.2. Injection room/holding area before the scan portable shields.

3.4.2.2.3. Hot laboratory designed for 511KeV energy level.

3.4.2.2.4. Imaging room or PET CT bays with control areas

3.4.2.2.5. Waiting area

3.4.2.2.6. Dedicated toilet for patients

3.4.2.2.7. Administrative areas

3.4.2.2.8. Decay room/ waste room

3.4.2.3. Injection/Holding room(s), hot laboratory, and PET/ CT bays are areas that shall need shielding for 511KeV emission.

3.4.2.4. Special consideration shall be given to indirect lighting, curtains and noise control.

3.4.2.5. There shall be a dedicated adjacent hot toilet for patients to use after uptake period.

3.4.2.6. Additional shielding is recommended for the nursing stations and the PET/CT control room.

3.4.2.7. If uncontrolled areas are located above or below the PET uptake and scanner rooms, the spacing between floors may need to be greater than normal or additional shielding added. The floors need to be able to support the additional weight associated with additional shielding.

3.4.2.8. Engage a medical consultation, a Medical Physicist or other professionals to survey the facility, and provide the facility with quality reports.

3.4.3. For detailed information, please refer to Diagnostic Imaging Services Regulation on the MOHAP website www.moh.gov.ae.

3.4.4. Diagnostic imaging services must comply with the FANR laws and regulations regarding the use of ionizing radiation and radioactive materials. For further information regarding FANR, law and regulations please visit FANR website www.fanr.gov.ae.

3.5. Radiation Oncology Services

3.5.1. The radiation therapy services shall consists of equipment for treatment of patients using radioactive rays

3.5.2. Patient privacy and dignity is a prime consideration in the design of radiation therapy unit.

3.5.3. The layout of the facility shall be planned taking into consideration equipment requirements, water and electrical utilities needed, room shielding requirements and climate control.

3.5.4. The facility layout shall be planned in accordance with the local radiation safety regulations and internationally accepted radiation safety standards and in consultation with the radiation oncologist, physicist and equipment manufacturer.

3.5.5. The room design, construction and shielding shall be as per FANR and the manufacturers recommendation.

3.5.6. The radiation therapy unit shall:

3.5.6.1. Be located on the ground floor or lower floors of the oncology center to accommodate the weight of the equipment and ease of installation and replacement.

3.5.6.2. Ensure properly designed rigid support structures located above the finished ceiling for ceiling mounted equipment.

3.5.6.3. Provide equipment and infrastructure for treatment of patients using radioactive rays.

3.5.10. Consideration shall be given to co-location of radiation therapy with other diagnostic facilities for patient convenience.

3.5.11. The radiation unit may have an inpatient facility for frail patients, patients travelling long distances and the occasional patient who has severe reactions to any of the treatments administered in the facility (a bed for every 10 patients).

3.5.12. The radiotherapy unit should include the following functional areas, but not limited to:

3.5.12.1 CT Simulation room with an adjacent control area and changing room.

3.5.12.2. Treatment planning room for physicist.

3.5.12.3. Film processing and storage area.

3.5.12.4. Physics laboratory/ Dosimetry equipment area (if thermo luminescent dosimetry (TLD) and film dosimetry are available, an area shall be designed for these activities)

3.5.12.6. Radiotherapy Room/ Bunkers to house the equipment to deliver treatment with an adjacent computer control area and changing rooms

3.5.12.7. Holding area/ Recovery area

3.5.12.8. Hypothermia room (may be combined with an examination room)

3.5.12.9. Mould room (optional)

3.5.12.10. Exam Room

3.5.13. If intra-operative therapy is proposed, the radiation oncology unit shall be only hospital based and located close to the operating unit or with a direct link.

3.5.14. Areas requiring specific protection measures (controlled areas) include:

3.5.14.1. Irradiation rooms for external beam

3.5.14.2. Therapy and remote after loading brachytherapy

3.5.14.3. Brachytherapy rooms

3.5.14.4. Simulator room

3.5.14.5. Radioactive source storage and handling areas

3.5.14. These areas shall maintain define controlled areas by physical boundaries such as walls or other physical barriers marked or identified with ‘radiation area’ signs.

3.5.15. The area of the control panel shall be considered as a controlled area, to prevent accidental exposure of patients by restriction of access to non-related persons, and distraction to the operator of a radiotherapy

machine.

3.5.16. Supervised areas may involve areas surrounding brachytherapy patients' rooms or around radioactive source storage and handling areas.

