

STANDARD

INTERNATIONAL REQUIREMENTS NOVEMBER 2014, VERSION 1.1

Managing Infection Risk

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CHANGES

Version	Reason for changes
1.0	First version released
1.1	Reformatted to DNV GL. Minor typographical errors corrected, no change made to requirements

Contents

1	FOREWORD	5
2	SCOPE	7
3	INFORMATIVE REFERENCES	7
4	TERMS AND DEFINITIONS	8
5	REQUIREMENTS AND GUIDANCE	13
5.1	INFECTION RISK MANAGEMENT SYSTEM	13
5.1.1	Infection risk management system	13
5.1.2	Infection risk management policy	13
5.1.3	Objectives, targets and program	13
5.1.4	Scope of Service	14
5.1.5	Planning and resources	14
5.1.6	Roles, responsibilities and authorities	15
5.1.7	Documentos requirements	17
5.1.8	Control of documents and records	18
5.1.9	Performance measurement and analysis of data	18
5.1.10	Change management	19
5.1.11	Consultation and communication	19
5.1.12	Infection risk management review	19
5.1.13	Conformity and compliance	20
5.1.14	Control of non-conformities	20
5.1.15	Contractors, visitors and suppliers	21
5.1.16	Control of supplies	21
5.1.17	Monitoring controls	21
5.1.18	Inspection and audit	21
5.1.19	Continual improvement	22
5.1.20	Corrective action	22
5.1.21	Preventive action	23
5.2	RISK ASSESSMENT	24
5.2.1	Planning and resources	24
5.2.2	Risk assessment timing and scope	24
5.2.3	Hazard identification	25
5.2.4	Risk assessment	26
5.2.5	Risk management	26
5.3	MICROBIAL SURVEILLANCE	27
5.3.1	Infection surveillance program	27
5.4	ANTIMICROBIAL USE AND SURVEILLANCE	29
5.4.1	Program	29
5.4.2	Microbiology laboratory	30
5.5	EMERGENCY RESPONSE AND CONTINGENCY PLANNING	31
5.5.1	Identification of emergency scenarios	31
5.5.2	Emergency response and planning	31
5.5.3	Emergency plans	31
5.5.4	Emergency exercises and simulations	32
5.5.5	Contingency plans	32
5.6	ACCIDENT AND INCIDENT INVESTIGATION	34

5.6.1	Accident / incident investigation	34
5.7	PERSONNEL AND COMPETENCY	35
5.7.1	Recruitment.....	35
5.7.2	Training.....	35
5.7.3	Competence.....	35
5.7.4	Continuity and succession planning	36
5.7.5	Exclusion	36
5.8	HUMAN FACTORS.....	37
5.8.1	Human Factors	37
5.9	OCCUPATIONAL HEALTH	38
5.9.1	Occupational health program	38
5.9.2	Occupational health surveillance program	38
5.9.3	Vaccination of personnel.....	38
5.9.4	Management of job-related illnesses and exposures	39
5.10	HEALTHCARE FACILITY REQUIREMENTS AND LAYOUT	40
5.10.1	Planning and design	40
5.10.2	Heating, Ventilating and Air Conditioning (HVAC)	41
5.10.3	Water	41
5.10.4	Commissioning and decommissioning	42
5.11	HEALTHCARE ENVIRONMENT.....	43
5.11.1	General.....	43
5.11.2	Inventory	43
5.11.3	Linen and clothing management.....	43
5.11.4	Staff clothing.....	44
5.11.5	Food and beverage services.....	44
5.11.6	Animals in healthcare facilities	44
5.12	EQUIPMENT AND MAINTENANCE	45
5.12.1	Selection of medical devices and equipment	45
5.12.2	Maintenance.....	45
5.12.3	Calibration, certification and validation.....	46
5.13	CLEANING, DISINFECTION, DECONTAMINATION AND STERILIZATION	47
5.13.1	Cleaning, disinfection decontamination and sterilization	47
5.13.2	Household and cleaning	47
5.13.3	Validation.....	47
5.13.4	Storage and segregation	48
5.13.5	Waste management.....	48
5.14	PATIENT CARE	49
5.14.1	The general patient pathway	49
5.14.2	Standard infection control procedures.....	50
5.14.3	Transmission-based precautions	51
5.15	HAND HYGIENE	52
5.15.1	Hand hygiene program	52
5.15.2	Hand Care.....	52
5.16	CLOTHING AND PERSONAL PROTECTIVE EQUIPMENT	54
5.16.1	Clothing and PPE.....	54
5.17	MOVEMENT AND TRANSPORT	55
5.17.1	Transportation of patients and materials	55
5.17.2	Routes and access controls.....	55
5.17.3	Information, communication and confidentiality	56
5.18	SECURITY	57
5.18.1	Physical security	57
5.18.2	Personal security.....	57

1 FOREWORD

Management systems approach – Introduction

This managing infection risk standard is based on a management system approach. This implies that identifying, understanding and managing a system of interrelated processes for a given objective, improves the organization's effectiveness and efficiency.

Application of the management systems approach principle leads to the following actions:

- a) defining the system by identifying or developing the processes that affect a given objective;
- b) structuring the system to achieve the objective in the most effective manner;
- c) understanding the interdependencies among the processes of the system;
- d) continually improving the system through measurement and evaluation, and;
- e) establishing resource constraints prior to action.

The systems approach outlined above has been successfully adopted by the International Organization for Standardization (ISO). Organizations which have already implemented systems for quality, environmental and / or occupational health and safety management, will find significant synergy between these systems and the one for infection risk management.

The management system approach enables an organization to effectively identify, monitor and control the organization's infection risk aspects of its activities.

An effective management system approach should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions that an organization undertakes to meet goals. This is known as the PDCA (Plan-Do-Check-Act) principle:

- Plan:** Planning, including identification of hazard and risk and establishing goals,
Do: Implementing, including training and operational issues,
Check: Checking, including monitoring and corrective action,
Act: Reviewing, including process innovation and acting to make needed changes to the management system.

In order to improve infection risk management the organization needs to focus on the causes of non-conformities and undesirable events. Systematic identification and correction of system deficiencies leads to improved performance and control of infection risk.

Keys to a successful infection risk management system

Some of the key factors in establishing and implementing a successful infection risk management system include:

- Commitment by top management:
 - providing adequate resources, prioritization and communication of infection risk policy;
 - integrating of infection risk management throughout the organization;
 - identifying opportunities for improvement and prevention, determining root causes and preventing recurrence.
- Focus on continual improvement:
 - making continual improvement an objective for every individual in the organization;
 - using periodic assessment against established risk-criteria to identify areas for potential improvement;
 - continually improving the effectiveness and efficiency of processes;

- promoting prevention activities;
- providing personnel in the organization with appropriate education and training including the methods and tools of continual improvement;
- establishing measures and goals for improvement;
- recognizing improvement.

Management system integration

This infection risk management standard is compatible with various World Health Organization (WHO) and US Centers for Disease Control (CDC) guidelines, together with requirements from a variety of internationally recognized management standards, including ISO 9001.

Application

The requirements of this standard are generic and are intended to be applicable to all healthcare organizations handling infectious materials, including patients and patient samples.

Where any requirements of this standard cannot be applied due to the nature of the organization and its processes, this can be considered for exclusion. Where exclusions are made, claims of conformity to this standard are not acceptable, unless such exclusions do not affect the organization's ability or responsibility to manage infection risk in the manner required by this standard. Any claims of exclusion shall be detailed and justification provided.

Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any program. Where any part of this standard is in conflict with any legal requirement, the conflicting part of the standard may be eligible for exemption if the legal requirement meets or exceeds the intent of this standard.

All organizations face challenges in putting the management system requirements of this standard in place. For small organizations the challenges are potentially greater due to minimal available resources, costs involved and difficulty in understanding and applying the standard. Small organizations are typically ones in which only a few people are involved, there is a simple communication flow and individuals undertake a wide variety of tasks. Decisions are made by just a few people. Small organizations should analyze each requirement clause of the standard and determine in which manner they can interpret and comply with it to suit the objective of the standard in identification and control of infection risk.

The more challenging requirement clauses in this respect may be the ones related to continual improvement. The organization should regard this as a recurring, step-by-step activity. When opportunities for improvement are identified, and justified, the organization needs to decide how they are to be implemented based on the available resources. The justification should be founded on an analysis of the potential gains in terms of improved control of risk. Improvements may typically address issues like:

- training and awareness programs;
- internal communications;
- effectiveness of reviews;
- preventive actions;
- effectiveness of follow-up activities;
- documented procedures and instructions.

2 SCOPE

The scope of this infection risk management system standard is to set requirements necessary to manage infection risks associated with the handling of patients or patients' samples in a healthcare setting.

The standard will enable organizations to:

- a) establish and maintain an infection risk management system to control or minimize risk to acceptable levels in relation to patients, personnel, the community and others as well as the environment which could be directly or indirectly exposed to biological agents or toxins;
- b) provide assurance that the requirements are in place and implemented effectively;
- c) seek and achieve certification or verification of the infection risk management system by an independent third party;
- d) provide a framework that can be used as the basis for training and raising awareness of managing infection risk guidelines and best practices within the scientific community.

The standard is performance-based and sets out requirements for and places responsibility on organizations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented.

The standard is structured in a manner where the specific requirements pertaining to each individual clause are defined and informative guidance has been provided as an aid in interpreting the requirements, where considered appropriate. This guidance is in the form of notes in association with the pertaining requirements clause and uses the terms "should" (recommendation), "may" (allowance) and "can" (possibility). Organizations wishing to implement this standard would be expected to consider all recommendations where the term "should" is used.

Contents of the notes shall not in any way be construed as being requirements.

3 INFORMATIVE REFERENCES

The guidance documents on managing infection risk used for the development of this standard are:

Publisher	Year	Title of Document	Abbreviation used
CEN	2008	Laboratory Biorisk Management System Standard.	CWA 15793
ISO	2008	ISO 9001:2008 Quality Management Systems – Requirements.	ISO 9001
WHO	2002	Prevention of Hospital Acquired Infections – A Practical Guide (2nd Edition).	WHO 2002 PHAI
WHO	2004	Practical Guidelines for Infection Control in Health Care Facilities.	WHO 2004 PGICHF
WHO	2009	Core Components for Infection Prevention and Control Programmes – Report of the Second Meeting – Informal Network on Infection Prevention and Control in Health Care.	WHO 2009 CC IPC
CDC	1998	Guideline for Infection Control in Health Personnel.	CDC 1998 GICHP
CDC	2002	Guidelines for Hand Hygiene in Healthcare Settings.	CDC 2002 GHH
CDC	2003	Guidelines for Environment Infection Control in Healthcare Facilities.	CDC 2003 GEICH

CDC	2006	Management of Multidrug-Resistant Organisms in Healthcare Settings.	CDC 2006 MDRO
CDC	2006	Influenza Vaccination Healthcare Personnel	CDC 2006 IVHCP
CDC	2007	Guidelines for Isolation Precaution: Preventing Transmission of Infectious Agents in Healthcare Settings.	CDC 2007 GIP
CDC	2008	Guidelines for Disinfection and Sterilization in Healthcare Facilities.	CDC 2008 GDSHF

4 TERMS AND DEFINITIONS

For the purposes of this document, the following terms and definitions apply to this standard:

4.1

accident

unintended event giving rise to harm

NOTE An accident is an incident which has resulted in harm.

4.2

audit (OHSAS 18001:2007)

systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled

NOTE 1 Independent does not necessarily mean external to the organization. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 For further guidance on audit evidence and audit criteria, see EN ISO 19011:2002.

4.3

biological agent (adapted from EU Directive 2000/54/EC)

any microorganism including those which have been genetically modified, cell cultures and endoparasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants

NOTE For the purpose of this standard prions are regarded as 'biological agents'.

4.4

certification

systematic, documented process to ensure systems perform in accordance with available certification standards or applicable validation guidance

4.5

cleaning (CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.

4.6

community

people outside the workplace potentially affected by the activities of the facility

4.7

competence (EN ISO 9000:2005)

appropriate education, training, skills and experience

4.8

containment (EN 12128:1998)

system for confining microorganisms or organisms or other entities within a defined space

4.9

continual improvement (adapted from OHSAS 18001:2007)

recurring process of enhancing the infection risk management system in order to achieve improvements in overall infection risk management performance consistent with the organization's infection risk management policy

NOTE The process need not take place in all areas of activity simultaneously

4.10 contractors

Personnel not directly employed by the healthcare organization

4.11 corrective action (OHSAS 18001:2007)

action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE 1 There can be more than one cause for nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

4.12 decontamination (adapted from ISO 15190:2003 and CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects, so objects are safe to handle, use or discard. In healthcare settings this process may include cleaning, disinfection, and sterilization.

