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U.S. DEPARTMENT OF AGRICULTURE

Statistics and their role in evaluating an Establishments process control procedures




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Objectives:

-Define Statistical Process Control

-Define Upper (UCL)and Lower Control Limits (LCL)

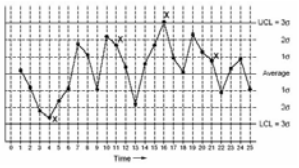
-Baseline Studies (Regulatory Requirements)

-Basic Statistics terms

-Process Standards (Chart use)

-Microbiological Sampling

-Evaluating Sampling Data

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Chapter 1- Statistical Control Definitions

A statistical control chart compares process performance data to computed "statistical control limits," drawn as limit lines on the chart. The process performance data usually consist of groups of measurements (rational subgroups) from the regular sequence of production while preserving the order of the data.

Mean, median, mode, and statistical variance are all measures of central tendency in statistics. In different ways they each tell us what value in a data set is typical or representative of the data set.

Control limits are used to detect whether the variation in a process we are observing is located within the expected limits

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Statistical Process Control (SPC)

- Statistical process control techniques are based on the principle that every product is produced by a process.
- All processes are subject to variation, which can be monitored and understood by statistical methods.
- A process that is in control is stable in terms of average level and degree of variation, meaning it is predictable within limits.

- Control is maintained by detecting and eliminating root causes of variation, that is, investigating causes of aberrant data points that are not always present or those not affecting all product output.

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Statistical Process Control (SPC) (cont.)

- Statistical process control initially involves evaluating data to determine process capability (the typical process performance level or baseline level).
- Then checking subsequent data to see whether they are consistent with this baseline level to ensure the process is in control and variations are within normal and acceptable limits.

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Upper and Lower Control Limits

- The upper control limit (UCL) and lower control limit (LCL), using SPC techniques, are boundaries used to depict a stable process.
- The UCL/LCL are calculated from the establishment's sampling data collected over time.
- The UCL/LCL show the expected limits or normal variation in the establishment's process and are typically depicted on a control chart.

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Upper and Lower Control Limits

- Many establishments may already have historical microbiological sampling data that must be used to set the UCL and LCL.
- If an establishment does not have historical sampling data, an establishment may choose to use the values cited in the FSIS baseline study, FSIS data resources, and FSIS guidance documents for its own control limit values until it has sufficient data to conduct its own SPC evaluation.
- Once the establishment collects sufficient data, FSIS baseline data are no longer the sole data source, instead, the establishment must use the data collected from its own sampling programs to conduct SPC analysis.

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Baseline Studies

- FSIS published in the Feb 17, 2005 Federal Register Notice (70 FR 8058), "Generic E. coli and Salmonella Baseline Results," using FSIS baseline study data.
- FSIS made these baseline results available for establishments to supplement or support an establishment's process control efforts in tandem with SPC to help define when a process may be out of control.
- The baseline data are for use as guidance to establishments and do not replace the criteria and standards incorporated in the regulations.

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Statistical Process Control
Some basic terms

Mean (often called the Average)
- The sum of the values divided by the number of values
- 3,5,6,8,10 5 values 3+5+6+8+10/5 = 32/5 = 6.4

Median
- The middle value of the dataset after ordering the dataset by size
- Splits the data into two equally-sized groups
- 3,5,6,8,10 The median value is 6

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Statistical Process Control
Some basic terms

Mode

- The value that occurs most frequently
  In our data set 3,5,6,8,10, the mode would not be useful, as no value appears more than the others.
- Let's use this data set: 1, 2, 3, 5, 3, 7, 3, 6 3 is the value (mode) that occurs most frequently.

Standard Deviation

- Measure of how much (spread) = (Control Limits) from the **Mean (average)** exists in a dataset
- Here is the equ tandard Deviation (SD):

$$\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$$

σ : Population standard deviation
x : Datapoint value
μ : Population mean
N : Population size

The following slides have an example on how to calculate the SD.