3.5.17. Certain staff members need to be monitored with individual dosimeters. Individual external doses can be assessed by using individual monitoring devices such as thermo luminescent dosimeters or film badges, which are usually worn on the front of the upper torso. These shall include:

3.5.17.1. Radiation oncologists
3.5.17.2. Radiotherapy physicists
3.5.17.3. Radiation protection officer
3.5.17.4. Radiotherapy technologists
3.5.17.5. Source handlers
3.5.17.6. Maintenance staff
3.5.17.7. Nursing or other staff who must spend time with patients under treatment with brachytherapy.

3.5.18. EXTERNAL BEAM THERAPY : May contain an examination rooms, a simulator room, a treatment planning room, a mould room (optional), a treatment room (bunker) and waiting areas.

3.5.18.1. External beam therapy equipment

3.5.18.1.1. A photon-energy teletherapy unit

3.5.18.1.2. An orthovoltage unit

3.5.18.1.3. Beam measurement and quality assurance and radiation protection physics equipment

3.5.18.1.4. A simulator, preferably a computed tomography (CT) simulator

3.5.18.1.5. A computerized treatment planning system (TPS)

3.5.18.1.6. Picture archiving and storage system

3.5.18.1.7. Patient immobilization devices and mould room equipment

3.5.18.2. The examination rooms shall

3.5.18.2.1. Be in close proximity to the treatment room.

3.5.18.2.2. Include standard and gynecological examination tables, a head and neck examination chair, appropriate examination instrument and medical supplies.

3.5.18.3. The simulator room shall:

3.5.18.3.1. Be large enough to accommodate the simulator, allowing the full range of motion of the treatment table.

3.5.18.3.2. Have provision for dimming of room lights.

3.5.18.3.3. Have adequate space for cabinetry to store treatment devices and daily used equipment that measure quality assurance.

3.5.18.3.4. Have cabinet space to store supplies for their fabrication, if the immobilization devices are to be fabricated in the simulator room.

3.5.18.3.5. Have hand-washing provision.

3.5.18.3.6. Have a viewing window for the control room.

3.5.18.3.7. Have light boxes.

3.5.18.4. The treatment planning room shall:

3.5.18.4.1. Be located in close proximity to the simulator room, although the two areas do not have to be adjacent.

3.5.18.4.2. Be large enough to house the treatment-planning computer with its video monitor, a printer and plotter, a digitizer tablet and other required computer

equipment.

3.5.18.5. The Mould Room shall:

3.5.18.5.1. Have exhaust hood, hand basin, and block room with storage (if applicable).

3.5.18.5.2. Be located away from busy areas of the facility.

3.5.18.5.3. Space for tools, a block cutter and counter-top workspace for pouring and mounting the blocks is required.

3.5.18.5.4. Storage space for supplies of Styrofoam, trays and shielding material for custom blocking.

3.5.18.5.5. Adequate ventilation if shielding materials are melted in this area.

3.5.18.5.6. A sink with a refuse trap, as plaster of Paris is frequently utilized.

3.5.18.6. The treatment rooms shall be as far as possible from highly occupied areas. The treatment room shall have:

3.5.18.6.1. Wall thickness and shielding requirements shall be specified by a radiation physicist or a radiation physics-consulting firm and in accordance with the manufacturer's specifications.

3.5.18.6.2. Large enough rooms to accommodate the treatment machine, allowing the full range of motion of the treatment table.

3.5.18.6.3. A door interlock or other suitable means to prevent unauthorized access.

3.5.18.6.4. A door with a fail-safe interlock to switch off the radiation beam (i.e. return the source to the shielded position) if the door is opened during a treatment. Restarting irradiation shall require both closing of the door and activation of a switch at the control console. This is

intended as a reminder to record the irradiation time given prior to opening the door.

3.5.18.6.5. A sign on the door to indicate that the room contains radiation sources or radioactive materials.

3.5.18.6.6. Visible light at the door that shows if the source is on or off (the light will be red when the source is on and green when it is off).

3.5.18.6.7. Battery operated detector of scattered radiation inside the room that shows when the source is on.

3.5.18.6.8. Emergency buttons located inside the room to shut off the radiation, and these shall be reachable without passing through the radiation beam.

3.5.18.6.9. Audio intercommunication to communicate with patients.

3.5.18.6.10. An area radiation monitor safe against a power failure visible on entering the room for a high dose rate machines.

