

21. Pharmaceutical Service

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:	
2. BASELINE/INTERNAL SURVEY INFORMATION:	
Title and name of person who completed this document:	
Post and position held:	
Date of survey:	
3. EXTERNAL SURVEY INFORMATION:	
Name of external surveyor:	
Date of external survey:	
GUIDE TO COMPLETION	ON OF FORM
N.B. Hospital staff are please to use BLACK ink at all time	nes. The external surveyors are requested to
use RED ink at all times.	
Please circle the rated compliance with the criterion, e.g. (Partially compliant), C (Compliant).	NA (Not applicable), NC (Non-compliant), PC
The default category affected is designated on the form to 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	for
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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21.1 Management of the Service

21.1.1 Standard

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Medication management is organised throughout the organisation to meet the needs of patients.

Standard Intent: As an important resource in patient care, medication use must be organised effectively and efficiently throughout a health organisation. Medication management is not only the responsibility of the pharmaceutical service but also of the managers and clinical care providers. How this responsibility is shared depends on the organisation's structure and staffing. In those facilities where there is no pharmacy, medications should be managed as per the requirements of the law. In facilities where there is a large central pharmacy, the pharmacy should organise and control medications throughout the organisation. Applicable laws and regulations are incorporated into the organisational structure and the operations of the medication management system used in the organisation.

A registered pharmacist who is qualified by education, training and experience, directly supervises the activities of the pharmacy or pharmaceutical service.

Documentation which guides the management of the service is available and consulted, e.g.

• current national acts and regulations relating to medication control guidelines, relating to professional practice.

	Criterion	Comments Recommendations
Criterion 21.1.1.1 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	A registered pharmacist with clearly defined responsibilities and accountabilities is designated to manage all aspects of the pharmaceutical service.	
Criterion 21.1.1.2 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	A registered pharmacist is appointed to act in the absence of the manager.	
Criterion 21.1.1.3 Critical: Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	The responsibilities of the pharmacy manager include ensuring compliance with laws, regulations and professional guidelines relating to the service.	

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Criterion 21.1.1.4	The responsibilities of the pharmacy manager include	
Critical:	ensuring compliance with	
Catg: Basic Process + Legality	pharmacy practice and	
Compliance	current pharmaceutical and other health professional	
NA NC PC C	guidelines, e.g. medical and	
Default Severity for NC or PC = 4 Very Serious	nursing.	
Criterion 21.1.1.5	There is an adequate number	
Critical:	of staff members available to meet patient needs during	
Catg: Basic Management + Patient Care	working hours and after hours.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

21.1.2 Standard

The pharmaceutical service is coordinated with other related services in the organisation.

Standard Intent: The pharmaceutical service works with all other departments in the organisation to ensure safe medication usage and control, and to limit adverse drug reactions.

This communication is provided through committee meetings such as those of the Drugs and Therapeutic Committee, Pharmacovigilance Committee and the Drug Information and Toxicology Office. Minutes of these meetings are circulated to all relevant departments.

Pharmaceutical staff members work with other professional staff to identify their needs for in-service training and provide such training as part of the organisation's in-service training programme.

Pharmacists visit wards and departments on a regular basis to check prescriptions, administration records and storage and control of medicines.

	Criterion	Comments
		Recommendations
Criterion 21.1.2.1	Collaboration exists between	
Critical:	the pharmacy staff and other relevant staff in the	
Catg: Basic Process + Efficiency	organisation to ensure safe	
Compliance	prescribing, ordering, storage, preparation, dispensing and	
NA NC PC C	administration of medicines.	
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.1.2.2	The organisation defines the	
Critical:	requirements of a complete order or prescription, taking	
Catg: Basic Management + Legalit	relevant legal specifications	
Compliance	into account.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

21.2 Access to Appropriate Medication

21.2.1 Standard

An appropriate selection of medications for prescribing or ordering is stocked or readily available.

Standard Intent: Every organisation must decide which medications to make available for prescribing and ordering by the care providers. This decision is based on the organisation's mission, patient needs, and the types of services provided. The organisation develops a list of all the medications based on the laws and regulations of the country. Medication selection is a collaborative process, which considers patient need and safety as well as economics. The organisation has a method, such as a committee, to maintain and monitor this medication list and to monitor the use of medication within the organisation. An in-stock list is produced periodically.

Management of medication use in an organisation requires an understanding of the sources and uses of medications, which are not prescribed or ordered within the organisation.

