A technical procedure designed for use at the bench should be clear and unmistakable. It should be accessible to appropriate personnel at all times, easy to follow and contain all necessary information. The form and style used for a written procedure is up to the individual laboratory and should be applied to all procedures used in that laboratory for consistency. Some laboratory procedures may not contain all the information provided in these guidelines (e.g., kit methods).

The following information has been modified from the CLSI Guidelines GP2-A, Vol. 4, No.2 and should be used when completing this assignment.

**Heading/Page Format:**
1. Appropriate demographics including name of the institution, department name, section name and address. (example: Hospital XYZ, Core Laboratory, Chemistry section, Lincoln, NE)
2. Name of individual/author who wrote the procedure
3. Name of the procedure that the new procedure replaces, when applicable.
4. Month and year the procedure is adopted.
5. Page number and total number of pages in the document (example: Page 1 of 10)

**Procedure Title:**
1. Use the name of the substance being tested as the first word of the title
2. Specify the type of specimen
3. State the specific method or instrumentation used as a subtitle
4. Example: Glucose in Urine
   Glucose oxidase/peroxidase, reagent strip method

**Principle:** Explain in narrative/paragraph form
1. Type of reaction taking place (example: The XYZ assay is based on Enzyme Immunoassay (EIA) technology)
2. Substance being measured
3. The reaction sequence (be specific and complete)
4. How and what type of response is measured (example: The intensity of the polarized fluorescent light is measured by the optical system of the instrument)
5. How the measured response is related to the test result. (example: The increase in ABS at 550 nm is directly proportional to the concentration of XYZ in the test sample)

**Clinical Significance:** Explain in narrative/paragraph form
1. The medical use of the analyte (example: Quantitative plasma glucose levels are useful in the diagnosis and management of patients with diabetes mellitus and hypoglycemia)
2. Causes of increased and decreased levels
3. Clinical reasons for performing the test, if appropriate (example: Increased levels of the drug XYZ is toxic to the liver)
**Specimen:** Keep ‘prompts’ that are included on the template (i.e., Patient Preparation, Type, etc)

1. State the conditions for patient preparation (note: if reference ranges are established using a fasting population, then patient preparation should be fasting as well)
   a. If no patient preparation is required, state as such
   b. Fasting requirements (example: 8 hour overnight fast)
   c. Any special dietary requirements (example: patient must consume a normal diet for 3 days prior to collection of the blood sample)
   d. Any specific drug regimens, including dosages

2. State the type and amount of specimen required
   a. Preferred specimen and any other acceptable specimen (example: serum is the preferred specimen; may also use heparinized plasma)
   b. Amount of specimen required, both optimum and minimum
   c. Acceptable collection containers, i.e. anticoagulants, preservatives, special tubes, sterility requirements

3. State criteria for collection
   a. List acceptable collection procedures (example: obtain EDTA whole blood using routine venipuncture technique)
   b. Include an outline of steps to be followed in complicated collection procedures (i.e., collection of blood cultures)
   c. Include special timing considerations (example: collect EDTA whole blood sample 5 hours after oral administration of drug XYZ)

4. State the stability of the specimen, and specific handling and storage requirements
   a. Transport conditions (example: transport specimen to the laboratory on ice)
   b. Specimen handling requirements (i.e., separate serum from cells within one hour of collection, protect from light)
   c. Special equipment required (example: use sterile glassware)
   d. Length of time specimen is stable and at what specific temperature(s)

5. State the criteria for unacceptable specimens. Include:
   a. Those physical characteristics of the specimen that may compromise test results (i.e., hemolysis, lipemia, icteric coloration, presence of particulate matter)
   b. The action to be taken by the laboratory when an unacceptable sample is received (example: centrifuge specimen prior to analysis when particulates such as fibrin strands are present)

**Reagents/Calibrators/Controls/Materials:** Keep ‘prompts’ that are included on the template

1. A bold statement of health or safety information associated with the reagent, calibrators, controls, supplies, equipment. Include the general category or class of hazard such as toxic, corrosive, explosive, biohazard, radiation, electrical, etc.

