

Standard Operating Procedure (Gen025) Data Integrity And Ethical Practices

Approval and Signatures

Laboratory Manager:_____

Date:_____

QA Manager:_____

Date:_____

Department Manager:_____

Date:_____

Sequoia Analytical has many policies and procedures in place to ensure data integrity and data quality and that promote ethical practices in the laboratory. The majority of those procedures are covered under the quality control requirements specified in the analytical methods performed and the quality assurance practices covered in our Quality Assurance Program Manual. The QA Manual directs analytical and systems auditing activities, performance evaluation activities, and training activities that assist in the assurance of data integrity and ethical practices in the laboratory.

However, Sequoia Analytical feels that it is prudent to enhance the industry standard procedures with additional policies. This standard operating procedure (SOP) GEN025 specifies three additional policies to promote and ensure data integrity and ethical practices in the laboratory. They are as follows:

1. All employees of Sequoia Analytical are required to read, understand and sign our **Ethics and Data Integrity Agreement**. This agreement summarizes activities considered by the Company to be a "misrepresentation of analytical data" and requires employees to agree to not participate in such activities and disclose any information concerning such activities in the laboratory. It also specifies the consequences of participating in such activities. On an annual basis, Sequoia conducts training seminars with the entire staff to emphasize the information conveyed in this agreement.
2. On an annual basis, all employees are required to attend a training seminar on SOP GEN044B, **Proper Raw Data Handling Procedures**. This SOP covers the specifics of manual integration, including when it is appropriate and when it is inappropriate. It also covers other procedures specific to gas chromatography and mass spectrometry that must be followed to ensure data integrity such as the use of audit trails and other documentation of manual adjustments.
3. Periodically, the Chief Operating Officer (COO) or Quality Assurance Personnel will use CequeLogic's **Mintminer** software to conduct electronic surveillance of organic analytical data generated using Target, Turbochrome and HP Chemstation data processing products. Mintminer is designed to scan a high volume of analytical raw data files according to specific custom data handling criteria such as excessive manual integrations or quality control data manipulation.

It is the responsibility of the Quality Assurance Directors, with the assistance of the President, the COO, and the Laboratory Directors to ensure that this procedure and the policies contained within are followed in each of Sequoia's facilities. All Ethics and Data Integrity Agreements and

documentation of training under items 1 and 2 above are to be kept in each employee's training file. Written reports on the outcome of data surveillance activities will be submitted to the President and the Laboratory Directors. This report is to include the number of files scanned, the number of files identified to have data integrity issues and any recommended action to be taken.

On a less formal basis, the Owner of Sequoia Analytical will conduct discussions on the issue of data integrity and ethical behavior with the staff. This will be done to emphasize the Company's commitment to data integrity and give the employees additional opportunities to gather information and ask questions.

With this procedure in place, Sequoia Analytical is confident that it can produce analytical data of the highest possible integrity.