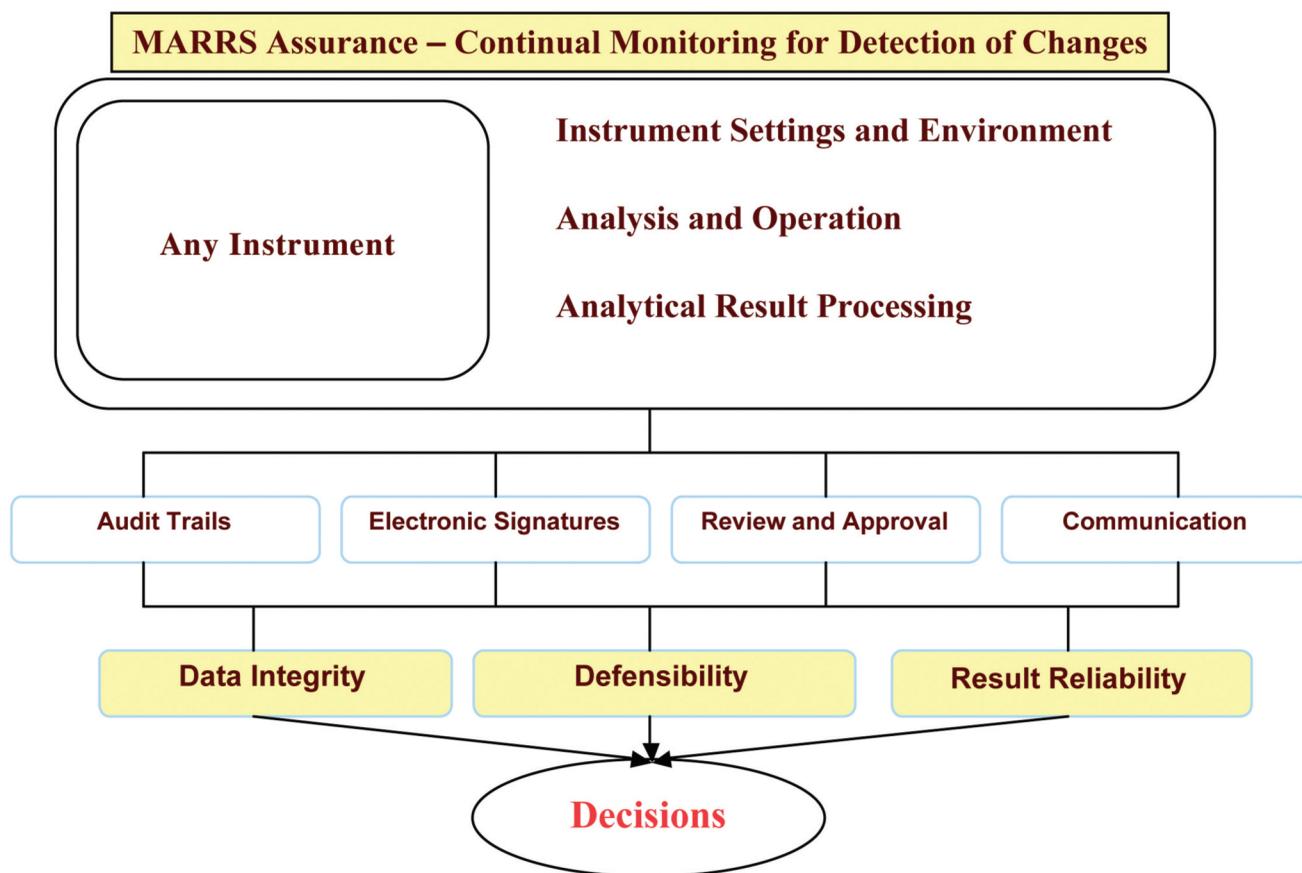


MARRS™ Assurance

Laboratories have the ability to personalize the *MARRS™ Assurance Security* to meet their dynamic security needs. While being 21 CFR Part 11 compliant, this system can be used for many other analytical industries. What makes *MARRS™ Assurance* unique is the ability to extend the compliance to the actual use of the data. Providing a defensibility mechanism for Quality Assurance to ensure that results used in decisions and studies have the upmost supportive quality. *MARRS™ Assurance* is intended to integrate with the entire laboratory Quality Assurance Program and other compliance systems.