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Let's use the sample set from previous calculations:
3,5,6,8,10

Step 1: Finding the mean
3+5+6+8+10/5 = 32/5 = 6.4

Step 2: Finding (x-μ²)
Complete table below.

$$\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$$

σ : Population standard deviation
x : Datapoint value
μ : Population mean
N : Population size

Data Point	Distance from mean	Square of distance from mean	
3	3-6.4= -2.6	$(-2.6)^2$ =	6.76
5	5-6.4=-1.4	$(-1.4)^2$ =	1.96
6	6-6.4=-0.4	$(-0.4)^2$ =	0.16
8	8-6.4=1.6	$(1.6)^2$ =	2.56
10	10-6.4=3.6	$(3.6)^2$ =	12.96

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Step 3: Finding the sum of $(x-\mu)^2$

The symbol ∑ means "sum", so in this step we add up the five values we found in Step 2.

6.76 +1.96 + 0.16 + 2.56 + 12.96 = 35.84

Step 4: In this step, we divide our result from Step 3 by the variable N, which is the number of data points. (We have 5 data points)

35.84/5 = 7.168 (round to 7.17)

Step 5: Just take the square root of the answer from Step 4 and we're done.

$\sqrt{7.17}$ = 2.677 (round to 2.68)
The Standard Deviation from the mean of our data is 2.68

$$\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$$

σ : Population standard deviation
x : Datapoint value
μ : Population mean
N : Population size

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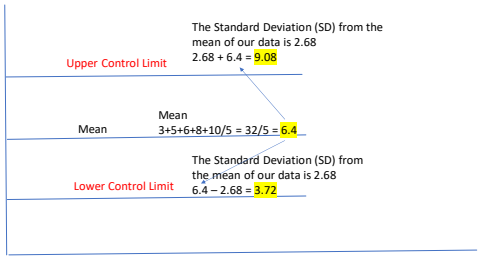

Here is the Statistical Control Chart using the SD to calculate the Upper Control Limit (UCL) and the Lower Control Limit (LCL). Data inside those limits would show process control!

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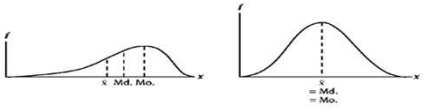
Statistical Process Control
Some basic terms

Why do we need different measures?

The shape of the data can be skewed, could have outliers or multiple modes.



The data on the right could be represented by either the mean, median or mode, but the skew on the left dataset makes the median a better choice

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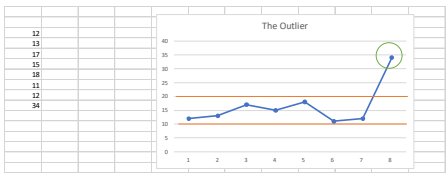
Statistical Process Control
Some basic terms-Outliers

An outlier is a data point in a data set that is distant from all other observations. A data point that lies outside the overall distribution of the dataset. Or in a layman term, we can say, an outlier is something that behaves differently from the combination/collection of the data.



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Statistical Process Control
Some basic terms–Outliers

Ex:
Suppose we had seven values of
5, 4, 5, 6, 7, 5, 17. Then, the mean is

(5+4+5+6+7+5+**17**)/7=**49**/7=**7**

However, the median and the mode of this set are still 5.
For this dataset, they would be better indicators of the central tendency than the mean.
Here, 17 is what we call an outlier

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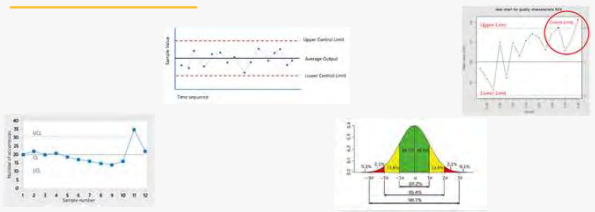
Chapter 2- Statistical Control Charts



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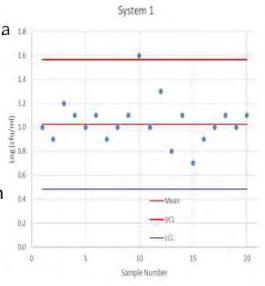
Statistical Process Control
Process Control Charts

Process control charts (Shewhart charts) are a statistical process control tool used to study how a process changes over time
-A control chart will have
a central line for the mean
an upper control limit (UCL) line
a lower control limit (LCL) line
-These values and lines are determined from historical data.

