

**APPLICATION OF QA REQUIREMENTS
FOR
EARTH-SCIENCE INVESTIGATIONS**

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**Presentation to
QUALITY ASSURANCE PANEL
U. S. NUCLEAR WASTE TECHNICAL REVIEW BOARD**

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STATUS OF QA IMPLEMENTATION IN USGS

- QAP in place, accepted, and operating
- Staff seriously attempting to comply
- Characterization objectives possibly attainable
 - in inordinate time
 - with inordinate expense
 - without increase of actual quality
- Optimism about reevaluation of QA program
- Participation in reevaluation and revisions
 - Emphasis on scientific method
 - Documentation of work performed
 - Refocus on characterization activities that are
 - Important to safety
 - Important to waste isolation

FABRICATED SYSTEM

vs.

EARTH SYSTEM

SYSTEM OR
STRUCTURE

- CONSTRUCTED UNDER STRICT CONTROLS

- EXISTS

DESIGN

- ACCEPTED PRACTICES
- REVIEWED IN DETAIL

- UNKNOWN
- MUST BE DEFINED

COMPONENTS

- DISCRETE AND STANDARDIZED
- MOST ARE DIRECTLY TESTABLE
- SAMPLING ALMOST UNLIMITED

- COMPLEXLY VARIABLE
- GENERALLY NOT TESTABLE FOR DESIRED FUNCTION
- SAMPLING VERY LIMITED

INHERENT
CHANGES

- AGING, CLOGGING, FATIGUE, CORROSION, ETC.
- CONTROL IMPACT BY DESIGN

- LARGE-SCALE, COMPLEX AND SIGNIFICANT -- E.G., FAULTING, CLIMATE

MITIGATION

- MOST COMPONENTS CAN BE REPLACED OR REPAIRED

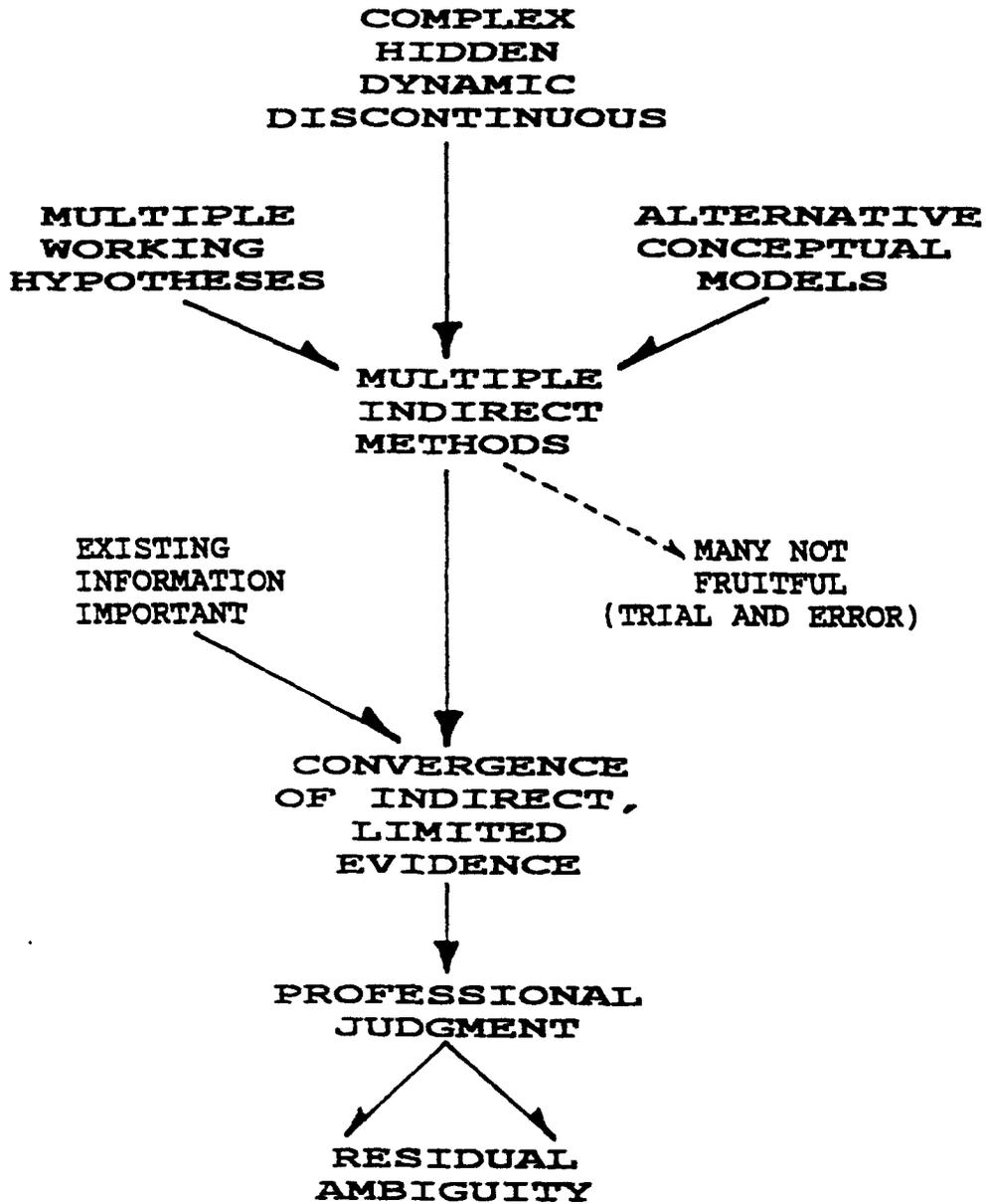
- MODIFICATION OF CHARACTERISTICS VERY LIMITED

