environment and manner. Failure to adhere to the ''core elements'' of an SOP (the proposed regulatory requirements) would be presumptive evidence of insanitation and enforcement action, where necessary, would be taken. As is now the case, inspectors will not permit an establishment to operate under insanitary conditions. Falsification of records designed to document daily sanitation activities would, in addition to indicating insanitation, be treated as a criminal act subject to prosecution.

As a more efficient tool for ensuring that establishments are carrying out their sanitation responsibilities, sanitation SOP's can provide the basis for improved utilization of FSIS inspectional resources. Sanitation SOP's thus support the transition to HACCP because, under HACCP, FSIS inspectors will be called upon to perform a number of additional safety-related inspectional tasks to verify that HACCP plans are working properly. If less time can be spent ensuring that basic sanitation requirements are being met, more time will be available for these new tasks.

Some plants already have SOP's, take their sanitation responsibilities seriously, and require a relatively modest investment of inspector time to ensure sanitation requirements are met. Other plants do not consistently perform well in the sanitation area and frequently require a substantial investment of inspector time to ensure basic sanitation compliance before daily operations begin.

In plants where procedural requirements are consistently followed and inspectional observations verify that good sanitation is being consistently achieved, FSIS expects that sanitation SOP's will provide the basis for adjusting the manner and frequency of FSIS preoperational sanitation inspection.

FSIS invites comment on the role sanitation SOP's should play in allocating responsibility between establishment employees and FSIS inspectors for preoperational sanitation, including the role FSIS employees should play in authorizing daily startup of operations.

Content of SOP's

Sanitation SOP's would, at a minimum, detail procedures the establishment will conduct to prevent direct contamination or adulteration of product before and during operations. Such procedures would constitute the required, core elements of an SOP. The SOP's would also identify establishment personnel responsible for evaluating the conduct and effectiveness of the sanitation SOP's, and for making corrections when needed. FSIS encourages establishments to incorporate additional sanitation procedures that provide increased assurance that insanitary conditions will be prevented.

Each establishment would maintain a daily record of the actions prescribed in the SOP, and make such records available to Program employees for inspection audit and verification. Records would, at a minimum, record deviations from the core elements of the SOP (the proposed regulatory requirements), along with corrective actions taken in conjunction with the monitoring of daily sanitation activities. Production could not start until the core elements of the sanitation SOP's that are applicable to preoperational sanitation have been completed.

The daily monitoring of the sanitation program by the establishment representative could include microbiological tests, routine organoleptic inspection of areas and equipment, and direct observation of sanitation procedures while being performed by designated employees.

FSIS will provide guidance materials, including examples, on development of sanitation SOP's prior to the implementation of this requirement.

The following are specific practices relating to sanitation that might be included in an SOP:

- Preoperational microbiological testing: Tests for verifying the efficacy of cleaning, sanitizing, and disinfecting procedures. Many establishments also currently perform preoperational microbiological testing for quality control purposes. The technology for preoperational sanitation microbiological testing is readily available and easy to use.
- Disinfection of equipment prior to startup: Some data exist to indicate that equipment should be sanitized immediately prior to the startup of operations.
- Use of an automated hand washer with approved sanitizing solution effective for up to six hours. This has been proven to be an important sanitary practice.
- Handwashing between each carcass in skinning and evisceration operation.
- Cleaning cattle prior to slaughter: Washing and drying, clipping, dehairing, and any other acceptable method to remove dirt, fecal matter and other potential sources of contamination from the exterior of animals before the edible portions of the carcasses are exposed. The hides of animals are a known source of carcass contamination. Feedlot cattle in general and most bovines during the winter and ''mud season'' carry heavy loads of mud, fecal material and bacterial contamination on the hide. Sanitary removal of the hide under these conditions is very difficult. One method to control this source of contamination is washing animals prior to slaughter. Another possibility is clipping the hair over the areas where opening cuts will be made and sanitizing the hide prior to cutting. Yet another procedure being tested is the complete removal of hair from the hide using a chemical hair remover (depilatory).

The Agency has been asked to consider making mandatory certain GMP's for sanitary slaughter by, among others, the American Meat Institute. The Agency is requesting comments on whether GMP's or other sanitation practices should be made mandatory elements of the sanitation SOP.

The adoption of HACCP systems by establishments would not replace the need for establishments to maintain sanitation SOP's. The proposed HACCP regulations require sanitation SOP's as a prerequisite to a HACCP plan. Sanitation activities that directly affect the control of a processing hazard would be determined according to the criteria discussed in the HACCP portion of this document, and would, where appropriate, be identified as critical control points in individual HACCP plans. Sanitation activities not identified as critical control points under HACCP should remain in the sanitation SOP's. Any SOP requirement incorporated into a HACCP plan could be removed from the SOP's for sanitation.

2. Antimicrobial Treatments

This proposed rulemaking would require, for the first time, that slaughtering establishments apply antimicrobial treatments or interventions to livestock and poultry carcasses. Under the proposal, any one or more of the treatments would have to be applied prior to the chilling or cooling operation. Mandating antimicrobial treatments is a new approach for FSIS. It reflects the judgment that, at least until significant progress is made in reducing or eliminating the presence of pathogenic microorganisms in livestock and poultry at the preharvest stage and in sanitary dressing techniques and practices, some amount of contamination of beef and poultry carcasses with pathogenic microorganisms is likely to occur—even in establishments that attempt to follow the best current practices. To reduce the food safety hazard posed by such pathogens, establishments should be