You can draw conclusions about whether a process is in control or not by comparing current data to these lines.



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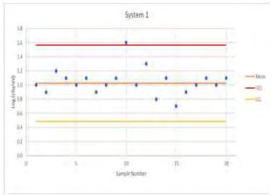
Statistical Process Control
Process Control Charts-Using Excel Data

Sample Numbe	Log (cfu/ml)	Mean	UCL	LCL
1	1.0	1.03	1.57	0.48
2	0.9	1.03	1.57	0.48
3	1.2	1.03	1.57	0.48
4	1.1	1.03	1.57	0.48
5	1.0	1.03	1.57	0.48
6	1.1	1.03	1.57	0.48
7	0.7	1.03	1.57	0.48
8	0.9	1.03	1.57	0.48
9	1.1	1.03	1.57	0.48
10	1.4	1.03	1.57	0.48
11	1.0	1.03	1.57	0.48
12	1.3	1.03	1.57	0.48
13	0.8	1.03	1.57	0.48
14	1.1	1.03	1.57	0.48
15	0.7	1.03	1.57	0.48
16	0.9	1.03	1.57	0.48
17	1.0	1.03	1.57	0.48
18	1.1	1.03	1.57	0.48
19	1.0	1.03	1.57	0.48
20	1.2	1.03	1.57	0.48



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Statistical Process Control
Data use

- A value of zero is not meaningful because in a microbiological context it means it is below the limit of detection.
- Meaningful data will allow enumeration and enumeration allows an establishment to plot these data on a process control chart and monitor trends in its data and process over time.
- The more quantifiable microbiological data available to an establishment, the better it can assess and subsequently control variations in its process.

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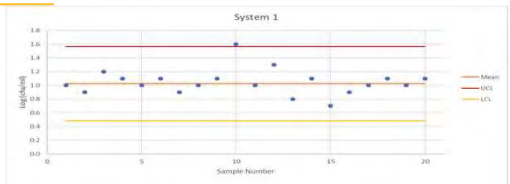
Statistical Process Control
Process Control Charts



- The control chart for System 1 depicts a pattern of test results that would be seen in a well-controlled system.
- In a well-controlled system, the majority of test results will be clustered around a central value.
- Note: Even in a well-controlled system, there is some frequency of isolated results above the acceptable level

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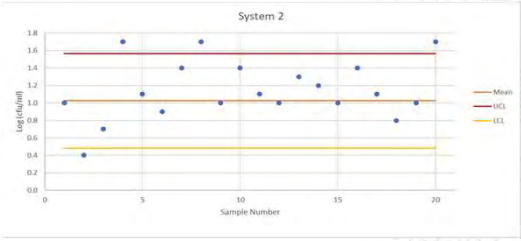
Statistical Process Control
Process Control Charts



What are your thoughts regarding this System?

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Statistical Process Control
Process Control Charts

- This chart depicts a loss of process control due to excess variability. This is reflected in both an increased number of results above the UCL, and an increase in scatter points directly below it as well.
- This chart suggests either a loss of control at a critical control point or the existence of another critical control point that had not been identified and controlled.

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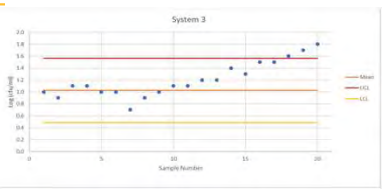
Statistical Process Control
Process Control Charts



- This chart depicts a situation where a component of the process is losing its effectiveness over time.
- The loss of process control is apparent by the upward trend in the data points toward the UCL.

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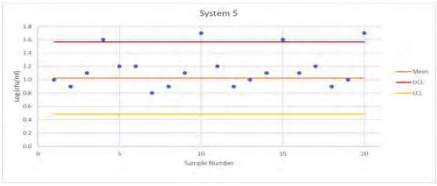
Statistical Process Control
Process Control Charts



- This chart depicts conditions where there is the existence of an intermittent but reoccurring problem within the process. Note the repeating pattern of the test results over time.
- An example of a situation where this pattern may be observed is the dripping of condensation onto product as it travels down a conveyor belt.

