DATE: March 11, 2002


ATTN OF: Implementation of the Contact-Handled Transuranic Waste Acceptance Criteria for
the Waste Isolation Pilot Plant (DOE/WIPP-02-3122, Revision 0), TRUPACT-II
Authorized Methods for Payload Control (May 2001, Revision 19), and Quality Assurance Program Plan for TRUPACT-II Gas Generation Test Program
(DOE/WIPP-01-3187, Revision 1).

SUBJECT: To: Distribution

Based on the U.S. Environmental Protection Agency's recent approval of the
Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation
Pilot Plant (CH-WAC), the CBFO has established the implementation period of
approximately sixty days for meeting the requirements contained in the CH-WAC
(DOE/WIPP-02-3122, Revision 0), the TRUPACT-II Authorized Methods for Payload Control (TRAMPAC) (May 2001, Revision 19), and the Quality Assurance Program Plan (QAPP) for TRUPACT-II Gas Generation Test Program (GGTP)
(DOE/CAO-00-3187, Revision 1). These documents can be found on the CBFO Web Page using the following link: http://www.wipp.ws/library/caolib.htm.

The implementation period will end on midnight, May 16, 2002. Beginning May
17, 2002, all sites shipping transuranic waste to the WIPP shall be in full
compliance with the provisions contained in the CH-WAC, the TRAMPAC, and the
QAPP for TRUPACT-II GGTP. Sites are no longer authorized to use the WAC
(DOE/WIPP-069), the Safety Analysis Report for the TRUPACT-II for Packaging
(Revision 18), or the QAPP for TRUPACT-II GGTP (Revision 0) on or after May
17, 2002.

Due to requests from various sites, CBFO has developed guidelines for the
implementation process. This guidance is attached. If additional guidance or
clarification is required beyond that in the attached CH-WAC implementation
guidance, the CBFO will address the applicable issues on a case-by-case basis.

If there are any questions regarding the CH-WAC or the attached implementation
guidance, please contact Reinhard Knerr (505-234-7374). If there are any
questions regarding the TRAMPAC or the QAPP for TRUPACT-II GGTP, please contact Marc Italiano (505-234-7484).

Kerry W. Watson  
CBFO Assistant Manager  
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Attachment

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Impacted Documents: There are a number of TRU Waste program documents that require modification due to the changes made to the Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant (CH-WAC) the Quality Assurance Program Plan (QAPP) for TRUPACT-II Gas Generation Test Plan (GGTP) (DOE/CA0-00-3178, Rev. 1) and the TRUPACT-II Authorized Methods for Payload Control (TRAMPAC). Depending on the type of document and the type of change, varying levels of CBFO review and approval are required. These documents are as follows:

1. Documents Requiring CBFO QA/Technical Review and Approval
   - TRAMPAC and associated QA Plan
   - QAPjP
   - Waste Certification Plan and associated QA Plan
   - QAPjP for GGTP

2. Documents Requiring CBFO QA/Technical Review and Concurrence
   - Payload container visual inspection procedures (i.e., container integrity inspection)
   - Radioassay plans and procedures
   - Payload certification procedures
   - TRUPACT-II Operations, Maintenance and Leak testing procedures
   - Any other procedures that require modification to implement the requirements in the CH-WAC, the TRAMPAC, and the QAPP GGTP.

3. Documents Requiring Reference Change Only
   - All TRU waste program documents that reference the Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-069 must be changed to Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-02-3122. However, the only change that is required to be made to the document is to change the reference from the WAC (DOE/WIPP-069) to the CH-WAC (DOE/WIPP-02-3122), the actual change to the document need not be completed prior to May 17, 2002, provided a “letter-to-file” (or other QA traceable record) is prepared and controlled. This letter/record shall commit to making the necessary editorial changes to the respective program document(s) the next time it is revised.

Document Submittal: In order to ensure that the CBFO has ample time and resources to review the modified documents and the applicable site has sufficient time to resolve any comments resulting from the review, the CBFO requests that site adhere to the following document submittal schedule:

1. Documents Requiring CBFO QA/Technical Review and Approval

2. Documents Requiring CBFO QA/Technical Review and Concurrence
   - Radioassay plans and procedures – COB April 15, 2002.
   - Payload certification procedures – COB April 15, 2002.
   - Any other impacted procedures – COB April 15, 2002.

3. Documents Requiring Reference Change Only
   - The next time it is revised (after May 17, 2002).
After these documents are revised to incorporate the CH-WAC, the QAPP GGTP, and the TRAMPAC modifications and approved by the sites, they should be sent to the CBFO without delay. The CBFO requests that the sites do not delay submittal of the revised draft documents for the purpose of making a single submittal to the CBFO. Due to the volume of documents that will need to be reviewed within the implementation period, the CBFO will not be conducting courtesy reviews of any documents. Only final drafts will be reviewed. As such, the CBFO will accept the documents by any of the following three methods:

1. Hardcopy: Formal transmittal from the generator site's DOE Field or Area Office to the CBFO. The documents must have been completely through the generator site's internal review process with all signatures in place.
2. Electronic: The documents must have been completely through the generator site's internal review process with all of the signatures in place. A scanned copy of the signed signature page must include the associated procedure.
3. Electronic: A "frozen" draft of the document with understanding that no further changes may be made to the document other than those in response to the CBFO's comments. This method allows flexibility to the sites by not having to go through the formal review and signature process until after CBFO's comments have been incorporated.

The CBFO also requests that electronic copies of the documents be submitted to the following e-mail address: site.documents@wipp.ws To ensure the documents get the proper review priority, the CBFO also requests that the subject line of the e-mail include the following: "CH-WAC/TRAMPAC Implementation - sitename - document number." The CBFO will provide further guidance with regard to the formal approval process on a case-by-case basis, as needed.

