

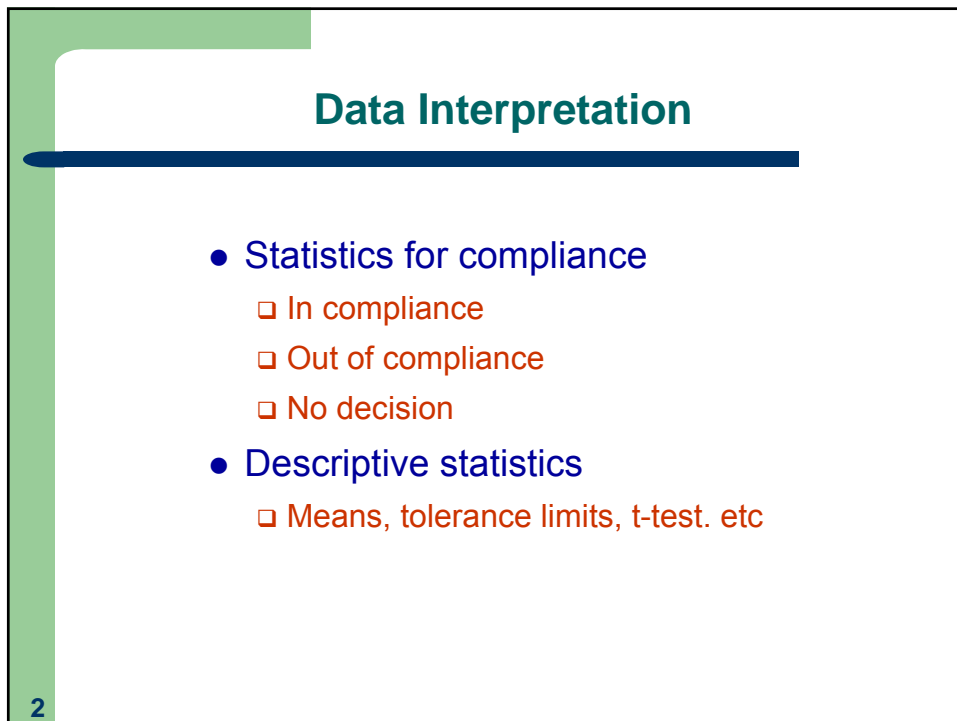
Compliance statistics
IH&S 725

Lecture Notes

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This slide features a green decorative shape on the left side. The title 'Compliance statistics' is in bold blue text, with 'IH&S 725' below it. 'Lecture Notes' is in green text. A dark blue horizontal bar is positioned below the title. The authors' names are listed at the bottom right, and the number '1' is in the bottom left corner.



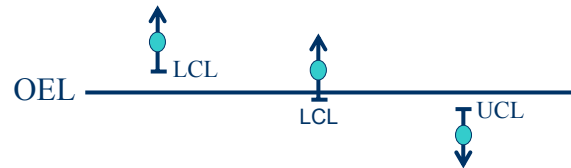
Data Interpretation

- Statistics for compliance
 - In compliance
 - Out of compliance
 - No decision
- Descriptive statistics
 - Means, tolerance limits, t-test. etc

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This slide has a green decorative shape on the left. The title 'Data Interpretation' is in bold green text, underlined with a dark blue bar. The content consists of two main bullet points in blue, each with three sub-bullets in orange. The number '2' is in the bottom left corner.

Compliance and Non-compliance



- ❑ If the LCL is above the OEL decide out of compliance.
- ❑ If the UCL is below the OEL decide not out of compliance.
- ❑ In all other cases decision depends on policies regarding uncertainty.

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Approaches to the compliance decisions

- Classical confidence interval approach
- NIOSH “standardized concentration” approach with CV_T
- OSHA “standardized concentration” approach with SAE – standard analytical errors

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Compliance Decisions - Continued

- Actually is a confidence interval of a single sample or a consecutive series of samples.
- Based on variability of sampling pump and the analytical method.
 - Sampling and Analytical Error (SAE)
- Does not consider representativeness (varying concentration levels), except for cases where a single day's sampling is divided into multiple time periods.
- $SAE = Z\text{-value} \times CV_T$
 - E.g., $SAE = 1.645 \times 0.076 = 0.125$
 - Z based on 95% single-sided
 - Use Z instead of T since supposed based on large numbers of trials

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Determining the SAE for an analytical method

- For OSHA methods, see:
 - Chemical Sampling Information page on the OSHA web site:
 - http://www.osha-slc.gov/dts/chemicalsampling/toc/toc_chemsamp.html
- For NIOSH methods
 - Based on overall precision (SrT)
 - NIOSH Manual of Analytical Methods:
 - <http://www.cdc.gov/niosh/nmam/nmammenu.html>.
 - The SAE must be calculated by multiplying the by the statistical constant 1.645.
Example: NIOSH Method 7500 for Methylene Chloride. $SAE = 1.645 \times SrT$, $SrT = 0.076$,
- For NIOSH methods with no calculated SrT and methods from ASTM or other organizations,
 - Contact the laboratory service provider directly to get the SAE.
 - Another possible solution is to use the SAE from a known method (such as an OSHA method) that uses the same media, quantification technique, etc. as the method with the unknown SAE.