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Statistical Process Control
Corrective Actions

- SPC principles require corrective action when sample results reach a certain threshold, such as the UCL, which is often three standard deviations above the running mean average.
- The establishment should consider trends in data within operations and assess the root cause of these changes.

- Randomness can be observed in the results, establishments may consider if an outlier is observed by performing a root cause analysis.
- It is not advisable that an establishment raise its UCL in response to upward trends or outliers in its sampling data since its UCL was initially calculated based on its process being in control.

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Chapter 3- Sampling and Process Control

An establishment employee selects the samples for generic E. coli testing. The purpose of generic E. coli testing is to verify the effectiveness of sanitation and process control in slaughter establishments.

Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys.

Establishments that slaughter livestock and poultry are required under the regulations to collect microbiological samples for indicator organisms

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Statistical Process Control Microbiological Sampling

- Generic E. coli Testing for Livestock, (other than swine)
- Each official establishment that slaughters livestock, other than swine, or ratites is required to test for Escherichia coli Biotype I, also known as "generic E. coli."
- An establishment employee selects the samples for generic E. coli testing. The purpose of generic E. coli testing is to verify the effectiveness of sanitation and process control in slaughter establishments.
- FSIS verifies that the establishment meets the regulatory requirements for generic E. coli testing

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Performance Standards

- Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys.
- Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.

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Statistical Process Control Microbiological Sampling

- Fecal contamination is one of the principal sources of pathogenic organisms that contaminate livestock carcasses.
- Generic E. coli is an indicator of fecal contamination because it is common in the intestinal tract of food animals. The intestinal tract is also the primary pathway for contamination of carcasses with pathogens such as E. coli O157:H7, and Salmonella.
- Ongoing E. coli testing by livestock slaughter establishments helps them determine whether the slaughter process is under control or whether carcasses are being contaminated with feces.

In other words, generic E. coli testing is a process control indicator for fecal contamination.

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Chapter 4-Regulatory Requirements

- When an establishment is collecting microbiolc samples to meet the regulatory requirements,
- How can the establishment use its test results t and refine its control limits to evaluate its resul process control?

- Establishments that slaughter livestock and po required under the regulations to collect micro samples for indicator organisms, as specified:

- 9 CFR 310.25 for cattle, sheep, goat;
- 9 CFR 310.18(c) for swine;
- 9 CFR 381.65(g) for poultry; and
- 9 CFR 381.94(a) for ratites

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Regulatory Requirements (cont.)

- An establishment must apply SPC principles to analyze trends in its own sampling data over time to assess its process, with the intention of optimizing its process control. SPC is required for establishments that sponge cattle, sheep, and goat (9 CFR 310.25) and for ratites (9 CFR 381.94(a)).

- Part of this evaluation is to evaluate, at some frequency, whether the defined control limits used are still appropriate, based on the application of SPC principles to an analysis of the establishment's own sampling results.

Sampling Requirements to Demonstrate Process Control in Slaughter Operations
https://www.fsis.usda.gov/sites/default/files/media_file/2021-11/19_HQ-Sampling-Requirements-Process-Control-Slaughter-Operations-03302020.pdf

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Microbiological Sampling

- An establishment's written sampling program must include a description of how the establishment evaluates its own sampling test results to determine if it is maintaining process control sufficient to prevent contamination with enteric organisms.

- This evaluation involves the use of statistical process control (SPC) techniques to calculate control limits that are used to determine whether the sampling results show the establishment's process is in (or out of) control.