Training: Sites are expected to have all applicable training completed on the modified documents in accordance with site procedures by May 17, 2002. Only appropriately trained and qualified personnel shall be allowed to perform radioassay and data validation/review. Standardized training requirements for radioassay personnel shall be based upon existing industry standardized training requirements (e.g., ASTM C1490, Standard Guide for Selection, training and Qualification of Nondestructive Assay (NDA) Personnel, ANSI N15.54, Radiometric Calorimeters – Measurement Control Program) and shall meet the specifications in the QAPD.

Site Surveillances or Audits: No special surveillances or audits will be required at the sites prior to the implementation of the CH-WAC, the QAPP GGTP, and the TRAMPAC modifications. Surveillances and/or regularly scheduled audits conducted after May 17, 2002, will assess the implementation and effectiveness of these changes.

Processing Radioassay Data: During the course of waste characterization, radioassay data is collected, processed, reviewed, and approved by a site. The activities that comprise radioassay measurement and approval can be bounded by the following five sequential steps:

1. Data collection and reduction,
2. Batch data report preparation,
3. Batch data report signature release at the data generation level,
4. Batch data report approval at the site project level (including related information and computations, if applicable), and
5. Reporting of the payload container radioassay testing results to the WWIS.

The CBFO is not requiring (or expecting) any sites to stop radioassay measurements or to approve their open batch reports and transfer the data to WWIS prior to the CH-WAC implementation date of May 17, 2002. As such, there will be instances where the activities that comprise radioassay measurement and approval will be impacted by the implementation date of May 17, 2002. Depending on where in the process this transition occurs, five different options for processing the data are provided to ensure that containers do not have to be re-assayed:
Option 1: **Steps 1 through 5 Completed Prior to the Implementation Date of May 17, 2002:** This data will be accepted as having met the requirements of the WAC (DOE/WIPP-069, Revision 7, Change Notice 2). No reconciliation with the requirements of the CH-WAC (DOE/WIPP-02-3122, Revision 0) needs to be performed.

Option 2: **Steps 1 through 4 Completed Prior to the Implementation Date of May 17, 2002:** Being that this data was collected, reduced, reported, released at the data generation level, and approved at the site project level prior to May 17, 2002, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified by radioassay; i.e., a reporting to the WWIS of either <LLD, or a number for the activity and/or mass of all 10 radionuclides identified in Section 3.3.1 of the CH-WAC (DOE/WIPP-02-3122, Revision 0) is neither practical nor feasible, since the data was processed according to the requirements in the previous WAC (DOE/WIPP-069, Revision 7, Change Notice 2). Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.

Option 3: **Steps 1 through 3 Completed Prior to the Implementation Date of May 17, 2002:** Being that this data was collected, reduced, reported, and released at the data generation level prior to May 17, 2002, the requirement for a replicate measurement was in effect, and weekly interfering matrix measurements were not required. Consequently, the site program office in reviewing and approving the data package on or after May 17, 2002, should indicate on the batch report the use of replicates (required in DOE/WIPP-069, Revision 7, Change Notice 2) in lieu of the use of a weekly interfering surrogate waste matrix (required in DOE/WIPP-02-3122, Revision 0). Also, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified as indicated above in Option 2. Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.

Option 4: **Steps 1 through 2 Completed Prior to the Implementation Date of May 17, 2002:** Being that the data was collected, reduced, and reported prior to May 17, 2002, the requirement for a replicate measurement was in effect, and weekly interfering matrix measurements were not required. Consequently, both data generation level review and site program office review and approval of the data package on or after May 17, 2002, should indicate on the batch report the use of replicates (required in DOE/WIPP-069, Revision 7, Change Notice 2) in lieu of the use of a weekly interfering surrogate waste matrix (required in DOE/WIPP-02-3122, Revision 0). Also, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified as indicated above in Option 2. Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.

Option 5: **Step 1 Executed Prior to the Implementation Date of May 17, 2002:** Being that the data was collected and may have been reduced prior to May 17, 2002, but was not reported in a Batch Data Report, the criteria in the CH-WAC (DOE/WIPP-02-3122, Revision 0) for Batch Data Reports may be followed. In addition, when the data was collected, the requirement for a replicate measurement was in effect, and weekly interfering matrix measurements were not required. Consequently, both data generation level review and site program office review and approval of the data package on or after May 17, 2002, should indicate on the batch report the use of replicates (required in DOE/WIPP-069, Revision 7, Change Notice 2) in lieu of the use of a weekly interfering surrogate waste matrix (required in DOE/WIPP-02-3122, Revision 0). Also, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified as indicated above in Option 2. Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.
If step 1 has been completed on or after the implementation date of May 17, 2002, then all five steps will have to meet the criteria in the CH-WAC (DOE/WIPP-02-3122, Revision 0) and cannot be qualified using any of these five options.

**CH-WAC Text and Clarification:** The following pages of documentation provide clarification to various sections of text within the CH-WAC based on questions and comments received from sites, discussion held with regulators, and information provided by various CBFO support organizations. If additional guidance or clarification is required beyond that in this guidance, the CBFO will address the applicable issue on a case-by-case basis and provide the information.

Subsection 3.1 Summary of WIPP Authorization Basis

1. **Text of interest (3rd paragraph):** "The WWIS is an electronic database equipped with edit/limit checks to ensure that the data representing the waste payload containers are in compliance with the CH-WAC."

   **Clarification:** The WWIS incorporates the Automated TRUPACT-II Authorized Methods for Payload Control (e-TRAMPAC) software, which is used to evaluate containers and assemblies of CH-TRU waste for compliance with each of the TRAMPAC requirements, including those summarized in this CH-WAC. The use of the WWIS e-TRAMPAC modules is required for TRAMPAC compliance determinations.

