STANDARDS FOR CHEMOTHERAPY SERVICES

STANDARD

Department: Quality Improvement

Document Identifier: SD/QM/003/02

STANDARD - CHEMOTHERAPY SERVICES

Introduction

Chemotherapy is used to treat many different disorders including but not limited to cancers of different types including blood, skin, bone, brain; in addition to autoimmune diseases including dermatological disorders; such as vitiligo, psoriasis, pemphigus, rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, vasculitis, and many others. Chemotherapeutic drugs are used often to kill, alter, or slow the reproduction of rapidly growing cancer cells. However, in the treatment of rheumatic or autoimmune conditions the doses of chemotherapeutic drugs are lower than the doses used for cancer treatment where they work by reducing immune system activity or alter hormonal activity.

Chemotherapeutic drugs can be administered in different forms: intravenously, topically or orally. Patients may receive chemotherapy on an inpatient or outpatient basis. Chemotherapeutic drugs are cytotoxic and have shown to be mutagenic, and/or teratogenic. Their side effects may vary based on the specific drugs used, it may cause nerve damage, infections, cognitive difficulties, loss of appetite, reduction of muscle mass and malnutrition, organ damage (reproductive system, heart, lungs, kidneys and liver), and others. Toxicities can occur acutely, after administration, within hours or days; or chronically, from weeks to years. As a consequence of the toxicities of these drugs and to ensure best patient care and outcomes, Healthcare Professionals (HCPs) require special training and experience to manage, prescribe, reconstitute, and administer chemotherapeutic drugs effectively and safely. In addition, specialized facilities and support services are required to manage the multiple side effects that may accompany use of these agents.

1. PURPOSE	
1.1	This Standard defines the minimum requirements including licensing and service specifications to ensure acceptable minimum levels of quality, performance, safety and reliability for the use and management of chemotherapy services for DHCA Licensed Healthcare Operators (HCOs).
1.2	This Standard defines qualified personnel, scope of practice and service limitations for the provision of chemotherapy for HCOs.
1.3	This Standard includes an Appendix giving supplementary guidance based on international evidence based best practices for the safe prescribing, dispensing, and administration of chemotherapy used in the treatment of cancer and autoimmune diseases. The aim is to assist in the prevention of clinical complications and adverse events, including but not limited to, medication errors and adverse reactions to improve patient safety.

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2. SCOPE OF APPLICATION

2.1	This Standard is applicable to all Healthcare Operators and Healthcare Professionals Licensed by DHCA providing or intending to provide chemotherapeutic drugs for treatment of cancer or autoimmune diseases.

3. STANDARD

3.1 LICENSURE OF HCOs PROVIDING CHEMOTHERAPEUTIC DRUGS

3.1.1	Chemotherapy may be provided by DHCA Licensed Healthcare Operators holding a Clinical Operating Permit for Single and Multi-Specialty Outpatient Clinics, Outpatient Surgical Clinics, Hospitals and other Inpatient Healthcare Facilities in accordance with the requirements of the Standards defined herein.
3.1.2	Each Healthcare Operator may provide chemotherapeutic drugs appropriate to its approved Licensure, Clinical Operating Permit and approved Clinical Specialties.
3.1.3	The Clinical Specialties where Chemotherapeutic drugs may be required includes, but are not limited to: 3.1.3.1 Oncology; 3.1.3.2 Hematology; 3.1.3.3 Immunology; 3.1.3.4 Rheumatology; and 3.1.3.5 Dermatology.
3.1.4	Chemotherapy must be managed in a safe environment where the qualified personnel, facilities, monitoring equipment, and emergency drugs and equipment are immediately available.
3.1.5	Each Licensed Healthcare Operator providing chemotherapy shall provide such services in accordance with all applicable regulations, rules, policies, and standards of DHCA

3.2 QUALIFIED PERSONNEL

3.2.1	Each Healthcare Operator providing chemotherapy shall appoint appropriately qualified Licensed Healthcare Professionals to deliver these services as required by this Standard, the DHCR Outpatient Clinic Quality Standards or equivalent accreditation standards, and other applicable DHCA regulations, standards, and policies.
3.2.2	Each Healthcare Operator shall have a documented process for determining appropriate staffing needs, by number and type of staff for the provision of chemotherapy.
3.2.3	A Licensed Oncologist, Hematologist, Rheumatologist and other specialists within their scope of practice, may write orders for chemotherapeutic drugs subject to the Healthcare Operator's Clinical Operating Permit.

