SAFE HANDLING OF CYTOTOXIC MEDICINES: A SELF ASSESSMENT TOOL ADAPTED TO RESOURCE-CONSTRAINT SETTINGS

Cyto-SAT

Version 01 (JANUARY 2017)

This tool was developed under the initiative of Pharm-Ed program at the Pharmacy of the University Hospitals of Geneva
www.Pharm-Ed.net http://pharmacie.hug-ge.ch/

Safe handling of cytotoxic medicines: a self assessment tool adapted to resource-constraint settings

Cyto-SAT

INTRODUCTION

Handling of cytotoxic medicines is a high risk process for the patients, the personnel and the environment. To reduce the risk of incidents and contamination, preventive measures must be implemented wherever cytotoxic drugs are transported, received, stored, prepared, administered and disposed.
This self-assessment tool was developed to help resource-constraint settings to identify their gaps and raise awareness on the risks related to cytotoxic medicines and to improve handling measures. Cyto-SAT is meant to be used as part of ongoing quality improvement activities.

Elaboration of the tool

Existing national and international recommendations for safe handling of cytotoxic drugs have been consulted by a working group of the University Hospitals of Geneva (Switzerland) to preselect 137 quality and safety standards. Finally 134 standards were validated and prioritized by a consensus of 28 international pharmaceutical experts in oncology practice (through a Delphi method)
Participation of experts from both developed countries and developing countries aimed to make the tool applicable in settings with limited resources while respecting the quality and safety of the process.

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References

The objective was to refer to different types of documents published in English or French such as recommendations from scientific societies, guidelines and regulations from organ of workers'protection and regulatory framework.

All the references below are available online on a free access.

ISOPP Standards of practice, International Society of Oncology Pharmacy Practitioners, 2007

QuapoS 4: Quality Standard for the Oncology Pharmacy Service with Commentary, DGOP e.V (German Society of Oncology Pharmacy)

ASHP Guidelines on Handling of Hazardous Drugs, American Society of Health System Pharmacists, 2006

USP (United States Pharmacopeia) Chapter 800: Hazardous Drugs-Handling in Healthcare settings, The Compounding Expert Committee, 2015

Suvapro: sécurité dans l'emploi des cytostatiques, Swiss Accident Insurance Fund, 2004

Chemotherapy Administration Safety Standards, American society of clinical Oncology (ASCO)/Oncology Nursing society (ONS), 2013,

OSHA technical Manual: Controlling Occupational Exposure to Hazardous Drugs, Occupational Safety & Health Administration (OSHA)

NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, National Institute for

Bonnes Pratiques de préparation (BPP), Agence française de sécurité sanitaire de produits de santé (Afssaps),2007

ISMP International Medication Safety Self assessment for Oncology, Institute for Safe Medication Practices, 2012

Safe Handling of Hazardous Chemotherapy Drugs in Limited-Resource Settings, Pan American Health Organization (PAHO), 2013

Hôpitaux Universitaires Genève

Pharm-Ed

Structure and content

The tool covers the different steps of the cytotoxic medicines circuit.
The quality and safety criteria have been organised in categories and sub categories as shown in the table opposite

The tool includes criteria specific to cytotoxic process but does not address the general procedures for drug management . Although it is largely self-explanatory, basic knowledge about pharmaceutical process is needed. Some preventive measures may also need to refer to the literature for further information.

CATEGORIES	SOUS-CATEGORIES	NB ITEMS
Management		**11**
Personnel	• Education and training	4
	• Health surveillance	3
Logistics	• Receipt	5
	• Storage	6
	• Transport	5
Prescription		**5**
Preparation	• Management and organisation	4
	• Preparation area of parenteral medicines	10
	• Hygiene and personal protective equipment	6
	• Preparation process set up	4
	• Preparation techniques	9
	• Packaging and labelling	3
	• Checking procedure	2
	• Documentation	3
	• Maintenance	2
	• Non sterile preparation	1
Administration	• Management	2
	• Hygiene and safety measures	5
	• Documentation	3
	• Work practices	4
Incident Management	• Surface contamination	6
	• Staff contamination	3
	• Extravasations	3
	• Quality assurance	1
Waste Management	• Cytotoxic waste disposal	7
	• Patients 'excreta	3
Cleaning	• Management and organisation	2
	• Cleaning practices	6
	• Laundry	2
Patient counselling		**4**
	TOTAL	**134**

INSTRUCTIONS

This assessment tool aims at assisting health facilities with ongoing quality and safety improvement of handling of cytotoxic medicines in resource-contraint settings.The tool is designed to be used in different contexts, however some adaptations or addition of items may be considered by some facilities to evaluate some internal procedures.

Before starting the assessment, please read carefully the instructions and go through all the items.
The standard is outlined in the first column and is completed by additional information in the second column

The item priority reflects the experts' opinion on the importance to fullfill the standards, considering the probability of occurrence of the prevented risks, the criticality of the risk, the effectiveness of the measure, how easy it is to implement, etc. the proritiy was classified as follow:

I or i*	: Indispensable (absolutely required even for occasional handling of cytotoxic medicines)
E or e*	: Essential (required for regular use of cytotoxic medicines)
D or d*	: Desirable (desirable if regular use and/or resources sufficient)

Prioritization is indicated in order to guide you in the elaboration of an action plan to improve the cytotoxic medicines flow and management.
**A differentiation is made if a consensus had been obtained or not among the experts at the end of the Delphi survey. The capital letter indicated that an experts'consensus had been reached while the lowercase letter indicated no consensus. Consensus was defined as more than 75% of the experts agreeing with the prirotiy.*

Please evaluate each item according to the scoring system below. As necessary, investigate and verify the level of implementation with other healthcare practitioners and staff.

Scoring system

1	There has been **no activity** to implement this item
2	The item has been **discussed and considered, but it is has not been implemented** yet. There may be a document and no implementation and some staff awareness.
3	The item is **partially implemented** in the facility or implemented only in some areas, for some patients, drugs and/or staff.
4	The item is **fully implemented** throughout the facility for all patients, drugs and/or staff
N.A	**Not applicable**; It is not possible to consider the item in the local context

*** 3 and 4 scores can be used only if there is a real implementation. Procedures or guidelines that are not applied are nor not enough.*

The last column allows to write some comments in order to justify the score or point out some ambiguity.