Subsection 3.3.1 Radionuclide Composition

2. **Text of interest (2nd paragraph):** "In addition, all radionuclides other than the ten WIPP-tracked radionuclides (i.e., $^{235}$U, $^{238}$Pu, $^{240}$Pu, $^{241}$Pu, $^{234}$U, $^{238}$U, $^{233}$U, $^{239}$Pu, $^{90}$Sr, and $^{137}$Cs) that contribute to 95% of the radioactive hazard for the payload container shall be reported on the TRUPACT-II bill of lading or manifest in accordance with 49 CFR §172.203 and 49 CFR §173.433. The activities and masses of these other radioisotopes shall also be reported to the WWIS along with their associated TMU, expressed in terms of one standard deviation for each waste container."

   **Clarification:** All isotopes comprising 95% of the radioactive hazard, whether they are one of the ten WIPP-tracked radionuclides or not, are reported in the WWIS. Trace amounts of nuclides need not be reported as long as 95% of the radioactive hazard is accounted for. Isotopes that are included in the list of the ten WIPP-tracked isotopes must be reported to WWIS as indicated in the 1st paragraph in Section 3.3 of the CH-WAC to establish the fact that a site has met the requirements for the 10 WIPP-tracked isotopes. Isotopes not on the WIPP-tracked list that do need to be identified to meet the 95% radioactive hazard reporting criterion do not need to be recorded in the batch report, WWIS, or the shipping papers. There are two exceptions to this general guidance:

   1. When an isotope, such as $^{235}$U (which is not on of the 10 WIPP-tracked radionuclides and may not contribute to 95% of the radiological hazard), is used to establish the isotopic ratio of another isotope(s) that is one of the WIPP tracked radionuclides, such as $^{234}$Pu and/or $^{238}$U, then, at a minimum, the isotopic ratio of that radionuclide (i.e., $^{235}$U in this example) must be reported in the Batch Data Report.

   2. For isotopes, such as $^{237}$Np, that contribute to the FGE mass, but are not required to be tracked as one of the 10 WIPP-tracked radionuclides or do not contribute to 95% of the radiological hazard, then, at a minimum, the isotope ratio of that radionuclide (i.e., $^{237}$Np in this example) must be reported in the Batch Data Report.

Site are permitted to report as much detail beyond the minimum required data with regard to the isotopic composition of the radionuclides to the WWIS as they desire.

Subsection 3.3.3 TRU Alpha Activity Concentration
3. **Text of interest:** "The TRU alpha activity concentration shall be reported to the WWIS; however, there are no reporting requirements for its associated TMU."

**Clarification:** This statement is not in conflict with Section A.5.2 of Appendix A which states that the TRU alpha activity concentration and its associated TMU (emphasis added) shall be documented for each container and reported in either the radioassay batch data report or other QA record or database. Whereas Subsection 3.3.3 applies to WWIS reporting requirements, Section A.5.2 pertains specifically to internal site reporting requirements. TMU data is retained by the site as a lifetime QA record (see Section 1.5.2.4 of the QAPD).

**Subsection 3.3.4 239Pu Equivalent Activity**

4. **Text of interest:** PE-Ci quantities shall be calculated for each payload container (see Appendix B) and reported to WIPP using the WWIS.

**Clarification:** The unit used for reporting 239Pu equivalent activity to the WWIS is PE-Ci (plutonium equivalent curies).

**Subsection 3.3.6 Decay Heat**

5. **Text of interest:** All

**Clarification:** The total decay heat from all containers in a TRUPACT-II shall be less than 40 W as specified in Appendix 6.2 of the TRUPACT-II Authorized Methods for Payload Control (Revision 19).

6. **Text of interest:** "The sum of the decay heat for each payload container plus its TMU shall be less than or equal to the limits of the assigned shipping category specified in table 5.5-1 of appendix 5.5 of the TRAMPAC."

**Clarification:** As defined in Table 5-2 of Section 5.0 of the TRAMPAC, payload containers of Waste Material Type II.1 and Waste Type III that meet the criteria for the application of dose-dependent G values (watt*year >0.012) shall be assigned a shipping category that uses a dose-dependent G value. This assignment revises the four-digit G value notation used in the numeric shipping category otherwise assigned to the payload container. The evaluation of payload containers and programmed reassignment of shipping category will be completed by WWIS (i.e., use of the dose-dependent G value for qualifying container is not optional). Sites may reassign shipping categories, as applicable, prior to entering data into the WWIS.

**Subsection 3.5.5 Headspace Gas Concentrations**

7. **Text of interest:** "Test category payload containers shall be tested to quantify the hydrogen/methane, VOC, and total gas generation rates (as appropriate) for purposes of determining if all applicable limits are met."

**Clarification:** As described in Section 5.0 of the TRAMPAC, qualification of payload containers under the test category is by one of two options: (1) measurement of the headspace gas or (2) full-drum testing to quantify the gas generation rate of the payload container.

**Subsection A.1 Introduction**

8. **Text of interest:** Existing radioassay data collected prior to the implementation of a quality assurance program pursuant to 40 CFR §194.22(a)(1) may be qualified in accordance with an alternate methodology that is approved by CBFO and employs one or more of the following methods:

a. peer review in accordance with NUREG-1297 (reference A1)
b. corroborating data
c. confirmatory testing (i.e., testing made on a representative sub-population of payload containers within a waste stream), or
d. demonstrating the equivalent of an alternate QA program (as described in reference A2, section 5.4).

Clarification: The listed methods are pursuant to 40 CFR §194.22(b) and require CBFO and EPA approval prior to implementation.

Subsection A.2.1 Methods for Confirmation of Isotopic Ratio AK

9. **Text of interest (4th paragraph):** If valid (emphasis added) AK does not exist, then the data generated on a WIPP-certified system can only be used to detect or calculate \(^{238}\)U, \(^{235}\)U, and \(^{233}\)U or to confirm their absence.

