the plan, record the results of monitoring, and store any records generated under the operating procedures. Establishments would also be required to train one or more individuals to carry out the operating procedures. Costs for this activity are estimated at \$50.4 million.

### 2. Use of an Antimicrobial Treatment

Establishments would be required to use an antimicrobial treatment on all meat and poultry carcasses. Of the 1,923 small slaughter establishments, it is estimated that approximately 70 percent now apply an antimicrobial treatment to meat and/or poultry carcasses. Therefore, for these establishments, no additional costs should be incurred. For those establishments that do not now use an antimicrobial treatment, costs are estimated at \$2.7 million.

## 3. Time/Temperature Requirements

Establishments would be required to provide written plans for complying with the proposed time, temperature, and monitoring requirements for carcasses and raw meat products, or with alternative procedures which would be permitted under this proposal. The written plan would include the establishment's designated control points, corrective actions, and, when applicable, the name of the processing authority. Some establishments may decide to hire a processing authority to develop such plans, while others may prepare their own plan. If an establishment chooses to follow alternative procedures, the establishment must hire a processing authority to develop the alternative procedures.

The refrigeration requirements set forth in this proposed rule may result in costs associated with purchases of refrigeration facilities. Although all establishments must have cooler rooms and most have refrigerated vehicles for shipping product, some small establishments may not have existing refrigeration facilities that would meet the proposed refrigeration requirements. The number and size of refrigeration units that may be required would depend on cooler room sizes and slaughter volumes of individual establishments.

Establishments would be required to monitor the temperatures of carcasses and raw meat products throughout their operations to ensure compliance with their plan, and maintain ongoing monitoring records for the previous 6 months. Costs for time/temperature requirements are estimated at \$28.8 million.

# 4. Microbiological Testing for Salmonella

Each establishment that slaughters livestock or poultry or produces raw, ground meat or poultry products would be required to collect and test one specimen of product per day at the end of the production process. The specimen would be tested for the presence of *Salmonella* (the target organism). Testing could be conducted in the establishment's own laboratory or in a commercial/contract laboratory. Results of the testing would be recorded daily. Costs for this activity are estimated at \$91.1 million.

As a general matter, this approach to process control verification testing provides a very efficient means of determining whether a slaughter establishment is consistently achieving the interim target for pathogen reduction. Many slaughter establishments currently conduct voluntarily, for a variety of purposes, significantly more frequent microbiological testing, and for many establishments the cost of testing a single sample per species per day will be relatively small (approximately \$30-35 per sample) in relation to the volume of a day's production.

For some small FSIS-inspected establishments, however, microbiological testing may be entirely new, and the cost of testing will be more significant in relation to the volume of production. For example, some specialty slaughter plants may slaughter only a few head of livestock per day and may slaughter multiple species, thus requiring multiple tests, despite a low volume of production.

FSIS has considered the potential impact of its proposed microbiological testing requirement on small businesses. FSIS is considering alternatives to minimize the burden on small establishments while still achieving the goal of verifying that the establishment's process control is achieving the interim target for pathogen reduction.

One alternative would be to allow certain small establishments additional time to prepare for and begin testing. FSIS is proposing that testing begin 90 days after publication of the final rule. By extending this period for small establishments, such establishments would have additional time to prepare for the testing and to find an efficient means of accomplishing it. In addition, as the testing gets underway in most establishments and the demand for efficient testing increases, FSIS expects that the market will respond by producing increasingly economical test methods for use by establishment

personnel and increasingly low-cost laboratory services for establishments that choose to contract outside the establishment for microbiological testing.

Another alternative for reducing the cost burden on small establishments would be to require less than daily testing to verify process control. For example, every-other-day testing could reduce costs by half. This would extend the time required to detect that any establishment is not achieving the target and to begin corrective measures.

FSIS invites comment on whether special consideration should be given to small establishments to reduce the cost burden of testing and on the alternatives outlined above, as well as any other possible alternatives. FSIS is particularly interested in comment on the criteria that should govern eligibility for such special consideration. As discussed above, for the purpose of allowing small establishments the maximum 3-year period to comply with the proposed HACCP regulation, FSIS is proposing to define a "small" establishment as one with annual sales of \$2.5 million or below. FSIS invites comment on whether this would be the right criterion for any special relief regarding testing or whether an alternative criterion, such as the number of head or a different dollar volume of sales, should be used.

## Long-Term Requirement

#### Implementation of HACCP Systems

Establishments would be required to develop and implement HACCP systems. Costs to develop, implement, and monitor HACCP plans for small establishments are estimated to be \$157.6 million. FSIS has determined that it is reasonable to allow small establishments additional time to meet the proposed HACCP requirements. Therefore, small establishments would have 36 months from the publication date of the regulation to implement their HACCP plan(s).

## D. Paperwork Requirements

The paperwork requirements in the current proposal, namely records and plans, represent an alternative to the current process of inspection. The industry's documentation of its processes, first in a plan and thereafter in a continuous record of process performance, is a more effective food safety approach than the sporadic generating of information by an inspector. It gives inspectors a much broader picture of production than they can generate on their own and gives them time to perform higher priority