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

I. MANAGEMENT

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
1	A risk analysis has been conducted in order to evaluate the working environment and to identify and assess hazards related to the flow of cytotoxic medicines within the facility (from the receipt to the use of the products)	A risk assessment approach is used to determine the containment strategies and/or work practices. This considers: overall working environment; equipment (i.e. ventilated cabinets, closed-system drug transfer devices, needleless systems and personal protective equipment); physical layout of work areas; volume, frequency and form of drugs handled (coated or uncoated tablets, powder or liquid); equipment maintenance; decontamination and cleaning; waste handling; potential workplace exposure; routine operations; spill response; and waste segregation, containment. and disposal, training and level of experience of the staff	I	ISOPP Section 5 & 19; QuapoS 1.3; USP <800>; Suva; OSHA; NIOSH						
2	A comprehensive safety management programme has been put in place to deal with all aspects of the safe handling of cytotoxic drugs	A staff member is responsible for coordinating the implementation of preventive measures and preparing guidelines, in close collaboration with other relevant staff within the facility.	I	ISOPP Section 5 & 19; QuapoS 1.3; USP <800>; Suva; OSHA;						
3	Policies and procedures ensure that guidelines for the safe handling of medicines are applied to all processes in which cytotoxic drugs are handled.	Policies and procedures are updated regularly. The frequency of uptdate is to be defined by the local institution, according of the context. Any changes must be documented.	e	ASHP ISOPP Section 9 & 20; QuapoS 1.3; USP <800>; Suva; OSHA;						
4	A self-assessment of compliance with safety guidelines regarding the safe handling of cytotoxic medicines is carried out regularly.	Each intitution should define its frequency according to local context.	e	BPP						

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CYTO-SAT

I. MANAGEMENT (continue)

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
5	Material Safety Data Sheets (MSDS) are readily available for all cytotoxic medicines used in the facility.	MSDS can be kept in a file, be available on a computer or be consulted via the internet.	e	ISOPP Section 2 & 21; ASHP ; OSHA						
6	A list of the cytotoxic medicines used in the facility is available and regularly updated.	The list can be kept in a file or be available on a computer.	e	ISOPP Section 1; USP <800>; OSHA; QuapoS 1.3						
7	Smoking, drinking and eating are forbidden in areas where cytotoxic medicines are prepared, stored and administered		i	ISOPP section 9; ASHP ; OSHA; Suva						
8	All staff know and understand the facility's policies and approach on quality assurance.	Documents are readily available and written in an easily understandable manner.	i							
9	There is a regularly updated organigram (organisational chart) indicating the roles and responsibilities of all the staff members involved in processes using chemotherapies, as well as their contacts details.		e	QuapoS appendix 2						
10	There are written job descriptions detailing the responsibilities, skills and tasks of each staff member.	Required national or international qualifications to handle cytotoxic can also be added	e							
11	There is a sufficient number of competent staff to ensure that high quality care is carried out safely.	The staff available daily should enable to fulfill the tasks and responsibilities according to this repository and to maintained an acceptable workload.	i	ISOPP Section 3						

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CYTO-SAT

II. PERSONNEL

II.1 Education and training

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
12	Based on their tasks and responsibilities, all staff involved in the handling of cytotoxic medicines have received adequate initial training on the type of products they are dealing with, cytotoxic risks, suitable protective measures and proper handling methods.	This includes pharmacy and nursing staff and doctors, plus support staff such as porters, cleaners, stock managers and waste management staff.	i	BPP 7.2; ISOPP Section 3&4; Suva; QuapoS 1.6; USP<800>;OSHA Section VI;						
13	There is regular continuous education for staff.	Training sessions are specific to the category of staff. An annual training plan should be prepared	e	BPP 7.2; ISOPP Section 3&4; Suva, QuapoS						
14	Both theoretical knowledge and practical skills are validated following training (according to the tasks and responsibilities of the staff)	E.g. oral or written tests; assessment using simulation exercises; or practical audits on the following subjects: - Knowledge of cytotoxic medicines handled and their risks; - Knowledge of SOPs related to their handling; - Proper use of personal protective equipment; - Proper handling and use of equipment and devices; - Managing incidents such as breakages, spills and exposure to cytotoxic medicines.	e	BPP 7.2; ISOPP Section 3&4; QuapoS 1.6;USP<800>						
15	All training and skill validations are documented.	Training records are kept for at least 5 years.	e	BPP 7.2; ISOPP Section 3&4; QuapoS 1.6, Suva, USP<800>; OSHA						

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CYTO-SAT

II. PERSONNEL (continue)

II.2 Medical surveillance

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
16	An occupational health surveillance programme is available for staff members who handle cytotoxic medicines	The occupational health surveillance includes: the evaluation of protective measures for pregnant and breastfeeding women; risk assessments in case of accidental exposure or proven or suspected deficiencies in technical protection systems; and investigations that must be carried out in suspected cases of disorders associated with exposure to cytotoxic medicines	i	ISOPP Section 3&19; Suva; ASHP ; QuapoS 1.5;USP<800>; BPP 7.2						
17	No pregnant and breastfeeding women are involved in the handling of cytotoxic medicines.	Pregnant or breastfeeding women must not take part in the preparation, reconstitution, administration, cleaning or disposal of cytotoxic medicines (consult also the stipulations of the national labour law if available)	I	ISOPP Section 3; Suva; ASHP ; QuapoS 1.5;USP<800>; BPP 7.2						
18	Staff involved in the preparation of cytotoxic medicines, with an upper respiratory tract infection or a cutaneous infection informs their superior before any manipulation	The decision to exclude temporarily or not the person from the preparation should be evaluated one by to avoid a risk of microbiological contamination of the preparation. A medical advice can be eventually sought	e	ISOPP Section 3						

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4	Fully implemented throughout
n.a	Not applicable in the context

III. LOGISTICS

III.1 Receipt

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
19	Cytotoxic medicine deliveries are only received and unpacked by trained staff.	The staff responsible for receiving cytotoxic medicines has been trained about the possible surface contamination of primary packaging and vials, the risks of breakages and the appropriate precautions to apply.	e	ISOPP Section 2; QuapoS 3.1						
20	Staff use approriate personal protective equipment when receiving and unpacking cytotoxic medicines	Protective gloves	e	ISOPP Section 2; QuapoS 3.1						
21	The reception of cytotoxic medicine deliveries is carried out appropriately.	Product deliveries are handled by trained staff who visually check the integrity of the packaging to identify any breakages or fissures. If products seem to be intact, reception and unpacking are carried out immediately, or the boxes are placed in a secure area (adequately labeled and with restricted access) until this can be done. Medicines that must stay in the cold chain are unpacked and refrigerated upon receipt.	e	ISOPP Section 2; QuapoS 3.1						
22	The staff receiving and unpacking cytotoxic medicines know the procedures to adopt in cases of accidental spills or leakages.	They are also able to apply those procedures in practice	I	ISOPP Section 2; QuapoS 3.1						
23	Staff washes their hands with soap after handling cytotoxic medicines.	Wearing gloves is not a substitute for washing hands.	i	ISOPP section 2						