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Sampling Regulatory Requirements

Establishments that slaughter livestock and poultry are required under the regulations to collect microbiological samples for indicator organisms, as specified:

- 9 CFR 310.25 for cattle, sheep, goat;
- 9 CFR 310.18(c) for swine;
- 9 CFR 381.65(g) for poultry; and
- 9 CFR 381.94(a) for ratites.

https://www.ecfr.gov/current/title-9/chapter-III

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9 CFR 310.25 for cattle, sheep, goat

310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.
(a) Criteria for verifying process control; E. coli testing. (1) Each official establishment that slaughters livestock must test for Escherichia coli Biotype 1 (E.coli) Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;
(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and
(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

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9 CFR 310.25 for cattle, sheep, goat

310.25 (5)
Criteria for evaluation of results,

An establishment excising samples from carcasses is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

Type of livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested	Maximum number permitted in marginal range (c)
Cattle	Negative*	100 CFU/cm²	13	3

Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 CFU/cm 2 carcass surface area.

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9 CFR 310.25 for cattle, sheep, goat

Establishments sponging carcasses shall evaluate E. coli test results using statistical process control techniques.

(6) **Failure to meet criteria**. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) **Failure to test and record**. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a) (1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

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9 CFR 310.25 for cattle, sheep, goat

Raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 1 to this paragraph:

Table 1 to paragraph (b)(1) - Salmonella Performance Standards

Class of Product	Performance Standard (percent (%) positive for Salmonella	Number of Samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1%	82	1
Cows/Bulls	2.7%	58	2
Ground Beef	7.5%	53	5

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9 CFR 310.25 for cattle, sheep, goat

- FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard.
- The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance.
- In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.

Further information on Pathogen Reduction:

https://www.sciencedirect.com/science/article/pii/S0749072015302863

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9 CFR 310.25 for cattle, sheep, goat

Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

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Sampling Regulatory Requirements

Let's briefly look at the sampling requirements for :

9 CFR 310.18(c) for swine;

9 CFR 381.65(g) for poultry; and

9 CFR 381.94(a) for ratites.

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9 CFR 310.18 (Swine Slaughter)

Official swine slaughter establishments, except for very low-volume establishments, must collect and analyze carcass samples for microbial organisms at the pre-evisceration and post-chill points in the process. Establishments that slaughter more than one type of livestock must test the type of livestock slaughtered in the greatest number. Establishments that bone their products before chilling (i.e., hot-boned products) must collect and analyze samples at the pre-evisceration point in the process and after the final wash instead of at post-chill. Very low-volume establishments must collect and analyze samples for microbial organisms at the post-chill point in the process. All swine establishments must sponge or excise tissue from the ham, belly, and jowl areas.

(i) Very low-volume establishments annually slaughter no more than 20,000 swine, or a combination of swine and other livestock not exceeding 6,000 cattle and 20,000 total of all livestock.

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9 CFR 381.65 (g) (Poultry)

Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements in paragraphs (g)(1) and (2) of this section to monitor their ability to maintain process control.

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9 CFR 381.65 (g) (Poultry)

Sampling locations. Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process.

(i) Very small establishments are establishments with fewer than 10 employees or annual sales of less than $2.5 million.

(ii) Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs.

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9 CFR 381.94 (a) -Ratites

Each official establishment that slaughters ratites shall test for Escherichia coli Biotype I (E. coli). Establishments that slaughter ratites and livestock, shall test the type of ratites or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) (ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) (iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

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Statistical Process Control (generic E. coli)

- Statistical Process Control (SPC) for generic E. coli is required with products that were not represented by the PR/HACCP Rule by a performance standard, because no relevant baseline studies were available at the time.
- The generic E.coli results published in the Federal Register Notice (2005) can complement SPC by providing establishments with an additional measure of process control.

https://www.govinfo.gov/content/pkg/FR-2005-02-17/pdf/05-3030.pdf

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Chapter 5- Sample Analysis

- FSIS has developed performance criteria for beef using the excision sampling technique.
- Generic E. coli performance criteria are not enforceable regulatory standards.
- Performance criteria are numbers published in the regulations that represent the highest expected microbial loads on carcasses when the slaughter process is under control.
- They give livestock slaughter establishments guidance about the effectiveness of their slaughter process in preventing fecal contamination.
- Test results that meet the criteria in the regulations provide evidence that the establishment is maintaining adequate process control for fecal contamination and sanitary dressing.

