

ICON QUALITY ASSURANCE

STANDARD AUDIT OF ONCOLOGY DEPARTMENTS

Contents

1. Practice Manager / Administrator.....	2
2. Oncologist / Nurse Manager.....	5
3. Pharmacist / Chemotherapy nurse manager	6
4. RTT Manager / Medical Physicist.....	8

Instructions

There are 4 SECTIONS with checklist items which are organised per areas within the practice. These are to be completed by the responsible manager.

Section 4 contains a supplement specifically for Medical Physics.

The checklist items must please be scored in the last column as either:

C – Compliant

WIP - Work in Progress

NC - Non-Compliant

NA: - Not Applicable.

Please contact Belinda Bailey at belinda.bailey@cancernet.co.za with any queries on Sections 1 to 3 and Yogi Govender ygovender@equrahealth.co.za with any queries on Section 4.

The use and origin of this document

This baseline checklist is for use as part of a continuous improvement program. ICON will be available to assist with this program. It is based on the National Core Standards of the Dept. of Health with additional Oncology measures.

The document is used for self-assessment, which takes place every 3 years. This will be followed by a site visit and follow up contacts via phone and email.

The Medical Physics supplement in Section 4 is completed annually and managed by Medical Physics – see page 10.

The document is endorsed by the SA Society of Clinical and Radiation Oncology

28 APRIL 2015 REVISED FEB 2016, DEC 2016 AND 8 FEB 2018.

1. Practice Manager / Administrator

Practice Admin Area with Records of Standard Operating Procedures (SOPs)		
1	A security and access policy. This policy should assist in minimising the clinical impact of down time caused by theft and vandalism of/ or the unauthorised tampering with – machines and equipment.	
2	Register of incident reports- in conjunction with clinical area: The practice encourages the reporting of errors and near-misses and has a formal process for evaluating the data, at least semi-annually.	
3	Actions are taken on all Continuous Quality Improvement needs and their implementation is monitored (e.g. responsible person/committee)	
4	A policy dealing with patient's death in your practice – in conjunction with clinical area	
5	No smoking policy	
6	The practice has a procedure for documentation and follow-up for patients who miss and cancel scheduled visits and/or chemotherapy treatment	

Human Resource Records		
7	New staff orientation process – in conjunction with clinical area; Orientation should include an introduction of new employees to all departments, service providers, and functions that affect patient care	
8	Policy on Competency assessment of new staff members – in conjunction with clinical area; Deficiencies in new employee training and experience must be identified and remedied before they can assume patient-care responsibilities	
9	Practice should establish policies and procedures ensuring that personnel who prepare, dispense and administer chemotherapy and monitor patients are competent to perform these functions. Staff performance is assessed annually for continuing demonstrated competency	
10	Evidence of qualifications and current registration with professional body for all professional staff members	
11	Confidentiality policies: Confidentiality clause in service agreement, signed by all staff members	
12	Staff are easily identifiable; Staff must wear name badges and distinguishes devices always	
13	An appropriate insurance or other cover for medico-legal incidents and damages claims	
14	Educational programs for all staff members. Staff attendance registers -in conjunction with all areas; Practices should provide opportunities for continuing professional and technical education related to treatment (CT/RT) management.	
15	At least one clinical staff member trained in Basic Life Support is present during chemotherapy administration. BLS training is every 2 years.	
16	Job descriptions and task lists and Organogram	
17	An oncologist/medical officer is immediately available to staff who administer chemotherapy	

Occupational Health & Safety Records	
18	There is health and safety committee and representative (where applicable). Minutes of meetings should be kept.
19	A policy exists regarding the management of OHS within your facility
20	A medical surveillance plan (physical examination) is in place for at-risk staff, based on health risk assessments – in conjunction with the clinical area
21	Procedures must be in place to address worker contamination. Protocols for appropriate medical attention must be developed.