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Direct Reading Instrument Error

- Direct-reading instruments do not have an SAE per se, but do have instrument error, which must be taken into account when determining if an overexposure exists with 95% confidence.
- For direct reading instruments (e.g. SafeLog 100, Toxilog, detector tubes), the instrument error will be the manufacturer's listed performance tolerances.
 - Examples: Quest Safelog 100 detectors with CO sensors have a manufacturer-listed accuracy of 5%. Therefore, the instrument error (equivalent to SAE) would be 0.05, and an overexposure can be documented if severity (Y) is greater than 1.05 (meaning the LCL > 1).
 - The Sensidyne Gastec MEK Detector Tube lists an accuracy of tolerance FOM Chapter XV, cont'd. 11 of 25%. The instrument error is thus 0.25, and overexposures can be documented if $Y > 1.25$.
- For noise dosimetry using Type 2 instruments, the instrument error is +/- 2 dBA.

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Full period single sample strategy

- Example: An IH collects a lead sample to evaluate the worker's exposure for compliance purposes. The concentration he measures is 55 ug/m^3
- Would this worker's exposure be considered to be non-compliant with the OSHA lead standard 1910.1025?

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Classical confidence interval approach

- Use one-sided confidence interval

$$CL_{1-\alpha} = x_i \pm t_{1-\alpha, \infty} * \left(\frac{S_r}{\sqrt{n}} \right)$$

Where S_r = relative standard deviation

$$t_{1-\alpha, \infty} = Z_{1-\alpha}$$

- CL step 1: Compare 8-hr TWA to PEL or other OEL.
 - If TWA > OEL then determine the LCL
 - If TWA < OEL then determine the LCL

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Classical confidence interval approach

- CI Step 2: Determine the relative standard deviation on the sample, S_r . $CV_{\text{pump}} = 0.05$

$$\begin{aligned} CV_{\text{Total}} &= \sqrt{CV_{\text{pump}}^2 + CV_{\text{sampling}}^2 + CV_{\text{analytical}}^2} \\ &= \sqrt{0.05^2 + 0 + 0.072^2} = 0.09 \end{aligned}$$

x_i is the measurement value

$$\begin{aligned} S_r &= CV_{\text{Total}} \times x_i \\ &= 0.09 \times 55 \frac{\mu\text{g}}{\text{m}^3} = 4.8 \frac{\mu\text{g}}{\text{m}^3} \end{aligned}$$

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Classical confidence interval approach

- CI step 3: Determine the one-sided CL we will need, then compute it:
 - What CI to use?
 - Lower since 8-hrTWA = 55, which is greater than PEL = 50
 - What is the Z-value to use?
 - 1.645 since 95% CI
 - Compute $LCL_{95\%}$

$$LCL_{1-0.05} = LCL_{0.95} = 55 \frac{\mu g}{m^3} - 1.645 * \left(\frac{4.8}{\sqrt{1}} \right) = 47 \frac{\mu g}{m^3}$$

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Classical confidence interval approach

- CI step 4: Compare PEL value and CI to determine compliance decision

$$LCL_{95\%} = 47 \mu g/m^3 \quad PEL = 55 \mu g/m^3$$

Since the 95% LCL is less than the PEL
conclude not clear that there is an overexposure
but not proven that acceptable, either.

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NIOSH “Standardization” approach

CV_T listed on sampling method. Includes all errors.

- Step 1: Calculate a “standardized” concentration, X :

$$X = \frac{x}{OEL} = \frac{55}{50} = 1.1$$

X = measured value
 OEL = exposure limit

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NIOSH “standardization” approach

- Step 2:
 - If X is less than 1 calculate UCL
 - Else calculate LCL

UCL and LCL are defined as:

$$UCL_{95\%} = X + (Z_{0.95} * CV_T)$$

$$LCL_{95\%} = X - (Z_{0.95} * CV_T)$$

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NIOSH “Standardization” approach

- NIOSH step 3: Calculate the LCL

$$\begin{aligned} LCL_{95\%} &= X - (Z_{0.95} * CV_T) \\ &= 1.1 - (1.645 * \sqrt{0.072^2 + 0.05^2}) \\ &= 1.1 - (1.645 * 0.09) = 0.95 \end{aligned}$$

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NIOSH “standardization” approach

- NIOSH step 4: Compare standardized concentration and CI to determine compliance decision
- Since the 95% LCL is less than 1 conclude no decision

$$LCL_{95\%} = 0.95$$

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OSHA “standardized concentration” approach with SAE

