

Republic of Botswana

25. Sterilising And Disinfecting Unit

These forms are designed to be used by both hospital personnel and external surveyors. The following information must be provided after each survey, before submitting the completed survey forms.

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1.NAME OF HOSPITAL/CLINIC/FACILITY:	
O DAGE INE (INTERNAL OUR) (EVINEORMATION	
2. BASELINE/INTERNAL SURVEY INFORMATION:	ant.
Title and name of person who completed this docume	
Post and position held:	
Date of survey:	
3. EXTERNAL SURVEY INFORMATION:	
Name of external surveyor:	
Date of external survey:	
GUIDE TO COMP	PLETION OF FORM
N.B. Hospital staff are please to use BLACK ink at	all times. The external surveyors are requested to
use RED ink at all times.	
Please circle the rated compliance with the criterio (Partially compliant), C (Compliant).	on, e.g. NA (Not applicable), NC (Non-compliant), PC
The default category affected is designated on the each criterion as follows: 1. patient and staff safety 2. legality 3. patient care 4. efficiency 5. structure 6. basic management 7. basic process 8. evaluation The seriousness of the default is designated on the form for each criterion as follows: 1. mild 2. moderate 3. serious 4. very serious	
	Documents Checked Surveyor: Surveyor:

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25.1 Management

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25.1.1 Standard

The sterilising and disinfecting unit (SDU) is managed to ensure the provision of a safe and effective service.

Standard Intent: Departmental and service managers are primarily responsible for ensuring that the mission of the organisation is met through the provision of management and leadership at departmental level. Good departmental or service performances require clear leadership from a suitably qualified individual. The responsibilities of each role in the department are defined in writing. Documents prepared by each department define its goals as well as identifying current and planned services. Lines of communication within each department are documented to ensure clear accountability.

Often the person in charge of the operating theatre assumes responsibility for the SDU/CSSD as well. Where the unit is physically separated from the theatre suite this may not be possible and another person assumes this function.

The person in charge of the unit should preferably be a professional nurse who can liaise with surgeons and other operating theatre personnel regarding their needs. This person should have knowledge of infection control processes and sterilising methods.

Policies and procedures are essential in a department to ensure that staff receive guidance in the functions carried out. Departmental policies may be standardised for similar departments, or unique to the particular department. They need to be indexed, available, signed, dated and have the authority of the organisational leaders. A system needs to be in place to ensure that departmental policies and procedures are known and implemented. Monitoring provides the information needed to ensure that the policies and procedures are adequately implemented and followed for all relevant services.

Of particular concern is that the policies or procedures should identify:

- how planning will occur
- the documentation required for the care team to work effectively
- special considerations
- monitoring requirements, and
- special qualifications or skills of staff.

Policies and procedures should cover at least:

- processes for cleaning sterilising equipment
- ordering of sterile supplies from suppliers
- receiving, checking and packing supplies received from the suppliers storage of sterile supplies
- recording of issues of stock and maintaining stock levels
- ensuring that supplies are kept sterile
- acting on incidents where the sterility of supplies has not been maintained
- provision of emergency and after-hours sterile supply/sterilisation services
- safe use of SDU equipment, including autoclaves i)
- sterilisation of liquids
- use of ethylene oxide.

Criterion	Comments
	Recommendations

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Criterion 25.1.1.1 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	A designated individual is responsible for the sterilising and disinfecting service.	
Criterion 25.1.1.2 Critical: Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	The manager ensures that policies and procedures, which include at least items a) to k) in the intent above, are available to guide the staff in the service and that they are implemented.	
Criterion 25.1.1.3 Critical: Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious	The manager plans and implements an effective organisational structure to support his/her responsibilities and authority.	
Criterion 25.1.1.4 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of the unit manager are defined in writing.	

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25.2 Facilities and Equipment

25.2.1 Standard

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The unit is designed to allow for effective sterilising and disinfecting of equipment and supplies.

Standard Intent: Departmental managers need to work closely with organisational managers to ensure that facilities and equipment are adequate. Departmental managers keep organisational managers informed of facilities which are inadequate, additional equipment requirements and the current state of facilities and equipment.

Even in a small one-room unit, the separation of activity sites and the flow of work can be achieved by careful planning. There should be a dedicated area for the cleaning of equipment and instruments.

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	Criterion	Comments
		Recommendations
Criterion 25.2.1.1	The design of the sterilising	
Critical:	and disinfecting unit and the layout of equipment ensure	
Catg: Basic Management + Physical Struct	flow of work from the soiled to the clean side of the unit.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.2.1.2	There is a washing and	
Critical:	decontamination area with clean running water and a	
Catg: Basic Management + Physical Struct	sink connected to the sewage system.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.2.1.3	There is a pre-packing area	
Critical:	with storage facilities for clean materials.	
Catg: Basic Management + Physical Struct		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 25.2.1.4 Critical: Catg: Basic Management +	There is a storage area for sterile packs with racks which allow for an adequate circulation of air.	
Physical Struct Compliance	on outdustries and	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 25.2.1.5	Adequate light and ventilation	
Critical:	are available.	
Catg: Basic Management + Physical Struct		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

25.2.2 Standard

Sterilising equipment is suited to its use.

Standard Intent: There are many methods of sterilising equipment. Whatever methods are used, staff members need to ensure that the equipment used is effective. Systems must therefore be in place which will ensure that sterility is obtained through the sterilisation processes.

The number of autoclaves required will depend upon the size of the hospital and the services provided. It will also depend upon how much is processed on site and how much is acquired pre-packed and sterilised. It will also depend on whether the needs of both the operating theatre suite and other departments/services are catered for.