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3.2.4	The Medical Director of the Licensed Healthcare Operator is responsible for the development and implementation of appropriate standards, policies and procedures for use and management of chemotherapeutic drugs, oversight and delineation of clinical privileges; coordinating the proficiency and update of clinical knowledge and skills; and clinical evaluations.
3.2.5	In the absence of relevant expertise, DHCR may guide Healthcare Operators and facilitate processes to determine clinical privileging of Licensed Healthcare Professionals for the prescription of chemotherapy.
3.2.6	All such Licensed Healthcare Professionals shall hold current and valid certification in Basic Life Support and Advance Cardiac Life Support (ACLS) /or Pediatric Advanced Life Support (PALS) as appropriate.
3.2.7	A Licensed experienced and competent nurse is the only healthcare professional, with the exception of a Licensed Oncologist, Hematologist, and Rheumatologist, who can administer and monitor prescribed chemotherapy. However, this can only be done in conjunction with and under the supervision of a Licensed designated physician.
3.2.8	All chemotherapeutic drugs must be constituted and dispensed by a licensed pharmacist trained and competent in the handling of chemotherapeutic drugs.
3.2.9	Each physician granted clinical privileges by a Licensed Healthcare Operator shall be suitably trained and qualified to administer chemotherapeutic drugs. They shall be proficient in: 3.2.9.1 Understanding the chemotherapy regimen; induction regimen, and maintenance regimen, and be able to apply combination chemotherapy to induce a synergistic effect and limit adverse effects; 3.2.9.2 Understanding the toxicity and limitations of the chemotherapeutic drug; 3.2.9.3 Safely administering chemotherapeutic drugs adopting safety precautions; 3.2.9.4 Monitoring the patient for cytotoxic effects.

3.3 PATIENT MANAGEMENT	
3.3.1	Each Licensed Healthcare Operator providing chemotherapy shall manage patients and treatment processes in accordance with this Standard, the DHCR Outpatient Clinic Quality Standards, the standards in use from the International Healthcare accreditation bodies and all other relevant DHCR regulations, standards, and policies.
3.3.2	Chemotherapeutic drug prescribing and administration shall be standardized throughout each Licensed Healthcare Operator, and supported by policies and procedures.
3.3.3	Patient Assessment: 3.3.3.1 An up-to-date patient history must be taken and carefully reviewed to identify any aspects of the patient's medical history that might affect the patient's response to chemotherapy.

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	3.3.3.2 Each patient shall receive a relevant age appropriate physical assessment by a qualified Licensed Physician to assess the fitness and appropriateness of the patient for chemotherapy.
3.3.4	Patient Preparation: 3.3.4.1 The patient must be reviewed and findings documented prior to each chemotherapy session. 3.3.4.2 The decision made for treatment to proceed must be ordered by the hematologist, oncologist, or designated physician. 3.3.4.3 There must be sufficient and appropriately trained and competent staff to provide education to patients regarding the status of their disease and condition, proposed chemotherapy session, and the likely outcomes. 3.3.4.4 Proper patient preparation and evaluation on the day of medication administration must include immediate access to an accredited laboratory. 3.3.4.5 The laboratory should be able to report the results of the patient's laboratory tests to the physician within a timeframe that permits evaluation for chemotherapy on the same day. 3.3.4.6 Appropriate laboratory tests and investigations must be carried out and checked prior to chemotherapy. 3.3.4.7 Patients on a course of treatment must be examined and assessed for chemotherapy side effects before each cycle if deemed indicated. 3.3.4.8 The parent(s)/guardian(s)/patient, as appropriate should be given a full explanation by the prescribing physician regarding the nature of the planned procedure, the route of administration and the drug(s) to be administered and protocol given.
3.3.5	Prescribing of Chemotherapeutic Drugs: 3.3.5.1 The physician must order the chemotherapy drug protocol on a standardized form. 3.3.5.2 The physician must prescribe all medications that are required in the protocol (anti-emetics, hydration, anaphylactic medications, and post medications). 3.3.5.3 Dose calculation must be based on current measurements of weight, height, and blood result (creatinine clearance). If deemed appropriate by the physician this calculation could be modified accordingly by using ideal body weight. 3.3.5.4 All orders for chemotherapy must contain the following: 3.3.5.4.1 Patient name and other unique identifier (medical record number); 3.3.5.4.2 Sex, age, address, and the date of birth of the patient; 3.3.5.4.3 Allergy, diagnosis, pertinent lab parameters; 3.3.5.4.4 Height, weight, body surface area for dose calculation;

