

# ARCHIVES

Reference: Good Laboratory Practice Standards, 40 CFR Part 160,  
Section 160.190

- Points covered in “Debate between Auditor Hilarity Klingon and Auditor Mack Pain”:
- Archive Requirements
- Limited Access
- Authorized Personnel
- Designated Archivist and Back-up Archivist
- Included on Organization Chart
- Written Job Descriptions
- Secure
- Lockable (Separately)
- Capable of protecting records from harm
- Indexed for easy retrieval
- File folder tabs / Yearly drawers / Database or Hard Copy
- Index kept in Archive

- Contents
- Data obtained during studies
- Capable of complete reconstruction of studies
- Common Data (Field Site Data common to multiple studies)
- Records of anything generating data
- Master Schedule
- Periodic (Monthly) printouts (“Snapshots in Time”)
- SOP’s (Originals)
- Personnel Records (Ex-employees)
- Exact Copies of Data
- May be substituted for originals for archiving
- To send Common Data to Study Directors
- But FIFRA “Books & Records” requires “retained” originals
- Quality Assurance Records
- All audits and inspections by site QAU
- Copies of Signed & Dated acknowledgements by Sponsor  
Management and Study Directors

## Going Out of Business

All original Common Data to an accepting Sponsor

Notify EPA of location of Data

Notify other Sponsors of location of Data