3.5.18.6.11. Provision for dimming of room lights.

3.5.18.6.12. Adequate space for cabinetry to store treatment devices, immobilization devices, blocks and daily used quality assurance equipment.

3.5.18.6.13. Provide secure mounting of patient positioning lasers to the wall at points appropriate for projection of lines through the iso-centre.

3.5.18.6.14. Have a specially designed electrically operated door at the entrance to the room. However, an alternative to this is an appropriately designed extended corridor /maze leading into the room.

3.5.18.6.15. Ensure space for a console immediately

outside the treatment area monitoring the treatment room door large enough to accommodate not only the control console for the unit but also a workspace for the Radiotherapy technologist, in addition to space for an intercom and closed circuit television system. It shall also accommodate any computer equipment associated with the treatment machine. This may include the record and verify (R&V) computer system, an information management system, and electronic imaging or treatment time, calculation systems. (A modern linac may involve up to six monitors and their associated computers).

3.5.18.7. An indirect penetration access (dosimetry) port from the control area through the concrete is required to allow the measurement of beam characteristics using an ion chamber in the field while the electrometer and physicist are in the control room, thereby avoiding excessively long extension cables.

3.5.18.8. For orthovoltage treatments, the room requirements are considerably simpler, although an external console area is still required.

3.5.18.9. It is desirable to have separate waiting areas for patients attending clinics and those awaiting treatment. The waiting area shall be adjacent to the treatment room, with space for seating patients receiving the therapy.

3.5.18.10. There shall be provision for patient holding area for patients on stretchers adjacent to the treatment area, preferably separated from ambulatory patients.

3.5.18.11. The provision of appropriate changing facilities close to the entrance of the treatment room, and shielded from the view of other patients and visitors.

3.5.19. LOW DOSE RATE BRACHYTHERAPY

3.5.19.1. A common hospital room without special shielding can be used

as LDR brachytherapy.

3.5.19.2. The room may be large enough to accommodate afterloader carts, portable bedside shields, and positioning visitor's chair far from the patient.

3.5.19.3. Rooms adjacent to the treatment room may be low occupancy.

3.5.19.4. May have either manual or remote afterloading equipment except for some situations (e.g. permanent implants and eye implants).

3.5.19.5. Either modality will require a source storage and preparation room, operating room, treatment-planning room and patient room.

3.5.19.6. These facilities shall not be too widely separated, in order to reduce distances over which patients and sources have to be transported as the relative proximity of these facilities can significantly influence procedure flow and efficiency.

3.5.19.7. Facility design shall incorporate features to avoid transport in elevators of patients containing radioactive sources.

3.5.19.8. There shall be sterilization facilities for applicators.

3.5.19.9. Source storage and preparation room shall:

3.5.19.9.1. Be designed in accordance to the FANR specifications and recommendations and be provided with a locked door to control access to the radioactive material.

3.5.19.9.2. Provide a sign posted on the door warning of the radiation hazard.

3.5.19.9.3. Contain shielded storage for all sources and have facilities for receiving, preparing, calibrating and returning sources.

3.5.19.9.4. Have a visible radiation monitoring area on entering the room and while preparing the sources.

3.5.19.9.5. Maintain space for a workbench.

3.5.19.9.6. Provide a cabinet for the necessary instruments, equipment, treatment aid and the required documents.

3.5.19.9.7. Provide space for source transportation trolleys.

3.5.19.9.8. Provide storage to allow decay of sources to safe levels.

3.5.19.10. The operating room shall

3.5.19.10.1. Preferably, have an X ray unit, with fluoroscopic capabilities to enable the position of the applicator or catheters to be checked, and if necessary repositioned, before the patient leaves the operating suite.

3.5.19.10.2. Availability of localization X rays (orthogonal or stereo-shifted X rays) required for dose calculation purposes. If no X ray unit is in the operating room, these functions must be available elsewhere.

3.5.19.11. Patient Treatment Room

3.5.19.11.1. Treatment planning for LDR brachytherapy is usually performed on a general TPS for teletherapy and brachytherapy using brachytherapy- planning software.

3.5.19.12. Patient Room

3.5.19.12.1. House each LDR brachytherapy patient in a separate room.

3.5.19.12.2. Ensure that shielded according

to FANR must comply with the FANR laws and regulations regarding the use of ionizing radiation and radioactive materials. For further information regarding FANR regulations and requirements please visit FANR website www.fanr.gov.ae .

