



United States Government

Department of Energy

memorandum

 Carlsbad Field Office
 Carlsbad, New Mexico 88221

DATE: September 4, 2008

REPLY TO
ATTN OF: CBFO:NTP:NC:GS:08-0864:UFC 5900.00

SUBJECT: Initial Certification Audit of ORNL-CCP

TO: William McMillan, DOE-OR
Farok Sharif, WTS



The Carlsbad Field Office (CBFO) has completed the initial certification audit of the Central Characterization Project (CCP) TRU waste program deployed at the Oak Ridge National Laboratory (ORNL) (hereinafter referred to as ORNL-CCP). Audit A-08-04 was conducted December 4-6, 2007 and Audit A-08-06 was conducted November 13-15, 2007. These were conducted by CBFO to evaluate the adequacy, implementation, and effectiveness of the ORNL-CCP technical program.

The audit teams determined that the ORNL-CCP TRU programs were in compliance with the "Waste Analysis Plan" (WAP) of the *WIPP Hazardous Waste Facility Permit (HWFP)*, the *Quality Assurance Program Document (QAPD)*, and the *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant (WIPP WAC)*. The audit team determined that the procedures were effectively implemented.

Transportation of contact-handled waste was audited during the LANL-CCP Audit A-07-13 at the Los Alamos National Laboratory on May 15-17, 2007 for the CCP transportation activities. Transportation was found to be adequate and effectively implemented. Surveillance S-07-25 was conducted for the Flammable Gas Sampling and Analysis activities at LANL-CCP on July 25-31, 2007. The CCP Flammable Gas Sampling and Analysis program was determined to be adequate, satisfactorily implemented, and effective.

The CCP Quality Assurance Program was audited under a separate audit on January 14-18, 2008 during the A-08-07 at Carlsbad, New Mexico. The quality assurance program was found to be adequate and effectively implemented.

Based on the results of the audits, conditions and limitations provided by the New Mexico Environment Department (NMED) and the U.S. Environmental Protection Agency (EPA), the CBFO is granting the ORNL-CCP authority for the characterization and certification activities for contact-handled retrievably stored debris (\$5000) waste at ORNL as identified in Table 1 below.

080915

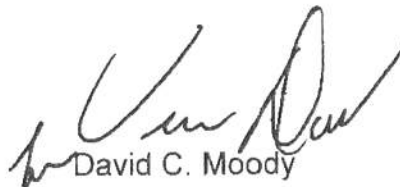


Characterization Process	S5000 Debris	
	Newly generated	Retrievably-Stored
Acceptable Knowledge	N/A	APPROVED
Load Management	N/A	N/A
Data Validation & Verification (V&V)	N/A	APPROVED
Visual Examination	N/A	N/A
Solids Sampling & Analysis	N/A	N/A
Headspace Gas Sampling ¹	N/A	APPROVED
Nondestructive assay (NDA) (SGS & DWAS/IPAN)	N/A	APPROVED
Real-time Radiography (RTR)	N/A	APPROVED
WIPP Waste Information System (WWIS)	N/A	APPROVED

¹ Analysis is performed by the Idaho National Laboratory, which is approved under a separate certification.

TRU waste characterization, certification, or transportation using significantly revised or new processes, procedures, or systems must be evaluated by the CBFO prior to their implementation. Included in this memo are the following attachments:

- *Attachment 1* describes the ORNL-CCP certification program status,
- *Attachment 2* contains the equipment certified at the site,
- *Attachment 3* contains the CCP procedures, and
- *Attachment 4* specific ORNL-CCP waste characterization process elements that must be reported. These process elements are identified as Tier 1 changes and Tier 2 changes. The ORNL-CCP shall not ship for disposal at WIPP any wastes affected by a Tier 1 process element change without prior CBFO approval, and ORNL-CCP shall report Tier 2 changes to CBFO on a quarterly basis.