- Compliance to Regulatory Agency and Industry
- Compliance to Standard Operating Procedures
- Compliance to Analytical Method Requirements
- Compliance to Client Requirements

MARRS™ Assurance Software



Security and Setup

MARRS™ Assurance Security is robust with the capability to self-define and manage Users, User Groups, Privileges, and Access Rights. User Groups can be defined to establish hierarchies of Review and Approval. For example a standard laboratory User Group may consist of Analyst/Technician, Secondary Review, Quality Assurance, and Management/Administrators.

In addition to security, laboratories can personalize the *MARRS™ Assurance Security* for:

- Continual Monitoring of instrument files, folders, and tables
- Electronic Signature Types
- Review and Approval
- Types of Review and Approval
- Instant Messaging
- Work Flow/Process Flow definition

Continual Monitoring, Electronic Signatures, Electronic Versioning, and Audit Trails

Laboratories can continually monitor instrument files, folders, and tables for changes and anomalies to the Instrument Environment, Instrument methods/setup, and Analytical data processing. Multiple Audit Trails capture the electronic signatures of User ID, Windows ID, Instrument ID, Review ID, and Approval ID. Electronic Versioning is on-going, providing a roll back feature to review the changes and anomalies. The Electronic Versioning mechanism can also do an electronic comparison of changes to files or tables to pinpoint specific data elements that have changed.

The *MARRS™ Assurance Security* provides the following Audit Trails:

- *Instrument Environment Audit Trail*: monitoring of files, folders, and tables
- *Analytical Processing Audit Trail*: result changes as data is processed, calculated, reviewed, automated Quality Assurance, analytical anomalies, Data Integrity ...
- *Analytical Review and Approval Audit Trail*: Tracks reviews and approvals as the data goes through the laboratory work flow.

Work Flow/Process Flow

The *MARRS™ Assurance Security* software allows laboratories to self-define and manage Work Flows/Process Flows for analytical data review and approval steps. For example, a standard laboratory process may contain a series of reviews and actions. Processed analytical data may follow these steps:

- 1) The Analyst/Technician reviewing the analytical data for Quality Assurance (QA) issues. The Analyst/Technician makes decisions based on the QA and provides analytical notes on decisions, then provides some conclusions.
- 2) The secondary review user picks up the Analyst/Technicians reviewed data and confirms the analytical notes, decisions, and conclusions for approval.
- 3) Specific QA issues and anomalies on the analytical data are sent to the QA Group for review and discussion.
- 4) A completed status is passed on to the Reporting Group.

Review Checklists

The *MARRS™ Assurance Security* software allows laboratories to self-define and manage Review Checklists to be used in Instrument Maintenance, Instrument Setup, Analytical Review, and Secondary Review. These checklists are then provided as a mechanism to ensure that proper procedures were followed by asking a series of questions of the user until the checklist is complete. The checklist is then electronically stored and provided in the Audit Trails.

Instant Messaging

Each user can setup Instant Messaging profiles to inform them when an action is required, an action is complete, an automated review summary, a notification of issues, etc ...

These Instant Messages are automatically emailed to the user when a process has occurred that matches the user profile.

Key Benefits

- Ensures dynamic compliance to requirements for FDA 21 CFR Part 11, NELAP, DOE, DOD, EPA, ISO, and Nuclear Regulatory Commission in data handling
- Integrates to present laboratory processes with no decrease in production
- Automates and streamlines the Quality Assurance reviews
- Communicates analytical issues and results throughout the laboratory
- Ensures data quality and integrity
- Total compliance from instrument to client

Add-on Features Available

- *MARRS™ Assurance Security* can be used with other instruments
- Audit Trail integration with other compliance systems
- User Scheduling for analytical studies, instrument maintenance, routine QA checks
- Non-Conformance Reporting and Tracking
- Production Analysis Module

About EISC

EISC is an international provider of scientific application software that specializes in laboratory data integration and automation. EISC's seamless, universal, connectivity platform assimilates and summarizes dynamic analytical instrument data into comprehensive analytical information. EISC was established in 1996 and is headquartered in Las Vegas, NV.