On occasion, medications not readily available to the organisation are needed. There are also occasions where medications are needed at times when pharmacies are closed. Each organisation needs to plan for these occurrences and to educate staff on the procedures to follow should they occur. When patient emergencies occur, quick access to appropriate emergency medications is critical. Each organisation plans the location of emergency medications, and the medications to be supplied in these locations. To ensure access to emergency medications when needed, the organisation establishes a procedure or process to prevent theft or loss of the medications, and to ensure that medications are replaced when used, or when damaged or out of date. Each organisation also needs to determine its role in providing medications to patients at discharge. Those who prescribe or order medication know what medications, if any, are available and how to obtain them.

	Criterion	Comments
		Recommendations
Criterion 21.2.1.1	Medicines appropriate for the	
Critical:	organisation's mission, patient needs and services	
Catg: Basic Management + Patient Care	provided are available for prescribing.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.2.1.2	There is a list of medicines	
Critical:	stocked in the organisation or readily available from outside	
Catg: Basic Process + Efficiency	sources.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 21.2.1.3	There is a method for control	
Critical:	of medication use within the organisation.	
Catg: Basic Process + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.2.1.4	There is a process to obtain	
Critical:	required medicines not stocked or not normally	
Catg: Basic Process + Efficiency	available to the organisation.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.2.1.5	There is a process to obtain	
Critical:	required medicines when the pharmacy is closed.	
Catg: Basic Process + Efficiency	priarriacy is closed.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.2.1.6	Emergency medicines are	
Critical:	available in the organisation within a time frame to meet	
Catg: Basic Process + Efficiency	emergency needs.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.2.1.7 Critical: Catg: Evaluation + Efficiency Compliance NA NC PC C	Emergency medicines are monitored and replaced in a timely manner after use or when expired or damaged.	
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.2.1.8	Policies and procedures related to the handling of	
Critical: Catg: Basic Process + Pat & Staff Safety	expired medicines are implemented throughout the organisation.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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21.3 Policies and Procedures

21.3.1 Standard

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There is a collaborative effort to develop and monitor policies and procedures for the pharmaceutical service.

Standard Intent: Safe pharmaceutical practices are guided by laws and regulations as well as organisational policies and procedures. Medical, nursing, pharmacy and administrative staff members participate in a collaborative process to develop and monitor the policies and procedures.

The clinical and managerial leaders use a collaborative process to develop policies and procedures and train staff in their implementation.

Of particular concern is that the policies or procedures identify:

- how planning will occur
- the documentation required for the care team to work effectively
- special consent considerations, e.g. trial medicines
- monitoring requirements
- special qualifications or skills of staff members involved in the care process
- availability and use of resuscitation medicines.

Clinical guidelines are frequently helpful and may be incorporated in the process. Monitoring provides the information needed to ensure that the policies and procedures are adequately implemented and followed for all relevant patients and services.

Policies and procedures should focus on high risk procedures, e.g.

- safe storage, prescribing, ordering, dispensing, transcribing and administration of medications in the organisation;
- Documentation requirements; b.
- C. keeping at least three months of buffer stock;
- d. use of verbal medication orders;
- availability and use of medication samples; e.
- documentation and management of any medications brought into the organisation for or by the patient;
- self-administration of medication by the patient;
- g. h. dispensing of medications at the time of the patient's discharge;
- i. preparation, handling, storage and distribution of parenteral and enteral nutrition products;
- Storage, handling, distribution and dispensing of controlled, high-alert and hazardous medications;
- Storage, handling, distribution and dispensing of investigational medications;
- Management of medications, used in clinical trials;

Security of staff, equipment and stock;

- management of adverse drug reactions; m.
- management of medication errors; n.
- management of expired medicines... 0.

	Criterion	Comments
		Recommendations
Criterion 21.3.1.1	Policies and procedures,	
Critical:	which include at least those from a) to o) in the intent	
Catg: Basic Process + Patient Care	above, are developed and	
Compliance	implemented.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.3.1.2	There is evidence that	
Critical:	policies and procedures have been developed	
Catg: Basic Process + Efficiency	collaboratively with all	
Compliance	relevant departments.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

21.4 Dispensing of Medicines

21.4.1 Standard

Dispensing of medications adheres to laws, regulations and professional standards of practice.

Standard Intent: A registered pharmacist reviews each prescription or order for medication. When questions arise, the individual who prescribed or ordered the medication is contacted.

The dispenser signs the prescription. When pharmacist assistants/technicians or interns dispense, they are supervised and their signatures as dispensers are countersigned by a registered pharmacist.