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	3.3.5.4.5 Generic name, dosage in standard units and route and the time of administration of the specific chemotherapeutic drug; 3.3.5.4.6 Chemotherapy protocol for treatment; 3.3.5.4.7 Other medications; 3.3.5.4.8 Schedule of administration; 3.3.5.4.9 Name, signature, and stamp of the authorized physician.
3.3.6	Checking and Administration of Chemotherapeutic Drugs: 3.3.6.1 There must be a review of procedures to detect and prevent both overdosing and under-dosing of chemotherapeutic and supportive care drugs, to assist in the prevention of medication errors, and to improve patient safety. 3.3.6.2 Doses ordered must be checked against the prescription, where the physician and nurse perform an independent double check. 3.3.6.3 Both physician and nurse must perform a Time Out to verify and check - correct patient, correct date/time, correct drug, correct dose and correct route for parenteral administration of chemotherapeutic drugs (intrathecal/ intravenous, etc.). 3.3.6.4 Correct documentation as well as monitoring and recording of any effects must follow the administration as per the health information management section.
3.3.7	Emergency 3.3.7.1 A Licensed Oncologist and/or Hematologist and/ or designated physician, who is able to treat complications, provide consultation, or resolve problems, if indicated must be on the premises and immediately available throughout the chemotherapy session. 3.3.7.2 If the Licensed designated physician is unavailable, s/he must make arrangements for an alternate competent physician to provide the necessary supervision. The alternate physician managing the chemotherapy service must be familiar with the protocols in use at the site, will be accountable for adequately supervising the treatment pursuant to the protocols, and must have training and clinical privileges to the same standard as the primary physician. 3.3.7.3 The Licensed Physician to whom responsibility is delegated shall be both suitably qualified and conversant with all relevant information regarding the chemotherapy regimen and the patient. 3.3.7.4 Procedures to manage chemotherapy extravasations must be established. 3.3.7.5 Medications for the treatment of anaphylaxis must be immediately available. 3.3.7.6 Appropriate equipment and drugs required for cardiopulmonary resuscitation and airway support must be readily available in the area where chemotherapy is provided. This shall include adequate and age appropriate: 3.3.7.6.1 suctioning facilities;

	3.3.7.6.2 airway control devices such as endotracheal tubes, tracheostomy kits and laryngoscopes; 3.3.7.6.3 defibrillators; 3.3.7.6.4 pulse oximeters, sphygmomanometer; 3.3.7.6.5 immediate access to an electrocardiograph, capnography and reversal agents as applicable. 3.3.7.7 Each Healthcare Operator providing chemotherapy shall have a written transfer agreement in effect with a paramedic service and a nearby hospital(s) preferably within DHCC for the immediate and safe transfer of patients that need emergency medical care. That inpatient facility must have: 3.3.7.7.1 an established inpatient oncology service which is age appropriate for the patient; 3.3.7.7.2 appropriate tertiary care services (ICU, CCU, etc.); 3.3.7.7.3 access to the complete oncology record of the patient including; diagnosis, medications administered, complicating medical conditions, complications, etc. 3.3.7.8 During such emergency cases, the attending Licensed physician must be notified and must assume the responsibility for arranging the patient's transfer to the appropriate hospital. A qualified and licensed physician must accompany the patient during transfer to the hospital.
3.3.8	Pharmacy Management of Chemotherapeutic Orders 3.3.8.1 Each Licensed Chemotherapy Facility must only administer chemotherapy under the written or electronic request of an Authorized Physician. 3.3.8.2 Verbal/ Telephonic orders for chemotherapy will not be accepted. 3.3.8.3 Changes to orders for chemotherapy treatment must not be processed until rewritten as a new order. 3.3.8.4 No abbreviations shall be used for chemotherapy orders. 3.3.8.5 Chemotherapy orders must be processed by a trained competent pharmacist. 3.3.8.6 The pharmacist must verify the order against the protocol/roadmap and ensure the order is complete. 3.3.8.7 The pharmacist must verify dosage calculations. 3.3.8.8 The ordering physician must be contacted if any element of the chemotherapy order is missing. 3.3.8.9 A second pharmacist must review and verify the order and calculations prior to admixture. 3.3.8.10 The first pharmacist must check and initiate the product prior to dispensing. 3.3.8.11 Chemotherapy and other hazardous drugs must be stored, prepared, and disposed of in adherence with DHCC and the Dubai Municipality regulatory waste management requirements relating to Health Safety and Environment approved code of practice.

