

409.53

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JUL 31 1987

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- 1 -

TO ADDRESSEE: See attached list

On Tuesday, August 25, 1987, the NRC will be holding a public meeting in room 118 of the Phillips Building to review its resolution of public comments on the Generic Technical Position entitled "Generic Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements". This GTP was noticed in the Federal Register for public comment in July 1986. A number of comments were received and the staff has prepared the attached comment resolution document and draft final GTP addressing them. The staff intends to discuss the issues raised in the public comments and the final positions currently contemplated for the GTP's, and to obtain feedback from members of the States and Tribes or DOE on the resolution of comments. Revisions may be made to the final positions based on comments received during this meeting.

H R Johnson for

John J. Linehan, Acting Chief
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

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 FROM: J. Linehan
 SUBJECT: RESOLUTION OF COMMENTS ON GENERIC TECHNICAL POSITIONS
 DATE: JUL 31 1987

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 N. Stewart

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NRC/GPA/PA
Mail Stop MNBB-3217
NRC

NRC/ACRS (20 copies)
Mail Stop H-1016
NRC

Mr. Abdul J. Alkezweeny
Council of Energy Resource Tribes
Nuclear Waste Policy Act Program
1933 Jadwin - Suite 135
Richland, WA 99352
509/943-5301
CST Nez Perce/Umatilla contractor

Mr. Bill Allen
Environmental Quality
U.S. DOI, Bureau of Indian Affairs
Albuquerque Area Office
P.O. Box 8327
Albuquerque, NM 87198
505/766-3167
FED

Ms. Joan Aron
4000 Massachusetts Avenue
Apt. #1616
Washington, DC 20016
NRC

Mr. Andrew Avel
DOE/DRD
Q&RD
P.O. Box E
Oak Ridge, TN 37831
FTS 626-0951

Mr. Dick Baker
Repository Technology Program
U.S. Department of Energy
Chicago Operations Office
9800 South Cass Avenue
Argonne, IL 60439
DOE

Mr. Robert Berger
U.S. DOI, Bureau of Indian Affairs
Envir. Services Desk, Code 204
1951 Constitution Avenue, NW
Washington, DC 20245
FED

Mr. Warren A. Bishop
Chairman, Nuclear Waste Policy Board
Washington Department of Ecology
Office of High-Level Nuclear
Waste Management
Mail Stop FV-11
Olympia, WA 98504
206/459-6000
S/T

Mr. Bruce Blanchard
Director
Office of Environmental Project Review
U.S. Department of Interior
Main Interior Bldg., Room 4239
Washington, DC 20246
FED

Ms. Mary L. Blazek
Oregon Department of Energy
625 Marion Street, NE
Salem, OR 97310
S/T

Dr. L. H. Bohlinger
Assistant Administrator
Nuclear Energy Division
State of Louisiana
P.O. Box 14690
Baton Rouge, LA 70898
504/925-4518
S/T

Mr. Stephen Bradhurst
President
Allen Bradhurst Corporation

245 E. Liberty, Suite 340
Reno, NV 89505
702/323-4141
CST Nye County, Nevada, contractor

Mr. William Burke
Nuclear Waste Project Manager
Confederated Tribes of the
Umatilla Indian Reservation
P.O. Box 638
Pendleton, OR 97801
503/276-3018
S/T X

Ms. Ellen Caywood
Associate Coordinator
Washington State Institute for
Public Policy
Seminar Bldg.
Evergreen State College
Olympia, WA 98505
206/866-6000 X6454
S/T

Ms. Gail Chehak
National Congress of
American Indians
804 D Street, NE
Washington, DC 20002
NPI

Ms. Lillian Cuoco
Fried, Frank Law Firm
1001 Pennsylvania Ave., NW
Suite 800
Washington, DC 20004-2505
342-3331
S/T Nez Perce attorney

Mr. Richard W. Donovan
Reg. Assistance Committee Chairman
Federal Emergency Management Agency
Region X, Federal Regional Center
130-228th Street, SW
Bothell, WA 98021
FTS 396-0293
FED

Mr. Spiros Droggitis
NRC/GPA/SLITP
Mail Stop AR-5037
NRC

Mr. Neal Moran
Public Affairs Specialist
U.S. Department of Energy
Office of Policy & Outreach (RW-43)
Washington, DC 20585
252-2838
DOE

Mr. Ben Easterling
U.S. Department of Energy
RW-42
Washington, DC 20585
252-2280
DOE

Ms. Margaret Federline
Ass't to Commissioner Carr
NRC/DCM
Mail Stop H-1149
NRC

Ms. Barbara Foster
National Conference of
State Legislatures
1050 Seventeenth Street, Suite 2100
Denver, CO 80265
303/623-7800
NPI

Mr. James Friloux
Program Manager
Louisiana Geological Survey
Nuclear Waste Repository Program
2133 Silverside Drive, Suite L
Baton Rouge, LA 70808
504/388-8533
S/T X

Mr. Steve Frishman
Office of the Governor
Nuclear Waste Programs Office
P.O. Box 12428
Austin, TX 78711
512/463-2198
S/T X

Mr. Roger Gale
Director
U.S. Department of Energy
Ofc. of Policy & Outreach (RW-40)

Mr. Robert Gamble
Roy F. Weston
955 L'Enfant Plaza, SW
Washington, DC 20024
646-6758
DOE DOE contractor/handles DOE mtg recording

Ms. Janet Gorn
NRC/GPA/CA
Mail Stop H-1159
NRC

Mr. Kevin Gover
Gover and Stetson
1225 Rio Grande Blvd., NW
Suite C
Albuquerque, NM 87104
S/T Nez Perce attorney

Mr. John W. Green
Mississippi Department of
Energy and Transportation
300 Watkins Building
510 George Street
Jackson, MS 39202
601/961-4733
S/T X

Mr. Fred Haag
New York Public Service Commission
3 Empire State Plaza
Albany, NY 12223
518/474-5541
NPI

Mr. Ronald T. Halfmoon
Manager
Nez Perce Indian Tribe-NWPA
P.O. Box 305
Lapwai, ID 83540
208/843-2253 Ext 331
S/T X

U. S. Department of Energy
Office of Geologic Repositories
RW-26
Washington, DC 20585
DOE

Mr. Dan Hester
Fredericks & Pelcyger
1881 Ninth Street
Suite 216
Boulder, CO 80302
303/443-1683
S/T Umatilla attorney

Ms. Susan L. Heston
U.S. Department of Energy
Salt Repository Project Office
110 North 25 Mile Avenue
Hereford, TX 79045
806/374-2320
DOE

Mr. Robert Holden
National Congress of
American Indians
804 "D" Street, NE
Washington, DC 20002
546-9404
NPI

Mr. James B. Hovis
Hovis, Cockrill, Weaver, and Bjur
316 N. 3rd Street
P.O. Box 487
Yakima, WA 98907
509/575-1500
S/T Yakima attorney

Mr. Terry Husseman
Program Director
Washington Department of Ecology
Office of High Level Nuclear
Waste Management
Mail Stop PV-11
Olympia, WA 98504
206/459-6670
S/T X

Mr. Russell Jim
Nuclear Waste Project Manager
Yakima Indian Nation
Confederated Tribes and Bands
P.O. Box 151
Toppenish, WA 98948
509/865-5121 Ext 393

Mr. M. F. Keel
U.S. DOI, Bureau of Indian Affairs
Ofc. of Trust Responsibilities
1951 Constitution Ave., NW
Code 203
Washington, DC 20245
FED

Ms. Janet Kotra
Asst to Commissioner Bernthal
NRC/DCM
Mail Stop H-1149
Ext. 43290
NRC

Mr. Steven P. Kraft
Director, Utility Nuclear Waste
Management Group
Edison Electric Institute
1111 Nineteenth Street, NW
Washington, DC 20036-3691
NPI

Mr. Dean M. Kunihiro
Regional State Liaison Officer
NRC Region V
FTS 463-3714
NRC

Dr. John T. Larkins
Special Assistant to Chairman Zech
NRC/DCM
Mail Stop H-1149
Ext. 41485
NRC

Ms. Judy Leahy
U.S. Department of Energy
Office of Geologic Repositories
RW-23
Washington, DC 20585
DOE

Mr. George Lear

Mail Stop 058-66
Ext. 74071
NRC

Mr. Darrell Lee
GAO Evaluator
U.S. Department of Energy
Room E 178
Washington, DC 20545
FED

Mr. Cecil Lewis
Park Ranger
U.S. DOI, National Park Service
Rocky Mountain Regional Office
P.O. Box 25287
Denver, CO 80225
FED

Mr. Roland Lickus
Regional State Liaison Officer
NRC Region III
FTS 388-5666
NRC

Ms. Maria Lopez-Otin
Assistant to Commissioner Roberts
NRC/OCM
Mail Stop H-1149
Ext. 41459
NRC

Mr. Robert R. Loux
Director
Nevada Nuclear Waste Project Office
1802 North Carson Street
Capitol Complex, Suite 252
Carson City, NV 89710
702/885-3744
S/T X

Mr. Jim Mecca
U.S. Department of Energy
Richland Operations Office
BWI Project Office
825 Jadwin Avenue
Richland, WA 99352
DOE

Dr. Viet Nguyen
EWA, Inc.
133 First Ave., N.
Minneapolis, MN 55401
612/332-0000
CST Yakima consultant

Mr. Gene Nodine
Moab District Manager
U.S. DOI, Bureau of Land Management
Moab District Office
P.O. Box 970, 125 W. 2nd Street
Moab, UT 84532
FED

Mr. James I. Palmer
State Liaison Officer
State of Mississippi
P.O. Box 139
Jackson, MS 39205
601/359-3100
S/T

Mr. Pete Parry
Superintendent
U.S. DOI, National Park Service
Arches, Canyonlands, Nat'l Bridges
446 South Main
Moab, UT 84532
FED

Mr. Michael Phillips
Union of Concerned Scientists
1616 P Street, NW, Suite 310
Washington, DC 20036
NPI

Mr. Max Powell
U.S. Department of Energy
Richland Operations Office
BWI Project Office, Room 574
P.O. Box 550
Richland, WA 99352
DOE

Mr. Wyatt M. Rogers
Senior Project Engineer
Council of Energy Resource Tribes
1580 Logan Street, Suite 400
CO 80503

Mr. Gary Sanborn
Regional State Liaison Officer
NRC Region IV
FTS 728-8267
NRC

Mr. Frank Scanlon
Deputy Attorney General
Tennessee Attorney General's Office
450 James Robertson Parkway
Nashville, TN 37219-5025
615/741-7403
S/T

Ms. Debra Shults
Tennessee Health Department
Division of Radiological Health
150 Ninth Ave., North
Nashville, TN 37219
615/741-7812
S/T

Mr. John Siegel
Atomic Industrial Forum, Inc.
7101 Wisconsin Ave.
Bethesda, MD 20814
NPI

Mr. Robert D. Siek
Director of Technical Services
Council of Energy Resource Tribes
1580 Logan Street
Denver, CO 80203
303/832-6600
CST Nez Perce/Umatilla contractor

Mr. Charles Smith
U.S. Department of Energy
Division of Program Integration
RW-43
Washington, DC 20585
DOE

Tennessee Dept. of Health & Environment
615-259-6100, 615-259-6111, 615-259-6112
Nashville, TN 37219
615/741-5782
S/T

Mr. David Stevens
1621 South Eastside Street
Olympia, WA 98501
CST Yakima consultant

Mr. David Stewart-Smith
Oregon Department of Energy
625 Marion Street, NE
Salem, OR 97310
503/378-3187
S/T X

Ms. Ruth Ann Storey
Director
Utah High-Level Nuclear Waste Ofc.
355 West North Temple
3 Triad Center, Suite 330
Salt Lake City, UT 84180-1203
~~801/538-5545~~ 533-5231
S/T X

Mr. Jerry Szymanski
U.S. Department of Energy
Nevada Operations Office
NNWSI Project Office
P.O. Box 14100
Las Vegas, NV 89114
DOE

Mr. Dean Tousley
Harmon, Weiss
2001 S Street, NW
Suite 430
Washington, DC 20009
328-3500
S/T Yakima attorney

Mr. Robert E. Trojanowski
Regional State Liaison Officer
NRC Region II
FTS 242-5597
NRC

Ms. Carol White
Federal Affairs Coordinator
State of Tennessee
309 John Severe Bldg.
500 Charlotte Ave.
Nashville, TN 37219
615/741-1676
S/T X

Mr. Frank Young
NRC/GPA/SLITF
Mail Stop AR-5037
NRC

C. R. McFarland
P.O. Box 3149
Carlsbad, NM 88220

Max Eisenberg, Director
Science and Environmental Health
Department of Health and Mental Hygiene
201 West Preston St.
Baltimore, MD 21201

Davis Scott
Office of State Planning
State of New Hampshire
2½ Beacon Street
Concord, NH 03301

encl. to letter of 7/31/87
from Linehan to addressee

GENERIC TECHNICAL POSITION
ON
ITEMS AND ACTIVITIES IN THE
HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM
SUBJECT TO
QUALITY ASSURANCE REQUIREMENTS

Division of Waste Management
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission

August 1987

409.53

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1.0 INTRODUCTION

The requirements which apply to radiological protection of public health and safety and the environment from disposal of high-level radioactive waste (HLW) in a geologic repository are defined in 10 CFR Part 60. These requirements address a pre-closure phase, which includes design, construction, waste emplacement, and possible retrieval of waste, and a post-closure phase, which includes containment and long-term isolation of waste. In the pre-closure phase, structures, systems, and components essential to the prevention or mitigation of an accident that could result in an off-site radiation dose of 0.5 rem or greater are termed "important to safety" (10 CFR 60.2). In the post-closure phase, the barriers which contribute to meeting the containment and isolation requirements of 10 CFR Part 60 are defined as "important to waste isolation." These structures, systems, components, and barriers (items), and the activities related to their characterization, design, construction, and operation need to meet quality assurance (QA) requirements to provide confidence in the performance of the geologic repository. The list of the items and activities important to safety or waste isolation is referred to as a "Q-list" and comprises the scope of the QA program specified in 10 CFR 60 Subpart G.

In order to obtain a license for a geologic repository, the U.S. Department of Energy (DOE) must demonstrate that all requirements in 10 CFR Part 60 are or will be met. To provide this demonstration DOE must implement a QA program for verifying and documenting the quality of work performed to support licensing findings. The purpose of this Generic Technical Position (GTP) is to provide guidance to DOE on approaches the NRC staff considers acceptable for identifying items and activities important to safety or waste isolation, and address measures needed to assure the quality of all items and activities that will be used to demonstrate compliance with the licensing requirements in 10 CFR Part 60. NRC staff positions on QA criteria for licensing, types of analyses appropriate to determine which items and activities are important to safety or waste isolation, staff information needs to assure adequate and timely staff involvement, and graded application of quality assurance measures to items and activities important to safety or waste isolation are provided.

2.0 BACKGROUND

The identification of items with safety significance has been an important issue in the nuclear power reactor program. It has been the subject of litigation in various reactor licensing hearings and has been the cause in

part, for extensive delays in schedules and large increases in cost for reactor plant construction. In the reactor program safety-related items are subject to the QA program requirements in 10 CFR 50 Appendix B. These items comprise the reactor list of quality components or "Q-list." Through reactor licensing experience the NRC has developed a body of practice which can be used to help determine which items are on the Q-list for a specific power plant. This body of practice includes, for example, a series of design basis accidents, a source term for release of radionuclides to the atmosphere, and meteorological conditions to be assumed during an accident. Listings of safety-related items also have been developed at the system level based on years of staff and industry experience with nuclear power reactors.