The organisation dispenses medications in the most ready-to-administer form possible, to minimise opportunities for error during distribution and administration. The central pharmacy and other medication distribution points throughout the organisation use the same system. The system supports accurate dispensing of medications in a timely manner. It is generally accepted that the dispensing process is divided into three phases:

Phase 1: Interpretation and evaluation of a prescription

Phase 2: Preparation and labelling

Phase 3: Provision of information and instructions to the patient

These three phases may be performed by a pharmacist or a pharmacist technician under the direct supervision of a pharmacist. Other cadres can dispense (medicine) as per the provisions of the Medicines and Related Substances Act of 2013 and Regulations thereof.

	Criterion	Comments
		Recommendations
Criterion 21.4.1.1	Medicines are prepared and	
Critical:	dispensed in a safe and clean environment.	
Catg: Basic Process + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 21.4.1.2	There is a uniform medication	
Critical:	dispensing and distribution system in the organisation.	
Catg: Basic Process + Efficiency	j	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.4.1.3	The system supports	
Critical:	accurate and timely dispensing.	
Catg: Basic Process + Efficiency	and a manage	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 21.4.1.4	Policies and procedures are	
Critical:	implemented to ensure that medications are dispensed on	
Catg: Basic Process + Patient Care	the written instructions of a	
Compliance	designated health worker qualified and/or experienced	
NA NC PC C	in their use.	
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.4.1.5	Policies and procedures are	
Critical:	implemented to ensure that medications are dispensed in	
Catg: Basic Process + Patient Care	conjunction with other	
Compliance	medications only after thorough checking for drug	
NA NC PC C	interactions by dispensing	
Default Severity for NC or PC = 4 Very Serious	staff.	
Criterion 21.4.1.6	Medicines are securely and	
Critical: D	legibly labelled with relevant information as required by	
Catg: Basic Process + Pat & Staff Safety	law or organisational policy.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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21.5 Control and Storage of Medication

21.5.1 Standard

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Adequate facilities are available for the safe storage and dispensing of medications.

Standard Intent: Secure storage systems ensure that pharmaceuticals and related substances are held under conditions, which conform to statutory and the manufacturer's requirements.

Arrangements, including alarm systems, door access controls, and safes/vaults used to store controlled medicines exist to ensure the security of medicines.

The pharmacy or pharmaceutical service stores and dispenses medications in a clean and secure environment, which complies with laws, regulations and professional practice standards. In particular, medications are clearly labelled, stored properly, and protected from heat, light and moisture.

Deep freeze, refrigeration, cold room and cool area facilities are provided for safe storage of certain medications. There is a mechanism to ensure that the temperature has been maintained throughout the life of the medications. Deep freezers and refrigerators are defrosted when necessary. Doors, hinges and seals are all functional.

Medications stored and dispensed from areas outside the pharmacy, for example patient care units, comply with the same safety measures.

There is a registry, log or other mechanism to monitor and account for controlled substances.

	Criterion	Comments
		Recommendations
Criterion 21.5.1.1	Separate designated areas	
Critical:	for the receipt and unpacking of incoming goods are	
Catg: Basic Management + Physical Struct	provided.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 21.5.1.2	Separate designated areas	
Critical:	for the storage of normal stock of medicines are	
Catg: Basic Management + Physical Struct	provided.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 21.5.1.3	Hazardous and flammable materials are stored in accordance with relevant regulations.	
Critical: D		
Catg: Basic Process + Legality		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.5.1.4	Separate designated storage	
Critical:	areas for materials under quarantine are provided, e.g.	
Catg: Basic Management + Physical Struct	expired stock, damaged goods and compounded	
Compliance	products awaiting testing and	
NA NC PC C	release.	
Default Severity for NC or PC = 3 Serious		
Criterion 21.5.1.5	Secure storage facilities are	
Critical:	available and include smoke detectors, security alarm	
Catg: Basic Management + Physical Struct	systems and/or barriers.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.5.1.6	Stock control systems are	
Critical: D	managed in the pharmacy and other related	
Catg: Basic Process + Efficiency	departments.	
Compliance	'	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.5.1.7	A management information	
Critical:	system is available which provides accurate statistics	
Catg: Basic Process + Efficiency	relating to pharmaceutical	
Compliance	receipts and issues.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.5.1.8	Medicines are stored in a clean environment.	
Critical:	Gean environment.	
Catg: Basic Process + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.5.1.9	The cold chain is maintained	
Critical: D	for medicines where necessary.	
Catg: Basic Process + Efficiency	Thecessary.	
Compliance	1	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.5.1.10	Medicine storage areas are	
Critical:	protected from heat, light and moisture and temperatures	
Catg: Basic Process + Efficiency	are monitored and recorded.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.5.1.11	Medicines identified for	
Critical:	special control (by law or	
Catg: Basic Process + Legality	organisational policy) are stored in a cabinet of	
Compliance	substantial construction, for	
NA NC PC C	which only authorised staff have a key.	
Default Severity for NC or PC = 4 Very Serious	,	
Criterion 21.5.1.12	Medicines identified for	
Critical: D	special control (by law or or organisational policy) are	
Catg: Basic Process + Legality	accurately accounted for.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4		