3.5.19.12.3. A sign shall be posted on the door warning of the radiation hazard.

3.5.19.12.4. A list with the maximum duration of daily visits by members of the public shall be posted on the door.

3.5.19.12.5. If several rooms are required, they shall be adjacent to each other.

3.5.19.12.6. The patient shall be attended by nurses with special training in the care of radiation therapy patients.

3.5.19.12.7. Each patient room shall have an attached toilet for patient convenience.

3.5.19.12.8. Storage for a bedside shield and emergency source container shall also be provided.

3.5.19.12.9. The patient rooms used to house the LDR brachytherapy patients until they are ready to be discharged may not need to have shielding in their walls if mobile lead shields around the patient's bed are made available.

3.5.19.13. Additional requirements for LDR remote after loading

3.5.19.13.1. The shielding requirements for uncontrolled areas surrounding the treatment area are unchanged.

3.5.19.13.2. Additional requirements for remote after loading include:

3.5.19.13.2.1. Additional floor space and required utilities (dedicated compressed air and power sources);

3.5.19.13.2.2. A door interlock or other suitable means to prevent unauthorized access to the patient rooms;

3.5.19.13.2.3. An area radiation monitor that is safe against a power failure in the patient rooms.

3.5.19.14. Procedures that are unique to LDR sources are:

3.5.19.14.1. The sources shall be inspected visually for possible damage after each use, by means of magnifying viewers and a leaded viewing window in a shielded work area.

3.5.19.14.2. There shall be a diagram at the source storage safe that shows the exact location of each source within the safe, thus reducing the time taken to locate and identify a source. Sources shall only be handled with long forceps or tongs.

3.5.19.14.3. When transporting sources, a

mobile shielded container is needed and the shortest route possible shall be used.

3.5.19.14.4. Sources that come into direct contact with body tissues will require cleaning and possible sterilization after each use. This can subject the sources to possible damage from heat, abrasion, chemicals and mechanical stresses. Therefore, these sources must be inspected after every use.

3.5.19.14.5. Work surfaces shall be easy to clean and brightly lit to make it easy to find any sources that have been dropped.

3.5.19.14.6. If the source storage and preparation room is also the applicator loading room, there shall be a sink for cleaning the applicators. However, a sink can also lead to a loss of sources to the sewage system when a source is left in the applicator or a patient removes a source and puts it in the sink, situations that are preventable by placing a filter in its drain.

3.5.20. HIGH DOSE RATE (HDR) BRACHYTHERAPY

3.5.20.1. Requires an ambience identical to operating theatre; a radiographic imaging system; a treatment room; a treatment planning area.

3.5.20.2. All these areas must be in close proximity to one another for effective procedure flow and efficiency.

3.5.20.3. The operation theatre and anaesthesia shall be required for the insertion of brachytherapy applicators.

3.5.20.4. An HDR brachytherapy facility can have:

3.5.20.4.1. A treatment room for the HDR unit, together with shared use of existing operating or procedure rooms and imaging systems, such as a simulator.

3.5.20.4.2. An integrated brachytherapy suite with a dedicated imaging system, requiring no transport of the patient between the different steps.

3.5.20.5. Based on room dimensions and design. The HDR treatment room/ bunker radiation suppression should be designed and decided by the Radiation Physicist.

3.5.20.6. Each of the walls, the ceiling and the floor of an HDR room is a primary barrier and shall be of adequate thickness to protect the staff and public, outside the treatment room.

3.5.20.7. The HDR unit shall be located within a defined area of the room and a chain or electrical interlock is used to ensure that it cannot be turned on (i.e. the source driven outside its protective housing) unless the HDR unit is in that prescribed area.

3.5.20.8. The room shall be designed so as to:

3.5.20.8.1. Ensure an interlock on the door that will cause the source to be retracted into its shielded housing if the door is opened during the time the source is on.

3.5.20.8.2. Ensure an indicator at the door of the HDR treatment room as well as at the treatment console indicating the treatment is on or off.

3.5.20.8.3. Maintain a battery-operated detector of scattered radiation inside the room that shows when the source is on.

3.5.20.8.4. Ensure that there are emergency procedures for safely removing the source from the patient and quickly storing it in a safe location in the event that it does not

retract all the way into its source housing when expected. This requires that a wire cutter sufficient to cut the source cable and a shielded storage container be located inside the treatment room.

3.5.20.8.5. Ensure that the door to the room shall be marked to indicate the radioactive materials that are within, and there shall be an indication of how to contact the person responsible for radiation safety in the event of an emergency.