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3.8 HEALTH INFORMATION MANAGEMENT	
3.8.1	Each Healthcare Operator providing chemotherapy services shall comply with DHCA regulations, policies, and standards for the management of patient health information and medical records.
3.8.2	Each Healthcare Operator providing Chemotherapy services shall ensure the confidentiality of patient health information as per the provisions of the DHCA Health Data Protection Regulation No. (7) of 2013 and Federal Law No. (2) of 2019 on the use of information technology and communications in the healthcare sector
3.8.3	When necessary only standardized diagnosis codes, procedure codes, symbols, abbreviations, and definitions must be used.
3.8.4	All Licensed Healthcare Professionals involved in the care of patients undergoing chemotherapy should have access as necessary to patients' health information to assess, plan, provide and document the care delivered.
3.8.5	All written documentation of the informed consent process must be available in the medical record prior to a procedure.
3.8.6	The patient medical record shall contain the name(s) of staff providing chemotherapy, with documentation of the related history, examination, and investigation findings.
3.8.7	Details of each chemotherapy session must be entered into the patient's medical record with outcome/complications, if any. This must include details of the patient pre-therapy assessment and the post-therapy course, including patient interactions, evaluation and management services, dosage, route and type of chemotherapeutic drug(s) and supportive care treatments. There must be professional review of laboratory, radiology and other important reports prior to filing.
3.8.8	Each Healthcare Operator providing chemotherapy must report applicable clinical and managerial performance measures to DHCR to monitor and improve patient care and outcomes as defined in the DHCR Performance Measures Policy.

3.9 PATIENTS RIGHTS AND RESPONSIBILITIES	
3.9.1	Each Healthcare Operator licensed to provide chemotherapeutic drugs shall provide patients and families with information regarding the DHCA Patients' Rights and Responsibilities in accordance with Schedule Two of the DHCA Governing Regulation Number (1) of 2013. This information must be displayed in English and Arabic throughout the facility for patients and visitors to review.
3.9.2	Each Healthcare Operator providing chemotherapy shall provide processes that support patients' and families' rights during care.
3.9.3	Informed consent must be obtained through a process defined by each Healthcare Operator providing chemotherapeutic drugs and carried out by trained staff in a manner and language the patient can understand in accordance with the DHCR Informed Consent Policy.

3.9.4	The patient or legal guardian must be informed of and agree to the administration of chemotherapeutic drugs, including the risks, benefits, limitations and possible alternatives.
3.9.5	Written and oral informed consent must be obtained by the prescribing physician at an appropriate time (not at the last moment) prior to the treatment commencing/ administration, to give the patient/care giver a chance to ask questions and understand the choices and risks before making a decision to undergo chemotherapy.
3.9.6	Risks, benefits, and alternatives must be clearly explained. Any change in the treatment plan requires a new consent form.
3.9.7	Legal guardians, in the case of minors or legally incompetent adult, must be informed of and agree to the administration of the chemotherapeutic drug, including its benefits, risks, and limitations, as well as possible alternative management.
3.9.8	Psychological preparation of patients, especially children and their care givers, is an important part of preparation for chemotherapy and must be managed by healthcare professionals with relevant training and experience.

3.10 MINIMUM FACILITY REQUIREMENTS	
3.10.1	Each Facility must comply with the minimal facility requirements of the most current FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities, and in accordance with its approved Class.
3.10.2	The design of each facility offering chemotherapy must make provision for accessible, efficient, and safe clinical care in a secure, supportive, and functional environment.
3.10.3	If pediatric chemotherapy is provided, each Healthcare Operator must ensure appropriate provisions for the separate management of pediatric patients and the needs of parents/carer.
3.10.4	Outpatient Facilities used for the preparation and reconstitution of chemotherapeutic drugs must have the following minimum facility, engineering controls (biological safety cabinets, isolators, or closed systems) and service requirements for facility and services. Requirements provide for a safe environment of patient care and the safety of employees in the functions of handling, processing and disposing of chemotherapeutic drugs. Typically, functional requirements are included in design layouts with appropriate facility containment areas and controls for the working environment.
3.10.5	An approved biological safety cabinet for the preparation of chemotherapeutic drugs to provide protection of personnel, product and environment – Preference is for a Class II Type B cabinet or Isolator Cabinet System – located in an ISO Class 7 Clean Room environment.
3.10.6	The exhaust system discharge must be HEPA filtered, with fan connected to an emergency power supply and status, (run/off), locally, monitored and alarmed.