David C. Moody
Manager

Attachment(s)

cc: w/attachments

V. Daub, CBFO	*ED
D. Gadbury, CBFO	ED
N. Castaneda, CBFO	ED
C. Fesmire, CBFO	ED
A. Holland, CBFO	ED
D. Miehl, CBFO	ED
M. Navarrete, CBFO	ED
J. Edwards, EPA	ED
M. Eagle, EPA	ED
T. Peake, EPA	ED
E. Feltcorn, EPA	ED
R. Joglekar, EPA	ED
J. Bearzi, NMED	ED
D. Haar, WTS	ED
D. Ploetz, WTS	ED
C. Kirkes, WTS	ED
J. Harvill, WTS	ED
D. Kump, WTS	ED
D. Speed, WTS	ED
C. Luoma, WTS	ED
R. Chatfield, WTS	ED
D. Hofer, WTS	ED
R. Reeves, WTS	ED
M. Strum, WTS	ED
D. Standiford, WTS	ED
P. Gilbert, LANL	ED
G. Lyshik, LANL	ED
W. Ledford, CTAC	ED
S. Percy, Triumph	ED
CTAC Document Coordinator	
WIPP Operating Record	
CBFO M&C	

**CENTRAL CHARACTERIZATION PROJECT AT
OAK RIDGE NATIONAL LABORATORY
CERTIFICATION PROGRAM STATUS**

The CBFO Director of the Office of the National TRU Program and the CBFO Quality Assurance Manager have evaluated the documentation supporting the compliance of the Central Characterization Project (CCP) TRU waste program deployed at the Oak Ridge National Laboratory (ORNL). Attachments 2, 3, and 4 provide complete lists of certified processes, procedures, documents, and systems deployed at the ORNL-CCP.

PROGRAM STATUS

- All program elements remain complete.
- The following site documents are current and demonstrate how the CCP complies with the CBFO requirements.
 - **QAPjP – CCP-PO-001, Revision 16 - CCP Transuranic Waste Characterization Quality Assurance Project Plan** (CBFO:NTP:DCG:GS:07-1824:UFC 5900.00 dated October 30, 2007).
 - **WCP - CCP-PO-002, Revision 20 - CCP Transuranic Waste Certification Plan** (CBFO:NTP:DCG:GS:07-1826:UFC 5900.00 dated November 1, 2007).
 - **CH-TRAMPAC – CCP-PO-003, Revision 10, CCP TRUPACT-II Authorized Method for Payload Control** (CBFO:NTP:CF:GS:06-1668:UFC:5900 dated November 7, 2006).
- Certified Systems - see Attachment 2 for the complete list of certified systems used by the CCP at the ORNL
- Standard operating procedures - see Attachment 3 for the complete list of certified procedures used by the CCP at the ORNL
- Tiering of TRU Waste Characterization Processes implemented by CCP at ORNL (based on EPA Baseline Inspections) - see Attachment 4

- CCP participated in the following performance demonstration programs (PDPs):
 - **HSG PDP CYCLE 21A (INL ECL)** approved for analysis of VOCs using the GC/MS-E, GC/MS-F, GC/MS-G, GC/MS-H, GC-1, GC-2 and GC-7 - Memo CBFO:NTP:MRB:GS:07-0878:UFC 5822.00 dated May 8, 2007.
 - **NDA PDP** – Cycle 14B approved for non-destructive assay of TRU waste drums using the system identified as DWAS/IPAN/SGS (OR01/ORN1). - Memo CBFO:NTP:MRB:GS:07-1870:UFC 5822.00 dated December 19, 2007.
- CBFO conducted Audit A-08-04 on December 4-6, 2007.
 - The Interim Audit Report was issued December 20, 2007.
 - The Final Audit Report was issued to NMED on March 7, 2008.
 - CARs 08-004 and 08-005 were issued on December 13, 2007.
 - CAR-08-004 was closed on February 26, 2008.
 - CAR-08-005 was closed on March 6, 2008.
- CBFO conducted Audit A-08-06 on November 13-15, 2007.
 - No CARs were issued.
 - The Final Audit Report was issued on December 6, 2007.
- CBFO conducted Audit A-08-07 of the CCP QA Program on January 14-18, 2008
 - The Final Audit Report was issued to the site on February 6, 2008.
 - CAR 08-011 was issued on January 28, 2008.
 - CAR 08-011 was closed on April 3, 2008.
- NMED approval on Audit A-08-04 was issued on April 24, 2008.
- EPA Baseline Report was issued on August 21, 2008.
- EPA QA Inspection Report was issued on March 31, 2008.
- EPA concurrence on the recertification memorandum was issued on September 3, 2008.