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n.a	Not applicable in the context

CYTO-SAT

III. LOGISTICS (continue)

III.2 Storage

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
24	Cytotoxic medicines are stored separately from the rest of the inventory, in a dedicated storage area (including those requiring storage in a refrigerator).	Product segregation prevents contamination and the risk of exposure. If segregation in a separate room for cytotoxics is impossible, storage of cytotoxics is in a clearly identified area.	e	ISOPP Section 2&17; QuapoS 3, USP<800>, ASHP						
25	The storage area for cytotoxic medicines is clearly defined and labeled. Access is restricted to authorised personnel only.	Easily recognizable warning labels should be placed to alert staff (e.g. "Danger/caution cytotoxics"), and security measures should limit access (e.g. locks, badges).	e	ISOPP Section 2&17; QuapoS 3, USP<800>, ASHP						
26	Storage areas contain equipment and monitoring system in order to ensure the correct storage conditions (temperature, light, humidity, exhaust air ventilation) and fulfill safety precautions.	Temperature is monitored and recorded on a logbook.	e	ISOPP Section 2&17; QuapoS 3.1, USP<800>, ASHP						
27	The storage area has sufficient general exhaust ventilation		e	ISOPP Section 6; USP <800>						
28	Only trained staff have access to the storage area for cytotoxic medicines, and they wear appropriate personal protective equipment when resupplying or stocktaking	Gloves should be worn when handling cytotoxic medicines, even in primary packaging and vials. Numerous studies have reported surface contamination of vials and primary packaging.	e	ISOPP section 2; ASHP ; QuapoS 3;Suva						
29	Staff wash their hands with soap after handling cytotoxic medicines when resupplying or stocktaking	Wearing gloves is not a substitute for washing hands.	e	ISOPP section 2						

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n.a	Not applicable in the context

CYTO-SAT

III. LOGISTICS (continue)

III.3 Transport

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
30	Cytotoxic medicines are transported in a manner that will prevent damage to and contamination of the environment, and maintain the integrity of the medicines themselves and the safety of the transporter.	This includes all in-house or inter-facility transport.	I	ISOPP Section 2; QuapoS 3.7,						
31	Cytotoxic medicines are transported in exclusively dedicated containers/boxes.		i	ISOPP Section 2; QuapoS 3.7, USP<800>, ASHP						
32	Transport containers/boxes for cytotoxic medicines are easily recognizable for any person who might handle them.	Easily recognizable warning labels must be attached to the containers and provide specific instructions regarding storage and measures to be taken in case of breakage.	e	ISOPP Section 2&17;QuapoS 3.7, USP<800>, ASHP, Suva						
33	Cytotoxic medicines are transported in very tough, leak proof containers that can be sealed and are made of a material that can easily be cleaned and decontaminated.	Vials must also be securely positioned within their containers in order to minimise impacts and risks of breakage. Ready-to-use preparations must first be placed in leak-proof bags	e	ISOPP Section 2;QuapoS 3.7, USP<800>, ASHP guidelines on HD, Suva						
34	Personnel transporting cytotoxic medicines know the procedures to carry out in case of an accidental spill.	Staff knows who to contact in case of an emergency.	i	ISOPP Section 2; QuapoS 3.7, USP<800>, ASHP						

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n.a	Not applicable in the context

CYTO-SAT

IV.PRESCRIPTION

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
35	Only authorised healthcare practitioners can prescribe chemotherapy treatment.	The facility has a readily available, up to date list of authorised prescribers.	I	ASCO/ONS						
36	Prescriptions are based on standard pre-prepared chemotherapy treatment protocols dependent on the diagnosis, available in the facility (these have either been developed in-house or with reference to external review board or nationally approved clinical research protocols or guidelines)	Standard treatment protocols are regularly revised and updated. They are readily available to all the staff involved in prescribing and validating the prescription. Any prescriptions that are off-protocol must be accompanied by the physician in charge of the chemotherapy's written justifications.	i	ISOPP section 11;QuapoS 3.5; ASCO/ONS						
37	Prescriptions are done in a structured way, with the use of of standardized, formatted (preprinted or electronic) prescription forms. They are nominative, readable, contain no abbreviations and clearly identify the prescriber, the department giving care and the facility.	No prescription (or prescription modification) that was only communicated orally should be validated	i	ISOPP section 11; QuapoS 3.5; ASCO/ONS						

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n.a	Not applicable in the context

CYTO-SAT

IV.PRESCRIPTION (Continue)

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
38	Prescriptions include the following information: patient identity (name, sex, date of birth) weight, height, body surface area, diagnosis, relevant laboratory results (e.g. clearance), name of the protocol, product INN, dosage regimen, dates and times of administration, start and duration of the treatment, pharmaceutical formulation and route of administration, solvent and infusion volume, premedications.	Use of standardized, preprinted or electronic prescription forms for chemotherapy treatment protocols is recommended.	I	QuapoS 3.5; ASCO/ONS						
39	Before preparation, all prescription/orders are analysed, cross-checked using the standard agreed chemotherapy protocol and then validated by the signature of a qualified person (e.g. a pharmacist).	Independently verify each order for chemotherapy before preparation, including confirming: that the prescription corresponds with standards protocols; drug names, regimen and volume; route and rate of administration; product/solvent and product/product compatibilities; dose calculations (including the variables used in this calculation), treatment cycle and day of cycle and cumulative doses.	I	ISOPP section 11; QuapoS 3.5; ASCO/ONS						

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2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION

V.1 Management and Organisation

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
40	Only trained, qualified personnel prepare cytotoxic medicines.	Each operator should be individually validated for both aseptic working methods and proper compounding techniques. (see Chapter on "Personnel")	I	Suva; USP <800>; ASHP ; ISOPP Section 6; QuapoS 1.6						
41	Preparation of oral or parenteral cytotoxic medicines takes place in a controlled area dedicated to this activity. Signs designating the hazard must be prominently displayed at the entrance.	It is recommended that the preparation of cytotoxic medicines should be centralised in order to minimise the risks of contamination and limit the number of people exposed. The preparation area should be located away from breakrooms and refreshment areas.	I	Suva; ASHP ; USP <800>; OSHA; BPP 7.3; ISOPP Section 6; QuapoS 2.1						
42	Access to preparation areas is restricted to authorised personnel involved in preparation of cytotoxic medicines and wearing appropriate personal protective equipment.		I	Suva; ASHP ; USP<800>; OSHA; ISOPP Section 6; QuapoS 2.1						
43	The quality, safety and aseptic conditions (if cleanroom) of the entire preparation process for parenteral/sterile cytotoxic medicines have been validated.	The objective of validation is to demonstrate that the processes used ensure to reproducibly obtain a cytotoxic preparation, with the correct products, within acceptable concentration limits, and that chemical and microbiolgical integrity of the product will be maintained for the established conservation period	i	ISOPP Section 6; QuapoS 3.4						

1	No activity
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n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.2 Preparation area of parenteral medicines

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
44	An administrative area is available for examining prescriptions, preparing production sheets and storing documentation and patient files.	This area is outside the preparation room, but close to it.	E	BPP; QuapoS 2.1, ASHP						
45	The preparation room only contains the necessary materials for the preparation	The objective is to limit the risk of confusion and to minimize the contamination in case of cleanroom	e	QuapoS 3.4						
46	The preparation of sterile cytotoxic (parenteral) medicines takes place in a cleanroom	The preparation of sterile cytotoxic drugs can be defined as an aseptic preparation and should follow GMP and PIC/S guidelines for aseptic procedures. Preparations realized in non-aseptic conditions (without a cleanroom) even with a BSC must not be kept more than 24h.	i	BPP; QuapoS 2.1; ISOPP Section 6; ASHP; WHO GMP						
47	The preparation room surfaces are designed to minimise particle shedding and prevent the build-up of particulate matter as per Good Manufacturing Practices.	Work surfaces and all other surfaces in the preparation room should be smooth and facilitate effective cleaning and disinfection.	i	Suva; ASHP; BPP 7.3; ISOPP Section 6; QuapoS 2.1;WHO GMP						
48	Ergonomic guidelines for the workspace are closely followed.	Notably, these include guidelines on air conditioning, lighting and the workspace, essential for the well-being of the staff and risk minimization of incidents	e	Suva; QuapoS 2.1						
49	The preparation of cytotoxic medicines is performed in a class II b or class III (vertical laminar-airflow hood) biosafety cabinet (BSC) or in an isolator with system externally vented through HEPA filters (high-efficiency particulate air).	A continuous monitoring device ensures confirmation of adequate airflow and/or cabinet performance. If the preparation is not done in a BSC or an isolator, it is only extemporaneous	i	Suva; OSHA; ISOPP Section 6; BPP; NIOSH; QuapoS 2.2; ASHP; WHO GMP						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.2 Preparation area of parenteral medicines (continue)

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
50	Access to the preparation room is through airlocks only, with adequate procedures to prevent simultaneous door opening (doors to the cytotoxic preparation room and to the external environment).	The airlock should provide facilities for gowning prior to personnel entering the preparation room.	e	ISOPP section 6; BPP 7.3; ASHP; QuapoS; USP <800>;WHO GMP						
51	A pass-through hatchenables the transfer of cytotoxic preparations between the cytotoxic prepration room and the external environment.	Ideally distinct from the staff airlock.	e	ISOPP section 6; BPP 7.3; ASHP; QuapoS; USP <800>;WHO GMP						
52	Pressure gradients are maintained between the different rooms in the preparation zone and monitored continuously.	The compounding room has negative pressure compared to the adjacent positive pressure airlock, thus providing inward airflow to contain any contamination in the compounding room. The positive pressure of the airlock also protects the preparation room from the outside environment.	e	ISOPP section 6; BPP 7.3; ASHP; USP <800>;WHO GMP						
53	Preparation rooms are ventilated effectively.	Air exchanges should be frequent enough to prevent room contamination and an accumulation of toxic products (at least 12 air exchanges/hour).	i	Suva; BPP 7.3; ISOPP Section 6; WHO GMP						

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n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.3 Hygiene and protective equipments

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
54	The personnel follow the general hygiene procedures related to medicine preparation.	Staff pay attention to hand hygiene (washing and disinfection) before and after drug preparation activity; they wear no jewelery, wrist-watches or makeup.	I	ASHP; BPP; NIOSH; WHO GMP						
55	Operators and assistants wear appropriate personal protective equipment during the preparation or reconstitution of cytotoxic medicines according to the working environment and collective protective equipment		e	Suva; USP <800>; NIOSH; ASHP ; WHO GMP						
56	During compounding, gloves in contact with cytotoxic vials are regularly changed or are immediately replaced when torn, punctured or directly contaminated.	According to recommendations, gloves should be changed every 30 minutes.	I	Suva; ASHP; USP <800>; NIOSH						
57	Personal protective equipment is removed (either discarded or laundered according to the appropriate procedure) before exiting the preparation area (in the airlock's "dirty area")		e	Suva						
58	Appropriate measures are used to avoid insects or other animals entering preparation areas.		i	BPP						
59	The storage and use of leftover cytostatics solutions, i.e. vials containing solution residues, is carried out according to a validated procedure that takes into account chemicophysical stability and the risk of microbiological contamination	The conservation and use of leftover cytotoxics more than 24 hours is only possible if the preparation is performed under strict aseptic conditions (cleanroom).	I	QuapoS 3.4;						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.4 Preparation process set up

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
60	Doors and windows are closed during compounding.	In an aseptic area, windows should be sealed anyway	i	Suva; QuapoS 2.2						
61	Before and after compounding, all unnecessary items are removed from the work surface and it is cleaned and/or disinfected	Cleaning with an alcohol -soaked wipe should be done before and after each work session. Periodic cleaning with a detergent solution and rinse with water and then disinfecting with alcohol should be done according to the local context (e.g. daily, weekly, monthly). Ventilation should be switched on at least 30 minutes before drug preparation starts and not stopped earlier than 30 minutes after work ends.	I	BPP; ASHP; QuapoS 3.4						
62	All the materials and products required for the preparation are assembled and checked by a certified person before work starts.	Production materials are prepared based on protocol. The drug and its strength, dosage, quantity, reconstitution fluid, as well as equipment and cleanliness, the expiry dates of all component materials, the accuracy of the labels generated and worksheets must all be verified. This verification must be documented.	i	BPP; ASHP; ISOPP Section 11						
63	All equipment is sterile or disinfected before use.	All items of equipment are sprayed or wiped down with alcohol or another appropriate disinfectant immediately before being placed in the BSC or the isolator pass-through. Materials with secondary sterile packaging should be "peeled off" (not applicable if isolators) and placed in the BSC without coming into contact with hands or other non-sterile objects.	I	QuapoS 3.4; ASHP						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.5 Preparation techniques