Clarification: The term “valid” in the context of this paragraph means sufficient and defendable. It is understood by the CBFO that these terms are still imprecise and are up to interpretation from any auditors. The CBFO is evaluating this concern and trying to determine how to provide more precise guidance to the sites.

Subsection A.2.2.3 Discrepancy Resolution

10. **Text of interest (1st sentence):** If there is a discrepancy between AK information related to isotopic ratios or composition, the site will evaluate the sources of the discrepancy to determine if the discrepant information is credible.

Clarification: If there is a discrepancy within the AK information that is related to either isotopic ratios or isotopic composition, the site will evaluate the sources of the discrepancy to determine if the discrepant information is credible. In effect, the sites should continue to process discrepancies as they are presently doing.

Subsection A.3 Data Quality Objectives

11. **Text of interest (Table A-3):** The confidence for meeting the TRU \(\alpha\)-activity concentration DQO is listed in the third column as N/A.

Clarification: When looking at 2-sided confidence intervals, the 1 sigma and 2 sigma confidence intervals of a normally distributed measurement are ~68% and ~95%, respectfully. When looking at 1-sided confidence intervals, the 1 sigma and 2 sigma confidence intervals of a normally distributed measurement are ~84% and ~97.5%, respectfully. Because the DQO only cares that the measurement plus error (not plus or minus the error) is below the limit, a 1-sided distribution is specified in Table A-3.

12. **Text of interest (1st paragraph under Lower Limit of Detection):** The lower limit of detection (LLD) for each radioassay system must be determined. Instruments performing TRU/low-level waste discrimination measurements must have an LLD of 100 nCi/g or less.

Clarification: The requirement for a total LLD of 100 nCi/g or less only applies to the determination of TRU alpha activity. The requirement for individual isotopes is simply to determine the LLD value based on the definition provided and use it accordingly. For purposes of WIPP related reports, only measured activities greater than the LLD are considered to be “detected” and reported as directly measured.

13. **Text of interest (1st paragraph under Calibration Procedures and Frequencies):** During calibration or re-calibration, system correction factors shall be established and algorithms adjusted such that the value of %R is set equal to 100%; i.e., the system is calibrated to 100%R.
Clarification: The objective of calibrating an NDA instrument is to obtain 100%R; i.e., to correctly determine with absolute accuracy the activity/mass of the radioactive material in the drum. However, it is understood that this is rarely possible, but rather is considered a goal. Typically, when calibrating NDA instruments, a calibration curve is fitted to a number of data points obtained with calibration sources. This curve will not usually pass through all the points, but will be as close as feasible for the particular curve shape used. While the calibration obtained will not allow 100%R for all regions of the curve, it will generally be within a few percent (though it could be larger, if the calibration is defined to include the determination of various matrix correction factors). This degree of accuracy is generally quite acceptable for NDA measurements of waste. Any deviation of the calibration curve from 100%R will be reflected in the assigned calibration uncertainty, which is incorporated in the TMU of the system.

14. Text of interest (2nd paragraph under Calibration Procedures and Frequencies): Calibrations(s) shall be performed in accordance with consensus standards, when such standards exist.

Clarification: The requirement to use consensus standards (e.g., ANSI or ASTM standards documents) for calibration applies only to those radioassay systems for which consensus standards exist and that are not already WIPP certified (as of May 16, 2002). However, a site’s calibration procedures must be revised to reflect this requirement. Radioassay systems previously certified by WIPP are not required to be recalibrated specifically to be re-calibrated in accordance with consensus standard. However, if during the course of operations it is determined that re-calibration is required, the radioassay system will then be subject to this new requirement.

15. Text of interest (2nd paragraph under Calibration Procedures and Frequencies): Primary calibration standards shall be obtained from suppliers maintaining a nationally accredited measurement program.

Clarification: A primary calibration standard (i.e., a source) is one designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity. It should be noted that the QAPD currently requires NIST-traceable calibration standards; however, the requirement to be NIST-traceable is in the process of being changed due to a lack of a regulatory driver.

If a site has generated their own NIST-traceable calibration standard and it has been confirmed to have the necessary pedigree in accordance with the site’s and CBFO’s QA programs, then that standard is considered acceptable.

16. Text of interest (1st paragraph under Calibration Confirmation): The replicate measurements shall be performed using nationally recognized standards, or certified standards derived from nationally recognized standards that span the range of use.

Clarification: The wording “that span the range of use” is to be interpreted as follows: A minimum of two source strengths is required – one from the lower one third of the range and one from the top third of the range or beyond. An example would be an instrument that had an operating range from 0.3g to 200g WG Pu. Then one source with a mass between 0.3 and 70 g and one greater than 134 would be required for the matrix checks. Obviously, a source very close to the LLD of the instrument would be expected to have a large %RSD, and might not be satisfactory for this test. Likewise, a source that greatly exceeded the upper limit of the range might not provide satisfactory results for accuracy. Additional sources could be used at the discretion of the NDA facility. It should be noted that this description of source strengths sufficient for “calibration confirmation” does not apply to the number or sizes of sources needed for calibration or recalibration of instruments; those requirements are addressed in the appropriate consensus standards.
17. **Text of interest (1st paragraph under Calibration Confirmation):** Calibration confirmation replicate measurements shall be performed on containers of the same nominal size as those in which actual waste is assayed and according to approved waste assay procedures.

**Clarification:** While this requirement allows some flexibility in the actual size and shape of the waste container being measured, it does not allow replicate measurements made on 55-gallon drums to be used for calibration confirmation of, for example 30-gallon, 85-gallon or 100-gallon drums. The intent was to allow any nominal 55-gallon drum to be represented by a single 55-gallon drum without having to confirm container outer diameters and heights or container volume.