In contrast to the reactor program where fairly prescriptive criteria have been developed, the principal criteria for identifying the Q-list for a geologic repository are broad performance objectives. In the pre-closure phase of the repository, structures, systems, and components important to safety are those items essential to the prevention or mitigation an off-site dose of 0.5 rem or greater. There are no explicit design basis accidents, source terms for releases, meteorologic conditions, or generic lists of items identified in the requirements or guidance. DOE therefore has flexibility in developing approaches for establishing this information. For post-closure, 10 CFR Part 60 also provides DOE some flexibility in determining what specific barriers will be relied upon to meet each performance objective and technical criteria described in 10 CFR Part 60.

3.0 REGULATORY FRAMEWORK

This section contains a summary of the applicable regulations and formal staff guidance providing the regulatory basis for the staff positions in this generic technical position.

To help ensure protection of radiological health and safety of the public and the environment, 10 CFR 60 Subpart G requires that DOE apply a QA program to "all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto" (10 CFR 60.151). This QA program shall be based on the criteria of 10 CFR 50 Appendix B "as applicable and appropriately supplemented" (10CFR 60.152) and shall "comprise all those planned and systematic actions [including quality control] necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service" (10 CFR 60.150). DOE must provide a description of

the 10 CFR 60 Subpart G QA program; including a list of those items and activities to which the QA program applies in the Safety Analysis Report provided with the license application (10 CFR 60.21(c)(4)).

Structures, systems, components, and activities important to safety are those items and activities essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). For post-closure the overall system performance objective for a geologic repository following permanent closure specifies that the geologic setting be selected and the engineered barrier system, shafts, boreholes, and their seals be designed to assure that releases of radioactive materials to the accessible environment conform to the environmental standards for radioactivity established by the Environmental Protection Agency (40 CFR Part 191), as incorporated into 10 CFR 60 (60.112). The performance objectives for certain barriers after permanent closure are specified in 10 CFR 60.113. The barriers and activities that contribute to meeting the specific and overall containment and isolation requirements of 10 CFR 60.112 and 60.113 are considered "important to waste isolation."

Staff guidance on the 10 CFR 60 Subpart G QA program is contained in the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Waste Repositories" (USNRC, 1984a). Additional guidance on use of performance assessment techniques for identifying barriers important to waste isolation is provided in the "Draft Generic Technical Position on Licensing Assessment Methodology for High-Level Waste Geologic Repositories" (USNRC, 1984b).

In addition to items and activities important to safety or waste isolation, other items and activities will be associated with demonstrating that DOE meets all of the 10 CFR Part 60 licensing requirements. For example, 10 CFR Part 20 requirements, which are referenced in 10 CFR Part 60, will need to be addressed in the license application. Although these additional items and activities are not covered by the 10 CFR 60 Subpart G QA requirements (which applies only to items and activities important to safety or important to waste isolation), assurance measures are needed to provide confidence that all requirements have been met. Certain assurance measures, such as use of written procedures, documentation of completed work, and monitoring of radiation levels, are currently prescribed in the regulations and, although not explicitly stated as quality assurance requirements, provide a basis for demonstrating compliance with the licensing requirements.

4.0 DEFINITIONS

This section provides a definition of significant terms used in the staff positions presented in this GTP. Definitions for other commonly used terms are provided in Appendix A, the Glossary.

Activities are deeds, actions, work, or performance of a specific function or task. In the HLW geologic repository program, the 10 CFR Part 60 Subpart G QA program applies to activities related to all systems, and structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation (10 CFR 60.151). For example, site characterization activities related to waste isolation may include waste package and exploratory shaft testing, and performance assessments. Activities such as control of design, purchasing, fabrication, inspection, and maintenance are specified in the QA program required by 10 CFR 50 Appendix B, and do not need to be identified as part of the Q-list.

Barrier means any material or structure that prevents or substantially delays movement of water or radionuclides (10 CFR 60.2).

Containment means the confinement of radioactive waste within a designated boundary (10 CFR 60.2).

Credible event or credible accident refers to an event or accident scenario which is sufficiently likely to warrant consideration in design of the geologic repository.

Design means (1) specifications, plans, drawings, blueprints, and other items of like nature; (2) the information contained therein or (3) the research and development data pertinent to the information contained therein.

Design basis accidents are postulated accidents that need to be considered in design of a structure, system, or component of the repository to assure adequate protection of public health and safety and the environment.

Items and activities important to safety include those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ,

of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2).

Items and activities important to waste isolation include the site, engineered barrier system, seals for shafts and boreholes, and any other items which contribute to achieving the performance objectives in 10 CFR 60 Subpart E.

Q-list as used in the geologic repository program, is a list of structures, systems, and components important to safety, barriers important to waste isolation and related activities that must be covered under the QA requirements of 10 CFR 60 Subpart G.

5.0 STAFF POSITIONS

5.1 Quality Assurance Criteria for Licensing

(a) Criteria for Q-list Items and Activities

DOE shall apply a QA program which meets the 10 CFR 60 Subpart G requirements to all systems, structures, and components important to safety, barriers important to waste isolation, and related activities (10 CFR 60.151).

(b) Criteria for Non-Q-List Items and Activities

In addition to items and activities important to safety or waste isolation, 10 CFR Part 60 contains requirements for other items and activities, such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for radiological protection of worker health and safety. For these items and activities, the staff endorses the use of the DOE Level II requirements as described in the Office of Geologic Repository QA Plan (USDOE, 1986 - see Attachment 1 to Supplement 8). Additional NRC guidance, such as Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment" (USNRC, 1979) should also be used for applicable areas of the repository program. The staff will review the implementation of the Level II program to assure that these DOE requirements are fulfilled.

(c) Information Not Collected Under 10 CFR 60 Subpart G QA

Data collection, interpretation, analysis, and other work collected outside of the DOE 10 CFR 60 Subpart G QA program but needed for licensing should be evaluated to determine its suitability. This information includes data collected by sources external to DOE, such as oil companies and universities. Staff guidance on this subject is provided in the "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," (USNRC, 1987).

5.2 Identification of Items and Activities Important to Safety

The threshold for determining which structures, systems, and components are important to safety is the potential for a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area before permanent closure. The activities related to these items are also considered important to safety and need to be conducted under a 10 CFR Subpart G QA Program.

(a) Analysis

DOE should use probabilistic risk assessment (PRA) techniques, to the extent practicable, to support the identification of structures, systems, components and activities important to safety. Engineering judgment and conservative assumptions will need to be used prior to site characterization, due to the limited data base available at that time. Conservative assumptions should include non-mechanistic failure of items, where data are insufficient to determine the failure modes and scenarios of those items. DOE should identify and consider accident scenarios having frequencies of occurrence greater than about 10^{-8} /year in determining which accident sequences should be used as the basis for design. It is not expected that all scenarios will need to be addressed in the design, only those causing a high risk to the public.

The PRA techniques used at licensing should include:

- (1) System modeling to depict the combinations of safety function and system successes or failures which constitute

accident sequences. DOE should employ modeling techniques, such as fault trees and event trees in these accident analyses.

- (2) Consequence analysis to evaluate the movement and deposition of radioactive materials released from the HLW facility. Source terms for individual events or accidents should be identified and justified.
- (3) Uncertainty analysis to evaluate uncertainties in the data base and in modeling.

All structures, systems, and components of the geologic repository whose failure could initiate an accident causing an off-site radiation dose of 0.5 rem should be on the Q-list. All structures, systems, and components of the geologic repository which are relied on to mitigate the consequences an accident also should be on the Q-list. For the purposes of defining the initial Q-list DOE should utilize an accident dose limit of .5 rem.*

(b) Redundancy

DOE shall, as a minimum, employ redundancy in those areas specified in 10 CFR Part 60 [e.g., 10 CFR 60.131(b)(5)(ii) and 60.131(b)(10)(iv)]. Additional redundancy, if any, shall be employed as needed to assure the offsite dose limit for an accident is not exceeded. Systems, structures and components used to provide redundancy shall be included on the Q-list.

(c) Use of Previously Established Guidelines and Standards

DOE may utilize existing nuclear power reactor guidelines and standards for initiating events (e.g., regulatory guides covering the design basis earthquakes, tornado wind velocities, and floods) in the identification of items and activities important to safety where these criteria can be shown to be applicable to the geologic repository.

(d) Retrieval Process

DOE should analyze the proposed retrieval process to identify items and related activities that are subject to the 10 CFR 60

* The Department has indicated that it is preparing a Petition for Rulemaking requesting NRC to amend 10 CFR part 60 to establish a 5 rem accident dose limit. Until the Petition for Rulemaking is dispositioned DOE should consider .5 rem as the accident dose limit.

Subpart G QA program to assure protection of public health and safety, in the event that retrieval is necessary.

5.3 Identification of Items and Activities Important to Waste Isolation

Items important to waste isolation should include those which may contribute to demonstrating compliance with the objectives related to post-closure performance of the repository system (e.g., the site, the waste package, engineered barrier system, shaft and borehole seals). DOE should allocate performance among the various components of the natural and engineered barrier systems to provide a basis for determining which items may be important to waste isolation.

As data are collected, performance assessments must be conducted to determine if the items relied on will meet the objectives. Until the results of final assessments are obtained, DOE should consider all items which may contribute to isolation of waste as important to waste isolation, so those items and related activities will be supported by adequate QA.

The activities related to characterization of these items, such as laboratory and field investigations, also are considered important to waste isolation and need to be conducted under a 10 CFR 60 Subpart G QA program.

5.4 Staff Information Needs

(a) License Application

DOE should submit with the license application a description of the QA program to be applied to items and activities following construction authorization [10 CFR 60.21(c)(4)]. DOE shall identify the structures, systems, and components important to safety [10 CFR 60.21(c)(1)(ii)(E) and 60.21(c)(3)], the barriers important to waste isolation, and related activities falling under the 10 CFR 60 Subpart G QA program.

(b) Site Characterization Plans

DOE should submit with the Site Characterization Plans (SCPs) a description of the QA program to be applied to items and activities during the site characterization phase. A preliminary Q-list should be provided in this description identifying major structures, systems and components important to safety, barriers important to waste isolation, and all major related activities to be conducted during the site characterization phase, such as waste package and exploratory shaft testing. Other activities related to the QA-list, such as designing, fabricating, inspecting, and purchasing, also should be described or referenced in the SCP.

Engineering judgement and conservative assumptions will be required for identification of items and activities on the Q-list presented in the SCP due to the limited data base. For example, at the SCP stage, all site characterization activities should be considered to be within the scope of the 10 CFR 60 Subpart G QA program, unless DOE can demonstrate they are not potentially related to items important to safety or waste isolation. The process for refinement of the preliminary Q-list based on design advancements and collection of new information should be generally described in the SCP.

Plans for development and implementation of the QA program to demonstrate that non-Q-list licensing requirements are met also should be described in the site characterization plans.

5.5 Graded Application of QA Measures

The 10 CFR 60 Subpart G requirements can be met using graded application of QA measures and should be applied to items and activities important to safety or waste isolation based on considerations such as the following:

- o The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, to safety or waste isolation.
- o The complexity of design or fabrication of an item or design and implementation of a test, or the uniqueness of an item or test.

- o The special controls and surveillance needed over processes, tests, and equipment.
- o The degree to which functional compliance can be demonstrated by inspection or test.
- o The quality history and degree of standardization of the item or test.

Additional guidance on the grading of quality assurance program elements is provided in Appendix 4A-1 Section 5.0 of NQA-1 (ANSI/ASME, 1986).

6.0 DISCUSSION

This discussion section provides the rationale for and amplification of the positions in Section 5.0 and is organized to follow the same headings.

6.1 Quality Assurance Criteria for Licensing

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste in a manner which will protect radiological health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and long-term isolation of waste following permanent closure of the geologic repository. In addition, 10 CFR Part 60 incorporates other standards such as 10 CFR Part 20 and the generally applicable environmental standards established by the EPA for the release of radioactive materials.

In order to obtain a license for receipt and possession of radioactive material at the geologic repository, the DOE must demonstrate that the repository system will function as required to protect radiological health and safety of the public and the environment. The 10 CFR Part 60 specifies requirements for the performance of structures, systems, components and activities important to safety (during pre-closure) and the performance of

barriers and activities important to waste isolation (following waste emplacement). 10 CFR 60 Subpart G specifies the QA program for these items and related activities to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

(a) **Criteria for Q-List Items and Activities**

The 10 CFR 60 Subpart G QA program applies to items and activities on the Q-list. As derived from 10 CFR Part 60 (60.152), this QA program is based on the 18 criteria of 10 CFR Part 50 Appendix B for siting, design, construction, operation, and decommissioning of nuclear power plants. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria may be supplemented as necessary to meet the specific requirements of the repository program. NRC staff guidance on the application of the Appendix B QA criteria to the site characterization phase of the repository program is provided in the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Facilities," (USNRC, 1984a).

In addition to the QA requirements in 10 CFR 60 Subpart G, items important to safety are subject to the design criteria of 10 CFR 60.131(b). These added criteria help to provide assurance that the margins of safety during normal and accident conditions are adequate throughout the life of the facility. They include protection of items important to safety against natural phenomena and environmental conditions, dynamic effects of equipment failure, and fires and explosions, as well as special emergency capabilities, criticality control, and shaft conveyance features.

(b) **Criteria for Non-Q-List Items and Activities**

Items and activities that are not important to safety or waste isolation must also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements. These include, for example, items and activities associated with meeting the design criteria contained in 10 CFR 60.131(a) for radiological protection of worker health and safety. Although these items and activities may not be included in the scope of

the 10 CFR 60 Subpart G QA program they will be encompassed in NRC staff review of the DOE license application for a HLW repository.

The DOE has described a QA program for these non-Q-list licensing-related activities in the Office of Geologic Repositories QA Plan (USDOE, 1986 - see Attachment 1 to Supplement 8). This program is referred to by DOE as a "Level II" program and is similar to that required for Level I or Q-list items and activities. The staff has reviewed DOE's Level II QA requirements and finds them acceptable for use with non-Q-list items and activities. The DOE should assure that these requirements are correctly implemented.

In addition to the DOE internal Level II requirements, NRC guidance for QA programs during normal operations are addressed in Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment" (USNRC, 1979). DOE should use this guidance in addition to supplement their Level II program, as appropriate.

(c) Information Not Collected Under 10 CFR 60 Subpart G QA

All data collection, interpretations, analyses, and other work to be used to support findings in the licensing process must be technically and procedurally defensible by the DOE. The staff expects that some information collected outside the 10 CFR 60 Subpart G QA program, termed "existing data" may be used or referenced by DOE in the licensing process for items and activities important to safety or waste isolation. Such data may have been generated by sources such as oil companies, university research programs, and DOE or DOE contractors prior to implementation of a 10 CFR 60 Subpart G QA program. DOE should review the quality and traceability of existing data to determine whether it is adequate and/or can be qualified as needed for licensing.

The staff has developed a position paper entitled "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories" (USNRC, 1987), which provides guidance to DOE on what the staff considers as appropriate methods of qualifying existing data for potential use in licensing. The methods addressed in the GTP include peer

reviews, corroborating data, confirmatory testing, and an equivalent QA program. DOE should use this guidance in development of programs for qualifying existing data. Such programs may be applicable to non-Q-list as well as Q-list related information that may be used in licensing. The programs developed for qualifying Q-list related information should be developed and implemented in consultation with NRC staff. The staff does not consider qualification techniques to be appropriate for increasing the QA on information generated by DOE or DOE contractors after implementation of an NRC approved QA program.

In addition to existing data, some materials that may be important to safety or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA program (e.g., materials for exploratory shaft construction at the Basalt Waste Isolation Project). DOE needs to review the supporting documentation on these materials (e.g. the technical specifications and QA records) to determine whether they meet the technical and QA requirements for their designated function. If not, DOE will need to "qualify" them for use to assure they will perform their intended function. Some methods recommended for qualification of existing data (such as confirmatory testing) may also be applied to qualify the existing materials and their supporting data (see the staff position paper referenced above).

