ENTERED

Maestas, Ricardo, NMENV

From: Allen, Randall - CTAC <randall.allen@wipp.ws>
Sent: Tuesday, February 12, 2013 11:37 AM
To: Maestas, Ricardo, NMENV
Cc: Harvill, Joe - CTAC; Miehls, Dennis - DOE; Navarrete, Martin - DOE
Subject: RE: Refresher Presentations
Attachments: 2013 CBFO Auditor-Tech Spec Refresher training.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Ricardo,
Per your request, I have a ached a PDF version of the slides presented during our refresher training.
Dennis and Mar ns E-Mail addresses:
Dennis.Miehls@wipp.ws
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Randall Allen
CTAC Audits & Assessments Mgr
CBFO Technical Assistance Contract (Portage, Inc.)
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4021 National Parks Hwy
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From: Maestas, Ricardo, NMENV [mailto:Ricardo.Maestas@state.nm.us]
Sent: Tuesday, February 12, 2013 9:22 AM
To: Allen, Randall - CTAC
Cc: Harvill, Joe - CTAC
Subject: Refresher Presentations

Good morning Randall,

Could you please send over the power point presenta ons for yesterday's refresher.
Could you also give the Dennis's and Mar n's email address. I'll let them know I'll be sending the latest dra of our NMED Observer Protocol soon.

Thanks!

Ricardo Maestas
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130215

CBFO-QA/CTAC Auditor Refresher Training – February 11, 2013

8:00 am	Welcome – Introductions – Administrative Issues - Allen
8:30 am	CBFO QA Welcome/Comments
8:45 am	Update on AK Issues / RH TRU Waste & the WCPIP - Blauvelt
9:30 am	Break
9:15 am	What is Still Out There - Blauvelt
10:00 am	Break
10:15 am	CAR Trend Report - Littlefield
11:00 am	Lunch
12:30 pm	Concerns, Issues, and Corrective Action Reports - Allen
1:30 pm	Break
1:45 pm	Recent Permit Modifications and Current Modification Requests - Most
3:15 pm	Break
3:30 pm	Question/Answer – NMED & CBFO QA

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Update on AK Issues
RH TRU Waste and the WCPIP

Auditor Training

February 11, 2013

Dick Blauvelt

This Presentation Will Discuss

- Review of AK Issues
- Latest on RH TRU Waste Certification
- Waste Characterization Program Implementation Plan (WCPIP) Update
- Other Changes-Real and Proposed

WAP AK Issue

Delineation of TRU Waste Stream

- Generator Will Delineate a Waste Stream Population that the Waste Stream Definition Will Support
- This Can Lead to Discussion of Delineation Within the Definition

WAP AK Issue

Delineation of a TRU Waste Stream

Waste Stream Definition

Waste materials that have common physical form, that contain similar hazardous constituents and that are generated from a single process or activity

Old Definition

Waste material generated from a single process or from an activity that is similar in material, physical form and hazardous constituents

WAP AK Issue

Delineation of a TRU Waste Stream

WAC Definition waste materials that have common physical form, that contain similar hazardous constituents and that are generated from a single process or activity

WCPIP Definition waste material that is 1) generated from a single process/activity and 2) similar in material, physical form and radiological properties

WAP AK Issue
Assignment of RCRA HWNs

- The Permit requires appropriate HWNs be assigned and justified
- The generator applies HWNs based on AK record augmented by characterization testing
- These characterization tests rarely yield additional HWN assignments

WAP AK Issue
Assignment of RCRA HWNs

- Assignment of RCRA HWNs
  - WIPP is exempt from LDR Requirements
  - As a result, HWNs have been Assigned "Conservatively"
  - Generators should use AK for HWN Assignment and Justification in a Consistent and Credible Manner

WAP AK Issue
Assignment of RCRA HWNs

- The Permit Language in the WAP was Changed to Address Issue of "Conservative" Assignment of HWNs
- **Old** If discrepancies exist between required information, then sites <u>shall</u> apply all HWNs indicated by the information..unless sites choose to justify an alternative assignment and document the justification

WAP AK Change
Assignment of RCRA HWNs

- **New** If discrepancies exist between required information, then sites may consider applying all HWNs indicated by the information, but must assess and evaluate the information to determine the appropriate HWNs *consistent with the RCRA requirements*

WAP AK Issue
Assignment of RCRA HWNs

- Waste Stream Specific Requirement
  - Documentation regarding how the site has historically managed the waste, including the historical regulatory status of the waste (i.e. HWNs assigned if any)

WAP AK Change
Assignment of RCRA HWNs

- Procedures are required "that ensure the assignment of EPA HWNs is appropriate, *consistent with the RCRA requirements*, and considers site historical waste management"

WAP AK Issue
Assignment of RCRA HWNs

- If Different Sources of Information Indicate Different Hazardous Wastes are Present, the Sites Shall Include All Sources of Information in its Records and may Choose to Either *Conservatively* Assign HWNs or Assign Only Those Deemed Appropriate and Consistent with RCRA Requirements

Other Language To Note

- Generator/Storage Sites Developed Criteria to Determine the Specific Circumstances under which a WSPF is Revised versus when a new WSPF is Required

- This is <u>Not</u> the WSPF Change Notice Process (But See CCP-TP-002 R24)

WSPF Change for 2012

- The Waste Stream Profile Form Change Notice (CN) is gone
- The CN has been Replaced (When Needed) by a WSPF Revision
- AKS Revised
  - Add TRUCON Codes
  - Revise Waste Stream Volume
  - WMPWE Change

AKSD Process

- AK Sufficiency Determination Process
  - Allows Approval of Waste Streams Without Chemical S&A and/or Without VE/RTR
  - Stipulations Added 3 Scenarios
  - Scenario 1-Neither VE/RTR nor Chemical sampling Required
  - Scenario 2-VE/RTR No-Chemical Sampling Yes
  - Scenario 3-VE/RTR Yes-Chemical Sampling N0

AKSD Experience

- Eight AKSDs Have Been Reviewed and Approved by the Permittee and NMED
- HSG AKSD for LANL RH debris stream submitted 05/02/07 (Approved 04/29/09 after only 727 days)
- HSG AKSD for BCL RH debris stream submitted 09/04/07 (Approved 3/13/09 after only 586 days)
- Six More BCLDP Waste Streams

AKSD Process Changes

- A Public Meeting must be held for each AKSD Approved by CBFO
- Comments must be Addressed and Submitted to NMED along with the AKSD for Review and Approval
- Only One AKSD at a Time Can be Submitted to NMED
- The Permittees Must Submit a List of Potential AKSDs for the Next Fiscal year by July 1

AKSD Process

- In 2011 the BCLDP Debris at Hanford was Submitted as a AKSD Candidate
- In 2012 the Request was Amended to IN-ID-BTO-030, an RH S3000 Stream Originally Generated at Bettis

Tracking WAP Compliance

- At First Audit of 2011 (ORNL)
  - Agreed on Path Forward for Existing AKSs
  - Documented Changes to Procedures and AKSs
  - Developed a Compliance Tracking Table
- Sites Completed the Table Prior to Audit
- Only Waste Streams Being Audited by AK Required AKS Review
- Changes Needed to AKSs Become a Freeze File and Recommended for Future Inclusion
- **In CY 2012 Audits, CCP and AMWTP Demonstrtated Full Compliance with this Process**.