18. **Text of interest (1st paragraph under Calibration Confirmation):** Accuracy is reported as percent recovery (%R).

**Clarification:** Refer to the Performance Demonstration Program Plan for Nondestructive Assay of Drummec Wastes for the TRU Waste Characterization Program (DOE/CBFO-01-1005) for the equation to calculate %R.

19. **Text of interest (1st paragraph under Calibration Confirmation):** Precision is reported as percent relative standard deviation (%RSD).

**Clarification:** Refer to the Performance Demonstration Program Plan for Nondestructive Assay of Drummec Wastes for the TRU Waste Characterization Program (DOE/CBFO-01-1005) for the equation to calculate %RSD. It should be noted that the equation for calculating %RSD in the PDP plan is different from the equation for calculating %RSD in Revision 7 of the WAC.

20. **Text of interest (1st paragraph under Calibration Confirmation):** The applicable range for accuracy shall not exceed ±30% on a non-interfering matrix.

**Clarification:** The phrase "shall not exceed ±30%" means the measured value shall not exceed ±30% of the true value (70%R < Source Activity < 130%R) for a non-interfering matrix.

21. **Text of interest (Table A-3.2 under Calibration Confirmation):** The footnote.

**Clarification:** The footnote pertains to the numerical values listed in the row labeled "Max %RSD."

Subsection A.4.2 NDA QC Requirements

22. **Text of interest (1st paragraph under Instrument Performance Measurements):** Performance checks shall include efficiency checks (when applicable), matrix correction checks and, for spectrometric instruments, peak position and resolution checks.

**Clarification:** Instrument performance measurements involving matrix correction checks necessitate the use of surrogate waste matrix containers including appropriate radioactive standards. Since some sites have indicated that surrogate matrix containers and/or standards may not be available in a time frame to meet the implementation deadline of May 17, 2002, the CBFO has approved the site's use of PDP surrogate waste matrices and standards for meeting this requirement. Any damage incurred by either the PDP surrogate waste matrix containers or radioactive standards during the performance of these measurements must be repaired at the site's expense and within a time frame not impactive to future PDP cycles.

23. **Text of interest (1st paragraph under Instrument Performance Measurements):** Performance checks shall include efficiency checks (when applicable), matrix correction checks and, for spectrometric instruments, peak position and resolution checks.

**Clarification:** This sentence is generic and applies to both the daily performance checks and weekly performance checks. Matrix correction checks are specific to weekly performance measurements.
24. **Text of interest (2nd paragraph under Instrument Performance Measurements):** To verify calibration, radioactivity standards must be selected such that, over a six month period, the operating range of the assay system is tested in each applicable surrogate waste matrix.

**Clarification:** The phrase "to verify calibration" does not refer to the subsection titled "Calibration Verification" contained in Section A.3. Rather, the phrase "to verify calibration" means, "to verify instrument performance."

25. **Text of interest (2nd paragraph under Instrument Performance Measurements):** To verify calibration, radioactivity standards must be selected such that, over a six month period, the operating range of the assay system is tested in each applicable surrogate waste matrix.

**Clarification:** The phrase "the operating range of the assay system" refers to the operating range for which the assay system was WIPP-certified. If over a six month period, however, the actual waste assayed spans a reduced portion of the full operating range of the assay system, then only the reduced portion of the full operating range of the assay system needs to be tested during the six month time period for each applicable surrogate waste matrix.

26. **Text of interest (2nd paragraph under Instrument Performance Measurements):** To verify calibration, radioactivity standards must be selected such that, over a six month period, the operating range of the assay system is tested in each applicable surrogate waste matrix.

**Clarification:** The word "applicable" refers only to those surrogate waste matrices that correspond to the actual waste matrices assayed by the system over the six month time period— not the full range of matrices for which the assay system was WIPP-certified.

27. **Text of interest (1st paragraph under Data Checks):** Background (for calorimetry: baseline or base power) and performance measurements shall be reviewed and evaluated at least weekly to determine continued acceptability of the assay system and to monitor performance trends. If daily performance checks result in data that are outside the acceptable range, the required responses in Table A-4.2 shall be followed.

**Clarification:** Only daily performance measurements are required to be checked using the criteria in Table A-4.2. The CH-WAC does not require either background measurements or weekly performance measurements to be tested using the criteria in Table A-4.2; however, NDA facilities must specify in site procedures the process or alternate criteria they use to determine if the weekly measurements are acceptable. These usually are based on some multiple of the expected fluctuations in the measured quantity; i.e., fluctuations in the daily background or weekly matrix check measurements, but this is not a WIPP requirement. It is understood that it may take sometime to develop a baseline, or for some of the matrices that may only be tested once per 6-month period, that the process or criteria may default to expert review of the data. With regard to background measurements, the CBFOs expectation is that the sites evaluate the daily background measurements at least on a weekly basis to determine continued acceptability of the radioassay system. The background measurements are not required to be monitored for performance trends because that would indicate that the background measurements were being varied to determine impact on the NDA system measurements on a daily basis - this is not something the CBFO is advocating or requiring. It is not the intent of the CH-WAC to have statistical control limits applied to background measurements. However, CBFO does expect that the sites understand the impact of the background radiation on the radioassay system and that when background levels are to the point that "continued acceptability of the radioassay system" is suspect or is known to be degraded, that corrective measures are put in place or radioassay measurements are suspended until the background radiation levels drop to an acceptable level.

28. **Text of interest (Table A-4.2 under Data Checks):** In the case where the data falls within the warning range, the required response is as follows: The performance check standard shall be rerun no more
than two times. If the rerun performance check(s) result in data within ±2σ, then the additional performance checks shall be documented and work may continue. If the system does not fall within ±2σ after two rerun performance checks, then the required response for the Action Range shall be followed.