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3.10.7	Hand wash stations must be provided where contact with chemotherapeutic drugs can occur, i.e. preparation rooms and patient treatment areas.
3.10.8	All rooms must provide for containment in the event of a spill or leakage of chemotherapeutic drugs.
3.10.9	Compounding and preparation rooms will require an ante room used for transiting from external circulation space.
3.10.10	Administration of chemotherapeutic drugs must be carried out in treatment areas providing appropriate comfort and privacy (e.g. chairs, recliners, bays, cubicles and or beds as appropriate to patient needs).
3.10.11	All patient treatment areas should be of adequate size to allow for the presence of necessary procedure equipment, patient, and staff.
3.10.12	All patient treatment areas must allow for the potential presence of emergency personnel and equipment and the safe care and transfer of the patient in case of a medical emergency.
3.10.13	Corridors in all possible areas used to transport patients on gurneys must have a minimum width of 2.44 meters as per FGI guidelines.
3.10.14	Chemotherapeutic drugs may only be provided by Licensed Healthcare Operators located in buildings which provide for the safe transport of patients in a medical emergency. When the Healthcare Operator is located in upper floors of a building then elevators must be able to accommodate the accompanied patient on a medical gurney.
3.10.15	Each Licensed Healthcare Operator providing chemotherapeutic drugs must ensure suitable and secure storage space for consumables, equipment, pharmaceutical drugs/products required for chemotherapy.
3.10.16	Each Licensed Healthcare Operator must have appropriate call systems with call points located in patient treatment, assessment areas, and toilets. Systems must be regularly performance tested and test results retained.
3.10.17	A Safety Management Program must be established to manage risks in the environment and reduce the risk of injury to patients and staff.

3.11 QUALITY OVERSIGHT AND ACCREDITATION	
3.11.1	Each Healthcare Operator licensed to provide chemotherapeutic drugs will be subject to this Standard, the DHCR Outpatient Clinic Quality Standards or equivalent, the DHCR Quality Oversight Policies, and other applicable DHCA regulations, standards and policies.
3.11.2	Prior to commencing chemotherapy services each Licensed Healthcare Operator must have in place written policies and procedures required for safe and effective practices in compliance with the accreditation standards of the approved accreditation agency and all other applicable regulations,

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	policies and standards. Written documents, including policies, procedures, and programs must be managed in a consistent and uniform manner.
3.11.3	The policies and procedures must include provision for annual / biennial review and revision as necessary as well as for provision of training of all staff of the facility, on the content of the policies and procedures.
3.11.4	Each Chemotherapy Facility must establish and maintain at all times a safety program and related policies & procedures for safe use and management of chemotherapeutic drugs including but not limited to: 3.11.4.1 Scope of use of cytotoxic chemotherapeutic drugs; 3.11.4.2 Clinical guidelines or evidence based chemotherapy protocols; 3.11.4.3 Spill management of chemotherapy spills and exposure; 3.11.4.4 Cleaning and decontamination of work surfaces; 3.11.4.5 Management of extravasations of chemotherapeutic drugs; 3.11.4.6 The management of anaphylaxis; 3.11.4.7 Adverse drug reactions management; 3.11.4.8 Prescribing and ordering chemotherapeutic drugs; 3.11.4.9 Dispensing chemotherapeutic drugs; 3.11.4.10 Administering chemotherapeutic drugs; 3.11.4.11 Safe handling; storage, transporting and waste management mechanisms of chemotherapeutic drugs; 3.11.4.12 Medical surveillance of chemotherapeutic drugs handlers and control of occupational exposure; 3.11.4.13 Ongoing staff education and training and competency programs for all staff involved in handling and administering chemotherapeutic drugs including ancillary services e.g. housekeeping staff. 3.11.4.14 Compounding policy and procedure manual, refer to Appendix 2 Compounding and Record Keeping of Chemotherapeutic Drugs.
3.11.5	Materials for patient education regarding diagnosis, treatment, and drugs administered should be available.
3.11.6	Policies and procedures must address all aspects of the management of chemotherapeutic drugs, including the appropriate documentation of the provision of chemotherapy, patient management and monitoring.
3.11.7	A policy for Pediatric Chemotherapy must include specific relevant protocols and the requirement of the qualified Licensed Physician, skilled in PALS.
3.11.8	The policies and procedures must include provisions for regular review as well as making provisions for training of all appropriate staff on the content of the policies and procedures.

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3.11.9	The Quality Assurance Committees of each Healthcare Operators providing chemotherapeutic drugs must monitor and review the quality and safety of chemotherapeutic drugs services provided in accordance with the requirements of the DHCA Healthcare Operators Regulation number (4) of 2013.
3.11.10	All staff members involved in chemotherapeutic drugs activities must continuously participate in risk management and quality improvement activities.
3.11.11	Each Healthcare Operator licensed to provide chemotherapeutic drugs must report all related sentinel events as per the applicable DHCA Sentinel Event policy.
3.11.12	Each Healthcare Operator licensed to provide chemotherapy must ensure the review of guidelines; review of pharmacovigilance of chemotherapeutic drugs, review of reported clinical incidents where chemotherapy is a factor; annual audit of the incidence of complications; and overview of staff training and continuing professional development. Results must be reported to the quality assurance committee.
3.11.13	Audit results will inform ongoing training, education and support of all team members involved in the care of patients who receive chemotherapy.
3.11.14	Each Licensed Healthcare Operator providing chemotherapy must define, follow, and document criteria for those conditions that are essential for the proper storage of chemotherapeutic drugs and for their disposal.
3.11.15	Each Chemotherapy Facility must comply with the infection control and Environmental Health and Safety management requirements.
3.11.16	Each Chemotherapy Facility must comply with the chemotherapeutic waste management regulatory requirements including; chemotherapeutic waste; collection, storage, packaging for disposal, recording, disposal, cleaning of waste containers, and develop an emergency contingency plan in case of a spill or exposure.