- OSHA step 1: Calculate a “standardized” concentration Y

$$Y = \frac{x}{\text{PEL}} = \frac{55 \mu\text{g} / \text{m}^3}{50 \mu\text{g} / \text{m}^3} = 1.1$$

x = measured concentration

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OSHA “standardized concentration” approach with Std Analytic Error (SAE)

- OSHA Step 2:
 - If Y is less than 1 calculate UCL
 - Else calculate LCL

$$\text{UCL}_{95\%} = Y + \text{SAE}$$

$$\text{LCL}_{95\%} = Y - \text{SAE}$$

where the $\text{SAE} = 1.654 * \text{CV}_T$

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OSHA “standardized concentration” approach with SAE - continued

- OSHA Step 3:
 - Find the SAE and calculate the LCL.
 - From OSHA method ID 121, the SAE is given as 0.14
- $$\text{LCL} = 1.1 - 0.14 = 0.96$$
- OSHA Step 4:
 - If $\text{LCL} > 1.00$ then overexposed

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Calculation method for consecutive samples

- The use of multiple consecutive samples will result in slightly lower SAEs than the use of one continuous sample since the inherent errors tend to partially cancel each other.
- However, the calculations are somewhat more complicated.
- If preferred, the CSHO may first determine if compliance or noncompliance can be established using the calculation method noted for a single sample measurement. If results fall into the "possible overexposure" region using this method, the more exact calculations should be performed.

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Full period consecutive samples

- How do we handle consecutive samples?
- Before we can answer the question we need to determine if all sample periods have equal true average concentrations
- That determination will dictate how we approach the calculation of the confidence interval
 - Full period equal true average exposures
 - Full period non-equal true average exposures

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Full period equal true average exposures

- During the course of an eight hour work shift you collect 3 lead samples. The lab using NIOSH method 7082 reports back to you the following results:
 - $X_1 = 0.055 \text{ mg/m}^3$; $T_1 = 100 \text{ minutes}$
 - $X_2 = 0.064 \text{ mg/m}^3$; $T_2 = 250 \text{ minutes}$
 - $X_3 = 0.049 \text{ mg/m}^3$; $T_3 = 100 \text{ minutes}$.
- Is this worker's exposure in compliance?

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Where full period, equal true average exposures

- Process steps
 - Determine the TWA concentration
 - Calculate the standardized concentration
 - Calculate the appropriate 95% confidence interval
 - Make a decision about exposure compliance

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Full period, equal true average exposures - continued

- Calculate the TWA and the standardized concentration.

$$\text{TWA} = \frac{(0.055 * 100) + (0.064 * 250) + (0.049 * 100) + (0 * 30)}{100 + 250 + 100 + 30}$$

$$= 0.055 \frac{\text{mg}}{\text{m}^3}$$

$$x = \frac{0.055}{0.05} = 1.1$$

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Full period, equal true average exposures - continued

- Calculate the appropriate 95% CI.

$$CI_{95\%} = x \pm t_{1-\alpha, \infty} * CV_T * \frac{\sqrt{T_1^2 + T_2^2 \dots + T_n^2}}{T_1 + T_2 \dots + T_n}$$

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Full period equal true average exposures - continued

- Calculate the appropriate 95% LCL.

$$LCL_{95\%} = x - t_{1-\alpha, \infty} * CV_T * \frac{\sqrt{T_1^2 + T_2^2 \dots + T_n^2}}{T_1 + T_2 \dots + T_n}$$

$$LCL_{95\%} = 1.1 - 1.645 * 0.09 * \frac{\sqrt{100^2 + 250^2 + 100^2 + 30^2}}{100 + 250 + 100 + 30}$$

$$= 1.1 - 1.645 * 0.09 * .602$$

$$= 1.1 - 0.089 = 1.01$$

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Full period equal true average exposures

- Make compliance decision

- Since $LCL > 1$ conclude overexposure
- How in this case was the result “non-compliance” and in the previous example involving a single full period sample we concluded “no decision”
- The difference was “number of samples”
 - ▢ [NIOSH Sampling Strategies Manual](#)

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Full period, non-equal true average exposures

- During the course of an eight hour work shift you collect 3 lead samples.
- You know the workers job is highly varied in task activity and duration and production rate.
- As a result you believe the true average exposures from your three sampling periods are non-uniform.
- Using NIOSH method 7082 you obtain the following:
 - ▢ $X_1 = 0.015 \text{ mg/m}^3$; $T_1 = 90 \text{ minutes}$
 - ▢ $X_2 = 0.045 \text{ mg/m}^3$; $T_2 = 240 \text{ minutes}$
 - ▢ $X_3 = 0.02 \text{ mg/m}^3$. $T_3 = 120 \text{ minutes}$
- Is this worker’s exposure in compliance?

