**1.0 PURPOSE**

1.1 To describe the process by which drugs including vaccines, human plasma fractions and insulin are stored safely and according to the manufacturer’s temperature requirement, and separating antiseptics, disinfectants and drugs for external use from injectables and drugs for internal use.

1.2 To describe the monitoring and recording process for all refrigerators and freezers located within the department, store room, and patient care areas.

**2.0 DEFINITION**

2.1 **Refrigerate:** (2 – 8 ºCentigrade / 35 – 46 degrees Fahrenheit).

2.2 **Freeze:** (Below 0 degrees Celsius, between -10 and -25 ºC). Consult manufacturer’s literature per products as some products required lower freezer temperatures than others.

2.3 **Room temperature:** Between (15 – 25 ºC).

2.4 **Digital read-out:** The temperature of the air within the unit right now.

2.5 **Scimetrics:** Refrigeration alarm system that monitors temperatures twenty four hours a day.

**3.0 RESPONSIBILITY**

3.1 **Pharmacist:** is responsible for performing monthly audits of patient care areas to ensure patient safety regarding the storage of medications.

3.2 **Pharmacy staff and Head Nurses:** are responsible for recording daily and maintaining a log sheet, for temperature of refrigerators in patient care areas, in the pharmacy and wards.

3.3 **Maintenance supervisor:** is responsible for calling the physical plant to repair the malfunction, when a refrigeration problem occurs.

3.4 **The charge nurse:** is responsible for calling maintenance, for after duty hour’s refrigeration problems, and other role in storing medications in the ward.

**4.0 CROSS REFERENCES POLICY**

4.1 Pharmacy Safety Measures (Handling of Hazardous Material.)
4.2 Narcotic and Controlled Drugs.

5.0 POLICY

5.1 All medications are well stored, separated and properly labeled upon display on the shelves.

5.2 All refrigerators and freezers located within the department will be routinely monitored to assure that the correct temperature range is maintained with respect to the items being stored in each respective refrigerator or freezer. Documentation of the monitoring activity will be maintained.

5.3 All antiseptics, disinfectants, and drugs for external use are stored separately from injectables and internal medications.

5.4 All medications are stored according to manufacturer’s recommendations (temperature, light, humidity, sanitation).

5.5 No food or drinks will be allowed inside medication refrigerators.

5.6 The pharmacy department will keep temperature records for at least three years.

6.0 PROCEDURE

6.1 Storage Of Medications In The Pharmacy And Wards:

6.1.1 All medications are stored in designated areas to ensure proper sanitation, temperature, light, moisture control, segregation, and security.

6.1.2 All medications are well separated and properly labeled upon display on the shelves in the store room, inpatient pharmacies, outpatient pharmacies, E.R., and other pharmacy units (TPN room, Narcotics & controlled drugs, etc.) as well as in the wards in the form of floor stocks, IV fluids, and refrigerated drugs.

6.1.3 The proper environmental control (i.e. proper temperature, light, and humidity, conditions of sanitation, ventilation and segregation) will be maintained wherever medicines and supplies are stored in patient care areas.

6.1.4 All clinic/unit must observe proper storage and labeling requirements for all medicines during the performance of their daily tasks and should demonstrate safety in regard to the potency of medications administered, such duties include:

6.1.4.1 Removal of outdated medications from active stock, returning them to the drug store where they will be quarantined together until all such medications are disposed of according to the policy and procedure “Drugs returned from clinics, departments, and nursing stations”.
6.1.5 Labeling of all medications prepared for IV administrations with patient name, date and time of preparation with employee initials, medication name and dose and solution base.  

6.1.6 Limiting use of multi-dose containers for single patient use unless reasonably justified.  

6.1.7 Multiple dose vials must be discarded according to the hospital’s stability guidelines.  

6.1.8 Vials marked, as single dose should be discarded immediately after use.  

6.1.9 Nitroglycerin sublingual tablets readily deteriorate once exposed to light, air and elevated temperatures. Once the bottle has been opened, it should be discarded within thirty days.  

6.1.10 **High-Alert Medications** are identified by special labels or color marks which are placed on all storage locations for High Risk Medications in the pharmacy and wards. Limited quantities of concentrated KCL 15% (2mmol/ml, 10ml vial) is kept as ward stock:  

6.1.10.1 In the Operating Room (OR) - to treat cardioplexia during cardiac surgery.  

6.1.10.2 In the Intensive Care Unit & Coronary Care Unit - to treat cardiac arrhythmias.  

6.1.11 **Look-Alike / Sound-Alike Medications** which have potential for confusion due to similarity in packaging or names are identified (light blue color tag) and stored separately as extra precautions to prevent error.  

6.1.12 **Multiple dose vials** that contain preservatives to make extended use possible are dated with the date opened and will be discarded 28 days after date opened. **Single dose vials / containers** are discarded immediately after a single use.  

6.1.13 **All Controlled Substances** are secured behind two locks. Administration and wastage is documented on the proper records, and prescription pads are secured at all times and not accessible to unauthorized persons.  

