It is important to recognize that this approach to verifying process control in meat and poultry production is designed to assess the effectiveness of a system over time in relation to a specified target level of performance. It is not a means of evaluating and approving individual product lots. The assumptions of an in-control process and randomly selected specimens allow the performance assessment to be separated from production volume considerations.

A number of alternative statistical criteria were considered as the basis for the proposed moving sum procedures, ranging from an 80 to a 99 percent probability of meeting the limit if the process is operating at the target level. The following table shows these alternatives with their corresponding window sizes and Acceptable Limits for *Salmonella* positives. For reasons discussed below, the 80 percent probability was selected.

Probability of passing at target	Target	Window size (in days)	Accept- able limit
80	1	82	1
	4	38	2
	12	19	2 3 3
	15	15	
	18	17	4
	25	16	5
90	1	53	1
	4	28	2
	12	15	3
	15	12	3
	18	14	4
	25 1	15 36	5 1
95	4	21	ו ס
	12	12	2 3
	12	10	3
	18	12	4
	25	11	5
99	1	15	1
	4	12	2
	12		3
	15	8 7	2 3 3
	18	8	4
	25	9	5

The alternative procedures differ in the probability they give for not exceeding the moving sum limit when a production process is operating at the commodity target. These probabilities range from 80 to 99 percent.

There are at least four considerations involved in selecting a verification procedure: (1) Sampling and testing costs; (2) the nature of the penalties for failing the verification procedure; (3) having a low probability of exceeding verification limits when the producer is meeting the target; and (4) having a high probability of exceeding limits when the producer is not meeting the target. The procedures based on a 99 percent probability of not exceeding the moving sum limit at the target satisfy consideration (3), but do not satisfy consideration (4). Establishment personnel would be very limited in their ability to detect production processes not meeting the target.

There are two ways to improve the ability of the verification procedure to detect when the production process is not meeting the target. One is to increase the number of specimens required to be tested each day, and the other is to lower the probability of passing at the target. In view of the increase in costs to producers that a higher sampling rate would entail and the fact that failing the test does not condemn product (considerations (1) and (2)), FSIS selected the procedures based on an 80 percent probability of passing at the commodity target. The 80 percent probability was selected because it enhanced the chance of detecting marginal performers and provides establishments with an incentive to gear their process controls to achieve frequencies of Salmonella contamination well below the proposed interim targets. FSIS retains the discretion to not require remedial measures by establishments that demonstrate they were meeting the interim targets but exceeded the Acceptable Limits by chance.

To further evaluate the moving sum verification procedures, the Agency simulated their performance at percent positive levels greater than the interim target. As an example, the Agency looked at the distribution of the number of days from startup to the first exceedance of the AL for broilers (target of 25 percent) assuming a process percent positive rate of 30 percent. The first exceedance occurred within 22 days in 50 percent of the trials, and it occurred within 70 days in 95 percent of the trials. In other words, a process running at 30 percent positive rate (5 percent above the target of 25 percent) is very likely to be detected within no more than 70 days.

Under the proposed moving sum rules, an establishment operating just at the target would have approximately an 80 percent long-run probability of satisfying (not exceeding) the moving sum limit. Over the long term, the moving sum value will not exceed the AL about 80 percent of the days, assuming that the production process stays on target. The proposed rules also mean that an establishment operating just at the target has a 20 percent chance of exceeding the Acceptable Limit and triggering remedial action. This is consistent with the Agency's objective in establishing interim targets as a first

step toward holding establishments accountable for meeting acceptable levels of food safety performance, because, due to the variability in pathogen levels, establishments consistently operating at or just below the target are likely to exceed the target from time to time.

The selection of 80 percent as the criterion for establishing the proposed moving sum rules is intended to provide establishments with an incentive to design their process controls in a manner that will achieve pathogen reduction significantly below the designated interim target. As in any random sampling scheme, there is a chance of actually having positive results, even if the process is meeting the criteria. However, an establishment can decrease its probability of exceeding the AL (by chance alone) by targeting its process to produce product with a lower frequency of positive samples. For instance, the establishment could gear its process controls toward a 20 percent target as opposed to the 25 percent target specified for broilers. This would benefit the establishment by providing a greater assurance of not exceeding the AL, since its own target is lower than the designated one.

A document giving a more detailed explanation of the moving sum verification procedure will be made available by FSIS to those wishing more information on this aspect of the proposal. Requests should be sent to Assistant Deputy Administrator for Science, FSIS, U.S. Department of Agriculture, Washington, DC 20250. FSIS welcomes comments on alternative ways by which the Agency and establishments may ascertain how well process controls are achieving national target levels.

9. Establishment Action Required for Exceeding Target Limits

The establishment will have 90 days from the effective date of the rule to establish microbiological testing regimes. Six months from promulgation of the regulations establishments will be required to track these interim target results using a moving sum verification procedure and report the results to FSIS. Two years after promulgation of the rules, establishments that are not achieving the interim targets for pathogen reduction will be required to take corrective action under FSIS supervision. In such instances, a review by the establishment of its production practices and process controls is required. A written report of the evaluation, including any identified process failures and proposed corrective actions, would be submitted to the