Other Interesting Issues

- Observable Liquid-Liquid that is observable using RTR or VE
- Observable Liquid Shall be Less than 1% by Volume of the Outermost Container at the time of RTR or VE
- Internal Containers with More than 60ml or 3% by Volume observable liquid, whichever is greater, are prohibited

Other Issues

- Containers with HWN U134 Assigned Shall Have no Observable Liquid (Also PCBs)
- Overpacking the Outermost Container That was Examined During RTR or VE or Redistributing Untreated Liquid Within the Container Shall Not be Used to meet the Liquid Volume Limits

Impact of Observable Liquid

- Waste Containers with Observable Liquids are Being Identified
- Judgement Calls are Made Regarding the Criteria

Other Issues

- Significant Effort by CCP to Assure Proper Designation of AK Source Documents
- Only Those AK Source Documents Used to Develop the AK Summaries are Listed
- CTAC Assures that all Source Docs (and AK attachments) are in Records

RH TRU Waste

- ANL Debris Stream at INL-Shipping (Still)
- ANL Debris Stream at ANL-Shipping
  - One Stream, 7 Radiological Distributions
- ORNL RH Debris Stream- On Hold
- BCL RH Debris Stream-Shipped (Except Hanford)
- LANL 16 Canisters-Shipped
- GE Vallecitos Debris-Shipped
- BAPL-Shipped

RH TRU Waste

- SNL-HCF-S5400-RH-Shipped
- ID-HFEF-S5400-RH-Shipped
- ID-MFC-S5400-RH Shipped
- ID-RTC-S3000 Shipped
- ID-INTEC-RH Shipped
- IN-ID-NRF-153 Shipping
- IN-ID-NRF-SPC Shipping
- SR-RH-FBL.01 Shipped

RH TRU Waste

- More RH Streams at INL
- More RH Streams at SRS
- More RH Waste at ORNL
- More RH Waste at LANL
- More RH Waste at Hanford

RH TRU Waste and the WCPIP

- WCPIP Developed to Address Unique Properties of RH Waste That Impact Characterization and Certification
- Developed to Address DQOs of Interest to EPA, i.e. Radiological and Physical Parameters and Residual Liquids > 1%

RH TRU Waste and the WCPIP

- Rev 0 Issued October 30, 2003
- Draft of Revision 1 Issued in July 2006 and Received Comments From EPA in Feb 2007
- Comments Received were Problematic and We Have Continued to Work to Rev 0
- A Second Attempt at Rev 1 was Finalized in March 2009
- Removed Pkg. Information to TRAMPAC and Added Section on AK Qualification by Use of Corroborating Data

RH TRU Waste and the WCPIP

- AK Is Compiled to Address the Relevant DQOs
  - Defense Determination
  - TRU Waste Determination
  - RH Determination
  - Activity Determination
    - Total Activity
    - <23 Ci/L
    - Ten Tracked Radionuclides

RH TRU Waste and the WCPIP

- AK Is Compiled to Address the Relevant DQOs
  - Physical Form (CPR, Ferrous and non-Ferrous Metals)
  - Residual Liquids (> 1%)

RH TRU Waste and the WCPIP

- For Each DQO (Except Defense Det.) the AK Must be Qualified By,
  - Confirmation
  - NQA-1 Equivalency
  - Peer Review
  - Corroborating Data
- AK That Does Not Quantify, Does Not Need to be Qualified 40CFR194.24 c(3)

RH TRU Waste and the WCPIP

- Confirmation Activities (Physical DQOs)
  - 100% VE (GEV, ORNL, et. al.)
  - 100% RTR (ANL at INL)
  - RTR(VE) 10-10-All (Not Used….Yet)
  - Review of existing VE/RTR Tapes (ANL, BCL)

RH TRU Waste and the WCPIP

- Confirmation Activities (Rad DQOs)
  - NDA
  - DA
  - Dose to Curie
  - Use of Representative Sampling Data
  - Use of Modeling (ORIGEN)

RH TRU Waste and the WCPIP

- NQA-1 Equivalency
- Used to Qualify AK Data Not Compiled Under a Certified Program
- Must Demonstrate That Data was Collected Under the Umbrella of an “NQA-1 Like” Program

RH TRU Waste and the WCPIP

- NQA-1 Equivalency Used to Qualify AK for Several RH Streams Examined to Date
- For BCL and LANL, Essentially All Data was Collected "Historically"
- NQA-1 Qualified Data Has Then Been Used in Other Qualification Methods (e.g. LANL Fuel Pin Mass Spec Data and ORNL Smear Data Used in Rad Confirmation)

RH TRU Waste and the WCPIP

- Peer Review
  - Used to Qualify LANL RH Packaging Records
  - Group of Unbiased Experts Extensively Reviewed the Data and Judged It to be "OK"
  - State Accepted Review of the Packaging Records… Eventually
  - Peer Review Used to Qualify Rad Results for BCLDP Filter Samples

Corroborating Data

- Characterization Data from related Waste Source or from a Different Time period of Generation
- Data from a related CH or RH waste Source
- Direct Analytical results from samples taken from the stream that are not adequate to address a given QAO requirement but sufficient to meet a DQO
- Data from a similar waste process generated at a different site or facility
- Corroborating Data Used to Support Rad Characterization of Sabotage Drum

RH TRU Waste and the WCPIP RH Documents

- CCP Has Prepared One AK Summary Report (5X0) Satisfying Both Sets of Requirements (WAP and WCPIP) But
- There is a WCPIP Rad Characterization Report (5X1)
- There is a WCPIP "NQA-1 Like" Report (5X3)