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
64	The preparation of cytotoxic medicines takes place on a impermeable-plastic-backed absorbent preparation mat in order to avoid contamination of the workbench.	Mats should be changed immediately a spill occurs and regularly during use; they should be discarded at the end of production.	e	Suva; USP <800>; QuapoS 3.4						
65	During preparation, adequate precautions are applied to avoid confusion or mix-up of patients' treatment.	Only one patient's treatment is prepared at a time, and only one particular drug is on the workbench at a time. Preparation of a series of doses, i.e. a batch of the same drug at the same dose (fixed dose), can be performed simultaneously.	I	ISOPP Section 11; ASHP						
66	The operator compounds preparations by strictly following the operating instructions.		I	QuapoS 3.6						
67	The operator uses proper working techniques under a BSC to maintain product asepsis.	There should be no disturbances or interruptions in airflow, minimum work distances from the grills must be respected, benches should be tidy, clean/dirty areas must be separate, vial septums must be disinfected using an alcohol swab, exiting and entering the work area during compounding should be avoided.	i	QuapoS 3.4; ASHP ; OSHA						
68	The operator uses proper working techniques to reduce the risks of chemical contamination or needlestick injuries or cuts.	The operator should for example: either use Luer-lock connections on needles and syringes to minimise the risk of separation in case of overpressurisation or use a needless system or closed-system transfer devices; possibility to use a sterile swab when opening an ampoule, or at the injection port of a vial or infusion bag. A safety box should be available for needles and sharp waste. Evacuating residual air from syringes should be carried out carefully using a sterile swab to limit the risks of contamination.	i	Suva; ASHP; ISOPP Section 7; NIOSH						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.5 Preparation techniques (continue)

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
69	The operator uses proper working techniques to prevent the build up of pressure differentials between the inside and outside of cytotoxic vials.	E.g: air venting device fitted with a 0.2 micron hydrophobic filter; wide bore needles (18G/1.2 mm).	e	ASHP; ISOPP Section 7						
70	The operator uses a syringe size appropriate to the sample volume.	The syringe should not be less than one-third full, in order to ensure the precision of the volume measured.	e	ASHP						
71	I.V tubing is primed prior to adding the cytotoxic product in the infusion bag.		e							
72	Once filled, chemotherapy infusion bags are ready for immediate use, that is, with the infusion set or administration system already connected and the tubes primed with the dilution solvent. The air has already been evacuated from syringes.	The aim is to avoid risk of exposure to the cytotoxic for the nurse when starting the administration	e	BPP 7.6; ASHP						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.6 Packaging and labeling

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
73	There are packaging instructions for each different preparation	Primary packaging must be suitable for the dosage form and volume that it is intended to contain. Container/content interactions must be avoided.	I	BPP						
74	The preparation is packed in adequate, sealed secondary packaging.	The use and characteristics of secondary packaging should be determined according to the risks of deterioration of the primary packaging until use, especially where there is a risk of breakage or leakage and is essential during transport of the preparation	e	BPP 7.6; ISOPP Section 11;						
75	The final product's primary packaging is adequately and unambiguously labelled according to Best Practices and local regulation	For example the label should include: name and address of the pharmacy that produced the preparation; the patient's family name, given name, date of birth; name of ward, department or therapeutic facility ordering the product; names, quantities and qualities of all the cytostatics and other active substances; type and volume of carrier solution; method of administration; day of administration in the course of treatment; instructions for use; instructions for storage; time and date of production; expiry date; and other quality control information such as transport information (cold chain), batch number (or logbook register number).	i	BPP 7.7 et 1.5; QuapoS 3.6; ISOPP Section 11						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

V. PREPARATION (Continue)

V.7 Checking procedure

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
76	Identity and volume of the drugs used are double-checked by the operator and using a reconciliation method	Checks should be performed either by visual inspection by another qualified person during the preparation; or using appropriate technology that directly, automatically records volumes on the container; or using weighing procedures with integrated balances and software that produce weighing tickets during the preparation process and for the final product; or by an analytical control on the final product. Whichever method is used, proof of the check must be recorded and attached to the production worksheet.	I	BPP; ISOPP Section 11						
77	No preparations are released and dispensed before the person in charge has reconciled and validated the final product in order to certify that the product fulfills the established specifications.	The following factors should be cross-checked: patient information on the label must match the medical prescription (if nominative prescription); the medicine information on the label must match the medical prescription and the preparation protocol; the dilution solvent must be appropriate (nature, quantity and compatibility); the container must be adequate for its content; the completeness of labelling; the product's organoleptic properties (e.g. colour, clarity, particle free); and finished pack integrity via a visual inspection.	I	BPP 7.11; ISOPP Section 11						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

V. PREPARATION (Continue)

V.8 Documentation

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
78	Specific production protocols exist for each different cytotoxic medicine.	Protocol specifications must include the following information: the cytotoxic medicine's name, pharmaceutical form and dosage; the types and names of the products to be used; types and names of the medical devices and equipment to be used; the proper preparation procedure; maximum permissible deviation from the value specified in the prescription; packaging and labelling types; information to appear on the label; information on shelf life; and information about special precautions to apply when handling the finished preparation.	i	BPP; QuapoS 3.6; ISOPP Section 11						
79	Production worksheets (describing the work done) are completed for each product prepared. This allows complete traceability at every step in preparation. Worksheets are stored for at least 1 year after the preparation's expiry date (or according to national regulations)	A standardized worksheet should be developed and it should record at least the following information: the preparation's name and, where appropriate, the name of the person who cross-checked its production; the batch number being manufactured; the date and time of the preparation; the operator's name; the names, batch numbers and expiry dates of the different products used (solvents and cytotoxic medicines); the theoretical and actual quantities of each starting product used; the in-process checking performed and the results obtained; the final quantity of product obtained; the type of packaging and number of units packaged, a specimen product label; the expiry date of the final product; notes on any special problems or deviations from normal preparation, including details; a signed authorisation for any deviation from the master formula; and signature of the person responsible of production.	e	BPP; ISOPP Section 11; QuapoS 3.6;						
80	Each preparation is recorded on a preparation logbook	The logbook can also be electronically available	e	BPP						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