4 DEFINITIONS	
4.1	**Chemotherapy:** (anti-neoplastic therapy) means all systemic parenteral chemotherapeutic drugs that control or kill cancer cells or alter immune system or hormonal activity.
4.2	**Clean Room**: a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation and retention of particles inside the room, and in which relevant parameters, e.g. temperature, humidity and air pressure are controlled as necessary.
4.3	**Compounding**: the mixing of ingredients to prepare a Product for Patient use, including through the use of dilution, admixture, repackaging, reconstitution or other manipulation of sterile products within a Licensed Pharmacy.

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4.4	**DHCA**: The Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body.
4.5	**DHCR**: is the regulatory arm of Dubai Healthcare City Authority. An independent licensing and regulatory authority for all healthcare providers, medical, educational and other business operating within DHCC.
4.6	**DHCC**: (Dubai Healthcare City): means the Dubai Healthcare City established in the Emirate of Dubai under Resolution No. (9) of 2003.
4.7	**FGI:** Facility Guidelines Institute, USA.
4.8	**Expiry Date**: the date (and time, when applicable) beyond which a Product should not be used. The Expiry Date is assigned on the basis of stability and risk level, whichever is the shorter period.
4.9	**Hazardous drug**: Any drug meeting at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous Chemotherapeutic drugs in structure or toxicity.
4.10	**HEPA Filter**: High Efficiency Particulate Air Filter having a minimum efficiency of 99.97%, tested on o.3 micron particles.
4.11	**Immediately Available:** physically located in the facility and ready for immediate response or utilization.
4.12	**ISO Class 7 Clean Room**: has no more than 352,000 particles per cubic meter equal to and larger than 0.5 microns. For ISO Class 7, the Fed Std. 209E rating is Class 10,000.
4.13	**Isolator**: compounding aseptic isolator.
4.14	**Licensed Healthcare Operator**: a hospital, clinic, laboratory, pharmacy or other entity providing Healthcare Services, holding a Clinical Operating Permit duly issued by the Registry of Companies in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
4.15	**Licensed Oncologist**: A Licensed Physician who specializes in the diagnosis and treatment of all types of cancer and other benign and malignant tumors. This specialist decides on and administers therapy for these malignancies, as well as consults with surgeons and radiotherapists on other treatments for cancer.

5 APPENDICES (as applicable)	
5.1	**Appendix 1 - Safe Handling and Management of Chemotherapeutic Drugs**
5.2	**Appendix 2 - Compounding Procedures and Record Keeping of Chemotherapeutic Drugs**

6 REFERENCE	
6.1	Safe Handling of Hazardous Chemotherapeutic Drugs in Limited-Resource Settings, WHO Washington, D.C. 2013.
6.2	The Facility Guidelines Institute for Design and Construction of Hospitals and Outpatient Facilities.

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6.3	NIOSH (National Institute for Occupational Safety and Health). 2013. Workplace solutions: medical surveillance for health care workers exposed to hazardous drugs. DHHS (NIOSH) Publication No. 2013-103. http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf.
6.4	Work precautions for handling hazardous drugs highlighted by NIOSH, OSHA, Joint Commission April, 2011.
6.5	U.S. Pharmacopeial Convention. 2011. Chapter 797: Pharmaceutical compounding—sterile preparations. In: The United States Pharmacopeia, 35th rev., and The National Formulary, 30th ed. Rockville, MD: U.S. Pharmacopeial Convention.
6.6	Perez Fidalgo JA, Garcia Fabregat L, Cervantes A, et al; Management of chemotherapy extravasation: ESMO-EONS Clinical Practice Guidelines. Ann Oncol. 2012 Oct;23 Suppl 7:vii167-73.
6.7	Side Effects of Chemotherapy Guide: National Cancer Institute (2012). http://www.cancer.gov/cancertopics/pdq/treatment/testicular/HealthProfessional.
6.8	Chemotherapy Services in England: Ensuring quality and safety A report from the National Chemotherapy Advisory Group AUGUST 2009.
6.9	American Cancer Society; 2015 http://www.cancer.org/cancer/cancerbasics/what-is-cancer.
6.10	Oncology Nursing Drug Handbook 2012: Gail Wilkes; Margaret Barton –Burke 2012 Jones & Bartlet Learning; pages 1244-1272.
6.11	3rd Edition 2011 Chemotherapy Biotherapy Guidelines and Recommendations for Practice. Martha Polovich; Julie Whitford; Mikaela Olsen. Chapter 4.
6.12	Oncology Nursing Society Safe Handling of Hazardous Drugs 2011 2nd Edition. Martha Polovich.
6.13	British Association of Dermatologists and British Photo dermatology Group guidelines for the safe and effective use of psoralen-ultraviolet A therapy 2015. https://www.ncbi.nlm.nih.gov/pubmed/26790656