RH TRU Waste and the WCPIP

- There is a Certification Plan for 40CFR194 Compliance (5X2)
- RH Waste May have Sampling Plans (5X5)
- The WCPIP Requires a Characterization Reconciliation Report (CRR) (More Documentation of Meeting DQOs and QAOs)

WCPIP Rev 2

- Revision to the WCPIP Began in Fall of 2009 in Interactions with EPA
- Overall objective was to "Clarify the Language and the Process" to Reflect Actual Practice (and Get Buy-in on Corroborating Data)
- The Exercise Took Longer Than Anticipated
- Finally Approved April 21, 2011

WCPIP Rev 2

- The AK and DTC Procedures in the Appendix were Deleted
- The Contents were Completely Reordered and the Document Objectives Clarified
- Entire Document was Reviewed Line by Line
- Significant Changes and Additions were Made in the Section on Radiological Characterization Methods
  - Determination of Absolute Concentrations in Waste
  - Sampling to Confirm or Derive Radionuclide Distributions

WCPIP Rev 2

- The Document Achieves Consensus on Understanding and Implementation
- One WSPF
- CCP-TP-005 was Revised to Incorporate AK Procedures Removed from the PIP

WCPIP Rev 3

- Rev 3 of the WCPIP was Issued September 19, 2012
- Mostly Editorial Changes
- Language Modifed Slightly in AK Qualification Section
- Little or No Impact on Implementation

Miscellaneous Other Changes Real or Proposed

- Calc. Packages Referenced in the Rad Characterization Technical Reports are not AK Source Docs
- Change Notice to WSPF May Return
- May Be a Permit Mod. Regarding HSG and Solids Sampling

Questions?

What is Still Out There?

Auditor Training
February 11, 2013

Dick Blauvelt

This Presentation Will Discuss

- History
- Who Has Shipped?
- Who is Shipping?
- What is Still to Come?

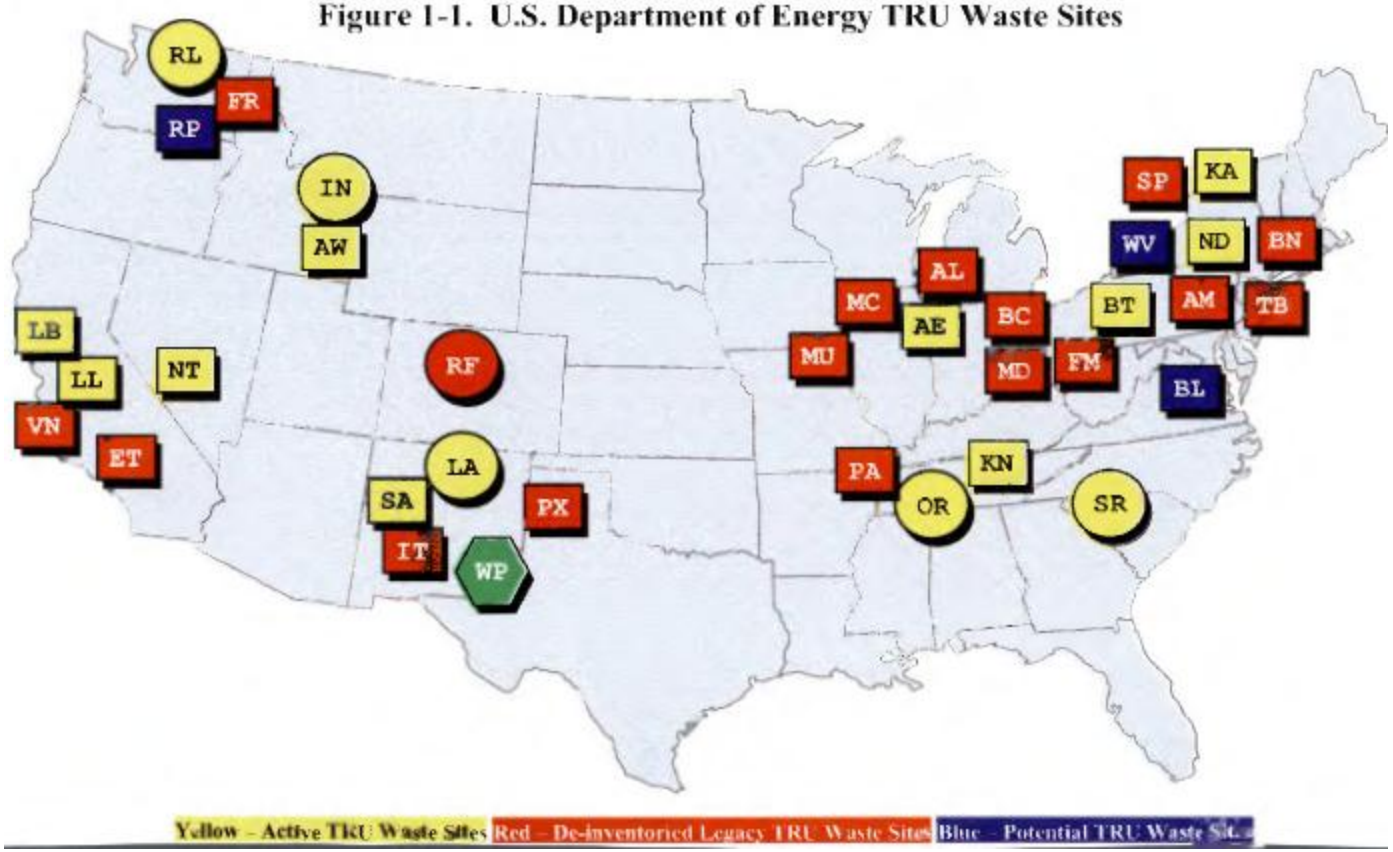
A Bit of History

- WIPP-”Ready For Waste in 88”
- WIPP-”Getting It Done in 91”
- First Shipment Received March 26, 1999 From LANL (The Quest for RCRA Free Waste)
- 500th Shipment January 7, 2002
- 5000th Shipment September 11, 2006
- 10000th Shipment October 22, 2011

A Bit More History

- In 14 Years of Operation WIPP Has Received 11100+ Shipments
- WIPP Trucks Have Traveled More Than 13.3 Million Miles
- WIPP Has Emplaced 85500+ M3 of Waste

