Recurring violations of fundamental HACCP requirements would be viewed as indicating an increased likelihood that other violations of inspection requirements exist and that additional enforcement actions may be required by FSIS.

Finally, in the event the Administrator finds that HACCP records have been deliberately falsified, the Agency would in addition to any suspension in effect, issue a complaint for withdrawal of inspection from the establishment and would refer the case to the Department of Justice for criminal prosecution.

3. Illustrations of the Application of HACCP

The HACCP approach to process control is systematic and establishment specific. The generic models prepared by FSIS and NACMCF to assist federally inspected establishments to develop HACCP plans would serve as guides for the processes described earlier in this document. In order to clarify these concepts, some examples are included to explain the contrast in operations conducted under the HACCP system from those conducted under the traditional mode of industry operation. Since each HACCP system is developed by an individual establishment to fit with its process(es), the following examples are meant to serve only as illustrations, and are not intended to serve as prescriptive blueprints for a specific HACCP plan.

When developing a HACCP plan, all aspects of a food's production must be considered. The development of a HACCP plan begins with the identification of the product, its distribution, and the intended consumer of the product. A hazard analysis is conducted, and the plan is developed by identifying critical control points, monitoring procedures, critical limits, and the remainder of the seven principles discussed earlier in this document.

The HACCP system places the responsibility for production of a safe and unadulterated product with the industry. The HACCP approach allows the establishment to focus on the process as it is occurring. If contamination is occurring, it should be immediately identified, allowing for prompt corrective action as well as providing an opportunity to determine the cause and take action to prevent a future recurrence of the problem. In a non-HACCP approach, the establishment may not discover contamination until much later in the process, if at all, resulting in delays, the possibility of producing and distributing unsafe product, and difficulty in implementing preventive measures.

The following are illustrations of the application of existing generic models and how they can be used by an establishment.

The HACCP System for Beef Slaughter

For beef slaughtering establishments, a generic HACCP plan which reviews the processing steps of slaughter operations can provide general guidance for developing an establishment's specific plan. The goal of HACCP for slaughter operations is to prevent, eliminate, or reduce both the incidence and levels of microorganisms pathogenic to humans. While beef slaughter operations do not include a lethal treatment (e.g., thermal process) that ensures the elimination of pathogenic microorganisms, a number of the processing steps can be controlled to minimize microbiological hazards.

A beef slaughter establishment performing a hazard analysis of its operation may identify several hazards, particularly enteric pathogens, such as *Salmonella*. CCP's where *Salmonella* contamination might occur can be identified and then controlled by establishing critical limits, monitoring those limits at an appropriate frequency, and taking corrective actions when deviations occur. Recordkeeping and verification procedures would also be identified for these CCP's in the establishment's specific HACCP plan.

For example, the intestinal tracts of animals can harbor large populations of enteric pathogens, such as *Salmonella*, even though the animals themselves are asymptomatic. As the slaughtered animals are eviscerated (removal of the intestinal tract and other organs), there is potential for spreading the *Salmonella* from the intestinal tract to the carcass, operator, or equipment, if the intestines are accidentally cut. Therefore, evisceration would be considered a CCP in a HACCP plan for beef slaughter.

Critical limits for the evisceration CCP might be zero percent occurrence of the following defects for a single carcass: fecal material, ingesta, urine or abscesses. The establishment employee(s) working at evisceration would monitor by observing carcasses for contamination defects and would take corrective actions if the critical limits were exceeded. Corrective actions might include: immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, a reduction in line speed, sanitization of evisceration tools in 180°F water, and sanitization of contaminated clothing in 120°F water or appropriate sanitizer.

Records resulting from this CCP might include a random post-evisceration carcass examination log. Verification might consist of supervisory review of records and operations, and random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.

In a non-HACCP approach, the establishment may discover contamination from evisceration much later in the process, causing delays before the contamination is removed and making implementation of preventive measures difficult.

Removing the hide from cattle is a major source of microbial contamination during the slaughtering process. Cattle entering the slaughter establishment carry with them microbial populations indicative of what occurred during the care and handling of the live animals. *Salmonella* and other types of bacteria can be spread during the skinning process through contact with hide, hands, and various pieces of equipment. Therefore, skinning would be a CCP in a beef slaughter HACCP plan.

Methods for control of contamination at skinning might include adequate training of the person doing the skinning to minimize contamination, including pulling the hide down and out from the carcass as opposed to upward and away; positive reinforcement through appropriate supervision; and proper cleaning and sanitization of equipment and carcass contact surfaces.

Monitoring at this CCP might include observation of the effectiveness of the skinning process for each carcass. Ways to ensure this is working would be to set critical limits. Critical limits for skinning might include less than or equal to 20 percent of carcasses with dressing defects.

If this critical limit is exceeded, corrective actions would be required. These could include: immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, and/or a reduction in line speed.

Records resulting from this CCP might include a random post-skinning carcass examination log. Verification might consist of a supervisory review of records, examination of random carcasses after skinning is complete using a sampling plan sufficient to assure process control, and reviewing control charts to confirm that sampling frequency is sufficient to detect 20 percent defect criteria. Additionally, baseline data might be established for expected bacterial numbers. Periodic