



Quality Assurance Audit Procedures

Tammy White
December 6, 2007
The Global Minor Use Summit
Rome, Italy





Quality Assurance Audit Procedures

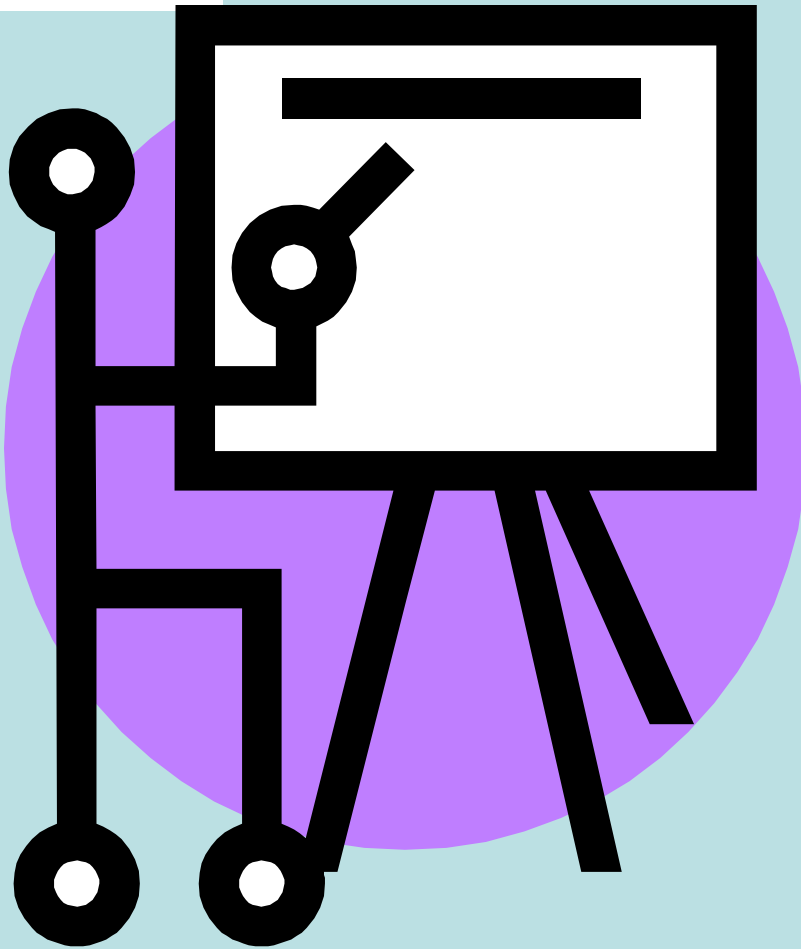
Overview:

Why Quality Assurance?

What is Quality Assurance?

How does Quality Assurance work?

Quality Assurance Audit Procedures



Why Quality Assurance?

- GLP Requirement
- Establishes Self Monitoring Program
- Adds Value

Quality Assurance Audit Procedures

GLP Requirement

To assure the quality and integrity of safety data, allow for accurate reconstruction of all experiments and support the approval and manufacture of safe regulated products

Quality Assurance Audit Procedures

GLP Requirement

1979 US Food And Drug Administration

1981 Organization of Economic Cooperation

1983 US Environmental Protection Agency (US EPA). Toxicology, Analytical Chemistry, etc

1989 US EPA revised the GLPs to include field testing (residue chemistry ecological effects, chemical fate and in certain cases efficacy)



Quality Assurance Audit Procedures

GLP Requirements, US EPA

Maintain a copy of the master schedule sheet for the test facility indexed by test article and containing the test system, nature of the study, study initiation date, current status, identity of the sponsor and name of the study director.

Maintain copies of all protocols for which the unit is responsible



Quality Assurance Audit Procedures

GLP Requirements, US EPA

Inspect each study at intervals adequate to ensure the integrity of the study (at least once)

Immediately report any problems likely to affect study integrity to management and the study director (SD)

Periodically submit to management and the SD written status reports on each study noting any problems and the corrective actions taken.



Quality Assurance Audit Procedures

GLP Requirements, US EPA

Maintain written and properly signed records of each periodical inspection

- Date of inspection
- Study inspected
- Phase or segment inspected
- Person performing the inspection
- Findings and problems
- Action recommended and taken to resolve existing problems
- Scheduled date for re-inspection

Quality Assurance Audit Procedures

GLP Requirements, US EPA

Review the final study report to assure that such report accurately describes the methods and SOPs and that the reported results accurately reflect the raw data

- Done according to the protocol/SOPs
- All GLP requirements included
- Circumstances affecting data quality reported
- Tables/text accurately reflect raw data
- Agency guidelines followed when applicable

Quality Assurance Audit Procedures

GLP Requirements, US EPA

Prepare a statement for inclusion in the final report

- Dates inspections were made
- Dates findings were reported to the SD and management

Quality Assurance Audit Procedures

GLP Requirements, OECD

- **QA is directly responsible to management**
- **Must be familiar with test procedures**
- **Must maintain copies of study plans, SOPs and an up-to-date master schedule**
- **Verify that the study plan contains all GLP required elements**
- **Conduct inspections to assure adherence to SOPs, and study plans (study, facility or process based)**

Quality Assurance Audit Procedures

GLP Requirements, OECD cont.

- **Audit the final report to assure it accurately and completely describes methods, procedures, and observations and reported results accurately and completely reflect the raw data**
- **Promptly reports inspection results in writing to management(s), SD and the PI**
- **Prepare a QA statement for the final report which includes the type of inspection, dates, phases, dates reported. The statement confirms that the final report accurately reflects the raw data.**



Quality Assurance Audit Procedures

Establishes Self Monitoring

- Provides Management with assessments:
 - that personnel are adequately trained
 - of ongoing study compliance with protocols/study plans, SOPs and GLP regulations
 - that resources are adequate for the performance of work
- Provides Regulatory Agencies with:
 - assurance that the testing facilities/test sites are being monitored for continual compliance

Quality Assurance Audit Procedures

Adds Value

- Assists in promulgating effective communication
- Assures that studies are re-constructable
- Assists in assuring data and reports are retained and available
- Assures study data and reports are of appropriate quality and can be submitted in multiple countries with comparable testing requirements



Quality Assurance Audit Procedures

What is Quality Assurance?

- US GLPs as: “any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies”
- OECD GLPs as: “an internal control system designed to ascertain that the study is in compliance with the Principles of GLP”

Quality Assurance Audit Procedures

What is Quality Assurance?

- A Monitor
- An Inspector
- An Auditor
- An Advisor





Quality Assurance Audit Procedures

What is Quality Assurance?

What does a Monitor do?

Conducts direct observations of in process activities and personnel for independent evaluation of regulatory compliance.



Quality Assurance Audit Procedures

What is Quality Assurance?

What does an Inspector do?

Conducts a critical appraisal of the capability, adequacy and/or current performance of a physical entity

Quality Assurance Audit Procedures

What is Quality Assurance?

What does an Auditor do?

Conducts a methodical examination, with the intent to verify raw, derived or transformed data, protocols/study plans, reports, standard operating procedures, memoranda, personnel records, notes, electronic records and related documentation for accuracy, integrity and adequacy for GLP compliance



Quality Assurance Auditing Procedures

What is Quality Assurance?

What does an Advisor do?

Provides Management and staff with informed opinion, advice and/or recommendations on issues pertaining to GLP studies and facilities/test sites.



Quality Assurance Auditing Procedures

How does Quality Assurance work?

- Establish a Quality Assurance Unit (QAU)
- Generate procedures that the QAU must follow for conducting inspections and audits
- Establish mechanisms for reporting inspection/auditing results to Management(s) and the Study Director/Principle Investigator (PI)



Quality Assurance Auditing Procedures

Establish a QAU

- Select personnel that are independent of study conduct
- Provide for training of personnel
- Provide resources for conducting needed inspections/audits (travel as appropriate)
- Provide management support of QAU recommendations for corrective actions when necessary



Quality Assurance Auditing Procedures

Generate Procedures that the QAU must follow for conducting inspections and audits

- Procedures must be in writing
- All QA personnel must follow these procedures
- All changes to procedures must be reviewed and approved by Management



Quality Assurance Auditing Procedures

Generate Procedures that the QAU must follow for conducting inspections and audits

- Procedures should include:
 - Facility Inspections
 - In-life inspections
 - Protocol/study plan audits
 - Data audits
 - Final and amended report audits



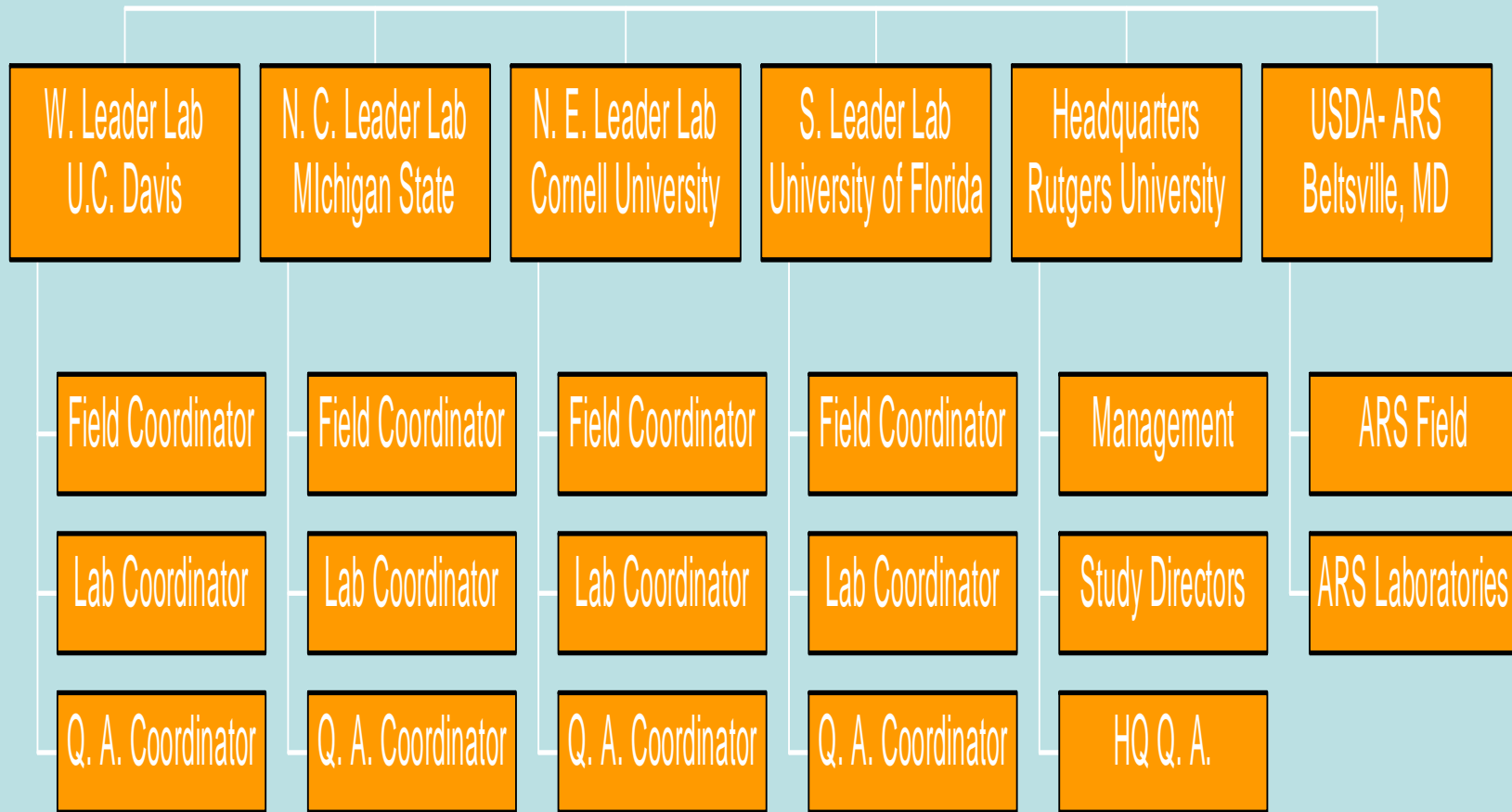
Quality Assurance Auditing Procedures

Generate Procedures that the QAU must follow for conducting inspections and audits