Figure 1-1. U.S. Department of Energy TRU Waste Sites



AE	Argonne National Laboratory
AL	Ames Laboratory — de-inventoried
AM	ARCO Medical Products — de-inventoried - shipped to the Offsite Source Recovery Program (OSRP)
AW	Materials and Fuels Complex
BC	Battelle Columbus Laboratories— de-inventoried - shipped to RL and SR
BL	Babcock and Wilcox Nuclear Energy Services (Potential)
BN	Brookhaven National Laboratory— de-inventoried - shipped to OSRP
BT	Bettis Atomic Power Laboratory —de-inventoried of legacy TRU waste; has continuing mission
ET	Energy Technology Engineering Center— de-inventoried - shipped to RL
FM	Fernald Environmental Management Project— de-inventoried - shipped to OSRP
FR	Framatome— de-inventoried - shipped to RL
IN	Idaho National Laboratory
IT	Inhalation Toxicology Research Institute (Lovelace Respiratory Research Institute) — de-inventoried - shipped to SA
KA	Knolls Atomic Power Laboratory-Schenectady
KN	Knolls Atomic Power Laboratory-Nuclear Fuel Services — de-inventoried of legacy TRU waste; has continuing mission
LA	Los Alamos National Laboratory
LB	Lawrence Berkeley National Laboratory — de-inventoried of legacy TRU waste; has continuing mission
LL	Lawrence Livermore National Laboratory — de-inventoried of legacy TRU waste; has continuing mission
MC	U.S. Army Materiel Command (Army) — de-inventoried of legacy TRU waste
MD	Mound Plant – de-inventoried - shipped to SRS
MU	University of Missouri Research Reactor — de-inventoried - shipped to AE, then to WIPP
ND	Nuclear Radiation Development Site, Inc. —de-inventoried of legacy waste; has continuing mission
NT	Nevada Nuclear Security Site – de-inventoried of legacy waste; has continuing mission
OR	Oak Ridge National Laboratory
PA	Paducah Gaseous Diffusion Plant (found to be non-TRU waste)
PX	Pantex Plant—shipped to LA then to WIPP
RF	Rocky Flats Environmental Technology Site — de-inventoried - shipped to WIPP
RL	Hanford Site (Richland Operations Office)
RP	Hanford Site (Office of River Protection) (Potential)
SA	Sandia National Laboratories — de-inventoried of legacy TRU waste; has continuing mission
SP	Separations Process Research Unit (found to be low level waste)
SR	Savannah River Site
TB	Teledyne Brown Engineering — de-inventoried - shipped to RF, then to WIPP
VN	General Electric Vallecitos Nuclear Center — de-inventoried - RH shipped to WIPP, CH shipped to IN
WV	West Valley Demonstration Project (Potential)
WP	Waste Isolation Pilot Plant

Active TRU Waste Sites (Formerly LQS)

- INL
- LANL
- SRS
- ORNL (on hold)
- Hanford (on hold)

Active TRU Waste SQ Sites

- ANLE-WIPP/intersite
- Bettis-WIPP/intersite
- Knolls-intersite
- LLNL-to WIPP/INL
- LBL-to INL
- AW-to WIPP
- NTS-to WIPP/INL
- Knolls NFS
- Sandia-intersite
- Nuclear Radiation Dev. Site-intersite

Small Quantity Sites (deinventoried)

- Ames-to ANL
- Brookhaven-to OSRP
- Mound-to SRS
- BCL-to RL and SRS
- MURR-to ANL
- Pantex-to LANL
- SPRU-LLW
- GE Vallecitos-to WIPP and RL
- ITRI-to Sandia
- Teledyne Brown-to RFETS/WIPP
- ARCO Medical Prod.-to OSRP

Small Quantity Sites (deinventoried)

- Framatome-to RL
- Fernald-to OSRP
- ETEC-to RL
- GE Vallecitos-to WIPP and RL
- Paducah-non-TRU
- USAMC-intersite

Estimating Stored Volumes and Future Projections

- Projecting Stored/Projected Volumes is Problematic
  - Sites Began Storing Waste "Retrievably" in the Early 1970s at LANL, Hanford, Idaho, Nevada and Savannah River
  - The Storage was/is in Most Cases in an Earthen Mound
  - The Waste was Characterized for Shipment and/or Disposal
  - Storage/Burial Records are not Complete
  - Much of the Waste Is Suspect TRU
  - There was the "90s Effect"

Estimating Stored Volumes and Future Projections

- Projecting Volumes of Waste TBG is Problematic, Nevertheless
- The Planning, Decision-Making, Here's What is Coming Tool for WIPP is the Annual Transuranic Waste Inventory Report (ATWIR)
- The Data is Compiled from the Generator Sites and the WIPP WDS
- It is Entered into the Comprehensive Inventory Database (CID)

Tru Waste Baseline Inventory Report (TWBIR)

- Important for EPA Compliance Certification Application (CCA)
- 1995 Version "Supported" the First CCA Decision.
- A Recertification was Due 5 Years After the First Emplacement or March 26 2004.

2004 CRA

- Based on TWBIR Site Data as of September 2002 (TWBIR 2004) Plus 3/4/2005 Update (INL+ Hanford-)
- Another CRA was Submitted in March of 2009 Based Upon ATWIR 2007 (TWBIR 2004)
- EPA Requested and Received an Update and Reviewed the 2009 CRA (ATWIR 2008/PAIR-2008)
- Recertification Received November 18, 2010
- Working on Next Submittal (2014)

Data Compiled

- Volumes (Stored and Projected)
- Waste Material Parameters
- Packaging Materials
- Complexing Agents
- Oxyanions
- Radionuclides (168 specific radionuclides)

Table 1-1. Historical Inventory Documents

Date	Title	Purpose
June 1994	WIPP Transuranic Waste Baseline Inventory Report	First attempt made by DOE complex to report all of its TRU waste at the waste-stream level.
December 1995	Transuranic Waste Baseline Inventory Report (TWBIR), Revision 2	Revisions 2 and 3 provided the inventory information to the Sandia National Laboratories-Carlsbad for the initial certification of WIPP.
June 1996	TWBIR, Revision 3	
March 2004	Appendix DATA, Attachment F of *Title 40 CFR 191, Subparts B and C, Compliance Recertification 2004*	Provided updated inventory information for the first recertification of WIPP in 2004.
March 2006	Transuranic Waste Baseline Inventory Report 2004	This was a revision of Appendix DATA, Attachment F. Provided updated inventory to support the Performance Assessment Baseline Calculation.
August 2008	Annual Transuranic Waste Inventory Report (ATWIR)–2007	The first annual inventory report that contained both scaled (calculations to represent a full repository) and unscaled data.
December 2008	ATWIR–2008	Annual inventory report that reported only unscaled data.
April 2009	Performance Assessment Inventory Report–2008	Provided data from ATWIR-2008 in the required format for performance assessment calculations.
December 2009	ATWIR–2009	Provided updated annual inventory information.
December 2010	ATWIR–2010	Provided updated annual inventory information.
December 2011	ATWIR–2011	Provided updated annual inventory information.