3.5.20.9. Procedures for brachytherapy

3.5.20.9.1. Treatment rooms shall be locked.

3.5.20.9.2. Only qualified persons shall do source transfer.

3.5.20.9.3. Great care must be taken when disposing the source - it MUST be returned to an authorized person or company.

3.5.20.9.4. Source inventories shall be maintained that show the location and current activity of each source at the facility with a unique identifier for each source. This may either be a colour coded or letter/number identifier.

3.5.20.9.5. Sources shall never be left on preparation surfaces.

3.5.20.9.6. Leak tests (using moist wipes) must be performed and documented on a periodic basis, and these must have a sensitivity sufficient to detect a very low increase above the background radiation level. For the HDR unit, the wipe tests are only performed on the afterloading drive assembly and transport containers, since the source itself has too high dose rate to allow this type of test.

3.5.20.10. Area surveys shall be performed periodically around the source storage facilities for HDR sources.

3.5.20.11. The storage facilities must be marked to indicate that they contain radioactive materials as well as a way to contact the individual responsible for radiation safety in the event of an emergency.

3.5.20.12. The storage facilities must be kept locked at all times with sufficient shielding and must be resistant to fire.

3.5.20.13. Every item in the source storage shall be labelled and be well organized in compartments with easy access when required.

3.5.20.14. After every brachytherapy treatment, the patient shall be monitored with radiation detection (GM type) survey meter to ensure that no radioactive source remains in the patient.

3.5.20.15. Identified qualified persons who receive and sign for the sources must do all source transfers according to the requirements of the regulatory authority.

3.5.20.16. Maintain a logbook to update every source movement.

3.5.20.17. Develop an emergency plan to retrieve a lost source

3.5.20.18. Responsibility for sources only ends after they have been safely disposed and disposal has been documented.

3.5.20.19. A hospital is NOT a suitable place for long-term storage of high activity sources.

3.5.20.20. Procedures that are unique to HDR sources are:

3.5.20.20.1. The HDR after loader needs to undergo routine quality assurance tests at the beginning of each treatment day.

3.5.20.20.2. The couplings and transfer tubes need to be checked before each HDR treatment, to ensure that there are no obstacles to prevent motion of the source.

3.5.20.20.3. Maintain an emergency container for emergency safety, precautions in the treatment room, as well as an emergency kit containing surgical clamps and long handled forceps for manipulation of the source guide tubes and applicators.

3.5.20.20.4. The emergency container shall be placed close to the patient and shall be sufficiently large that it can accept the entire applicator assembly containing the source removed from any patient.

3.5.20.21. Interlocks and signs

3.5.20.21.1. The doors to the source storage rooms need to be locked and have a sign indicating that there are radioactive materials stored within.

3.5.20.21.2. There shall also be an indication of the responsible person to contact in the event that entry is needed, for example, for fire safety purposes.

3.5.20.22. Equipment

3.5.20.22.1. Only authorized persons shall operate the equipment.

3.5.20.22.2. Un-authorized persons shall not access the unit.

3.5.20.22.3. All radiation equipment shall be locked when not in use.

3.5.20.22.4. A plan for acquisition and commissioning of equipment shall be developed consistent with the training of staff and the pace at which new technology can be integrated into patient care.

3.5.20.22.5. The need for external training of the radiation oncology professional staff (physicians, physicists and technologists) shall be described, as well

as the need for on-site technical experts for training and helping to manage program implementation and monitoring its progress.

3.5.20.22.6. External training of personnel shall be identified.

3.5.20.22.7. Equipment consisting of radiation generators or containing sealed sources needed for medical exposures shall:

3.5.20.22.7.1. Conform to the applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or equivalent standards.

3.5.20.22.7.2. Conform to performance specifications, operating and maintenance instructions, including protection and safety instructions, provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to accompanying documents, and translated into the local language where appropriate;

3.5.20.22.7.3. When equipment manufactured in one country is to be exported into another country with the IAEA's assistance, documentary evidence (i.e. a copy) of the national standards of the exporter has to be provided with the quotation (bid) to assess whether the national standards are actually equivalent to the IEC and ISO standards.

3.5.20.23. Quality assurance (QA) of the radiotherapy program and radiation protection of the patient

3.5.20.23.1. Ensure a consistent and safe fulfilment of the dose prescription to the target volume with minimal dose to normal tissues and minimal exposure to personnel and the public.

3.5.20.23.2. The main areas shall include:

3.5.20.23.2.1. A documented quality assurance program consists of policy statements, written management procedures, work instructions, data sets and reference documents, prescription sheets, request forms, records, etc.

