

Commonly Asked Questions from Small and Very Small Plants on Statistical Process Control (1)

1. How can a small or very small establishment meet the requirement of 9 CFR 310.25 that requires establishments sponging carcasses to evaluate *E. coli* test results using statistical process control techniques showing at least the most recent 13 test results?

9 CFR 310.25(a)(2)(v)(A) states that very low volume establishments that collect samples by sponging should collect at least one sample per week, starting the first full week of operation after June 1 of each year. They should continue sampling at a minimum of once each week the establishment operates until June 1, or until 13 samples have been collected, whichever comes first.

Very low volume establishments annually slaughter:

- no more than 6,000 cattle or 20,000 swine
- a combination of cattle and swine not over 6,000 cattle and 20,000 of both types

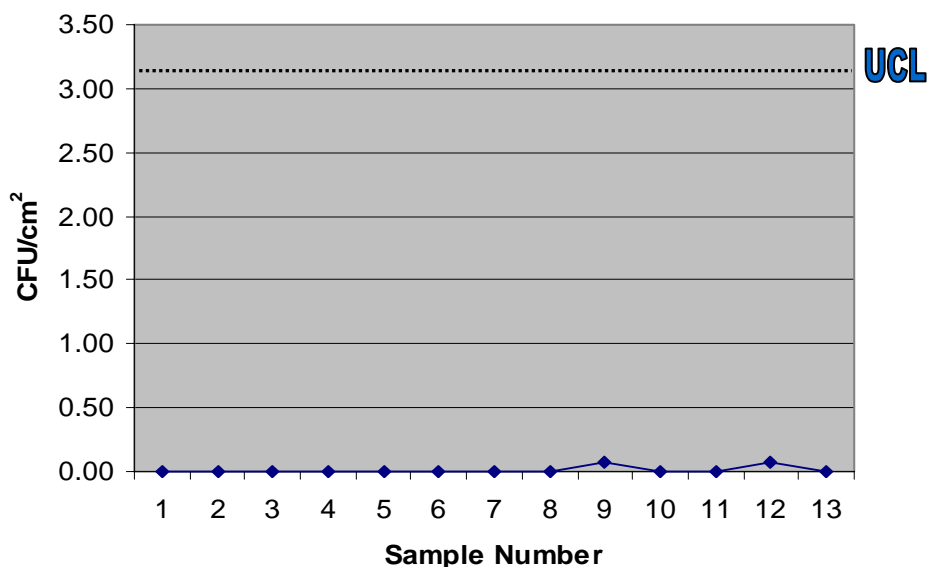
Establishments can meet the requirements of 9 CFR 310.25(a)(4) by recording the individual sample result on a Statistical Process Control (SPC) chart using 0.0 cfu/cm² as the lower control limit (LCL) and 3.1 cfu/cm² as the upper control limit (UCL).¹ The sampling should occur at the brisket, flank, and rump. The establishment plots its test results on a control chart and compares them to the UCL and LCL to evaluate process control. These limits are derived from baseline data collected by FSIS.

The following is a hypothetical example of charting test results using 0.0 cfu/cm² and 3.1 cfu/cm² in SPC.

Day 1.....0.00 cfu/cm ²	Day 8.....0.00 cfu/cm ²
Day 2.....0.00 cfu/cm ²	Day 9.....0.08 cfu/cm ²
Day 3.....0.00 cfu/cm ²	Day 10.....0.00 cfu/cm ²
Day 4.....0.00 cfu/cm ²	Day 11.....0.00 cfu/cm ²
Day 5.....0.00 cfu/cm ²	Day 12.....0.08 cfu/cm ²
Day 6.....0.00 cfu/cm ²	Day 13.....0.00 cfu/cm ²
Day 7.....0.00 cfu/cm ²	

¹ The baseline results from the *Nationwide Sponge Microbiological Baseline Data Collection Programs* for Young Chickens, Young Turkeys, Goose, Cattle, and Swine can be found at the following link (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/02-046N.pdf>), as published in the Federal Register (70 FR 8060, February 17, 2005).

SPC



Note: This chart was derived from baseline results.

EVALUATION OF PROCESS CONTROL:

For an establishment that uses this chart to meet the SPC regulatory requirements, the following evaluation criteria apply.

- No more than 3 sample results out of 13 are above 0.00.....Process is in control.
- More than 3 sample results out of 13 are above 0.00.....Process is out of control and the establishment should take action to bring it back into control.
- One sample result is above 3.1 cfu/cm².....Process is out of control and the establishment should take action to bring it back into control.

If an establishment collects more than 13 samples, the same evaluation criteria are used, but they are applied to a moving window of the last 13 samples.

Establishments can supplement the SPC process by taking additional sponge samples from points on the carcass other than the brisket, flank, and rump. These points may be areas where workers handle the carcass (e.g., touching the shank and/or loin in order to turn or pull the carcass for cleaning and observation). Persistent and consistent tracking of the microbiological results from these additional areas will provide a broader view about the microbiological profile resulting from routine sanitary dressing procedures. Microbiological assessments of organisms other than generic *E. coli* (e.g., aerobic plate count) that may be present more frequently and at a higher level than generic *E. coli* may provide helpful information about on-going controls.