2012 ATWIR
CH/RH Volume Changes

	2011	2012	
Hanford	21700M3	22500M3	+853M3
INL	35300M3	28500M3	-6760M3
LANL	10200M3	9960M3	-290M3
ORNL	1420M3	1560M3	+138M3
SRS	9700M3	7390M3	-2320M3
SQS	1730M3	1600M3	-126M3
Total	*80000M3*	*71500M3*	*-8500M3*

2012 ATWIR

- Latest Published CH Data (12/31/2011)
- INL 28100M3 Stored 34900M3
- LANL 6800M3 Stored 6950M3
- RL 15800M3 Stored 16900M3
- SRS 3370M3 Stored 4420M3
- ORNL 835M3 Stored 889M3
- Other Sites 285M3 Stored 341M3

2012 ATWIR

- Projected Volumes of CH TRU (Doesn't "Currently" Exist in Any Form)

INL	150.0 M3	0.0
Hanford	4300 M3	2490
LANL	3080 M3	3220
ORNL	110 M3	64.9
SRS	3980 M3	5240
Other Sites	1370 M3	1185

2012 ATWIR

- Latest Published RH Data (12/31/2011)
- INL 230M3 Stored 387
- MFC 8.85M3 Stored 16.8
- LANL 79.2M3 Stored 79.2
- RL 1530M3 Stored 1440
- ORNL 458M3 Stored 447
- SRS 29.7M3 Stored 40.6
- O. S. 46.2M3 Stored 22.4

2012 ATWIR

- Projected Volumes of RH TRU (Doesn't "Currently" Exist in Any Form)
  - LANL 0.0 M3 0.0
  - Hanford 914 M3 851
  - INL 0.0 M3 0.0
  - MFC 100 M3 96.1
  - ORNL 155 M3 18.7
  - SRS 11.2 M3 8.7
  - Other Sites 23.0 M3 41.6

Potential TRU Waste

- Currently Not Slated for Shipment
  - Insufficient Waste Information
  - No TRU Determination
  - Non Defense Issue
  - Other Regulatory or Physical Condition
    - RH > 23 Curies
    - RH > 1000 Rem/hr
    - TRU with D001, D002, D003

Potential TRU Waste

- Currently Not Slated for Shipment
  - Pre 1970 Buried TRU Waste
  - All Waste Streams from the ORP
  - Potential TRU Volumes
    - 8190M3 CH TRU
    - 1520M3 RH TRU
  - Notable Potential Sites
    - West Valley (1717 M3 CH)
    - Hanford ORP (1556 M3 CH, 474 M3 RH)

Bottom Line

- There is CH and RH TRU Waste Still Needing WIPP and/or TRAMPAC Characterization and Certification
- Characterization and Certification will be More Difficult and Yield Smaller Volumes
- CTAC Should Have a Role in These Activities

Questions?

CAR Trend Report

Monthly and Semi-Annual

CTAC - 14 Jan 2013

PORTAGE

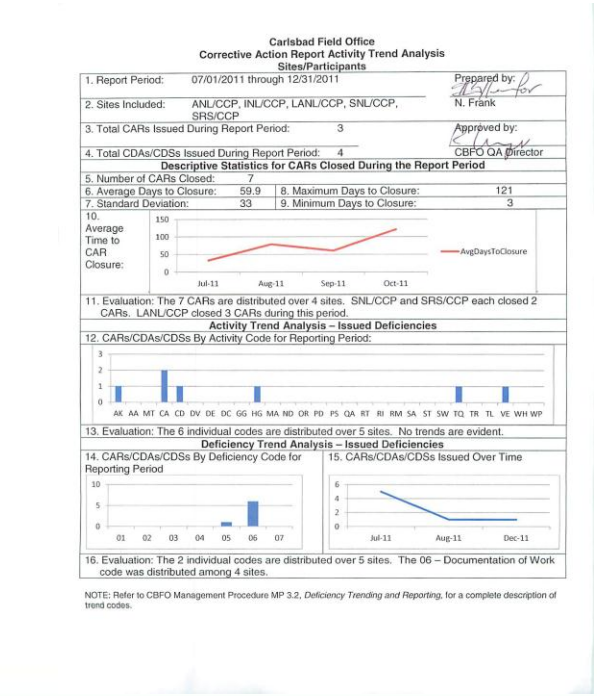
Driving Requirement

- CBFO Management Procedure 3.2, Section 5.3 requires that CBFO QAM publish “a semiannual draft Deficiency Summary that identifies the number of deficiencies by Activity Category code number and Deficiency Category code number.”

- The report is to be distributed to the CBFO upper management and the “Responsible Organizations” to take action on adverse trends.

“Before” versus “After”

Historically, report content included…	For the future, CBFO QAM requested…
Focus on the six month window only.	View of multiple periods for trending.
Primarily descriptive statistics.	Primarily presents visual graphics.
Analysis centered on the statistics.	Report of events and actionable trends.



Carlsbad Field Office
Corrective Action Report Activity Trend Analysis
Sites/Participants

1. Report Period: 07/01/2011 through 12/31/2011
2. Sites Included: ANL/CCP, INL/CCP, LANL/CCP, SNL/CCP, SRS/CCP
3. Total CARs Issued During Report Period: 3
4. Total CDAs/CDSs Issued During Report Period: 4

Prepared by: N. Frank
Approved by: CBFO QA Director

Descriptive Statistics for CARs Closed During the Report Period

5. Number of CARs Closed: 7
6. Average Days to Closure: 59.9
7. Standard Deviation: 33
8. Maximum Days to Closure: 121
9. Minimum Days to Closure: 3
10. Average Time to CAR Closure: AvgDaysToClosure — Jul-11, Aug-11, Sep-11, Oct-11
11. Evaluation: The 7 CARs are distributed over 4 sites. SNL/CCP and SRS/CCP each closed 2 CARs. LANL/CCP closed 3 CARs during this period.