3.5.20.23.2.2. Clinical Policies

3.5.20.23.2.3. Treatment plan and delivery

3.5.20.23.2.4. Quality control program for machine and equipment performance maintenance programs

3.5.20.12.2.5. Investigative procedures for accidental medical exposures

3.5.20.24. Patient-specific QA practices include, but are not limited to, the following:

3.5.20.24.1. Patient identity is verified by two (2) independent methods at the beginning of each encounter.

3.5.20.24.2. Patient-specific QA is done before initiation of intensity-modulated radiation therapy.

3.5.20.24.3. Independent check of dose calculation is done for every new or changed treatment before treatment is started.

3.5.20.25. Machine-Specific QA Practices: These include, but are not

limited to, daily, monthly, and annual radiation treatment machine QA procedures.

3.6. Chemotherapy Unit

3.6.1. A chemotherapy unit provides the clinical treatment and management of patients undergoing chemotherapy treatment for cancer using specific cytotoxic agents or one or more anti-cancer drugs that are destructive to malignant cells and tissues. The chemotherapy unit can be:

3.6.1.1. A part of a hospital

3.6.1.2. A satellite unit- on a hospital campus; but not in the hospital.

3.6.1.3. Freestanding unit – positioned in a community setting for e.g. a villa. But it not allowed to have this unit in commercial building or mall. it must have an contract/ agreement with a hospital with an Intensive Care Unit (ICU), which must be accessible within a maximum of 10 minutes' drive from it to receive patients in case of emergency.

3.6.1.4. Integrated Cancer Care – a part of an oncology center that provides diagnostic services, radiation therapy and/ or surgical facility.

3.6.2. The chemotherapy unit shall be designed to provide:

3.6.2.1. The best and easy access for patient who may arrive by public transportation, vehicles, wheel chair or ambulance. This access or exit should provide privacy for patient.

3.6.3. The patient can be treated in an outpatient except the acute leukemia patient where they shall be treated in a multispecialty health facility with inpatient, outpatient & ICU services.

3.6.4. In case a chemotherapy unit is a freestanding facility it shall:

3.6.4.1. Maintain a contract with the closest hospital with inpatient services to manage emergencies or complications.

3.6.4.2. Provide an in-house ambulance service.

3.6.5. The Chemotherapy Unit shall have the following functional areas:

3.6.5.1. Reception/ Waiting area

3.6.5.2. Consultation room

3.6.5.3. Sterile preparation room/ Buffer area

3.6.5.4. Anteroom/ pharmacy

3.6.5.5. Patient treatment areas/ procedure room with treatment chairs or beds

3.6.5.6. Isolation room(s)

3.6.5.7. Clean utility/ Dirty utility

3.6.5.8. Medication preparation room with a 100% exhaust Class II B2 safety cabinet

3.6.5.9. Staff areas

3.6.5.10. Support areas

3.6.5.11. Storage areas for clinical, non-clinical and bulk items storage e.g. fluids, equipment including infusion/syringe pump storage

3.6.6. The chemotherapy unit shall maximize the use of natural light and outdoor view.

3.6.7. Sterile Preparation Room (SPR) / Buffer area and Anteroom / pharmacy

3.6.7.1. The Sterile preparation room shall preferablally be on the same floor as the patient treatment area and the cytotoxic and hazardous should be prepared in a minimum Class II Type B Biological Safety Cabinet in SPR.

3.6.7.2. The sterile preparation room shall maintain with negative pressure with minimal microbial contamination.

3.6.7.3. There shall be provision of an adjacent anteroom, to minimize the particulate contamination. Between these two room the differential of at least 0.01 inch water column (negative pressure).

3.6.7.4. Water sources shall be kept to a minimum within the SPR.

3.6.7.5. Floors, walls, ceilings and all exposed surfaces shall be nonporous and washable.

3.6.7.6. Cleaning in the SPR shall take place at a time when no operations are in progress.

3.6.7.7. Shelves and supplies shall be kept to a minimum in the SPR to decrease the number of airborne particulates.

3.6.7.8. A warning sign shall clearly identify that access to the SPR is controlled and limited to authorized personnel only.

3.6.7.9. Doors shall not be left open.

3.6.7.10. The door opening for both sterile preparation room and anteroom shall not open at same time in order to keep pressure differential between the two rooms.

