

**§482.25(b)(2)(iii) - Only authorized personnel may have access to locked areas.**

**Interpretive Guidelines §482.25(b)(2)(iii)**

The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.

A hospital has the flexibility to define which personnel have access to locked areas, based on the hospital's needs as well as State and local law. For example, a hospital could include within its definition of "authorized personnel" ancillary support personnel, such as engineering, housekeeping staff, orderlies and security personnel as necessary to perform their assigned duties. The hospital's policies and procedures must specifically address how "authorized personnel" are defined for purposes of this section. It is not necessary for the policy to name specific authorized individuals, but the policy should be clear in describing the categories of personnel who have authorized access, as well as whether there are different levels of access authorized in different areas of the hospital, or at different times of day, or for different classes of drugs and biologicals, etc.

The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored. Whenever unauthorized personnel have access, or could gain access, to those locked areas, the hospital is not in compliance with this requirement and is expected to re-evaluate and tighten its security measures.

**Survey Procedures §482.25(b)(2)(iii)**

- Determine whether there is a hospital policy and procedure defining authorized personnel that are permitted access to locked areas where drugs and biologicals are stored.
- Determine whether there is a hospital policy and procedure for limiting access to locked storage areas to authorized personnel only.
- Observe whether or not access to locked storage areas is limited to personnel authorized by the hospital's policy.