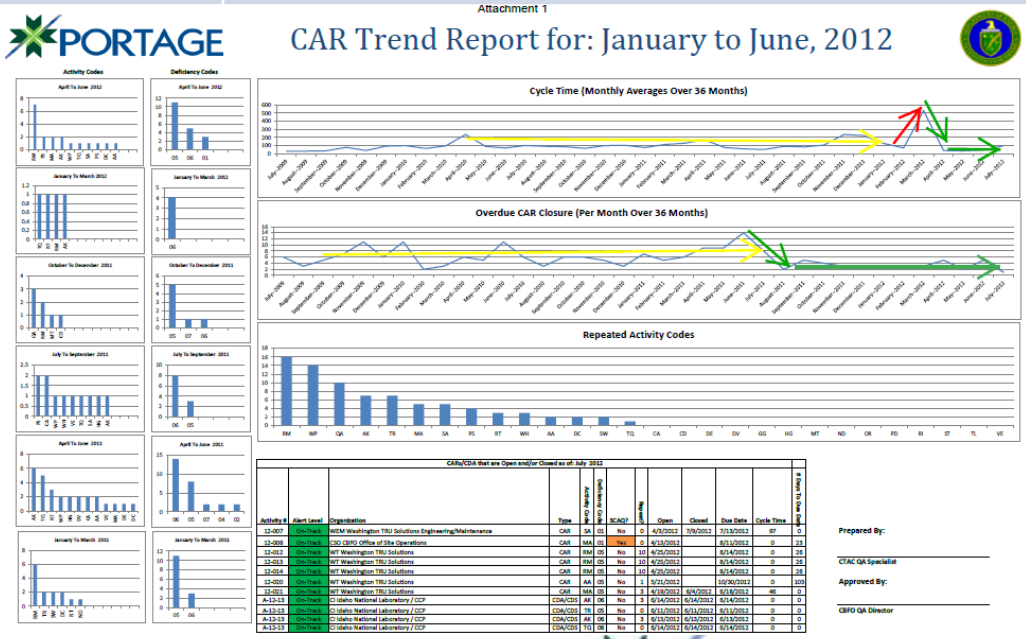
Activity Trend Analysis – Issued Deficiencies

12. CARs/CDAs/CDSs By Activity Code for Reporting Period: AK AA MT CA CD DV DE DC GG HG MA ND OR PD PS QA RT RI RM SA ST SW TQ TR TL VE WH WP
13. Evaluation: The 6 individual codes are distributed over 5 sites. No trends are evident.

Deficiency Trend Analysis – Issued Deficiencies

14. CARs/CDAs/CDSs By Deficiency Code for Reporting Period: 01 02 03 04 05 06 07
15. CARs/CDAs/CDSs Issued Over Time: Jul-11, Aug-11, Dec-11
16. Evaluation: The 2 individual codes are distributed over 5 sites. The 06 – Documentation of Work code was distributed among 4 sites.

NOTE: Refer to CBFO Management Procedure MP 3.2, *Deficiency Trending and Reporting*, for a complete description of trend codes.



Attachment 1

PORTAGE

CAR Trend Report for: January to June, 2012

Activity Codes — April To June 2012; January To March 2012; October To December 2011; July To September 2011; April To June 2011; January To March 2011

Deficiency Codes — April To June 2012; January To March 2012; October To December 2011; July To September 2011; April To June 2011; January To March 2011

Cycle Time (Monthly Averages Over 36 Months)

Overdue CAR Closure (Per Month Over 36 Months)

Repeated Activity Codes: RM WP QA AK TR MA SA PS RT WH AA DC SW TQ CA CD DE DV GG HG MT ND OR PD RI ST TL VE

CARs/CDA that are Open and/or Closed as of: July 2012

Activity #	Alert Level	Organization	Type	Activity Code	Deficiency Code	SCAQ?	Repeat	Open	Closed	Due Date	Cycle Time	# Days To Due Date
12-007	On-Track	WEM Washington TRU Solutions Engineering/Maintenance	CAR	SA	01	No	0	4/3/2012	7/9/2012	7/13/2012	97	0
12-008	On-Track	CBO CBFO Office of Site Operations	CAR	MA	01	Yes	0	4/13/2012		8/11/2012	0	23
12-012	On-Track	WT Washington TRU Solutions	CAR	RM	05	No	10	4/25/2012		8/14/2012	0	26
12-013	On-Track	WT Washington TRU Solutions	CAR	RM	05	No	10	4/25/2012		8/14/2012	0	26
12-014	On-Track	WT Washington TRU Solutions	CAR	RM	05	No	10	4/25/2012		8/14/2012	0	26
12-020	On-Track	WT Washington TRU Solutions	CAR	AA	05	No	1	5/21/2012		10/30/2012	0	103
12-031	On-Track	WT Washington TRU Solutions	CAR	MA	05	No	3	6/18/2012	6/4/2012	6/18/2012	46	0
A-12-13	On-Track	CI Idaho National Laboratory / CCP	CDA/CDS	AK	08	No	3	6/14/2012	6/14/2012	6/14/2012	0	0
A-12-13	On-Track	CI Idaho National Laboratory / CCP	CDA/CDS	TR	08	No	0	6/11/2012	6/11/2012	6/11/2012	0	0
A-12-13	On-Track	CI Idaho National Laboratory / CCP	CDA/CDS	AK	08	No	3	6/13/2012	6/13/2012	6/13/2012	0	0
A-12-13	On-Track	CI Idaho National Laboratory / CCP	CDA/CDS	TQ	08	No	0	6/14/2012	6/14/2012	6/14/2012	0	0

Prepared By:

CTAC QA Specialist

Approved By:

CBFO QA Director

PORTAGE

“Before” Explanation

- Report contains numerical statistics and four graphs.
- The graphs have a one-line description of what the graph depicts.
- The cover memorandum contains some level of analysis in text, but is focused on the statistics versus the events and trends.

“After” Explanation

- The three main objectives to address:
  - Cycle time: CAR issued until CAR closed.
  - Overdue: CAR closed after scheduled due date.
  - Repeated: CAR for same Activity and Deficiency within the same organization within three years.
- The assessment schedule covers three years, so the report covers three years - six semi-annual reporting periods for trending.

