

5. **Q:** To convince the Inspector, can we maintain or use segregation by system (if the space is limited)? For example, if the operator takes the wrong materials, the system will reject the materials.
A: There are 2 kinds of separation: a. physically and b. by system (automated warehouse, however the system has to be validated)
6. **Q:** a) How long the retention of obsolete documents (such as instructions), because PIC/S book article 4.11 only explain about records?
Q: b) How is to develop the SOP of storage area for product recall, product reject and product release?
A: a) Related document is also required to retain the same periods.
A: b) You need control very strictly not to use these rejected products for sale. You need segregate these product and lock and indication should be adopted.
7. **Q:** In the PIC/S book article 3.3 explained that “lighting, temperature, humidity, and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the medicinal products ...”. While, operational instruction of Indonesia GMP application (POPP CPOB), there is recommendation, for example for the temperature of grade E room is 20 – 27°C. Should we follow the specification from POPP CPOB? Or can we decide our own specification?
A: PIC/S Part I, article 3.3 gives general requirements without specific criteria, including consideration of “indirect” impact on quality. The POPP CPOB standard of 20 to 27°C may intend to avoid operators’ sweating which may indirectly increase contamination risk. PIC/S is an informal cooperation scheme between member inspectorates, and each inspectorate can provide more specific and/or stricter local requirements than PIC/S GMP Guide. If the above mentioned temperature is a legal binding requirement in Indonesia, Indonesian companies have to comply with it.