**Chapter B4 – Aseptic Preparation Service**

1. **Basic Information**

*(Please use separate form for each type of service, e.g. TPN compounding, cytotoxic reconstitution, stem cell laboratory, etc.)*

|  |  |
| --- | --- |
| Name of Service aseptic preparation is affiliated to |  |
| Location of Service |  |
| Scope of Service |  |
| Number of aseptic preparation room  (room(s) where aseptic preparation is actually conducted) |  |
| Operating hours |  |

1. **Medical Practitioner-in-charge/Pharmacist-in-charge**

|  |  |
| --- | --- |
| Name in English |  |
| Name in Chinese |  |
| Post Title |  |
| Qualification(s) / Training |  |

1. **Staffing**

3.1 Manpower\* (Including the Medical Practitioner-in-charge/Pharmacist-in-charge)

|  | **Rank** | **No.** |
| --- | --- | --- |
| Resident medical practitioner |  |  |
| Pharmacist |  |  |
|  |  |  |
| Chemist |  |  |
| Dispenser |  |  |
| Medical Laboratory Technologist |  |  |
| Others |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

*\* “Proposed manpower” for new hospital*

3.2 Other requirements

|  |  |
| --- | --- |
| 1. All staff participating in the aseptic preparation service are appropriately trained and assessed, with reference to guidelines issued by local or international authorities, prior to undertaking the tasks they are assigned to perform | Choose an item. |
| 1. Schedules for periodic retraining and reassessment of aseptic technique of staff involved in aseptic preparation are established, undertaken and documented as appropriate | Choose an item. |
| 1. There is a pre-defined responsibilities to each grade/rank of staff | Choose an item. |
| 1. Where medicines are dispensed, the dispensing is performed under the supervision of a pharmacist or medical practitioner | Choose an item. |
| 1. Regular evaluation is carried out on the practice adopted against the procedures (with respect to all activities carried out in the service, e.g. compounding, cleaning, etc.) to ensure effective implementation | Choose an item. |

1. **Critical or Major Equipment**
   1. Equipment list (*e.g. isolator, laminar airflow cabinet, hot cell, pharmaceutical refrigerator, cyclotron, analytical equipment, etc.)*

| **Type of equipment** | **Quantity** | **Schedule of maintenance as per the manufacturer’s recommendation** | **Date of last service / maintenance#** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*# Not applicable for new hospital*

* 1. Other requirements

|  |  |
| --- | --- |
| 1. All equipment is installed, operated, maintained and calibrated according to manufacturer’s recommendation | Choose an item. |
| 1. There are operating manuals and procedures for use of equipment | Choose an item. |
| 1. There are procedures and schedules for cleaning, disinfection and decontamination of equipment | Choose an item. |
| 1. Staff using equipment have completed training in the safe and proper use of the equipment | Choose an item. |
| 1. There is preventive maintenance schedule established for all critical or major equipment | Choose an item. |

1. **Aseptic Preparation Facilities and equipment**

|  |  |  |
| --- | --- | --- |
| 1. Healthcare standard complied for the aseptic preparation facility, i.e. the accommodation(e.g. PIC/S Grade B, ISO Class7) | **Name of Room** | **Standard complied** |
|  |  |
|  |  |
|  |  |  |
|  |  |  |
| 1. Healthcare standard complied for the aseptic preparation environment, i.e. the equipment, | **Name of Equipment** | **Standard complied** |
|  |  |
| such as the pharmaceutical isolator or laminar airflow (biosafety) |  |  |
| cabinet (e.g. EU GMP Grade A, ISO Class 5) |  |  |
|  |  |  |
| 1. Healthcare standard complied for the aseptic preparation facility, i.e. the accommodation, is regularly monitored | | Choose an item. |
| 1. Ventilation system of the aseptic preparation facility, i.e. the accommodation, is regularly maintained and complying with relevant statutory requirements and international standards | | Choose an item. |
| 1. Healthcare standard complied for the aseptic preparation environment (i.e. the equipment in which aseptic preparation is performed) is regularly monitored | | Choose an item. |
| 1. The aseptic preparation equipment (e.g. the pharmaceutical isolator or laminar airflow (biosafety) cabinet) is regularly maintained according to the manufacturer’s recommendation | | Choose an item. |

1. **Service Delivery and Care Process**

|  |  |
| --- | --- |
| 1. There are written policies and procedures developed with reference to guidelines issued by local or international authorities and implemented on service delivery and care process, including the following: | |
| 1. control of access to specified work areas | Choose an item. |
| 1. cleaning and disinfection of equipment and work areas | Choose an item. |
| 1. environmental surveillance of the aseptic preparation areas and devices and action for deviation | Choose an item. |
| 1. procurement, receipt, handling and storage of starting materials, equipment, devices used, and preparation of in-house reagents / materials | Choose an item. |
| 1. quality control for starting material and products | Choose an item. |
| 1. packaging, release and transport of products | Choose an item. |
| 1. handling of spillage of chemical, radioactive and cytotoxic drug | Choose an item. |
| 1. cryopreservation, storage and distribution / disposal of prepared products as applicable | Choose an item. |
| 1. infection control practice | Choose an item. |
| 1. donor eligibility criteria (for cell and tissue products), including but not limited to infectious disease testing | Choose an item. |
| 1. reporting and management of adverse event and product complaints and product tracking mechanisms | Choose an item. |
| 1. risk assessment of the operations at the service | Choose an item. |
| 1. The preparation and release of each individual product for use in patient is under the supervision of a pharmacist or a medical practitioner | Choose an item. |
| 1. There are written policies and procedures on detailed product processing, labelling, checking, release procedures and recording, including details of staff involved | Choose an item. |
| 1. Tracking mechanism is established for products and related starting materials from the source to processing and final deposition (e.g. patient) | Choose an item. |
| 1. Contingency plans are established for detection of product failure through monitoring systems, recalls and alerts | Choose an item. |
| 1. Appropriate personal protective equipment and garment is available for staff involved in the aseptic preparation service according to their job responsibilities | Choose an item. |
| 1. A quality assurance system is set up to ensure the products are prepared in such a way that they are fit for their intended purposes and that their quality consistently complies with the defined requirements, including but not limited to the requirements for audits | Choose an item. |