“After” Explanation (continued)

- The top run chart is for the average cycle time.
- Starting point is the issue date from CBFO QA.
- Ending point is the date CAR Closure Package is received from responsible organization.
- Since April of 2012, the average cycle time per month has been between 50 and 100 days.

“After” Explanation (continued)

- The second run chart is for the accumulated number of overdue CARs by month.
- Overdue is defined as a CAR submittal from the responsible organization being received after the expected due date.

“After” Explanation (continued)

- The Repeated Activity Codes Pareto chart in the middle of page is for repeat CARs.
- A repeat is defined as a CAR issued for the same Activity and Deficiency Codes to the same organization within a three year period.

“After” Explanation (continued)

- The series of Pareto charts on the left side bar are for Activity and Deficiency Codes by quarter. (NOTE: the Y-axis scale varies according to quantity)

- The table at the bottom of the page is the currently open CARs.

Other Potential Applications

- Almost any metric can be simplified to red, yellow, green conditions and measured as a trend.
- Assessments – cycle times of the stages (planned versus actual, report generation from closing meeting until published, findings, etc.)
- NCRs, ECOs, etc are also candidates.

Questions?

Thank you!

Quality Assurance

- **Provider of product or service**
  - **Provider's goals**
    - Efficiency $$
    - Stay in business – satisfy customer

- **Customer/Client/Stakeholder**
  - **Customer's goals**
    - Expectations/Specifications
    - Value and consistency

Changes

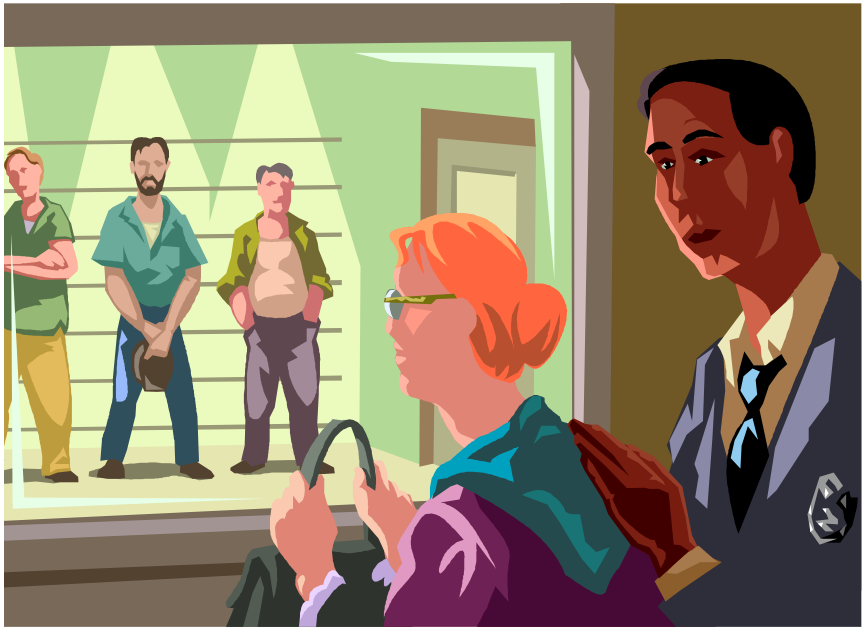
- CTAC Contract
- Change of CBFO QA
- Change of CBFO Management
- Changes to NMED Organization
- Change of M&O Contract

Change has a considerable physiological impact on the human mind. To the fearful it is threatening because it means that things may get worse. To the hopeful it is encouraging because things may get better. To the confident it is inspiring because the challenge exists to make things better.
King Whitney Jr.

He who rejects change is the architect of decay. The only human institution which rejects progress is the cemetery.
Harold Wilson

Corrective Action

Identification of Conditions Adverse to Quality



Permit Attachment C6

C6-1 Introduction

A deficiency is any failure to comply with an applicable provision of the WAP.

C6-4 Audit Conduct

• The site of DOE approved laboratory personnel will be given the opportunity to correct any deficiency that can be corrected during the audit period. Deficiencies and observations will be documented and included as part of the final audit report.

• Those items that affect the quality of the program, and/or the data generated by that program, which are required by the WAP will be documented on a Corrective Action Report.

• When a deficiency is identified by the audit team, the audit team member who identified the deficiency prepares the CAR. DOE reviews the CAR, determine validity (assures that a requirement has in fact been violated), classify the significance of the deficiency, assign a response due date, and issue the CAR to the site of DOE approved laboratory.

NQA-1

Corrective Action

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.

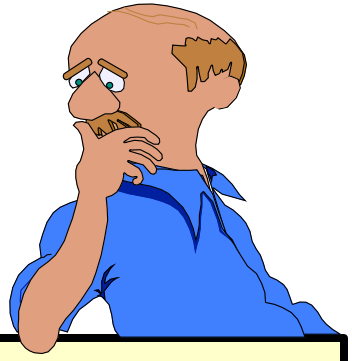
CBFO QAPD
1.3.3 Corrective Action

A CAQ occurs when a QA requirement has not been met.

Classification of CAQs is based on the effect the CAQ has on compliance to regulatory requirements for safety, operability, TRU waste characterization, TRU waste site certification, TRU waste containment, and the effective implementation of the QAPD. Any CAQs identified during CBFO audits or surveillances at the generator/storage sites that are determined to be noncompliant with an HWFP condition or requirement require corrective action plans (CAPs) ….

Concerns

Concerns:
Documentation of practices noted during the audit that could be dispositioned as an exemplary practice, a condition adverse to quality (CAR), a condition that is corrected during the audit (CDA), an Observation, or a recommendation as set forth in the standards, procedures, or DOE Orders that govern implementation of a given activity. The Audit Concern Form may be used to document issues for discussion during the team caucus.



Discuss with ATL to determine whether the concern is:

- Valid
- Self-disclosed by auditee
- Supported by the technical specialist

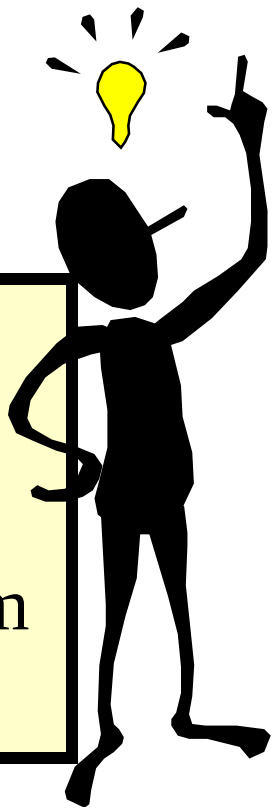
Levels of Concerns

- Exemplary Practices
- Recommendation
- Observation
- CDA
- CAR

Exemplary Practice

A practice that *significantly exceeds requirements* or is a particularly *innovative* or *effective* method for meeting requirements. An idea that can be recommended for use throughout the WIPP Project.

