Chapter 3

1. Premises and equipment

The premises should be equipped in the appropriate way, to ensure that the required storage conditions are maintained. Medical products should be stored at a **controlled temperature** and in **marked areas** in which only **authorized personnel** can come. Premises and storage facilities should be monitored from appropriate devices taking into account three factors:

- **Temperature**
- **Damp**
- **Hygiene**

In fact, they should:

- **Be clean and free from waste and dust**
- **Have a clean-up program with instructions and records**
- **Be submitted to appropriate clean-ups procedures for cleaning any spillage, thus avoiding every risk of contamination**
- **Be equipped in order to protect medical products from rats, insects and other animals**

Some types of medical products need particular conditions for the storage, such as:

- **Products under quarantine** – so that, medical products whose shipment is briefly blocked - must be separated from the others through labeling

- **Dangerous or radioactive products** must be stored in a designated area, following the local or international regulation.

2. Mapping

The mapping of the areas consists in the t**emperature detection within the controlled areas**. This process has the purpose to verify the correct air flow within the cells. Mapping takes place through the installation of temporary probes , which monitor and record the temperature during a specific period of time. It's important to take account of the **size and the conformation of the cells**, so that the temperature's study will be reliable.

The mapping of the temperature should be done in certain conditions, such as:

- **During extreme seasons, in both summer and winter**
- **In case of fully operative cells and empty cells**
- **For a significant period of time**

Following this way, the report of the mapping should provide operating instructions for each area and also for its identification for the storage.

3. Equipment

It should be respected **a maintenance plan** to guarantee the functionality of the key equipment. For example, the probes need a **calibration at defined intervals**, which is done in compliance with a local or international standard; in addition, it should be set up a **system for the temperature monitoring**. The logistic provider should identify the

qualification procedures of the key equipment and also those of the key procedures validation.

The equipment's repair, maintenance and calibration should be recorded and the outcome should be saved.

4. How to manage a computerized system.

First of all, it should be demonstrated through a validation, that the computerized system is able to achieve the established results. In addition, a **written and detailed description** should be available and data should be protected from unauthorized alterations: for this reason, only authorized people can have access to the system.

Finally, **a procedure for the breakdown or malfunction of the system** should be defined.