



Are You Prepared for an Audit?

**Jordan Publico, B.S., RLATG, ILAM, RQAP-GLP
Senior Quality Assurance Auditor
Charles River, Insourcing Solutions (CRIS)**

Presentation Objectives

- Types of Audits
- Federal Regulations
- Preparation
- Conducting the Audit
- Reporting Findings
- Evaluating Responses



Types of Audits

Internal:

- Client and Corporate Assessments; Daily QC.
- Institutional Animal Care and Usage Committee (IACUC); Semi-annual.

External:

- Regulatory: FDA, USDA, USFW, CDC, DEA, etc.
- Voluntary: AAALAC



Code of Federal Regulations

- The Code of Federal Regulations (CFR) is the codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States. The CFR is divided into 50 titles that represent broad areas subject to federal regulation.

CFR continued.

- The CFR annual edition is the codification of the general and permanent rules published by the Office of the Federal Register as part of the National Archives and Records Administration (NARA) and the Government Publishing Office (GPO).
- The online version is updated daily.



Good Laboratory Practice (GLP)

21 CFR Part 58

- Inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study
- Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately

GLP cont. – 21 CFR Part 58

- Maintain written and properly signed records of each periodic inspection showing:
 - Date of the inspection
 - The study inspected
 - The phase or segment of the study inspected
 - The person performing the inspection
 - Findings and problems
 - Action recommended and taken to resolve existing problems
 - Scheduled date for re-inspection (if applicable)

Preparation



Preparation

- Select inspections appropriate for the study.
- Verify schedule and location in advance
- Review the protocol/s.
- Review applicable SOPs.
- Determine appropriate PPE for inspection.

Incorporating USDA / AAALAC into Your Audit

- Why look for items that may be USDA findings?
- Your facility SOPs should support USDA and AAALAC requirements
- Keep your eyes open for low hanging fruit!
 - Lights out
 - Hoofs, nails needing trimming
 - Scaling on cages
 - Damaged caging, carriers, gaps between doors (anything that may impact animal safety)
- Determine how to report items to management – your findings may not directly impact study conduct.



Preparation

- Schedule adequate time.
- Review facility activity scheduled during inspection.
- Consider joint inspection.
- Review recent inspections – look for trends.
- Prepare required documents.

Quality Control Checklist

Quality Control Checklist

Quality Team Member: _____ Date of review: _____

Area Lead Reviewer: _____ Date of review: _____

QA/PM Reviewer: _____ Date of review: _____

Area(s) Reviewed: _____

- | | Yes | No |
|---|--------------------------|--------------------------|
| 1) Are room(s), label(s), logs(s) etc. current and legible:
If no, what data was reviewed: _____
What is the concern: _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 2) Are there any animal abnormalities observed and/or untreated.
If yes, what is the animal/enclosure and nature of concern:
_____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 3) Is equipment preventative maintenance on schedule:
If no, what and when did PM last occur: _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 4) Building/Animal Room/Enclosure clean and secure.
If no, what and when was it last cleaned: _____
What does not lock/secure properly: _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 5) Are water quality tests and system checks completed on schedule:
If no, what and when was it last completed: _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 6) Are feed and storage areas maintained with no expired items:
If no, what is the concern: _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 7) Are Sign(s), SOP(s), Protocol(s), Work Order(s) etc. current:
If no, what document(s) need updated:
_____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 8) Are eye wash station checks and first aid supplies current:
If no, what equipment/supplies need checked and/or replaced:
_____ | <input type="checkbox"/> | <input type="checkbox"/> |

Any additional observations:



Are your systems working?

- Organization & Personnel
 - Master Schedule
 - QA Records
 - Organization Chart
 - Selection of Personnel Records
- General Facility Walkthrough
 - Animal Areas
 - Animal Supply Facilities
 - Test & Control Article Facilities



Are your systems working?

- General Facility Walkthrough
 - Animal Areas
 - Animal Supply Facilities
 - Feed / Water Analysis
 - Test & Control Article Facilities
 - Labeling
- Archive
 - Index
 - Access
 - Conditions

Conducting the Audit

- Who will escort the auditor/s?
- Who is/should be present?
 - Manager
 - Study Director
 - Quality Assurance Unit (QAU)
 - Attending Veterinarian

The Inspection

- Stop
- Look
- Listen
- Don't Interfere!
- What if you see problems?