The Entrance, Kitchen, Storage Rooms, Cupboards, Toilet and Waste Disposal Area	
22	Cleanliness and hygiene are maintained on a systematic basis

The Information Areas for Patients – as needed	
23	Information brochure/card with contact details and opening hours, etc.
24	Standard operating procedure on orientation and education of all new patients, including potential side-effects and management thereof – in conjunction with all areas.
25	A patients Complaints Procedure (all patients should be aware of this process)
26	Information booklets on side-effects and management of chemotherapy treatment – in conjunction with the chemotherapy nurse manager.
27	Patient privacy is ensured when examined, counselled, and phoned

The Information Areas for Staff	
28	The Treatment Protocols, e.g. ICON Treatment Protocols
29	DOH Licenses should be displayed (where applicable), as well as Department of Radiation control licences for Radiotherapy services
30	Roster of on-call duties, with names and contact details (includes Doctors, Physicists & Radiotherapists) – in conjunction clinical areas.

Facilities & Equipment	
a) Linen/Laundry:	
31	Check that al laundry is handled in line with infection control and safety requirements
32	The storage of linen must be in a separate room with an extractor fan and door vent OR a cupboard with door vents
b) Waste management:	
33	A current waste management policy and procedure - refer to DOH (Western Cape Health Care Waste Management Act, 2007)

34	A contract and service level agreement should be in place with approved and legally compliant waste removal service provider	
	c) Patient waiting area and reception:	
35	Patient waiting area with comfortable seating.	
36	A wheelchair or bed is available for waiting patients	
37	An area allowing private patient discussions.	
	d) Sluice room:	
38	For collection and temporary storage of used equipment and dirty/soiled linen	
	e) Clean room/cupboard:	
39	For storage of sterilized packs, dressings, sterile equipment	
	f) Patient toilets:	
40	The doors from patient ablution and toilet facilities must be equipped with a standard emergency release lock that can be opened from the outside.	
41	Fitted with Grab rails and an emergency call system	
	g) All areas - Disaster Plan information:	
42	Fire Escape accessible and clearly indicated	
43	Emergency plan displayed in all areas	
44	Firefighting equipment, displaying valid service dates	

Completed by:

Signed:

Date:

2.Oncologist / Nurse Manager

<i>The Consent Forms in File</i>	
1	There is a practice specific process for obtaining informed consent from patients prior to treatment
2	A consent form for record keeping of information and sharing information with Health funders is signed by the patient

<i>Patient Records SOPs</i>	
3	Follow-up arrangements are made and documented in-patient records
4	Toxicity assessment documentation is available for planning subsequent treatment cycles
5	The practice must have evidence of an efficient filing system.
6	There is a documented contingency plan for ensuring continuing availability of the patient record in the event of a disaster e.g. fire
7	There is a protocol for safe keeping of any electronic medical records
8	There is a protocol for correspondence with the patient's GP and referring doctors both at the time of initial consultation and treatment planning as well as at the time of treatment completion to explain follow up plan.

<i>The Available Support Services Include:</i>	
9	Pathology, haematology and biochemistry services
10	Radiology
11	Referral process to an Oncology social worker in place
12	Referral process to Palliative care services in place
13	Emergency medical service and admission facilities

Completed by:

Signed:

Date:

3. Pharmacist/Chemotherapy Nurse Manager

Pharmacy Admin Area - Records of Standard Operating Policies (SOP) include:		
1	Policy on Receipt, Checking of all drugs prior to administration, e.g. expiry dates, correct quantity, correct drug, etc.	
2	The chemo prescription must be cross-checked and verified by a second staff member	
3	Policy on the Storage and Transport of hazardous drugs	
4	Procedure for the removal of expired, damaged, or contaminated stock	
5	Policy for products requiring special storage/Refrigeration (stored and handled under correct conditions)	
6	Policy on Fridges cleaning (once a month). Policy on Chemotherapy medicine fridges not to be used for other purposes, e.g. food storage	
7	Policy on Decontamination of all appropriate medical equipment, e.g. drip stands, infusional pumps, Biohazard Cabinets, etc.	
8	If trained oncology nurses do the mixing, they must mix under the direct supervision of an Oncologist with a Dispensing License	