	Criterion	Comments
		Recommendations
Criterion 25.2.2.1	There are one or more	
Critical:	autoclaves or their equivalents capable of	
Catg: Basic Management + Physical Struct	sterilising porous loads (gowns, drapes and	
Compliance	dressings) as well as	
NA NC PC	wrapped and unwrapped instruments.	
Default Severity for NC or PC Very Serious	= 4	

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	1	
Criterion 25.2.2.2	Autoclaves are appropriate to their use and the	
Critical:	manufacturer's instructions	
Catg: Basic Management + Physical Struct	are complied with.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.2.2.3	Sterilising equipment is	
Critical:	included in the organisation's equipment replacement and	
Catg: Basic Management + Physical Struct	maintenance programme.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 25.2.2.4	Where liquids are sterilised,	
Critical:	an autoclave with a fluid cycle and a reverse osmosis or	
Catg: Basic Management + Physical Struct	distillation plant are also provided.	
Compliance	, p. 6 / 16 / 16 / 16 / 16 / 16 / 16 / 16 /	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 25.2.2.5	Where ethylene oxide is used	
Critical: D	as a sterilising agent, the installation complies with	
Catg: Basic Management + Physical Struct	relevant safety standards and legislation.6	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.2.2.6	Autoclave sterilising ability is	
Critical: D	tested daily and the results thereof are recorded.	
Catg: Basic Process + Efficiency	and recorded.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 25.2.2.7	The sterility of each pack is	
Critical:	shown on indicator tapes which are suited to the	
Catg: Basic Process + Efficiency	processes used.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

25.2.3 Standard

The sterility of equipment and supplies is maintained.

Standard Intent: Once sterility has been obtained, it is possible that this sterility may be lost in the storage, issue or distribution of sterile supplies. Systems need to be in place to ensure that packages reach the user sterile and intact.

	Criterion	Comments
		Recommendations
Criterion 25.2.3.1	There is a mechanism to	
Critical:	ensure that sterile supplies in stock are dated and used on	
Catg: Basic Process + Efficiency	a first in, first out basis.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.2.3.2	The maintenance of sterility is	
Critical:	checked before any sterile packs are distributed.	
Catg: Basic Process + Efficiency	packe are diethicated.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.2.3.3	There is a system for the	
Critical:	ordering, storage, maintenance and distribution	
Catg: Basic Process + Efficiency	of sterile supplies.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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25.3 Quality Improvement

25.3.1 Standard

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A formalised proactive quality improvement approach is maintained in the service.

Standard Intent: This refers to the implementation of organisational quality improvement processes (Service Element 8).

It is the responsibility of the management of the organisation to ensure that standards are set throughout the organisation. Within each department or service, it is the responsibility of the managers to ensure that standards are set for that particular department. This requires coordination with the organisation's central/management/coordinating quality improvement structures or systems. Departmental managers use available data and information to identify priority areas for quality monitoring and improvement.

- Quality monitoring could include:
 a) availability of required items for the departments/services
- loss of instruments
- loss of sterility of packs
- d) handling complaints related to the service.

	Criterion	Comments Recommendations
Criterion 25.3.1.1 Critical: Catg: Evaluation + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	There are formalised quality improvement processes for the service that have been developed and agreed upon by the personnel of the service.	
Criterion 25.3.1.2 Critical: Catg: Evaluation + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	Indicators of performance are identified to evaluate the quality of the service.	
Criterion 25.3.1.3 Critical: Catg: Evaluation + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	The quality improvement cycle includes the monitoring and evaluation of the standards set and the remedial action implemented.	

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25.4 Prevention and Control of Infection

25.4.1 Standard

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The department/service implements infection prevention and control processes.

Standard Intent: This refers to the implementation of organisational processes for infection prevention and control (Service Element 9).

	Criterion	Comments
		Recommendations
Criterion 25.4.1.1	The department identifies the	
Critical:	procedures and processes associated	
Catg: Basic Process + Pat & Staff Safety	with the risk of infection and implements strategies to	
Compliance	reduce risk.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.4.1.2	Infection control processes	
Critical:	include prevention of infection from contaminated	
Catg: Basic Process + Pat & Staff Safety	instruments.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.4.1.3	Infection control processes	
Critical:	include the provision and correct usage of	
Catg: Basic Process + Pat & Staff Safety	disinfectants/bactericidal agents.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.4.1.4	Infection control processes	
Critical:	include prevention of infection by the provision and correct	
Catg: Basic Process + Pat & Staff Safety	use of personal protective equipment.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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25.5 Risk Management

25.5.1 Standard

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The department/service implements risk management processes.

Standard Intent: This refers to the implementation of organisational risk management processes (Service Element 7).

	Criterion	Comments
		Recommendations
Criterion 25.5.1.1	The department conducts on-	
Critical:	going monitoring of risks through documented	
Catg: Basic Process + Pat & Staff Safety	assessments as part of the organisational risk	
Compliance	management processes.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.5.1.2	A system for the monitoring of	
Critical:	negative incidents/near misses/sentinel events is	
Catg: Basic Process + Pat & Staff Safety	available and includes the documentation of	
Compliance	interventions and responses to recorded incidents.	
NA NC PC C	to recorded incidents.	
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.5.1.3	Security measures are in	
Critical:	place and implemented for the safeguarding and	
Catg: Basic Process + Pat & Staff Safety	protection of staff.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 25.5.1.4	Fire safety measures are	
Critical:	implemented.	
Catg: Basic Process + Pat & Staff Safety		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 25.5.1.5	Organisation policy on	
Critical:	handling, storage, transporting and	
Catg: Basic Process + Pat & Staff Safety	disposal of healthcare waste is implemented.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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