Standardized Methods and Flexible Methods Approaches

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STANDARDIZED METHODS APPROACH

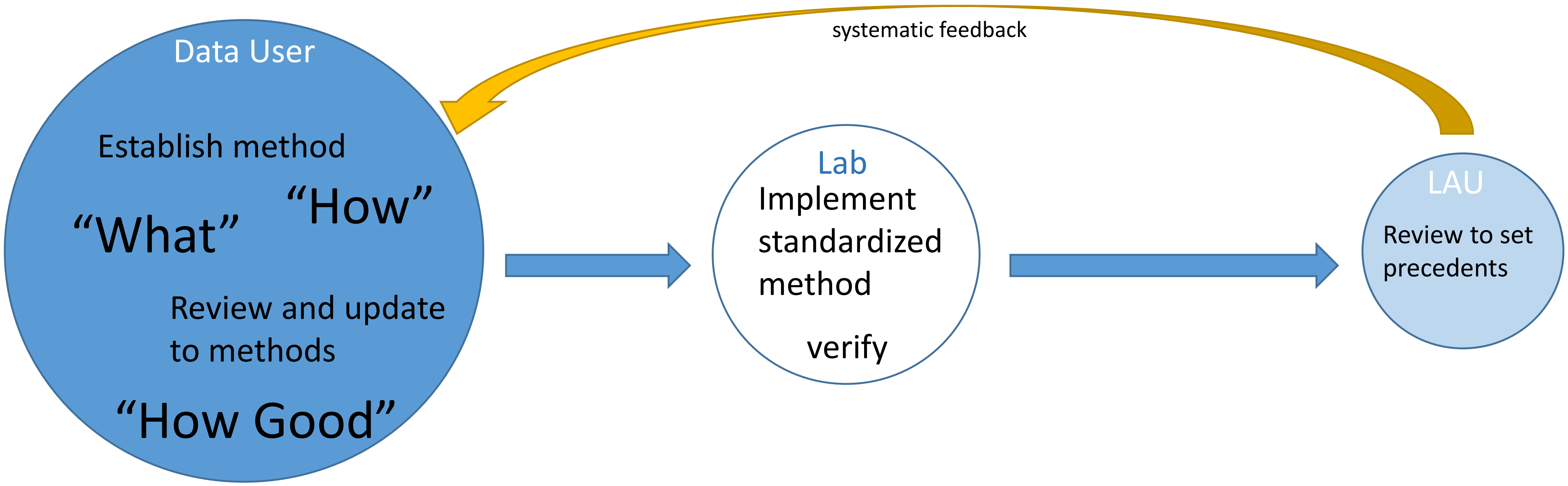
Methods and processes purposely developed and validated to generate data meeting specific data use needs.

Approach Characteristics

- Initial data user decision-making – “what”, “how good” and “how”
- Method is designed to meet specific data use objectives
- Designed with appropriate quality requirements (QA/QC)
- Designed for consistent data acquisition
- Often used in high risk data situations
- Easier to accredit

Example – EPA Drinking Water Methods

- Specifically designed, validated, and peer reviewed by the EPA to provide very specific data to support protecting human health.
- Designed to achieve low detection levels and deliver data of acceptable quality
- Prescribes all essential preparation, instruments, QA/QC, and other method processes.
- Modifications that have not been validated by the EPA are not permitted.



Standardized Methods Approach

FLEXIBLE METHODS APPROACH

“Conveys "what" needs to be accomplished, but not prescriptively "how" to do it. It is a measurement system based upon established performance criteria for accuracy and precision with use of analytical test methods. Under this measurement system, laboratories must demonstrate that a particular analytical test method is acceptable for demonstrating compliance.”

Cannabis Science Task Force Recommendations: Laboratory Quality Standards for Pesticides in Cannabis Plants and Products https://apps.ecology.wa.gov/publications/SummaryPages/2003005.html