RECOMMENDATION

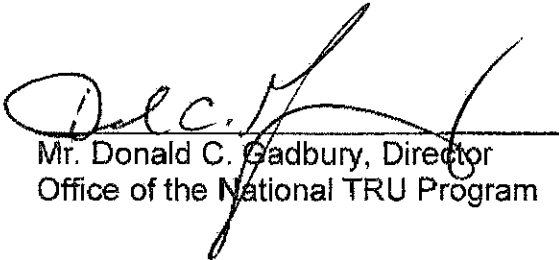
The recommendation to the CBFO Manager is to grant the CCP authority for certification, characterization, and transportation of contact-handled, retrievably-stored debris (S5000) waste at the ORNL. Attachments 2, 3, and 4 list the systems and procedures that constitute the bounds of this authority.

CONCURRENCE



Ms. Ava Holland
Quality Assurance Manager

8-29-08
Date



Mr. Donald C. Gadbury, Director
Office of the National TRU Program

8-29-08
Date

CENTRAL CHARACTERIZATION PROJECT LIST OF PROCEDURES AT OAK RIDGE NATIONAL LABORATORY		
#	Procedure No.	Procedure Title
1.	CCP-PO-001	CCP Transuranic Waste Characterization Quality Assurance Project Plan
2.	CCP-PO-002	CCP Transuranic Waste Certification Plan
3.	CCP-PO-003	CCP Transuranic Authorized methods for Payload Control (CCP CH-TRAMPAC)
4.	CCP-PO-005	CCP Conduct of Operations
5.	CCP-PO-006	Corrective Action Reporting and Control double check ftp site
6.	CCP-PO-008	CCP Quality Assurance Interface with the WTS Quality Assurance Program CERTIFIED?
7.	CCP-PO-016	CCP Control of Measuring, Testing, and Data Collection Equipment
8.	CCP-PO-026	CCP Configuration Management Plan
9.	CCP-PO-027	CCP/TRU Waste Processing Center/Oakridge National Laboratory Interface Document
10.	CCP-QP-001	CCP Graded Approach
11.	CCP-QP-002	CCP Training and Qualification Plan
12.	CCP-QP-004	CCP Corrective Action Management
13.	CCP-QP-005	CCP TRU Nonconforming Item Reporting and Control
14.	CCP-QP-006	CCP Corrective Action Reporting and Control
15.	CCP-QP-008	CCP Records Management
16.	CCP-QP-010	CCP Document Preparation, Approval, and Control
17.	CCP-QP-011	CCP Notebooks and Logbooks
18.	CCP-QP-014	CCP Quality Assurance Trend Analysis and Reporting
19.	CCP-QP-015	CCP Procurement
20.	CCP-QP-016	CCP Control of Measuring, Testing, and Data Collection Equipment
21.	CCP-QP-017	CCP Identification and Control of Items
22.	CCP-QP-018	CCP Management Assessment
23.	CCP-QP-019	CCP Quality Assurance Reporting to Management
24.	CCP-QP-021	CCP Surveillance Program
25.	CCP-QP-022	CCP Software Quality Assurance Plan
26.	CCP-QP-023	CCP Handling, Storage and Shipping
27.	CCP-QP-025	CCP Lessons Learned Program management Control Procedure
28.	CCP-QP-026	CCP Inspection Control
29.	CCP-QP-027	CCP Test Control
30.	CCP-QP-028	CCP Records Filing, Inventorying, Scheduling, and Dispositioning
31.	CCP-QP-030	CCP Written Practice for the Qualification of CCP Helium Leak Detection Personnel
32.	CCP-TP-001	CCP Project Level Data Validation and Verification
33.	CCP-TP-002	CCP Reconciliation of DQOs and Reporting Characterization Data
34.	CCP-TP-003	CCP Data Analysis for S3000, S4000, and S5000 Characterization
35.	CCP-TP-005	CCP Acceptable Knowledge Documentation
36.	CCP-TP-028	CCP Radiographic Test and Training Drum Requirements
37.	CCP-TP-030	CCP CH TRU Waste Certification and WWIS Data Entry
38.	CCP-TP-033	CCP Shipping of CH TRU Waste
39.	CCP-TP-053	CCP Standard Real-Time Radiography (RTR) Inspection Procedure
40.	CCP-TP-058	CCP NDA Performance Demonstration Program
41.	CCP-TP-068	CCP Container Management at the Idaho National Laboratory (INL) and TRU Waste Processing Center (TWPC)
42.	CCP-TP-082	CCP Preparing and Handling Waste Containers for Headspace Gas Sampling

