**Worksheet 2: QC Investigation 907\***

Analyte Under Investigation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Instrument XYZ Chemistry Analyzer Date June 20XX

Controls Affected: Level 1\_\_\_\_\_\_\_\_ Level 2 \_\_\_\_\_\_\_\_\_\_\_ Level 3 \_\_\_\_\_\_\_\_\_\_ Other \_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1:2S | 1:2.5S | 1:3S | 1:4S | (Random or Systematic) |
| 2:2S | 4:1S | 10x | 3:1s | (Systematic) |
| R:4S |  |  |  | (Random) |

QC Flags:

The change began: suddenly\_\_\_\_ or gradually\_\_\_\_ at run#\_\_\_\_ on date \_\_\_/\_\_\_/\_\_\_.

Recent data are distributed: above\_\_\_\_ below\_\_\_\_ or evenly about\_\_\_\_ the mean.

The % of data prior to the change within ±1 SD is: approximately 68%\_\_\_\_ < 68%\_\_\_\_ > 68%\_\_\_\_

A new lot number of reagent was started at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

A new bottle of reagent was started at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

A new lot number of calibrator was started at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

A new bottle of calibrator was started at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

A new box of controls was started at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

A new bottle of control was started at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

Instrument maintenance occurred at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

A change in the analytical process occurred at run #\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_

Other test(s) affected:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| Instrument | Wavelength | Reagent | Calibrator |
| Dispenser | Test Principle | Supply Shipment | Other: |

The common denominator is:

**Information**:

The QC chart mean is assigned: Correctly\_\_\_\_ Too high\_\_\_\_ Too Low\_\_\_\_

The QC chart SD is assigned: Correctly\_\_\_\_ Too high\_\_\_\_ Too Low\_\_\_\_

Probable error type is: Systematic\_\_\_\_ Random\_\_\_\_ Either Random or Systematic\_\_\_\_

Patient results may be erroneously: High\_\_\_\_ Low\_\_\_\_ Imprecise\_\_\_\_

The change in method accuracy\_\_\_\_ or precision\_\_\_\_

 Coincides with a change in: Reagent\_\_\_\_ Calibration\_\_\_\_ Instrumentation\_\_\_\_ Controls\_\_\_\_ Process\_\_\_\_

**Action:**

Repeat Controls\_\_\_\_(and All patient samples\_\_\_\_or Borderline patient samples\_\_\_\_) with:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Fresh Reagent | New Lot of Reagent | Fresh Calibrator | New Lot of Calibrator | Fresh Controls | Alternate Controls |

Clean or maintain instrument\_\_\_\_ Arrange instrument service from manufacturer\_\_\_\_

Consult with supervisor, director, or technical specialist\_\_\_\_ Temporarily discontinue reporting patient results\_\_\_\_\_

Refer patient samples to another laboratory\_\_\_\_ Assess current mean and SD against target and TEa\_\_\_\_

If change not corrected with action above and TE<TEa, re-assign QC chart mean \_\_\_\_\_ SD\_\_\_\_\_

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigation performed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_**

**\*Worksheet Template from Brooks, Zoe (2001) Performance-Driven Quality Control, p180**