4.13 disinfection (ISO 15190:2003)

process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms.

4.14 document (OHSAS 18001:2007)

information and its supporting medium

NOTE The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.

4.15 event (adapted from ISO/IEC Guide 73:2002)

occurrence of a particular set of circumstances

4.16 facility

operational unit and associated buildings and equipment used to manage biological agents and toxins

NOTE 1 This includes the healthcare facility, together with the supporting infrastructure, equipment and services including ancillary rooms such as laundry areas, food preparation areas, sterile service rooms and storage rooms.

4.17 harm (adapted from ISO/IEC Guide 51:1999)

adverse effect on the health of people, animals or plants, on the environment or on property

4.18 hazard (adapted from OHSAS 18001:2007)

source, situation, or act with a potential for causing harm

4.19 hazard identification (OHSAS 18001:2007)

process of recognizing that a hazard exists and defining its characteristics

4.20 healthcare associated infection (Adapted from CDC and WHO)

Healthcare-associated infections (HAI) are infections that patients acquire during the course of receiving healthcare treatment for other conditions and are neither present nor incubating upon patient's admission

4.21 incident

event with a potential for causing harm

NOTE 1 An accident is an incident which has resulted in harm.

NOTE 2 An incident where no harm is caused may also be referred to as a "near miss", "near hit", "close call" or "dangerous occurrence".

NOTE 3 An emergency situation is a particular type of incident

4.22 inspection (EN ISO 9000:2005)

conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging

4.23 inventory

itemized record of stored supplies of biological agents or valuable biological materials

4.24 medical device (ISO 13485:2003 NOTE This definition has been developed by the Global Harmonization Task Force (GHTF))

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

4.25 nonconformity (OHSAS 18001:2007)

non-fulfillment of a requirement

NOTE A nonconformity can be any deviation from: relevant work standards, practices, procedures, legal requirements, etc.: infection risk management system requirements.

4.26 organization (OHSAS 18001:2007)

company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration

NOTE For organizations with more than one operating unit, a single operating unit may be defined as an organization.

4.27 personal protective equipment (PPE) (adapted from: ISO 15190:2003)

material, including clothing (e.g. gown, gloves, respirators, safety glasses), used to prevent exposure to or contamination of a person by chemical or biological matter

4.28

personnel

a generic term to describe individuals working in the healthcare facility (see also staff and contractors). Role may either be patient facing (e.g. nursing) or support services (e.g. engineering, catering).

4.29

preventive action (OHSAS 18001:2007)

action to eliminate the cause of a potential nonconformity or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

4.30

procedure (adapted from OHSAS 18001:2007)

specified way to carry out an activity or a process

4.31

record (OHSAS 18001:2007)

document stating results achieved or providing evidence of activities performed

4.32

risk (ISO/IEC Guide 51:1999)

combination of the probability of occurrence of harm and the severity of that harm

4.33

risk assessment (OHSAS 18001:2007)

process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable

4.34

safety (ISO/IEC Guide 51:1999)

freedom from unacceptable risk

4.35

staff

personnel directly employed by the healthcare organization

4.36

standard operating procedure (SOP)

set of written instructions that document a routine or repetitive activity followed by an organization

4.37

source (ISO/IEC Guide 73:2002)

item or activity having a potential for a consequence

4.38

sterile (EN 556-1/ISO-TS 11139:2006/ ISO 13408-1:2011)

condition of a medical device that is "free from viable micro-organisms"

4.39

sterilization (ISO/TS 11139:2006,ISO 134108-1:2011)

validated process used to render a product free from viable microorganisms

4.40

validation (adapted from EN ISO 9000:2005)

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

4.41

verification (adapted from ISO 9000:2005)

confirmation, through the provision of objective evidence that specified requirements have been fulfilled

4.42

workplace (OHSAS 18001:2007)

any physical location in which work-related activities are performed under the control of the organization

NOTE When giving consideration to what constitutes a workplace, the organization should take into account the occupational health and safety effects on personnel who are, for example, travelling or in transit (e.g. driving, flying, on boats or trains), working at the premises of a client customer, or working at home.

5 REQUIREMENTS AND GUIDANCE

5.1 Requirements and Guidance

5.1.1 Infection risk management system

5.1.1.1 The organization shall establish, document, implement and maintain an infection risk management system appropriate to the size, scope of services and activities of the organization.

Notes:

The system should be integrated in the overall quality management system of the organization, together with other areas as appropriate (e.g. security, environment).

Aspects concerning infection risk management should specifically address areas, including but not limited to:

- a. Identifying and determining all processes needed to deliver healthcare services in relation to responsible infection risk management, including those that may have been outsourced or are delivered by a third party;*
- b. Determine the sequence of activities in processes and the interactions between and within processes;*
- c. Determining indicators, criteria and methods for evaluation needed to ensure that both the operation and control of the processes are effective;*
- d. Ensuring the availability of relevant information necessary for the operation and infection risk management of all processes.*

5.1.2 Infection risk management policy

5.1.2.1 The organization's top management shall develop, authorize and sign a policy concerning the management of infection risk. It shall clearly state the overall infection risk management objectives and a commitment to improving performance in relation to infection risk.

The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities and commit to:

- a. Protecting personnel, patients, contractors, and visitors from healthcare associated infections (HAI);
- b. Reducing the risk of exposure to infectious agents;
- c. Complying with all legal requirements applicable to the infectious agents present in the healthcare facility and with the requirements of this standard;
- d. Effectively informing all staff, patients, contractors, visitors, the community and relevant third parties and communicating individual obligations with regard to managing infection risk;
- e. Continually improving infection risk management performance.

Notes:

This may for example include the incorporation of managing infection risk in the organization's mission statement, or be reflected in organizational structure and thus lines of reporting for safety and infection risks to reach top management.

5.1.3 Objectives, targets and program

5.1.3.1 Documented infection risk management objectives and targets for effective prevention and control of infection risk at relevant functions and levels in the organization shall be established, implemented and maintained.

Notes:

The prevention of transmission of infectious agents should be incorporated into the objectives of the organization's patient and occupational safety programs.

When planning and conducting the measurement of objectives, targets and the program, the organization should consider issues including but not limited to:

- a. Preventing the occurrence of HAI in patients, healthcare workers, visitors and other persons associated with healthcare facilities;*
- b. Preparing healthcare facilities for the early detection and management of epidemics and to organize a prompt and effective response;*
- c. Contributing to a coordinated response to control community-acquired infectious diseases, endemic or epidemic, that may be "amplified" via healthcare;*
- d. Contributing to preventing the emergence of antimicrobial resistance and / or dissemination of resistant strains of microorganisms; and minimize the environmental impact of these infections or their management.*

5.1.4 Scope of Service

5.1.4.1 The organization shall establish and maintain procedures to ensure the scope of service for the healthcare facility is defined, documented and reviewed with regard to infection risk. Changes to the scope of services shall be subject to a formal change management process.

Notes:

The scope of service should include the nature of the activities authorized to be conducted in the organization / unit and their definitions (e.g. diagnostics, treatment, care, rehabilitation).

When planning and conducting activities, the organization should consider the core components of infection prevention and control (IPC) programs including but not limited to:

- a. Organization of IPC programs;*
- b. Technical guidelines;*
- c. Human resource needs, including:
 - i. Program staffing;*
 - ii. Training;*
 - iii. Occupational health issues for healthcare workers.**
- d. Surveillance of disease and assessment of compliance with IPC practices;*
- e. Microbiology laboratory support;*
- f. Environment;*
- g. Evaluation of IPC programs;*
- h. Links with public health and other services / societal bodies.*

Activities associated with the scope of services should be specified and supported by formal procedures / SOPs, approved in accordance with the requirements for controlled documents.

5.1.5 Planning and resources

5.1.5.1 The organization shall establish and maintain procedures to determine and allocate the resources needed to implement and maintain the infection risk management system and continually improve its effectiveness.

Notes:

The organization should have a process in place to ensure there is sufficient resource capacity and capability to manage workflow and the infection risk management program, whether planned or under emergency or other abnormal working conditions.

5.1.6 Roles, responsibilities and authorities

- 5.1.6.1 Top management shall take ultimate responsibility for the organization's infection risk management system.

Notes:

Overall responsibility for management of infection risk rests with top management but tasks may be delegated through the organization provided that they are passed to competent individuals with adequate resources to perform the activities safely and securely. In smaller organizations, one individual may hold more than one role.

- 5.1.6.2 Top management shall demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain and improve the infection risk management system.

- 5.1.6.3 Top management shall ensure that roles, responsibilities and authorities related to infection risk management are defined, documented and communicated.

Notes:

It is important to define roles and responsibilities and that there is clear communication within the organization in terms of the actions that need to be taken, and who has the required authority. In assigning roles and responsibilities, potential conflicts of interest should be considered and avoided.

- 5.1.6.4 A Management Representative shall be designated with operational responsibility for overseeing the system for management of infection risk. Functions of the Management Representative shall include:
- Providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe operation of the organization;
 - Reporting to top management on the performance of the infection risk management system and any need for improvement;
 - Ensuring promotion of the infection risk management system throughout the organization;
 - Instituting review, audit and reporting measures to provide assurance that the system is appropriate and it is being implemented and maintained effectively.

Notes:

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority to oversee the infection risk management system.

Management Representatives are those with significant operational, budgetary and personnel authority at the departmental or higher level, and may include members of top management. The Management Representative should be an individual with decision making authority at a level whereby he / she can allocate resources and make decisions regarding the infection risk management needs of the organization (including required resources to conduct risk assessments and other management and administrative activities) independently of the need to implement the program of work.

- 5.1.6.5 The organization shall constitute a committee to act as an independent group on managing infection risk issues. The organization shall determine the roles, responsibilities and authority of the infection risk management committee.

Notes:

The functions of the managing infection risk (MIR) committee (often referred to as Infection Control Committee or ICC) may be provided by, at least in part, other committees as part of their roles and functions (e.g. a quality management committee). However, where this is the case the role of the MIR

committee must be clearly stated in terms of reference and reflected in the standing agenda and composition of the committee members.

The committee should consider issues including but not limited to:

- a. Contributing to the development of institutional infection risk policies and codes of practice;*
- b. Reviewing and approving a yearly program of activity for surveillance and prevention;*
- c. Reviewing epidemiological surveillance data and identify areas for intervention;*
- d. Reviewing staff training programs in infection control and safety management;*
- e. Ensuring safety materials such as protective equipment and products are made available;*
- f. Reviewing and approving risk assessments from an infection risk perspective;*
- g. Reviewing information relating to significant accidents / incidents, data trends, associated local / organizational actions;*
- h. Coordinating the handling of infection risk emergencies and outbreaks;*
- i. Defining themes for audits, reviewing results and ensuring follow-up and close-out of actions.*

The committee should have documented terms of reference, a standing agenda and maintain adequate minutes / other records as appropriate.

The committee should include representation from relevant departments and disciplines, including but not limited to representative(s) from:

- a. Infection risk management advisor / infection control officer;*
- b. Physicians;*
- c. Infection control nurses;*
- d. Nursing services;*
- e. Pharmacy staff;*
- f. Microbiology laboratory personnel;*
- g. Occupational health professional;*
- h. Facility manager;*
- i. Cleaning, decontamination and sterilization personnel;*
- j. Home health;*
- k. External partners (e.g. nursing homes);*
- l. Patient advocacy groups.*

Depending on the role and composition of the committee, not all representatives may be required to attend as standing members, and may be called on an as needed basis.

5.1.6.6 The organization shall designate a qualified individual(s) to provide advice and guidance on infection risk management issues who shall be independent of those responsible for managing or providing patient care. The infection risk management advisor shall report directly to top management.

Notes:

This role is often recognized as infection control officer, infection control professional, infection control practitioner or infection control advisor.

The infection control advisor (ICA) is important for the development, implementation, maintenance and continual improvement of an infection risk management program based on a management system.

The advisor / officer should be competent to perform the role, and allocated sufficient time and other resources to do the job effectively. Depending on the size of the organization and the nature of the care provided this role maybe filled by one individual or by a team.