CENTRAL CHARACTERIZATION PROJECT LIST OF PROCEDURES AT OAK RIDGE NATIONAL LABORATORY		
#	Procedure No.	Procedure Title
43.	CCP-TP-086	CCP CH Packaging Payload Assembly
44.	CCP-TP-093	CCP Sampling of TRU Waste Containers
45.	CCP-TP-106	CCP Headspace Gas Sampling Batch Data Report Preparation
46.	CCP-TP-160	CCP Random Selection of Containers for Headspace Gas Sampling and Analysis
47.	CCP-TP-165	CCP Real-Time Radiography #6 Operating Procedure
48.	CCP-TP-166	CCP Drum Waste Assay System Imaging Passive/Active Neutron Operations
49.	CCP-TP-167	CCP Drum Waste Assay System Imaging Passive/Active Neutron Calibration
50.	CCP-TP-168	CCP Drum Waste Assay System Imaging Passive/Active Neutron/Segmented Gamma Scanner Data Generation Level Validation
51.	CCP-TP-169	CCP Operating the Mobile Segmented Gamma Scanner
52.	CCP-TP-172	CCP Calibrating the Mobile Segmented Gamma Scanner

**CENTRAL CHARACTERIZATION PROJECT
LIST OF CERTIFIED EQUIPMENT AND PROCESSES AT OAK RIDGE NATIONAL LABORATORY**

WIPP WWIS #	Site Equipment # or Title	Description	Components	Software	NDA Calibrated Range, Operating Range and TMU
Nondestructive Assay					
16SG1	DWAS/IPAN/SGS-01	Drum Waste Assay System /Imaging Passive/Active Neutron/Segmented Gamma Scanner – 55 gallon drums Procedure CCP-TP-166, CCP-TP- 167, CCP-TP-168, CCP-TP-169 and CCP-TP-172	<input type="checkbox"/> Coaxial detector with collimator <input type="checkbox"/> LEGe detector with collimator <input type="checkbox"/> Digital signal processors <input type="checkbox"/> 3 He Neutron detectors <input type="checkbox"/> Neutron generator system <input type="checkbox"/> Shielded assay chamber with turntable	<input type="checkbox"/> NDA 2000 <input type="checkbox"/> Genie 2000 <input type="checkbox"/> DWAS.exe <input type="checkbox"/> DWASAnalysis.exe <input type="checkbox"/> DNGI.exe <input type="checkbox"/> DWAS_SGS_QC.exe <input type="checkbox"/> FRAM44.exe	<p>The SGS component is described in MV-SGS-0101-CAL-001, <i>Segmented Gamma Scanner-01 (SGS-01-01) Calibration, Confirmation and Verification Report</i>, with a matrix density range of 0.0 to 0.72 g/cm³ and an upper calibration range of 45 grams total plutonium. The Total Measurement Uncertainty (TMU) is described in CI-SGS01-TMU, <i>Total Measurement Uncertainty for the MCS Melton Valley Segmented Gamma Scanner</i>.</p> <p>The DWAS/IPAN neutron component is described in BII-5183-CVR-001, <i>Calibration and Validation Report DWAS IPAN</i>. For passive mode, the operational range is from lower limit of detection (LLD) to 2.050 g ²⁴⁰Pu_{EFF} with a MOD index range from 1.045 to 17.572. For active mode, the operational range is from LLD to 14.710 g ²³⁹Pu_{EFF} with an ABSMOD index range from 22.251 to 176.800 in terms of matrix. The TMU is described in BII-TMU-5183-001, <i>Total measurement Uncertainty Report DWAS IPAN</i>.</p>

CENTRAL CHARACTERIZATION PROJECT LIST OF CERTIFIED EQUIPMENT AND PROCESSES AT OAK RIDGE NATIONAL LABORATORY					
WIPP WWIS #	Site Equipment # or Title	Description	Components	Software	NDA Calibrated Range, Operating Range and TMU
Nondestructive Examination					
16RR1	MCS RTR #6	Real-Time Radiography Mobile Characterization System RTR #6 – 55 gallon drums Procedure CCP-TP-165	<input type="checkbox"/> Shielded x-ray enclosure with a hydraulic drum loading door and manually opened personnel door <input type="checkbox"/> Conveyer cart including drum manipulation equipment <input type="checkbox"/> X-ray imaging system including x-ray tube, image intensifier, and video camera <input type="checkbox"/> Video/audio recording equipment <input type="checkbox"/> Mobile platform	<input type="checkbox"/> N/A	N/A

**CH Tiering of TRU Waste Characterization Processes Implemented by CCP at ORNL
(Based on November 13-15, 2007 EPA Baseline Inspection No. EPA-ORNL-CCP-CH-11.07-8)
EPA DOCKET NO. A-98-49, II-A4-103**

WC Process Elements	ORNL-CCP WC T1 Changes	ORNL-CCP WC T2 Changes ^a
Acceptable Knowledge (AK) and Load Management	Implementation of load management. Implementation of AK for wastes other than retrievably-stored debris (i.e., retrievably stored soil/gravel and solids and/or any type of newly-generated waste).	Notification to EPA upon completion of AK accuracy reports. Notification to EPA upon completion of new versions or updates/substantive changes ^b of the following: <ul style="list-style-type: none"> - Changes to AK-NDA communications and memoranda - Changes to site procedure - AK Summaries that describe wastes beyond the 144 containers described in this report - Radiological Discrepancy Resolution Reports (AK-AK and AK-NDA) pertinent to Waste Stream OR-NFS-CH-HET - Completed Attachment 4 and 6 and associated memoranda for Waste Stream OR-NFS-CH-HET - AK Summaries/AK Waste Stream Profile Forms (WSPFs) and AK documentation reports
Non Destructive Assay (NDA)	New equipment or physical modifications to approved equipment. Extension or changes to approved calibration range for approved equipment.	Notification to EPA upon completion of changes to software for approved equipment, operating range(s), and site procedures that require CBFO approval.
Real-Time Radiography (RTR)	N/A	Notification to EPA upon the following: <ul style="list-style-type: none"> - Implementation of new RTR equipment or substantive changes^c to approved RTR equipment - Completion of changes to site RTR procedures that require CBFO approval
Visual Examination (VE)	Not approved at this time.	Not approved at this time.
WIPP Waste Information System (WWIS)	Implementation of load management.	Notification to EPA upon the following: <ul style="list-style-type: none"> - Completion of changes to WWIS procedure(s) requiring CBFO approvals

^a Upon receiving EPA approval, ORNL-CCP will report all T2 changes to EPA at the end of each fiscal quarter.

^b "Substantive changes" are changes with the potential to impact the site's WC activities or documentation thereof, excluding changes that are solely related to ES&H, nuclear safety, or RCRA, or that are editorial in nature.

^c Modifications to approved equipment include all changes with the potential to affect NDA data relative to waste isolation and exclude minor changes, such as the addition of safety-related equipment.

CHAK Tiers

Tier 1 AK Changes will require EPA review and approval prior to implementation and will apply to any new waste category not evaluated during the baseline inspection. These include the following:

- Implementation of load management
- Implementation of AK for wastes other than retrievably-stored debris (i.e., retrievably-stored solids and soil/gravel and/or any newly-generated waste)

ORNL-CCP must report and submit documentation on T1 changes when it is ready for EPA review. Upon initial review, EPA will inform ORNL-CCP and CBFO whether a site inspection is necessary. EPA may request additional information, choose to conduct a desktop review, and/or confer with ORNL-CCP personnel. Upon evaluation (with or without site inspection), EPA will issue an approval letter, and only upon receiving the EPA approval can ORNL-CCP dispose of the new waste at the WIPP or implement the activity deemed to be a T1 change.

