



U.S. Department of Energy
Office of Civilian Radioactive Waste Management

DATA VERIFICATION & DATA/SOFTWARE QUALIFICATION TECHNICAL EXCHANGE

Presented to:
Nuclear Regulatory Commission

Presented by:
Dr. Robert F. Wemheuer

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YUCCA
MOUNTAIN
PROJECT

Legacy 1 main - 2nd floor

Introduction

Information/Data

- **Yucca Mountain Project uses many forms of inputs subject to appropriate quality control (e.g. Technical Information and Data)**
- **Data is defined in the Yucca Mountain Site Characterization Project (YMP) Quality Assurance Requirements Description (QARD), Supplement III, as “...information developed as a result of scientific investigation activities, including information extracted from reference sources, and performance assessment analysis.”**

Background

- **Corrective Action Report (CAR) LVMO-98-C-002 reported deficiencies in the documentation of data listed as “Qualified” in the Technical Data Management System (TDMS)**
- **Deficiencies existed in data collected by the Management and Operating Contractor (M&O), U.S. Geological Survey (USGS), National Laboratories and subcontractors thereto**
- **Extent of deficient condition investigations resulted in all data being categorized as “To Be Verified” (TBV)**
- **Processes and procedures were developed to screen and track indeterminate quality legacy data used in calculations, analyses and models**

Background (continued)

- Remedial actions were implemented 06/30/99 so that new data was properly acquired and documented
- *record search* Initial efforts to reestablish data pedigree focused upon verification of the objective evidence that was available to show that the data had been properly acquired and documented
- For data which could not be verified, qualification processes and procedures were utilized
- In accordance with the QARD and Repository Safety Strategy, a data grading approach was formulated to differentiate between data supporting Principal Factors and non-Principal Factors

Acronyms

AMOPE – Assistant Manager, Office of Project Execution

AMR – Analysis Model Report

AP – Administrative Procedure

ATDT – Automated Technical Data Tracking

CAR – Corrective Action Report

DIRS – Document Input Reference System

DOE – U.S. Department of Energy

DR – Deficiency Report

DSQD – Data/Software Qualification Department

DTN – Data Tracking Number

IOC – Interoffice Correspondence

M&O – Management & Operating Contractor

OQA – Office of Quality Assurance

PMR – Process Model Report

POC – Point of Contact

PVAR – Process Validation and Reengineering

QA – Quality Assurance

QARD – Quality Assurance Requirements Description

RISWeb – Record Information System

RPC – Records Processing Center

TBD – To Be Determined

TBV – To Be Verified

TDMS – Technical Data Management System

USGS – United States Geologic Survey

VL – Verification Level

YMP – Yucca Mountain Site Characterization Project

Data Terminology

- **Accepted:** Data considered to be established fact (e.g., such as engineering handbooks, natural laws, physical constants) or generally accepted by the scientific or engineering community
- **Acquired:** Data obtained as a result of a data gathering activity or procured from project field and laboratory sources. Raw data converted to scientific or engineering terms is acquired data
- **Corroborative:** Data used to support or substantiate other data. This data does not directly support the safety case, but may be used to augment arguments
- **Data Tracking Number (DTN):** A unique identifier assigned to each data set to be tracked in the TDMS