Functions of the ICA should include but not be limited to:

- a. Assisting top management in promoting awareness of infection risk requirements throughout the organization;*
- b. Ensuring the practical establishment, implementation and maintenance and the continual improvement of the infection risk management system;*

- c. Ensuring that the processes of the infection risk management system are established and maintained;
- d. Advising and assisting on infection risk management issues within the organization (e.g. management, infection risk management committee, occupational health department, security);
- e. Reporting to top management on the performance of the infection risk management system, including the need for improvement;
- f. Assisting in the development and dissemination of guidelines for infection risk management;
- g. Verifying, in conjunction with other relevant personnel, that all relevant infection risk considerations within the healthcare organization have been addressed;
- h. Advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / infection risk management committee;
- i. Ensuring that all relevant activities are performed in compliance with infection risk management regulations and that required infection risk management authorizations for work are in place.

5.1.6.7 The infection risk management advisor shall have delegated authority to stop work (where safe to do so) and investigate where there are concerns regarding infection risk.

5.1.6.8 The organization shall have access to occupational health expertise in relation to infection risk.

Notes:

Infection risk management should be integrated in the occupational health program and address non-infection related issues potentially affecting worker health (e.g. exposure to chemicals found in disinfectants, use of heat, allergic reaction to materials in personal protective equipment (PPE)).

Functions of the occupational health advisor for infection risk should include but not be limited to:

- a. Providing input into infection risk assessment from an occupational health perspective;
- b. Advising on first aid / emergency treatment measures and follow-up;
- c. Liaising with external healthcare providers, and coordinating medical examinations, surveillance and vaccination programs.

5.1.7 Documentos requirements

- 5.1.7.1 The organization shall establish and maintain an infection risk management manual that includes, but is not limited to:
- a. The purpose and scope of the infection risk management program, including details of and justification for any exclusions;
 - b. An organizational chart indicating the lines of reporting, illustrating distribution of responsibilities and functions, as well as the interrelations between personnel and groups with influence on infection risk management conditions within the organization;
 - c. A description of the interaction of the processes of the infection risk management system;
 - d. Instructions and technical procedures for patient care and prevention and control of HAI.

Notes:

The manual should address issues including but not limited to:

- a. Standard Precautions;
- b. Transmission-based Precautions;
- c. Isolation measures;
- d. PPE requirements;
- e. Vaccination needs;
- f. Aseptic technique and device management for clinical procedures according to scope of care;
- g. Prevention of targeted categories of HAI (e.g. surgical site infections, central line associated infections, ventilator associated pneumonia, urinary tract infections) and pathogens (e.g. C.difficile, multidrug-resistant organisms).

5.1.8 Control of documents and records

5.1.8.1 Necessary records, documents and data shall be established, controlled and maintained to provide evidence of a functioning infection risk management system.

Notes:

Where appropriate, documents should be identified and controlled based upon the nature of the work and need for record keeping. Patient records should provide appropriate information in order to control infection risks, including but not limited to:

- a. Anamnesis / patient history should include information relevant to infection risk;*
- b. Infection risk control measures should be part of documentation when patients are moved or discharged.*

Controlled documents should be defined and may include but are not limited to:

- a. Risk assessments, standard operating procedures (SOPs) and infection prevention and control manuals;*
- b. Job hazard analyses and charts of authority;*
- c. Audit and inspection checklists;*
- d. Design records and commissioning / test plans, maintenance plans and records and all associated data;*
- e. Training records;*
- f. Equipment certifications.*

5.1.8.2 Records, documents and data shall be handled in such a way that they remain legible, readily identifiable and retrievable.

Notes:

Data should be construed as documents in this context and procedures established to define controls including but not limited to:

- a. Identification, storage, protection, retrieval, retention time and disposal of records;*
- b. Approval of documents prior to issue or public release to ensure sensitive information such as patient details is not inadvertently released;*
- c. Review, update and re-approval of documents;*
- d. Change control and revision process.*

5.1.9 Performance measurement and analysis of data

5.1.9.1 Appropriate data shall be determined, collected and analyzed to assess the suitability and effectiveness of the infection risk management system and to evaluate where continual improvement of the system can be made. Results of the analysis shall be applied in the management review.

Notes:

The analysis may include data generated as a result of monitoring, measurement, audits, and analysis and from other sources.

Such analyses may be conducted at least annually and more often if justified by the risks and the scope of operations.

5.1.10 Change management

5.1.10.1 All changes associated with the design, operation and maintenance of the healthcare organization and facilities that may impact on infection risk shall be subject to a defined and documented change management process. Changes shall be reviewed, verified and validated as appropriate, and approved before implementation. This should include evaluation of the effect of the changes on the infection risk.

Notes:

Changes that should be subject to the change management process may include but not be limited to:

- a. Modifications to buildings and equipment or their operation, which may or would have an effect on infection risk (e.g. operation room / theatre);*
- b. Introduction of altered staffing arrangements (such as temporary presence of on-site contractors or students, temporary reassignments of personnel);*
- c. Changes to the program of work, including alterations to work flow or volume which may or would have an effect on infection risk;*
- d. Changes associated with design and redesign of patient care processes, methodologies, technologies etc. (e.g. implementation of evidence-based medicine and/or evidence based guidelines)*
- e. Modifications to personnel policies and visitor protocols;*
- f. Modifications to disinfection and other waste management methodologies;*
- g. Changes associated with PPE provision and usage.*

5.1.11 Consultation and communication

5.1.11.1 The organization shall determine and implement mechanisms to ensure that relevant and current infection risk information relating to its activities is communicated effectively, at timely and appropriate intervals, to and from personnel and other relevant parties.

Notes:

Relevant information may include but not be limited to:

- a. Information regarding infection rates;*
- b. Information relating to infection risk;*
- c. Changes associated with design and redesign of patient care processes, methodologies, technologies etc. (e.g. implementation of evidence-based medicine and/or evidence based guidelines)*
- d. Information regarding infection risk in patient care should be documented and communicated throughout the patient pathway to relevant team-members and personnel and / or collaborating units.*

In the workplace this could mean regular team meetings and briefings, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others including:

- a. Patients, relatives and other visitors;*
- b. Local, national and international governmental organizations;*
- c. Relevant regulatory agencies;*
- d. Certifiers/accreditation agencies;*
- e. Emergency services and healthcare providers;*
- f. Contractors and suppliers (e.g. cleaners, maintenance providers, security personnel);*
- g. Local community representatives (e.g. through a community liaison committee).*

5.1.12 Infection risk management review

5.1.12.1 Top management shall review the organization's infection risk management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for

changes to the system, procedures, including the infection risk management policy and objectives. Records from the management review shall be maintained.

Notes:

The management review should be conducted at a defined frequency determined by the needs of the organization, but at least annually.

The review should consider information including but not limited to:

- a. Process performance and service conformity;*
- b. Results of audits;*
- c. Results of surveillance activities;*
- d. Status of risk assessment activities;*
- e. Status of preventive and corrective actions;*
- f. Results of accident / incident investigations;*
- g. Follow-up actions from previous management reviews;*
- h. Changes that could affect the IPC management system;*
- i. Recommendations for improvement.*

The review output may contain information including but not limited to:

- a. Improvement of the effectiveness of the infection risk management system;*
- b. Improvement of services related to patient and customers' requirements;*
- c. Improvement related to the requirements and risk assessments;*
- d. Resource needs.*

5.1.13 Conformity and compliance

5.1.13.1 The organization shall ensure that all relevant requirements are identified and fulfilled within the infection risk management system.

Notes:

The organization should adopt measures to identify legal and other requirements for the healthcare facility in relation to infection risk, but also other regulations including for example: worker protection and rights, environmental impact and general health and safety (e.g. fire, electrical).

There is a need to monitor for new and upcoming requirements, as well as those already in existence. This information should be kept up to date and the requirements incorporated into the infection risk management system of the organization.

The organization should have a documented list of the legal requirements, and in addition other guidelines, standards or other best practice that the organization will adopt and comply to, including but not limited to:

- a. National legislative requirements;*
- b. Local legal requirements;*
- c. International and national evidence-based guidelines (e.g. WHO, CDC).*

5.1.14 Control of non-conformities

5.1.14.1 The organization shall ensure that situations which do not conform to the requirements of the infection risk management system are identified and controlled to prevent undesirable consequences. Records of the nature of the non-conformity and any subsequent action taken should be maintained.

Notes:

The controls and related responsibilities and authorities for dealing with non-conforming situations should be defined in a procedure.

5.1.15 Contractors, visitors and suppliers

5.1.15.1 The organization shall establish and maintain procedures to ensure that contractors, visitors, suppliers and sub-contractors adhere to the requirements of the established infection risk management system. Criteria for selection, evaluation and re-evaluation of suppliers shall be based on their ability to provide products / services that comply with the requirements of the infection risk management program. These criteria shall be established with records of results maintained and actions from evaluations recorded.

Notes:

Top management should design a process and procedure to direct contractor's adherence to the established infection risk management system. Such procedure may include e.g.:

- a. Worker health requirements;*
- b. Specifications relating to products and supplies;*
- c. Training needs;*
- d. Familiarity with infection risk management system requirements.*

5.1.16 Control of supplies

5.1.16.1 The organization shall establish and maintain procedures to ensure that purchases (including services) conform to specified requirements in relation to the infection risk management system.

Notes:

While not all suppliers will provide products / services that may impact on infection risk, there are many that will. Suppliers that should be considered include but are not limited to:

- a. Cleaning services;*
- b. Laundry contractors;*
- c. Medical equipment suppliers;*
- d. Equipment and facility maintenance services;*
- e. Waste management or disposal services.*
- f. Catering suppliers and / or services*

5.1.17 Monitoring controls

5.1.17.1 Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

Notes:

The controls can be monitored by regular audits, by utilizing corrective action reporting processes where problems have been identified, by investigation of incidents and accidents and improving controls and their implementation and by ensuring that adequate resources are provided to maintain the effectiveness of the controls.

5.1.18 Inspection and audit

5.1.18.1 The organization shall establish and maintain procedures to ensure an effective inspection and audit program is established, implemented and maintained, appropriate to the infection risks associated with the healthcare organization. Audits shall be performed by competent individuals who are independent of the activity being audited.

Notes:

Inspections may be frequent checks on specific areas conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels / concentrations, maintenance of directional air flow, compliance to hand hygiene guidelines, isolation measures).

- 5.1.18.2 Inspections and audits shall be conducted at planned intervals to determine if the infection risk management system conforms to the documented plans and that it is effectively implemented and maintained. Records of findings of inspections / audits, including action taken to close out any non-conformities or improvement opportunities shall be maintained.
- 5.1.18.3 Management shall be responsible for the area being inspected / audited and ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities arising from audits and inspections shall include the verification of the actions taken and the reporting of verification results.

5.1.19 Continual improvement

- 5.1.19.1 The organization shall have a system in place to ensure the suitability and continual improvement of the effectiveness of the infection risk management system through the use of the infection risk management policy, objectives, audit results, analysis of data, corrective and preventive actions and management review.

Notes:

The organization should strive to continue to develop and refine the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved through goal setting and targets placed upon those working within the facility, and monitoring progress to ensure the goals are achieved.

5.1.20 Corrective action

- 5.1.20.1 The organization shall ensure action is taken to eliminate the causes of non-conformities with the requirements of their infection risk management system in order to prevent recurrence. The corrective actions shall be appropriate to the effects of the nonconformities encountered.

Notes:

The organization should establish documented procedures to define requirements including but not limited to:

- a. Identifying and reporting the non-conformities;*
- b. Reviewing the non-conformities;*
- c. Determining the causes of non-conformities;*
- d. Evaluating the need for action to ensure that non-conformities do not recur;*
- e. Determining and implementing action needed;*
- f. Recording the results of action taken;*
- g. Reviewing the effectiveness of the corrective actions taken.*

5.1.21 Preventive action

5.1.21.1 The organization shall determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

Notes:

The organization should establish documented procedures to define requirements including but not limited to:

- a. Determining potential nonconformities and their causes;*
- b. Evaluating the need for action to prevent occurrence of nonconformities;*
- c. Determining and implementing action needed;*
- d. Recording the results of action taken;*
- e. Reviewing the effectiveness of the preventive actions taken.*

The controls and related responsibilities and authorities for dealing with non-conforming situations should be defined in a procedure.

5.2 Risk Assessment

5.2.1 Planning and resources

- 5.2.1.1 The organization shall establish and maintain procedures to ensure that a risk assessment system is established, implemented and maintained for all relevant activities with regard to infection risk.
- 5.2.1.2 The organization shall establish procedures to ensure resource requirements are identified, and adequate resources provided, including the assignment of trained personnel for infection risk assessment management, performance of work, and verification activities, including internal review.

