



SOP ON THE RECORDING OF RAW DATA

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SOP ON THE RECORDING OF RAW DATA

1. Purpose:

The purpose of this procedure is to define how raw data shall be recorded and maintained in the laboratory, in order to establish an audit trail.

2. Scope:

This procedure applies to all records and information of raw data generated in the laboratory such as all original observations, derived data, calculation records, and transfer of raw data from the worksheets to the final report.

3. Responsibilities:

The analyst shall be responsible for recording all original observations, calculations, conversions and raw data transfer onto the worksheet for the tests carried out. The sample supervisors and technical signatories of specific analyses/sample type will review all raw data, records and calculations submitted by the analyst and verify them before preparation of the final report.

4. Procedure:

- i. The analyst shall record all raw data pertaining to the test work or operation. These shall include such data as original observations, calculations, measurements and any other information identifiable to the specific test.
- ii. All raw data shall be recorded in the appropriate worksheet and or on the relevant monitoring forms. Chromatograms or other equipment printouts shall be labelled appropriately to provide clear identity of test items.
- iii. As far as possible, dates of analysis carried out should also be included.
- iv. The records shall clearly provide the necessary details to enable repeatability of tests under conditions as close as possible to the original.
- v. During analysis using gas and liquid chromatographs, the following data (but not limited to) shall be recorded in the worksheet as applicable:



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- Date of commencement of analysis and worksheet number,
 - Sample code number(s) and weight(s) of sample taken for the analysis,
 - SOP number or reference of the method used for analysis.
 - Information on the verification of the analytical balance used, including the date/time of verification of the balance.
 - The details of sample spike levels and pesticides used to spike, where applicable,
- vi. Show all calculations, with the data used in calculating the results; make reference to any software location, or formulas used.
- vii. In case the data is generated from inorganic analysis, the following details are recorded in the laboratory workbook:
- Date of commencement of analysis and worksheet number,
 - Sample code number(s) and sample weight(s) taken
 - Standards series used
 - Equipment used: ensure that sample and calibration information is programmed into the equipment software as appropriate.
 - Equipment used, and as far as possible equipment conditions.
- viii. The analyst shall make sure that the computer software used for analysis of any raw data is suitably validated and approved for use (especially for in-house developed software) and maintained properly and in working condition. Any malfunctions should be recorded in the appropriate instrument log register and the Technical Officer informed. A password shall be used to avoid access by unauthorised persons.
- ix. In case mistakes occur during recording of raw data, such mistakes shall be crossed out once, countersigned and left still legible. The corrected action shall be written alongside and then initialled.
- x. The integrity of the generated raw data shall be observed fully and held in total confidence by the analyst and other responsible persons.
- xi. The Laboratory Manager shall be responsible for all customer enquiries, - or a person designated to so respond.



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- xii. All raw data recorded in the worksheets shall be verified and countersigned by the analyst, Sample supervisor and checked by Technical signatory. The Laboratory Manager countersigns the worksheet.
- xiii. The analyst shall be responsible for all data processing.
- xiv. All records of raw data shall be stored and retained in a safe place for ease of retrieval.
- xv. In case of any query requiring data retrieval, it should be noted by the responsible person (analyst or supervisor or designated person), giving the date, the type of data and initialled with the reasons for retrieval.
- xvi. Processed raw data shall be stored for a period of 10 years or as specified by the test in a laboratory.
- xvii. The storage will be done in the archive by the archivist. The raw data shall be stored in labelled shelves, labelled, and recorded to allow easy retrieval.
- xviii. Chromatograms and other equipment print-outs shall be stored in a lockable storage area, and transferred to the document archive when appropriate.

5. Amendment list

Amendment No.	Date approved	Nature of amendment
1	03/07/2024	Changed the compiler and the effective date.



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6. Revision List

Revision No.	Effective date	Nature of revision
3	28/05/08	Inclusion of instructions on data required to be entered in the laboratory workbook.
4	20/05/13	Deletion of details in number 4 iv) "The sample sequence of analysis, layout of the chromatograph as appropriate with details of the injection. Equipment and equipment conditions (as much as possible give details of column used, column conditions, flow rates of gases used, detector used and detector conditions, Record the peak areas of injections in the laboratory workbook. Inclusion of the to the laboratory worksheets as "Available in the C Forms register" (in the records section).
5.	08/05/15	Change compiler and approver Include worksheet in recording of raw data
6	02/02/16	Change of revision, effective date, compiler, approver.
7	05/05/20	Phasing out of workbook and adoption of worksheets for raw data transfer. Removal of the term deputy lab manager from part (x) of the procedure Deletion of listing of internal worksheets from the procedure captured in contract review procedure

7. Records:

- Current Internal Laboratory Worksheets
- Chromatograms or Equipment print-outs or charts.
- Analytical reports.