

Maintaining Quality & Data Integrity



Kelly Mason

Typical Definitions of Quality & Data Integrity

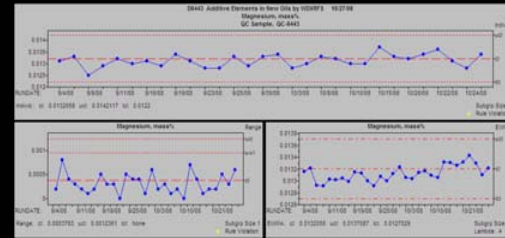
- **International Laboratory Standards or Guidelines:**

- CLSI Guide GP26-A2(Application Of A Quality Systems Model For Laboratory Services)
- ISO 15189 (Medical Laboratories Particular Requirements For Quality And Competence)
- ISO 17025 (General Requirements For The Competence Of Testing And Calibration Laboratories)
- Clinical Pathology Accreditation (CPA) - (Standards For The Medical Laboratory)
- ASTM 6792 (Standard Practice For Quality System In Petroleum Products And Lubricants Testing Laboratories)
- etc.

Typical Components Of A Quality Laboratory System



- Calibration
- Statistical Quality Control
- Benchmarking
 - External crosscheck programs (round robin testing)
 - Blind repeat analysis
 - Comparison to method published capabilities
- Recording, Documentation, And Storage Of Data
- Equipment Maintenance
- Customer Interface Agreement
- Non-Conformance And Customer Inquire Reports
- Etc.



What Is Meant By Maintaining Quality & Data Integrity?

Integrity

- Firm Adherence to Documented Procedures
- Protected From Theft or Catastrophic Events
- Legally Defensible Data



Quality

- Results Have Accuracy – Fit For Purpose
- Complete Documentation of Data
- Consistent (Precision) – Fit For Purpose

More than a Quality Slogan?

Why Is Data Integrity And Maintaining Quality Important?



- **Supplier – Customer Interactions/Transactions**
- **Organization’s Policy (Business/Organization Ethics)**
- **Government Regulations/Compliance**
- **Profitability (Business or Funding)**

What Influences Data Integrity And Maintaining Quality?

- **External Demands**
 - Funding Institutions
 - Production/Manufacturing
 - Marketing
 - Commercial Disputes
- **Work Volumes Exceeding Capacity**
- **Business/Funding Needs**
- **Research Targets**
- **Personal Demands**
- **etc.**

