



## *Quality System Standards – The Family Tree*

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Presented by: Kirstin Daigle  
Stone Environmental, Inc.

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# Introduction

- **Acronyms Defined**
- **Back to Basics**
- **Umbrella Image: The Common Metaphor**
- **Family Tree: A New Metaphor for Quality Systems Standards**
- **Quality System Standards Overview**
- **Hierarchy**
- **Relationships**
- **Q&A**

## Jargon: Quality System Standard Acronyms

QSS	=	Quality System Standard
OECD	=	Organization for Economic Cooperation and Development
GLP	=	Good Laboratory Practices
ISO	=	International Standards Organization
IEC	=	International Electrotechnical Commission
FDA	=	Food and Drug Administration
EPA	=	Environmental Protection Agency
TNI	=	The NELAC Institute
NELAP	=	National Environmental Laboratory Accreditation Program
NEFAP	=	National Environmental Field Accreditation Program
DoD	=	Department of Defense
QAPP	=	Quality Assurance Project Plan
SAP	=	Sampling and Analysis Plan

# What is a Standard?

*A specified way of doing something*

**What do Standards do for Your Business?**

**Help Ensure Quality**

**Facilitate Trade**

**Unify Practices**

**Promote Compatibility**

**Create Efficiencies**

**Level the Playing Field**

**Boost Credibility**

**Establish Competency**

# What is a Quality System Standard (QSS)?

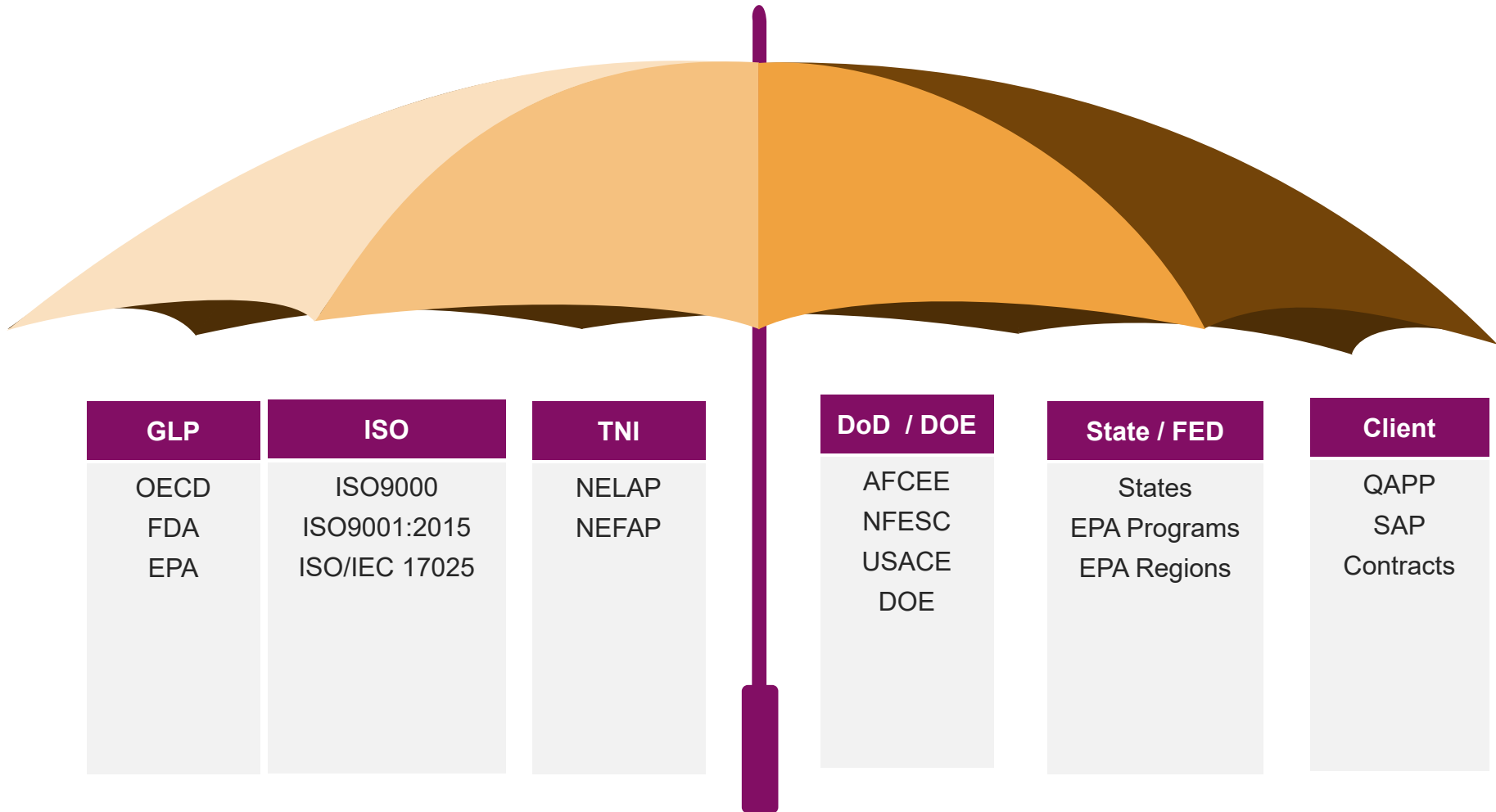
A document that establishes the requirements for a quality management system

A quality management system (QMS) is a set of policies, processes, procedures and responsibilities for achieving quality policy and objectives.

Quality System Standards for Testing establish the policies, procedures and responsibilities for ensuring that data derived from testing activities are:

Reliable, Relevant & Adequate  
*for*  
Intended Use

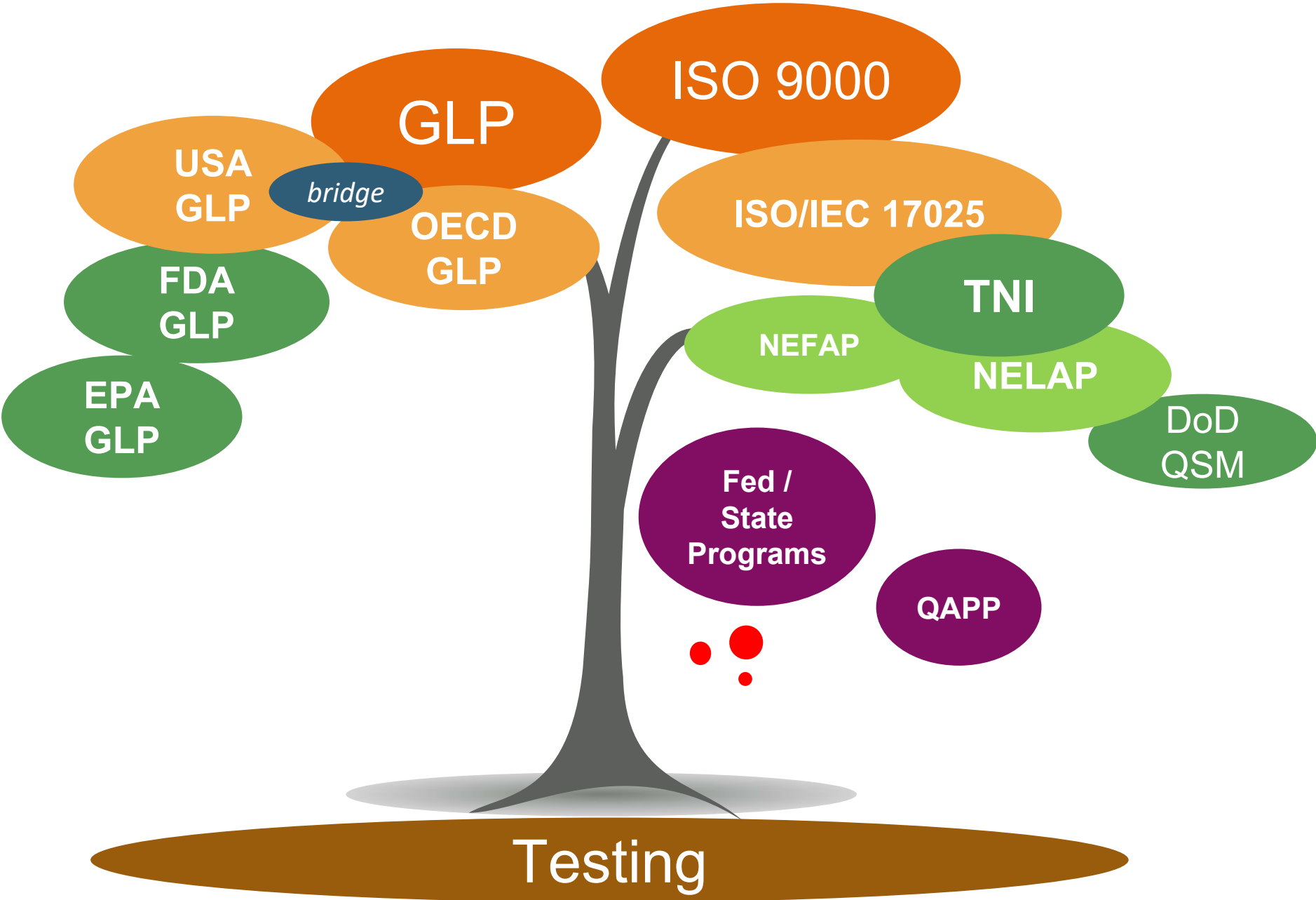
# The Umbrella Metaphor



# Problem with the Umbrella Metaphor

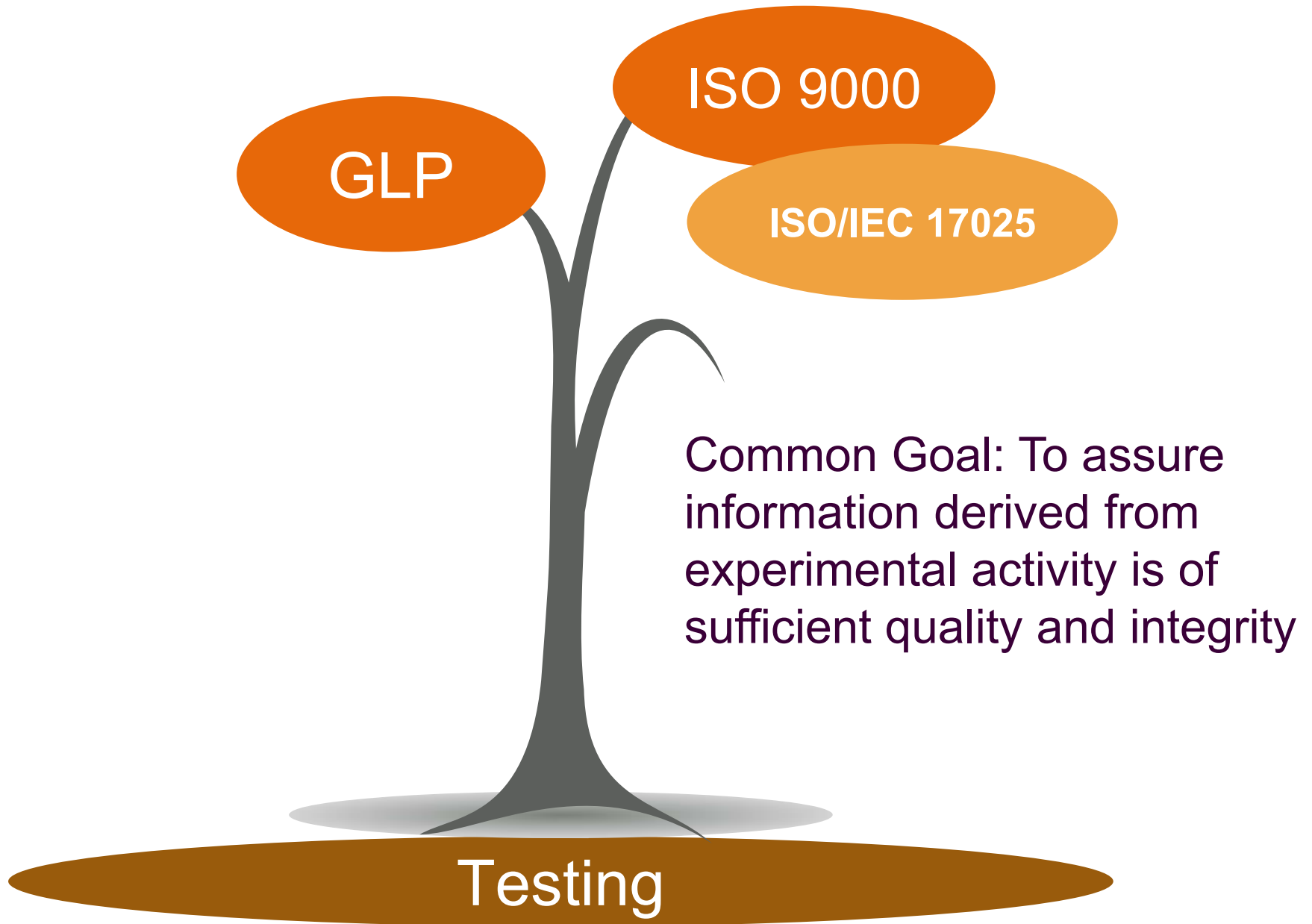


# Quality System Standards - The Family Tree





# Quality System Standards – GLP & ISO



# General Comparison of GLP and ISO/IEC 17025

## GLP

### REGULATORY STANDARD

- Often Written into Law
- Any Industry
- *Specific Application*
- Emphasizes Individual Study
- No Accreditation

## ISO/IEC 17025

### COMPETENCY STANDARD

- Voluntary or Mandated
- Testing & Calibration Laboratories
- *Broad Application*
- Emphasizes Management Systems
- Non-Government Body Accreditation

# Good Laboratory Practices (GLP) Applications

## OECD GLP

- International & Intergovernmental
- More Flexible
- Consensus Based Guidance

## USA GLP

- US Regulatory (FDA & EPA)
- More Prescriptive
- Regulatory Interpretation (FAQ)

# GLP: Which Application Should I Use?

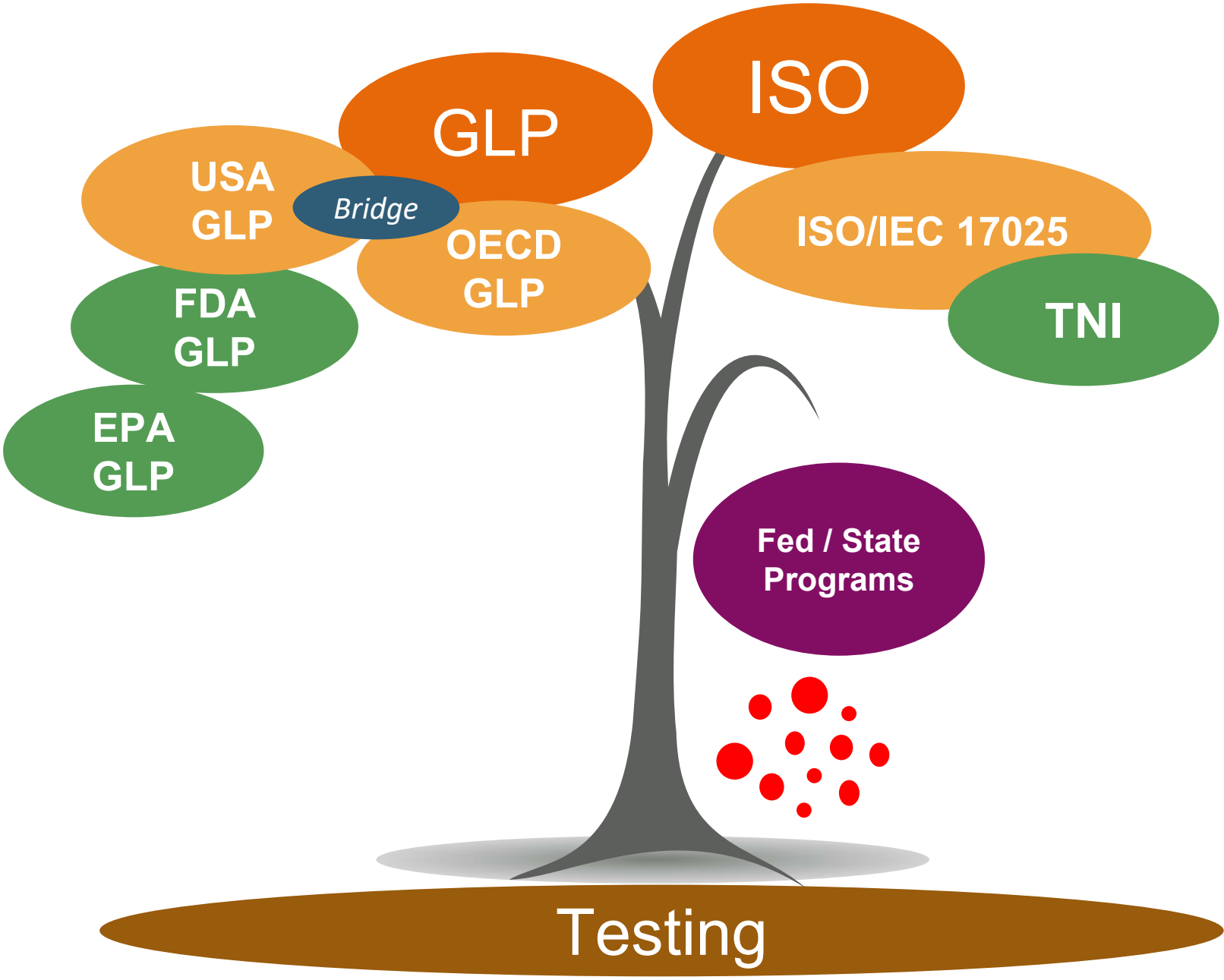
## What is the purpose of your study? Where will the data be submitted?

**OECD:** Principles applied to non-clinical safety testing of test items contained in pharmaceutical, pesticide and cosmetic products, veterinary drugs including food and feed additives and industrial chemicals. (International)

**FDA:** Prescribed practices for conducting non-clinical laboratory studies that support or are intended to support applications for research and marketing permits for products regulated by the Food and Drug Administration to assure quality and integrity of safety data filed under the Federal Food Drug and Cosmetic Act and the Public Health Service Act.

**EPA:** Prescribed practices for conducting studies relating to health effects, environmental effects and chemical fate testing to ensure quality and integrity of data submitted pursuant to testing agreements and rules under the Toxic Substances Act (TSCA).

# Quality System Standards - The Family Tree



# TNI Standard

- Accreditation Standard – Mandated or Voluntary
- Incorporates Full Text of ISO/IEC 17025
- Includes clarifying language and additional requirements
- Developed by Consensus
- Widely Recognized and Accepted in Environmental Testing Community

**NELAP:**

**National Environmental Laboratory Accreditation Program**

**NEFAP:**

**National Environmental Field Accreditation Program**

# Quality System Standards – Department of Defense

## DoD Consolidated Quality System Manual (DoD QSM)

- AFCEE (Air Force Center for Environmental Excellence)
- NFESC (Naval Facilities Engineering Service Center)
- USACE (US Army Corps of Engineers)
- DOE (Department of Energy)