Report findings

- Report observations as appropriate:
 - Animal Housing Records.
 - Documentation during the Inspection.
 - Test Article Records.
 - Equipment Records.
 - Labeling – specimens & reagents.
 - Personnel Records.
- Ensure management documents Corrective and Preventative Action (CAPA) and submits on time.

Evaluating Responses

- What is final decision?
 - Has operations been halted due to an audit finding?
 - Were any animal health and/or safety concerns cited?
 - Was a fine issued?
 - Are Upper Management/Corporate Compliance aware that an audit was conducted and by whom?

Quality is doing the right thing the first time when no one is looking!

References:

- www.fda.gov
- www.usda.gov
- www.aaalac.org
- www.sqa.org
- www.aalas.org



Contact information

Jordan Publico, B.S., RLATG, ILAM, RQAP-GLP

jordan.publico@crl.com

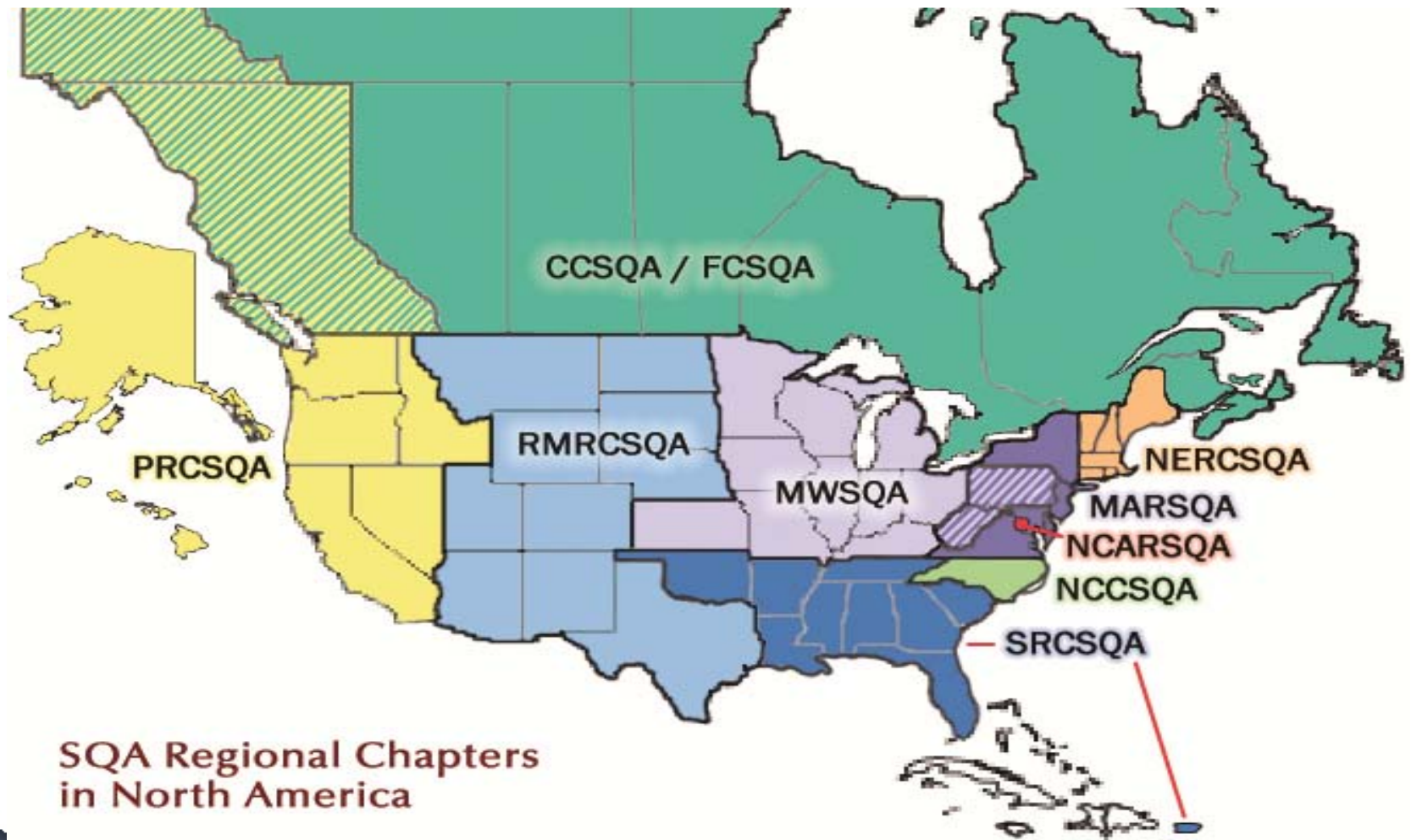
National Capital Area Regional Chapter Society of Quality Assurance
NCARSQA President 2015, Past President 2016. SQA AHSS