Data Integrity

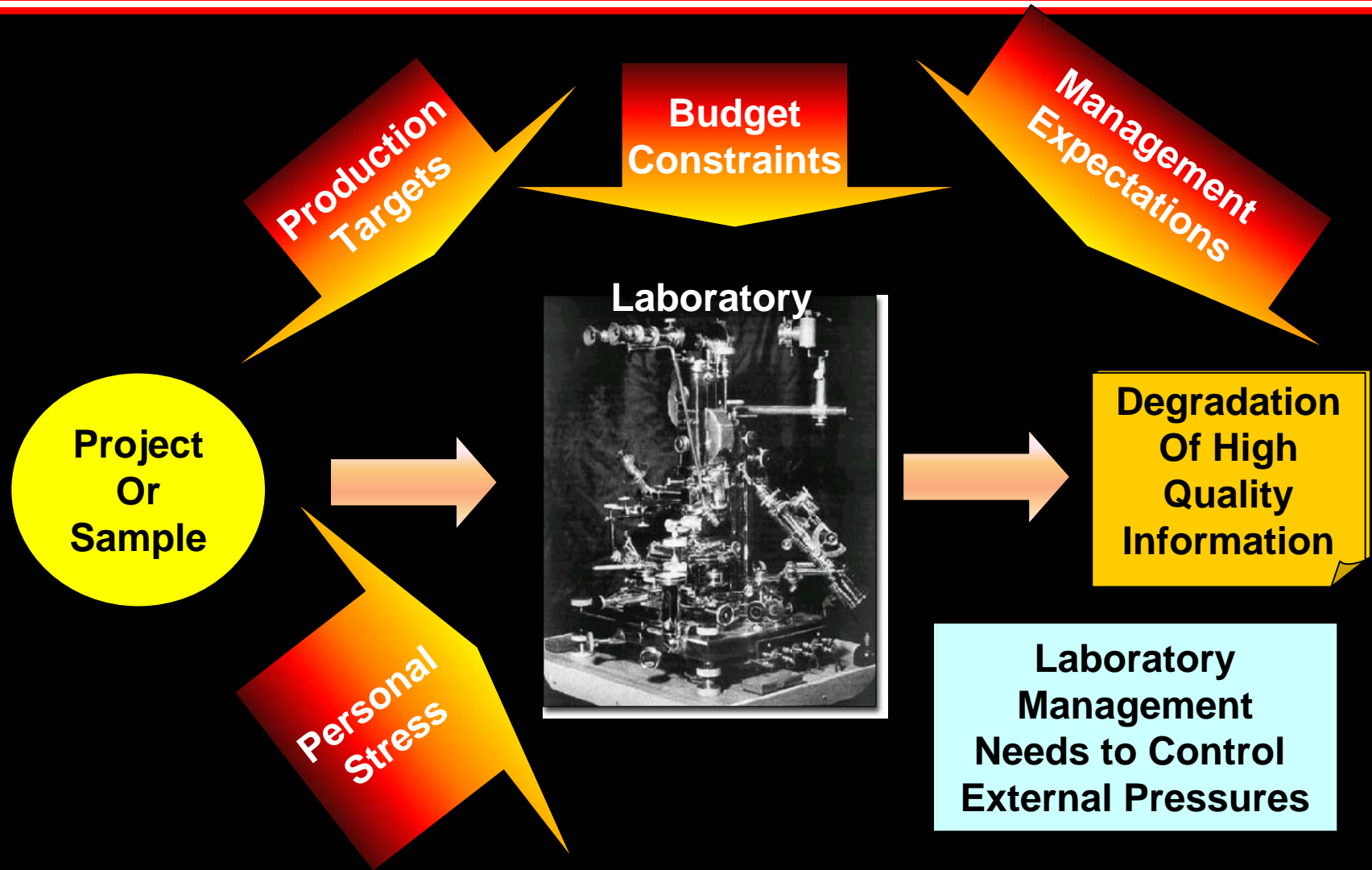


Data Integrity Policy

- Each person is responsible and held accountable for honestly producing and communicating data and information which are:
 - Accurate
 - Precise
 - Complete
 - Timely
 - Highest Integrity



Data Integrity Model



Maintaining Quality



Quality Assurance

- QA must include one or more of the following:
 - Calibration
 - Preventive Maintenance
 - Audits (i.e. Test Method Assessment)
 - Inter Lab Cross Checks/Round Robins
 - SQC Samples (including outside labs)
 - Test Performance Reviews (Test Performance Index)
 - Record & Track Customer Complaints



Test Performance Index, D6792

- *test performance index, TPI, n*—an approximate measure of a laboratory’s testing capability, defined as the ratio of [documented] test method reproducibility to site precision [or actual laboratory precision].
- Site Precision is usually extracted from QC data.

• **TPI =**
$$\frac{\text{Documented Reproducibility}}{\text{Site Precision}}$$

| TPI Value (when PR<4) | Outcome |
|---------------------------|------------------------|
| >1.2 | Satisfactory |
| ≥ 0.8 and ≤ 1.2 | Suggests Investigation |
| <0.8 | Needs Improvement |

All Employees Must...

- Know and Understand Data Integrity and Quality Assurance Policy
- Record Test Results Completely and Accurately Following Documentation Requirements
- Avoid Selective Reporting or Falsification of Data

General Expectations

- Quality Assurance Is In Place
- Specified Test Methods Or Approved Modified Methods Are Used
- Results Are Recorded Accurately And Completely
- Systems Are In Place To Deter, Detect, And Correct Inaccurate Data
- Supervisors Are Promptly Made Aware Of Inaccuracies In Data

Record Retention Policy

- Permanent -- Numbered Technical Correspondence, Reports, Laboratory Notebooks (And Associated Paper And Electronic Files Referenced In Lab Notebooks)
- 15 Years – Analytical Monitoring Data And Instrument Log Books
- 5 Years -- Raw Data From Analysis (I.E. GC, MS Etc.)

Data Records – Laboratory Notebooks

- Property Of Organization; Responsibility Of Individual
- Data Records Should Chronicle Research Efforts
- Subject Legal Scrutiny (i.e. Patent Interference Proceedings And Litigation)
- Must Follow Organization's Documentation Policy
- All Relevant Information Should Be Entered In Sufficient Detail So That Knowledgeable Others Could Reproduce The Work
- **Management Audits Compliance Periodically**



Summary

Maintaining Quality & Data Integrity Means That The Data Producing Organization Is Confident Of Their Data. In Other Words, The Data Generated Can With Stand Challenges Of:

- Completeness of Records**
- Accuracy**
- Precision**
- Adherences To Documented Methods**

Laboratory Management Sets The Tone For Success!

Backup

ExxonMobil's DIAF Objectives

The Data Integrity Assurance Framework (DIAF) objective is to assure honest, accurate, complete and timely communication and proper representation of test data to ExxonMobil's businesses, customers and regulatory bodies. It is ExxonMobil's policy to choose the course of highest integrity in obtaining and communicating such data. This framework for data integrity assurance is designed to guide operating organizations in discharging their ongoing responsibilities on behalf of the corporation.

Analytical Method Document Requirements

| Section ref from 91-003 | Description From 91-003 |
|-------------------------|---------------------------------|
| 2.1.1 | Title |
| 2.1.2 | Date Of Revision |
| 2.1.3 | Introduction |
| 2.1.4 | Scope |
| 2.1.5 | Referenced Documents |
| 2.1.6 | Theory |
| 2.1.7 | Summary of Method |
| 2.1.8 | Definitions Terminology |
| 2.1.9 | Apparatus |
| 2.1.10 | Reagents and Materials |
| 2.1.11 | safety |
| 2.1.12 | sampling |
| 2.1.13 | calibration and Standardization |
| 2.1.14 | Procedure |
| 2.1.15 | Calculations |
| 2.1.16 | Report |
| 2.1.17 | Quality Control |
| 2.1.18 | Precision and Bias |
| 2.1.19 | Additional Information |
| 2.1.20 | Document History |
| 2.1.21 | Disclaimer |