V. PREPARATION (Continue)

V.9 Maintenance

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
81	Equipment used to prepare cytotoxic medicines and air-treatment systems are serviced according to a planned maintenance schedule.	Each intervention during a service must be recorded on a maintenance log, e.g. replacement of HEPA filters, equipment calibration, etc.	i	Suva; OSHA; ISOPP Section 6 & 21; BPP; NIOSH; QuapoS 2.2; ASHP						
82	Surrounding conditions (microbiological contamination, particulate contamination) are regularly monitored according to a planned monitoring programme.	if cleanroom	i	ISOPP Section 11; USP <800>; QuapoS 3.4						

V.10 Non sterile preparation

83	All activities likely to result in particle generation, for example, crushing tablets, mixing or filling capsules, should be performed in a Biological Safety Cabinet (BSC)	Whenever possible, sterile and non-sterile preparation activities should not be performed within the same BSC.	e	ISOPP Section 9; USP <800>;						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VI. ADMINISTRATION

VI.1 Management and organisation

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
84	Written administration and surveillance protocols exist and are updated for every chemotherapy available in the facility.	Protocols should include: products' generic names and their different dosages; administration route (if necessary precision of medical device to be used) with the duration and chronology of administration of cytotoxic products and supporting medication; surveillance instructions; and what actions to take in case of complications.	e	ISOPP section 12						
85	Only trained, entitled personnel are permitted to administer cytotoxic medicines to patients.	See chapter on "Personnel".	I	ISOPP section 2; ASCO/ONC; ASHP; Suva						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VI. ADMINISTRATION (continue)

VI.2 Hygiene and safety measures

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
86	Access to the chemotherapy administration area is limited to healthcare personnel, patients and a limited number of relatives, if essential; the latter are informed of the potential risks.	Children and pregnant and breastfeeding women should avoid the chemotherapy administration area.	e	ASHP						
87	Healthcare personnel correctly apply hand hygiene measures during treatments and respect the rules for ensuring asepsis.	Hand hygiene (washing and disinfection) should be compliant with WHO recommendations, including no jewellery.	I							
88	When administering parenteral cytotoxic medicines, staff wears appropriate personal protective equipment (PPE) and removes them before leaving the chemotherapy administration area.	PPE should include trousers, a long-sleeved gown, gloves. If there is a risk of splashing or an aerosol, protective googles and a mask are also recommended.	e	Suva; USP <800>; NIOSH; ASHP						
89	If a direct contact occurs between a cytotoxic product and gloves or a gown, they are immediately changed and hands are thoroughly rinse with water washed.	Some experts recommend that soap or disinfectant should not be used as they can alter the skin's protective barrier. Gloves should also be changed between treating each patient.	I	Suva; OSHA						
90	After administration of the chemotherapy, staff wash their hands with soap and water.		I	Suva; OSHA						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VI. ADMINISTRATION (continue)

VI.3 Documentation

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
91	Traceability of chemotherapy administrations is ensured by treatment administration sheets developed based on protocols. All the fields on the sheet are completed and signed by the personnel who administer treatment.	The use of standardised/pre-printed or electronic forms are recommended. These documents should include the products administered (generic name), their dosage, the time, chronology and duration of administration, surveillance and clinical parameters monitored and the signature of the administering personnel.	e							
92	Before administering chemotherapy, the personnel verify the accuracy of information on the prepared product against the administration protocol. The verification is documented.	A check-list should be used to verify: the patient's identity; the drug name, dosage and volume; route of administration; date of administration; information regarding product conservation; expiry date until end of administration; and the medicine's appearance and physical integrity.	I	ASCO/ONS						
93	The personnel question the patient to verify that his/her identity (given name, family name, date of birth) matches the administration plan and the information written on the product.	A checklist should be used to verify and document the control.	I	ASCO/ONS						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

VI. ADMINISTRATION (continue)

VI.4 Work practices

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
94	Personnel administer cytotoxic medicines safely by using work practices that reduce the risk of exposure and contamination dependent on the different routes of administration: intravenous (infusion or direct injection), subcutaneous, intramuscular, vesical, intraperitoneal, intrathecal, aerosolization, oral or topical.	Administration techniques should use infusion sets and pumps with Luer-lock fittings, or needleless administration system. A disposable plastic-backed absorbent pad should be placed on the work surface or the patient's arm during administration to absorb any leakage. Sterile gauze should be placed around any IV push or connection sites before injection and during removal in order to contain any possible leakage.	E	OSHA; ASHP						
95	Priming IV sets or evacuating air from syringes containing cytotoxic medicines is not carried out in the chemotherapy administration area but in the preparation room.	Alternative methods (e.g retropriming) are possible as far as the risk of exposure of the healthcare personnel is minimized during the administration	e	OSHA; ASHP; NIOSH						
96	The infusion is safely removed from the patient and the entire infusion line discarded intact into the cytotoxic waste container. Needles are never disconnected from syringes; they are disposed of together in a sharp container for cytotoxic medicines.	This is done to avoid the risk of aerolization	i	OSHA; ASHP; NIOSH; Suva						
97	Crushing cytotoxic tablets or opening capsules in an open mortar should be avoided.	This is done to avoid the risk of generating airborne particles of the products. The extemporaneous preparation of oral cytotoxic drugs should be performed with appropriate personal protective equipment associated with containment measures and under a collective protective equipment.	I	ISOPP Section 9						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VII. INCIDENT MANAGEMENT