3.6.7.11. Telephones and hands-free devices shall be used to communicate with staff in the SPR.

3.6.7.12. All staff shall wear appropriate personal protective equipment (PPE), prior to entering the SPR.

3.6.7.13. Chemotherapy gowns should be worn in the SPR nor lab coats.

3.6.7.14. The anteroom shall be used for all preparation and loading and unloading of cartons.

3.6.7.15. Cardboard boxes shall not be stored in the anteroom.

3.6.7.16. Hazardous drugs shall be stored separately from others.

3.6.7.17. Hazardous drugs that are volatile at room temperature shall be stored with in a contained negative pressure room with at least 12 air exchanges per hour.

3.6.7.18. Cytotoxic spill kits should be available near the storage area. All individuals involved in transportation of cytotoxic agents shall have quick access to it.

3.6.7.19. When transporting cytotoxic drugs there are some consideration to take to prevent breakage, minimize exposure and contain spills.

3.6.7.20. Routine cleaning of the anteroom, SPR, BSC shall be documented e.g. Daily- cleaning interiors of BSC, Hazardous drug garbage disposal, etc. Weekly- Clean IV admixture dispensing trays, clean transfer carts. Monthly- Clean refrigerator shelves, clean storage shelves, clean non-transfer carts, clean hazardous drugs and supply bins.

3.6.7.21. They shall clean sinks, furniture and floors daily and walls, ceilings and window blinds monthly.

3.6.7.22. Trained and supervised housekeeping staff shall be employed to safely carry out housekeeping responsibilities in the anteroom, with in the SPR and in vicinity of the BSC in order to minimize hazardous drug exposure to themselves and the environment in accordance with written protocols.

3.6.7.23. They shall clean sinks, furniture and floors daily and walls, ceilings and window blinds monthly.

3.6.7.24. Cytotoxic drugs shall be packed in sealable plastic bags.

3.6.7.25. The bagged contents shall be transported inside a closed container with and disposable absorbent pad to contain spillage and cushion contents.

3.6.7.26. Eye wash should be provided and all staff in the SPR shall have easy access to it.

3.6.8. Patient treatment areas shall consist of treatment bays to provide chemotherapy to patients.

3.6.9. The treatment bays size shall be a minimum of nine (9) sq. meters with a clear width of three (3) meters along the back of the bay to ensure appropriate service placement, infusion equipment and curtain track placement for treatment chairs.

3.6.10. Spaces shall be twelve (12) sq. meters where patients receive chemotherapy infusions in beds rather than chairs.

3.6.11. The size of the clean utility shall be twenty (20) sq. meters if drug fridges are required to store chemotherapy intravenous fluid bags in this area.

3.6.12. Staff workstation shall preferably have an unobtrusive view of all patient treatment areas. The inclusion of decentralized staff areas may be considered in larger units that have multiple rooms or treatment spaces.

3.6.13. There shall be provision of working spaces for visiting multidiscipline team members.

3.6.14. Privacy for persons receiving treatment is a critical element hence the unit shall be designed to:

3.6.14.1. Ensure privacy of personal discussions and medical records.

3.6.14.2. Acoustic privacy shall be considered during the facility design.

3.6.14.3. Provide an adequate number of rooms for discreet discussions and treatments to occur when required.

3.6.14.4. Enable sufficient space within each treatment space to permit curtains to be easily closed whenever required.

3.6.14.5. Appropriately locate windows and doors to enhance visual and acoustic privacy.

3.6.14.6. Special consideration shall be given to selection of sound absorbing materials and finishes and use of sound isolation construction.

3.6.15. Consideration to the type of floor finishes as staff movement to/from and between patients during chemotherapy treatments and review is constant e.g. cushioned vinyl.

3.6.16. Nurse call and emergency call facilities shall be provided in all patient areas (e.g. bed/chair spaces, toilets etc.) and clinical areas. The alert to staff members shall be done in a discreet manner.

3.6.17. Provision of duress alarm system shall be provided for the safety of

staff members who may at times face threats imposed by clients / visitors. Call buttons shall be placed at all reception / staff station areas and consultation / treatment areas where a staff may have to spend time with a client in isolation or alone. The combination of fixed and mobile duress units shall be considered as part of the safety review during planning for the unit.

3.6.18. Per two chairs one unit of medical gases (oxygen and suction) shall be provided.

3.6.19. The design of all aspects for the unit shall take into consideration the need to ensure a high level of infection control in all aspects of clinical and nonclinical practice.

3.6.20. Isolation room(s) numbers shall be reviewed as part of the planning aspects of the project relevant to the proposed service needs.