FUNCTIONAL
PERFORMANCE

- HIGH CERTAINTY WITH FACTOR OF SAFETY

- HIGH RESIDUAL UNCERTAINTY

EARTH CHARACTERISTICS AND PROCESSES



**NATIONAL RESEARCH COUNCIL
POSITION STATEMENT**

- U. S. Waste Disposal Program
 - Inflexible, prescriptive -- based on high certainty
 - Unrealistic, vulnerable -- because of inherent uncertainty regarding geologic medium
 - Unforeseen delays, rising costs, frustration among field personnel, loss of public confidence

- Quality Assurance
 - System that is hostile to surprises in a world that is full of them
 - Flexibility more likely to lead to a safe repository than are rigid, predetermined protocols

- Alternative
 - Broad goals -- iterative assessments of ultimate performance
 - Scientific method -- develop and test concepts
 - flexibility
 - peer review
 - Priority to major uncertainties and risks

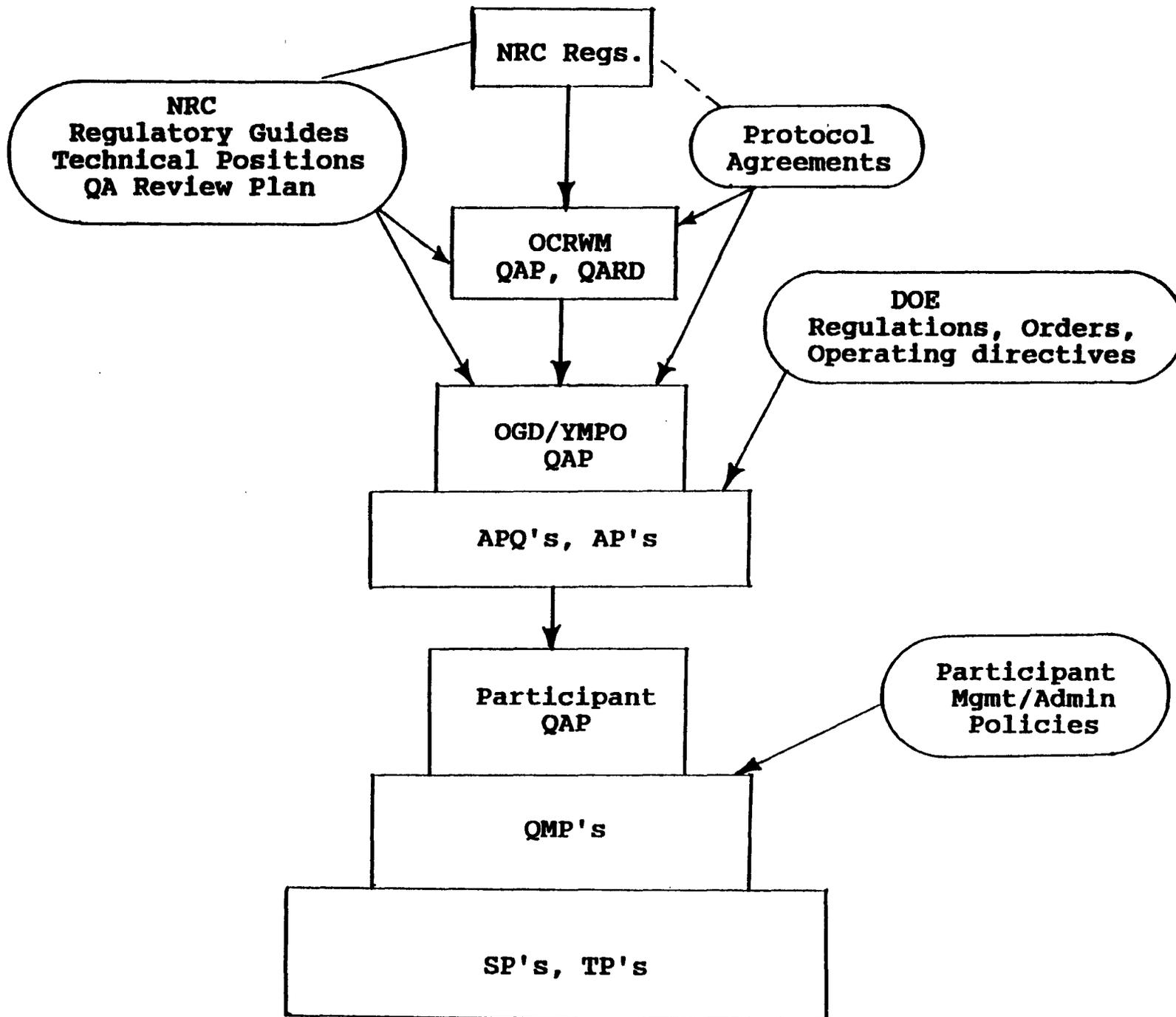
SELECTION AND GRADING OF QA ACTIVITIES

• CONSIDERATIONS

- + Importance to safety and waste isolation
 - Design/construction of critical systems and operations
 - Assessment of safety/isolation performance
 - Information critical to design/assessment
- + Potential for damage to site
 - Focused controls to minimize/mitigate damage
- + Inherent limitations
 - Realistic expectations

• CURRENT REQUIREMENTS

- Overly conservative definition of importance to safety or waste isolation; lumps "site characterization" and "licensing information"
- Burdensome approach to exemption of criteria discourages focusing QA effort on important elements



SELECTED EXAMPLES

PROCUREMENT

- Procedures, as implemented, do not distinguish between items, materials and services that are closely related to safety or waste-isolation and those that are not
- Proliferation of forms, signature requirements, and time/effort
- Commercial-grade, "history-of-quality" items and services are not exempted
- Reputable vendors decline business

SAMPLE MANAGEMENT

- Rigid, though ambiguous requirements
- Emphasize control/archiving rather than use/data
- Some aspects guarantee unsuitable samples
- PI's responsible can and should refuse samples

OUTSIDE INFORMATION

- Existing guidelines marginally appropriate for use in activities with highest quality grade
- Much too prescriptive for middle and lower grades
- PI judgment/good scientific practice adequate for required uses in regional studies, scoping evaluations, and as corroborative information

SCIENTIFIC PLANS AND PROCEDURES

CURRENT REQUIREMENTS

- Excessive detail, beyond realistic ability to plan
- Inflexible format, often inappropriate or irrelevant to topic
- Burdensome and time-consuming process for approval and reapproval