6.1.14 **Nutritional Products:** All parenteral nutrition bags must be stored in the drug fridge or fridge designated for PN at temperature between “2 to 8 C”. The expiry date is stated on the labels. Pharmacy should be notified of any unused bags. Discard in clinical waste. Parenteral nutrition bags should be removed from the fridge at least 1/2 hour prior to use, to allow fluid to reach room temperature. If the bag is in any way damaged or leaking please notify the Pharmacy Department immediately and send the bag to the pharmacy so that the cause can be determined. The compounded products of PN are good for 24 hours only.  

6.1.15 **Sample Medications** are not stored in any inpatient unit. They are stored and arranged alphabetically in a locked cabinet in the OPD.
pharmacy with a list of the Sample Medications and their expiration dates. Samples are labeled when dispensed without using abbreviations.

6.1.16 **All Emergency Medication Carts** are secured with serial numbered locks (Plastic seal) issued by the nursing department. They are checked daily in each shift and documented to verify lock is not broken and the medications are not expired. Other emergency medications that are kept outside the crash carts are safely stored in cabinets with the floor stocks in the nursing stations.

6.1.17 Other drugs which require special storage precautions and safe handling procedure (e.g. **Flammables, chemicals, narcotic & controlled drugs, & hazardous drugs and wastes**), are labeled as such treated according to their special storage and handling requirements and precautions in the pharmacy, with spill kits and fire extinguishers on hand (See policy for Pharmacy Safety Measures, and policy for Narcotic and Controlled Drugs).

6.1.18 In patient care areas medications will be stored in medication shelves or specialized compartments and secured drawers at all times when not in use.

6.1.19 Medications will be stored in an orderly manner (Products for internal use are separated from for external use) in areas only accessible to designated and authorized personnel.

6.1.20 Pharmacist will perform monthly inspections of patient care areas to ensure compliance with the proper patient safety considerations regarding the storage of medications’ stock. Areas maintain copies of past Pharmacy Unit inspections including corrective action taken when an infraction occurs. Nurses will inspect medications on the floors on weekly basis.

6.1.21 Medications will not be dispensed or distributed beyond the expiration date, “First expiry/First out” (FEFO) principle will be followed.

6.1.22 Any expired, discolored, damaged, or inappropriately labeled medication shall be returned to the pharmacy store for proper disposal. Unused or not needed medications for a specific patient (or not intended for stock) are also returned to the pharmacy for processing or disposal by the pharmacy store.

6.1.23 Any notification of a drug quality issue (e.g. discoloration, precipitation, etc.), the medication will be recalled and reported to the MOH Medical Supply and the Saudi FDA, as required.

6.2 **Storage of Antiseptics, Disinfectants And Drugs For External Use:**

6.2.1 All antiseptics, disinfectants, and drugs for external use are stored separately from injectables and other internally used medications. This
applies to the pharmacy store, Inpatient and outpatient pharmacies, and the wards.

6.3 **Storage Of Refrigerated Drug Items:**

6.3.1 Refrigerated medications must be stored at appropriate temperatures according to the following:

- **Room temperature:** between 15-25 ºC
- **Cool place:** between 8-15 ºC
- **Refrigerator:** between 2-8 ºC
- **Freezer:** between -10 and -25 ºC

6.3.2 Pharmacy staff in Inpatient, OPD, ER and store room, and Head Nurses in patient care areas is responsible for recording daily and maintaining a log sheet for temperature of refrigerators in the pharmacy and wards.

6.3.3 Medication refrigerators should have a working thermometer ensuring the proper temperature range.

6.3.4 Notify the maintenance department of any problem, which will in turn evaluate the situation and contact the respective supervisor for repair if required.

6.3.5 Corrective action for units displaying temperature outside desired range should be taken immediately by first calling the maintenance department for repair within **30 minutes**. If not repaired then transfer all contents to a similar unit within the department, attach an inventory list to the broken unit, listing all items removed, quantity and new location. Attach a copy of the inventory list to the temporary new location. Inform the maintenance manager of the refrigeration problem and the transfer of the inventory. During normal hours the maintenance supervisor is responsible to call physical plant to repair the malfunction. For after hour's refrigeration problems, the charge nurse is responsible for calling maintenance.

6.3.6 Medication refrigerators should not be used to store food, drinks, biological samples, or culture media.

6.3.7 A temperature log must be maintained for each medication refrigerator and will be checked at least once daily.

6.3.8 The documentation must indicate that the temperature is monitored on a daily basis.

6.4 **Refrigerators: 2 types** –

6.4.1 Large units (room size) refrigerators:

- **6.4.1.1** Used for storing large quantities of refrigerated drug items such as vaccines, insulin, heparins, and other drugs, these refrigerators are found in the Pharmacy Store and the Main Pharmacy.
6.4.1.2 Equipped with a temperature monitoring device which is connected to the maintenance department who will in turn evaluate the situation and contact the respective area supervisor if required.

6.4.2 Small and medium size refrigerators:

6.4.2.1 Used to store small stocks of refrigerated drug items and is available in inpatient, outpatient, and ER pharmacies and also in patient care areas.