3.6.21. Hand washing facilities with liquid soap dispenser, disposable paper shall be readily available for staff within the unit.

3.6.22. Storeroom for general storage, fluids and equipment shall be located in the perimeter of the unit and accessible by a palette lifter if required for delivery of bulk fluids and clinical stores.

3.6.23. The chemotherapy unit shall maintain a crash cart to deal with emergencies.

3.6.24. Annually quality measures shall be audited and this information shall be shared with licensing department.

3.6.25. Services that support and are linked with chemotherapy may include:

3.6.25.1. Physiotherapy (Lymph oedema management)

3.6.25.2. Occupational therapy

3.6.25.3. Dietetic / Nutrition services

3.6.25.4. Clinical Psychology

3.6.25.5. Social work services

3.6.25.6. Community and outreach cancer services

3.6.25.7. Palliative Care and hospice

3.6.25.8. Complementary therapies (e.g. relaxation, stress management and massage)

3.6.25.9. Wig and prosthesis services.

3.6.26. Cytotoxic waste:

3.6.26.1. Breakable contaminated needles, syringes, ampoules, broken glass, vials, intravenous sets and tubing, intravenous and intravesical catheters etc. shall be placed into designated leak-proof; puncture proof sharps containers that clearly and visibly display the cytotoxic hazard symbol.

3.6.26.2. Non-breakable contaminated materials including disposable gowns, gloves, gauzes, masks, intravenous bags, etc. shall be placed in thick sealed plastic bags, hard plastic or cytotoxic containers that clearly and visibly display the cytotoxic hazard symbol. When full, the bags and containers shall be placed in the oncology waste container.

3.6.26.3. Clearly marked chemotherapy waste receptacles shall be kept in all areas where cytotoxic drugs are prepared or administered. They should be separated from general waste.

3.6.26.4. Cytotoxic waste shall be destroyed in an appropriately licensed incinerator approved for the destruction of cytotoxic drugs. If the access is not available the acceptable alternative should be provided.

3.6.26.5. Special written protocol shall be maintained for:

3.6.26.5.1. Management of an incident in case a patient/family member is contaminated with a cytotoxic agent.

3.6.26.5.2. Management of cytotoxic spill in or outside the BSC.

3.6.26.5.3. Safe transportation of cytotoxic agents.

3.7. Surgical Care

3.7.1. For detailed information on operating theatre, critical care, airborne infection isolation, emergency area and inpatient, services refer to the "Hospital Regulation" on www.moh.gov.ae

3.8. Support areas for Oncology Patient care

3.8.1. The support areas for an oncology center can be clerical space or rooms for typing and clerical work.

3.8.2. Medication station/ medication preparation area- there shall be a medication dispensing station or a medication preparation area. Provisions shall be made for the controlled storage, preparation, distribution, and refrigeration of medications

3.8.3. Medicine Storage Area- An enclosed area closes to the medication station or medication preparation area.

3.8.4. Health records filing cabinets and storage shall be provided for the safe and secure storage of patient's health records with provisions for easy retrieval.

3.8.5. Nourishment area- a nourishment station is provided.

3.8.6. Clean Supply room- This room is used for preparing patient care items, it shall contain the following:

3.8.6.1. Work counter

3.8.6.2. Hand-washing station

3.8.6.3. Storage facilities for clean and sterile supplies.

3.8.7. Soiled workroom -A soiled workroom shall be provided with in close proximity to the and shall contain the following:

3.8.7.1. A flushing-rim sink with hand wash station

3.8.7.2. A work counter

3.8.7.3. Storage cabinets

3.8.7.4. Waste receptacles

3.8.7.5. A soiled linen receptacle

3.8.8. Equipment and supply storage- The oncology center shall make provisions for the following requirements:

3.8.8.1. General storage area for supplies and equipment.

3.8.8.2. Special storage for staff personal belongings with lockable drawers or cabinets.

3.8.8.3. Storage areas for non-clinical records, documents, and office supplies.

3.8.9. The storage area shall have easy access and have temperature controlled.

3.8.10. All material shall be clearly marked with expiration dates.

3.8.11. Clean linen storage- if blankets or other linens are used, a clean linen storage area shall be provided.

3.8.12. Wheel chair storage place shall be provided out of the direct line of traffic for at least one (1) facility-owned wheelchair.

Safety: There must be provision for emergency electric power supply for equipment in case of power failure. Fire safety equipment shall be accessibly placed with visibly displayed directions to use the equipment.