VII.1 Surface contamination

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
98	There is a standard operating procedure in place in the facility regarding cleaning up spills or breakages involving cytotoxic medicines that is known by every staff who handle cytotoxics.	Any accidental leak or spillages must be contained (the zone must be identified and marked out) and cleaned up immediately by trained staff wearing appropriate personal protective equipment.	I	ISOPP Section 14, Suva, QuapoS 4.2, USP<800>, ASHP						
99	All staff members who might be involved in handling cytotoxic medicines have received training appropriate to their roles regarding the procedures and measures to be taken in case of a spill or a breakage.	Staff should undergo training and simulation exercises.	i	ISOPP Section 14, Suva, QuapoS 4.2, USP<800>, ASHP						
100	Fully equipped spill kits are readily available wherever cytotoxic medicines are handled (in receipt, storage, transport, production and reconstitution, and administration zones).	The spill kits' locations are known, signposted and easily accessible if needed.	I	ISOPP Section14, Suva, QuapoS 4.2, USP<800>, ASHP						
101	Clearly signposted spill kits contain all the materials needed to clean up cytotoxic medicine spills.	Content: instructions for use of the kit, warning material for identifying and marking out the contaminated area, an impermeable protective gown, boots or overshoes, goggles, P3-type respirator mask, at least 2 pairs of appropriate gloves, plastic dustpan and broom or squeegees, cotton wool and absorbent swabs, liquid soap and alcohol, absorbent granules for liquids, containers for sharp waste, clearly labeled cytotoxic waste containers, spill report form.	I	ISOPP Section14 , Suva, QuapoS 4.2, USP<800>, ASHP						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VII. INCIDENT MANAGEMENT (continue)

VII.1 Surface contamination (continue)

102	Used materials are directly discarded according to the waste management procedure.	If economic issues, some objects could be cleaned and decontaminated according to an adequate procedure (e.g. safety glasses , shovel etc.)	I	ISOPP Section14,SuvaQuapoS 4.2, USP<800>, ASHP						
103	Spill kits are replaced as soon as possible in case of future incidents.	Ideally, a replacement kit should be available in advance.	i	ISOPP Section14						

VII.2 Staff contamination

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
104	There is an established standard operating procedure for managing accidental staff chemical contamination. It is displayed in areas where cytotoxic medicines are compounded or administered.	All contaminated clothing should be immediately removed and appropriately discarded or laundered. Contaminated areas of skin should be immediately thoroughly rinsed with water. Medical attention should be sought rapidly.	I	ISOPP Section 14, Suva, QuapoS 4.2, ASHP						
105	The equipment and materials for managing the emergency treatment for chemical contaminated staff are located in areas where cytotoxic medicines are preprared, administered	Close proximity of an emergency shower or water supply. For eyes, a sterile isotonic solution (0.9% sodium chloride) is recommended	I	ISOPP Section 14; ASHP						
106	All staff members involved in handling cytotoxic medicines have received appropriate training according to their tasks. They know the procedures and measures to take in case of staff contamination.		I	ISOPP Section 14; QuapoS 4.2						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VII. INCIDENT MANAGEMENT (continue)

VII.3 Extravasation

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
107	There is an established standard operating procedure for managing extravasation of cytotoxic medicines	Treatment protocols for managing extravasations might differ depending on the agents: "non vesicant", "irritant" and "vesicant" agents.	I	ISOPP Section 14; QuapoS 4.3						
108	Nursing, medical and pharmacy staff are trained to apply preventive measures and to manage and follow-up after extravasation.	Any extravasation must be documented on a monitoring form.	e							
109	An emergency kit for dealing with extravasation is readily available in areas where chemotherapies are administered.	The kit must contain written instructions on how to treat affected areas and how to use the specific antidotes contained in it.	i	ISOPP Section 14; QuapoS 4.3						

VII.4 Quality assurance

110	All incidents involving cytotoxic medicines are reported, monitored, analysed, recorded and any corrective measures applied are followed up on and evaluated.	All incidents must be reported on a incident report form. Its causes should be analysed in order to avoid future repetition.	e	ISOPP Section 14 , USP<800>, ASHP						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VIII. WASTE MANAGEMENT

VIII.1 Waste disposal

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
111	The facility's cytotoxic waste disposal is compliant with current local regulations and is described in a written procedure.	Some countries differentiate between slightly contaminated and heavily contaminated waste.	I	ISOPP section 15; QuapoS 4.1; USP <800>; BPP 7.10; ASHP; OSHA; Suva						
112	Cytotoxic waste disposal is handled separately. Specific segregation, packaging,collection, transport, storage exist to protect staff, patients and the environment from contamination.	Cytotoxic waste is considered to be all those materials which have come into contact with cytotoxic drugs during the processes of reconstitution and administration. This should include syringes, needles, empty or partially used vials, gloves, single-use personal protective equipment and materials used to clean-up of cytotoxic spills. In addition, cytotoxic drugs which have expired, or which must be destroyed for any other reason, are also treated as cytotoxic waste. Some regulations differenciate between slightly contaminated (traces of cytotoxics) and heavily contaminated (leftovers, expired vials, etc) waste	i	ISOPP section 15; QuapoS 4.1; USP <800>; BPP 7.10; ASHP						
113	Suitable, clearly labelled cytotoxic waste containers are available in all areas of the facility where cytotoxic medicines are handled.	Cytotoxic waste containers should be of a specific colour and labelled with a danger symbol at all times. Thick, leak-proof plastic bags placed inside a covered waste container should be used for collection of cytotoxic waste solely. The lid should always be closed, exept when disposing waste.	I	ISOPP section 15; QuapoS 4.1; BPP 7.10; ASHP; OSHA; Suva						
114	Needles and syringes are disposed in puncture-resistant containers. Syringes and needles are not separated after the injection but discarded together	Needles and syringes are disposed in puncture-resistant containers. Syringes and needles are not separated after the injection but discarded together	I	ISOPP section 15; OSHA; Suva						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VIII. WASTE MANAGEMENT (continue)

VIII.1 Waste disposal (continue)

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
115	Only trained personnel handle cytotoxic waste containers; they wear approriate personal protective equipment.	a minima :Gloves	e	ISOPP section 15; QuapoS 4.1; ASHP; OSHA						
116	The facility's storage areas for containers of cytotoxic waste awaiting destruction remain locked and are clearly identified. Storage areas are sheltered, protected from bad weather, cool, have adequate ventilation and are far away from patients and personnel areas in order to minimize the risk of exposure	Cytotoxic waste should only be stored at the facility for a short duration before being transferred for final destruction.	E	ISOPP section 15; OSHA						
117	Cytotoxic waste is incinerated at 1200°C	Depending on national regulations, waste with low levels of chemical contamination can follow different types of disposal	i	WHO; QuapoS 4.1						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