IMPACTS

- Waste of scientific resources
 - Nonproductive effort consumes time and money
- Invites QA control of entire process
- Discourages improvement of methods, approaches
 - Prescribed mediocrity
- Prevents (or places scientist at risk for) necessary field modifications
 - Lost information
- Some top scientists unavailable or lost
- Poorer overall QUALITY

QA IMPLEMENTING PROCEDURES
PROBLEMS AND PROPOSED SOLUTIONS

- Pyramiding and mixing of QA and management requirements
 - Focus on regulatory QA requirements
 - Interactions with NRC on guidance

- Wordy, unclear, redundant, and inconsistent
 - Careful preparation within systematic framework
 - Participation of users throughout planning, preparation, and review
 - Thoughtful and documented review/response process

- Overly prescriptive
 - Emphasize expected results
 - Flexibility in compliance methods

**TOTAL QUALITY MANAGEMENT
FOR SITE CHARACTERIZATION**

- Parallel, separate, but interactive functions
 - Management
 - Investigations
 - Quality Assurance
- Overlapping of boundaries -- conscious decision

- MANAGEMENT AND ADMINISTRATION
 - Maintain focus on objectives
 - Foster and support scientific method
 - Remove or mitigate impediments
 - Realistic schedules and budgets
 - Provide context for characterization, design, and performance assessment
 - Control impacts of external agreements
 - Interactions with NRC

**TOTAL QUALITY MANAGEMENT
FOR SITE CHARACTERIZATION
(Continued)**

- **SCIENTIFIC INVESTIGATIONS**
 - Flexible planning, tailored to specific tasks
 - Planning by investigators, scientific integrators
 - Identify impacts of activities/results on safety and waste isolation
 - Propose nature and application of controls
 - Review and advice -- technical, QA, and management
 - Approval delegated to closest feasible management level
 - Interactions with NRC

- **QUALITY ASSURANCE**
 - Proactive role -- assist in reaching objectives
 - Limit to items/activities with potentially significant impact on safety or waste isolation
 - Assistance in applying criteria/controls within concept of graded QA
 - Decline acceptance of management responsibilities
 - Audit for performance, not process
 - Interactions with NRC

PLAN OF INVESTIGATION

- Incorporate Guidance

- + Objectives within framework of subsequent project goals
- + Realistically graded quality level of final product
- + Constraints -- budget, schedule, etc.

- Define

- + Scope of Investigation
- + Expected products, within framework of subsequent use
- + Alternative conceptual models, if applicable
- + General approach, protecting flexibility
- + Graded quality level of principal elements
- + Major decision/hold points, if predictable
 - Affect constraints or attainment of objectives
 - Branching decision reviews
- + Documentation requirements
- + Special considerations
 - Interfaces
 - Sample control
 - Site integrity

PLAN OF INVESTIGATION
(Continued)

• Processing - Initial

- + Review and comment by technical review panel and QA
- + Recommendation by contiguous management
- + Approval by closest feasible management
- + Monitored by QA unit

• Implementation

- + Detailed approach/technical procedures, where needed
 - Defined by Principal Investigator
 - Reviewed/recommended by technical review panel and QA
 - Approved by contiguous management
- + Thorough but flexible documentation
- + Monitored by QA unit

PLAN OF INVESTIGATION
(Continued)

• Changes

- + Guidance elements -- Repeat initial processing steps, but
approval by guidance originator
- + Elements defined in plan -- Repeat initial processing steps
-- Document by amendment/revision
- + Detailed approach/procedures -- Review panel and QA
-- Approved by contiguous
management
-- Document by amendment/
revision
- + Necessary field changes -- By PI or on-site CI
-- Impact evaluated by PI and review
panel
-- Impact and corrective action, if
required, certified in memorandum
by contiguous management
- + Monitored by QA unit

CONCLUSIONS

- Program operating within requirements, but with problems
- Sources of problems both external and internal
- Problems are correctable
- Review of causes and proposed solutions underway
- TQM: Separate but interactive roles
 - Management promotes, protects, expedites scientific process
 - Investigators define and apply scientific process
 - QA assists in developing controlled, documented scientific process
- Interactions with NRC are essential