Notes:

The roles and responsibilities of personnel who perform and verify work affecting infection risk management should be defined and documented, particularly for people who need the organizational freedom and authority to do one of the following:

- a. Initiate action to prevent or reduce the adverse effects of infection risk;*
- b. Control further treatment of infection risks until the level of risk becomes acceptable;*
- c. Identify and record any problems relating to the management of infection risks;*
- d. Initiate, recommend or provide solutions through designated channels;*
- e. Communicate and consult internally and externally as appropriate.*

5.2.2 Risk assessment timing and scope

- 5.2.2.1 The organization shall establish procedures to ensure the approach to infection risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive.

Notes:

The following should trigger either a new infection risk assessment or review of an existing one:

- a. Commencement of new work (e.g. introduction of new medical services);*
- b. New construction / modifications to facilities, medical equipment or its operation;*
- c. Introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-staff personnel);*
- d. Significant alterations to SOPs or working practices (e.g. surgical treatment procedures, disinfection / waste management methodologies, PPE provision);*
- e. When unexpected events that may have relevance for the management of infection risks are observed (e.g. emergence of infectious disease with relevance to the hospital);*
- f. When actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major accident exposure);*
- g. When considering emergency response and contingency planning requirements;*
- h. As part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency);*
- i. Infection risk assessments should be conducted when particular situations determine the need for specific, clinical infection risk assessment for individual patients and/or patient pathways, including but not limited to:*
 - i. Patient pathway for high-risk patient categories (e.g. hip-surgery, multi-organ failure);*
 - ii. Patients with symptoms consistent with those of infectious disease;*
 - iii. Identifying patients with high risk for e.g. multi drug resistance.*

5.2.3 Hazard identification

- 5.2.3.1 The organization shall establish procedures to ensure hazards associated with infection risk are identified and documented.

Notes:

The first stage in the risk management process is to identify all hazards that are relevant for infection risk. It is useful to involve the whole work team in this process and to use inputs from organizational experts on infection risk, safety and risk management.

Individuals who may be included in conducting / reviewing infection risk assessments could include:

- a. Hospital management;*
- b. Physicians;*
- c. Nursing;*
- d. Infection control specialists (e.g. infection control officer);*
- e. Facilities and maintenance;*
- f. Transport;*
- g. Securing;*
- h. Cleaning, disinfection and sterilization;*
- i. Equipment suppliers;*
- j. Security;*
- k. Other specialist suppliers or contractors (e.g. laundry, medical waste).*

There are many defined methodologies and approaches available for conducting hazard identification, risk assessment and control and the approach taken will vary depending upon the nature of the situation and the level of detail required.

A hazard may be a physical situation (e.g. use of a piece of equipment with sharp edges, a blade or needle), an activity (e.g. intubation of a patient) or a material (e.g. a patient sample, contaminated linen). The essence of a hazard is that it has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be.

Infection hazards should be identified and assessed in relation to their potential harm to patients, or other parties associated with the work of the hospital (e.g. staff, contractors, visitors).

A hazard identification exercise can use information including but not limited to:

- a. Group experience and knowledge;*
- b. External or specialized expertise not found in the hospital;*
- c. Results of previous infection risk assessments;*
- d. Surveys of previous accidents / incidents;*
- e. Surveillance data;*
- f. Information on hazardous organisms;*
- g. Epidemiological data;*
- h. Guidelines and codes of practice;*
- i. Facility drawings;*
- j. SOPs, manuals, etc.;*
- k. Process maps.*

Defined methodologies and approaches are available for conducting hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with the organization and associated activities. Hazard identification should be appropriate in nature, structure and recorded to a level whereby others can review the process.

5.2.4 Risk assessment

- 5.2.4.1 The organization shall establish procedures to ensure that suitable methodologies for assessing and recording infection risks are identified, implemented and maintained.

Notes:

The infection risk assessment should categorize risks to identify those which need to be eliminated or controlled.

Descriptions of likelihood and consequence, together with the acceptability of risk levels should be defined and used in the assessment. Such a classification can be achieved for example through the use of a risk matrix identifying likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be relevant and appropriate.

Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. After definition and implementation of control measures the risks should be reviewed to decide if the remaining risk is acceptable or whether additional controls need to be identified and implemented.

5.2.5 Risk management

- 5.2.5.1 The organization shall establish procedures to ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.

Notes:

The risk management approach should include a control plan to include:

- a. Who is responsible and accountable for implementation of the plan;*
- b. What resources are to be utilized (e.g. people, budget);*
- c. Timetable for implementation;*
- d. Details of the mechanism and frequency of review of compliance with the plan.*

Risk management strategies should include the hierarchies of control. The hierarchy of control is a sequence of options which offer a number of ways to approach the hazard control process:

- a. Eliminate the hazard;*
- b. Substitute the hazard with a lesser risk;*
- c. Isolate the hazard;*
- d. Use engineering controls;*
- e. Use administrative controls;*
- f. Use PPE.*

5.3 Microbial Surveillance

5.3.1 Infection surveillance program

5.3.1.1 The organization shall establish and maintain procedures to ensure measures required for an effective infection surveillance program are identified and implemented.

Notes:

Where appropriate, surveillance methods, indicators and case definitions may be agreed upon at a national or international level. However, information on community or regional trends in the incidence and prevalence of epidemiologically-important micro-organisms that may impact transmission of micro-organisms within the healthcare facility should be periodically reviewed and included in decisions on appropriate surveillance regimes (e.g. influenza, RSV, pertussis, invasive group A streptococcal disease, MRSA, VRE).

The objectives of the surveillance program should include:

- a. Improving awareness of clinical personnel and other healthcare workers (including administrators) about infection risk and antimicrobial resistance, in order to enhance understanding and appreciation of the need for preventive action;*
- b. Monitoring trends relating to the incidence and distribution of HAI, their prevalence and, where possible, risk-adjusted incidence for intra- and inter-organizational comparisons;*
- c. Identifying the need for new or intensified prevention programs, and evaluating the impact of prevention measures;*
- d. Use of appropriate standardized approaches and methodologies, including but not limited to:
 - i. Active surveillance (prevalence and incidence studies);*
 - ii. Targeted surveillance (site-, unit-, priority-oriented);*
 - iii. Risk-adjusted rates for comparisons.**
- e. Identifying possible areas for improvement in patient care, and need for further epidemiological studies.*

When planning and conducting surveillance activities, the organization should consider issues including but not limited to:

- a. Patients, personnel and units to be monitored;*
- b. Type of infections and relevant information to be collected for each case;*
- c. Frequency and duration of monitoring;*
- d. Methods for data analysis, feedback and dissemination;*
- e. Sources of data (e.g. ward activity (patients), laboratory tests);*
- f. Procedures to ensure confidentiality and anonymity.*

While surveillance is focused in high-risk sectors, some surveillance activity should occur for the rest of the organization. This may be most efficiently performed on a rotating basis (laboratory-based or repeated prevalence studies).

Data collection requires multiple sources of information as no method, by itself, is sensitive enough to ensure data quality and should be validated at a pre-determined frequency (e.g. annually).

5.3.1.2 The organization shall establish and maintain procedures to ensure measures required for an effective environmental surveillance program are identified and implemented.

Notes:

Environmental surveillance would normally be restricted to occasions relating to a suspected or confirmed outbreak, or as part of preventive strategies during construction.

When considering environmental surveillance, the organization should consider issues including but not limited to the need for:

- a. Water sampling to detect waterborne diseases (e.g. bacteria in hemodialysis system, bacteria in the plumbing system);*
- b. Air sampling to detect airborne pathogens (e.g. air sampling to evaluate microbial contamination of high-risk areas such as operating rooms / theatres);*
- c. Environmental surface sampling of concerned pathogen (e.g. VRE, C. difficile).*

5.4 Antimicrobial Use and Surveillance

5.4.1 Program

5.4.1.1 The organization shall establish and maintain program to ensure measures required for the proactive minimization and appropriate selection of antimicrobials to ensure they are effectively identified, specified, dispensed and monitored with regard to infection risk and antimicrobial resistance.

Notes:

The goal of this program is to prevent the emergence, transmission, and persistence of antimicrobial resistant microorganisms.

When planning and conducting activities, the organization should consider issues including but not limited to:

- a. Establishing an antimicrobial policy;*
- b. Establishing prescribing procedures;*
- c. Ensuring educational programs;*
- d. Monitoring of appropriate usage;*
- e. Conducting surveillance of antibiotic resistance;*
- f. Identifying and adopting up-to-date antimicrobial guidelines, including the prevention and control of MDRO.*

All antibiotic use should be justifiable on the basis of the clinical diagnosis and known or expected infecting microorganisms. Appropriate specimens for bacteriological examination should be obtained before initiating antibiotic treatment.

Antimicrobial use should be monitored and reported, including the amount of different antimicrobials used during a given period and trends in antimicrobial use over time. Use in specific patient areas such as the intensive care units or hematology / oncology units should also be monitored.

When planning and conducting antibiotic selection, the organization should consider issues including but not limited to:

- a. Nature of the disease and that of the pathogenic agent(s);*
- b. Sensitivity pattern and patient tolerance;*
- c. Aiming for use of as narrow a spectrum as possible;*
- d. Adopting appropriate classification categories (e.g. unrestricted, restricted or reserved or excluded).*

5.4.1.2 The organization shall establish an antimicrobial use committee and define it's role and functions.

Notes:

This may be a function of or a sub-committee for the infection control committee, medication committee or similar, or it may be a standalone committee.

When planning and conducting activities, the organization should consider activities of the committee including but not limited to:

- a. Recommending antibiotics for the formulary;*
- b. Reviewing and approving practices;*
- c. Auditing antibiotic use;*
- d. Overseeing educational programs;*
- e. Establishing prescribing policies.*

Audits should be undertaken under the auspices of the Antimicrobial Use Committee. Antimicrobial use should be audited based on changes observed in use, resistance of organisms, or concerns about poor patient outcomes. Physicians who are caring for patients should also participate in planning the audit and analysis of data.

5.4.2 Microbiology laboratory

5.4.2.1 The organization shall identify and have access to appropriate microbiological laboratories.

Notes:

When selecting an appropriate laboratory, the organization should consider issues including but not limited to:

- a. The quality of laboratory techniques are standardized and assured in order to obtain valid data for clinical decisions and selection of appropriate antimicrobials;*
- b. Standardized procedures are established for antimicrobial testing;*
- c. Appropriate microbiological data requirements have been defined and are reported in a timely manner;*
- d. Monitor and report trends in prevalence of bacterial resistance to antimicrobial agents;*
- e. Participate in activities of the Antimicrobial Use Committee.*

Laboratory reporting should include trends in the incidence of target multidrug-resistant organisms (MDRO) in the healthcare facility over time, monitored using appropriate statistical methods to determine whether or not rates are decreasing or additional interventions may be required.

5.5 Emergency Response and Contingency Planning

5.5.1 Identification of emergency scenarios

5.5.1.1 The organization shall establish and maintain procedures to define, record and analyze credible and foreseeable emergency scenarios relevant to infection risk.

Notes:

In order that emergency planning can take place, it is necessary to consider all credible emergency scenarios. It is unlikely that all potential scenarios will be credible; however, all reasonable threats should be considered and recorded and, where appropriate, together with the rationale as to why issues were dismissed.

Scenarios considered may include:

- a. Infected / potentially infected worker or other contact (e.g. family member, cleaner, contractor, responder, community member);*
- b. Outbreak among patients, personnel or community, including epidemics and pandemics;*
- c. Emerging disease in the community;*
- d. Potential loss of biological agents or toxins through theft or any other reason;*
- e. Failure of disinfection / sterilization regime;*
- f. Physical healthcare facility and equipment failure, including control system failure;*
- g. Utility failure including electricity, gas, steam and water supplies;*
- h. Environmental release of infected / potentially infected materials;*
- i. Impact of fire, flood, breach of security, explosion or natural disaster (e.g. earthquake, extreme weather conditions, disease pandemic);*
- j. Act of bioterrorism or deliberate release of biological agents;*
- k. Intense media attention relating to infection risk issue.*

5.5.2 Emergency response and planning

5.5.2.1 The organization shall establish and maintain procedures to identify the potential for incidents and emergency situations involving infection risk in order to prevent their occurrence, respond to emergency situations and limit their impact.

Notes:

Local, regional and national planning among other facilities of similar nature for disaster management is encouraged.

It is recommended that emergency planning cover all aspects of infection risk and include general safety, security and medical issues.

