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 ESSAP. 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 logbooks on a periodic basis, at least semi-annually, 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 Manager

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

2.4 Archival Coordinator

- Assign new logbook numbers.
- Maintain a list of logbooks.
- Archive inactive logbooks.

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-site specific or non-project specific information will be recorded in bound logbooks.

3.3 Electronic logbooks will be protected by passwords or restricted access folders.

3.4 The Archival Coordinator will maintain a list of logbook numbers, intended uses, persons to whom they are assigned, and assigned locations.

3.5 The Laboratory Manager or designee will maintain a list of logbooks for which he or she is responsible. Transfer of responsibility will be documented by the Archival Coordinator.

3.6 Information will be recorded in accordance with the Quality Assurance Manual, Section 11, Critical Records Handling and Storage. The Laboratory Manager or designee will provide direction to employees in the proper use of the logbooks.

3.7 Inactive or completed logbooks will be returned to the Archival Coordinator for archival in accordance with the Critical Records Handling and Storage Procedure.

3.8 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.