Recommendation



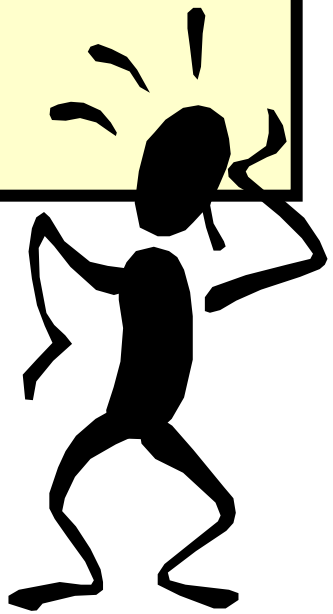
Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing process or quality program requirements.

Definition - Observation

Documentation of marginally acceptable conditions that, if not controlled, might later escalate into a deficiency. Observations are not deficiencies and do not require a response.

Definition - CAQ

An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies.



Definition – SCAQ, Part 1

A CAQ is considered significant when:

- **If uncorrected, the condition adverse to quality could have a serious effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the quality assurance (QA) program;**

Definition – SCAQ, Part 2

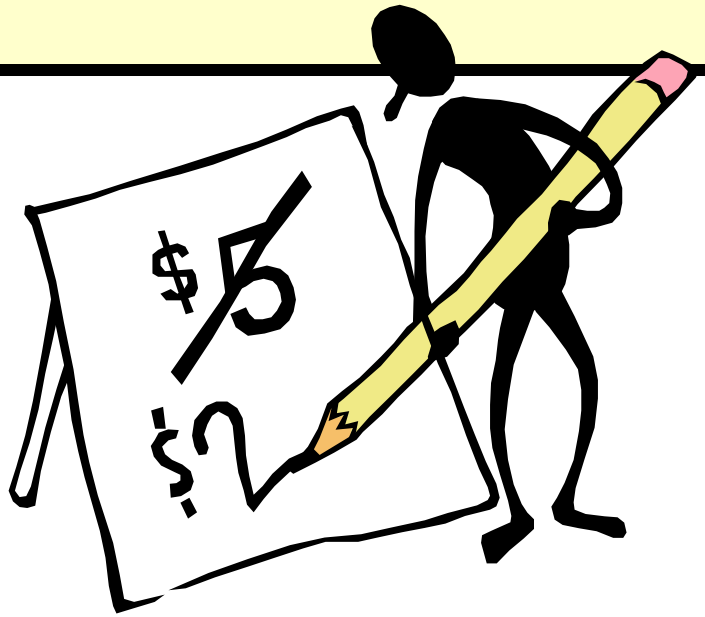
- **The condition adverse to quality requires immediate notification of regulatory entities (e.g., 10 CFR Part 21, HWFP Module I.E.13);**
- **The condition adverse to quality indicates a significant failure or breakdown in the implementation of QA Program requirements;**
- **Repeated attempts to resolve a condition adverse to quality have been unsuccessful;**

Definition – SCAQ, Part 3

- **The condition adverse to quality is identified in items or activities important to safety or waste isolation and compromises the ability to prevent or mitigate the consequences of an accident, thereby presenting a significant hazard to safety and health of workers and/or the public.**

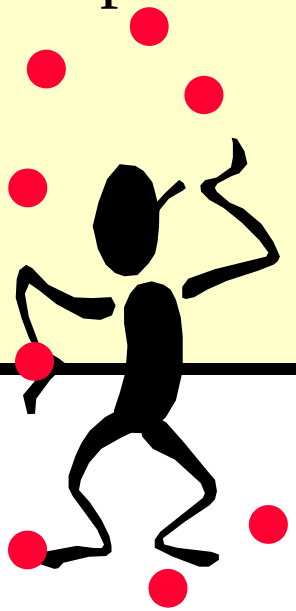
Definition - CDA

Isolated deficiencies that do not require a root cause determination or actions to preclude recurrence, and correction of the deficiency **<u>is</u>** verified prior to the end of the audit.



Definition - CAR

A document used to identify and rectify CAQs and track the associated corrective actions. CARs address CAQs that are primarily programmatic in nature, as opposed to nonconformance reports (NCRs), which address CAQs relating to a specific item such as a piece of hardware or data.



Input For CAQ/CDA

Input for CAQs and CDAs identified during the audit include:

- ❖The specific requirement violated
- ❖Description of the condition adverse to quality
- ❖How many of the objective evidence reviewed (sample size)
- ❖Total number of objective evidence (population)
- ❖Auditee personnel concern was discussed with
- ❖If the CAQ or CDA affects waste already shipped or certified to ship to WIPP and if so time, date and who was notified within the Office of the National TRU Program

This information is provided on the concern form.

Program Characteristics

- **Adequacy - Approved procedures contain all of the appropriate requirements from upper-tier documents.**
- **Implementation - Approved procedures are being followed.**
- **Effectiveness - Approved procedures are producing an acceptable product.**

CDAs

Corrected During The Audit (CDA) - Isolated Deficiencies

- **One or two forms not signed or not dated (isolated)**
- **One or two individuals have not completed a reading assignment (isolated)**
- **Corrected and verified prior to audit completion**

Identifying Quality Problems

- **There are pitfalls to allowing conditions adverse to quality to be corrected without initiating formal corrective action**
  - **May violate your own QA program requirements**
  - **Without a formal evaluation of the extent of the condition, CAQs that are, in fact, not isolated should have been a CAR**
  - **CDAs are trended**

Adequacy Concerns that are CAQs or Potential SCAQs

- ❖Requirements are missing/not addressed
- ❖Requirements are not correctly stated
- ❖Requirements are misinterpreted
- ❖Critical process steps are not described
- ❖Critical steps are out of sequence

Document these on a CAR in addition to the Concern Form; the audited organization is required to take positive corrective actions.

Implementation Concerns that are not tied to a requirement are not CAQs.

Implementation Concerns that are CAQs

- **Important or critical steps of the process are not being done**
- **Any step routinely not being done**
- **A previously identified CAQ where corrective action has not been initiated or it has been ineffective (repetitive)**