Tier 2 AK Changes do not require EPA approval before implementation but require that ORNL-CCP provide notification to EPA upon completion of the following:

- Notification to EPA upon completion of new versions or updates/substantive modifications to AK accuracy reports (prepared annually)
- Notification to EPA upon completion of new versions or updates/substantive modifications to AK-NDA communications and memoranda for Waste Stream OR-NFAS-CH-HET and/or forthcoming waste streams
- Notification to EPA upon completion of new versions or updates/substantive modifications to site AK procedures
- Notification to EPA upon completion of new versions or updates/substantive modifications to all AK Summaries that describe wastes beyond the 144 containers described in this report and updates to the existing Waste Stream OR-NFS-CH-HET summary
- Notification to EPA upon completion of new versions or updates/substantive modifications to Radiological DRRs (AK-AK and AK-NDA) pertinent to Waste Stream OR-NFS-CH-HET
- Notification to EPA upon completion of new versions or updates/substantive modifications to completed Attachment 4 and Attachment 6 for Waste Stream OR-NFS-CH-HET
- Notification to EPA upon completion of AK accuracy reports, new WSPFs, or revisions to existing WSPFs (and attachments)

Following EPA approval, at the end of each fiscal quarter, ORNL-CCP must provide EPA with information on T2 changes. EPA will evaluate these changes and inform ORNL-CCP whether the changes raise any concerns and require a response or if ORNL-CCP can continue to implement those changes.

CH NDA Tiers

Tier 1 NDA Changes require EPA review and approval prior to implementation. They include the following:

- New NDA equipment other than the DWAS IPAN/SGS system¹
- Physical modifications to the DWAS IPAN/SGS NDA system approved²
- Extension or changes of the approved calibration range(s) for the DWAS IPAN/SGS system

The last bulleted item above refers to the extension of a system's approved calibration range with respect to determination of the disintegration rate (activity) or physical characteristics (matrix) of any of the two NDA systems approved as a result of this inspection. An EPA technical inspection involves the evaluation of several characteristics of a measurement system. A key characteristic is the range of conditions for which the instrument is capable of producing technically defensible data with respect to the following two aspects:

- Activity—the nuclear disintegration rate of specific radiation types (neutron or gamma), typically special nuclear material or TRU radionuclides; units of activity and mass are interchangeable
- Physical characteristics—the physical attributes of waste matrices as they relate to a radiometric system (i.e., how the matrix's physical properties interact with the radiations that originate within the sample and affect the system's ability to detect them); examples include attenuation of photons (gamma) and moderation and absorption of neutrons

During the inspection, the system's technical capabilities being evaluated represent the conditions observed, and they define the operational envelope in which WIPP measurements will occur. Changes to a system's calibrated range with respect to disintegration rate and/or matrix may represent an essentially different set of conditions from those evaluated during the inspection. For this reason, a change to a system's calibrated range is considered a T1 change. A system's operating range is generally, but not always, a subset of a calibration range; that is, systems that are calibrated to make valid neutron measurements from 0.36 g to 30.1 g ²⁴⁰Pu_{EFF} may operate in a subset of this range. This typically occurs when a system is calibrated for material control and accountability (MC&A) measurements as well as for WIPP assays, as is the case with many NDA systems used for TRU assays. Provided the system's calibrated range is valid, a site can designate a different operating range(s) within the calibrated range as a T2 change (i.e., a subset of the calibrated range).

¹ New NDA equipment refers to a system or component not previously evaluated by EPA at ORNL-CCP. Specifically, this is defined as a physically distinct or different system or apparatus; an assay system that is reported to be the equivalent of or identical to a previously approved system, but which EPA has not formally inspected and approved, is a new system and EPA must approve it prior to its implementation to characterize WIPP wastes.

² Physical modification to the DWAS IPAN/SGS system includes all changes and/or modifications to this system that have the potential to affect the quality of NDA data used for the purposes of WC and/or waste isolation. This does not include minor changes or safety-related changes (e.g., addition of handrails) that do not have the potential to affect WC data.

Similarly, for physical characteristics, NDA systems are often calibrated with respect to a range of sample attributes—for example, a matrix density range upper limit of 0.72 g/cm^3 for the DWAS SGS component or an ABSMOD index range of 22.251 to 276.800 for the active neutron mode of the DWAS IPAN, discussed earlier in this report. This range may include materials that are commonly referred to using terms such as “debris (S5000),” which is within the calibrated density range and would be expected to be within the ABSMOD range. Actual waste assays may be restricted to a portion or subset of this range for a variety of technical and/or administrative reasons. Changing the calibrated range by extending the density range beyond 0.72 g/cm^3 for the DWAS SGS unit, the MOD range beyond 1.045 to 17.572, or the ABSMOD range beyond 22.251 to 276.800 for the DWAS IPAN unit is a T1 change. Provided the original approved density range is valid, changing the operational range(s) of an approved NDA system—that is, decreasing it relative to the originally approved range—is a T2 change, as discussed below.