Clarification: In Table A-4.2, it is intended that the action taken for the “Warning Range” is as follows: If the first performance check rerun is less than 2σ, then proceed with waste assay measurements; there is no requirement to perform another performance measurement. If the first performance check is greater than 3σ, then go to the response required for the “Action Range.” If the first performance check is between 2σ and 3σ, then make one more performance measurement. If that measurement is less than 2σ, then proceed with waste assay measurements; otherwise go to the response for the “Action Range.”

29. Text of interest (Table A-4.2 under Data Checks): In the second column of Table A-4.2, the absolute value of the data (|Data|) is used in defining the acceptability range.

Clarification: In the context of Table A-4.2, data is defined as follows: Data = μ(mean) − μ(measured), where μ(mean) is the expected value for the performance measurement (usually the mean value of a number of previous measurements from which the value of σ is obtained), and μ(measured) is the value of the performance measurement being “checked.”

Subsection A.5.2 Data Reporting

30. Text of interest (3rd bullet of 2nd paragraph): Background and performance data or control charts for the relevant time period.

Clarification: The instruction to include background and performance data or control charts for the relevant time period also pertains to the weekly matrix check, as follows: The guidance here is to include in each testing batch data package the matrix check result from the most recently acquired measurement obtained before or during the dates the waste assay data is acquired. In addition, the allowable limits for that data, as specified in facility documents, must be reported with the actual result. For example, if the weekly matrix measurement is always obtained on a Monday, then each data package obtained on that Monday or later in the week would have that Monday matrix check result and acceptable limits. If a testing batch is collected for a period longer than a week, it should include any additional matrix checks obtained during that period, with acceptable limits specified. (It is noted that because the matrix-check cycle length could be as long as six months, the matrix check result included in a particular testing batch data report may not be for the same type of matrices as the waste containers in that particular package.)

31. Text of interest (5th bullet of 2nd paragraph): Activities and/or masses of individual radioisotopes present and their associated TMUs (curies and/or grams).

Clarification: It is recognized that the methods used by NDA facilities to report results to the site project office may vary somewhat at different sites. The guidance here is for sites to decide the details of how facilities report the NDA measurement results to the project office, within the following guidelines. The NDA facility may report either activity or masses or both to the project office. However, the project office must report both mass and activity in the WWIS, as specified in the section 3.3.1 of the WAC and in the guidance provided above for that section. That section also specifies, under certain circumstances, that the results entered into the WWIS must be reported as <LLD or zero for some isotopes. If this determination is made at the NDA facility, the results reported in the testing batch data package can be stated as <LLD or zero for particular isotopes, as appropriate, instead of a numerical value (presumably less than the instruments LLD) and TMU. Thus, the data related to individual isotopes reported in the testing batch data package, may be stated in terms of activity, mass, <LLD, or zero, or combinations thereof, as specified in site procedures.
Similarly, the information listed under the heading "Other radiological properties..." can be calculated by the NDA facility and included in the testing batch data package, or it can be calculated and recorded elsewhere prior to entry in the WWIS, using the activities/mass data provided in the batch data report.

Appendix D    Payload Container Integrity Checklist

32. **Text of interest (Item #9):** Examine the payload container regions near vents, top lid fittings, bottom fittings, welds, seams and intersections of one or more metal sheets or plates.

**Clarification:** The term "vents" refers to "filter vents."
Impacted Documents: There are a number of TRU Waste program documents that require modification due to the changes made to the Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant (CH-WAC) the Quality Assurance Program Plan (QAPP) for TRUPACT-II Gas Generation Test Plan (GGTP) (DOE/CAO-00-3178, DOE/WIPP-01-3187, Rev. 1) and the TRUPACT-II Authorized Methods for Payload Control (TRAMPAC). Depending on the type of document and the type of change, varying levels of CBFO review and approval are required. These documents are as follows:

1. Documents Requiring CBFO QA/Technical Review and Approval
   - TRAMPAC and associated QA Plan
   - QAPjP
   - Waste Certification Plan and associated QA Plan
   - QAPjP for GGTP

2. Documents Requiring CBFO QA/Technical Review and Concurrence
   - Payload container visual inspection procedures (i.e., container integrity inspection)
   - Radioassay plans and procedures
   - Payload certification procedures
   - TRUPACT-II Operations, Maintenance and Leak testing procedures
   - Any other procedures that require modification to implement the requirements in the CH-WAC, the TRAMPAC, and the QAPP GGTP.

3. Documents Requiring Reference Change Only
   - All TRU waste program documents that reference the Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-069 must be changed to Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-02-3122. However, the only change that is required to be made to the document is to change the reference from the WAC (DOE/WIPP-069) to the CH-WAC (DOE/WIPP-02-3122), the actual change to the document need not be completed prior to May 17, 2002, provided a "letter-to-file" (or other QA traceable record) is prepared and controlled. This letter/record shall commit to making the necessary editorial changes to the respective program document(s) the next time it is revised.

Document Submittal: In order to ensure that the CBFO has ample time and resources to review the modified documents and the applicable site has sufficient time to resolve any comments resulting from the review, the CBFO requests that site adhere to the following document submittal schedule:

1. Documents Requiring CBFO QA/Technical Review and Approval

2. Documents Requiring CBFO QA/Technical Review and Concurrence
   - Radioassay plans and procedures – COB April 15, 2002.
   - Payload certification procedures – COB April 15, 2002.
   - Any other impacted procedures – COB April 15, 2002.

3. Documents Requiring Reference Change Only
   - The next time it is revised (after May 17, 2002).
After these documents are revised to incorporate the CH-WAC, the QAPP GGTP, and the TRAMPAC modifications and approved by the sites, they should be sent to the CBFO without delay. The CBFO requests that the sites do not delay submittal of the revised draft documents for the purpose of making a single submittal to the CBFO. Due to the volume of documents that will need to be reviewed within the implementation period, the CBFO will not be conducting courtesy reviews of any documents. Only final drafts will be reviewed. As such, the CBFO will accept the documents by any of the following three methods:

1. **Hardcopy**: Formal transmittal from the generator site's DOE Field or Area Office to the CBFO. The documents must have been completely through the generator site's internal review process with all signatures in place.