Society of Quality Assurance (SQA)

- SQA is an association of over 2,200 QA professionals who are dedicated to implementing industry, governments, academia requirements, information sharing, and consulting.
- Good Clinical Practices (GCPs)
- Good Laboratory Practices (GLPs)
- Good Manufacturing Practices (GMPs)

SQA Chapters





National Capital Area Regional Society of Quality Assurance (NCARSQA)

- 1• Education Programs.
- 2• Dexter Goldman Memorial Scholarship Award eligibility.
- 3• NCARSQA Educational Scholarship Award eligibility.
- 4• Leadership Training and Networking Opportunities.
- 5• Newsletters.
- 6• Company profiles and job postings advertised on website and newsletters.
- 7• NEW BRAND! NEW WEBSITE!

COMING SPRING 2015!

www.NCARSQA.org

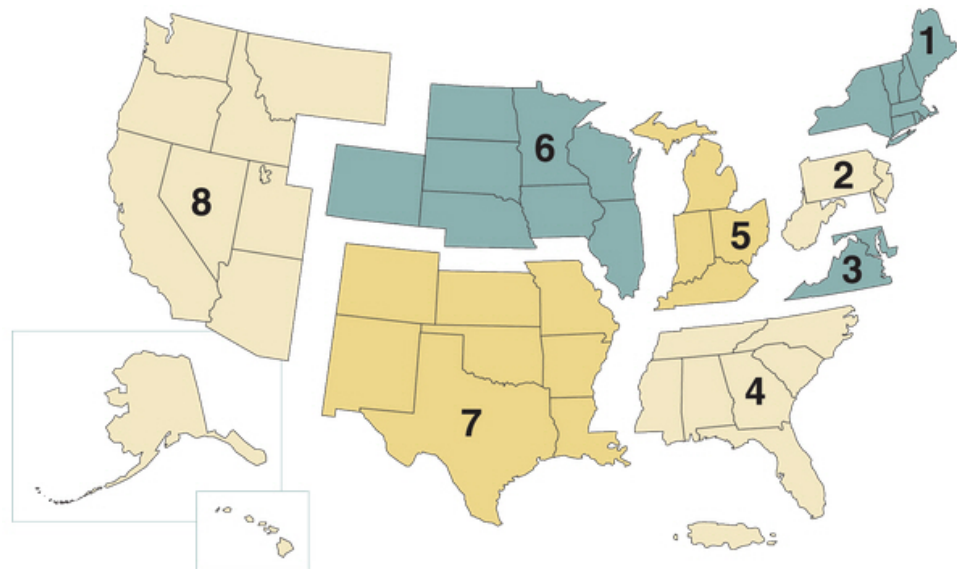


American Association for Laboratory Animal Science (AALAS)

- AALAS is an association of professionals that advances responsible laboratory animal care and use to benefit people and animals.
- AALAS provides educational materials to laboratory animal care professionals and researchers, administers certification programs for laboratory animal technicians and managers, publishes scholarly journals, supports laboratory animal science research, and serves as the premier forum for the exchange of information and expertise in the care and use of laboratory animals.

AALAS Districts

- 1: Northern Mountain
- 2: Central PA.
- 3: National Capital Area Branch (NCAB)
- 4: Appalachian
- 5: Central OH.
- 6: Central IL.
- 7: Mile-High
- 8: Western Mountain



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The headlines **you make**
in this life will be based on
the difference **you made**
in the lives of others.