6.2 Identification of Items and Activities Important To Safety

Items and activities important to safety are those items and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose of 0.5 rem or greater to an individual in unrestricted areas (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, components and activities shall be on the Q-list as items or activities important to safety. This rationale for placing a system, structure, component or activity on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function and do not generate an offsite dose of greater than 0.5 rem.

(a) Analysis

DOE should use PRAs to the extent practicable to support the

identification of structures, systems, components and activities important to safety in the license application. PRAs have been shown to be a useful licensing tool for systematically evaluating the safety of nuclear facilities. In addition, use of this approach for the operations phase of the program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the period following emplacement of waste in a geologic repository. Since the geologic repository will be a first-of-a-kind facility, the staff recognizes that there may be limited data from operational experience available for initiating events and failures. In cases where data are limited, engineering judgement and conservative bounding assumptions will need to be used. Conservative assumptions should include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

The PRA should utilize the following techniques:

- (1) System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques often used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

Event tree analysis first identifies all events that could conceivably lead to an accident. These are referred to as "initiating events." Following this, all significant sequences of events that could follow each initiating event are examined.

A fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident is examined to determine how failures of components within that system could cause the failure of the entire system.

An illustrative example of an accident analysis, is provided below using failure of the hoist used to lower canisters into the emplacement areas of the repository as the potential initiating event. Events that need to be examined in an event tree to analyze the accident scenario(s) that may result from this hoist failure will include the response of a canister to the fall (i.e., whether it breaches on impact), the type and amount of radionuclides released in the vicinity of a canister if it does breach, the ability of monitoring systems to detect a release and activate mitigating systems, and the response of the mitigating systems to a release. If failure of a mitigating system could contribute to an off-site dose, individual components within the mitigating system need to be reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

- (2) Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the HLW facility. The energy, magnitude, and timing of radiological releases resulting from various accidents need to be considered in this analysis.
- (3) Uncertainty analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. Uncertainties inherent to PRAs should not be under emphasized. However, the insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

To the extent practicable, probabilities of scenarios and releases will need to be developed. In the evaluation of potential accidents, some scenarios may be found to be so unlikely, they need not be considered in design of the repository. There is little data available on the reliability

of items unique to the repository to support detailed risk assessments at the early phases of this program. Therefore, the staff expects that conservative bounding assumptions will be made and justified to assure that accidents will be prevented or mitigated as required to protect public health and safety.

DOE should identify and consider accident scenarios having frequencies of occurrence greater than about 10^{-6} /year in determining which accident sequences should be used as the basis for design. It is not expected that all scenarios will need to be addressed in the design, only those causing a high risk to the public.

All structures, systems, components and related activities of the geologic repository whose failure could initiate an accident which, could cause an off-site radiation dose of 0.5 rem should be on the Q-list. The staff also considers that structures, systems, components and related activities whose failure may initiate such an accident cannot be removed from the Q-list due to the addition of mitigating features. Equipment relied on to perform a safety function should meet the requirements of 10 CFR 60 Subpart G.

For the purpose of design basis accident calculations, justification such as reliability data, design margins, and in-service and qualification testing will need to be provided by DOE in order to demonstrate that failure of an item is not credible. The validity of such justification will need to be assured by application of a 10 CFR 60 Subpart G QA program.

The NRC Office of Nuclear Regulatory Research has an ongoing study for assessing pre-closure accidents. The latest reports published under this study (Harris, et. al., 1985) contains examples of initiating events, accident scenarios, and discussions of possible consequences using a specific design for a HLW facility.

(b) Redundancy

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit is not exceeded. In a redundant system, the

failure of one train of the system will not compromise or prevent the associated safety function from being performed. For the high-level waste repository, several sections of 10 CFR 60 [60.131(b)(5)(ii) and 60.131(b)(10)(iv)] address requirements for redundancy. Additional redundancy should be employed whenever there is a potential for exceeding the dose limit for an accident. The results of PRAs should help to indicate the need for redundancy by identifying those areas where structures, systems, and components are not sufficiently reliable to perform their safety functions and assure the accident dose limit is not exceeded. The items needed to provide redundancy for items important to safety also shall be on the Q-list.

(c) Use of Previously Established Guidelines and Standards

Many guidelines and standards have been developed in the reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the associated Q-list. While some of these guidelines and standards may not be directly applicable to a geologic repository, DOE should consider their use, to the extent practicable, to help eliminate the need to develop acceptable new approaches. NRC staff will review these guidelines and standards to assure acceptability as DOE may choose to apply them to applicable aspects of the repository program.

A recent DOE-sponsored publication, "Evaluation of Regulatory Guides Potentially Useful to Geologic Repository Development" (Chang, 1986), although not yet endorsed by DOE or NRC, is a useful source of information and provides a basis for future discussions between DOE and NRC staffs.

(d) Retrieval

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). Analyses of retrieval operations need to be conducted by DOE to identify Q-list items and activities. These analyses need to include, for example, re-mining operations, conveyance shafts, and equipment which may be used in the retrieval process. These analyses should be conducted in a timely manner so that the items and activities

related to planning, characterization, design, and construction of these items can be evaluated and covered by the applicable QA requirements.

6.3 Identification of Items and Activities Important to Waste Isolation

The term "important to waste isolation" refers to those items and activities that will contribute to meeting the containment and isolation performance objectives of 10 CFR 60 Subpart E. The four primary performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:

- o ground water travel time,
- o waste package containment period,
- o maximum yearly release rate from the engineered barrier system,
- o the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the EPA standard in 40 CFR Part 191).

The items and activities important to waste isolation relied on to meet these performance objectives should include:

- o components of the engineered barrier system (waste package and underground facility), shaft and borehole seals,
- o components of the natural barrier system (e.g., host rock, and geochemical retardation characteristics),
- o items and activities necessary to support the determination of whether the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers, and
- o items and activities in the preclosure phase that could affect post-closure performance.

The identification of the barriers on the Q-list is relatively simple for the post-closure phase since there are so few. Identification of activities related to these barriers is more difficult as the

activities to be considered include, for example, characterization of the site; design activities; construction, fabrication and testing of engineered barriers, including waste package; and specific work activities such as drilling, inspecting, and data reduction.

The broad performance objectives for waste isolation provide DOE with some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example a 300 to 1000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers may be important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. DOE is expected to allocate performance among barriers based on available data before site characterization begins. These initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocation of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization. Performance allocation, data collection, and performance assessments may likely be an iterative process.

Prior to and during the early phases of site characterization, when the relative importance of items and activities to waste isolation is not known, all activities DOE plans for characterization of barriers as well as those barriers themselves should be covered by a 10 CFR 60 Subpart G QA program. At the time of the license application, specific barriers may not need to be on the Q-list if they will not be relied on to meet the system performance objectives and if they will not detract from the performance of those barriers which will be relied on. This will only be evident after extensive data are collected and analyzed in performance assessments. Until that time, it is prudent to consider all items related to post closure performance and for which characterization activities are planned to be important to waste isolation. These characterization activities also are considered important to waste isolation and should be treated as such. Failure to apply QA in a manner commensurate with the potential importance of an item or activity may adversely affect the credibility of information used in the license application.

In determining which barriers are important to waste isolation and how much each contributes to performance, the DOE should utilize as a basic reference the guidance given in the NRC staff's "Draft Generic Technical Position on Licensing Assessment Methodology for High-Level Waste Geologic Repositories" (USNRC, 1984). This document presents information on the identification of credible scenarios, determination of the likelihood of these scenarios, development of conceptual models that describe the scenarios, formulation of mathematical models that are consistent with the conceptual models, incorporation of data and associated uncertainties into the numerical models, assessment of the consequences of the scenarios, and the comparison of the results with numerical performance objectives.

6.4 Staff Information Needs

Q-list items and activities should be identified prior to conducting related work or purchasing related items and services. During operation, systems important to safety may include the ventilation system, waste transport system, instrumentation, the electrical system, and the rock support system. After emplacement of the wastes there are various components or systems that are likely to be important to isolation, such as the waste form, backfill, waste package, and natural barriers. Major site characterization activities to be on the Q-list include waste package and backfill testing, borings, and in-situ testing at depth.

(a) License Application

DOE should submit with the license application a description of the QA plans to be applied to items and activities during construction, the period of operations, and performance confirmation. A final list of items and activities important to safety or waste isolation should be provided with the description of the 10 CFR 60 Subpart G QA program as part of the license application [10 CFR 60.21(c)(4)]. Analyses to identify systems, structures, and components important to safety shall also be provided in the license application [10 CFR 60.21(c)(1)(ii)(E) and 60.21(c)(3)]. DOE should furnish information supporting development of the final Q-list and the applicable 10 CFR 60 Subpart G QA program in the periodic SCP

updates so that the staff will be thoroughly familiar with the content of the list prior to the license application.

(b) Site Characterization Plans

Prior to submission of the license application, DOE is required to submit a site characterization plan. In order for the NRC staff to identify licensing issues early so that they may be resolved by the license application, the methodology for determining the scope of items and activities important to safety or waste isolation, a preliminary Q-list, and a description of the 10 CFR 60 Subpart G QA Program applicable to items and activities on the Q-list for the site characterization phase should be provided. While changes in the level of detail and content of the Q-list are likely to occur between the SCP and the license application based on an increased level of knowledge and maturity of design, DOE should provide a provisional Q-list in the SCP based on available information. This provisional list should include items and activities important to safety and waste isolation and should be supported by conservative analyses to assure all potential items and activities are identified at least at the system and major component level. As the design matures and more information is collected, items may be removed from or added to the Q-list. Changes of this type are expected and should be documented with supporting analysis and rationale. The process for refinement of the preliminary Q-list based on design advancements, data collection and analyses should be identified in the SCP to support the staff's evaluation of the QA plans. The staff will periodically review the process for adding and removing items from the Q-list to assure that it is adequate and reliable. It is important to emphasize the need for conservatism in developing the provisional Q-list. Information on items and activities which are added to the Q-list after site characterization activities begin, that was not collected under a 10 CFR 60 Subpart G QA program, may not be adequate to support licensing.

It may be difficult to determine what items and activities will be important to safety prior to site characterization due to limited site data and design detail. With the limited data base available at this time, application of a rigorous probabilistic analysis may not be practicable. Accident scenarios including initiating events as well as dose consequences for accidents

will therefore need to be identified and estimated using conservative engineering judgment. The available information base may include data collected and analyzed for other similar activities, such as external events for reactor facilities, design basis accidents for independent spent fuel storage installations (ISFSIs) and refueling operations at nuclear power plants where these can be shown to apply directly to the high-level waste facility. Although the repository operational system represents a new and unique nuclear facility, comparisons can be made with similar nuclear facilities in order to facilitate knowledgeable decisions and avoid duplication of effort. Use of analyses for similar facilities should be carefully conducted and the information obtained should be rigorously examined to assure that key differences in facilities have not been overlooked.

6.5 Graded Application of QA Measures

To meet the requirements and provide adequate confidence in the quality of the items and activities within the scope of the Q-list, the application of QA measures may be varied. This flexibility is provided in 10 CFR 60 Subpart G through reference to 10 CFR 50 Appendix B. Criterion II of Appendix B states that the QA program shall provide for control over activities affecting the quality of structures, systems, and components to an extent consistent with their importance to safety. It is expected that probabilistic and performance assessment analyses will provide qualitative and quantitative evaluations of the importance to safety or waste isolation of particular structures, systems, or components for developing the scope of the QA program. These evaluations can then provide a logical framework for application of graded QA measures.

NQA-1 (ANSI/ASME, 1986) is a consensus standard which provides more detailed guidance on grading QA for nuclear facilities. NQA-1 Appendix 4A-1 contains these criteria for grading QA measures.

- o The impact of malfunction or failure of the item on safety or waste isolation. For example, components may play a major role in safety, perform supporting functions for primary equipment, perform redundant functions (i.e., two items may perform identical functions but only one may be needed to prevent or mitigate an accident), or perform functions for low consequence

events or accidents with very low probabilities of occurrence. QA measures should be applied to a degree consistent with the importance to safety or isolation of a specific item or activity. Likewise, data will vary in degrees of importance to safety or waste isolation. PRAs also provide a framework for grading of QA measures based on the risk associated with the failure of individual components.

- o The complexity of design and fabrication of an item or design and implementation of a test, or uniqueness of the item or test. First-of-a-kind items or tests or complex items or tests may require extensive design efforts or extensive inspection or peer review during their development to assure satisfactory results.
- o The special controls and surveillance needed over processes and equipment. Processes and equipment which affect the quality of components, data or analyses and whose effects on the components, data or analyses cannot be easily measured or evaluated in the final product, such as welding and heat treatment, should be controlled as prescribed by Criterion IX of 10 CFR 50 Appendix B.
- o The degree to which functional compliance can be demonstrated by inspection or test. Proof of the quality of a component can sometimes be demonstrated by inspection and/or testing of a final product. In such cases, the in-process control program may be reduced. The limiting case is whether an end product test can properly assess the degree of compliance to quality requirements and thereby eliminate the need for in-process control.
- o The quality history and degree of standardization of the item or test. If a manufacturer or organization has been producing a particular standard item or conducting a standard test for a long period and if the quality history of the item or test indicates acceptable performance, QA measures may be applied to that item or test to reflect the demonstrated performance. Conversely, if certain characteristics are determined to be unsatisfactory based on operational data, additional QA measures may be required to assure that experienced deficiencies are identified and corrected or controlled.

In implementing the above guidance for items important to safety, the amount and types of inspection, testing, and record keeping will be

the most variable measures in the grading program. The following examples of how grading can be accomplished are helpful in interpreting the guidance given above. Assume that a standard Commercial grade radiation detector is used in the pre-closure phase as one of several indicators that an accident has occurred and that safety systems, such as the ventilation system, need to be activated. If this detector is important to safety due to the function(s) it performs, the designer working under the 10 CFR 60 Subpart G QA program would need to review the information supplied by the manufacturer on the range, accuracy, power requirements, environmental conditions under which the specific radiation detector will operate and other pertinent information about the device and its use to determine its acceptability for the intended application. Following this review, the designer would confirm that the available instrument would be suitable for its application in the facility, or make revisions to the design to accommodate the instrument. After specifying or referencing the necessary requirements in the purchase order, a receipt inspection would be conducted to assure that the instruments received were in accordance with the purchase order. After receipt, the instrument would be installed, calibrated, tested, and maintained in accordance with the requirements of the manufacturer and/or designer. The repository designer and constructor should have the required Subpart G QA programs in place for the work that they performed on the device and for selecting and auditing the supplier, while the manufacturer of the device may only implement a portion of a Subpart G QA program. The specific controls selected by the designer's and constructor's organizations, along with the manufacturer's standard controls, could suffice.

As a contrasting example, the hoist used to transport waste packages can be considered. If failure of the hoist had the potential for contributing to an off-site dose of 0.5 rem or greater and assurance was needed that such a failure would not occur. Essentially all elements of the Subpart G QA program might be applied to the design, fabrication, installation, and inspection of the hoist. The manufacturer of the hoist might be required to establish its own Subpart G QA program including all elements of Appendix B, with in-process inspections, design reviews, training programs, etc. Also the purchaser would probably conduct surveillances, source inspections, and audits of the hoist manufacturer to assure that the QA program was being carried out properly. Numerous detailed and complex inspections might be required to assure that the device were safe and reliable. The records associated with these activities would be extensive.

For items and activities important to waste isolation, QA measures should not be significantly graded in the early phases of site characterization. The characteristics of individual components or phenomena of the natural or engineered systems are not well known prior to extensive data collection and analysis and their contribution to meeting the numerical performance objectives of 10 CFR Part 60 cannot be confidently established at that time. Until a defensible basis for grading QA measures can be established, a conservative level of QA should be applied to testing and design of barriers in the event that subsequent data analyses show them to be important in meeting the isolation and containment requirements of 10 CFR Part 60. Some flexibility in this approach may be permitted if conservative performance goals are established for individual components or phenomena and for routine or simple tests or components.