   Example:

   **Caution:** this product contains human sourced and/or potentially infectious components. Follow Standard Precautions at all times when handling these reagents.
2. List all prepared reagents, reagent kit components, include:
   a. Chemical composition, matrix and concentration (example: <0.01% XYZ Fluorescein Tracer in TRIS buffer containing surfactant and sodium azide)
   b. Usual source/supply company and catalog number(s)
   c. Handling/storage requirements for each reagent
      1) Temperature
      2) Stability (shelf life), expiration date. Note: if an “after opening” expiration date is not indicated by the manufacturer, you may specify the expiration date as “the expiration date indicated on the reagent vial”.
   c. Special storage/handling instructions (example: work under safety hood; store in explosion proof refrigerator; bring to room temperature before use)
   d. Parameters used to determine acceptable reagent performance (example: initial ABS values >0.100 against a water blank indicate reagent contamination)

3. State specific directions for preparation of each reagent that may be produced in the laboratory, including:
   a. Chemical composition, matrix, concentration
   b. Degree of accuracy required for measuring reagents (example: measure 0.05 grams of XYZ salt into a 500 ml volumetric flask, and QS to 500 ml with d-H2O)
   c. Quality of glassware, volumetric equipment, solvent, water required
   d. Instructions for special cleaning/handling of glassware and volumetric equipment
   e. Storage requirements, expiration date, stability, and safety considerations

4. List the calibrators/standards used. Include:
   a. The chemical composition and matrix
   b. Concentrations presented in tabular form
   c. Usual source/supply company and catalog number(s)
   d. Storage requirements, stability, expiration date. Note: if an “after opening” expiration date is not indicated by the manufacturer, you may specify the expiration date as “the expiration date indicated on the calibrator vial”

5. List the control materials used. Include:
   a. Chemical composition and matrix
   b. Concentration ranges presented in tabular form
   c. Usual source/supply company and catalog number(s)
   d. Storage requirements, stability, expiration date. Note: if an “after opening” expiration date is not indicated by the manufacturer, you may specify the expiration date as “the expiration date indicated on the control vial”.

Example:

Caution: all components contain sodium azide as preservative. Sodium azide is harmful if swallowed; seek medical attention immediately and refer to MSDS sheet for proper first aid procedures. Contact of sodium azide with acid liberates toxic gas; contact of sodium azide with copper pipes/plumbing forms highly explosive metal azides: when discarding down drain, flush with copious amounts of running water to prevent azide build up.
**Calibration:** Keep the ‘prompts’ that are included on the template.

1. Indicate how patient values are determined from calibration curve
   Example: 4-parameter logistic curve fit method is used to generate a calibration curve to determine unknown test results
2. List concentrations of calibrators in tabular form
3. Frequency: list when calibration procedures should be performed; indicate the type of calibration performed and when to do it (example: Perform a full calibration using all 6 calibrators, in duplicate, upon initial set-up of the IMX System, when a new lot number of reagent is put into use….; all subsequent runs with the same lot number require a mode-1 calibration using the mode-1 calibrator)
4. Preparation: list detailed instructions for preparing calibrators and/or working calibrators.
   a. Directions for measurement, required glassware, volumetric equipment, water
   b. Temperature equilibration time required after removal from refrigerator storage before use where appropriate
5. Procedure: list detailed stepwise instructions for performing a calibration. Differentiate a full calibration from a mode-1 calibration. Example:
   1. Remove calibrators from refrigerator
   2. Mix gently; avoid bubbles
   3. Load calibrators in carousel by holding calibrator bottle vertically and dispense a minimum of 4 drops into…etc…
      For a full calibration:
      a. Place calibrator A in carousel positions 1 and 2; calibrator B in etc…
      b. Place abc control in carousel position 13, xyz control in etc….
      For a Mode-1 calibration:
      a. Place the mode-1 calibrator in carousel position 1
      b. Place abc control in carousel position 2, etc…
4. Initiate assay
5. When assay complete, return reagents to refrigerator
6. Determine if calibration is valid
6. Acceptance/corrective action:
   a. Specify parameters used to determine validity of calibration (example: RERR +/- 20; all controls must be within the 95% acceptable range)
   b. Explain procedure to follow when calibration fails
**Quality Control:** Keep the ‘prompts’ that are included on the template