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Appendix 1: Supplementary Guidelines

Safe Handling and Management of Chemotherapeutic Drugs

1. Preparation:

1.1. Chemotherapeutic drugs should be prepared within the pharmacy department or in a pharmacy-controlled facility within a clinical area.

1.2. In every instance, Chemotherapeutic drugs should be prepared to the same standard out of hours as within normal working hours.

1.3. No Chemotherapeutic drugs should be prepared out of a pharmacy controlled facility.

1.4. All Chemotherapeutic drugs should be prepared by appropriately trained and competent staff.

1.5. All Chemotherapeutic drugs prepared by a pharmacy department will have a shelf-life assigned to it, based on the stability of the product.

1.6. If Chemotherapeutic drugs are prepared in an environment other than the pharmacy department (a pharmacy-controlled facility within a clinical area), they should be used immediately after preparation. The administration of infusions produced in this way should be completed ideally within 12 hours of preparation with a maximum of 24 hours' timeframe.

1.7. Stocks of Chemotherapeutic drugs should be distinctively labelled with visual warning signs in separate bins or shelves, segregated from other drugs.

1.8. Proper manipulative technique to maintain the sterility of the drug and to prevent the generation of contaminants must be used consistently.

1.9. Personal Protective Equipment should be used when handling and preparing chemotherapeutic drugs (use of protective gloves, gowns, respiratory protection; respirator not surgical masks, and eye and face protection). Spill kits must be readily available in the HD storage area, and all personnel must be trained to perform spill cleanup.

1.10. Material safety data sheet immediately available in work place.

2. Transport:

2.1 The Chemotherapeutic drugs prepared by the pharmacy department must be packaged double-bagged or in sealed containers to ensure no escape, leak or spillage during handling and carriage.

2.2 All compounded products must be double packaged and packaging must be suitable for the product and robust enough to withstand normal conditions of transport and handling. Packaging must be:

- **a.** Robust;
- **b.** tamper proof;
- **c.** able to provide protection for the handler;

d. able to contain any leakage;

e. labeled to identify of the nature of the contents;

f. labeled to state the name of the sender and recipient;

2.3 Procedures should be available for dealing with spillage during transport. Any such spillage incident should be recorded in writing by the person or persons involved on either a purpose designed form or an incident reporting form.

2.4 Persons transporting Chemotherapeutic drugs must be trained in the actions to be taken in the event of a spillage and the reporting of such an incident.

2.5 If products require refrigeration, the cold chain should be monitored and protected.

2.6 The product should be received by a staff member who will be responsible for opening the package and ensuring that it is stored safely and in an appropriate manner until required for use.

3. Storage:

3.1. Storage at the clinic should be according to current recommendations for drug storage in hospitals. There should be an area specifically for hazardous drugs and it should be labeled as such. The physical storage requirements set out on the label should be met e.g. refrigeration between 2-8 degrees Celsius.

4. Labelling:

4.1. Labels must include the following information:

a. Patient's name and location;

b. unique identification number, dispensing date;

c. name drug/s;

d. where appropriate, the vehicle (solvents, diluents or infusion solutions) into which the drug has been dissolved or diluted;

e. the intended route of administration;

f. the generic name of the chemotherapy drug;

g. the quantity of drug;

h. the final volume for bolus doses and the approximate final volume for infusions;

i. infusion time and rate;

j. shelf-life;

k. storage requirements;

l. manufacturers recommendations, as set out in the latest Summary of Product Characteristics;

4.2. The labeling and packaging details required for administration should be visible to enable examination before the final protective covering is opened.

4.3. The person receiving the Chemotherapeutic drugs and storing it prior to administration must be able to identify the intended patient name and all other details without opening the final protective covering.