During the field investigations, the amount of inspection and control that is placed on the various activities may vary due to the complexity of the tests and the amount and importance of the information to be collected. If, for example, a boring is planned for the sole purpose of obtaining an additional ground water level measurement to confirm existing gradients, it may not be necessary to place a large number of controls on the drilling of this boring; for example, a full-time inspector may not be required to observe the drilling. If, on the other hand, the purpose of the boring was to obtain accurate measurements of the orientation of joints and fractures, and to obtain ground water samples for chemical analysis, the controls which should be imposed would be more stringent. The drilling rig may need to be inspected prior to operation to assure that the appropriate equipment and procedures were in place to achieve the desired objective. Any drilling fluid introduced into the hole would likely be analyzed and have a tracer added, and controls might be placed on the types of additives which could be used in the hole. In this example, it would be likely that a full-time inspector would be on the drill site to assure that all procedures were followed and documentation completed. Boring completion and testing of this hole should be documented in a detailed series of field reports. In both cases, the NRC staff would expect documentation showing that information was obtained correctly. However the level of effort would be considerably different for these two situations.

7.0 SUMMARY

This GTP provides guidance on approaches the staff considers acceptable for identifying items and activities within the scope of the 10 CFR 60 Subpart G QA program. It also gives guidance on how to apply QA to these and other items and activities in order to demonstrate compliance with the requirements of 10 CFR Part 60. DOE should use PRA techniques, to the extent practicable, to identify items and activities important to safety. DOE should identify barriers important to waste isolation and their related activities based on performance allocation and performance assessments. The final Q-list should be contained in the description of the 10 CFR 60 Subpart G QA program included in the license application and a provisional Q-list should be presented in the SCP. The provisional Q-list should be based on available data, engineering judgment, and conservative assumptions. In addition to addressing items and activities on the Q-list, DOE should apply an appropriate level of QA to non-Q-list items and activities that will be needed to support other licensing requirements, such as those in 10 CFR 60.131 for radiological protection of workers. DOE may apply graded QA measures to items and activities on the Q-list based on the criteria in NQA-1 Appendix 4A-1 (ANSI/ASME, 1986) when information is available to support such grading.

8.0 REFERENCES

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APPENDIX A
GLOSSARY

Accessible environment: (1) The atmosphere, (2) the land surfaces, (3) surface water, (4) oceans, and (5) the portion of the lithosphere that is outside the controlled area (10 CFR 60.2). The overall system performance for the geologic repository is calculated at this boundary.

Activities: Deeds, actions, work, or performance of a specific function or task. In the HLW geologic program, the 10 CFR Part 60 Subpart G QA program applies to activities related to all systems, and structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation (10 CFR 60.151). For example, site characterization activities related to waste isolation may include waste package and exploratory shaft testing, and performance assessments. Activities such as control of design, purchasing, fabrication, inspection, and maintenance are specified in the QA program required by 10 CFR 50 Appendix B, and do not need to be identified as part of the Q-list.

Backfill: Material used to fill access tunnels, shafts, and other openings, excluding waste emplacement holes, and forming part of the underground facility. (An example is bentonite clay mixed with crushed rock and secondary minerals used to fill repository drifts).

Barrier: Any material or structure that prevents or substantially delays movement of water or radionuclides (10 CFR 60.2).

Consequence analysis: A method by which the consequences of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

Containment: The confinement of radioactive waste within a designated boundary (10 CFR 60.2).

Credible event or credible accident: An event or accident scenario which is sufficiently likely to warrant consideration in design of the geologic repository.

Design: (1) specifications, plans, drawings, blueprints, and other items of like nature; (2) the information contained therein or (3) the research and development data pertinent to the information contained therein.

Design basis: Information which identifies: a) the specific functions to be performed by the structures, systems, or components of a geologic repository; b) assumptions regarding design controlling parameters; c) the specific parameter values selected as a basis for the design; and d) the supporting rationale for assumptions and parameter value selection.

Design basis accidents: Postulated accidents that need to be considered in design of a structure, system, or component of the repository to assure adequate protection of public health and safety and the environment.

Design process: An iterative process of developing a geologic repository design from the preliminary stages where the level of uncertainty in design inputs is high, to a final stage where the level of uncertainty is low enough to meet established performance criteria.

Engineered barrier system: The waste packages and the underground facility (10 CFR 60.2). The maximum radionuclide release rate is measured at this boundary (10 CFR 60.113(a)(1)(11)(B)).

Finding: NRC assessment of compliance or noncompliance with a specific requirement. A finding addressing a numerical performance objective will be reached after the following are weighed; the results of a reliability analysis and the laboratory and field tests upon which it is based, expert opinion, and empirical studies.

Geologic repository: A system which is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes: (1) the geologic repository operations area, and (2) the portion of the geologic setting that provides isolation of the radioactive waste (10 CFR 60.2).

Geologic repository operations area: A high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted (10 CFR 60.2).

High-level radioactive waste (HLW): (1) Irradiated reactor fuel, (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel, and (3) solids into which such liquid wastes have been converted (10 CFR 60.2).

Items and activities important to safety: Includes those engineered structures, systems, and components essential to the prevention or mitigation of an

accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2).

Items and activities important to waste isolation: Includes the site, engineered barrier system, seals for shafts and boreholes, seals, and any other items which may contribute to demonstrating that the performance objectives in 10 CFR 60 Subpart E will be met.

Licensing assessment: An assessment of whether a license application complies with all of the requirements that it purports to meet. For this program it is the sum of the individual findings for each of the requirements of 10 CFR Part 60.

Non-mechanistic failures: Postulated failures which are not based on previously observed modes or mechanisms but which are assumed to provide conservatism in risk assessments.

Packing: The material that is placed in the waste emplacement hole in the annular space between a canister or overpack (if one is present) and the host rock. The packing is a component of the waste package which serves to control the release of radionuclides from the waste package by sealing against water, modifying the water chemistry, sorbing or retarding the transport of radionuclides or by establishing other improvements in environmental parameters. (An example is a mixture of bentonite clay and crushed rock placed in the annulus between the overpack and host rock).

Performance assessment: The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to determine compliance with the numerical criteria associated with 10 CFR Part 60.

Performance allocation: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components.

Performance confirmation: The program of tests, experiments, and analyses which is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met (10 CFR 60.2).

Performance goals: The numerical values of performance assigned to the mined geologic disposal system, its subsystems, or components of its subsystems. Achievement of performance goals is evaluated using performance assessments, primarily to guide testing and design. Performance goals may be changed as characterization, testing, and design progress, whereas performance objectives remain fixed by regulation.

Quality assurance: Those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service. Quality assurance includes quality control, as defined below.

Quality control: Those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, system, structure, or component to predetermined requirements (10 CFR 60.150).

Q-list: As used in the geologic repository program, is a list of structures, systems, and components important to safety, barriers important to waste isolation and related activities that must be covered under the QA requirements of 10 CFR 60 Subpart G.

Reliability: The probability that a system or component, when operating under stated environmental conditions, will perform its intended function adequately for a specified interval of time.

Reliability analysis: An analysis that estimates the reliability of a system or component.

Risk: A measure of the probability and severity of adverse effects (consequences); the expected detriment per unit time to a person or population from a given cause.

Risk analysis: An analysis that combines estimates of the probabilities of scenarios with estimates of the consequences of those scenarios, while considering the uncertainties associated with both.

Scenario: An account or sequence of a projected course of action or event.

Scenario analysis: The process of identifying scenarios and estimating the probability of their occurrences.

Site: The location of the controlled area (10 CFR 60.2).

Site characterization: The program of exploration and research, both in the Laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of a particular site relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts, limited subsurface lateral excavations and borings, and in-situ testing at depth needed to determine the suitability of the site for a geologic repository, but does not include preliminary borings and geophysical testing needed to decide whether site characterization should be undertaken (10 CFR 60.2).

Site characterization plan: A general plan for site characterization activities for a candidate site for a high-level waste repository, as required in the Nuclear Waste Policy Act and 10 CFR Part 60.

System or component performance: How each element or a combination of all elements of the engineered barrier system of the geologic repository contributes to meeting the numerical performance objectives set forth in 10 CFR 60.113.

Waste package: The waste form and any containers, shielding, packing and other absorbent materials immediately surrounding an individual waste container (10 CFR 60). The minimum waste package containment time is calculated at this boundary [10 CFR 60.113(a)(1)(II)(A)].

Unrestricted area: Any area, access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

Underground facility: The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals (10 CFR 60.20).

Waste form: The radioactive waste materials and any encapsulating or stabilizing matrix (10 CFR 60.2).

Q-LIST

PUBLIC COMMENTS

General Comments

1. Comment (DOE):

The identification of an item on the Q-List has DOE specific design implications, e.g., ability to withstand seismic events (60.131). These design requirements have no meaning for activities such as site characterization testing. This anomaly has led to difficulties in implementing the QA program. DOE will be proposing that the Q-List be limited to hardware items only. DOE will develop a methodology for defining which activities will be subject to Subpart G QA requirements. This approach will require a change in definitions and in other places in the GTP as noted.

The following is the suggested definition for "Activities" as noted on Page 4, Section 4.0 "Activities" as deeds, actions, work, or performance of a given function. With respect to a geologic repository, activities include such things as site characterization, facility and equipment construction, facility operation, performance confirmation and assessment, permanent closure, and decontamination and dismantling of surface facilities (60.151), as well as designing, purchasing, fabricating, handling, shipping, storing, clearing, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying (50-App. B, Introduction).

All activities related to structures, systems, and components important to safety and to engineered barriers important to waste isolation should be subject to graded quality procedures commensurate with the item's safety function. No activities should be placed on the Q-List. However, activities should be compiled on a "Quality Activities List" and should include those related to structures, systems, or components important to safety or to engineered barriers important to waste isolation.

Response:

The design requirements in 10 CFR 60.131(b) apply to structures, systems, and components important to safety, while the QA requirements in 10 CFR 60.151 apply to these same items as well as items important to waste

isolation and related activities. If DOE prefers to identify these items and activities on two lists, the relationship between the items and activities on each list should be clearly described. Unless specifically cited, the design requirements do not apply to the activities cited in 10 CFR 60.151. DOE should note that items as well as activities are subject to graded QA under the Subpart G QA program.

2. Comment (DOE):

We believe the concept of including activities on the "Q-List" is not advisable since the design requirements that are appropriate for structures, systems and components on the "Q-List" are not germane. We instead propose providing NRC with a separate list of those activities which relate to structures, systems and components important to safety and waste isolation.

Response:

See response to Comment 1.

3. Comment (TX):

In light of the "QA Review Plan", this GTP is unnecessary. As observed in previous GTP's, NRC is again prescribing to the DOE rather than providing guidance.

Response:

The staff does not believe that the QA Review Plan provides the detailed guidance necessary to ensure that the Q-list is developed in a comprehensive and timely manner. Because of the importance of the QA program to demonstrating licensability of this first-of-a-kind facility, the staff believes that it is necessary to provide detailed guidance to DOE on defining the scope of that program.

Note also Comment 5 which states that the staff is not providing enough detail.

4. Comment (DOE):

Generally, the DGTP's address the topics adequately; however, they are

more prescriptive than we had expected them to be. On a number of occasions the staff has stated that, because of its first-of-a-kind nature, the regulatory guidance pertaining to the high-level waste management program would have to be more performance-oriented rather than prescriptive. There are some places in the DGTP's, however, where this thought has not been successfully implemented.

Response:

See response to Comment 3. It is unclear in what areas the commentor believes that the staff is being too prescriptive with this guidance.

5. Comment (YIN):

The NRC "Draft Generic Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR 60 Quality Assurance Requirements" is extremely general and does not provide adequate guidance to the DOE.

Response:

In contrast to this statement, Comments 2 and 3 indicate that the staff is being too prescriptive. The staff believe that the level of detail provided in this GTP is appropriate at this point in the program. DOE is responsible for developing a Q-list and QA programs to meet the QA requirements of the HLW program. The purpose of this GTP is to provide guidance to DOE on approaches the NRC staff consider acceptable to accomplish this effort.

6. Comment (DOE):

This Draft GTP, either directly or by implication, can be read as having predetermined certain items as being on the Q-List. Examples: page 4, 4.0 Activities - "exploratory shaft testing"; page 4, 4.0 Barriers - "shafts, boreholes"; page 13, 6.1 (c) last para. - entire paragraph. It is recommended that any predetermination be avoided.

Suggested changes: Page 5, Section 4.0, "Q-List", delete "... and related activities..."; Page 4, 4.0 "Barrier" delete "(including bulkheads and seals)"; Page 13, 6.1(c) last para., delete "(e.g., materials...)".

Response:

The staff has provided specific examples to explain the more general

concepts discussed. These examples were selected on the basis of what the staff anticipates might reasonably be within the scope of the Subpart G QA program, in light of 10 CFR 60.151, and therefore merit careful consideration by DOE in development of the Q-list. Note also that in section 6.1(c), last paragraph, the term "may be" is used with regard to the example given.

Changes: Section 4.0, in the definition of Activities - ", as applicable" has been added following "exploratory shaft testing"; and in the definition of Barriers - "(including bulkheads and seals)" has been deleted.

7. Comment (YIN):

This GTP does not clearly allow for interaction between interested parties and the DOE, particularly during the development and implementation of non-standard tests. Such interaction is crucial given the uncertainties in the data base and problems associated with performance risk assessment (PRA) techniques used to identify items and activities important to safety. Interaction is also recommended for the determination of barriers important to waste isolation based on performance allocation and assessments. In addition, the GTP does not allow for review and comment of quality assurance requirements by parties other than the DOE.

Response:

Interactions between interested parties and DOE are allowed for under NWPA and addressed in other DOE/NRC policy documents. The NRC staff does not consider it necessary to address these interactions in this GTP. While NRC review of DOE's QA program is the only involvement specifically addressed in the GTP, involvement of other parties is not precluded.

8. Comment (MS):

The use of conservative bounding assumptions may be acceptable, but it should be stated that these assumptions should be arrived at by a consensus of several scientific opinions and not randomly established. There should be some language included on how the assumptions should be established.

Response:

DOE will need to demonstrate that the assumptions made are conservative

enough to provide the margin of error needed on a case-by-case basis. For assumptions made on controversial scientific issues, one method of doing this would be through consensus of scientific opinions.

Change: The need for DOE to demonstrate conservatism has been highlighted.

9. Comment (WA):

The state realizes that in some cases data is limited and recommends the use of conservative bounding assumptions and engineering judgement during the identification of items for the QA list.

Response:

The staff agrees and believes that these points are addressed in the GTP (see especially sections 5.2(a), 5.3, 6.2(a) and 6.3).

10. Comment (DOE):

A major concern is the use of 0.5 rem as the dose limit for design basis accidents. The whole body dose of 0.5 rem is specified in 10 CFR 20 as the off-site dose limit for normal operation. To use the same dose limit for both normal operations and design basis accidents is unduly restrictive and inconsistent with previous NRC practice. DOE will propose a 5.0 rem off-site dose limit for design basis accidents. The supporting position is extensive and will be the subject of a separate communication.

Suggested Change: Page 6, Section 5.2, delete second sentence "The design basis..." Page 13, Section 6.2, delete 4th sentence "Therefore the 0.5..."

Response:

Although 10 CFR Part 60 did not specifically address the design basis accident, in the response to comments on the promulgation of 10 CFR Part 60, the staff explicitly rejected the recommendation of several comments that 5 rem be established as a design basis accident (DBA). Consequently, considerable uncertainty would be attached to establishing the criteria for a design basis accident outside of the rulemaking process.

The staff has reviewed the position DOE since provided regarding the 0.5 rem accident dose limit (letter from J. Knight to J. Linehan, March 3, 1987) and is prepared to discuss the issue with DOE. However, until an alternate value is approved, it would be prudent for DOE to consider 0.5 rem as the DBA dose limit. See also Comment 12.

