



## What Is the OPP Approach to the Next Generation of Laboratory Requirements

# Planetary Protection Quality Management System

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## *Quality is a measure of compliance with descriptions of intent*

### Spacecraft Mission/Project

- A credible verification approach that validates implemented PP processes by providing assessment (validation) strategies including data acquisition, processing, end use, and reporting
- Process validation via the generation of appropriate data quality objectives, process implementation and data capture that supports those objectives.
- Laboratory compliance with analytical data quality objectives via standardized laboratory management and procedural requirements
- Demonstration of compliance throughout the process evaluation, and independent internal assessment

### Office of Safety and Mission Assurance

- Implementation of a risk-based assessment program that accounts for the criticality of the mission, systems, subsystems, components, subassemblies, parts and materials, and the likelihood and severity of consequences if compliance is not achieved.
- Process validation via the concurrence with appropriate data quality objectives, process implementation and data capture that supports those objectives.

# OPP's Quality Assurance Focus

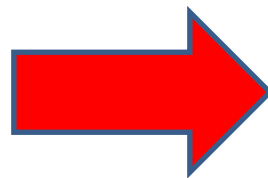


Photo Credit: APL

**Heavily biased towards auditing the mechanics of data acquisition and has lost focus on resulting data and data outcomes.**

**Direct assay data itself validates hardware bioburden status at moment in time but not over the entire assembly process.**

**The process has become prescriptive and not performance based.**



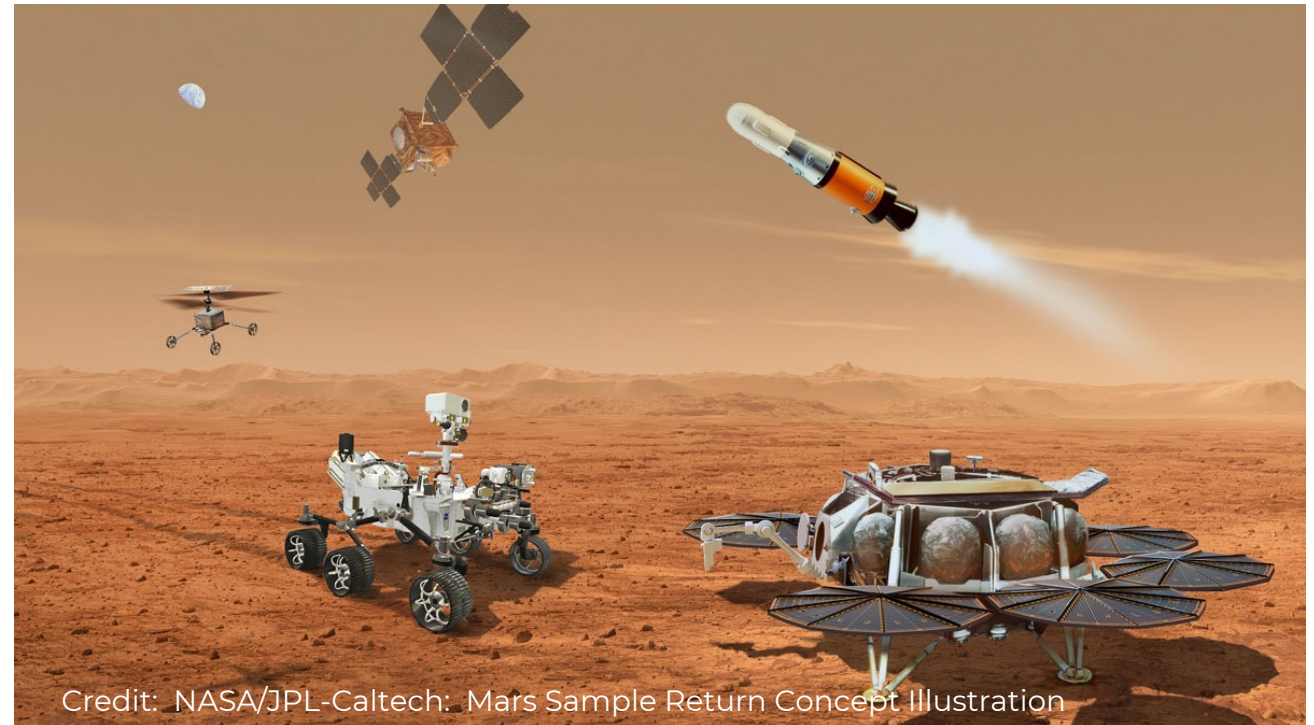
**OPP's quality assurance focus is process validation via the generation of appropriate data quality objectives, process implementation and data capture that supports those objectives.**