Pharmacy Equipment & Storage Areas Regulations:		
9	Anti-neoplastic mixing area/room is separate from the treatment area: with a separate Clinical hand wash basin and tap	
10	Floors should not to be fitted with a carpet	
11	On-site Medical Refrigerator (for the storage of chemotherapy drugs) with alarm for refrigeration failure that will notify a responsible person in the event of a sudden rise of temperature required	
12	All Medical Refrigerators for the storage of chemotherapy drugs, must be equipped with a back-up system to provide uninterrupted power supply to fridge(s) in the event of an electrical power failure	
13	An appropriate log must be kept of all temperatures (fridge & store room temp.)	
14	An accurately calibrated thermometer to record temperatures twice daily.	
15	Biohazard/Laminar Flow Cabinets: Regular services (minimum annually) must be recorded	
16	If Generators/UPS are used; policy in place to simulate power failure & fridge temperature conditions. Records of monthly tests available.	
17	Infusional pumps used for the administration of chemotherapy must be serviced annually. Records of service dates to be kept.	
Drug Storage room:		
18	A safe and secured temperature-controlled area must be provided for the storage of drugs in accordance with manufacturers' instruction or other legal requirements. Only authorised personnel must be granted access.	
19	Appropriate security and storage of Schedule 5, 6 & 7 substances. A policy on the management of these medicines in place.	

Chemotherapy Admin area - Standard Operating Procedures Records:		
20	Record of more than 1 nurse on duty to cross check drugs prior to mixing and prior to administration.	
21	Policy on Chemotherapy Administration Protocol document that is used and applied daily	
22	Policy on Identification of patients based on 3 patient identifiers	
23	Policy on The Spillage of Cytotoxics	
24	Policy on Prevention and Management of extravasations	
25	Policy on Reporting and Management of Anaphylactic reactions and other adverse reactions	
26	Policy on Management & Reporting of Needle Stick injuries	
27	Policy on the Collection and Disposal of Cytotoxic waste	
28	Policy on Sharps Disposal	

Chemotherapy Treatment Area contains:		
29	Emergency trolleys appropriately stocked and regularly checked.	
30	BLS Algorithm displayed clearly	
31	Basic equipment requirements including: Defibrillator, Oxygen cylinder with regulator, Portable suction machine, CPR Board, Blood Pressure monitoring, Ambubag.	
32	Suitable chairs made of a washable material.	
33	Patients seating arranged to enable nursing staff to directly observe all patients	
34	Floors not fitted with a carpet.	
35	Clinical hand wash basins with soap and paper towel dispenser	
36	Chemotherapy Spilling kit	

The Patient's Chemo Admin Records contains:		
37	Chemotherapy Prescription Document containing all the required information, see example Annexure B – ICONs Chemotherapy Prescription Document	
38	Chemotherapy Administration Record containing all the required information, see example Annexure B – ICON 's Chemotherapy Administration record	
39	A nursing record/process, with each entry signed and dated by the responsible nurse.	
40	A patient assessment document for each day of treatment, with appropriate action records	
41	Infusion times (start & stop times) of all drugs administered	
42	Documentation of verification (double checking) when chemotherapy is administered	
43	Documentation of post-chemotherapy instructions, e.g. pre-medication for next treatment session, details of medication taken at home, etc.	

Completed by:

Signed:

Date:

4. RTT Manager

<i>Radiation Therapy Prescription and Request Forms</i>		
1	Evidence of diagnosis, clinical assessment and consultation notes preceding radiation treatment	
2	Radiation prescription containing intent, modality, technique, dose per fraction and fraction number and the relevant clinical information	
3	Radiation prescriptions are filed and stored together with the treatment record	
4	Radiation is prescribed by a Radiation Oncologist	
5	Prescription is signed before commencement with radiation treatment with fraction numbers and total dose, daily treatment record and weekly treatment checks by RO	

<i>Treatment Records Before Radiation Therapy</i>		
6	Policy and protocols on handing education brochures to all patients	
7	Policy and protocols on contouring organs at risk (OAR) per ICRU/RTOG/ESTRO guidelines	
8	Tumour and Organ at risk (OAR) reporting per internationally accepted protocols (e.g. ICRU, RTOG, ESTRO).	
9	Informed Consent signed	

