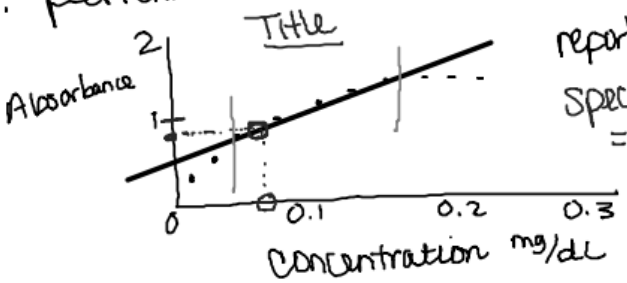
9/15 Quality Assurance Cont'd

Performing a Calibration

1. prepare a reagent blank (pure reagent, used to set zero analyte reading) and method blank (generally DI water, used to verify 100%T or zero base reading)
2. prepare all calibrators (standards) & run as directed
3. Record values from calibration
4. Analyze data for signal validity (compare to expected values)
   * 2SD from perfect to be ok.
5. perform calibration curve



reportable range: 0.04 mg/dL to 0.16 mg/dL

Specimen reading was 0.8 absorbance
= 0.06 mg/dL

The range can be described as one of two types:

- linear range: the concentration range in which the calibration curve is linear – indicating the method's sensitivity remains constant.
- dynamic range: the concentration range over which there is a measurable response and the sensitivity is a function of the analytes concentration.

Determining the range allows limits to be set for the method.

Minimum Detectable Concentration: the low end of the range
values below this are reported as < min. det. conc or "non-detected"

Maximum Detectable Concentration: the upper end of the range
values above are reported as > max det. conc

What if the value is outside the acceptable range?

① too high: dilute the specimen (run multiple times)

② too low: spike the specimen with known standards

Example: Spec + 1.0 mg/dL standard → reading 1.02 mg/dL
Spec + 2.0 mg/dL standard → reading 2.02 mg/dL
Spec + 4.0 mg/dL standard → reading 4.02 mg/dL

you can deduce that specimen is 0.02 mg/dL

Accuracy = how close you are to the actual (known) value

$$100 \times \frac{\text{mean value} - \text{known value}}{\text{known value}}$$

Precision = how close the values are to each other, repeatability
consistancy

$$100 \times \frac{\text{standard deviation}}{\text{mean}} \approx \text{coefficient of variation}$$

Evaluation of Data (Stats)

A variable: attribute that describes something and can vary between one item & another

Discrete: a quantitative variable that is not locked into a range, but may have defined terms
whole #, integer, fraction

Continuous: a quantitative variable that must exist within a set range of values.

Population = entire set of data (N)

Sample = consists of observations drawn from the population (n)

μ = mean of the population $\quad \mu = \frac{\sum x}{N}$

$\bar{x}$ = mean of the sample $\quad \bar{x} = \frac{\sum x}{n}$

Gaussian Distribution (Bell curve)

Range = max value − min. value

variance: $\quad s^2 = \frac{[\sum (x-\bar{x})^2]}{(n-1)}$

Standard deviation: $\quad S = \sqrt{\frac{\sum_i^n (x_i-\bar{x})^2}{(n-1)}}$

<u>Empirical Rule</u> (only applies to bell-shaped curves)

68.3% of the observations lie w/in 1SD of the mean
95.5% of the observations lie w/in 2SD of the mean
99.7% of the observations lie w/in 3SD of the mean

Confidence interval (t) = range of values that have the probability of finding true mean (μ).

$\mu = \bar{x} \pm \frac{t \cdot s}{\sqrt{n}}$ where t is found using degree's of freedom ($n-1$) and confidence level.