Photo Credit: NASA

## What this means to Projects

- Planetary Protection under the Office of Safety and Mission Assurance is moving toward process validation via standardized quality approaches
- A systematic quality-based approach expands the framework for alternate approaches and methods to demonstrate compliance with PP requirements
- It empowers the Project to validate its own PP processes, thus feeding into OPP concurrence via validated and comprehensive data sets.
- Shifts the ownership of PP compliance to the Project



Credit: NASA/JPL-Caltech: Mars Sample Return Concept Illustration



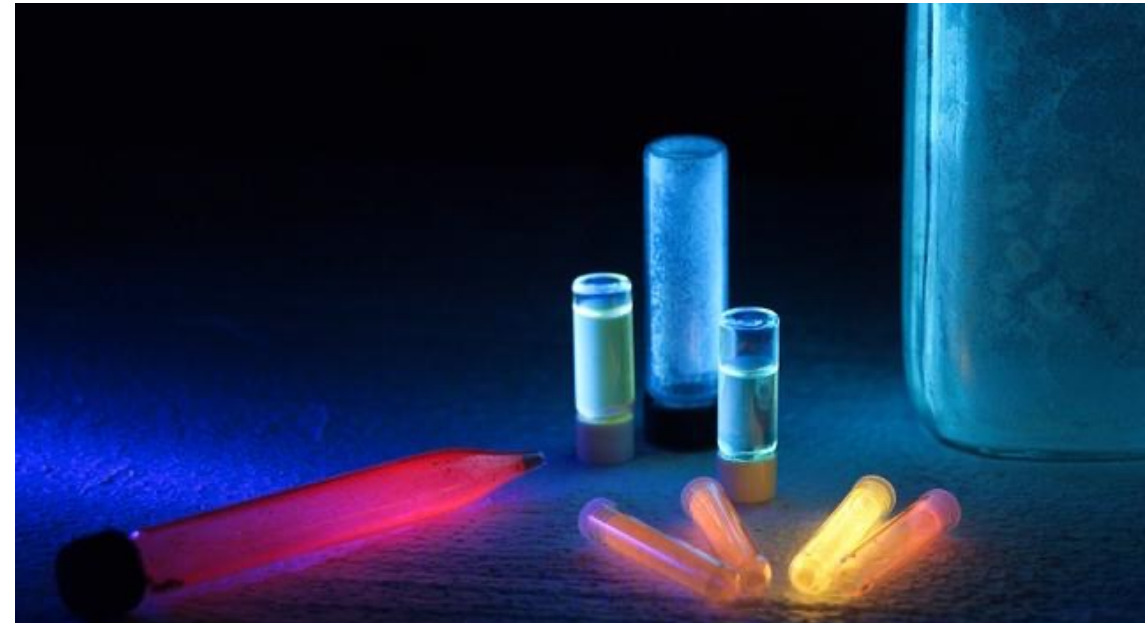
# Path Forward: Culture Change Toward Standardization

## Aligning NASA Standards to Industry Standards

### Standardization of Approach

What we can take now from Industry

- **Standardization of Format – Technically and Topically**  
The technical requirements we need to have in place to “standardize” assay methods: Topically operating requirements that look like Industry
- **Substitute Existing Standards as Applicable**
- **Develop Validation Requirements – Prescriptive and Performance Based or Hybrid**



Astrochemistry Laboratory; nebula like gases forming cellular like structures 'amino acids' PAH's (by blacklight) : [ARC-2002-ACD02-0139-004](https://www.nasa.gov/images/content/105957main_astrochem_020202_0139_004.jpg) | [NASA Image](https://www.nasa.gov/images/content/105957main_astrochem_020202_0139_004.jpg)

**There are two general approaches to developing a quality assurance program: a prescriptive approach, in which we prescribe an exact method of quality assessment, and a performance-based approach in which we can use any form of quality assessment, provided that we can demonstrate an acceptable level of statistical control [Poppiti, J. *Environ. Sci. Technol.* 1994, 28, 151A–152A].**

**Prescriptive Based:** duplicate samples, blanks, standards, and spike recoveries are measured using a specific protocol. We compare the result of each analysis to a single predetermined limit, taking an appropriate corrective action if the limit is exceeded. Prescriptive approaches to quality assurance are common for programs and laboratories subject to federal regulation. For example, the Food and Drug Administration (FDA) specifies quality assurance practices that must be followed by laboratories that analyze products regulated by the FDA.

**Performance Based:** a laboratory is free to use its experience to determine the best way to gather and monitor quality assessment data. The tools of quality assessment remain the same— duplicate samples, blanks, standards, and spike recoveries—because they provide the necessary information about precision and bias. What a laboratory can control is the frequency with which it analyzes quality assessment samples and the conditions it chooses to signal when an analysis no longer is in a state of statistical control.

Reference: evaluating Quality Assurance Data: David Harvey, [15.4: Evaluating Quality Assurance Data - Chemistry LibreTexts](#)

# Performance Based Validation

## Quality Assurance Approaches are Common and Available in Industry

They feature similar language and requirements including:

- ✓ Laboratory Management Systems and Process Evaluation
- ✓ Data Quality Evaluation and Criteria
- ✓ Method and Analyst Proficiency
- ✓ Risk Evaluation
- ✓ Corrective Action Requirements

## Participating Organizations using Process/Performance Based Paradigms

- American Industrial Hygiene Association (AIHA)
- International Organization for Standardization (ISO)
- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)
- National Environmental Laboratory Accreditation Conference (NELAC) –uses ISO standards
- ASTM International Standards

## Data Quality Objectives

- Qualitative and quantitative statements describing a process or study objectives that define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support data acceptance decisions

## Performance and Acceptance Criteria

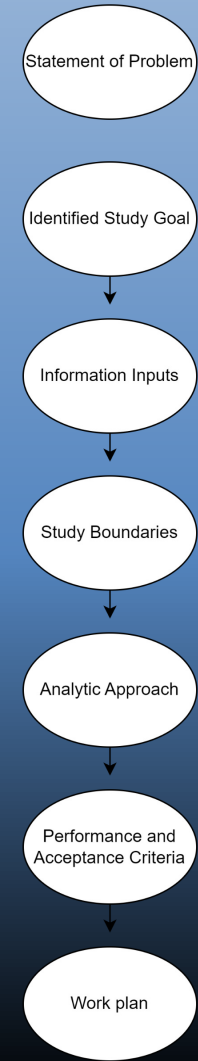
- Performance criteria represent the full set of specifications that are needed to design a data or information collection effort such that, when implemented, generate newly collected data that are of sufficient quality and quantity to address the project's goals.
- Acceptance criteria are specifications intended to evaluate the adequacy of one or more existing sources of information or data as being acceptable to support the project's intended use.

From: EPA Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA/240/B-06/001 February 2006

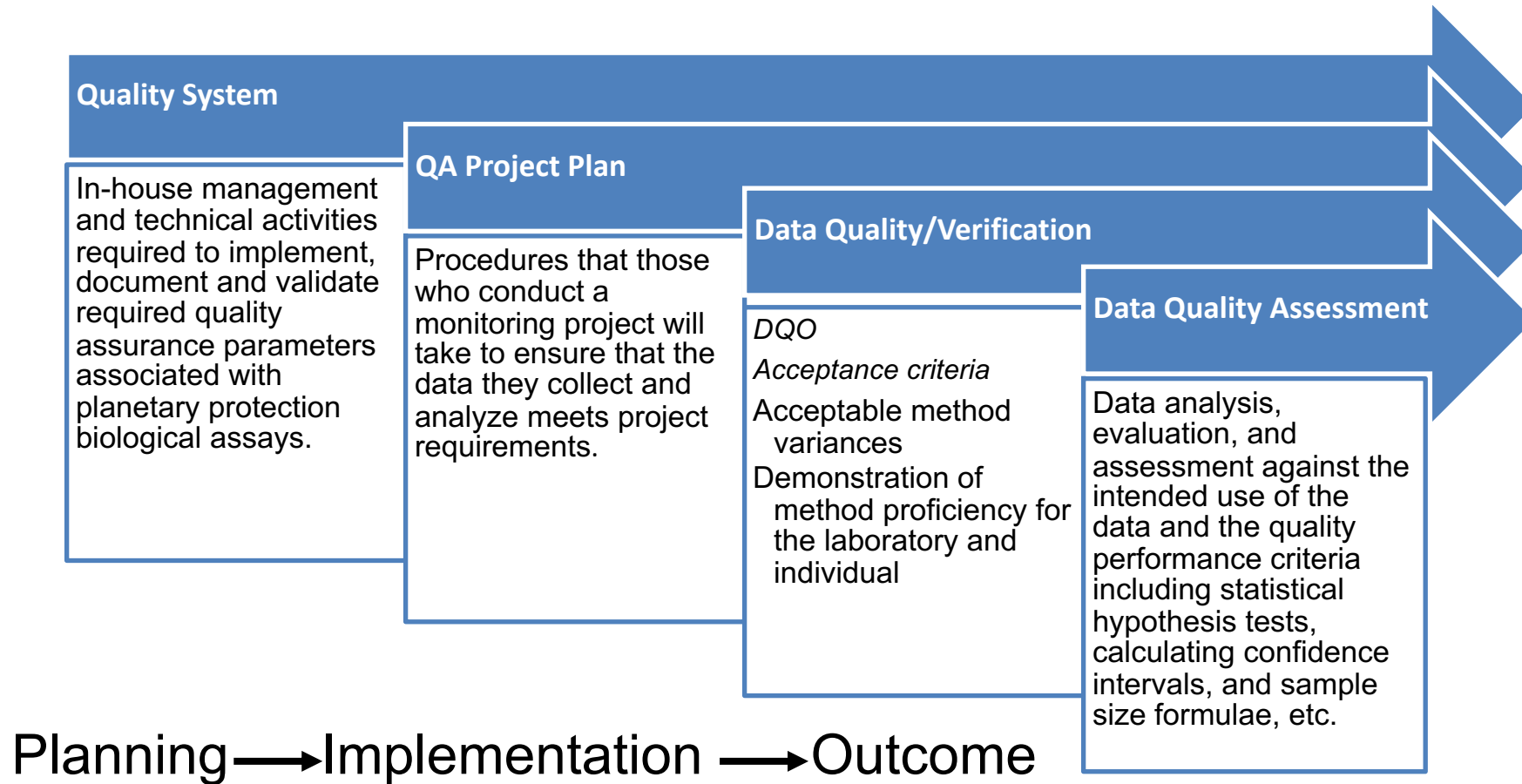
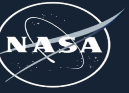


# DQO Based Approach

- Analyses defines the type and quality of data needed for end use
- Planning and data evaluation criteria is critical before data acquisition
- Boundaries and limitations of studies are addressed
- The analytical approach is based upon statistical evaluations of risk and resolution strategies
- Performance criteria based upon error, confidence level, and other statistical indicators
- Work plan implements all of the criteria above to ensure comprehensive and defensible data package

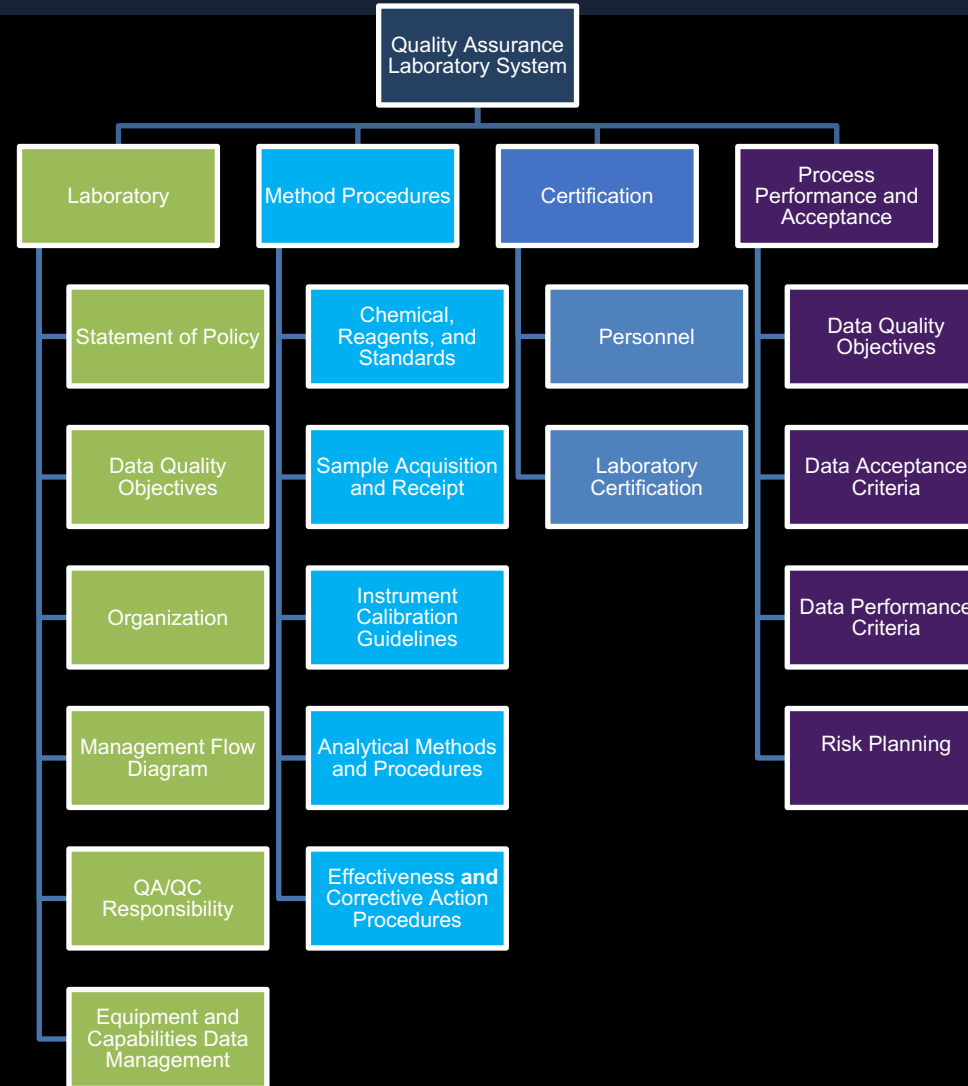


# Performance Based Validation

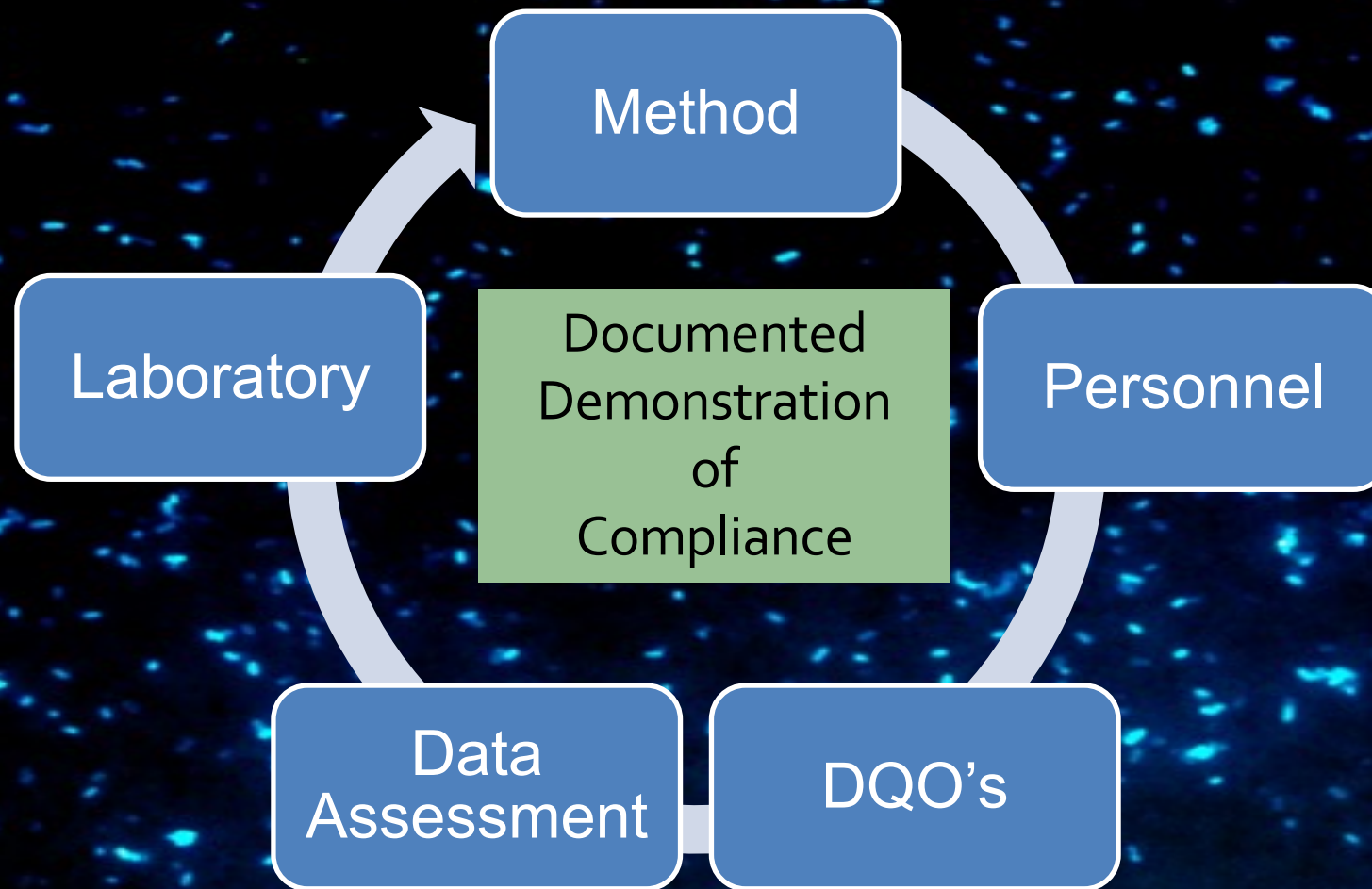


From: EPA Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA/240/B-06/001 February 2006

# Laboratory Plan



# Validation via Continual Process Monitoring and Evaluation



- **PP validation is moving towards a process-based quality paradigm**
- **Verifying the process implementation and performance of planetary protection requirements over a Project's lifecycle**
- **Transferring the demonstration of compliance from NASA OPP to the Project**
- **Adopting standardized analytical approaches between NASA and industry to support both NASA and commercial endeavors**



## Source/Reference Documentation

- NASA Policy
  - NPR 8715.24 Planetary Protection Provisions for Robotic Extraterrestrial Missions
  - NPR 8735.2C Hardware Quality Assurance Program Requirements for Programs and Projects (Updated w/Change 1)
- Interagency and Industrial Standards
  - EPA Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA/240/B-06/001 February 2006
  - ISO/IEC 17025:(2017) General Requirements for Competence of Testing and Calibration Laboratories
- Other
  - Poppiti, J. Environ. Sci. Technol. 1994, 28, 151A–152A
  - Evaluating Quality Assurance Data: David Harvey, [15.4: Evaluating Quality Assurance Data - Chemistry LibreTexts](#)