2. **Electronic**: The documents must have been completely through the generator site's internal review process with all of the signatures in place. A scanned copy of the signed signature page must include the associated procedure.

3. **Electronic**: A "frozen" draft of the document with understanding that no further changes may be made to the document other than those in response to the CBFO's comments. This method allows flexibility to the sites by not having to go through the formal review and signature process until after CBFO's comments have been incorporated.

The CBFO also requests that electronic copies of the documents be submitted to the following e-mail address: site.documents@wipp.ws To ensure the documents get the proper review priority, the CBFO also requests that the subject line of the e-mail include the following: "CH-WAC/TRAMPAC Implementation - sitename - document number." The CBFO will provide further guidance with regard to the formal approval process on a case-by-case basis, as needed.

**Training**: Sites are expected to have all applicable training completed on the modified documents in accordance with site procedures by May 17, 2002. Only appropriately trained and qualified personnel shall be allowed to perform radioassay and data validation/review. Standardized training requirements for radioassay personnel shall be based upon existing industry standardized training requirements (e.g., ASTM C1490, Standard Guide for Selection, training and Qualification of Nondestructive Assay (NDA) Personnel; ANSI N15.54, Radiometric Calorimeters – Measurement Control Program) and shall meet the specifications in the QAPD.

**Site Surveillances or Audits**: No special surveillances or audits will be required at the sites prior to the implementation of the CH-WAC, the QAPP GGTP, and the TRAMPAC modifications. Surveillances and/or regularly scheduled audits conducted after May 17, 2002, will assess the implementation and effectiveness of these changes.

**Processing Radioassay Data on Certified NDA Systems**: During the course of waste characterization, radioassay data is collected, processed, reviewed, and approved by a site. The activities that comprise radioassay measurement and approval can be bounded by the following five sequential steps:

1. Data collection and reduction,
2. Batch data report preparation,
3. Batch data report signature release at the data generation level,
4. Batch data report approval at the site project level (including related information and computations, if applicable), and
5. Reporting of the payload container radioassay testing results to the WWIS.

The CBFO is not requiring (or expecting) any sites to stop radioassay measurements or to approve their open batch reports and transfer the data to WWIS prior to the CH-WAC implementation date of May 17, 2002. As such, there will be instances where the activities that comprise radioassay measurement and approval will be impacted by the implementation date of May 17, 2002. Depending on where in the process this transition occurs, five different options for processing the data are provided to ensure that containers do not have to be re-assayed:
Option 1: **Steps 1 through 5 Completed Prior to the Implementation Date of May 17, 2002:** This data will be accepted as having met the requirements of the WAC (DOE/WIPP-069, Revision 7, Change Notice 2). No reconciliation with the requirements of the CH-WAC (DOE/WIPP-02-3122, Revision 0) needs to be performed.

Option 2: **Steps 1 through 4 Completed Prior to the Implementation Date of May 17, 2002:** Being that this data was collected, reduced, reported, released at the data generation level, and approved at the site project level prior to May 17, 2002, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified by radioassay; i.e., a reporting to the WWIS of either 0, <LLD, or a number for the activity and/or mass of all 10 radionuclides identified in Section 3.3.1 of the CH-WAC (DOE/WIPP-02-3122, Revision 0) is neither practical nor feasible, since the data was processed according to the requirements in the previous WAC (DOE/WIPP-069, Revision 7, Change Notice 2). Sites need to identify in either the Batch Data Report (such as in a case narrative), applicable procedures, other QA records (e.g., an NCR), or the appropriate WWIS comment field the rational for addressing these allowed variances from the requirements of the CH-WAC.

Option 3: **Steps 1 through 3 Completed Prior to the Implementation Date of May 17, 2002:** Being that this data was collected, reduced, reported, and released at the data generation level prior to May 17, 2002, the requirement for a replicate measurement was in effect, and weekly interfering matrix measurements were not required. Consequently, the site program office in reviewing and approving the data package on or after May 17, 2002, should indicate on the batch report the use of replicates (required in DOE/WIPP-069, Revision 7, Change Notice 2) in lieu of the use of a weekly interfering surrogate waste matrix (required in DOE/WIPP-02-3122, Revision 0). Also, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified as indicated above in Option 2. Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.

Option 4: **Steps 1 through 2 Completed Prior to the Implementation Date of May 17, 2002:** Being that the data was collected, reduced, and reported prior to May 17, 2002, the requirement for a replicate measurement was in effect, and weekly interfering matrix measurements were not required. Consequently, both data generation level review and site program office review and approval of the data package on or after May 17, 2002, should indicate on the batch report the use of replicates (required in DOE/WIPP-069, Revision 7, Change Notice 2) in lieu of the use of a weekly interfering surrogate waste matrix (required in DOE/WIPP-02-3122, Revision 0). Also, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified as indicated above in Option 2. Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.

Option 5: **Step 1 Executed Prior to the Implementation Date of May 17, 2002:** Being that the data was collected and may have been reduced prior to May 17, 2002, but was not reported in a Batch Data Report, the criteria in the CH-WAC (DOE/WIPP-02-3122, Revision 0) for Batch Data Reports may be followed. In addition, when the data was collected, the requirement for a replicate measurement was in effect, and weekly interfering matrix measurements were not required. Consequently, both data generation level review and site program office review and approval of the data package on or after May 17, 2002, should indicate on the batch report the use of replicates (required in DOE/WIPP-069, Revision 7, Change Notice 2) in lieu of the use of a weekly interfering surrogate waste matrix (required in DOE/WIPP-02-3122, Revision 0). Also, the associated radionuclides reported to the WWIS on or after May 17, 2002, need only include those radionuclides that were quantified as indicated above in Option 2. Sites need to identify in the Batch Data Report (such as in a case narrative) the rational for addressing these allowed variances from the requirements of the CH-WAC.
If step 1 has been completed on or after the implementation date of May 17, 2002, then all five steps will have to meet the criteria in the CH-WAC (DOE/WIPP-02-3122, Revision 0) and cannot be qualified using any of these five options.