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21.6 Quality Improvement

21.6.1 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 management of the organisation to ensure that standards are set throughout the organisation. Within each department or service, it is the responsibility of managers to ensure that standards are set for the 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:

a) completion of prescriptions

b) the use of antibiotics and other medications c) medication errors d) adverse medication effects e) patient and family expectations and satisfaction f) audits of medication storage/use in the departments g) monitoring of financial aspects h) out of stock items, aged items i) analysis of complaints, negative incidents, patient satisfaction.

The following will be evaluated:

- problems identified in this service for which quality improvement activities were initiated
- the processes put in place to resolve the problems
- identification of indicators to measure improvement
- the tool(s) used to evaluate these indicators
- the monitoring of these indicators and corrective steps taken when goals were not achieved
- graphed results, where appropriate.

	Criterion	Comments
		Recommendations
Criterion 21.6.1.1	There are formalised quality	
Critical:	improvement processes for the service that have been	
Catg: Evaluation + Efficiency	developed and agreed upon	
Compliance	by the personnel of the service.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.6.1.2	Indicators of performance are	
Critical:	identified to evaluate the quality of the service.	
Catg: Evaluation + Efficiency	quanty or and control.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.6.1.3 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.	
Criterion 21.6.1.4 Critical: Catg: Evaluation + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	A documentation audit system is in place.	
Criterion 21.6.1.5 Critical: Catg: Evaluation + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	Clinical audits are undertaken to monitor the quality of care provided.	

21.7 Patient Rights

21.7.1 Standard

The department/service implements processes that support patient and family rights during care.

Standard Intent: This refers to the implementation of organisational policies on patient and family rights (Service Element 5).

Compliance will be verified during observation of patient care processes, patient record audits and patient interviews.

	Criterion	Comments
		Recommendations
Criterion 21.7.1.1	There are processes that	
Critical:	support patient and family rights during care.	
Catg: Basic Management + Patient Care		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.7.1.2	Measures are taken to protect	
Critical:	the patient's privacy, person and possessions.	
Catg: Basic Process + Patient Care Compliance	and possessions.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.7.1.3	The personnel respect the	
Critical:	rights of patients and families to accept treatment and to	
Catg: Basic Process + Patient Care		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

21.8 Prevention and Control of Infection

21.8.1 Standard

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 21.8.1.1	The department identifies the	
Critical:	procedures and processes associated with the risk of	
Catg: Basic Process + Pat & Staff Safety	infection and implements strategies to reduce risk.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.8.1.2	Infection control processes	
Critical:	include prevention of infection while undertaking sterile	
Catg: Basic Process + Pat & Staff Safety	procedures.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.8.1.3	Infection control processes include prevention of infection	
Critical:	during the process of preparation and dispensing of	
Catg: Basic Process + Pat & Staff Safety	medication.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.8.1.4	Infection control processes	
Critical:	include prevention of water contamination during the	
Catg: Basic Process + Pat & Staff Safety	preparation of suspensions/liquid	
Compliance	medications.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

21.9 Risk Management

21.9.1 Standard

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 21.9.1.1	The department conducts on-	
Critical:	going monitoring of risks through documented	
Catg: Basic Process + Pat & Staff Safety	assessments as part of organisational risk	
Compliance	management processes.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.9.1.2	A system for monitoring	
Critical:	incidents/near misses/sentinel/adverse	
Catg: Basic Process + Pat & Staff Safety	events is available and includes the documentation of	
Compliance	interventions and responses to recorded incidents.	
NA NC PC C	no recorded incidents.	
Default Severity for NC or PC = 4 Very Serious		

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Criterion 21.9.1.3	Security measures are in place and implemented to ensure the safety of patients,	
Catg: Basic Process + Pat & Staff Safety	personnel and visitors.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 21.9.1.4	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		
Criterion 21.9.1.5	Organisation's policy on	
Critical:	handling, segregation, storing and disposing of healthcare	
Catg: Basic Process + Pat & Staff Safety	waste is implemented.	
Compliance]	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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