

QCP4

CONTROL OF LABORATORY LOGBOOKS

1.0 PURPOSE

To establish a standard operating procedure for control of logbooks used to record laboratory data and information for IEAV. Logbook(s) may be bound or electronic.

2.0 RESPONSIBILITIES

2.1 Laboratory Manager or designee

- Identify critical laboratory records, for which logbooks are required.
- Initiate new logbooks and terminate completed or inactive logbooks.
- Maintain list of active logbooks and their current locations.
- Instruct employees in the proper use of specific logbooks.
- Review each logbook semi-annually if the logbook has been modified, document findings, and implement corrective actions, when necessary.

2.2 Laboratory Staff

- Make logbook entries, as appropriate, for laboratory activities being conducted.

2.3 Quality Assurance Specialist

- Perform reviews and audits of logbooks, document findings, and track corrective actions.

3.0 PROCEDURE

3.1 The Laboratory Manager or designee will identify those activities which require logbooks.

3.2 Information pertinent to the performance or condition of equipment, materials, operations, and activities, which may be relevant to the quality of data developed by the laboratory, will be recorded. When instruments and equipment are able to generate such information, e.g., computer printouts and discs, those records can be designated as logbooks. Otherwise, non-task specific or non-project specific information will be recorded in bound or electronic logbooks.

- 3.3 For non-electronic logbooks, the person responsible for the last entry is responsible for closing the page. Logbook pages will be closed by signature or signature initials immediately following the last entry and a single strike-through of unused page lines that has been initialed and dated. The person responsible for performing the closure is the individual performing the last entry as soon as practicable thereafter. Electronic logbooks will be protected by passwords or restricted access folders.
- 3.4 The Laboratory Manager or designee will maintain a list of logbooks for which he or she is responsible. The list of logbooks will be kept electronically in the logbook folder under the lab folder.
- 3.5 Information will be recorded in accordance with the Quality Program Manual, Section 11, Critical Record Handling and Storage. The Laboratory Manager or designee will provide direction to employees in the proper use of the logbooks.
- 3.6 Periodic reviews and audits of logbook entries and use will be performed as described under Section 2.0 above. These will be documented in the logbooks themselves.
- 3.7 The Laboratory Manager will terminate completed or inactive logbooks. A note with the signature and date in the logbook will be documented to indicate the logbook is completed or inactive.