

Standard Operating Procedure (Gen044b)

Proper Raw Data Handling Procedures

Computerized data systems provide the analyst with the ability to manipulate raw instrument data. Guidelines for manipulation of data are not provided in the methods; most methods were written prior to widespread implementation of computerized data systems. This standard operating procedure provides guidelines to assist analysts in exercising good judgment when manipulating raw data and provides a method for documenting any changes that are made.

Approval and Signatures

Laboratory Manager: _____

Date: _____

QA Manager: _____

Date: _____

Department Manager: _____

Date: _____

Procedure:

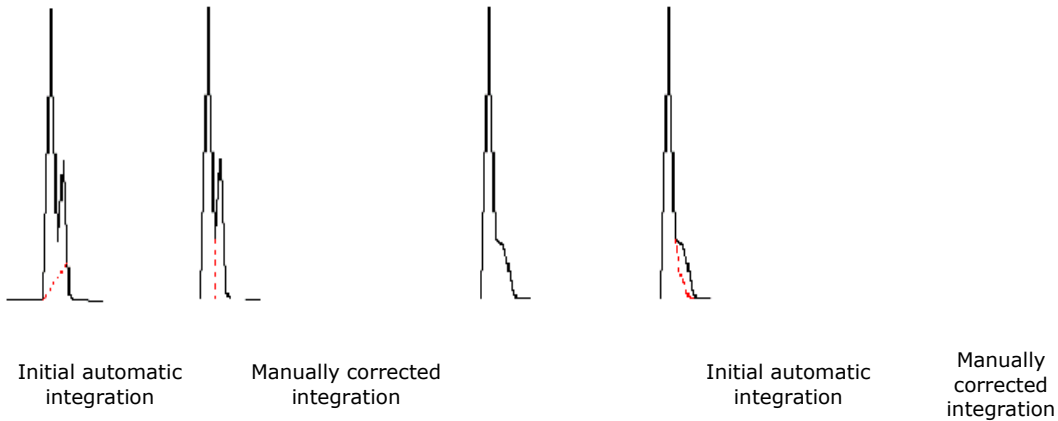
Date and Time Issues

Each analyst who reviews raw data prior to reporting ensures that the correct date and time are listed on the raw instrument data. If the date or time is not correct, draw a single line through the incorrect date or time on the hardcopy of the raw data. Write the correct date or time beside the line, initial the change, and place with data files. There must be notation of the problem in the run log. Repeated problems of an instrument's ability to printout correct dates and times requires immediate attention.

It is never appropriate to change dates or times to give the appearance that holding times have been achieved. Any analysts observed doing this will face termination.

Manual Adjustment of Peak Areas

The analyst must adjust the area of the peak in some situations. While software generally handles integration properly, there are cases when automated integrations need adjustment for consistency in measuring areas under peaks. Examples in GC would be when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest.

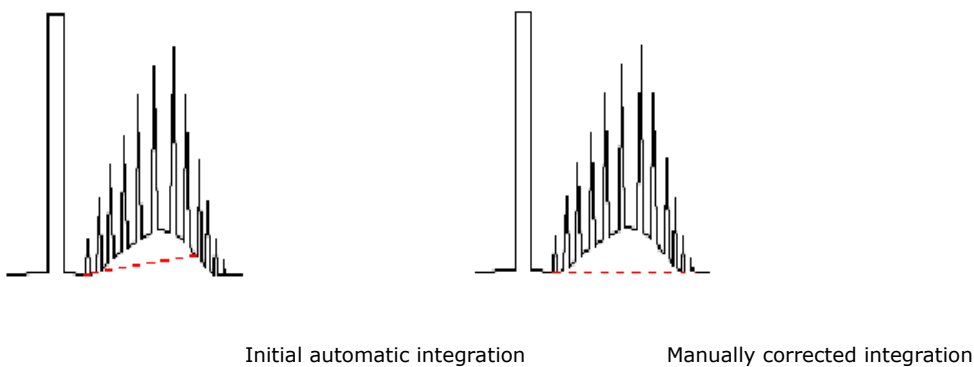


In GC/MS, manual integration of peaks should only occur when integration by software is incorrect. Examples would be when the software has selected an incorrect isomer, missed a peak, or when a shouldered peak needs separation. Integration for calibration curves, daily continuing calibration standards, and samples should be handled in the same manner for each analyte. Adjustment of a peak area is never warranted when its purpose is to make calibration or QC measures meet acceptance criteria.

Any manual changes must be initialed and dated by the analyst on the hardcopy and noted in the run log. If manual adjustments are made, the file must contain the original data/chromatograms or quantitation reports and the data after adjustments. *If the instrument software has the capability of producing an audit trail, this feature must be made active.*

Manual Adjustment of Baselines

The analyst must adjust the baseline in some situations. Examples would be when performing multi-component analyses such as PCB's and TPH or when the baseline has been incorrectly assigned. The analyst should only adjust the baseline when the computer has incorrectly assigned the baseline. The analyst must seek their supervisor's approval. The analyst is never allowed to adjust the baseline for the purpose of increasing or decreasing peak area resulting in acceptable QC measures. Where relevant, the same manipulations to standards and samples must be performed.



Documentation Requirements

Any manual changes must be initialed and dated by the analyst on the hardcopy and noted in the run log. If manual adjustments are made, the file must contain the original data/chromatograms or quantitation reports and the data after adjustments. *If the instrument software has the capability of producing an audit trail, this feature must be made active.*

In the event an analyst is unsure of whether data requires manual changes, it is their responsibility to seek input and approval of the appropriate supervisor and/or Quality Assurance Manager. Documentation of that approval must be provided in the files.

Acknowledgement of Training

**Standard Operating Procedure GEN 044B
Proper Manual Integration Procedures**

By my signature below, I acknowledge that I have received training on proper techniques for performing manual integration. I also understand I must follow the requirements for properly documenting any manual changes. I understand that it is my responsibility to seek input and approval of the appropriate supervisor and/or quality assurance manager before making any manual changes. I understand that if I do not follow these procedures, I face serious disciplinary action that could include termination.

Printed Name: _____

Date: _____

Signature: _____