Changes: Certain changes clarifying the staff's position have been incorporated.

11. Comment (MS):

Although 10 CFR 60.2 states that the dose to the whole body, or any organ may not exceed 0.5 rem at or beyond the nearest boundary of the unrestricted area at any time, it would be more conservative to use a dose that is below the statutory limit to assess items that are important to safety.

Response:

The 0.5 rem dose in the 10 CFR 60.2 definition of Important to Safety applies to accident conditions. This dose does not constitute a statutory limit. See response to Comment 10.

12. Comment (WA):

The state realizes that the 0.5 rem dose-equivalent limit is not the same value used by NRC-regulated power reactors in their emergency response plans for notification and evacuation. However, because the Draft GTP uses 0.5 rem for design basis accidents, the state feels a more conservative approach will result. This level will allow for the inclusion of additional components in QA reviews and will result in a more comprehensive QA program.

Response:

See response to Comment 10.

13. Comment (MS):

There is also a great deal of emphasis placed on the use of regulatory guides for nuclear power plants. Although a geologic repository may

borrow technology from nuclear power plants, it should be noted that a geologic repository is a first-of-a-kind activity and regulatory guides for power plants may not be adequate to address potential problems encountered.

Response:

The staff realizes that a geologic repository is a first-of-a-kind facility. However, there are some similarities between the geologic repository and nuclear power plant programs. Therefore regulatory guides developed based on power plant experience may provide valuable guidance which is adequate and applicable to the geologic repository. The NRC plans to evaluate these regulatory guides on a case-by-case basis as DOE may propose their use.

14. Comment (YIN):

Many of the techniques used to identify items and activities important to safety and waste isolation rely upon sparse, unavailable, or possibly unreliable data. As new data or information becomes available, especially in relation to post-closure barriers, the GTP fails to provide for QA procedures to conform to these changes. In addition, mitigative procedures to ensure the overall safety of the repository have not been sufficiently stressed.

Response:

This GTP states that the staff expects DOE to take a conservative approach to classifying items for the Q-list, especially at the early stage of the HLW program when information is needed to ensure, as much as practicable, that adequate QA has been applied to items and activities even as new information becomes available and the importance of individual items is better defined.

QA procedures regarding change are included in the 10 CFR 60 Subpart G QA program but are not within the scope of this GTP. They are addressed in the staff's QA Review Plans. In addition, requirements for mitigative features are addressed through the definition of items important to safety. The staff does not consider additional discussion of these subjects to be needed, or appropriate.

15. Comment (DOE):

It is recommended that the terms "important to safety" and "important to

waste isolation" be clearly defined once in the text and in the Glossary. These terms are defined several times throughout the text and the definitions are not always the same. The GTP should use the legal definitions from the regulations.

Response:

The definition of "Important to Safety" presented in Section 4.0 is repeated verbatim from 10 CFR 60.2. "Important to Waste Isolation" is not specifically defined in 10 CFR 60. The definition provided in Section 4.0 of the draft GTP was derived from the concepts presented in 60.102. This definition has, however, been revised based on additional comments.

Change: All definitions in Section 4.0 have also been added to the glossary.

16. Comment (WA):

In addition to addressing items on the QA list, USDOE should apply an appropriate level of QA to non-list items that will be needed to support other licensing requirements, such as those in 10 CFR 60.131 for radiological protection of workers.

Response:

The staff agrees and believes this point is addressed in the GTP (see Sections 5.1(b) and 6.1(b)).

17. Comment (MS):

There is concern over the fact that some DOE contractors have had problems with quality assurance programs in the collection of data that may need to be used in licensing. The State realizes that existing data must be qualified but there is concern that the function of and deficiencies related to existing information have not been evaluated and documented so that it can be considered in future work.

Response:

The process of qualifying existing information includes evaluating the function of and deficiencies related to that information. The staff

provides guidance on this subject in the GTP on "Qualification of Existing Data for High-Level Nuclear Waste Repositories", which is referenced in Section 5.1 of the final GTP.

COMMENTS CITING TEXT

18. Comment (YIN) Page 1, Section 1.0:

The GTP states that the emphasis for quality assurance requirements is on pre-closure structures, systems, and components since the number to be considered is large. This emphasis is unjustified. Although the number of natural and engineered barriers for post-closure is less than those for pre-closure, these barriers are extremely important to waste isolation. Therefore, these barriers must be evaluated with equal emphasis.

In addition, a large number of activities are related to post-closure barriers and must also be considered.

Response:

The staff was not suggesting that the emphasis for QA requirements is on pre-closure structures, systems, and components but rather to explain that the emphasis of the GTP is on identification of those items. The reason given is that the number of items to be considered in identification of barriers important to waste isolation are comparatively few and that most activities planned to characterize natural and engineered barriers will need to be within the scope of the Subpart G QA program, as they relate to items important to waste isolation.

Change: Section 1.0, paragraph 2 was deleted to avoid confusion.

19. Comment (DOE) Page 2, Section 2.0:

Section 2 implies that as a result of many years of reactor licensing experience the NRC and industry have developed a body of practice for developing Q-Lists which identify all safety related items, and that such lists include "a series of design basis accidents, a source term for release of radionuclides to the atmosphere, and meteorological conditions to be assumed during an accident." In reactor licensing, in fact, the Q-List is a list of quality components (hence Q-List); these components are assigned varying levels of quality depending on their contribution to safety, or on the risk to the public health and safety associated with

their failure. Hypothesized accident conditions, source terms, or meteorological parameters are used to assess the safety of the facility under severe conditions and they are treated corresponding to assigned levels of quality but are not themselves on a Q-List.

Suggested Change: Delete the fifth sentence ("For example, a series of design basis accidents...") in the first paragraph.

Response:

As written, the sentence "a series of design basis accidents,...and meteorological conditions to be assumed during an accident have been defined" might be interpreted as being items belonging on the Q-list. However, the intent is that a body of practice, including hypothesized accident conditions, source terms, and meteorological parameters, can be used to help identify Q-list items.

Change: Section 2.0, sentences 4 and 5 were rewritten as follows - "...a body of practice which can be used to help determine which items are on the Q-list for a specific power plant. This body of practice includes, for example, a series..."

20. Comment (YIN) Page 2, Section 2.0:

The GTP states that "In contrast to the reactor program where fairly prescriptive criteria have been developed, the principal criteria for identifying the Q-List for a geologic repository are broad performance objectives." This allows the DOE some flexibility in developing a Q-List. However, it is not certain such flexibility will result in a comprehensive Q-List. The importance of QA requirements may demand a more explicit and detailed set of criteria.

Response:

The detailed Q-list used in reactor licensing has been developed through years of experience with these facilities. The criteria acceptable for development of a Q-list for a HLW repository are defined in this GTP. However since this is a first-of-a-kind facility, and the program is at the early stages, these criteria are necessarily broad. NRC is recommending that DOE take a conservative approach in applying QA in order to compensate for uncertainties and lack of supporting information. The NRC will carefully evaluate DOE's program to ensure that items and activities important to safety or waste isolation are identified on the

Q-list and that an appropriate level of QA is applied to those items and activities that will be used to support the license application.

21. Comment (NV) Page 2, Section 3.0, Paragraph 4:

The definition of the phrase "important to safety" is stated as follows: "Structures, systems, and components important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2)".

The use of this definition alone for determining the Q-List is inadequate for the Yucca Mountain site. In preliminary studies,^{1,2} the DOE has shown that this criteria will easily be met because the Yucca Mountain site is located in an area of very low population density and the location of the "maximum individual" will be at least 4 km (2.5 mi) from the surface facility. The following two accidents are conceived as the most serious¹: 1) aircraft impacting on a hot cell of the surface facility, and 2) transportation accident and fire at the loading dock involving a spent fuel shipment. The 50-year total body dose commitments are 0.068 and 0.021 rem respectively. For a sabotage act consisting of an explosive attack on a transportation cask at the entrance of the repository surface facility², the 50-year total body dose commitment to the maximum individual is slightly less than 0.5 rem. By refining these calculations, the DOE may be able to show that the Yucca Mountain site does not necessarily require a Q-List and that the classification of the waste handling building could be lowered from a quality level I to a quality level II or even III. This would give DOE a serious incentive for selecting Yucca Mountain over the other two sites since the lowering of the classification of the waste handling building would reduce the construction time by several years and make it possible to achieve a starting operation date of 1998. The NRC should specifically address the example discussed above and make its position easily understood.

¹ Jackson J.L., Gram H.F., Hong K.J., Ng H.S., and Pendergrass, A.M., Preliminary Safety Assessment Study for the Conceptual Design of a Repository in Tuff at Yucca Mountain, SAND83-1504, December =, 1984.

² Jackson J.L., and Tomasko D., Preliminary Safeguards Assessment for the Protective Nevada Nuclear Waste Storage Investigations Project Repository, SAND83-1133, January, 1985.

Response:

The analysis for determining which systems, structures, and components are important to safety must be performed under the assumption that there is a person at the nearest boundary of the unrestricted area.

To briefly address the State's concern, the selection of a repository site will require much more comprehensive technical and programmatic justification than reduced construction time. The staff considers risk to the public, as indicated through analysis of potential accident scenarios leading to identification of items on the Q-list, to be a critical factor in site acceptability.

22. Comment (DOE) Page 3, Section 3.0:

Reference to the EPA standards should be deleted as they will be included in the proposed revision to 10 CFR 60.

Suggested Change: Page 3, section 3.0, delete "(10 CFR 60.112) and add ", as proposed to be incorporated in 10 CFR 60 (51 FR 22288).

Response:

For the sake of clarity, the staff still considers it appropriate to reference the origination of the generally applicable environmental standards promulgated by EPA, even though they are incorporated in 10 CFR Part 60.

Change: The referenced sentence has been reworded as "...conform to the environmental standards for radioactivity established by the Environmental Protection Agency (40 CFR Part 191) as incorporated into 10 CFR Part 60 (60.112)."

23. Comment (DOE) Page 3, Section 3.0, paragraph 2:

The Draft GTP states that "DOE (shall) apply a QA program based on the criteria of 10 CFR 50 Appendix B as applicable and appropriately supplemented..." to "... all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto" (10 CFR 60.151).

By contrast, 10 CFR 60.152 states that "DOE shall implement a quality assurance program based upon the criteria of Appendix B of 10 CFR 50 as applicable, and as appropriately supplemented by additional criteria as required by 60.151." (We have underlined the regulation wording that is different than the Draft GTP). 60.151 requires that the QA program "applies to all structures systems and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto."

A few observations are appropriate.

1. The GTP seems to be citing 10 CFR 60.151. However, the language is taken, in part, from 10 CFR 60.152.
2. The language in the GTP is not the exact language of the regulation (See underlined words above.). This invites misinterpretation.
3. It is our interpretation of 10 CFR 60.151 that it limits the QA program to things which are important to safety or waste isolation.

By contrast, we construe the GTP as requiring QA for a broader spectrum of program elements. The GTP appears to require QA for all the repository, its subsystems, and components which will enable the repository to perform satisfactorily in service (page 3 para. 2).

Suggested Change: Page 3, Section 3.0, change the second sentence as follows: "...necessary to provide adequate confidence that the systems, structures, and components important to safety and engineered barriers important to waste isolation of the geologic..." Change first sentence as follows: "...as applicable and appropriately supplemented" (10 CFR,150) to "all systems..."

Response:

The sentence referenced here is cited from 10 CFR 60.150. It does not address what items and activities QA applies to, but rather what actions QA comprises.

Changes: Section 3.0, the wording of the two referenced sentences has been changed as follows - "...as applicable and appropriately supplemented" (10CFR60.152) to "all systems...thereto" (10CFR60.151). This QA program shall "comprise all those..."

With respect to the broader spectrum of program elements to which QA applies, Subpart G of 10 CFR Part 60 is only applicable to items and activities important to safety or waste isolation. The staff however, has also endorsed QA measures for use in non-Q-list but licensing related items and activities.

24. Comment (DOE) Part 4, Section 4.0:

Barriers which contribute to meeting the containment and isolation requirements of 10 CFR 60 are not necessarily "important to waste isolation." Only those that are essential to meeting the requirements, or for which credit is taken, are "important to isolation." (Refer to 10 CFR 60.2 "Important to Safety").

Suggested change: "In the post-closure phase, the engineered barriers that are essential, or for which credit is taken, for meeting the containment and isolation requirements of 10 CFR 60 are defined as important to isolation." Page 18, Section 6.3, 10th line, change "The items and activities ...and should include:" to "... and may include:"

Response:

The term "contribute" was used in reference to those barriers that will be essential to meeting the requirements of 10 CFR 60, and will be relied on to demonstrate these requirements are met, or may otherwise significantly impact achievement of the performance objectives. Any of these should be considered important to waste isolation. This definition was not, however, intended to include as important to waste isolation, those barriers whose contribution may be trivial and will not be relied on.

Changes: Section 4.0, in the definition of Barriers - the words "(including bulkheads and seals)" were deleted. Also, the term Barriers Important to Waste Isolation has been changed to Important to Waste Isolation to be consistent with the term Important to Safety and the following definition has been changed to read "...includes the site, engineered barrier system, seals for shafts and boreholes, and any other items which may contribute to achieving the performance objectives of 10 CFR 60 Subpart G."

25. Comment (DOE) Page 4, Section 4.0:

The Draft GTP includes definitions which are inconsistent with 40 CFR 191 and 10 CFR 60. The definition for "Barriers Important to Waste Isolation" cannot be more global than the definition for "Barrier".

Suggested changes: In definition of "Barrier" delete the parenthetic statement "(including bulkheads and seals)." Change the definitions for "Barriers important to waste isolation" to "Barriers important to waste isolation are those engineered barriers that are essential, or for which credit is taken for, meeting the containment and isolation requirements of 10 CFR 60".

Response:

See response to Comment 24.

26. Comment (MD) Page 4, Section 4.0:

The definition of "credible accident" needs improvement. The usage related to reactors was that this is any accident which has a reasonable probability (50%) of occurrence during the 40-year life of the power plant. We believe similar usage would be appropriate here.

Response:

The staff has reviewed the need to establish a probability cutoff for accident scenarios and considers that no basis for such a cutoff can be established at this time. DOE should identify and consider accident scenarios having frequencies of occurrence greater than about 10^{-8} /year in determining which accident sequences should be used as the basis for design. It is not expected that all scenarios will need to be considered in the design, but sequences with a high risk will need to be adequately covered in the design.

Changes: Section 5.2(a) and 6.2(a). A discussion of probability has been added to both sections, see GTP for actual text.

27. Comment (YIN) Page 4, Section 4.0:

"Credible event" and "credible accident" are defined as referring to "... an event or accident scenario which is sufficiently likely to warrant consideration..." In order to be consistent with the overall theme of the GTP, i.e., a conservative approach, a clear definition of what is meant by "sufficiently likely" should be given. Such terms must be clearly defined

so that all parties involved can agree the scenarios and events which can or cannot be ignored.

Response:

See response to Comment 26.

28. Comment (MD) Page 5, Section 4.0:

Add a definition for the "design basis accident", since it is used frequently in the document.

Response:

Change: The following definition has been added to Section 4.0 and the Glossary - Design basis accidents are postulated accidents that need to be considered in design of a structure, system, or component of the repository to assure adequate protection of public health and safety and the environment.

29. Comment (DOE) Page 5, Section 5.1(b):

The second sentence ("while these items") is confusing because the term "requirements" is used twice but with different meanings.

Suggested Change: Revise the sentence to read: "While these items and activities are not subject to the QA requirements in 10 CFR 60 subpart G, DOE should implement a program to assure compliance with those aspects of 10 CFR 60 which apply to items other than structures, systems, and components important to safety and engineered barriers important to waste isolation."

Response:

This section has been revised such that the comment no longer applies.