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Statistical Process Control Sample Analysis

- Some establishments conduct their own analyses. FSIS assumes establishments following the "Guidelines for E. coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments" will conduct their sampling in a manner that does not jeopardize the integrity of the sample or the reliability of the test results.
- https://www.fsis.usda.gov/sites/default/files/import/Guideline_for_Ecoli_Testing_Cattle_Swine_Estab.pdf
- Because these guidelines are not regulatory requirements, the establishment may choose to use a comparable sampling technique.
- Establishment laboratory employees might have a copy of the Association of Official Analytical Chemists (AOAC) procedures or articles from peer-reviewed scientific journals that describe their procedure.

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Statistical Process Control

An example of a method a company may use to develop a SPC program is as follows.

The establishment:
- Conducts a series of preliminary generic E. coli tests during operations
- Charts the results in CfU/cm2
- Collects test results long enough to have a true picture of its performance (about 30 days usually)
- Determines the typical range of generic E. coli counts found normally
- Sets upper and lower control limits based on test results

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Verifying Statistical Process Contro

EIAO are to verify that the establishment is evaluating the test results using statistical process control techniques.

In this context, EIAO are to verify that an establishment that uses statistical process control has assessed the historical
—normal performance of the slaughter process when it was in control and developed criteria that will indicate when the process may not be in control.

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Verifying Statistical Process Control

EIAO are to verify that the establishment uses generic E. coli testing results to identify times when the slaughter process is trending toward a loss of control and takes necessary actions to reestablish control.

EIAO are not to focus on the particular method the establishment uses to set process control criteria.

Instead, they are to review the generic E. coli testing results and verify that the establishment has set generic E. coli criteria to define process control and responds to results outside those criteria

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Statistical Process Control Chart example

- The following slide example of a SPC chart plots test results in terms of test number, along the horizontal X-axis, against cfu/cm2 on the Y-axis. This livestock slaughter establishment set a centerline value for its process control, which indicates the center point of the acceptable range of test results.
- The upper control limit (UCL) line marks the highest test result value considered acceptable by the company. The test result shown at test **number 6** is above the upper control limit.
- The company recognized that this result was probably due to a variation in its process that needed to be identified, eliminated, and prevented from recurring.
- According to the chart, the establishment measures were effective because the following test result was back in the acceptable range.

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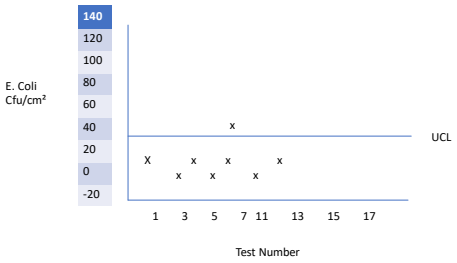
Statistical Process Control (E. coli Control Chart)



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Using Regulatory Performance Criteria (m/M Values) to Evaluate Test Results

- Cattle establishments that choose excision of three sites must use the m/M performance criteria published in the regulations for evaluating test results when they are available.
- Regulatory m/M criteria apply only to cattle sampling when the excision sampling technique is used.
- When performance criteria are published in the regulations, the E. coli test results are compared to the regulatory criteria and
- may fall into one of three categories: acceptable, marginal (represented by “m”), and unacceptable (represented by “M”).

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Using Regulatory Performance Criteria (m/M Values) to Evaluate Test Results

Marginal results ("m") are those that fall within the worst 20% of overall industry performance in terms of E. coli counts (results taken from baseline study).

More than three marginal results in the last 13 tests are unacceptable.

• Results in the worst 2% of overall industry performance (results taken from the baseline study) are called the maximum or "M" value. Any single
test result exceeding "M" is unacceptable.

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Using Regulatory Performance Criteria (m/M Values) to Evaluate Test Results

- The m/M values taken from the regulations are applied to a moving window of the last 13-documented test results.
- That means that the establishment considers all of the last 13 test results when determining if the process is in control.
- Every time a new test result is added to their records, the oldest test is dropped, and the new test becomes one of the most recent 13 results.
- For the slaughter process to be judged in control no more than three sample results can be above the "m" marginal line. If four sample results are above "m", the process is out of control.