5.5.3 Emergency plans

5.5.3.1 The organization shall ensure that the infection risk control measures in place are reasonable and proportionate to the scale and nature of the emergency.

Notes:

The plans should address as a minimum:

- a. The identification of those responsible for devising, implementing and testing the control measures specified;*
- b. The need to respond during out-of-hours emergencies as well as those that occur during normal working hours;*
- c. Provision for periods of reduced personnel availability (e.g. during weekends and holiday periods);*
- d. The need for emergency access / exit, including the ability to override access controls as appropriate;*
- e. Provision for healthcare workers and first responders and their families (e.g. prophylaxis, post-exposure treatment, isolation requirements, vaccination).*

- 5.5.3.2 Emergency plans shall be effectively established with and communicated to all personnel and relevant third parties, and tested, with the intention that everyone is aware of their obligations.

Notes:

In the event of an emergency situation there may be a requirement to involve parties external to the organization. The organization may choose to sign memoranda of understanding or agreements with key local responders. It may also be necessary to inform and educate such parties as to their role and any risk exposures they may face and ensure that their actions will not unnecessarily increase the risk associated with the emergency (e.g. access to restricted areas). Contact information should be documented and made available to personnel responsible for coordinating the emergency response activity.

Based upon the credible scenarios identified, the organization should identify external agencies to establish their role in responding to a given situation, including but not limited to:

- a. Police and security services;*
- b. Fire services;*
- c. Transport providers and couriers;*
- d. Laboratory services;*
- e. Local and national government officials (e.g. law enforcement, environmental services);*
- f. Staff and staff associations;*
- g. Family and other relevant community members (e.g. civil and religious groups);*
- h. Relevant voluntary services (e.g. Red Cross).*

5.5.4 Emergency exercises and simulations

- 5.5.4.1 The organization shall ensure that structured and realistic emergency exercises and simulations are conducted at regular intervals, to test plans, prepare personnel, and learn from any good practices or deficiencies identified.

Notes:

Exercises and simulations should be conducted in order to provide an assurance that plans are effective and to learn from any lessons that arise.

Exercises should be planned and every effort made to ensure they are realistic representations of the events they are designed to simulate. However, such activities should also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of the exercise should be documented and reviewed for lessons learned, and feedback provided to appropriate personnel on performance. Any actions arising should be recorded, allocated to named individuals and measures set in place to ensure they are closed out effectively.

5.5.5 Contingency plans

- 5.5.5.1 Adequate contingency measures shall be in place to ensure the patient care can be provided while infection risks are minimized.

Notes:

In the event of an emergency or unforeseen event, there may be disruption to normal operating conditions. Such eventualities should be considered proactively and contingency plans set in place. Activities should address the need for adequate redundancy, replacement and other measures. Emergency procedures established should ensure that there is adequate contingency planning to ensure adequate provision for ongoing community health needs, as well as support for the emergency situation.

When planning and conducting contingency measures, the organization should consider issues including but not limited to:

- a. The need for and availability of alternative facilities or personnel;*

- b. Backup systems (e.g. power, water, gas, HVAC);*
- c. Alternative means of decontaminating or sterilizing materials;*
- d. Back up of supplies such as clean / sterile medical equipment, PPE, detergents and clean linen;*
- e. Ability to restrict access to areas where necessary.*

5.6 Accident and Incident Investigation

5.6.1 Accident / incident investigation

5.6.1.1 The organization shall establish and maintain procedures to define, record, analyze and learn from accidents and incidents involving infection risk. The accident / incident investigation system shall include measures to identify, categorize and formally investigate major accidents or incidents with major accident potential.

Notes:

Procedures should be set in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel, and may include actual accidents resulting in harm, as well as events of actual or potential exposure (often referred to as near misses).

Accidents and incidents provide an indication that the systems designed to manage infection risk may have failed, and it is essential that lessons are learned and improvements are made where possible.

Accidents / incidents may include, but are not limited to:

- a. Needle sticks and injection injuries;*
- b. Work-related infections;*
- c. Failure to apply required precautions when handling known infected patients / materials;*
- d. Breakdown in sterilization procedures;*
- e. Failure to maintain clean / dirty separation;*
- f. Inappropriate use of PPE;*
- g. No observance of hand washing requirements.*

The accident / incident investigation procedures should include:

- a. Identifying those responsible for maintaining the accident / incident reporting system;*
- b. Defining what constitutes an accident / incident, and what triggers recording and reporting;*
- c. Specifying required documentation to support the system;*
- d. Identifying the reports that will be generated, their frequency and distribution;*
- e. Ensuring analysis of trends;*
- f. Identifying root causes using individuals trained in investigation techniques;*
- g. Providing feedback at regular intervals and action tracking mechanisms to ensure that lessons learned result in action to avoid the repeat of such events and / or minimize their potential impact;*
- h. Guidance as to when information should be reported to relevant authorities (including police and security services).*

In the event that a major accident / or incident with major accident potential, personnel trained in investigation and root cause analysis should be employed as part of the investigation team.

An outbreak is defined as an unusual or unexpected increase of cases of a known HAI or the emergence of cases of a new infection. Systematic planning and implementation of an outbreak investigation may include but not be limited to:

- a. Planning the investigation;*
- b. Case definition;*
- c. Describing the outbreak;*
- d. Control measures and follow-up;*
- e. Communication.*

5.7 Personnel and Competency

5.7.1 Recruitment

5.7.1.1 The organization shall establish and maintain procedures to ensure that qualifications, experience and aptitudes are considered as part of the recruitment process for all relevant activities with regard to infection risk.

Notes:

When planning and conducting recruitment activities, the organization should consider issues including but not limited to:

- a. Subjecting all potential candidates to a formal selection process, including relevant background checks based on risk (e.g. employment references, health review, security checks);*
- b. Implementing appropriate controls if existing personnel are transferred to areas where there may be an increased risk profile;*
- c. Conducting an assessment of the need for the above controls for non-staff personnel (e.g. contractors, students), and measures implemented to ensure they are applied where necessary.*

Healthcare personnel may include but are not limited to physicians, nurses, technicians, therapists, pharmacists, nursing assistants, laboratory personnel, autopsy personnel, emergency medical service personnel, dental personnel, students and trainees, contractual personnel not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to infectious agents (e.g. volunteer, dietary, housekeeping, maintenance, and clerical personnel).

5.7.2 Training

5.7.2.1 The organization shall establish and maintain procedures to ensure that a training and educational program is in place for infection risk. The program shall address a definition of infection risk training needs, provision of required training, determination of effectiveness of training, provision of refresher training, and restrictions on personnel to ensure they do not perform tasks for which they are not trained.

Notes:

All personnel should have general training and awareness on infection risk, together with task-specific training relevant to their role and specific activities. The program should ensure that all non-staff positions (including visiting physicians and personnel employed by outside agencies) meet the same requirements as staff, either through programs offered by the agencies or by participation in the healthcare organizational program designed for full-time personnel.

5.7.3 Competence

5.7.3.1 The organization shall establish and maintain procedures to ensure that a competency program is in place for infection risk, based on appropriate education, training and experience. The program shall address definitions of infection risk competency needs, demonstration or evidence of ability to perform tasks under supervision and unsupervised in the actual work situation, and restrictions on personnel to ensure they do not perform tasks for which they are not competent.

Notes:

Competence is defined in relation to appropriate education, training and / or experience, together with a demonstrable ability to perform the task in a safe / secure manner. No healthcare workers should be exempt from demonstrating competence irrespective of rank, experience or background.

5.7.4 Continuity and succession planning

- 5.7.4.1 The organization shall establish and maintain procedures to ensure that that adequate back-up and contingency measures are in place to address the need for continuity and succession planning with regard to infection risk.

Notes:

The organization should identify roles and individuals to ensure that the integrity of the organization's processes is not compromised through short or long-term absence.

Such measures may include succession planning for personnel (including contractors) to ensure that no one individual holds critical knowledge regarding the safe and secure operation of the healthcare facility with respect to infection risk, that has not been made available to others in the event of their departure or unavailability.

5.7.5 Exclusion

- 5.7.5.1 The organization shall establish and maintain procedures to ensure that measures are set in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the organization and / or facility where deemed necessary through risk assessment.

Notes:

Such procedures may address:

- a. Removal of access to the healthcare facility (e.g. removal of passes, changes of keys, access codes, other security devices);*
- b. Immediate physical removal of personnel if deemed necessary.*

5.8 Human Factors

5.8.1 Human Factors

5.8.1.1 The organization shall establish and maintain procedures to ensure that a program is established to address risk associated with human behavior with regard to the management of how workers interact with the healthcare organization, its equipment, patients and for all relevant activities with regard to infection risk.

Notes:

Safety culture (or safety climate) refers to a work environment where a shared commitment to safety on the part of management and the workforce is understood and followed. Commitment from top and senior management is especially important in order to incorporate the desired safety culture across the organization.

A safety culture may be created through:

- a. The actions management takes to improve patient and worker safety;*
- b. Worker participation in safety planning;*
- c. The availability of appropriate protective equipment;*
- d. Influence of group norms regarding acceptable safety practices;*
- e. The organization's socialization process for new personnel.*

The organization should ensure that factors associated with behaviors, and the need for individual support and communication are managed responsibly, both to protect workers and patients from direct hazards and to ensure they can function optimally within the healthcare facility.

HAI can be caused by inappropriate behavior or human frailties, and a preventive and proactive approach to managing risk associated with the individual should be pursued, including the specific inclusion of such issues in risk assessments. The use of competent experts in assessing this area should be considered.

Measures should be set in place to address human factors issues in situation including but not limited to:

- a. Overcoming organizational hierarchies and power structures where these may have a detrimental impact on infection risk management;*
- b. Human reliability and behavioral safety, including adherence to infection control procedures (such as for e.g. hand hygiene);*
- c. Communication, consultation and feedback;*
- d. Conflict management and resolution;*
- e. Empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified;*
- f. Avoidance of "blame culture", including willingness to report accidents, incidents or unsafe conditions / behaviors, and protection of workers who do so;*
- g. Ergonomics, including equipment and work practice design to take account of individual needs;*
- h. Respecting individual privacy and dignity (patients, healthcare workers and other relevant parties).*

5.9 Occupational Health

5.9.1 Occupational health program

5.9.1.1 The organization shall establish and maintain procedures to ensure that a program is established to address occupational health of personnel with regard to infection risk.

Notes:

All personnel in healthcare setting may be at risk of acquiring infection through occupational exposure. The system should address the infection risk between all relevant parties, including but not limited to transmission between patients and healthcare personnel and vice versa. Thus, an occupational health program must be in place to prevent and manage infections in healthcare workers.

An occupational health program should include, but not be limited to:

- a. Reviewing personnel health at recruitment, including immunization history and previous exposures to communicable diseases (e.g. tuberculosis) and immune status;*
- b. Determining the need for vaccination, PPE provision and emergency measures that encompass isolation / testing in the event of exposure.*
- c. Ensuring vaccination and training in appropriate use of PPE, safe sharp-handling and other protective measures;*
- d. Monitoring health including the immune status of the individual as appropriate to work conditions.*

Information covered by the occupational health program should be treated in confidence. All individuals should have access to healthcare consultation either with a corporate or institutional occupational health healthcare facility or an independent healthcare provider, and be informed as to the nature of any treatments / vaccinations they may receive and the inherent risks and benefits of these treatments / vaccinations.

5.9.2 Occupational health surveillance program

5.9.2.1 The requirements of the health surveillance program shall be determined by a defined health hazard identification and risk assessment process addressing all relevant personnel.

Notes:

Personnel considered to have significant risk of exposure should be identified and their healthcare needs considered. Risk to non-staff personnel should be addressed as part of the system (e.g. visiting physicians, contractors).

Hazard identification and risk assessment process should be responsive to emerging needs.

5.9.3 Vaccination of personnel

5.9.3.1 The organization shall establish and maintain procedures to ensure a vaccination system is established, implemented and maintained for all relevant activities with regard to infection risk.

Notes:

The need for vaccination should be identified based on the worker health risk assessment and cover all groups and personnel identified as being potentially exposed to infectious agents. Measures should be taken to ensure that the vaccinations have been given, current certificates are valid and adequate records are maintained including the need for boosters. Contractors and other non-staff personnel should be required to provide evidence of vaccination or evidence of established immunity where appropriate.

The organization should monitor the efficacy and effectiveness of vaccinations, including measures to identify non-responders to vaccination, and a policy should be in place to address issues surrounding such individuals to ensure they are not placed at an unacceptable level of risk or pose such a risk to others on the basis of their immune status. Areas requiring vaccinations to enter should be posted.