ORNL-CCP will report and submit documentation for T1 changes when it is ready for EPA review. In the case of the first two T1 NDA changes listed above, CBFO should assume that an EPA inspection is likely. In the case of the last T1 NDA change, EPA will inform ORNL-CCP and CBFO whether a site inspection is necessary. EPA may request additional information, choose to conduct a desktop review, and/or confer with ORNL-CCP NDA personnel. Upon evaluation (with or without site inspection), EPA will issue an approval letter. Only upon receiving the EPA approval can ORNL-CCP continue to use the equipment affected by the change.

Tier 2 NDA Changes do not require prior EPA approval but do require ORNL-CCP to notify EPA upon implementation of such changes and to submit a brief description of the changes. These include the following:

- Changes to software for the DWAS IPAN/SGS system
- Changes to the approved operating range(s) for either the SGS or IPAN operating range(s) (see discussion above)
- Changes to procedures that address the DWAS IPAN/SGS system's calibration and/or operation that require CBFO approval

Examples of changes to software would include the following:

- Changing a system's operating system (e.g., first use of NDA 2000, MGA, or PCFRAM)
- Identification of a systematic problem with a software package and subsequent modifications to address the problem, (e.g., use of an incorrect value for a radionuclide's transition probability or branching ratio in the data reduction software)
- Introduction of a new version of an existing software package beyond what is in currently
- Use

Regarding changes to the approved operating ranges, reducing a system's operating range because of performance-related problems or equipment failure would be a T2 change. For

example, if the DWAS failed to pass a PDP cycle for a specific matrix or activity range and ORNL-CCP or CBFO formally restricted its use as a result of those, this would be a T2 change.

Any changes to the WC activities from the date of the baseline inspection must be reported to and approved by EPA according to Table 1. Following EPA approval, ORNL-CCP will provide EPA with information concerning T2 changes at the end of each fiscal quarter. EPA will evaluate these changes and communicate with ORNL-CCP as to whether the changes raise any concerns and require an ORNL-CCP response, or whether ORNL-CCP can continue to implement the changes. Consistent with EPA's authority under 40 CFR 194.24(h), the agency may request information relative to these changes if EPA deems the information is necessary to ensure continued compliance with EPA regulations.

CH RTR Tiers

Tier 1 NDA Changes require EPA review and approval prior to implementation. There are no T1 RTR changes at this time.

Tier 2 RTR Changes that do not require EPA approval prior to implementation but require reporting and submission of documentation discussing changes by ORNL-CCP include the following:

New RTR equipment or substantive changes to approved RTR equipment
Changes made to ORNL-CCP RTR procedure(s) that require CBFO approval

Every 3 months from the date of EPA approval, ORNL-CCP will provide information concerning T2 changes. If new RTR equipment is in use, an EPA inspection may be necessary. EPA will evaluate changes and communicate with ORNL-CCP whether the changes raise any concerns and require a response from ORNL-CCP, or whether ORNL-CCP can continue to implement the changes.

CH WWIS Tiers

Tier 1 WWIS Changes that require EPA review and approval prior to implementation include the following:

- Addition of load management for CH TRU containers at ORNL-CCP

ORNL-CCP will report and submit documentation for T1 changes when it is ready for EPA review. Upon initial review, EPA will inform ORNL-CCP and CBFO whether a site inspection is necessary. EPA may request additional information, choose to conduct a desktop review, and/or confer with ORNL-CCP WWIS personnel. Upon evaluation (with or without site inspection), EPA will issue an approval letter. Only upon receiving the EPA approval can ORNL-CCP implement the load management or any other activity deemed to be a T1 change for WIPP wastes.

Tier 2 WWIS Changes that do not require EPA approval prior to implementation but that require reporting and submitting documentation include the following:

- Changes made to WWIS procedure(s) that require CBFO approval

Every 3 months from the date of EPA approval, ORNL-CCP will provide information concerning T2 changes. EPA will evaluate changes and communicate with ORNL-CCP whether the changes raise any concerns and require ORNL-CCP response, or whether ORNL-CCP can continue to implement the changes.