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Using Regulatory Performance Criteria (m/M Values) to Evaluate Test Results

The following table from the regulations shows the m/M values for E. coli performance criteria set by the Agency for excision testing of cattle.

Species	Lower Limit of marginal range (m)	Upper Limit of marginal range (M)	Number of sample tested (n)	Maximum # permitted in marginal range (c)
Cattle	Negative	100 CFU/cm²	13	3

An example of how to use the table is to consider a cattle slaughter establishment that uses the excision sampling method. An E. coli test result is:
• Acceptable if it comes back negative
• Marginal if the test result is positive but not above 100 Cfu/cm2
• Unacceptable if it is above 100 Cfu/cm2

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Chapter 6-FSA Questions/Scenarios

The following scenarios are developed to help the EIAO answer questions in the FSA tools using statistics to show process control.

You will be asked to answer some questions using the data provided to you.

For example:

General FSA Tool:

G5 Decision Making Analysis (1 to 2 pages) Provide an overall analysis of the FSA findings and the thought process used to arrive at the FSA recommendation. **The support for the recommendation is derived from the sampling results** (including the results from RLm, IVT, or IIT sampling), PHRE, in-plant observations, and the HACCP system design and implementation documented in the tools.

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Scenario 1

The EIAO has been assigned to perform an FSA at a Red Meat (Cattle) Slaughter establishment.
Using 9 CFR 310.25 (5)…

The establishment is excising samples from carcasses to determine if it is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

Sample #	1	2	3	4	5	6	7	8	9	10	11	12	13	

QUESTION
FSA Meat Tool: M8 -Considering all source materials used (i.e., self-supply through slaughter and outside source materials) and products produced (i.e., non-intact beef and non-intact beef components), does the establishment have measures in place to support that STEC has been reduced to below detectable levels and is a hazard "not reasonably likely to occur?"

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Scenario 1-Discussion

Using 9 CFR 310.25 (5):Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

Noting that samples 5, 7, 8, and 11 (4) are above the Upper Limit of 100 CFUs/cm^2, what would be your response to the question…

Does the establishment have measures in place to support that STEC has been reduced to below detectable levels and is a hazard "not reasonably likely to occur?

Use the chart from the regulations to make your determination.

Species	Lower Limit of marginal range (m)	Upper Limit of marginal range (M)	Number of sample tested (n)	Maximum # permitted in marginal range (c)
Cattle	Negative	100 CFU/cm^2	13	3

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Scenario 2

The EIAO has been assigned to perform an FSA at a Poultry Slaughter establishment.
Using 9 CFR 381.65 (g))…

Sampling locations.
Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process.

Poultry FSA Tool

Sampling and Testing for Process Control Organisms

P62 Does the establishment conduct sampling and testing for process control organisms? (NOTE: poultry slaughter establishments are required to sample process control organisms, see Modernization of Poultry Slaughter Inspection Final Rule for requirements 9 CFR 381.65 (g)?

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Scenario 2

Information gathered by the EIAO when reviewing establishment records and discussion with management:

-EIAO review of the establishment pre-requisite program titled WOG Rinse, showed that the establishment performs the sampling frequency equivalent to the regulatory frequency. One sample is taken per 22,000 birds as was observed during the FSA. WOG Rinse Records reviewed also showed this.

-EIAO review of the establishment's sampling plan for generic E.coli showed that establishment uses the regulatory sampling procedure and testing method. Direct observation of this sampling procedure showed that the establishment is utilizing the regulatory sampling plan.

-EIAO review of the establishment generic E.coli testing results showed that over the past 60 days the establishment has routinely met their limits as determined by m/M.

-EIAO conversation with establishment management showed that any unacceptable events or trends associated with the generic E.coli testing results will prompt a further evaluation to determine whether or not action is required. No positives above the regulatory levels in the last six months.

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Scenario 2- Discussion

- Does the establishment conduct sampling and testing for process control organisms? (NOTE: poultry slaughter establishments are required to sample process control organisms, see Modernization of Poultry Slaughter Inspection Final Rule for requirements 9 CFR 381.65 (g)?
- Using the data provided, what would be the support for your answer to the question?