<i>Treatment Records During Radiation Therapy</i>		
10	Protocols in place for using at least 3 patient identifiers to be recorded in the patient's records	
11	Adherence to protocols for image matching	
12	RT's note weekly progress of patients or patient complaints	
13	Weekly treatment checks by RO's/MO's; completions checked	
14	Alerts noted on the treatment record or patient folder and is visible to all staff	
15	Record and Verify systems SOPs are implemented as part of workflow	

Radiation Treatment Area - Standard Operating Procedures records		
16	The availability and evidence of adherence to the Protocols and procedures on the preparation and delivery of a course of radiation or brachytherapy must be available and includes the following:	
17	Policy and protocol on the consent process preceding a course of radiation and brachytherapy treatment	
18	Protocols on the CT scanning and simulation processes to allow for 2D, 3D and advanced techniques	
19	Protocols on the manufacturing of immobilization devices for accuracy in set up	
20	Protocols on set up procedures to ensure reproducibility for entire treatment courses	
21	Protocols on planning procedures for 2D, 3D and advanced techniques	
22	Protocols on treatment procedures including daily QA with imaging and dosimetry	
23	Imaging protocols for all techniques of radiation therapy	
24	Protocols on the management of waiting lists	
25	Protocols to deal with scheduled and unscheduled breaks in treatment	
26	Comprehensive Quality Assurance Protocol	
27	Reporting structure with regards to adverse events	
28	Evidence of how these events are managed to prevent accidents	
29	Protocols on the re-irradiation of patients, in terms of overlap of fields and doses to organs at risk	
30	Policy and Protocols on source handling in the event of an after-loader source being stuck	

Completed by:

Signed:

Date:

8Feb 2018

Medical Physicist

This section is managed by Medical Physics and is completed annually

Radiation Safety Management area		
<i>Radiation Monitoring</i>		
1	Evidence of safety precautions in the handling of radioactive sources	
2	Radiation badge management by safety officer	
3	Register of all radiation badges	
4	Register of the dose accrued by all staff members	
5	Evidence of safety measures to prevent exposure accidents	
6	Protocols available on management of over exposures of staff	
7	Evidence of all staff wearing radiation badges when working in the radiation area	
8	Evidence of QC and QA procedures (daily, weekly, and monthly)	

<i>The Reporting of Complications and/or adverse events arising from Radiotherapy</i>		
9	Adverse event protocol	
10	Register of incident reports and adverse events	
11	Quality improvement plan based on analysis of risk	
12	Reporting structure	
13	Evidence of how these events are managed to prevent accidents	
14	Audits of identified deficiencies or areas requiring action	

Radiation Treatment Area – Standard Operating Procedures		
<i>Protocols and Procedure of Radiation or Brachytherapy</i>		
15	Comprehensive Quality Assurance Protocol	
16	Protocols to deal with scheduled and unscheduled breaks in treatment	
17	Licensing and authorisation in place with roles identified and defined within department	
18	Internal Rules are available	

Radiation Therapy Planning and Treatment Equipment		
<i>Linear Accelerators & Orthovoltage Protocols</i>		
19	Procedures for operating the Linacs (Manuals)	
20	Protocols on the QC procedures as per SASQART	
21	Records on the QC procedures are stored	
22	Maintenance and service records are available	
23	Evidence of adherence to protocols on the QA procedures following upgrades and maintenance	
24	Independent yearly SASQART quality review including TRS 398 & any 2 additional tests from SASQART	

Treatment planning systems		
25	Procedures on the operating of the TPS (Manual)	
26	Protocols on the QC procedures as per SASQART	
27	Records on the QC procedures are stored	
28	Evidence of adherence to protocols on the QA procedures following upgrades and maintenance	

QA Equipment		
29	Evidence on the maintenance of the equipment	
30	Records of calibration/traceability (TRS 398) of local standard ionization chamber are available	

Reference:

1. Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement (QUATRO)
Endorsed by EFOMP, ESTRO, IAEA and IOMP

Completed by:

Signed:

Date: