U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

NUCLEAR WASTE TECHNICAL REVIEW BOARD
FULL BOARD MEETING

SUBJECT: APPLICATION OF EXISTING DATA

PRESENTER: SUSAN JONES

**PRESENTER'S TITLE
AND ORGANIZATION: CHIEF, REGULATORY INTERACTIONS BRANCH
YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT
LAS VEGAS, NEVADA**

**PRESENTER'S
TELEPHONE NUMBER: (702) 794-7613**

RENO, NEVADA
APRIL 21-22, 1993

NUREG-1298

- Definitions

- Guidance

DOE Use of Existing Data

- Process

- Policy

NUREG-1298

"Qualification of Existing Data for High Level Nuclear Waste Repositories"

- Generic technical position

- Published by NRC staff in 1988

NRC Staff Position

"<u>Data</u> related to systems, structures, and components <u>important to safety,</u> to design and characterization of barriers <u>important to waste isolation,</u> and to activities related thereto which are <u>used in support of a license application</u> should be qualified to meet the quality assurance requirements of 10 CFR 60, Subpart G."

NUREG-1298 (IV)(1.)

NUREG-1298 Definition: Qualification of Data

"A formal process intended to provide a desired level of confidence that data are suitable for their intended use."

Data Types

Generally Accepted

- Information generally accepted by engineering and scientific communities e.g., handbooks

Existing

- Developed by DOE program prior to implementation of 10CFR60 subpart G QA program

- Developed outside the DOE program e.g., scientific journals

Qualified

- Collected under 10CFR60 subpart G QA program

- Existing data qualified per guidance in NUREG-1298

NUREG-1298: Four Methods or Combination

- **Peer review**
- **Corroborating data**
- **Confirmatory testing**
- **Equivalent QA program**

or any other method accepted by NRC on a case-by-case basis

Qualified QA Programs

4INQOD5P7.125.NWTRB/4-21/22-93
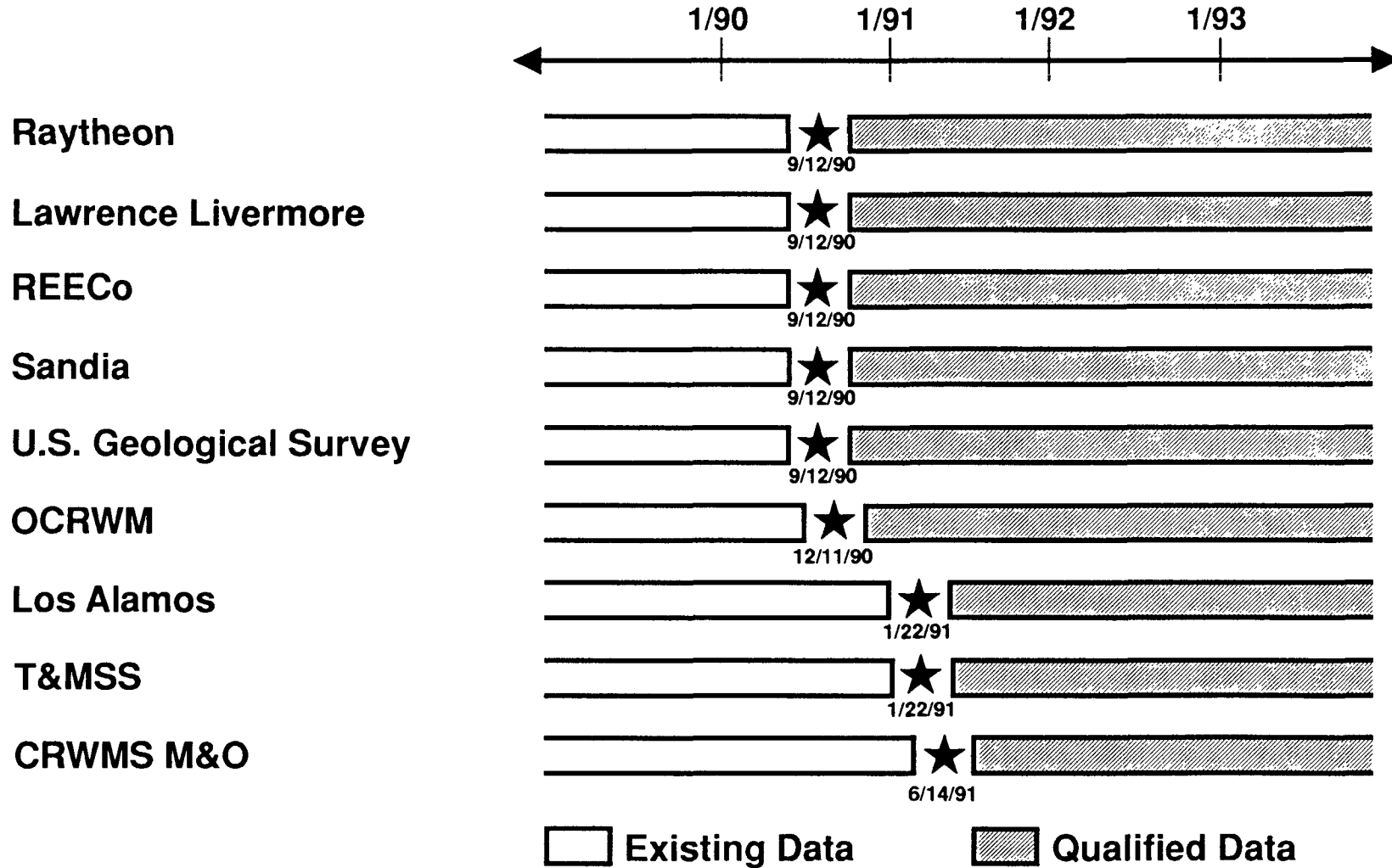
DOE has Adopted the Guidance from NUREG-1298

- **Quality Assurance Requirements and Description Document (DOE/RW/0333P)**

    - Supplement III.2.4 Data Validation and Qualification

- **Administrative Procedure 5.9Q, Qualification of Existing Data**

Any Data Can be Used in a
License Application

Existing data will be qualified only in those cases where

- **The existing data are needed to directly establish a licensing position**

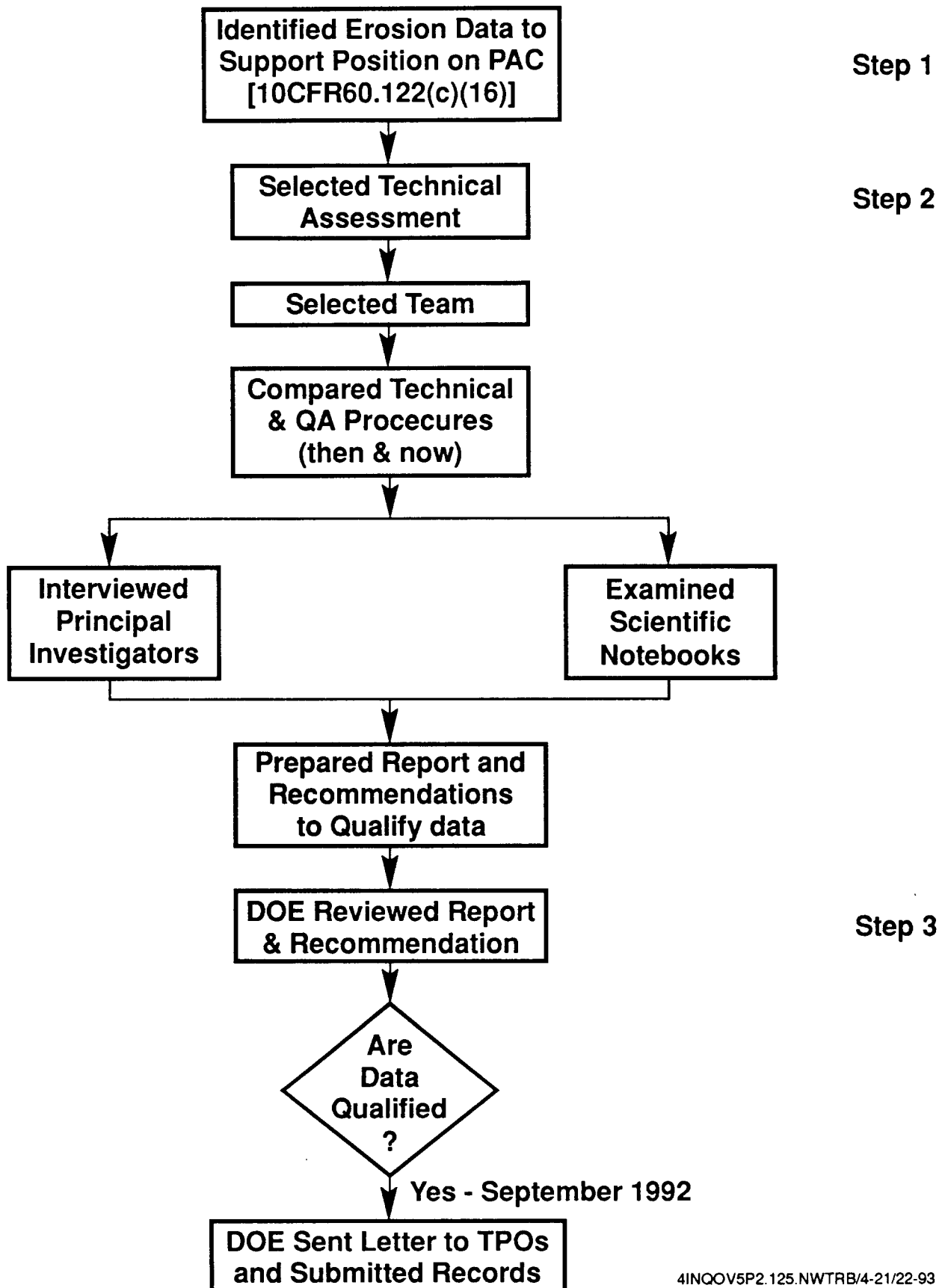- **And no alternative qualified data can be used**

DOE Qualification Process - AP-5.9Q

```
                    ┌─────────────────┐
                    │    Identify     │
                    │  Existing Data  │         Step 1
                    │     Set for     │
                    │  Qualification  │
                    └─────────────────┘
                             │
        ┌────────────────────┴────────────────────┐
        ▼                                          ▼
┌─────────────────┐                      ┌─────────────────┐
│    Conduct      │                      │    Conduct      │
│    Technical    │                      │   Peer Review   │    Step 2
│   Assessment    │                      │   (QAAP-3.3)    │
│   (QMP-02-08)   │                      └─────────────────┘
└─────────────────┘                               │
        └────────────────────┬────────────────────┘
                             ▼
                    ┌─────────────────┐
                    │     Review      │         Step 3
                    │ Recommendations │
                    └─────────────────┘
                             │
                             ▼
                        ◇ Are
                          Data            No      ┌─────────────────┐
                        Qualified  ──────────────▶│    Provide      │
                          ?                        │  Instructions   │
                        ◇                          │ to Participants │
                             │                     └─────────────────┘
                            Yes
                             ▼
                    ┌─────────────────┐
                    │     Update      │
                    │   Data Bases    │
                    │      and        │
                    │    Use Data     │
                    └─────────────────┘
```
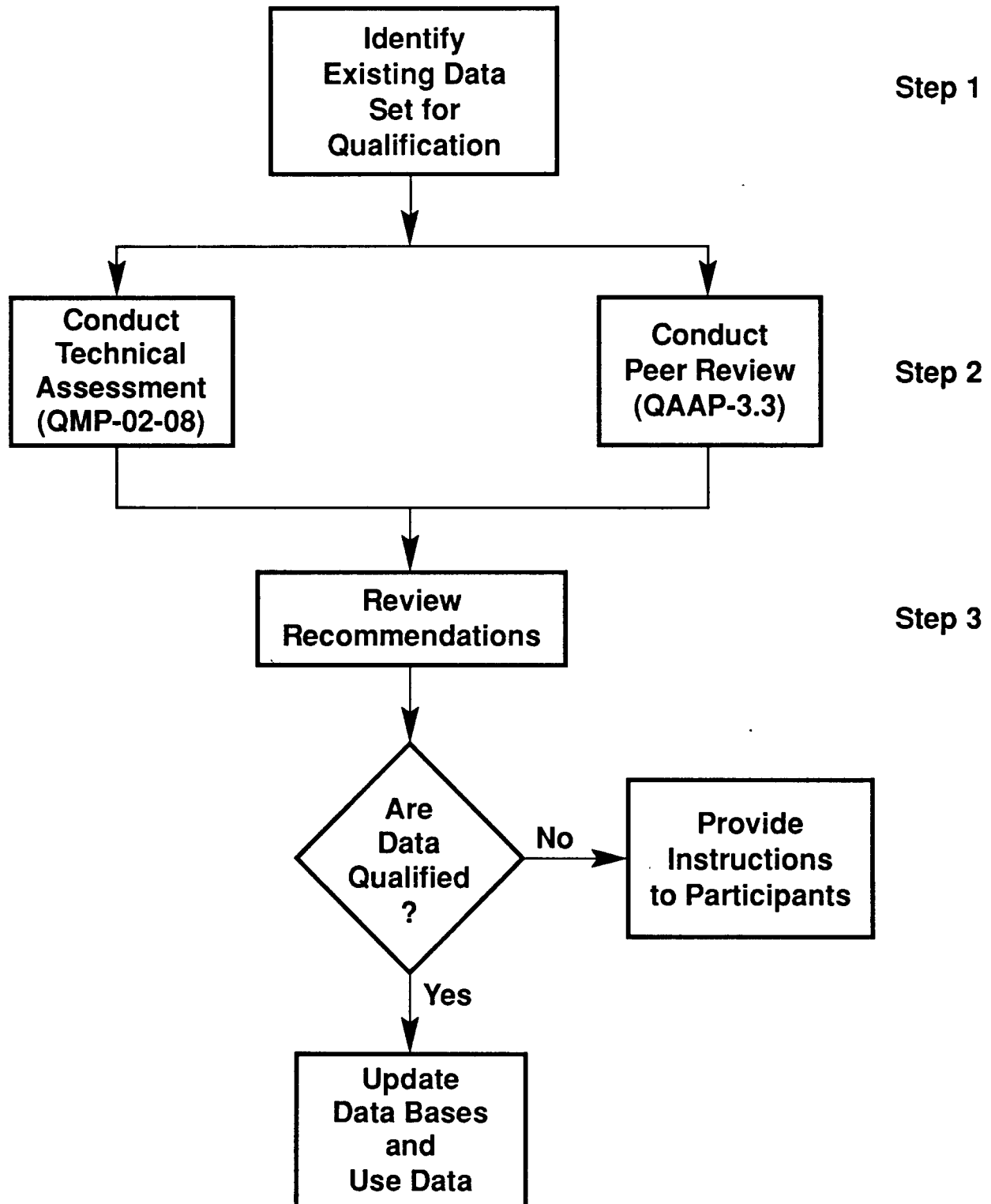
AP-5.9Q: Questions Considered
in the Qualification Process

1. Will the existing data be relied on to establish a licensing position for which no alternative qualified data can be used?

2. To what extent do the controls under which the data were generated meet, in whole or in part, 10 CFR 60, Subpart G, requirements?

3. Are there existing technical or peer reviews that would lend confidence to the quality of the data? Were the data published in a refereed journal?

4. What, if any, corroborative data or confirmatory testing results are available?

5. Is additional confirmatory testing necessary?

Example of Qualification Process:
Extreme Erosion

Identified Erosion Data to
Support Position on PAC
[10CFR60.122(c)(16)]   Step 1

Selected Technical
Assessment   Step 2

Selected Team

Compared Technical
& QA Procecures
(then & now)

Interviewed
Principal
Investigators

Examined
Scientific
Notebooks

Prepared Report and
Recommendations
to Qualify data

DOE Reviewed Report
& Recommendation   Step 3

Are
Data
Qualified
?

Yes - September 1992

DOE Sent Letter to TPOs
and Submitted Records

4INQOV5P2.125.NWTRB/4-21/22-93

DOE Policy

Perform the investigations in the SCP in a manner to ensure that sufficient data to support a license application are developed under a 10 CFR 60 Subpart G Quality Assurance program

The Decision to Qualify Existing Data

- **Is a licensing decision**

- **Made as part of the issue resolution process**

- **On a case-by-case basis as components of the license appliction are prepared**