1. Frequency: list when and which controls are required. (example: all 3 levels of control, in duplicate need to be run with every 6 point calibration)

2. Preparation: list detailed instructions for preparing control materials.
   a. Directions for preparation, required glassware/volumetric equipment, water
   b. Temperature equilibration time required after removal from refrigerator storage before use where appropriate

3. Acceptance/corrective action:
   a. List the acceptable ranges/values for each control level in tabular form
   b. Indicate how the acceptable ranges/values for controls were established (example: statistical analysis by laboratory; adopted from the manufacturer’s package insert)
   c. Indicate the criteria used for accepting control values (example: all levels of control must be within the acceptable range)
   d. State corrective actions to be taken when acceptable range/value is exceeded

4. Describe how quality control data are recorded and stored (example: control values are reported into the LIS)

**Procedure:**

1. Include cautionary statement for handling biohazardous materials that may be infectious:
   Example: Caution: when handling biohazardous materials, gloves and lab coats/gowns must be worn.

2. Write detailed instructions in a step-wise manner
   a. Use the imperative form
      Correct: Fill the container with 3.0 ml deionized water
      Not correct: The container is filled with 3.0 ml deionized water
   b. Keep instructions free of extraneous material such as explanations or justifications

   Example for automated procedure:
   1. Verify all system maintenance has been performed on XYZ analyzer
   2. Verify calibration is acceptable
   3. Program instrument following instructions found in the XYZ Systems Operators Manual
   4. Include here detailed directions of kit components and/or test samples that need special inspection before loading onto instrument
   5. Load reagent pack onto instrument
   6. Load test samples onto instrument
   7. Initiate reaction/assay
   8. When reaction complete, return reagent packs to refrigerator
   9. Verify run is acceptable; verify patient results are valid; report results

**Calculations:**

1. Give detailed step-wise instructions

2. Include the equation used to calculate the value
   Example: manual dilution factor = \( \frac{(\text{volume of sample}) + (\text{volume of diluent})}{\text{volume of sample}} \)

3. Provide an example
**Reporting Results:** Keep the ‘prompts’ that are included on the template

1. Give detailed step-wise instructions
   Example to be used in this procedure write-up exercise:
   a. Verify all controls to be within acceptable limits
   b. Flagged patient results must be carefully reviewed by the operator
   c. Follow standard procedure of your laboratory when entering patient data into the LIS

2. List reference ranges/values including the source used (example: established using statistical analysis; adopted from the manufacturer’s package insert)
   Note: if reference ranges are established using a fasting population, then patient preparation should also be fasting

3. List critical values
   a. If no critical values are known then indicate as such
   b. Identify procedure to follow when reporting a critical value

**Limitations:** Keep the ‘prompts’ that are included on the template

1. State the linearity of the procedure and include:
   a. Detailed instructions to follow if test sample exceeds linearity
   b. Example of dilution protocol
   c. Example calculation

2. State the (lower) detection limits and include:
   a. Detailed instructions to follow if test result is lower than the detection limit (example: if test result is $\leq$ 2, then report: $<$2 uU/L)

3. State known interfering substances

**Procedure Notes:**

1. List information concerning the procedure that is too voluminous to include in the Principle or Procedure sections
   a. Explain reasons for special precautions
   b. List possible sources of error
   c. Include helpful hints
   d. Include a statement describing the clinical situations that may influence the validity of test results, if applicable

**References:**

1. Include all items used as sources of information
   a. Package insert
   b. Textbooks (used to determine clinical significance)
   c. Literature references
   d. Standards publications
   e. Written personal communications