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Statistical Process Control Determination Workshop

In this workshop, you will be tasked to determine if an establishments sampling program is "in control."

You will be given data that the establishment has collected from their Generic E.coli sampling program.

You will need to create a Statistical Process Control Chart. Use the data to determine the mean (m) and the Standard Deviation (SD) from the mean to determine the Upper and Lower control limits (UCL/LCL).

Mean: The sum of the values divided by the number (N) of values.

Standard Deviation:

$$\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$$

σ : Population standard deviation
x : Datapoint value
μ : Population mean
N : Population size

See next slide for data

Cattle
Negative
100 CFU/cm²
13
4

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Sample #	1	2	3	4	5	6	7	8	9	10	11	12	13
CFU/cm²	50	66	109	76	111	65	78	65	132	88	65	121	66

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Workshop Answer Key

Step 1-Calculate the Mean (m):

50+66+109+76+111+65+78+65+132+88+65+121+66 / 13 = 1092 / 13 = 84 (Mean)

84 is the value we will use to calculate the Standard Deviation from the value

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Step 2: Finding (x-μ²) Mean=84
Complete table below.

Data Point	Dis6tance From Mean	Square of Distance from Mean	
50	50-84 = (-34)	$(-34)^2$ =	1156
66	66-84 = (-18)	$(-18)^2$ =	324
109	109-84 = (25)	$(25)^2$ =	625
76	76-84 = (-9)	$(-9)^2$ =	81
111	111-84 = (27)	$(27)^2$ =	729
65	65-84 = (-19)	$(-19)^2$ =	361
78	76-84 = (-8)	$(-8)^2$ =	64
65	65-84 = (-19)	$(-19)^2$ =	361
132	132-84 = (48)	$(48)^2$ =	2304
88	88-84 = (-4)	$(-4)^2$ =	16
65	65-84 = (-19)	$(-19)^2$ =	361
121	121-84 = (37)	$(37)^2$ =	1369
66	66-84 = (-18)	$(-18)^2$ =	324

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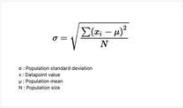
Step 3: Finding the sum of $(x-\mu)^2$

The symbol ∑ means "sum", so in this step we add up the five values we found in Step 2.

1156
324
625
81
729
361
64
361
2304
16
361
1369
324



8075 is the sum of the 13 values

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Step 4: In this step, we divide our result from Step 3 by the variable N, which is the number of data points. (We have 13 data points)

8075 / 13 = 621.15

Step 5: Just take the square root of the answer from Step 4 and we're done.

√621.15 = 24.92

The Standard Deviation from the mean of our data is 24.92

84 – 24.92 = 59.08 Lower Limit

24.92 + 84 =108.92 Upper Limit

Now we can place our values on the chart using the Mean and Upper and Lower Control Limits

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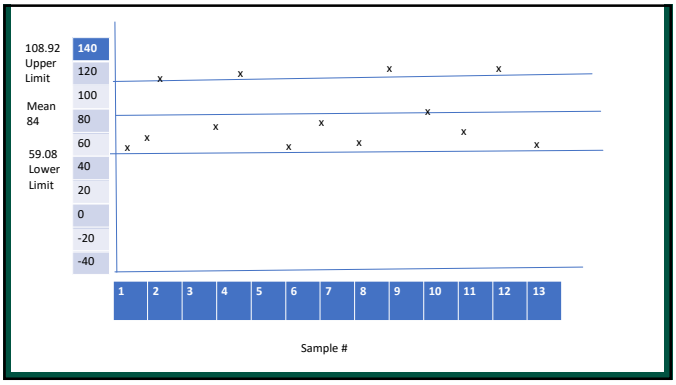

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Process Control Determination

Since 4 data points are above the Upper Limit of 108.9

established by the Standard Deviation from the mean…

109
111
132
121

For the slaughter process to be judged in control no more than three sample results can be above the "m" marginal line. If four sample results are above "m", the process is out of control.

It could be determined that this process is out of control

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