30. Comment (NV) Page 5, Section 5.1(b):

Activities listed in 10 CFR 60.131(a) which are related to safety but not subjected to the QA programs are briefly addressed in a generic way. One of the more important regulations of that part is 10 CFR 60.131(b)(9),

compliance with mining regulations. In the regulation, the Commission states explicitly that any deviation from relevant design requirements in 30 CFR, Chapter I, Subchapters D, E, and N will give rise to a rebuttal presumption that this requirement has not been met. The high level waste repository is not subject to the Federal Mine Safety Act of 1977 and it is not clear at this time how DOE will address the MSHA and OSHA safety regulations. The Commission does not have any experience in the enforcement of mine safety regulations. A fatality occurred during the enlargement of the waste shaft at the Waste Isolation Pilot Plan (WIPP), a project administered by the DOE, because proper enforcement of mine safety regulations was lacking. Therefore, it is very important that, in the QA program, the Commission address with specific detail the subject of compliance with mining regulations.

Response:

10 CFR 60.131(a) refers to general design criteria for structures, systems, and components related to maintaining radiation doses. 10 CFR 60.131(b)(9) requires compliance with mining regulations for worker protection "as may be necessary to provide reasonable assurance that all structures, systems, and components important to safety can perform their intended function." The paragraph referenced from the draft GTP does not contradict the requirements.

While worker health and safety is important, the staff does not consider it appropriate to address compliance with mining requirements in context of the QA requirements discussed in this GTP.

31. Comment (YIN) Page 5-6, Section 5.1(b):

As it now reads, the GTP does not require a QA program to be applied to "... items and activities which are not needed to support licensing, but are important to repository operation based on occupational health and safety, reliability, cost, and other programmatic considerations." Furthermore, the NRC intends to review these items and activities only to see that they are correctly classified but does not plan to review any QA measures which may be applied to these items and activities. Since these items and activities are important to repository operation, some QA guidelines should be provided even though these items and activities are not addressed in 10 CFR 60 Subpart G.

Response:

Certain items and activities not subject to the 10 CFR 60 Subpart G QA program are addressed in other NRC regulations, such as the radiological safety of workers. The QA program requirements for these items and activities were therefore addressed in 5.1(b) of the draft GTP. See the revision to 5.1(b) for more detailed discussion of these requirements and NRC's involvement to assure compliance with those requirements. The staff does not address QA criteria for non-licensing related areas of the HLW repository program (position 5.1(c)) since the NRC does not have regulatory authority over them.

Licensing findings related to important to safety or waste isolation requirements are defined as Level I. In addition, however, other findings must be made on areas such as worker radiological health and safety. The staff has reviewed the description of the Level II program in the OGR QA Plan dated August 1986 that DOE will apply to these areas and finds it acceptable.

32. Comment (NV) Page 6, Section 5.1 (c):

The text states, "Data collection, interpretation, analysis, and other work not conducted under the DOE 10 CFR 60 Subpart G QA program but needed for licensing should be evaluated to determine its suitability for use in licensing." If such data is determined to be critical for licensing then the information should be gathered and analyzed under an approved QA program.

Response:

Because information was not collected under a 10 CFR 60 Subpart G QA program does not mean that it was collected in absence of another QA program, which had been approved by the responsible organization. It may be necessary or desirable to use information collected outside the DOE HLW program, or by DOE/DOE contractors prior to implementation of the Subpart G QA program, to support licensing findings. The staff is indicating that such information may be used by DOE if DOE demonstrates that it meets the applicable requirements. Only information to be used to support licensing findings against items and activities important to safety and waste isolation need to meet the requirements of a 10 CFR 60 Subpart G QA program.

See Section 6.1(c) of the GTP for more detailed discussion.

33. Comment (YIN) Page 6, Section 5.2:

The threshold for determining which structures, systems, and components are important to safety is a radiation dose of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area. This criteria does not include persons (i.e., workers) within the restricted area. Radiation safety limits for workers should be considered in determining the safety of various structures, systems, and components.

Response:

The protection of workers from radiation hazards is addressed in 10 CFR 60.11(a) and 60.131(a). This provision requires DOE to comply with the radiation doses, levels, and concentrations set forth in 10 CFR Part 20 for the restricted area.

34. Comment (WA) Page 6, Section 5.2(a):

Items important to safety are those essential to the prevention or mitigation of an accident that could result in a radiation dose of 0.5 rem or greater to an individual in an unrestricted area. Therefore, the 0.5 rem value is the threshold for determining what structures, systems, and components should be on the list of items related to safety. The state recommends that USDOE use risk assessment modeling to determine the probability for the failure of an individual component to lead to the 0.5 rem dose-equivalent. Scenarios where the failure of an individual component causes an off-site individual to receive 0.5 rem would be the reason to include that component on the QA list.

Response:

The staff agrees and believes that these points are addressed in the GTP (see Sections 5.2(a) and 6.2(a)).

35. Comment (NV) Page 6, Section 5.2 (a):

The use of probabilistic risk assessment (PRA) techniques is encouraged in the identification of structures, systems and components important to safety in the license application. In theory the use of PRA is a meaningful exercise, but in practice it has not gained recognition because most accidents, witness the recent accident at Chernobyl, are the result of human errors. In recommending the use of PRA, the Commission should

place special emphasis on the identification and analysis of scenarios involving human error. The draft GTP fails to do so.

Response:

Human reliability analysis, wherein human error probabilities are quantified in event trees, is a PRA technique that should be used in identification of potential accident scenarios associated with operations of a geologic repository. Therefore the staff believes the discussion in Section 6.2 should be adequate. See also response to Comment 64.

A reference in the nuclear industry is: NUREG/CR 1278, Handbook on Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications.

Change: The reference noted above has been added to the bibliography in the final GTP.

36. Comment (MS) Page 6, Section 5.2(a):

The use of probabilistic risk assessments may be acceptable, but NRC should address the uncertainties associated with this approach.

Response:

The staff agrees that it is necessary to consider the uncertainties in use by PRAs in both data base and modeling. To clarify this position, discussion regarding uncertainty analysis has been added to Sections 5.2(a) and 6.2(a). See also response to Comment 64.

37. Comment (DOE) Page 6, Section 5.2 (a)(1):

It is clear from this draft generic technical position that use of event/fault trees is mandated by the NRC. This may be overly prescriptive in that it focuses on one technique among several alternatives. For example, another structured approach called MORT (Management Oversight and Risk Tree) has been, and is used by DOE as the standard accident investigation method for all DOE facilities.

Suggested change: Page 6, Section 5.2(a)(1), second sentence should state "Fault trees, event trees, MORT or similar structured analytical methods, should be utilized in system modeling."

Response:

The Management Oversight and Risk Tree (MORT) has to date been used primarily to investigate accidents after they have occurred rather than identifying items important to safety prior to an accident. The NRC staff agrees, however, that MORT is a valid technique that could be used, where applicable.

Change: Section 5.2(a)(1), Sentence 2 has been changed to read "DOE should employ modeling techniques such as fault tree and event tree in these accident analyses."

38. Comment (DOE) Page 7, Section 5.2(a)(1):

There is a major concern relative to the concept of "credible accidents" in the following paragraphs:

- page 7, section 5.2(a), last paragraph;
- page 13, section 6.2, first para., 3rd sentence;
- page 15, section 6.2(a)(2), last para., 2nd sentence.

On page 7, the concept of credible accidents appears to be set aside but it is included on pages 13 and 15.

Suggested Changes: Page 7, Section 5.2(a) delete "... irrespective of the probability of failure,..." page 13, Section 6.2, first paragraph, delete "... (made not credible)" page 16, 1st line, delete "... So unlikely as to be incredible," and add "...sufficiently unlikely."

Response:

The changes suggested in this comment have been incorporated.

39. Comment (YIN) Page 7, Section 5.2(b):

The DOE is required to employ redundant systems in certain areas (10 CFR 60.131(5)(ii) and 60.131(b)(10)(iv)). According to the GTP, the need for other redundant systems is to be determined based on the analyses used in identification of Q-List items and activities. The NRC should provide specific guidance on the criteria to be used to determine if a redundant system is necessary.

Response:

For items important to safety, redundancy is needed whenever there is a potential for exceeding the accident dose limit. The need for redundancy, other than that specified in 10 CFR 60, therefore depends on reliability of items and activities important to safety and must be determined on a case-by-case basis. While analyses used to identify items important to safety will likely indicate where redundancy is needed, the staff does not believe specific criteria are appropriate or practical.

Changes: Sections 5.2(b) and 6.2(b) have been reworded to clarify the staff's position on this subject.

40. Comment (NV) Page 7, Section 5.2 (e) :

It is stated that the DOE should analyze the retrieval process to identify items and activities that may be on the Q-List and subject to the 10 CFR 60 Subpart G QA program in the event retrieval is necessary. In the important documents^{3 4} that were used to select three sites for characterization for the first repository, the DOE makes reference to the regulations pertaining to retrievability but fails to analyze the retrieval process. The word "should" at the beginning of the paragraph should be replaced by the word "shall".

³ DOE (Department of Energy), Environmental Assessment - Yucca Mountain Site, Nevada Research and Development Area, Nevada, DOE/RW-0073, 3 volumes, May, 1986.

⁴ DOE (Department of Energy), A Multiattribute Utility Analysis of Sites Nominated for Characterization for the First Radioactive-Waste Repository - A decision-aiding Methodology, DOE/RW-0074, May, 1986.

Response:

The staff does not believe the term "shall" to be appropriate here, since 10 CFR 60 does not literally state that DOE is required to analyze the retrieval process to identify items important to safety. GTPs are not substitutes for regulations. However, DOE will have to identify any items that will be important to safety during all repository activities, in order to demonstrate compliance with the 10 CFR 60, Subpart G QA program.

Change: Section 5.2(d), has been revised to clearly state that analysis of the retrieval process will be necessary to ensure that DOE has identified all items and activities important to safety.

41. Comment (YIN) Page 8, Section 5.3:

The GTP allows the DOE to allocate performance among the various components of the natural and engineered barrier systems to determine the importance of each barrier and the extent to which each barrier contributes to isolation. The degree of performance assumed will provide a basis for the amount and type of testing needed during site characterization. However, the GTP does not provide a basis for how performance of individual barriers will be determined, and subsequently, the performance allocation may be qualitative. Because of the importance of barriers to waste isolation, it is crucial that their performance be critically assessed.

Response:

The staff agrees that it is crucial to assess the performance of barriers which are determined to be important to waste isolation. However, the specifics of performance allocation are beyond the scope of this GTP. Performance allocation is the subject of on-going public interactions between NRC and DOE.

Changes: Revisions have been made to Sections 5.3 and 6.3 to add clarification to the subject.

42. Comment (YIN) Page 8-9, Section 5.4(b):

The GTP suggests that the DOE submit a description of the QA program to be applied to items and activities occurring during the site characterization phase. It is recommended that plans for monitoring and mitigation also be included with the QA program.

Response:

Monitoring and mitigation activities as they relate to the performance of specific site characterization testing and data collection are addressed in criteria of the QA program. Monitoring and mitigation plans for performance confirmation are, however, outside the scope of this GTP.

43. Comment (DOE) Page 8-9, Section 5.4(b):

This sentence requires in the SCP "... a schedule for refinement of the preliminary Q-List based on design advancements and collection of new information." It is not clear that such a schedule can be constructed at the time of filing the SCP with sufficient confidence to be of use to the NRC, nor has NRC identified the regulatory purpose of such a schedule.

Suggested Change: Delete this last sentence of the first paragraph of Section 5.4(b).

Response:

The staff agrees that any such schedule would be subject to change and of questionable use to the NRC. The intent, however, was to identify the process by which DOE plans to refine the preliminary Q-list based on data collected, performance assessments, other analyses, etc..

Changes: Section 5.4(b), the words "a schedule for refinement of the preliminary Q-list" have been changed to "The process for refinement of the preliminary Q-list based on design advancements, data collection and analyses should be identified in the SCP to support the staff's evaluation of the QA plans."

44. Comment (WA) Page 9, Section 5.4(b):

The state is in agreement with the GTP statement that, "All site characterization activities should be considered to be within the scope of the 10 CFR 60 Subpart G, QA program, unless USDOE can demonstrate they are not related to items important to safety or waste isolation." The SCP should describe how the QA program was developed and implemented.

...In summary, our position is that a well-developed QA program is required before the initiation of repository characterization activities.

Response:

The staff states in Section 5.4(b) that a description of the QA program for site characterization and a preliminary Q-list be provided in the SCP. Development and implementation of the QA program are processes which the staff (and other involved parties) are, and intend to continue, reviewing. Therefore these processes should not need to be described in the SCP to support the staff's review of that document.

The staff agrees that a well-developed QA program should be implemented prior to initiation of site characterization activities. We believe that this is clearly stated in the GTP. While 10 CFR 60 requires that a Subpart G QA program be applied to items and activities important to safety and important to waste isolation, there is no milestone for when the overall QA program must be developed and implemented.

45. Comment (DOE) Page 9, Section 5.4(b), 1st full paragraph:

The first sentence states that "All site characterization activities should be considered to be within the scope of the 10 CFR 60 Subpart G QA program, unless DOE can demonstrate they are not related to items important to safety or waste isolation." This is too global a requirement. Testing and collection of data needed for design optimization, for example, need not be covered by 60.151. The decision whether a given item or activity must be subject to 60.151 requirements must be left to the judgment of the DOE; a judgment which the NRC will certainly wish to monitor.

Suggested Change: Delete the first sentence of the second paragraph of Section 5.4(b): "All site..."

Response:

The staff maintains that at this early stage of the program, all site characterization activities should be considered to be within the scope of the 10 CFR 60 Subpart G QA program unless DOE can demonstrate that they are not related to items important to safety or waste isolation. We believe that this approach is prudent and necessary to assure that information which may need to be used to support licensing findings is adequate, especially where that information may not be reproducible. The staff does not consider it acceptable to rely on qualifying information collected during the site characterization phase if that information is later found to be needed for licensing.

Change: Section 5.4(b), second paragraph, first sentence, "All site characterization..." has been changed to "At the early stage of the program, all site characterization..."

46. Comment (TX) Page 9, Section 5.4(b):

The NRC should specify that DOE shall have a 10 CFR 60, Subpart G QA program in place prior to the initiation of site characterization activities.

Response:

10 CFR 60.151 requires that DOE apply a Subpart G QA program to activities related to items important to safety and waste isolation, but does not specify when the program must be in place. The point the staff was attempting to make is that while information previously collected may be qualified for use, the staff does not consider it acceptable to initiate new activities without an acceptable QA program in place.

Change: The last sentence in Section 5.4(b), second paragraph as been deleted since the discussion in 6.4(b) better addresses this thought.

47. Comment (DOE) Page 9, Section 5.4(b) last paragraph:

The paragraph should be omitted. We are unable to identify a regulatory basis for requiring DOE to describe in the SCP their plans to develop and implement a program to assure and document conformance with non Q-List requirements. In addition, this GTP is not the appropriate document to address the requirements of the SCP

Suggested Change: Delete last paragraph of Section 5.4(b).

Response:

The cited paragraph is stated as a staff recommendation, not a requirement. In addition, the staff considers it appropriate to identify the milestone at which the staff expects to see implementation of the guidance in this document, especially since the subject addressed in this GTP is critical to the program.

48. Comment (MS) Page 9, Section 5.5:

There is a concern that ANSI/ASME NQA-1 is a hardware oriented mechanical equipment standard and whether it can be revised to a standard applicable to groundwater hydrology, mining and similar activities required by site characterization. Inherent difficulties in the application of standard QA practices to research and development activities and to performance assessment should be recognized.

Response:

The reference to ANSI/ASME NQA-1 found in the GTP refers specifically to Appendix 4A-1 on graded QA measures. The staff recognizes that NQA-1 is hardware oriented and therefore intends to endorse that standard only when the needed modifications are addressed. The guidance from NQA-1, Appendix 4A-1 on graded QA discussed in this GTP has been modified for applicability to the research and development activities within the geologic repository program.

49. Comment (YIN) Page 9, Section 5.5:

The GTP indicates that items and activities important to safety or waste isolation may be assigned graded QA measures. These measures are based upon five considerations, including assessment of the impacts of malfunction and the complexity of design. An assessment of such features is purely subjective and may incorporate personal bias. Therefore, it is highly recommended that all graded QA measures of items and activities important to safety or waste isolation be evaluated by outside parties in addition to the DOE. These evaluations should be taken into account by the DOE.

Response:

The staff agrees that some of the considerations listed as a basis for grading QA measures will involve subjective judgement. With a first-of-a-kind facility such as the repository, subjectivity can not be avoided. However, the staff believes that subjectivity will be reduced, and compliance with the requirements can be demonstrated, if all five considerations are taken into account when using graded application of QA measures. In addition, DOE's approach to grading and application of graded QA measures for items important to safety or waste isolation will be reviewed by NRC staff for acceptability.

50. Comment (MD) Page 9, Section 5.5:

Specify whether the "impact" used to grade QA measures is in terms of dose, probability, or other factors.

Response:

As used in the referenced section, "impact" ultimately relates to dose

and/or the performance objectives found in 10 CFR 60 Subpart E. The affect of the failure of an item, or use of erroneous information to support repository design, on the repository performance should be considered as a basis for application of graded QA measures.

51. Comment (NV) Page 10, Section 6.1:

It is stated that 10 CFR Part 60 incorporates other standards such as 10 CFR Part 20 and the generally acceptable environmental standards established by the EPA for the release of radioactive materials. Reference should also be made to 30 CFR, Chapter I, Subchapters D, E, and N. The incorporation of these regulations in the QA program should be discussed.

Response:

See response to Comment 30.

52. Comment (YIN) Page 10-11, Section 6.1 (a):

The GTP states that the "10 CFR 60 Subpart G QA requirements apply to items and activities on the Q-List . The QA requirements include, as applicable and approximately supplemented, the 18 criteria of 10 CFR Part 50 Appendix B for siting, design, construction, operation, and decommissioning of nuclear power plants." These items apply to nuclear power plants and may not be applicable or appropriate for nuclear waste repositories. The NRC must ensure that all referenced QA guidelines concerning power plants are applicable and, most importantly, sufficient to ensure the safety of the repository.

Response:

The sentence referenced is a restatement of the regulations. 10 CFR 60.152 states that DOE shall implement a QA program based on the criteria of 10 CFR 50 Appendix B as applicable and appropriately supplemented by additional criteria as required by 10 CFR 60.151 (which refers to the scope of the QA program). The NRC staff agrees that all of these criteria may not be applicable or sufficient with regard to the geologic repository program. The staff is taking steps to address these concerns. For example, guidance on the application of Appendix B to the site characterization phase of the geologic repository is provided in the "NRC

QA Review Plan" (referenced in the GTP). The staff is committed to ensuring that the QA applied to the geologic repository is sufficient to protect radiological health and safety of the public.

Change: This sentence has been reworded to more clearly refer to the requirements and address this concern.

53. (Comment (YIN) Page 11-12, Section 6.1(b):

The GTP states: "The staff considers the guidance on QA for radiological monitoring programs during normal operation provided in Regulatory Guide 4.15, Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment" (USNRC, 1979) to be applicable to such programs for a HLW facility."

The GTP should determine if these guidelines are indeed sufficiently applicable. Although guidelines may be "applicable", they may not provide sufficient guidance for radiological monitoring for a HLW facility. Additional guidelines specific to the repository may be required.

Response:

The staff considers the guidance on QA described in Regulatory Guide 4.15 to be appropriate as guidelines for radiological monitoring of the HLW facility. Additional guidance will be provided if needs are identified as the repository program progresses.

54. Comment (NV) Page 12, Section 6.1 (b):

The text states "DOE's level II applies certain NQA-1 requirements and may be an acceptable approach for non-Q-List items and activities used to support licensing findings. DOE should provide to the staff additional information on the development and implementation of the quality levels program for review prior to the submittal of the SCPs." DOE should justify their approach to using level II for non-Q-list items and activities to support licensing findings. All licensing findings should be Level I; important to safety and waste isolation. The second sentence is not staff guidance but a request for additional information. It has no place in the GTP.

Response:

Licensing findings related to important to safety or waste isolation requirements are defined as Level I. In addition, however, other findings must be made on areas such as worker radiological health and safety. The staff has reviewed the description of the Level II program in the August 1986 OGR QA Plan which DOE will apply to these areas and finds it acceptable.

With respect to the staff's request for information in the GTP, this is within the guidelines for staff positions and is consistent with GTP's already issued. In certain cases, staff information needs are defined so that DOE can plan and perform work to support the staff's review responsibilities.

55. Comment (DOE) Page 12, Section 6.1(c), first paragraph:

A statement should be inserted in this paragraph to allow acceptance of work done by DOE, project contractors, research labs, universities, etc., that worked under DOE Level II Programs without having to qualify the information or data gathered. Some information may be needed for licensing which predates either the DOE Level II Program or 10 CFR 60 Subpart G. Such information should be reviewed for licensability. It is suggested that, on line 10 of this paragraph the "Subpart G QA" be expanded to include DOE Level II.

Suggested Change: Insert the following after the second sentence:
"Information collected under QA Programs that satisfy QA requirements of DOE's Level II program may be acceptable to NRC for non-Q-list items and related activities used to support licensing findings."

Response:

The staff acknowledges the fact that DOE may need or want to use "existing information" on non-Q-list items and activities in licensing. Since such information should be technically and procedurally defensible to support licensing, it will need to be qualified. Existing information on non-Q-list items and activities to be used in licensing will need to be reviewed and qualified, as appropriate, to meet the Q-level II requirements, as opposed to the 10 CFR 60 Subpart G QA requirements for Q-list items and activities.

Change: Discussion in Section 6.1(c) has been modified to address this subject.

56. Comment (NV) Page 13, Section 6.1(c):

Relative to use of materials important to safety or waste isolation not purchased under the 10 CFR 60 Subpart G QA program, the text states, "DOE needs to evaluate these materials to determine whether 10 CFR 60 Subpart G applies and, if necessary, what actions are necessary to qualify them for use". Does NRC have guidance and criteria of what constitutes "qualification" in this context? If such guidance or criteria exists, it should be so stated.

Response:

The 10 CFR 60 Subpart G QA program specifies requirements for items important to safety and waste isolation. Through reference to 10 CFR 50 Appendix B, those requirements include criteria for control of nonconforming materials, parts or components. This criteria may apply, on a case-by-case basis, to "existing material" which do not conform with the requirements.

In addition, guidance in the GTP on Qualification of Existing Information should be used since the function, quality and reliability of materials are often documented in specifications and QA records. Review of this supporting data should enable DOE to determine what requirements need to be met to assure the material will perform its intended function. It may then also be possible to use the same method recommended for qualification of existing information (such as corroborating data and confirmatory testing) to qualify the existing materials with their supporting data.

Change: Discussion in Section 6.1(c), has been expanded to address these ideas.

57. Comment (NV) Page 13, Section 6.1(c):

Section (c) should clearly state that DOE use the GTP on "Qualification of Existing Data" as guidance in establishing programs for reviewing non-QA gathered data and determining suitability for use.

Response:

GTPs, such as the one entitled "Qualification of Existing Data for High-Level Nuclear Waste Repositories," provide staff guidance that DOE should use but do not constitute requirements.

Change: Section 6.1(c) has been modified to indicate that DOE should use the guidance in the GTP on "Qualification of Existing Data."

58. Comment (WA) Page 13, Section 6.2:

The pre-closure safety items should contain QA activities related to design control. Acceptable activities in this area include:

- a. review of design specifications, design information, and design activities.
- b. design control program implementation at the time of SCP submissions.
- c. organizational responsibilities described for preparing, reviewing, and approving design information documents.
- d. development of procedures requiring design drawings, criteria, and analyses be approved by the QA organization.
- e. use of independent peer reviews for design activities involving untried testing and analysis procedures.
- f. ensuring design changes are subject to the same design controls applicable to the original design.

Response:

The design control activities listed in this comment are addressed in criteria for the 10 CFR 50 Appendix B as incorporated into 10 CFR 60 Subpart G QA program. While these generic QA activities are not contained on the Q-list, they do apply to items and activities listed therein (including those important to safety).

59. Comment (DOE) Page 13, Section 6.2:

There are cases where the language apparently "changes the rules" as the concept of credible accidents is discussed. In the context of this GTP the words "prevented", "credible", and "with certainty" are not considered interchangeable. Examples: p. 13, para. 6.2, p. 25, 1st paragraph.

Suggested Change: It is recommended that one concept and one word be used throughout with the result that only one "rule" is being articulated. For consistency with Part 60, we suggest that "credible events" be used.

Response:

While the staff agrees that use of the term "credible" in the first example cited is unclear, the staff does not think that the language used in the GTP to discuss the concept of credible accidents is inconsistent with 10 CFR 60 or "changes the rule."

Changes: Discussions addressing the concept of credible accidents/events have been modified, as appropriate, to provide clarity.

60. Comment (YIN) Page 13, Section 6.2:

The GTP defines "items important to safety" as "those items essential to the prevention or mitigation of an accident that could result in a radiation dose of 0.5 rem or greater to an individual in unrestricted areas (10 CFR 60.2)". The GTP should include a definition of "unrestricted areas" in the glossary provided since the term "items important to safety" is used throughout the entire GTP.

Response:

The staff agrees.

Change: The 10 CFR 60.2 definition of unrestricted area has been added to the Glossary.

61. Comment (MD) Page 13, Section 6.2:

Is the PRA risk proportional to dose times probability, or some other factor? Note that item (2) on page 7 sets a dose limit regardless of probability.

Response:

Risk is a combination of consequence and probability. The consequence factors that can be used include the release caused by an accident, the dose to an individual, or the health effect realized, while the

probability factors include probability of an accident, of exposure to an individual, or of an individual realizing a health effect.

For the HLW repository, items whose failure could result in an off-site dose of 0.5 rem or greater are important to safety. A number of techniques are utilized in PRA's, such as those discussed in 6.2(a) of the GTP, to systematically describe potential accident scenarios and evaluate the consequences. Therefore, the staff is recommending DOE use PRA not as a method to determine risk (in terms of dose times probability), but as a tool to identify what is important to safety and waste isolation.

Changes: The applicable discussions have been modified to provide clarification in the final GTP.

62. Comment (YIN) Page 13, Section 6.2(a):

Probabilistic risk assessment (PRA) techniques may be used to provide a framework for grading QA measures based on the risk associated with the failure of individual components. Review and assessment of these techniques by independent parties is necessary to ensure the integrity of the program.

Response:

The staff recommends the use of PRAs to support the identification of Q-list items and to provide valuable information that could be used in design of the repository. The staff will review the application and results of PRA techniques to determine their acceptability. In keeping with the openness of this program, the staff anticipates that other affected parties, such as the Indian Tribes and States, will also participate in a review of these techniques.

63. Comment (NV) Page 14, Section 6.2(a):

At the top of the page, the text states, "Since the geologic repository will be a first-of-a-kind facility, the staff recognizes that complete data will not be available for initiating events and failure." Nevada is concerned about what this statement connotes and the signal it gives to DOE. The message portrayed is that since this is a first-of-a-kind facility, less than complete data is acceptable to the NRC. Alternatively, the message should be that since this is a first-of-a-kind facility, only a complete and thorough data base will be acceptable. We

request this statement be changed to reflect a conservative position of the NRC which should be the "watch word" of the program.

Response:

The intent of the referenced sentence is to ensure that DOE compensates for uncertainties due to limitations in data by applying a conservative approach to including items important to safety on the Q-list.

Change: The words "complete data" have been replaced with "data from operational experience" to address this concern.

64. Comment (NV) Page 14, Section 6.2(a):

While we support the use of PRA in defining the items important to safety, the staff should discuss the rationale used to conclude that techniques proposed are appropriate for a geologic repository, especially items important to safety. The text provides strong guidance without any discussion as to whether it is appropriate guidance.

Response:

The GTP indicates that PRA techniques should be used to the extent practicable to support the identification of items important to safety for the HLW facility. PRAs have been used in assessing the safety of nuclear facilities currently in operation which are comparable in many respects to above-ground features of the repository system. These features include, for example, the hot cell, ventilation system, electrical system, and radiation monitoring devices. Through experience in assessing the safety of similar nuclear facilities, PRA techniques have been identified as a useful tool to systematically identify and quantitatively prioritize structures, systems and components important to safety.

The staff recognizes that the first-of-a-kind nature of the geologic repository will impose uncertainties on any method used to analyze safety/risk and that PRA techniques have inherent limitations. However, we believe that PRA techniques have useful applications and are appropriate for the HLW program.

65. Comment (YIN) Page 14, Section 6.2(a):

It is stated in the GTP that "The PRA should utilize the following techniques: (1) System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques often used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur."

While it is true that fault trees/event trees provide a useful approach to failure analysis, the NRC should acknowledge the limitations of this approach. For example, it is quite difficult in this type of analysis to account for synergistic interactions between various failure modes. In addition, the majority of computer codes employed to generate fault trees use simple multiplication and addition of probabilities for AND/OR gates. This results in difficulties in assessing the effect of the timing of one failure on the probable time of the next failure.

Response:

See response to Comment 64.

66. Comment (DOE) Page 14, Section 6.2(a)(1), paragraph 2:

The requirement to identify "all conceivable events" is difficult if not impossible.

Suggest deletion of "all" conceivable and, in next sentence, delete "all".

Response:

The staff believes that to conduct an adequate event tree analysis, a comprehensive set of accident scenarios should be considered. This includes the identification of all initiating events and event sequences that could conceivably lead to an accident. The staff acknowledges that this task will be difficult but believes it is necessary to assure that all potentially significant accident sequences will be included in the safety analyses for a geologic repository.

67. Comment (NV) Page 14, Section 6.2 (a) (1):

Reference is made to the hoist failure scenario. There are several analyses of this scenario in the DOE report literature. A good example is the DOE report WTSD-TME-063, Probability of a Catastrophic Hoist Accident at the Waste Isolation Pilot Plant. Most of these reports refuse to acknowledge the possibility of human error. Furthermore, they make use of a very limited data base that may not even apply to the hoist system in question. As an example, the data base reflects incidence of events in the commercial U.S. Mining industry, which uses predominantly drum type hoist systems. The hoist systems used or recommended in the nuclear waste repository program (WIPP included) are of the tower-mounted friction type. The Commission should comment on these analyses and let it be known whether they can be used as valid precedents or whether more rational approaches are required.

Response:

Staff comments on these reports would be inappropriate in the context of this GTP. The purpose of using the hoist failure scenario in this GTP was to provide an illustrative, though hypothetical, example to support the discussion of accident analyses. The staff will, however, consider such literature when evaluating the adequacy of the proposed hoist system.

68. Comment (YIN) Page 15, Section 6.2(a)(1):

The GTP provides an example accident scenario and later states that the scenario may be unlikely and, thus, need not be considered. To be consistent the GTP should omit the conclusion that this example need not be considered.

Response:

This statement was intended to indicate that in evaluation of potential accidents, some scenarios may be found to be so unlikely, they need not be considered in design of the repository. However, the staff believes that all potential accident scenarios need to be evaluated to determine the associated consequences and risks.

Change: The referenced discussion has been revised to incorporate the first sentence above.

69. Comment (YIN) Page 15, Section 6.2(a)(1):

Furthermore, the GTP states that probabilities of scenarios and releases need to be developed. If this is the case, the NRC should provide limits on probabilities to ensure that accidents which are dismissed fall below some specified probability of occurrence. The GTP does not provide this guidance in its present form.

Response:

See response to Comment 26.

70. Comment (MS) Page 15, Section 6.2(a)(1):

On page 15 is a discussion of scenarios that do not need to be considered. The better approach is listed on page 7 in that irrespective of the probability of failure scenarios that may yield a 0.5 rem dose to a citizen in an unrestricted area should be considered.

Response:

See response to Comment 68.

71. Comment (YIN) Page 15, Section 6.2(a)(2):

Consequence analyses are to be performed by the DOE to determine the expected off-site dose of radiation. Consequence analyses are dependent upon identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive material. Such information is not well quantified and will lead to uncertainties. Therefore, parameters that are used in consequence analyses must be bounded to ensure accurate evaluations.

Response:

See response to Comments 36 and 64.

72. Comment (MD) Page 15, Section 6.2(a)(1):

Some guidance should be given on the lower bound for probability which allows an accident to be dropped from consideration.

Response:

See response to Comment 26.

73. Comment (MD) Page 15, Section 6.2(a)(1), paragraph 2:

It states that "conservative bounding assumptions will be made and justified to demonstrate that the subject equipment will be reliable." Could they also be used to demonstrate that the consequences are acceptable, or that the probability is too low to consider?

Response:

See response to Comment 26.

74. Comment (YIN) Page 15, Section 6.2(a):

The GTP defines the Q-List as "All structures, systems, and components of the geologic repository whose failure could initiate an accident which, if unmitigated, could cause an off-site radiation dose of 0.5 rem... Therefore, the NRC attempts to quantify the items on the Q-List by tying together all structures, systems, and components of the geologic repository whose failure could initiate an accident exceeding the 0.5 rem limit. However, this requires extensive probability analysis by the DOE of every structure, system, and component of the geologic repository to ascertain if it should be on the Q-List. It seems, therefore, that the NRC should provide quantitative guidance and/or QA guidelines on this probability analysis, which will also be used to categorize each structure, system, and component of the geologic repository for inclusion or omission from the Q-List. The GTP does not provide this guidance. The GTP must ensure that each system, structure, and component of the repository falls under some sort of QA guideline.

Response:

See response to Comment 5 which addresses the purpose of the GTP and the responsibility for developing the Q-list and the QA program.

75. Comment (DOE) Page 16, Section 6.2(a), first full paragraph:

In the second line the word "large" is difficult to define.

Response:

Change: The word "large" has been deleted.

76. Comment (MD) Page 16, Section 6.2(a), top of page:

Following up on comments above, what is "incredible"?

Response:

See response to Comment 26.

77. Comment (NV) Page 16, Section 6.2(a):

At the top of the page, the word "incredible" should be defined as it is used in this context. The text should provide guidance on the criteria the staff will use in judging "incredibility".

Response:

See response to Comment 26.

78. Comment (NV) Page 16, Section 6.2(a):

This section notes a report which contains examples of initiating events, accident scenarios, and possible consequences. Reference to this report has no place in the GTP, unless the NRC study of pre-closure accidents will consider all possible events, accidents and consequences, and the referenced report is a progress report.

Response:

The GTP provides guidance to DOE on approaches the NRC staff consider acceptable for identifying items and activities important to safety and waste isolation. The NRC study cited is the only report known to NRC staff that describes a methodology to identify and quantitatively prioritize structures, systems, components, and operations which are important to safety during the preclosure phase of the geologic repository. The report was not intended to identify all possible events, accidents and consequences, but rather to develop a methodology. The

staff thinks this reference provides a potential source of information, which in fact has already been referenced in DOE documents.

79. Comment (NV) Page 16, Section 6.2(c):

The discussion of non-mechanistic failures should be expanded to discuss in detail under what circumstances the staff would accept use of non-mechanistic failures in place of PRAs.

Response:

The staff is not suggesting that non-mechanistic failures substitute for PRAs. The thought is that where data are insufficient to reliably determine the failure modes of an item, the item should be assumed to fail in order to provide conservatism in analysis of potential accident scenarios. Items should be considered on a case-by-case basis to determine if non-mechanistic failures should be assumed in accident analyses. See also response to Comment 80.

Note: The discussion of non-mechanistic failures has been incorporated into Sections 5.2(a) and 6.2(a) of the final GTP.

80. Comment (YIN) Page 16, Section 6.2(c):

The GTP states that "Non-mechanistic failures, (i.e., postulated failures which are not based on previously observed failure modes but which are conservatively assumed to maximize consequences) need not be used in safety assessments." This position on non-mechanistic failures is inconsistent with the general tone of the GTP, i.e., the GTP states that "Accident scenarios including initiating events as well as dose consequences for accidents will therefore need to be identified and estimated using conservative engineering judgement" (p. 21). It would seem appropriate, therefore, for the DOE to include non-mechanistic failures in its safety assessments.

Response:

The intent of addressing non-mechanistic failures is to indicate that in conducting accident analyses, an item need not be assumed to fail if information and/or experience is available to demonstrate its reliability. However, where information is insufficient to determine an item's failure modes and mechanisms, DOE should assume the item fails to provide

conservative results in the associated analyses. While the discussion of non-mechanistic failures should be clarified, the staff believes this concept is consistent with the general tone of the GTP.

Changes: A definition for non-mechanistic failures has been added to the glossary. Note also that the discussion of non-mechanistic failures has been incorporated into Sections 5.2(a) and 6.2(a) of the final GTP.

81. Comment (MD) Page 16 Section 6.2(c):

Clarify use of non-mechanistic failures. It seems that if the data are insufficient to support PRAs, then such assumptions are always needed, and use of "may" is inappropriate.

Response:

The staff agree. See response to Comment 80.

82. Comment (NV) Page 17, Section 6.2(d):

The text indicates that criteria and standards developed for reactors and other nuclear programs may be applicable for the geologic repository program. In this GTP the staff should define which criteria and standards are applicable to the repository program.

Response:

The intent of referencing the guidelines and standards developed in the reactor and other nuclear programs is to acknowledge a source of potentially useful information which DOE has previously indicated an interest in (note the report cited). The staff intends to review any previously established information that DOE chose to use in the repository program to determine its acceptability. The staff believes this approach to be consistent with the NRC's role in the HLW program. See also response to Comment 13.

Change: Sections 5.2(c) and 6.2(c), have been modified to provide clarification.

83. Comment (MD) Page 17, Section 6.2(d):

Why should natural disaster standards for nuclear power plants not be applicable to a repository? Does the NRC envision a different level of safety here? If not, the standards apply directly.

Response:

Due to inherent uncertainties in defining design basis events and the potential risks to the public health and safety, a high degree of conservatism is employed in defining natural disaster events for nuclear power plants. If the potential risk to public health and safety from natural disasters at the geologic repository are shown, on a case-by-case basis, to be far less, than less conservative standards may be more appropriate and practicable. Therefore, while the standards developed for a geologic repository may be different than for a nuclear power plant, the level of protection provided for public health and safety should remain the same.

Note: Sections 5.2(c) and 6.2(c) have been modified to provide clarification.

84. Comment (DOE) Page 17, Section 6.2(d), paragraph 2:

Reference to a document, which has not been endorsed by DOE or NRC, could be interpreted as having tacit endorsement.

Suggested Change: Delete this paragraph.

Response:

The paragraph cited clearly states that the publication (Chang, 1986) has not been "endorsed by DOE or NRC" but that it is a "useful source of information and provides a basis for future discussions."

85. Comment (DOE) Page 17, Section 6.2(e):

Analyses to identify structures systems, and components which may be important to safety during a potential retrieval operation should be prepared as part of the retrieval planning and not earlier. Since the nature of the retrieval operation may depend on conditions which make retrieval necessary, even in the face of exposures above 0.5 rem, and

since the state of technology which would be utilized at that time is likely to be different from today's, early analyses would be speculative and likely of little use. What is important now is that the option for retrieval not be foreclosed. For this reason, DOE intends to apply appropriate quality procedures to those structures, systems and components whose failure could make retrieval impracticable.

Suggested change: Delete starting in the third line to end of paragraph "...to identify Q-List items and activities..."

Response:

The NRC staff believe that DOE should consider retrieval operations during design of the repository, at which time associated items and activities that may belong on the Q-list should be identified. As details on retrieval operations may not be addressed until late in the process of repository design, the staff did not request analysis of retrieval operations at a specific point in time and recommended instead that DOE conduct these analyses in a timely manner. In so doing, the staff is suggesting that DOE perform analyses and identify Q-list items and activities whenever design, site characterization, construction, or performance confirmation may impact the ability to retrieve waste safely.

86. Comment (MD) Page 17, Section 6.2(e):

Since some aspects of retrieval operations may bear on original repository design and construction, this should be included here.

Response:

See response to Comment 85.

87. Comment (YIN) Page 19, Section 6.3, paragraph 1:

The GTP states "Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. DOE is expected to allocate performance among barriers based on available data before site characterization begins. These initial allocations of performance will provide a basis for determining how much site characterization testing will be needed. For barriers contributing substantially to the performance objectives, more data will be needed than for those with

little or no contribution. The initial allocation of performance among the barriers is likely to change based on new data and the results of performance assessments."

In summary, the DOE is expected to allocate performance among barriers based on available data; these initial allocations of performance will provide a basis for determining how much site characterization testing will be needed. Initial allocation of performance among the barriers is likely to change based on new data and the results of performance assessments.

The GTP does not provide an adequate methodology or procedure for determining how the quantity of site characterization testing for a particular barrier will be modified as the initial allocation of performance among the barrier changes. In other words, the performance assessment will determine how much site characterization testing is needed, but it is not clear how the quantity and/or quality of site characterization testing is changed as more data requires a re-evaluation of the initial allocation of performance among the barriers. The GTP must allow for this occurrence.

Furthermore, in the next paragraph the GTP states that "...all activities DOE plans for characterization of barriers as well as those barriers themselves should be covered by a 10 CFR 60 Subpart QA program... Until that time [of license application], it is prudent to consider all barriers for which characterization activities are planned to be on the Q-List. Failure to apply QA in a manner commensurate with the potential importance of an item or activity may adversely affect the credibility of information used in the license application." Should it be assumed that the level of QA will increase, (or conversely, decrease) as more data is obtained and the allocation of performance among the engineered barriers changes? It is important that the level of QA be reviewed to ensure that it is consistent with the modified performance assessment.

Response:

This comment focuses on how changes in performance allocation will affect the quantity of data collected and level of QA to be applied to items important to waste isolation. The main point the staff is making is that performance allocation is expected to change as performance assessments are conducted, based on data collection and analyses. The GTP indicates that DOE should be conservative in the initial performance assessment so that, in light of uncertainties, waste isolation can be demonstrated.

88. Comment (MD) Page 19, Section 6.3, paragraph 1:

Add "new" to read "results of new performance assessments."

Response:

This section has been revised such that the comment no longer applies.

89. Comment (MD) Page 19, Section 6.3:

Paragraph 2 makes a very important point that all items are initially on the Q-List. This should be mentioned in appropriated other points in the document for emphasis. It is "hidden" and "buried" here.

Response:

The staff agrees that the point made in this statement is important. However, it should be taken in context and not generalized. The point is that until extensive data are collected and analyzed in performance assessments, it are prudent for DOE to consider all items related to post-closure performance, and for which characterization activities are planned, to be important to waste isolation.

Change: The applicable discussion in Sections 5.2 and 6.2 have been modified to provide clarification, as appropriate.

90. Comment (DOE) Page 19, Section 6.3, paragraph 3:

In classifying items important to waste isolation, the draft GTP indicates that DOE should refer to the "Draft Generic Technical Position on Licensing Assessment Methodology for High-Level Waste Geological Repositories." We understand that the GTP will be substantially revised, probably renamed, and published in mid-1987. It is difficult to review or respond meaningfully to the subject Draft GTP if it attempts to incorporate methodology in another document which will not be published together in order to provide meaningful response to NRC on either GTP.

Suggested Change: Delete this paragraph.

Response:

DOE is correct in stating that the GTP on Licensing Assessment is in the

process of revision and may not be final until late 1987. However, the revisions, which include a new title, are being made primarily for the purpose of clarification. The staff positions presented therein will not change appreciably in intent or concept. Therefore the staff believes the draft GTP on Licensing Assessment is a source of useful information and a valid reference in this GTP.

91. Comment (DOE) Page 20, Section 6.4, paragraph 2:

"Obvious or likely candidates" is inappropriate.

Suggested Change: Please delete sentence.

Response:

While the staff does believe that certain items or activities represent obvious or likely candidates, the referenced sentence has been deleted to avoid misinterpretation.

92. Comment (MD) Page 20, Section 6.4(a):

This paragraph contains "should" and only one "shall". Surely NRC intends these to be requirements, so they should be changed to "shall" in every case. The same applies to "should" in the first and last lines on the page.

Response:

Section 6.4 provides guidance on what the staff needs to review and evaluate DOE's program in a timely and effective manner. The 10 CFR 60 requirements contained in this discussion are cited as such. As the term "shall" refers to a requirement and the term "should" refers to staff guidance/recommendations, it would not be appropriate to replace these terms as used in the reference paragraph.

93. Comment (YIN) Page 23, Section 6.5:

The GTP cites NQA-1 (ANSI/NSME, 1983) as a consensus standard which provides detailed guidance on grading QA for nuclear facilities. The GTP has slightly modified NQA-1 Appendix 4A-1 for repository work.

One item or guideline for grading QA measures involves the quality, history, and degree of standardization of the item or test. The GTP states: "If a manufacturer or organization has been producing a particular standard item or conducting a standard test for a long period and if the quality history of the item or test indicates acceptable performance, QA measures may be applied to that item or test to reflect the demonstrated performance." The GTP should also include a sentence stating that the demonstrated performance should be checked and verified. Past performances under conditions similar to those expected to be encountered in the repository must be reviewed to see that the demonstrated performance is indeed applicable and can be used to grade QA measure.

Response:

Change: The applicable discussion has been changed to indicate that the quality history should be verifiable as well.

94. Comment (MD) Page 24, Section 6.5:

Why would there be only partial QA on the manufacturer of an instrument, followed by full QA on the supplier? In this instance, the supplier can't really do anything to correct problems built in by the manufacturer. Is there some confusion of terms here?

Response:

The staff has used the term "manufacturer" and "supplier" interchangeably in the referenced discussion.

Change: The term "supplier" has been replaced by "manufacturer" in the referenced discussion. Also, the term "off-the-shelf" has been changed to "commercial grade" to conform with the definition used in ANSI/ASME NQA-1a-1986.

95. Comment (NH) Page 26, Section 7.0:

Overall, both documents are well thought out, well written, straightforward and appear to be comprehensive in addressing the subject matter. We only have one specific comment on the Draft GTP on quality assurance requirements. We realize that quality assurance is a very specialized field with a jargon all its own, and by and large the Draft

GTP does a good job of explaining the various terms and techniques peculiar to the discipline. However, the summary is unintelligible to all but the trained quality assurance professional. Since the summary tends to be one of the more important sections to the untrained reader, it should highlight the most important aspects of the document in a clear, concise, easily understandable manner. This summary relies much too heavily on jargon and appears to be thrown together very quickly without much thought.

Response:

The staff has improved the clarity of the summary by rewriting portions of the section. However we consider it necessary to emphasize the importance of the section on "Staff Positions" in this and other NRC GTPs. This section is intended to concisely summarize the staff's positions on issues related to the scope of the GTP. It is these positions that require the most attention during public review and comment to assure that significant concerns are identified and consensus can be reached, as appropriate, on the issues addressed.

Change: Section 7.0, the Summary, has been revised to provide clarity.

96. Comment (MD) Page 26, Section 7.0:

Following up on the comments on page 20, "should" on this page should be replaced by "shall" in every case.

Response:

The 10 CFR 60 requirements contained in this discussion are cited as such. As the term "shall" refers to a requirement and the term "should" refers to staff guidance/recommendations, it would not be appropriate to replace these terms as used in the reference paragraph.