

## Prerequisite Program-GMPs and SOPs

Prerequisite program is a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. Some establishments may use prerequisite programs, such as **Good Manufacturing Practices (GMPs)** and/or **Standard Operating Procedures (SOPs)** to reduce the likelihood of certain hazards. GMPs are minimum sanitary and processing requirements and SOPs are step-by-step directions for completing important procedures. GMPs are fairly broad and general and can be used to help guide the development of Standard Operating Procedures (SOPs), which are very specific. GMPs are not designed to control specific hazards, but are intended to provide guidelines to help establishments produce safe and wholesome products. SOPs, on the other hand, are very specific instructions for performing a procedure and may address a specific hazard. Sanitation SOPs (SSOPs) may be considered by establishments to reduce the likelihood of occurrence of some food safety hazards. For example, the SSOP may address washing and sanitizing of knife and hands between carcasses to reduce potential contamination with pathogens.

Based on the regulatory requirements of 9 CFR 417.2(a) and 9 CFR 417.5(a)(1), FSIS believes that the results of testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from prerequisite programs that are not referenced in the hazard analysis, HACCP plan, or Sanitation SOP.

If a hazard is judged reasonably likely to occur, the establishment must address the hazard with a CCP and **cannot** substitute a prerequisite program to control the hazard. Sometimes, however, an establishment determines that the hazard is not reasonably likely to occur, using the justification that a prerequisite program, properly implemented, is preventing the hazard from occurring. If the Consumer Safety Inspector determines that a prerequisite program is used as a justification for not addressing a hazard with a CCP in the HACCP plan, the CSI should notify the District Office. These programs must be evaluated by a specially trained individual, such as an EAIO.