The organization should ensure that the required or recommended vaccines are made available to the concerned personnel at no cost for the personnel.

Vaccination should be seen as a risk mitigation strategy and its use should in no way infer that other controls such as hand hygiene or use of PPE can be relaxed.

5.9.4 Management of job-related illnesses and exposures

5.9.4.1 The organization shall establish and maintain procedures for diagnosis and treatment of job-related illnesses and exposures and implementation of measures to prevent further transmission of infection are established, implemented and maintained for all relevant activities with regard to infection risk.

Notes:

All personnel should be encouraged to report any suspected or known exposures promptly.

Decisions on work restrictions should be based on the mode of transmission and epidemiology of the disease.

The term "exclude from duty" can be interpreted as exclusion from the healthcare facility and from healthcare activities outside the healthcare facility. Personnel who are excluded should avoid contact with susceptible persons both in the healthcare facility and in the community.

When planning and conducting exclusion policies, the organization should consider issues including but not limited to:

- a. How such policies may be enforced, taking into consideration prevailing regulations, workers' rights and need to maintain confidentiality and respect for the individual;*
- b. Measures to encourage personnel to report their illnesses or exposures and not to penalize them with loss of wages, benefits, or job status;*
- c. Controlling contractors and other non-staff staff who may need to be excluded from work.*

5.10 Healthcare Facility Requirements and Layout

5.10.1 Planning and design

5.10.1.1 The organization shall establish and maintain procedures to address planning, design and redesign of the healthcare facility with regard to infection risk. The organization shall ensure that new construction and physical healthcare facility modifications are carried out according to an approved plan.

Notes:

A formal design process means a structured and documented approach where the needs of the healthcare facility are determined through risk assessment. Engineering and operational solutions to be incorporated shall take into consideration the risk posed by the properties of materials that will be stored and handled in the healthcare facility and the nature of the services to be carried out.

The design should be fully documented, including a description of the tests and the standards of acceptance to assure performance. The process should be documented and transparent to provide an assurance that it has been comprehensive and thorough.

The design process should include the identification and review of relevant legislation and codes of practice (including building codes as well as those relating infection risks) and risk assessments. The requirements identified from these sources should be incorporated into the design plans. The design should be documented to provide an assurance that it has been comprehensive and thorough, but also to provide the basis for the design intent should this be required at a later date (e.g. during redesign or decommissioning). A description of the tests and the standards of acceptance to assure performance should also be incorporated.

When planning and conducting design activities, the organization should consider issues including but not limited to:

- a. Systematically identifying and incorporating all relevant legislative requirements;*
- b. Employing information from recognized standards, guidelines, industry good practices;*
- c. Incorporating information identified in healthcare facility-specific risk assessments;*
- d. Incorporating mandatory adherence agreements for infection control into construction contracts, with penalties for noncompliance and mechanisms to ensure timely correction of problems.*

The design process should identify a multidisciplinary team and include consultation with all relevant parties associated with the healthcare facility and its operation. Such individuals may include, but not be limited to:

- a. Medical personnel;*
- b. Nursing personnel;*
- c. Pharmacy personnel;*
- d. Radiology and imaging personnel;*
- e. Representatives from end users;*
- f. Patient representatives;*
- g. Infection control specialists, infection risk management committee;*
- h. Security personnel;*
- i. Designers (architects and engineers);*
- j. Constructors;*
- k. Maintenance engineers;*
- l. Materials and equipment suppliers;*
- m. Commissioning agents;*
- n. Certifiers;*
- o. Regulators;*
- p. First responders;*
- q. Other relevant parties identified in risk assessments.*

5.10.1.2 The organization shall establish and maintain procedures to ensure that the layout and design are suitable for all relevant activities with regard to infection risk.

Notes:

Planning should take into consideration the materials and construction measures that will be adopted and their suitability in minimizing infection risk, including but not limited to:

- a. *Ability to clean and disinfect, including:*
 - i. *Access to areas requiring cleaning (i.e. location as well as presence of smooth easily accessed surfaces);*
 - ii. *Ability to withstand disinfectants;*
 - iii. *Ability to withstand wear and maintain integrity.*
- b. *Absence of sharp edges or other hazards;*
- c. *Ability to repair if needed;*
- d. *Resistance to harboring, promoting survival or supporting growth of infectious agents.*

Planning should take into consideration the need for adequate layout in minimizing infection risk, including but not limited to:

- a. *Providing adequate floor space for beds, including inter-bed space to reduce risk of cross contamination / infection;*
- b. *Regulating traffic flow to minimize exposure of high-risk patients and facilitate patient transport;*
- c. *Ensuring adequate facilities for transmission-based containment and isolation.*

Adequate spacing between each bed in multi-bed rooms or open plan wards is recommended in order to reduce risk of cross contamination / infection occurring from direct or indirect contact or droplet transmission.

5.10.2 Heating, Ventilating and Air Conditioning (HVAC)

5.10.2.1 The organization shall establish and maintain procedures to ensure HVAC systems are adequately designed, constructed and maintained for all relevant activities with regard to infection risk.

Notes:

HVAC systems should be designed in accordance with recognized guidelines and standards, and monitored, maintained and validated at defined intervals in accordance with manufacturer's recommendations.

Specific guidelines and requirements may exist for high risk environments, including isolation rooms where additional controls may be applied including double door entry, directional airflow, increased air changes per hour and HEPA filtration. A risk assessment should be carried out to determine the appropriate number of airborne infection isolation (AII) rooms and / or protective environment (PE) rooms to serve the patient population

The nature of the infectious agents that may be present and the associated routes of transmission should be considered in the design HVAC systems. The intended direction of the airflow in an isolation room and potential interruptions need to be understood, together with an understanding of the room layout in relation to activities being performed there (e.g. clinical, cleaning, visitors). Such factors should be taken into consideration when determining patient position, entry to the room and movement of people and equipment within the room in relation to air flows.

5.10.3 Water

5.10.3.1 The organization shall establish and maintain procedures to ensure water supplies and waste water handling systems are adequately designed, constructed and maintained for all relevant activities with regard to infection risk.

Notes:

Water supply systems should be designed in accordance with recognized guidelines and standards, and monitored, maintained and validated at defined intervals in accordance with manufacturer's recommendations.

Specific guidelines and requirements may exist for certain functions and / or environments, including but not limited to:

- a. Water used for catering (e.g. cooking, food preparation, dish washing);*
- b. Drinking, ice machines and ice;*
- c. Hand washing;*
- d. Patient care and hydrotherapy;*
- e. Miscellaneous medical equipment connected to water systems;*
- f. Cleaning and disinfection of medical equipment;*
- g. Sterilization;*
- h. Dialysis water quality and dialysate.*

Drains and other waste water handling systems should be subject a risk assessment to ensure they cannot become a source of infection for patients and workers, including maintenance personnel who may need to make interventions on systems.

5.10.4 Commissioning and decommissioning

5.10.4.1 The organization shall establish and maintain procedures to ensure a formal commissioning and decommissioning process is established and maintained for all relevant activities with regard to infection risk.

Notes:

Commissioning should ensure that the healthcare facility is constructed and performs as intended. The commissioning process should start at the design phase at the first stage of scope of services definition to assure that the expectations for the building are achievable. The commissioning process should provide the benchmark for acceptable healthcare facility operation and the description of the program to be put in place to maintain that level of performance.

A commissioning plan should be developed in detail in parallel with the physical concept to assure that the expectations for the building are measurable. The commissioning plan should clearly identify, with examples, all steps from beginning to end including conditions of acceptance of each step, as a pre-requisite of proceeding to the next. The commissioning plan should identify all steps required before operation is commenced initially or resumed after temporary shut down.

The decommissioning process should identify the decontamination procedures that have to be in place for temporary or final shut down of the healthcare facility. The decommissioning program should not only describe the procedures to be undertaken, but also, the standards of acceptance when those procedures are performed. This may be documented through clearance certificates and permits to work, which identify when and under what conditions the decommissioned healthcare facility can be re-entered.

5.11 Healthcare Environment

5.11.1 General

5.11.1.1 The organization shall establish and maintain procedures to ensure inventory needs (e.g. beds, furniture, linen, clothing, food, waste and animal management).

5.11.2 Inventory

The organization shall establish and maintain procedures to ensure the selection, purchasing and maintenance of inventory, with regard to infection risk. The system shall apply to all relevant, activities and personnel.

Notes:

Inventory in a healthcare facility includes but is not limited to

- a. Beds;
- b. Furniture (e.g. sofas, chairs, tables, nightstands);
- c. Lights and lamps;
- d. Carpets.

Personnel who may be required to maintain the inventory may include, but are not limited to:

- a. Clinical personnel;
- b. Engineering and maintenance;
- c. Catering services;
- d. Cleaning;
- e. Transport.

5.11.3 Linen and clothing management

5.11.3.1 The organization shall establish program for the selection, collection, separation / segregation, transportation and storage of clean and contaminated / potentially contaminated linen and clothing, to ensure it can be adequately cleaned, disinfected, decontaminated and sterilized.

Notes:

Linen and laundry in a healthcare facility includes but is not limited to:

- a. Bed sheets, blankets and pillow cases;
- b. Mattresses and pillows;
- c. Specialized bedding (e.g. air fluidized bed);
- d. Towels and face cloths / flannels;
- e. Patient personal clothing and apparel;
- f. Staff uniforms, scrub suits;
- g. Surgical drapes, gowns, caps and aprons;
- h. Curtains and blinds (including windows and surrounding beds).

A program for laundry and linens should include but not be limited to:

- a. Quality requirements for fabrics, textiles, and clothing according to purpose of use;
- b. Requirements on cleanliness regarding microbial burden values;
- c. Routines for handling of contaminated laundry, the laundry process, special laundry situations, mattresses and beddings, textiles, beddings, uniforms etc.;
- d. Requirements regarding safe packaging, transport, and storage of clean textiles and linens.

5.11.4 Staff clothing

- 5.11.4.1 The organization shall establish effective, risk-based procedures for control of staff clothing to ensure it remains fit-for-purpose with regard to infection risk. Procedures shall address selection, use and restrictions on clothing, including use in public areas and home laundering.

Notes:

The organization should ensure procedures are in place to address issues including but not limited to:

- a. Restricting use of clothing outside patient areas, public areas within the healthcare facility and outside the premises;*
- b. Restricting home laundering for unsuitable items and situations;*
- c. Restricting items that can be worn inside and outside of areas designated as requiring specific precautions with regard to infection control (e.g. isolation rooms).*

5.11.5 Food and beverage services

- 5.11.5.1 The organization shall establish risk-based procedures for the selection, preparation, storage, transportation and delivery of food and beverage, to prevent foodborne infections and / or outbreaks.

Note:

The organization should ensure procedures are effectively implemented to ensure food is selected, prepared, delivered and waste removed in a manner which minimizes the risk of foodborne illness to patients, staff and others who may be affected.

When planning and conducting food and catering activities, the organization should consider issues including but not limited to:

- a. Ensuring that adequate methods are used to assess and manage food safety issues, especially when highly susceptible patients are being managed (e.g. Hazard Analysis and Critical Control Points (HACCP) approach);*
- b. Ensuring food waste is effectively collected, transported and subject to adequate disposal;*
- c. Ensuring catering workers do not attend work if unwell or suspect they may be a source of infection themselves;*
- d. Considering risk from movements of food within the healthcare facility, including but not limited to:*
 - i. Minimization of journeys (e.g. appropriateness of 'on-demand as opposed to communal delivery of meals) and identifying appropriate transport routes;*
 - ii. Precautions required when catering staff deliver food to patient areas;*
 - iii. Potential need to decontaminate catering equipment which may have been exposed to contaminated / potentially contaminated areas.*

5.11.6 Animals in healthcare facilities

- 5.11.6.1 The organization shall establish risk-based procedures to control the use and access of animals in healthcare activities with regard to infection risk.

Notes:

Procedures should be developed to control infection risk associated with the potential presence of animals in healthcare facilities. This may apply to service-animals (e.g. guide dogs) or animals used for therapy, as well as animals receiving treatment in human healthcare facilities.

When planning and conducting activities related to presence of animals in the healthcare facility, the organization should consider issues including but not limited to:

- a. Ensuring requirements regarding vaccination, general health, cleanliness and veterinarian control are addressed;*
- b. Ensuring additional education and training needs for personnel handling animals in activities or therapy are met;*
- c. Adopting precautions to mitigate allergic reactions.*

5.12 Equipment and Maintenance

5.12.1 Selection of medical devices and equipment

5.12.1.1 The organization shall establish procedures for the selection of equipment, medical devices and other items which may require to be cleaned, decontaminated, disinfected and /or sterilized, to ensure this can be carried out effectively.