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Full period non-equal true average exposures - continued

- Process steps same as before but calculation of the CI more involved
 - Determine the TWA concentration
 - Calculate the standardized concentration
 - Calculate the appropriate 95% confidence interval
 - Make a decision about exposure compliance

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Full period non-equal true average exposures-continued

- Calculate the TWA.

$$\begin{aligned} \text{TWA} &= \frac{(0.015 * 90) + (0.045 * 240) + (0.02 * 120) + (0 * 30)}{90 + 240 + 120 + 30} \\ &= 0.03 \frac{\text{mg}}{\text{m}^3} \end{aligned}$$

- Calculate standardized concentration.

$$x = \frac{0.03}{0.05} = 0.61$$

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Full period non-equal true average exposures - continued

- Calculate the appropriate 95% CI.

$$CI_{95\%} = x \pm t_{1-\alpha, \infty} * \frac{CV_T}{OEL} * \left(\frac{\sqrt{X_1^2 T_1^2 + X_2^2 T_2^2 \dots + X_n^2 T_n^2}}{(T_1 + T_2 \dots + T_n) * \sqrt{1 + CV_T^2}} \right)$$

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Full period non-equal true average exposures - continued

- Calculate the appropriate 95% UCL.

$$\begin{aligned}
 ULC_{95\%} &= x + t_{1-\alpha, \infty} * \frac{CV_T}{OEL} * \left(\frac{\sqrt{X_1^2 T_1^2 + X_2^2 T_2^2 \dots + X_n^2 T_n^2}}{(T_1 + T_2 \dots + T_n) * \sqrt{1 + CV_T^2}} \right) \\
 &= 0.61 + 1.645 * \frac{0.09}{0.05} * \left(\frac{\sqrt{0.015^2 * 90^2 + 0.045^2 * 240^2 + 0.02^2 * 120^2}}{(90 + 240 + 120 + 30) * \sqrt{1 + 0.09^2}} \right) \\
 &= 0.61 + 1.645 * 0.09 * \frac{11.15}{24.1} = 0.61 + 0.068 = 0.68
 \end{aligned}$$

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Full period, non-equal true average exposures - continued

- Make our compliance decision
- Since $UCL=0.68$,
 - then $UCL < 1$
 - conclude no overexposure condition

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Partial period consecutive samples

- Handled as the full period consecutive sample except that the evaluation point to determine compliance is no longer 1.
- The partial period criteria (PPC) is

$$PPC = \frac{\text{period of standard}}{\text{sample period}}$$

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Partial period consecutive samples - continued

- Decision criteria – limited to non-compliance only:
 - If $LCL > PPC$ then classify as non-compliant exposure
 - If $x > PPC$ and the $LCL \leq PPC$ classify as possible non-compliant exposure
 - If the standardized concentration is $< PPC$ no statistical test for non-compliance would be used

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Partial period consecutive samples example

- During the course of an eight hour work shift you collect 3 lead samples.
- The workers job task activity and duration and production rate are fairly consistent.
- Using NIOSH method 7082 you obtain the following results:
 - $X_1 = 0.11 \text{ mg/m}^3$; $T_1 = 100 \text{ minutes}$
 - $X_2 = 0.068 \text{ mg/m}^3$; $T_2 = 120 \text{ minutes}$
 - $X_3 = 0.087 \text{ mg/m}^3$. $T_3 = 90 \text{ minutes}$
- Is this worker's exposure in compliance?

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Partial period consecutive samples

example solution

- Determine TWA concentration

$$\text{TWA} = \frac{0.11 * 100 + 0.068 * 120 + 0.087 * 90}{100 + 120 + 90} = 0.087$$

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Partial period consecutive samples

example solution

- Calculate standardized concentration

$$x = \frac{0.081}{0.05} = 1.74$$

- Calculate the PPC

$$\text{PPC} = \frac{480}{310} = 1.54$$

Since $x > 1.54$ we want to calculate the LCL

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Partial period consecutive samples example solution

- Calculate the appropriate confidence limit

$$\begin{aligned} \text{LCL}_{95\%} &= x + t_{1-\alpha, \infty} * \text{CV}_T * \frac{\sqrt{T_1^2 + T_2^2 \dots + T_n^2}}{T_1 + T_2 \dots + T_n} \\ &= 1.74 - 1.645 * 0.09 * \frac{\sqrt{100^2 + 120^2 + 90^2}}{100 + 120 + 90} \\ &= 1.74 - 1.645 * 0.09 * 0.58 \\ &= 1.74 - .086 = 1.65 \end{aligned}$$

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Partial period consecutive samples example solution

- Since $x > \text{PPC}$ and the $\text{LCL}_{95\%} = 1.65$ which is greater than the PPC of 1.54, conclude over-exposure

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