6.4.2.2 Some of these refrigerators are equipped with a portable temperature monitoring device (thermometer) in the pharmacy areas, while other refrigerators have the device (thermometer) mounted on the unit itself as in patient care areas.

6.4.3 The small units' refrigerators are checked daily. If any problem, the maintenance department will be contacted to evaluate the situation and correct the problem or contact the respective area supervisor if required.

6.5 Storage of Vaccines, Human Plasma Fractions & Insulin:

6.5.1 Delivery from Medical Supply Stores:

6.5.1.1 The Drug store pharmacist ensures that the supplied vaccines, human plasma fractions and insulin were in good conditions during delivery from Medical Supply Stores.

6.5.1.2 If the Drug store pharmacist verified that the supplied vaccines, human plasma fractions and insulin were broken, he/she must inform the Medical Supply immediately by a written notification (a copy to Head of Pharmacy Dept.) to be returned or replaced.

6.5.1.3 The Drug store pharmacist ensures to keep all the vaccines, human plasma fractions and insulin in a suitable temperature. These products should be kept under specified storage temperature during and after supply from company, until it reaches the Drug Store Refrigerator and then, being transferred to In-patient, Out-Patient Pharmacies and Nursing Units.

6.5.2 Vaccines, human plasma derivatives and insulin are kept in a temperature between +2 °C & +8 °C and not allowed to freeze except for Oral Polio vaccine which is kept below –20 °C.

6.5.3 As a general rule, multi-dose vaccines should be kept for one hour after opening if there is no preservative. Vaccines which contained a preservative should be discarded after THREE HOURS from the opening time. Insulin vials should be kept in the refrigerator for ONE MONTH after opening. Unused human plasma derivatives should be discarded immediately after opening.
6.5.4 Specific rules:
6.5.4.1 Oral Poliomyelitis vaccine stable for three hours in the refrigerator.
6.5.4.2 Tetra-act HIB vaccine stable for 24 hours in the refrigerator.
6.5.4.3 BCG vaccine stable for four hours after opening in the refrigerator.
6.5.4.4 Insulin Flexpen stable for one month after first use and can be kept at room temperature.

6.5.5 In-Charge Nurses are instructed to give particular attention to the importance of shaking vaccine containers after the addition of diluents immediately before use.

6.5.6 The Head of Pharmacy and/or designee monthly checks the hospital staff clinic for:

6.5.6.1 Availability of the vaccines.
6.5.6.2 Proper storage at proper temperature.
6.5.6.3 The Staff Nurse daily checks the refrigerators temperature of the staff clinic.
6.5.6.4 No food stuff is allowed to be kept inside medicine refrigerators.

6.5.7 Various medication stores in hospital is as follows:

6.5.7.1 Drug store
6.5.7.2 Inpatient nursing unit
6.5.7.3 Outpatient clinics
6.5.7.4 Emergency Room
6.5.7.5 In-patient Pharmacy
6.5.7.6 Out-patient Pharmacy

6.5.8 Table below provides a list of available vaccines and required temperature for storage:

<table>
<thead>
<tr>
<th>Vaccine Names</th>
<th>Storage Temperature</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hemophilus vaccine</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>Single dose</td>
</tr>
<tr>
<td>2. BCG Vaccine “N.B. Protect from light”</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>4 hours</td>
</tr>
<tr>
<td>3. Di Te vaccine (Diphtheria Tetanus vaccine)</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>One hour</td>
</tr>
<tr>
<td>4. DPT vaccine (Diphtheria, Pertussis, Tetanus vaccine)</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>One hour</td>
</tr>
<tr>
<td>5. Hepatitis B vaccine</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>Single dose</td>
</tr>
<tr>
<td>6. Inactivated hepatitis A virus vaccine</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>Single dose</td>
</tr>
<tr>
<td>7. Inactivated split influenza vaccine</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>Single dose</td>
</tr>
<tr>
<td>8. Measles vaccine “N.B. Protect from light”</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>Single dose</td>
</tr>
<tr>
<td>9. Meningococcal Meningitis type A&amp;C vaccines, N.B. Protect from light.</td>
<td>$+2$ to $+8 , ^\circ C$</td>
<td>Three hours</td>
</tr>
</tbody>
</table>
10. MMR (Mumps, Measles, Rubella vaccine) + 2 to + 8 °C Single dose
11. Oral poliomyelitis vaccine (N.B. after thawing it can be kept between +2 and +8 degrees °C for six months). - 20 to -26 °C Three hours
12. Rabies vaccine + 2 to + 8 °C Single dose
13. Scorpion venom antitoxin + 2 to + 8 °C Single dose
14. Snake venom antitoxin + 2 to + 8 °C Single dose
15. Tetanus antitoxin (for passive immunization) + 2 to + 8 °C Single dose
16. Tetanus toxoid for active immunization + 2 to + 8 °C One hour
17. Typhoid vaccine (Typhim Vi) + 2 to + 8 °C Single dose

7.0 FORMS

7.1 Physician’s Order Sheet.
7.2 Temperature Monitoring Log Sheet.

8.0 EQUIPMENT

8.1 N/A.

9.0 REFERENCES

9.1 CBAHI resource manual.