Based on ISO/IEC 17025:2005 & TNI Standard Volume 1

Includes additional definition and requirements specific to DoD objectives

# Quality System Standards – Other

## Non-NELAC State Programs

### EPA Programs

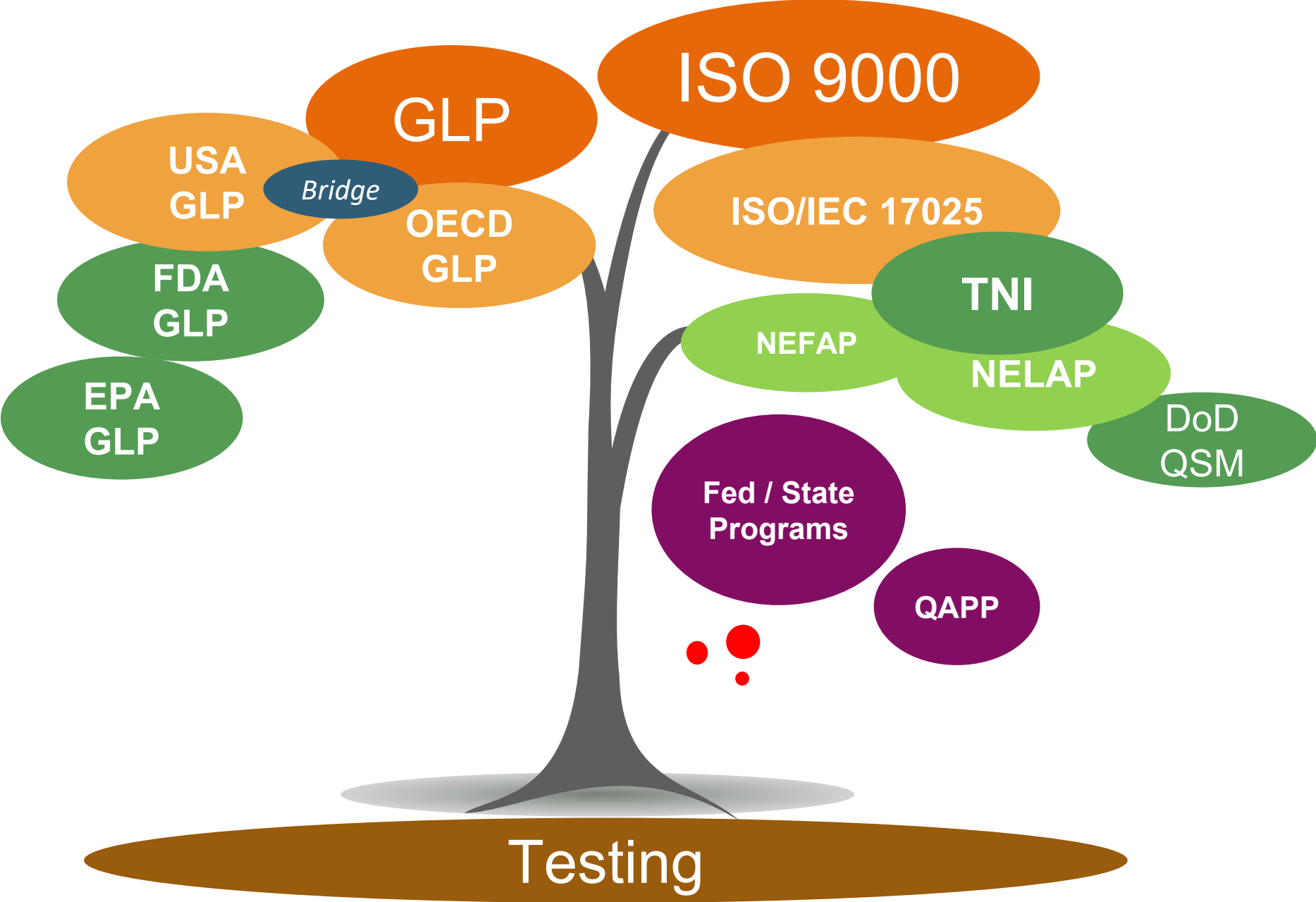
- **Contract Laboratory Approval Program (CLP)**
- **EPA Drinking Water Manual**
- **EPA Regulations**
- **40CFR Part 136: Clean Water**
- **40CFR Parts 141 and 143: Drinking Water**

### Client Contracts

- **Quality Assurance Project Plans (QAPP)**



# Quality System Standards - The Family Tree



# References & Resources

*OECD Position Paper Regarding the Relationship between OECD Principles of GLP and ISO/IEC 17025, Organization for Economic Cooperation and Development, Paris 2016*

*OECD and USA GLP Applications, Del Huntsinger, Ann IST Super Sanita 2008, Vol. 44, No. 4-403-406*

*Comparison Chart of FDA and EPA Good Laboratory Practice (GLP) Regulations and the OECD Principles of GLP, US Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs (ORA) June 2004*

*Society for Quality Assurance*

[www.sqa.org](http://www.sqa.org)

*Organization for Economic Cooperation and Development*

[www.oecd.org](http://www.oecd.org)

*US Food and Drug Administration*

[www.fda.org](http://www.fda.org)

*US Environmental Protection Agency*

[www.epa.org](http://www.epa.org)

*International Standards Organization*

[www.iso.org](http://www.iso.org)

*The NELAC Institute*

[www.nelac-institute.org](http://www.nelac-institute.org)

*DoD Environmental Data Quality Workgroup*

[www.denix.osd.mil/edqw/documents/](http://www.denix.osd.mil/edqw/documents/)



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**Thank you.**

For more information / [www.stone-env.com](http://www.stone-env.com)

Contact / [kdaigle@stone-env.com](mailto:kdaigle@stone-env.com)