Note:

When planning the purchase of medical devices, equipment (e.g. blood-pressure cuff, rollators, crutches, wheelchairs) or other items which may become contaminated, a formal specification and approval process should be adopted to ensure items will be fit-for-purpose with regard to infection risk. Medical devices and equipment should be classified in terms of infection risk (e.g. as critical, semi-critical or non-critical)

When planning and conducting selection of medical devices and equipment, the organization should consider issues including but not limited to:

- a. Ensuring that validated methods are available for cleaning, disinfection and sterilization of sensitive equipment, especially if not suitable for autoclaving (e.g. sensitive medical devices);*
- b. Engaging relevant internal and external parties (e.g. in-house decontamination, disinfection and sterilization specialists, suppliers) to ensure processes support selection of these items (e.g. appropriateness of available means of disinfection / sterilization);*
- c. Ensuring process flow / timing, space, storage and transport requirements can be met with respect to need for adequate and validated cleaning disinfection, decontamination and / or sterilization;*
- d. Ensuring risk of transferring infection via medical instruments, equipment and other items is considered as part of assessment for selection, processing / reprocessing.*

5.12.2 Maintenance

5.12.2.1 The organization shall establish and maintain procedures to ensure that maintenance needs have been effectively identified, specified and implemented in terms of all relevant materials and activities with regard to infection risk.

Notes:

All medical devices and equipment used should be specified to ensure they can perform in line with predetermined criteria. The need for an appropriate and effective maintenance planning with regard to infection risk should be addressed as part of that specification process.

Medical devices and equipment that may need calibration and / or certification should be identified and this may include equipment for cleaning, disinfection and sterilization, medical devices and other equipment.

When planning and conducting maintenance activities, the organization should consider issues including but not limited to:

- a. Identifying equipment in accordance with identified work needs, which can be demonstrated as fit for purpose;*
- b. Controlling movement of equipment to and from the healthcare facility, including decontamination requirements.*

When planning and conducting maintenance activities, the organization should consider issues including but not limited to:

- a. Controlling purchase / acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel;*
- b. Ensuring maintenance activities are performed by competent individuals, and that risks associated with the work have been subjected to risk assessment;*

- c. *Identifying and recording maintenance requirements at time of purchase / acquisition of medical devices and equipment;*
- d. *Creating and maintaining a maintenance register for all applicable equipment;*
- e. *Establishing procedures for cleaning and decontamination of maintenance equipment and tools to minimize infection risk (e.g. disinfectors, autoclaves);*
- f. *Identifying and conducting planned maintenance activities at an appropriate frequency;*
- g. *Ensuring adequate provision for unplanned (breakdown) maintenance to ensure integrity of the healthcare facility is maintained at all times;*
- h. *Determining and monitoring predictive maintenance requirements and associated indicators and monitors;*
- i. *Ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement;*

5.12.3 Calibration, certification and validation

5.12.3.1 The organization shall establish and maintain procedures to ensure that medical devices and equipment that may impact on infection control are calibrated, certified and validated in a manner consistent with the intent and requirements of the infection risk management program.

Notes:

When planning and conducting calibration activities, the organization should consider issues including but not limited to:

- a. *Identifying and recording calibration requirements at time of purchase / acquisition;*
- b. *Identifying the standards / tests that will be used to ensure the equipment is correctly calibrated;*
- c. *Creating a documented and up-to-date calibration register for all applicable equipment;*
- d. *Ensuring calibration is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment.*

When planning and conducting certification activities, the organization should consider issues including but not limited to:

- a. *Identifying and recording certification requirements at time of purchase / acquisition of equipment, including relevant and current standards against which to certify;*
- b. *Ensuring competent and independent certifiers are used for the certification process;*
- c. *Ensuring certification is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment.*

When planning and conducting validation activities, the organization should consider issues including but not limited to:

- a. *Identifying and recording validation requirements at time of purchase/acquisition;*
- b. *Identifying the standards / tests that will be used to ensure the equipment is correctly validated;*
- c. *Creating a documented and up-to-date validation register for all applicable equipment;*
- d. *Ensuring validation is scheduled and conducted in the line with manufacturer's requirements and / or other specified intervals as identified by risk assessment;*
- e. *Ensuring competent and independent validation companies are used for the validation process.*

5.13 Cleaning, disinfection, decontamination and sterilization

5.13.1 Cleaning, disinfection decontamination and sterilization

- 5.13.1.1 The organization shall establish and maintain procedures to ensure measures required for cleaning, decontamination, disinfection and sterilization are effectively identified, specified, implemented and monitored for all relevant medical devices, general equipment, materials and activities with regard to infection risk. Procedures shall proactively address the need to minimize quantities of potentially contaminated materials and waste.

Notes:

When planning and conducting cleaning, decontamination, disinfection and sterilization activities, the organization should consider issues including but not limited to:

- a. *Risk-classification of all relevant medical devices, general equipment, materials and activities based on purpose for use (e.g. non-critical, semi-critical, critical)*
- b. *Potential health and safety hazards associated with processes adopted (e.g. exposure to harmful chemicals, excessive heat / pressure);*
- c. *Ensuring all disinfectants contain sufficient active compound for their intended use under a given circumstance (e.g. when organic matter may be present, loss of active ingredient over time);*
- d. *Ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of waste and potentially infectious material inside and outside the healthcare facility.*

5.13.2 Household and cleaning

- 5.13.2.1 The organization shall establish and maintain a program for household and cleaning to ensure that all areas are cleaned and maintained according to the intended use and the risk of contamination and ability to spread.

Notes:

Strategies for cleaning and disinfecting surfaces in patient-care areas should be based on risk assessment and as a minimum take into account:

- a. *Potential for direct patient contact;*
- b. *Degree and frequency of hand contact, and*
- c. *Potential contamination of the surface with body substances or environmental sources of microorganisms (e.g., soil, dust, and water)*

Arrangements for household and cleaning should include, but not be limited to:

- a. *Clear definition of specific roles and responsibilities for cleaning;*
- b. *Clear, agreed and available cleaning procedures including, but not limited to:*
 - i. *Effective arrangements for the appropriate cleaning of equipment that is used at the point of care (e.g. hoists, beds, commodes, rollators / wheeled walkers);*
 - ii. *Surfaces, contact points, floors and other surroundings;*
 - iii. *Specific needs based on route of transmission and alert microorganisms (e.g. isolation rooms);*
 - iv. *Handling and cleaning of cleaning equipment*
- c. *Sufficient resources dedicated to keeping the environment clean and fit for purpose;*
- d. *Consultation with Infection risk management advisor when internal or external contracts are being prepared;*
- e. *Procedures of how staff can request both urgently and routinely;*
- f. *Control measures for evaluation and monitoring of cleanliness / quality of cleaning.*

5.13.3 Validation

- 5.13.3.1 The organization shall effectively identify, collect, analyze and report performance criteria and associated data to demonstrate that the methods selected for cleaning,

decontamination, disinfection and sterilization are capable of achieving the required parameters in relation to cleaning, decontamination, disinfection and sterilization under the specific conditions used in the healthcare facility.

Notes:

Validation measures should consider issues including but not limited to:

- a. An ability to maintain adequate conditions throughout the cycle, including contact times;*
- b. Manufacturer's recommendations regarding materials used (agents used and materials to be subjected to treatment);*
- c. Ensuring methods are available for effective decontamination of mixed waste (e.g. infectious waste that have radioactive materials);*
- d. Material compatibility issues (e.g. interaction with stainless steel or rubber seal);*
- e. Implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and use of indicators).*

5.13.4 Storage and segregation

5.13.4.1 The organization shall establish effective procedures for the handling and storage of processed / reprocessed medical devices and other equipment to ensure they remain fit-for-purpose with regard to infection risk.

Notes:

Handling and storage of medical instruments and equipment is an essential component in ensuring the item maintains its level of disinfection or sterilization. Storage requirements should be subject to risk assessment to ensure a clean, dry environment is provided, with protection from any damage, including potential sources of contamination.

5.13.5 Waste management

5.13.5.1 The organization shall establish procedures to ensure that contaminated and potentially contaminated waste is identified, handled, recorded and stored effectively in order to ensure cross contamination of other areas or items does not occur.

Notes:

The organization should consider sources of waste including but not limited to:

- a. Clinical waste;*
- b. Medical equipment;*
- c. Needles, syringes and sharps;*
- d. Clothing and PPE;*
- e. Paper and plastic waste;*
- f. Waste water, including that from sinks and showers;*
- g. Air, filters and air handling systems;*
- h. Discarded equipment used in the healthcare facility.*

When transporting and storing waste, the organization should consider issues including but not limited to:

- a. Providing adequate facilities and procedures for the short and long term storage of waste;*
- b. Ensuring appropriate containers and other materials are used during storage and transportation (e.g. carts, bags, sharps containers);*
- c. Adequately segregating waste to minimize risk of cross contamination.*

5.14 Patient Care

5.14.1 The general patient pathway

5.14.1.1 The organization shall establish and maintain procedures to ensure that a system is established, implemented and maintained for all relevant patient care activities with regard to infection risk.

Notes:

Controls identified as appropriate should apply to all individuals who may come into contact with the patient or their environment, including but not limited to:

- a. Healthcare workers;*
- b. Contractors;*
- c. Visitors;*
- d. Other patients.*

The infection risk management decisions should be based on relevant data, including but not limited to:

- a. Infection risk assessments;*
- b. Institutional experience / epidemiology;*
- c. Trends in community and institutional and community acquired data;*
- d. Local, regional, and national epidemiology;*
- e. Information on emerging infectious disease threats.*

When planning and conducting patient care activities, the organization should consider areas including but not limited to:

- a. Diagnostics, treatment and care of emergency care patients;*
- b. Resuscitation;*
- c. Handling, use and administration of medication, blood and blood products;*
- d. Treatment of patients in respirator or comatose patients;*
- e. Treatment and care of patients with infectious disease or immunosuppressive patients;*
- f. Treatment of patients with dialysis;*
- g. Diagnostics, preparation, treatment and care of patients undergoing surgical and / or invasive procedures;*
- h. Care, handling, transport and communication of deceased persons and post mortem-related activities.*

5.14.1.2 Clinical risk assessments shall be used by the organization to identify patients and / or procedures that are associated with a high risk of infection and as such be subject to additional precautions beyond standard precautions.

Notes:

When planning and conducting patient care activities, the organization should consider high risk populations including but not limited to patients:

- a. Known or suspected to be infected with infectious agents;*
- b. Who are immunocompromised (e.g. radiotherapy);*
- c. With respiratory disorders;*
- d. With chronic conditions (e.g. diabetes, autoimmune diseases);*
- e. Undergoing novel therapies (e.g. new invasive procedures, bedside procedures, surgical methods and techniques gene therapy with the use of viral vectors);*
- f. Undergoing transplantations of biological products (e.g. blood, organs, xenotransplantations).*

When planning and conducting patient care activities, the organization should consider high risk procedures / activities including but not limited to:

- a. Surgical site infections (SSI);*
- b. Central line associated bloodstream infections (CLABSI);*

- c. *Catheter associated urinary tract infections (CAUTI);*
- d. *Ventilator-associated infections (VAPI);*
- e. *Infections caused by spore forming bacteria (e.g. C. difficile);*
- f. *Infections with multidrug-resistant pathogens (e.g. MRSA);*
- g. *Emerging infectious disease / novel pathogens (e.g. SARS);*
- h. *Agents of bioterrorism.*

5.14.1.3 The organization shall establish and maintain procedures to identify and control areas that represent high risk with regard to infection risk.

Notes:

When planning and conducting infection control activities, the organization should consider areas including but not limited to:

- a. *Intensive care units;*
- b. *Dialysis units;*
- c. *Burn units;*
- d. *Pediatrics;*
- e. *Ambulatory care;*
- f. *Non-acute healthcare settings;*
- g. *Long-term care;*
- h. *Home care.*

When planning and conducting infection control measures, the following categorizations should be considered:

- a. *Administrative (e.g. delay or avoidance of high risk interventions);*
- b. *Physical (e.g. isolation rooms with directional airflow);*
- c. *Clinical (e.g. prophylactic treatment);*
- d. *Behavioral / culture (e.g. observance of cough etiquette).*

5.14.2 Standard infection control procedures

5.14.2.1 The organization shall establish and maintain procedures relating to Standard Precautions for the control of HAI that apply to all patients / activities.