5. Administration of Chemotherapeutic drugs:

5.1. Use of safe handling precautions.
5.2. Wash hands before Chemotherapeutic drugs handling.
5.3. Have access to a spill kit.
5.4. Put on Personal Protective Equipment before removing HD from the delivery container.
5.5. Inspect the delivery container and its contents before handling.
5.6. Wear two pairs of chemotherapy-tested gloves (NIOSH 2004).
5.7. Wear a chemotherapy gown.
5.8. Wear a face shield if there is a chance of the Chemotherapeutic drugs splashing.
5.9. Wear a respirator if Chemotherapeutic drugs aerosols may be present. Use locking connections (e.g., Luer-Lok™) whenever possible to securely attach IV tubing, syringes, and needles.
5.10. Avoid priming Chemotherapeutic drugs into gauze pads, sinks, or trash containers.
5.11. Perform all manipulations below eye level.
5.12. Discard used administration sets and syringes intact to avoid contamination during disconnection.
5.13. Dispose of equipment used in Chemotherapeutic drugs administration in designated waste containers.
5.14. Remove PPE in such a way as to prevent contamination of hands and clothing.
5.15. Dispose of used PPE, do not hang up gowns and reuse them.
5.16. Wash hands with soap and water immediately after removing PPE.
5.17. Cleaning and Decontamination of Chemotherapy Drug Equipment and Work Surfaces.
5.18. Cleanup of Hazardous Drug Spills should ideally be located in places where Chemotherapeutic drugs are received, stored, transported, compounded, and administered and where patient waste and drug waste are handled.

6. Safe Handling of Contaminated Bed Linen:

6.1. Staff should wear protective gloves when handling contaminated linen.
6.2. Place contaminated linen in a labeled bag.
6.3. Prewash contaminated linen separately and then wash with the regular laundry.

7. Medical Surveillance of Hazardous Drug Handlers:

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7.1. Maintain a list of all workers who are exposed to Chemotherapeutic drugs as a part of their job assignment.

7.2. Have all Chemotherapeutic drug handlers complete periodic questionnaires to track the frequency and duration of contact with these agents, their use of PPE, and any health events that are potentially related to exposure.

7.3. Conduct periodic observations of drug preparation and administration practices to determine the need for refresher training in work practices that reduce exposure.

7.4. Carefully document spills, spill cleanup activities, and accidental exposure.

7.5. Share the results of medical surveillance with the employees who handle Chemotherapeutic drugs.

7.6. Develop policies that guide employees in how to pursue surveillance.

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Appendix 2: Supplementary Guidelines

Compounding Procedures and Record Keeping of Chemotherapeutic Drugs

1.1 A manual shall be established to set out the Guidelines for compounding and record keeping for chemotherapy admixture compounding in a licensed chemotherapy facility, it should include; Chemotherapy mixing / preparation and delivery procedures.

1.2 Methodologies for the formulation and compounding of preparations.

1.3 Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

- **a.** Capsule weight variation;
- **b.** Adequacy of mixing to insure uniformity and homogeneity;
- **c.** Clarity, completeness, or pH of solutions.

1.4 Validation of the competency and proficiency in the art of compounding for all Licensed Pharmacists and Licensed Technicians.

1.5 Appropriate Policies related to venting and exhaust in cases where toxic compounds or fumes are present.

1.6 Use of Personal Protective Equipment when Handling Chemotherapeutic drugs.

1.7 Records required to be maintained in compliance with this policy shall be retained for a minimum period of two (2) years from the date of last activity and be available.

1.8 There shall be recorded procedures for compounded products to include; Components, amount, order of procedure, and equipment to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.

1.9 Each Licensed Facility engaged in sterile compounding shall have current reference materials related to sterile products compounded therein.

1.10 Each Licensed Facility engaged in compounding of chemotherapeutic drugs shall maintain a log, either manual or electronic for all sterile compounded products dispensed from the pharmacy. This log shall be maintained for a minimum of two years from the date that the sterile compounded product was dispensed. The log shall include the following:

- **a.** Date prepared;
- **b.** Name or initial of pharmacist responsible for the preparation, and technician if applicable;
- **c.** Name of patient;
- **d.** Prescription number (if applicable);
- **e.** Name of sterile compounded product including strength or concentration;
- **f.** All containers shall be labeled, as a minimum, with the following:
  - Patient's Name and identifier, if applicable;
  - Prescribing physician name, if applicable;

- Name of drug, including concentration or amount;
- Date prepared and Expiration date;
- Name or initials of pharmacist who prepared the product;
- Directions, if applicable;
- Route and rate of administration, if applicable.