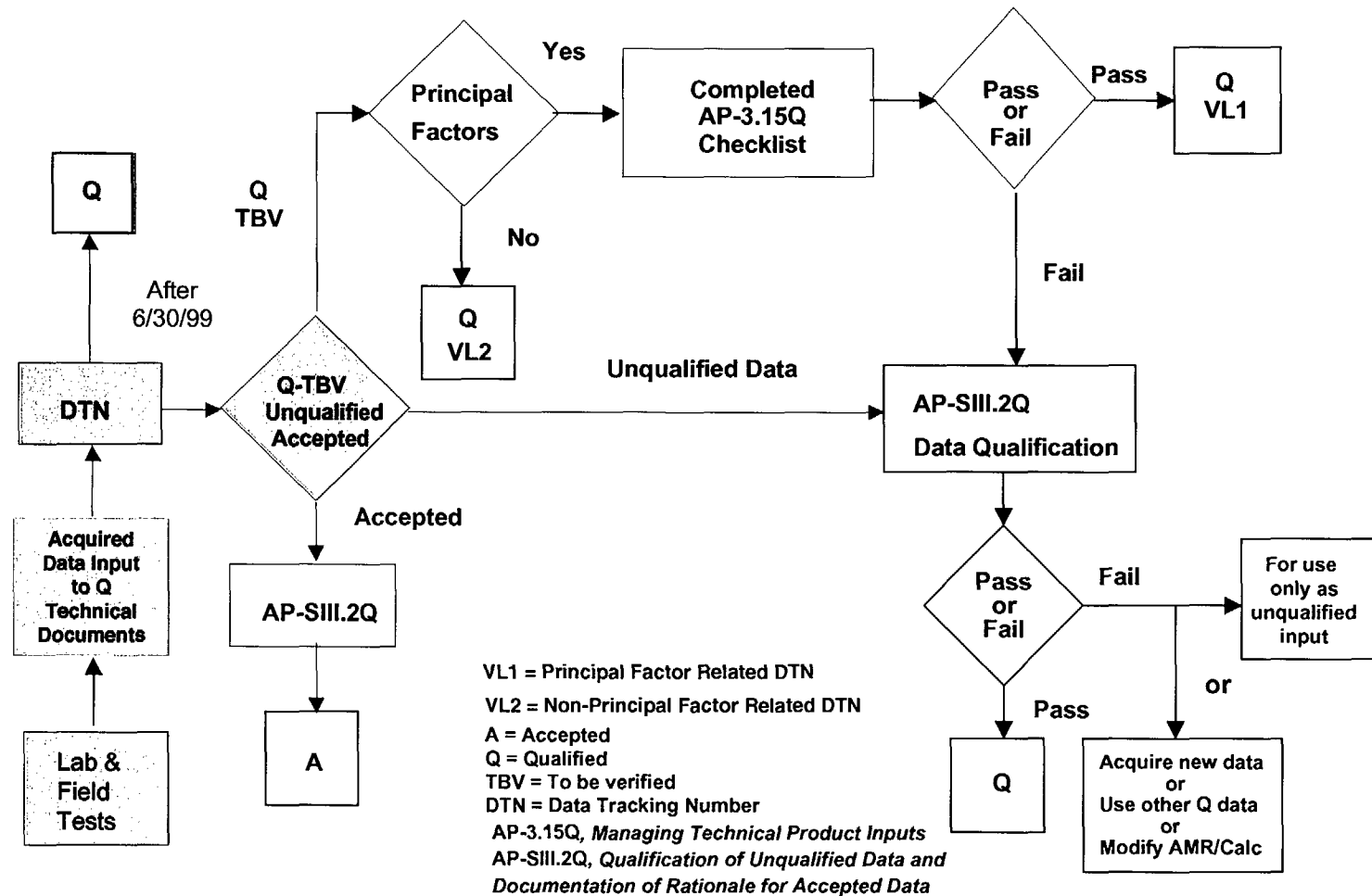
Data Terminology (continued)

- **Developed:** Data that has been refined by analysis, reduction or interpretation
- **Legacy:** Data acquired or developed before the new Process Validation and Reengineering (PVAR) procedures were implemented on June 30, 1999
- **Qualified:** Data acquired or developed under an approved Quality Assurance (QA) program meeting the requirements of 10 CFR 60, Subpart G; or which have undergone a qualification process
- **Unqualified:** Data not acquired or developed in accordance with an approved QA program that meets 10 CFR 60, Subpart G and do not meet the definition of accepted data

Data Terminology (continued)

- *DTN supporting principal factors*
Qualified/Verification Level - 1: Qualified data that have been processed through the Administrative Procedure (AP)-3.15Q (*Managing Technical Product Inputs*) Data Confirmation Checklist. Supports Principal Factors
- **Qualified/Verification Level - 2: Qualified data that were obtained using procedures in effect prior to June 30, 1999 and have not been confirmed using the Data Confirmation Checklist process. Supports factors that are not critical to the safety case argument**

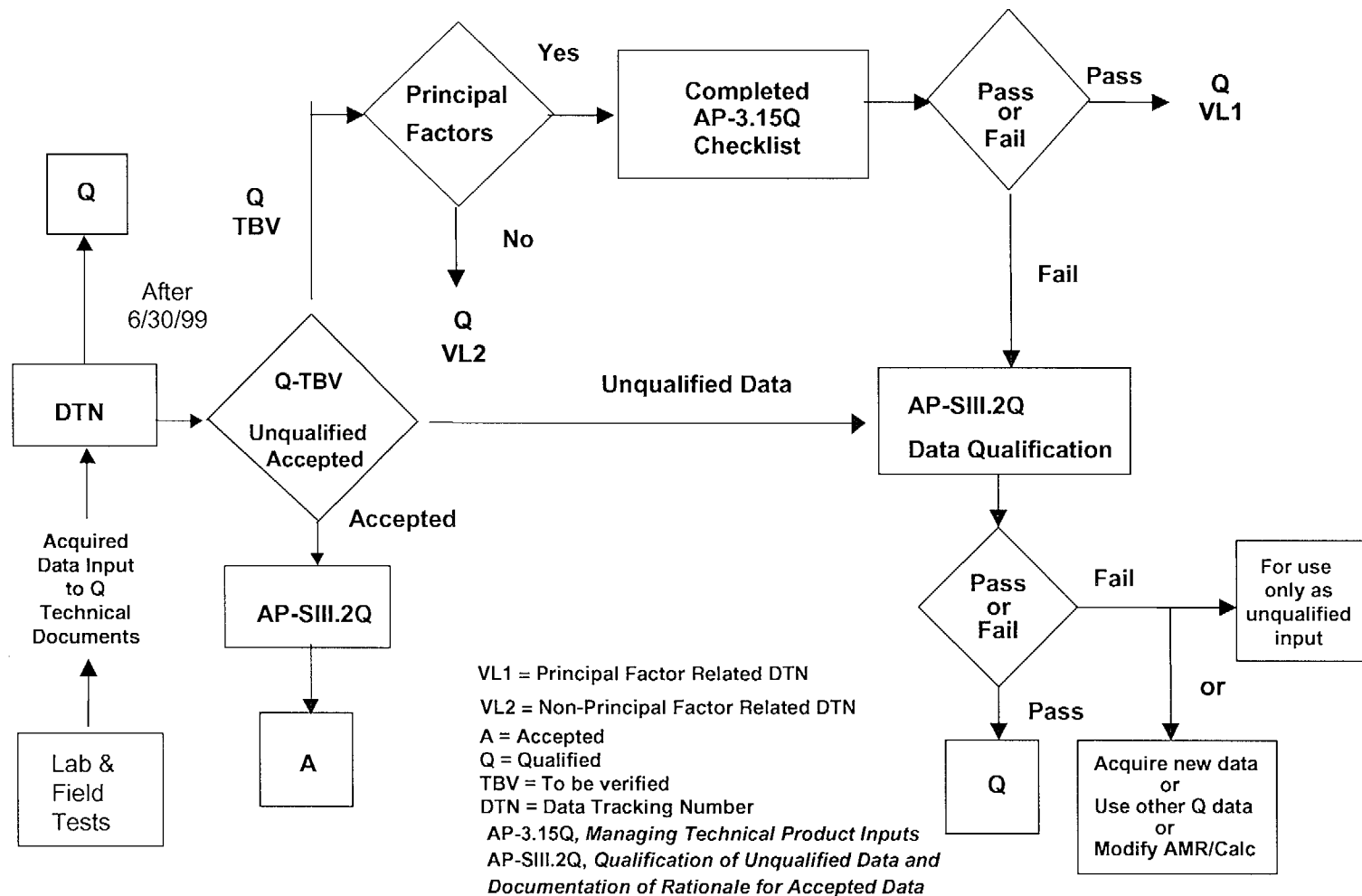
Data Origination & Classification Process



Data Prioritizing/Grading

- Map Analysis Model Reports (AMRs) and Process Model Reports (PMRs) as defined in AP-3.15Q grading criteria
- Screen Principal Factors that support AMRs
- Screen AMR inputs for effect on conclusions
- Assign Verification Level (VL) 1 or 2 designation
- Verify VL-1 data and document on AP-3.15Q Data Confirmation Checklist if data used in Principal Factor
- Data used in non-Principal Factors are qualified, but Data Confirmation Checklists will not be applied
- Unqualified data supporting principal factors, or other factors, must be qualified in accordance with AP-SIII.2Q (*Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data*)

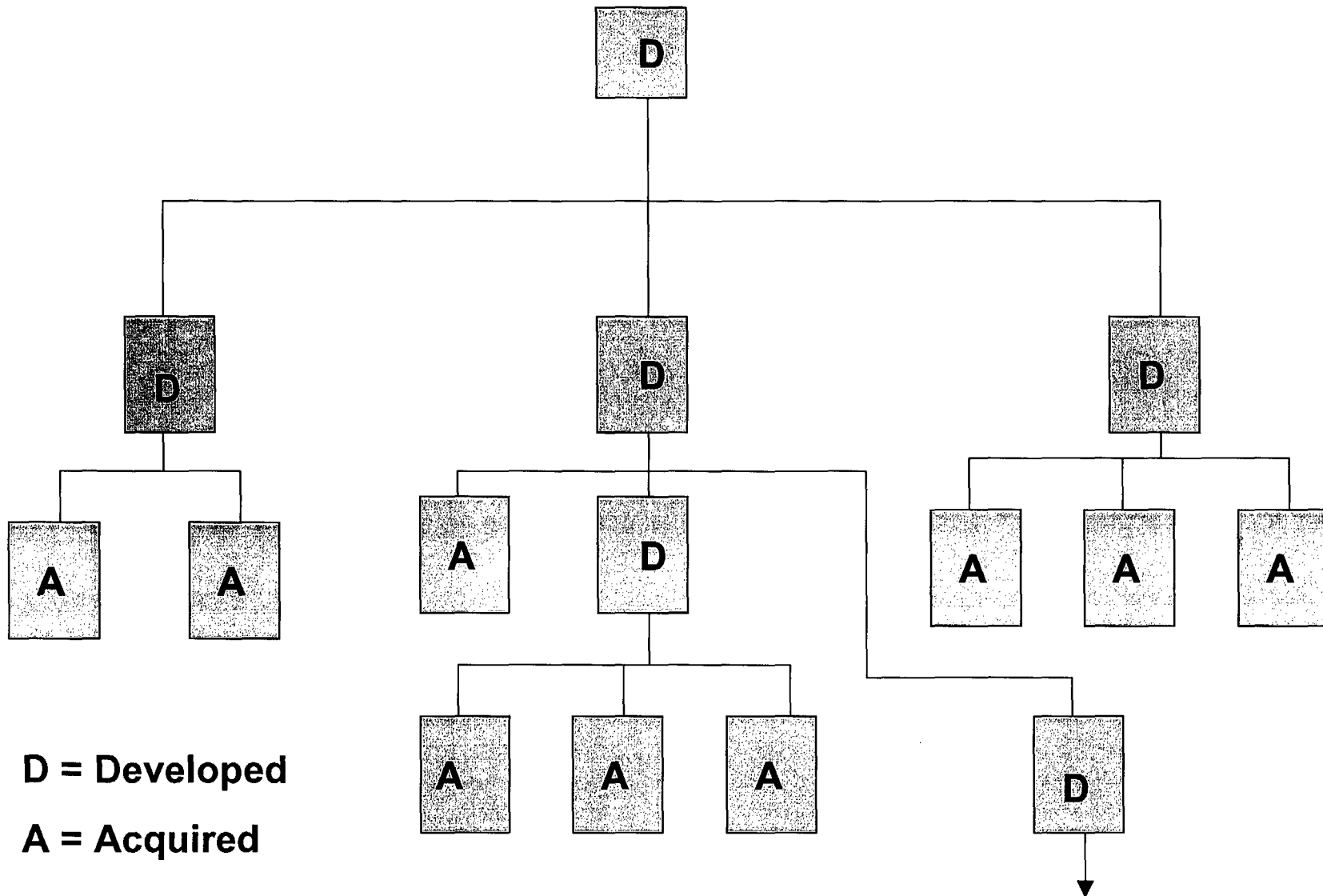
Data Verification Process



Identification of Data

- **AMR/PMR Leads are responsible for identifying and grading data requiring verification and qualification on the Document Input Reference System (DIRS)**
 - **Early identification of DTNs is essential for schedule success**
- **AP-3.15Q controls the manner in which DTNs are identified, graded and used**
- **A DTN may be used many times as a source DTN**
- **A DTN may be used as either input to AMRs or as a source DTN**

A DTN “TREE”



Steps of the Data Verification Process

- Data verification planning is controlled by a generic AP-2.21Q (*Quality Determinations and Planning for Scientific, Engineering, and Regulatory and Regulatory Compliance Activities*) Technical Work Plan
- Identify data requiring verification on DIRS
- Prepare Checklist per AP-3.15Q, *Managing Technical Product Inputs*
- Prepare Records Roadmap *- Tie all information related together in one location*
- Remove TBV (as applicable)
- Prepare and submit Records Package

Checklist Preparation

- Checklist is required for data generated prior to June 30, 1999 if used as input to AMRs as Principal Factors
- Primary purpose is to provide defensibility for data used to support Principal Factor arguments
- Responses to each item should be in text form and adequate to address the issue
- The response will rely on the content of cited records to demonstrate compliance with procedural requirements
- The text of the response should tie the various records together to explain the data collection/reduction process
- References to records should be by reference to accession number or by cross-reference to the records road map
- If an issue is identified, a review of the impact of that issue on data quality should be included in the response or attached to the checklist

Completion of Verification Process

- **Data Confirmation Checklist is reviewed and approved by Responsible Manager**
- **Technical Work Plan require review by Data/Software Qualification Department (DSQD) on all M&O verification packages prior to Responsible Manager removal of TBV**
 - **Provides consistency across entire Project**
- **Responsible Manager notifies the TBV/To Be Determined (TBD) Administrator, by memorandum, of DTN resolution**
- **If Verification was successful, Responsible Manager requests update of the TBV/TBD designator**
- **TBV/TBD Administrator requests the Automated Technical Data Tracking (ATDT) Administrator to change the TBV status**

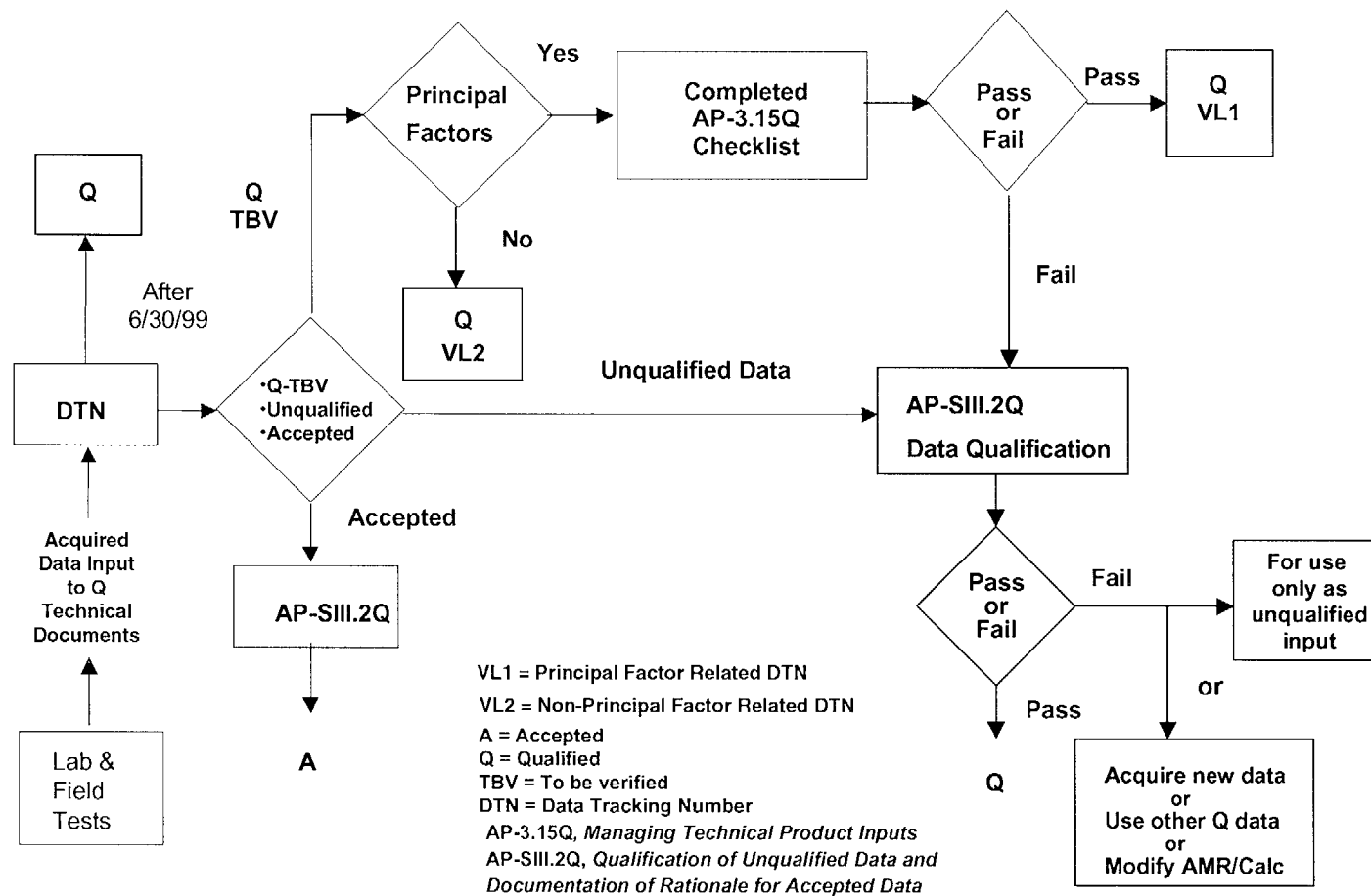
Records Roadmap

- **The records roadmap is a summary listing of all the records identified or referenced on the Data Confirmation Checklist**
- **Road map entries should be consistent with the actual record in Record Information System (RISWeb). That is, record titles, Records Processing Center (RPC) record types, page counts, etc., should match what is specified in the records system**

Data Verification Records

- **DIRS reports become part of the technical product records package**
- **The following items are sent to the RPC**
 - **Data Confirmation Checklist**
 - **Records Roadmap**
 - **Resolution Request Interoffice Correspondence (IOC)**
 - **Memorandum of TBV/TBD closure**

Data Qualification Process



Steps of the Data Qualification Process

- **Identify/prioritize data requiring qualification**
- **Group data by similar characteristics**
- **Prepare a specific AP-2.21Q Technical Work Plan for each qualification package**
- **Prepare recommendation on method, etc. for U.S. Department of Energy (DOE) Assistant Manager, Office of Project Execution (AMOPE) concurrence if DTN supports Principal Factors**
- **Conduct qualification task**
- **Prepare Data Qualification Report**
- **Review and approve Data Qualification Report**
- **Submit report to AMOPE for concurrence (VL-1 only)**
- **Designate Data as Qualified, Remove TBV/TBD**
- **Prepare and submit records package**

Conduct Data Qualification Task

- **Data qualification must be performed in accordance with the approved AP-2.21Q Technical Work Plan**
- **Methods used for qualification activities are:**
 - **Equivalent QA program**
 - **Corroborating data**
 - **Confirmatory testing**
 - **Peer Review**
 - **Technical assessment**
- **Document the results of the data qualification task in a Data Qualification Report**

Data Qualification Report

- **Contents:**
 - **Executive summary**
 - **Scope of task**
 - **Data sets qualified**
 - **Expertise of team**
 - **Methods of qualification and rationale**
 - **Documentation of technical reviews**
 - **Evaluation criteria**
 - **Recommendation criteria**
 - **Data generated by evaluation**
 - **Evaluation results**
 - **Recommendation for/against changing qualification status**
 - **Identification of any supporting information**
 - **Reference to Development Plan**

Review and Approve Report

- Review report in accordance with AP-2.14Q (*Review of Technical Products and Data*)
 - TDMS Data Qualification Oversight Point of Contact (POC) must be a reviewer
 - OQA must be a reviewer
- Approve by Responsible Manager
- Submit report to TDMS Data Qualification Oversight POC
- Submit report to AMOPE for concurrence (VL-1 only)

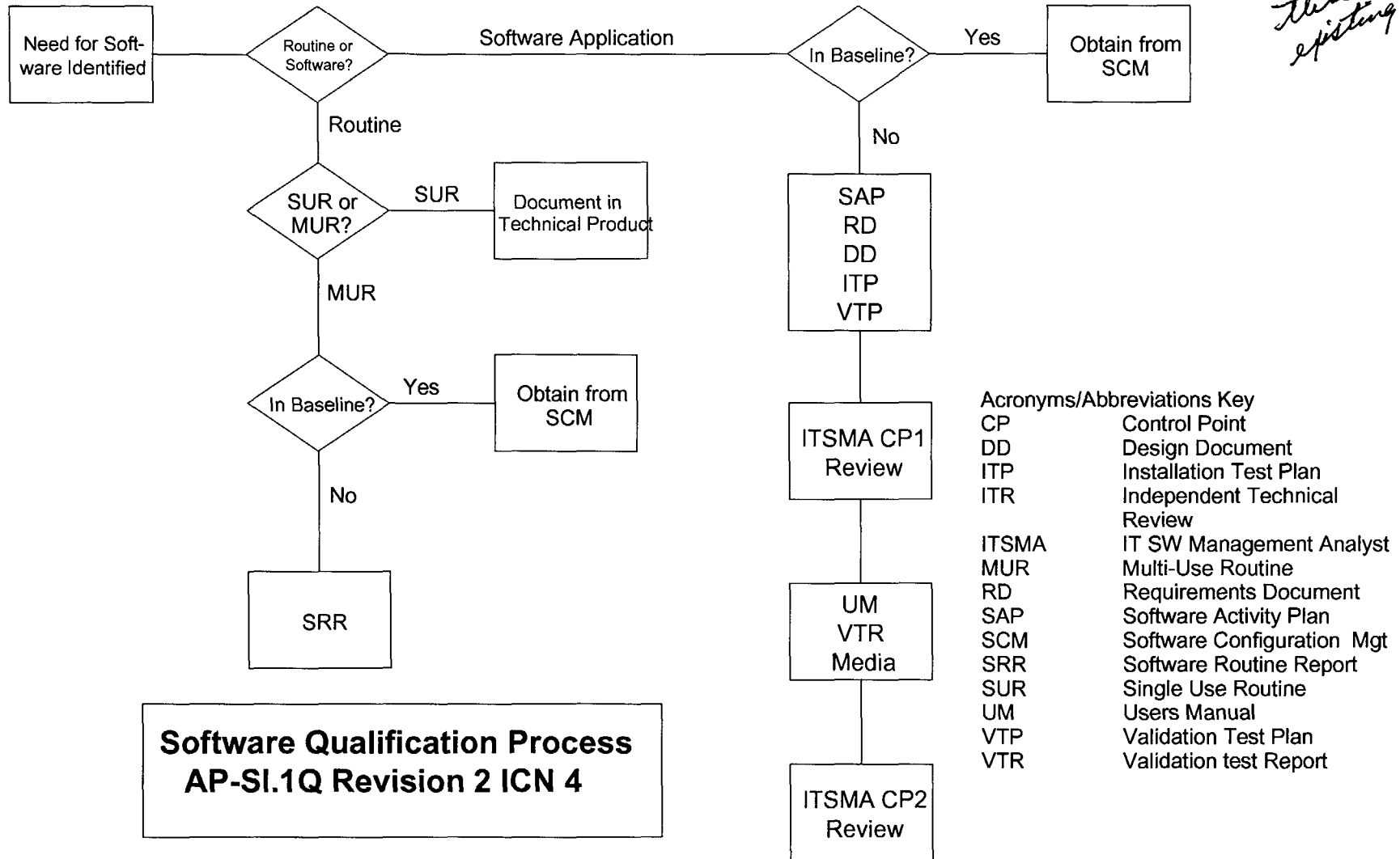
TBV Removal & Records

- **Notify ATDT Database Administrator of**
 - **Change in status of data**
 - **Accession number of qualification records package**
 - **DTNs**
 - **Method of qualification**
- **Submit data qualification records package**
 - **AMOPE concurrence/rejection of recommendation**
 - **Approved Data Qualification Package**
 - **Data Qualification Report**
 - **Report review documentation**
 - **Documentation of acceptance/rejection of qualification report**

Software Qualification Process

Software Qualification Process

*new procedure
now being
circulated;
this is the
existing procedure*



Steps of the Software Qualification Process

- The software qualification process is performed to qualify software used in quality-affecting products of the M&O and USGS
- Teams comprised of members from Software Configuration Management (Information Technology), Software Qualification Group (DSQD) and Technical Product authors (M&O, Labs, USGS) perform the qualification work
- Revision of AP-SI.1Q, (*Software Management*) is in process to streamline the procedure and incorporate QA grading

Software Deficiency Reports

- **DSQD software qualification personnel are managing the work associated with the resolution of Deficiency Reports (DR) generated due to issues with documentation and operational problems**
 - **DR LVMO-00-D-039 cites inaccurate documentation and validation of software routines and macros by developers**
 - ♦ **Commercial software used without identification of specific use**
 - ♦ **Developed software not adequately documented**
 - **DR LVMO-00-D-099 cites software codes submitted to configuration management which could not be installed and run**
 - ♦ **Typical installation problems include lack of supporting installation files, compiler errors and lack of adequate installation instructions**
- **Corrective Actions and resolution of both DRs is projected to take until March 30, 2001**

Summary



Technical Exchange Summary

- **Provided background for the data program development, including definitions of terms and acronyms**
- **Provided an overview of the data verification/qualification and software qualification process**
- **Demonstrated how the data verification/qualification and software qualification processes resolve the issues of traceability and reproducibility to ensure defensible, regulatory compliant documents are produced**

Backup Information

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
DOCUMENT INPUT REFERENCE SHEET**

A.
Name: _____
Phone: _____

1. Document Identifier No./Rev.:		Change:	Title:						
Input Document		3. Section	4. Input Status	5. Section Used in	6. Input Description	7. TBV/TBD Priority	8. TBV Due To		
2. Technical Product Input Source Title and Identifier(s) with Version							Unqual.	From Uncontrolled Source	Un-confirmed
2a									

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
DATA CONFIRMATION CHECKLIST**

QA: QA

Page: of:

TBV No.:

DTN:

Title from Technical Data Information Form:

Instructions

Detailed instructions are provided at the end of this attachment. Note: If a question asks for identification of a record(s), enter the required information on the Record Road Map.

1.
 - A. Data--Identify source DTN, where applicable, and identify records containing raw data (i.e., electronic data files) and data formatted for presentation. Check that data files and formatted data are readily traceable and interpretable, including traceability from records to the TDMS and between related records in the records package (e.g., explanation of file naming conventions, header rows adequately defined, etc.).
 - B. Identify the records documenting any calculations or data reduction (e.g., spreadsheet calculations or hand calculations) that were used to reduce or analyze the data.
2. Procurement--Were calibration or analytical services procured? If Yes,
 - A. Identify the procurement document (subcontract/memorandum purchase order/purchase order) that describes the specific procurement process.
 - B. Identify the supplier submittal (calibration certifications, certificates of analysis, etc.) specific to the procurement(s) identified.
 - C. Submit the information identified in Paragraphs 2.A and 2.B to the Office of Quality Assurance (OQA) to evaluate in accordance with LP-16.1Q-OCRWM, *Review of Procurement Records for Use in the Verification Confirmation of Data or Technical Information*.
 - CALIBRATION (Complete after receipt of OQA review results)
 - D. Identify the records where the use of the measuring and test equipment is documented. Do the records support the calibration requirements for the measuring and test equipment?
 - E. If evidence (records) documenting the procurement of calibration services cannot be identified or located, is the quality of the data significantly affected? Explain:
 - ANALYTICAL SERVICES, INCLUDING DATA ACQUISITION/DEVELOPMENT SERVICES (Complete after receipt of OQA review results)
 - F. Identify objective evidence (records) that the performance of the analytical services adhered to generally accepted practices (e.g., vendor audits, technical reviews, and/or acceptance of deliverable required by contract/work agreement).
 - G. If evidence (records) of adequate procurement services (analytical services, including data acquisition/development services) is missing or inadequate, provide a statement explaining the impact to the data. Explain:

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
DATA CONFIRMATION CHECKLIST
(continued)

QA: QA

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3. **Software**--Were software (including routines or macros) (as defined in AP-SI.1Q, Software Management) used to gather, convert, or otherwise manipulate technical information? If Yes,

A. Identify the software version, title, and unique identifier (if available). Is the software on the current software baseline? Identify software tracking number.

OR

B. Address in accordance with AP-SI.1Q.

Comments or Other Information:

Checklist Completed By: (Printed Name)

Signature:

Date:

Reviewed for adequacy, including identification of objective evidence:

Responsible Manager: (Printed Name)

Signature:

Date:

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
DATA CONFIRMATION CHECKLIST
(continued)

QA: QA

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RECORD ROAD MAP - TEMPLATE

Record Accession Number	Record Title	Document Type(s)	Record Type(s)*	Contents of Record (use pagination of RISweb to reference a specific record page)

* Only data, procurement or software record types must be listed if identified in the checklist. Other types may be listed as applicable to the checklist response.

YMP Data Status as of 12/22/2000

PMR	% Data Qualified	% Data Verified	% Software Qualified
Biosphere	89	100	92
Disruptive Events	92	100	100
EBS	84	97	96
ISM	85	100	100
Near Field	87	100	100
SZ F&T	81	100	89
UZ F&T	81	93	98
Waste Form	87	91	100
Waste Package	90	93	100
December 22, 2000 Goals	80	90	80

Data status as of 12/22/2000

Software status as of 12/22/2000

Green = Meets or above December 22, 2000 Goal

Yellow = Below December 22, 2000 Goal