Notes:

The use of Standard Precautions is recommended by both WHO and US CDC. Standard Precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. They are based on the principle that all blood, body fluids, secretions, excretions, non-intact skin, and mucous membranes may contain transmissible infectious agents.

When planning and conducting Standard Precautions, the organization should consider practices including but not limited to:

- a. *Aseptic techniques and antisepsis;*
- b. *Hand-hygiene;*
- c. *Clothing and use of PPE;*
- d. *Safe injection practices;*
- e. *Cough-etiquette;*
- f. *Appropriate handling of patient care equipment and soiled linen;*
- g. *Environmental cleaning and spills management;*
- h. *Appropriate handling of waste;*
- i. *Patient placement;*
- j. *Patient transportation.*

5.14.3 Transmission-based precautions

5.14.3.1 The organization shall establish and maintain procedures relating to the identification and care of patients / activities that require additional Transmission-based Precautions beyond those offered by Standard Precautions.

Note:

When planning and conducting Transmission-based Precautions, the organization should consider practices including but not limited to:

- a. Contact precautions;*
- b. Droplet precautions;*
- c. Airborne precautions.*

Proactive approaches should be developed and implemented to ensure early detection and management of potentially infectious persons at initial points of patient encounter (e.g. triage areas, testing, use of PPE, isolation precautions) in outpatient settings and at the time of admission to healthcare facilities / long-term care facilities (LTCF).

When establishing procedures for Transmission-based Precautions the following should be considered, but not limited to:

- a. Categorizing / identification of patients at risk;*
- b. Routes of transmission;*
- c. Symptoms;*
- d. Patient placement;*
- e. Use of PPE;*
- f. Patient transport;*
- g. Handling of patient care equipment;*
- h. Environmental measures;*
- i. Visitors;*
- j. Education and training.*

5.15 Hand Hygiene

5.15.1 Hand hygiene program

5.15.1.1 The organization shall establish and maintain procedures to ensure hand hygiene measures are effectively identified, specified, implemented and monitored for all relevant parties and activities with regard to infection risk.

Notes:

As a minimum the system should address hand hygiene needs for but not limited to:

- a. Healthcare workers;*
- b. Contractors;*
- c. Visitors;*
- d. Patients.*

Hand hygiene is a key control area with regard to infection risk and the implementation and monitoring of an effective system is essential in managing infection risk effectively. The system in place should include but not be limited to:

- a. Identifying and ensuring compliance with appropriate product and performance standards for issues including but not limited to:
 - i. The length of natural nails;*
 - ii. The use of artificial nails and extenders;*
 - iii. Length of uniform sleeves;*
 - iv. Use of hand jewelry.**

5.15.1.2 The hand hygiene program shall address appropriate techniques to be used under different circumstances and how to perform them.

Note:

Procedures should specify when and how to conduct effective hand hygiene including but not limited to:

- a. Promoting awareness of risks regarding the types of patient-care activities that can result in hand contamination;*
- b. Hand washing with soap and water, including general use and for visibly soiled hands;*
- c. Use of soap and water alternatives (e.g. alcohol-based hand rubs);*
- d. Hand disinfection;*
- e. Surgical hand disinfection.*

Hand hygiene should be included in training and awareness materials for all relevant personnel.

5.15.1.3 A risk-based and systematic process shall be used in identifying the location and position of hand hygiene facilities and products.

Notes:

Procedures should specify but not limited to:

- a. Criteria for selection of hand hygiene agents and formulations, including potential effectiveness against specific infectious agents where known;*
- b. Specific validation criteria and testing requirements where appropriate;*
- c. Appropriate dispensers and solutions, including location, signage, ease of use, visibility, etc.*

5.15.2 Hand Care

5.15.2.1 The organization shall have a strategy for the prevention, identification and remediation of hand hygiene related issues, including required actions to manage personnel suffering skin damage / chronic skin complaints.

Notes:

Hand / skin care should be addressed as part of both the hand hygiene and occupational health programs.

Information on the potential for impact on skin (as well as eyes and other tissues possibly affected) should be included as part of product selection and specifications, including but not limited to:

- a. Ensuring potential health impacts are communicated to all personnel potentially affected, including control measures to be implemented and potential signs of damage;*
- b. Evaluating potential adverse interactions between hand hygiene products, skin care products and gloves;*
- c. Ensuring individuals with chronic skin complaints are subject to a specific health risk assessment to ensure products are suitable for their condition and their condition does not represent a threat to patients and others.*

5.15.2.2 The hand hygiene evaluation system shall include measures for monitoring of compliance to hand hygiene practices and providing feedback on performance.

Notes:

The organization should ensure that monitoring of compliance with the system for hand hygiene is implemented effectively across the organization, including inclusion in the audit and inspection program, accident / incident reporting mechanisms, etc.

Formal feedback should be provided on compliance levels and the need for adequate improvement measures and plans where targets are not being met.

5.16 Clothing and Personal Protective Equipment

5.16.1 Clothing and PPE

5.16.1.1 The organization shall establish and maintain procedures to ensure clothing and PPE needs are identified and specified for all relevant parties and activities with regard to infection risk, including availability, use / re-use, decontamination / sterilization, maintenance and disposal. The system shall apply to all relevant parties including staff, contractors, visitors and patients.

Notes:

In all areas where patient care is delivered, adequate supplies of clothing and PPE necessary for the consistent observance of Standard Precautions should be provided.

Clothing and PPE should be used in conjunction with, but never as a substitute for basic infection control measures such as hand hygiene, or other administrative and engineering controls.

Clothing and PPE should be used in accordance with established standards and manufacturer's specifications and made available by the employer at no cost to the employee. Where the user is not an employee, measures should be set in place to ensure that adequate clothing and PPE is available and used appropriately (e.g. visiting physicians, contractors).

Measures for consideration should include:

- a. Ensuring adequate information is used in selecting clothing and PPE (e.g. risk assessments, review and analysis of tasks, employee feedback);*
- b. Ensuring all personnel who have to use protective clothing and equipment are identified and supplied with correct fitting clothing and PPE, including but not limited to:*
 - i. Healthcare workers with direct / indirect patient contact;*
 - ii. Maintenance personnel;*
 - iii. Transportation staff;*
 - iv. Kitchen and catering staff;*
 - v. Personnel engaged in cleaning, decontamination, disinfection, laundry and waste handling;*
 - vi. Families, friends and other visitors (e.g. clergy);*
 - vii. Emergency services;*
 - viii. Security guards.*
- c. Explicitly addressing selection and use of clothing and PPE in SOPs, training and competency assessments;*
- d. Ensuring adequate procedures are in place for cleaning / laundering of clothing and PPE, including the need for validation where appropriate;*
- e. Defining and conducting an appropriate program to ensure that routine checks and maintenance of clothing and PPE are defined and carried out;*
- f. Defining and addressing the need for and provision of replacement and spare clothing and PPE;*
- g. Identifying and controlling the hazards associated with clothing and PPE itself (e.g. impaired dexterity or visibility);*
- h. Providing adequate clothing and PPE for use during both normal and emergency working conditions.*

5.17 Movement and Transport

5.17.1 Transportation of patients and materials

5.17.1.1 The organization shall establish and maintain procedures to ensure safe transportation of patients, specimens and other potentially contaminated materials with regard to infection risk.

Note:

The organization should adopt a risk-based approach to the identification of patients, equipment and areas where access controls may be required, taking into consideration the risk of presence of infectious materials, susceptible individuals or other pertinent factors.

The system should address transportation, movement and access needs within the facility, as well as sources of patients / materials as well as recipients (e.g. care homes, clinics, laundry / waste disposal providers).

Procedures should address the following as a minimum, but not limited to:

- a. Ensuring potentially contaminated or particularly vulnerable individuals can be identified by with due concern for patient confidentiality;*
- b. Ensuring that patient and bed is clean and that wounds and secretions are covered before transportation);*
- c. Ensuring adequate and appropriate mechanisms are in place for control of infectious materials during transport (e.g. surgical masks);*
- d. Identifying and controlling materials, equipment, vehicles, etc. used in movement and transportation and appropriate methods for of decontamination / disposal;*
- e. Ensuring equipment, patient specimens / organs and other items can be adequately identified and controlled with regard to movement and transportation (e.g. isolation, tagging, traceability records, signage, use of covers / containers);*
- f. Identifying and implementing adequate and proportionate emergency response and contingency plans associated with transportation.*

5.17.2 Routes and access controls

5.17.2.1 The organization shall adopt a risk-based approach in proactively identifying transport routes and limiting access and / or undue traffic in areas where there is a risk of contamination or cross-contamination, including areas where infectious patients or materials may be present, as well as areas where there is the potential for introduction of infectious materials to susceptible individuals.

Note:

Measures should be set in place to ensure that movements of people and materials are limited in areas where there is a risk of transmission of infectious disease. Areas where such limitations apply should include, but are not limited to:

- a. Patients and areas subject to isolation precautions;*
- b. Operating theatres;*
- c. Isolation rooms / wards;*
- d. Intensive care units;*
- e. Areas where immunocompromized or immunosuppressed individuals may be present;*
- f. Food preparation areas;*
- g. Areas where sterile supplies are prepared and or stored;*
- h. Waste handling areas.*

Appropriate controls on movement and access may include procedures, training, signage, physical access controls, etc.

Identifying and controlling transportation routes including but not limited to:

- a. *Ensuring due regard for clean / dirty separation (e.g. avoidance of clean areas, immunocompromized patients);*
- b. *Minimizing distances travelled for both clean / sterile items and potentially contaminated materials and patients;*
- c. *Optimizing the timing of movement activities;*
- d. *Avoiding areas where cross-contamination can occur (e.g. waste through clean storage areas);*
- e. *Identifying controlled routes when infected patients / materials are being transported, including the need for dedicated / controlled elevator and routes avoiding public spaces.*

5.17.3 Information, communication and confidentiality

5.17.3.1 The organization shall ensure that relevant information needs with regard to infection risk are adequately identified and communicated to all relevant parties associated with the movement of patients, specimens and other potentially contaminated materials.

Note:

Information needs for stakeholders should be included in the risk assessment, including how potentially sensitive and / or confidential information relating to a patient's status can be addressed whilst providing adequate protection to staff and the patients themselves.

5.18 Security

5.18.1 Physical security

5.18.1.1 The organization shall ensure procedures are established, implemented and maintained for all relevant activities with regard to infection risk to ensure that the controls for the physical security of personnel, patients, cultures, specimens, samples and other potentially contaminated materials are implemented and maintained.

Note:

Measures should be set in place to minimize the potential for release or removal of infectious material from the facility due to a breach in security. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms.

In planning and conducting security risk assessments the organization should consider:

- a. Theft or diversion of infectious material or related equipment, documents or data;*
- b. Sabotage including vandalism and tampering;*
- c. Break-in and intrusion.*

When planning and conducting activities, the organization should consider potentially contaminated materials to include but not be limited to:

- a. Clothing and PPE;*
- b. Patient clothing / belongings;*
- c. Laundry;*
- d. Syringes and other medical devices;*
- e. Needles, scalpels and other sharp objects;*
- f. Wheel chairs and other means of transportation;*
- g. Cadavers, tissues and organs;*
- h. General waste from high risk areas.*

5.18.2 Personal security

5.18.2.1 The organization shall establish and maintain procedures relating to personal security to ensure that a system is established, implemented and maintained for all relevant activities with regard to infection risk. Procedures shall address the need for preventive measures designed to minimize the need for physical intervention.

Notes:

The nature and extent of the personal security measures should be determined as part of the risk assessment process. Wherever possible, a preventive approach should be adopted in attempting to minimize the need for and extent of any physical intervention that may be required.

Care should be taken to coordinate security measures with those of infection risk to manage and minimize conflicting priorities.

The risk assessment should consider all relevant factors in determining the level of preparedness required, including but not limited to:

- a. The crime rate and likely response needs of the area in which the healthcare organization operates;*
- b. Potential infections carried by those who may require physical intervention;*
- c. Affected personnel, including but not limited to:*
 - i. Physicians;*
 - ii. Nursing staff;*
 - iii. Porters and other support staff;*
 - iv. Security guards.*
- d. PPE requirements, including those to protect against potential transmission routes, including but not limited to:*

- i. Biting;*
- ii. Spitting;*
- iii. Inhalation.*
- e. Need for support from specialist staff (e.g. police or trained guards), including alarms and response times;*
- f. Appropriate training, including de-escalation and other preventive measures.*