VIII. WASTE MANAGEMENT (continue)

VIII.2 Patients'excreta

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
118	Trained personnel handle the excreta (vomit, urine, faeces, blood, or puncture liquid) of patients undergoing chemotherapy (for at least 7 days after treatment), they wear the appropriate personal protective equipment, including for cleaning toilets.	Gown and gloves and if necessary a mask and protective boots. For the management of excreta at home, information should be provided to the patients' family and caregivers (see chapter patient information)	E	ISOPP section 15; OSHA; QuapoS 4.9; NIOSH						
119	Contaminated linen should be placed in a bag clearly identified and forwarded to the laundry	See chapter on "Cleaning".	E	ISOPP Section 15; QuapoS; OSHA						
120	Mattresses and pillows are protected with plastic covers and wiped-down between patients.		e	QuapoS 4.9;						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

IX. CLEANING

IX.1 Management and Organisation

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
121	Cleaning and maintenance tasks are only carried out by trained personnel.	Cleaning staff have received appropriate training on cytotoxic medicines and safety measures they should apply.	e	ISOPP Section 15; QuapoS; OSHA						
122	Cleaning activities are conducted in accordance with the established procedure and documented in cleaning logs.	Cleaning and disinfection procedures provide detailed information on which areas require cleaning (logistics, preparation and administration rooms) cleaning frequency (e.g. daily, weekly), and the products and cleaning techniques to be used. They should be reviewed regularly and updated when required.	e	Suva; ISOPP section 13; QuapoS 3.4; NIOSH						

IX.2 Cleaning practices

123	Cleaning staff wears the personal protective equipment appropriate to the various tasks to be performed.	The level of personal protection differs according to the type of area to be cleaned. For instance, cleaning of the preparation room requires the same PPE as for the preparation activities. For other areas, staff should at least wear gloves that are chemically resistant to cleaning agents, as well as a splashproof gown. (note: for cleaning up accidental spills, see chapter on "Incidents")	e	Suva; ISOPP Section 13; NIOSH; USP <800>						
124	Single-use, disposable cleaning equipment is used preferably. Should this be impossible, the equipment used must be used exclusively for cleaning and disinfecting of cytotoxic areas.	Cleaning materials (e.g. wipes, mops and disinfectants) for use in the clean room should be made of materials that generate low amounts of particles.	E	ISOPP Section 13; Suva; QuapoS 3.4						
125	Cleaning is only carried out using moistened materials.	No vacuum cleaners, no dry sweeping.	I	Suva;						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

IX. CLEANING (continue)

IX.2 Cleaning practices (continue)

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
126	Staff washes their hands thoroughly with soap immediately after cleaning activities.		I	ISOPP Section 13						
127	The cleanroom is cleaned in an appropriate manner.	Cleaning should proceed from the cleanest area in the room to the dirtiest. This should imply a cleaning workflow from the ceiling to the floor, moving outwards from the ventilation tool to the exit.	I	ISOPP Section 13						
128	The inside of the biosafety cabinet or the isolator is cleaned by the preparation operators	In addition to daily cleaning of the workbench before and after a work session, a comprehensive cleaning process (included the lower part of the BSC, under the workbench) is performed weekly. Inside the BSC, cleaning should start from the top (upstream), close to the HEPA filter, to move down, starting with the rear wall of the BSC, its sides and lastly, the work surface (downstream). The cleaner should be very careful not to wet HEPA filters. If working with isolators, independently of the cleaning at each working session, they should be thoroughly cleaned and regularly sterilized according to a validated frequency (daily, weekly or monthly) depending on the level of activity and the microbiological monitoring of the environment	I	ISOPP Section 13						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

IX. CLEANING (continue)

IX.3 Laundry

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
129	Contaminated, reusable protective clothing (gowns) and linen soiled with patient excreta are placed in clearly labelled laundry bags and are washed separetely from other clothing.	Laundry should start with a cold prewash cycle and then continue using the normal washing process	E	ISOPP section 16; QuapoS 4.9; BPP 7.10						
130	Laundry staff and patient relatives have received instructions and know the procedure on how to handle contaminated linen and clothing and wear adequate personal protective equipment	resitant gloves, gown with long sleeves	e	ISOPP section 16; QuapoS 4.9, OSHA						

1	No activity
2	Discussed and considered but not implemented
3	Partially implemented in some or all areas
4	Fully implemented throughout
n.a	Not applicable in the context

CYTO-SAT

X. PATIENT COUNSELING

	ITEMS	ADDITIONAL INFORMATION	PRIORITY	REFERENCES	1	2	3	4	N.A	COMMENTS
131	The patient's informed consent for chemotherapy treatment is obtained	Before the initiation of a chemotherapy treatment, patient is given information about the diagnosis, the treatment and its goals, as well as the potential risks and necessary follow-up. The consent process follows appropriate professional and legal regulations.	i	ASCO/ONS; QuapoS						
132	Patients and/or caregivers are taught about the treatment including possible side effects and how to manage them, the risks of possible drug interactions and the precautionary measures to take with regard to a patient's excreta. For oral chemotherapy at home, information related to storage, handling, administration, and planning for missed doses and disposal are also provided.	Patient information materials are appropriate for the patient's and the caregiver's levels of understanding and literacy.	I	ASCO/ONS; QuapoS						
133	Patients and/or their caregivers are informed about warning signs and know who to contact and how in case of an emergency or other specific circumstances.		I	ASCO/ONS						
134	Any patient counseling session is documented and added to the patient's file.		e	ASCO/ONS						

RESULT SUMMARY

CATEGORIES	SUB-CATEGORIES	TOTAL PTS	MAX PTS
Management			**44**
Personnel			**28**
	Education and training		16
	Health surveillance		12
Logistics			**64**
	Receipt		20
	Storage		24
	Transport		20
Prescription			**20**
Preparation			**176**
	Management and organisation		16
	Preparation area of parenteral medicines		40
	Hygiene and personal protective equipment		24
	Preparation process set up		16
	Preparation techniques		36
	Packaging and labelling		12
	Checking procedure		8
	Documentation		12
	Maintenance		8
	Non sterile preparation		4
Administration			**56**
	Management		8
	Hygiene and safety measures		20
	Documentation		12
	Work practices		16
Incident Management			**52**
	Surface contamination		24
	Staff contamination		12
	Extravasations		12
	Quality assurance		4
Waste Management			**40**
	Cytotoxic waste disposal		28
	Patients ‘excreta		12
Cleaning			**40**
	Management and organisation		8
	Cleaning practices		24
	Laundry		8
Patient counselling			**16**

Action plan

Short-term objectives

Medium-term objectives

Long-term objectives

Date:

Name (s)

Signature (s)