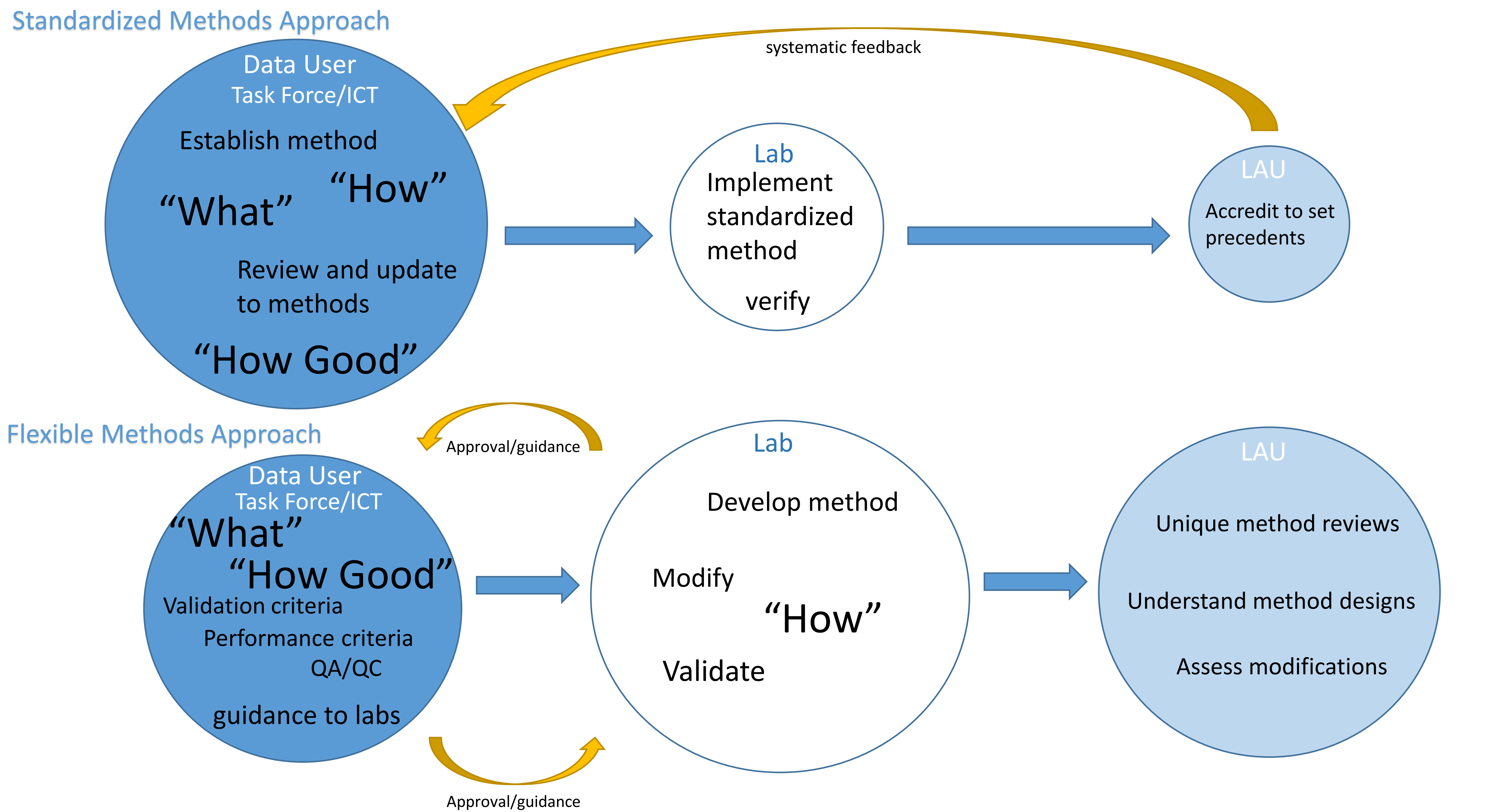
Approach Characteristics

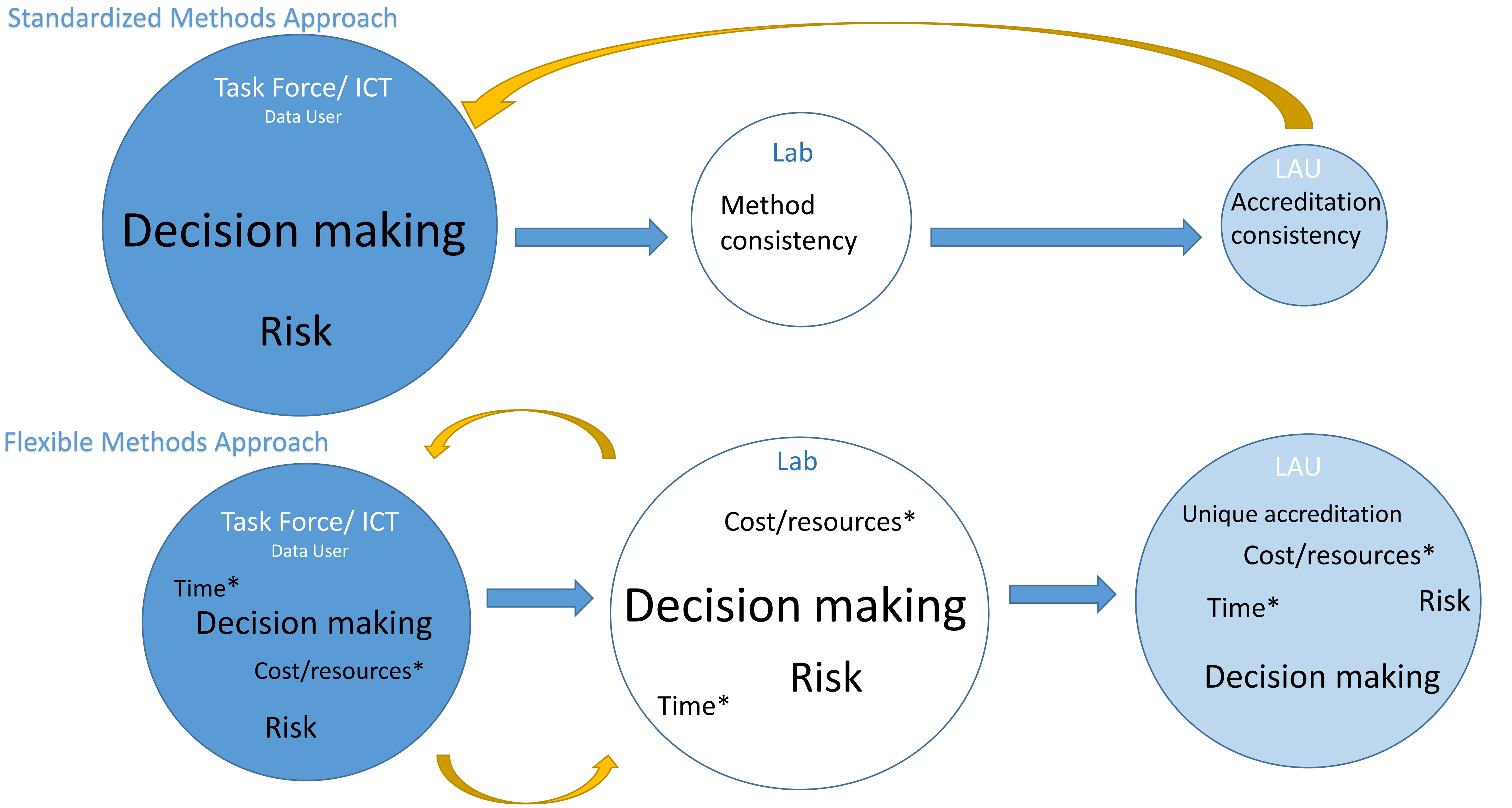
- Initial data user decision-making and development of quality requirements - "what" and "how good"
  - Performance requirements
  - Method validation
  - Other QA/QC
- Flexible "how"
  - Lab selects or develops method(s)
  - Lab determines if method meets regulatory requirements
  - Lab proves method performance
- Labs' method selection, method modifications and validation may require review by the data user.
- Used in lower risk data situations, and in conjunction with highly designed quality systems designs
- More difficult to accredit

Example: USDA PDP SOPs plus WA specific requirements

- PDP-QC - Chemical Compounds, PDP Commodity Groupings, Method Validation and Quality Control (Rev. 9, 09/01/19)
- PDP-LABOP - Sample Processing and Analysis (Rev. 10, 07/01/18)
- PDP-DATA - Data and Instrumentation (Rev. 6, 04/01/18)
- PDP-ADMIN - Administrative Procedures for the Pesticide Data Program (Rev. 7, 07/01/2019)
- PDP Glossary - Abbreviations and Terms used in SOPs (Rev. 10, 01/01/15)

- Summary of Adaptations to the USDA PDP SOPs [CSTF; 2020]


Standardized Methods Approach
systematic feedback
Data User
Task Force/ICT
Establish method
"What"
"How"
Review and update to methods
"How Good"
Lab
Implement standardized method
verify
LAU
Accredit to set precedents
Flexible Methods Approach
Approval/guidance
Data User
Task Force/ICT
"What"
"How Good"
Validation criteria
Performance criteria
QA/QC
guidance to labs
Lab
Develop method
Modify
"How"
Validate
LAU
Unique method reviews
Understand method designs
Assess modifications
Approval/guidance



*Cost/resources and time is a relational to the on-going lab decisions

Questions?