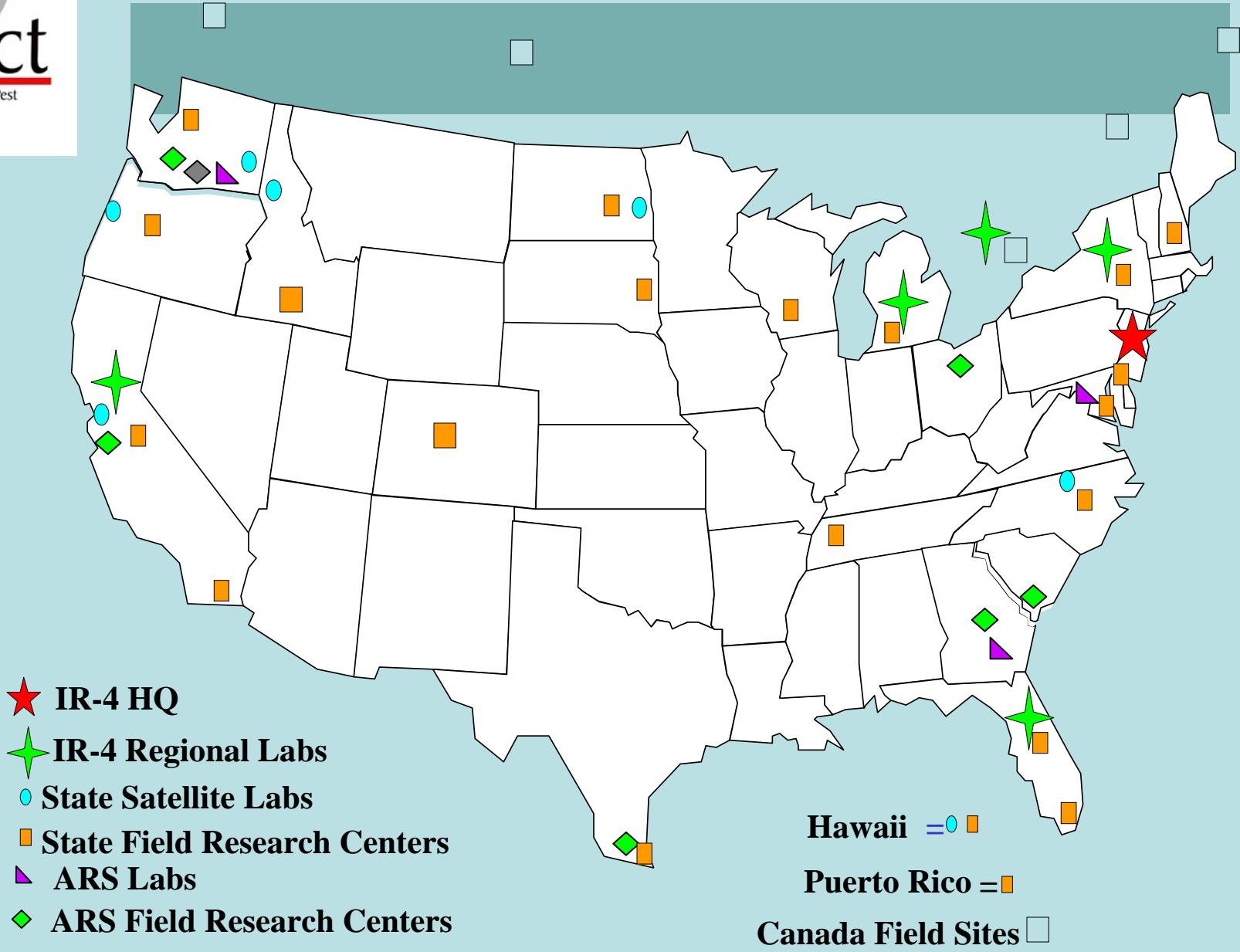
- **Recommended Procedures should include:**
 - Handling Agency Inspections
 - Retaining QA records
 - Training of QA staff
 - Reporting and responding to QA inspection reports
 - Quality Assurance files; organization and management



The IR-4 Project



IR-4 Facilities





Regional QA Personnel Distribution

* Regional Quality Assurance Coordinator

Western Region QA	North Central Region QA	North Eastern Region QA	Southern Region QA	IR-4 HQ QA	USDA ARS QA
James McFarland* Martin Beran Renee Harada	Michael Chen* Derek Killilea Bryan Jensen	Barbara Anderson*	Kathleen Knight* Vacant	Tammy White Jane Forder Bharti Patel	Regina Hornbuckle Diane Bradway Ken Kanagalingam



QA Laboratory Distribution 2007

Region	NE	NC	S	W	HQ
Labs	NYR	MIR	FLR	CAR	BER
				HIR	TIR
				WUR	YAR
					BAR
					UCR
					PTR
					VAL
					CER
					SYN
					RCR
					FMC
					MOR
FRDS	9	14	8	20	9



Quality Assurance Auditing Procedures

Copies of the GLPs and other resource documents are available at:

<http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html>

or

www.oecd.org

or

<http://www.sqa.org/newsite/public/rqap-references-glp.asp>



Quality Assurance Auditing Procedures

Thank You