Processing Radioassay Data on Non-Certified NDA Systems (i.e., those radioassay systems whose certification is not scheduled until on or after May 17, 2002): In some instances, generator/storage sites may be in the process of preparing NDA systems for initial certification. In such instances, the QC checks of adequacy, implementation, and effectiveness of the system and associated methodology have not been subjected to review and approval by either the CBFO or the EPA. As such, additional considerations need to be made for these non-certified systems to ensure that all elements of the related radioassay program can be effectively and efficiently transitioned on May 17, 2002, when the CH-WAC (DOE/WIPP-02-3122, Revision 0) becomes effective.

Depending on how far along the generator/storage site is in preparing the NDA system for initial certification, different options present themselves. These options fall into three general categories:

1. **early stage**: The generator/storage site is either planning or in the process of developing the required program documents for performing NDA including plans, procedures, work instructions, etc. No work documents have been completed or finalized.

2. **intermediate stage**: The generator/storage site is in the process of qualifying the NDA system and associated methodology (i.e., calibrating the system, completing the QAQs for accuracy/precision, etc., using site-approved procedures). At a minimum, portions of the early stage have been completed in order to have site-approved procedures available to begin the qualification process.

3. **late stage**: Both the early and intermediate stages have been completed and the generator/storage site is in the process of collecting data in preparation for the initial certification of the NDA system.

It should be noted that these categories are not meant to be finite or restrictive, rather are provided as a generalization for the purposes of this implementation guidance. It is also understood that a site may be between categories or may be in two or all three categories simultaneously.

The following discussion assumes a priori that the generator/storage site has taken due diligence to ensure that the NDA system and associated methodology are adequate, implemented, and effective. If not, they are at risk that neither the NDA system nor the data acquired by the NDA system will be certified by the CBFO.

**Option 1**: If a site is in the early stage of the NDA system initial certification, then the site is expected to implement the requirements of the CH-WAC (DOE/WIPP-02-3122, Revision 0) immediately. This approach mitigates the need to prepare, review, and approve two sets of documentation (including plans, procedures, etc.) unique to satisfying the requirements in the WAC (DOE/WIPP-069, Revision 7, Change Notice 2) and the CH-WAC. This approach also eliminates the requirement to train operators to the two sets of procedures. Since the NDA system is not certified and will, in conjunction with all support documentation, operational procedures, and generated data, be reviewed during a scheduled certification audit that will be conducted after the May 17, 2002 implementation date of the CH-WAC, no NCR or other such QA mechanism will be required. This process is similar to that used by the sites in preparation for certification prior to the approval of the QAPP by the EPA.

Additionally, it should be noted that a site further along the process of preparing for the initial certification of their NDA system may opt to re-start the preparation process using Option 1.

**Option 2**: If a site has started the intermediate stage in accordance with the WAC, the qualification of the NDA system and associated methodology (including its calibration and compliance with QAQs) may be completed in accordance with the WAC. However, all such actions must be
completed by the May 17, 2002 implementation date of the CH-WAC. Failure to do so will require the unfinished analysis/documentation to be completed in accordance with the CH-WAC.

In addition, when the CH-WAC becomes effective, the sites will need to generate a simple gap analysis (cross-walk is not required) comparing the requirements contained in the old and new plans/procedures to demonstrate the adequacy of the plans/procedures put in effect prior to the implementation date of May 17, 2002. This gap analysis (e.g., a narrative justifying the changes) will identify the components that are impacted by the changes, if any, and thoroughly address the impact of the changes on the qualification of the NDA system, if any. The NDA system and associated methodology do not need to be specifically re-qualified under the CH-WAC provided the NDA system was correctly qualified (i.e., able to pass the initial certification audit) and no substantive differences were identified in the gap analysis.

In all cases, the gap analysis must be formally transmitted to the CBFO at least 14 working days prior to the NDA system's initial certification audit. The CBFO will forward the gap analysis to the EPA approximately two weeks prior to the audit for their review.

Option 3: If a site has started collecting radioassay data in accordance with the WAC, then the guidance in Option 2 for the qualification of the NDA system and its associated methodology must be followed (i.e., the gap analysis). The actual data should be processed in accordance with the guidance provided for processing radioassay data (Options 1-5).

The generation and processing of radioassay data generated on or after May 17, 2002, must be in accordance with the CH-WAC. Any data generated in accordance with the WAC prior to the May 17, 2002 implementation date may be processed in accordance with the guidance provided for processing radioassay data. However, at least one batch data report generated per the requirements of the CH-WAC must be available for the NDA system's initial certification audit. The purpose of which is to provide a demonstrative test of the process used to generate the Batch Data Report utilizing the revised criteria within the CH-WAC. It should be noted that the CH-WAC does not have limits on the size of a batch data report.

Option 4: This final option pertains to the situation where there is a mixture of procedures/documents that implement the WAC and the CH-WAC prior to the implementation date of May 17, 2002. Because this option is a mixture of the other options, the guidance for those options should be followed as best possible. Where there is a disconnect or a barrier that would prohibit completion of the Batch Data Reports or collection of data, an NCR is used to hold the Batch Data Reports until the May 17, 2002 implementation date is reached, at which point the reports can be released.

For example, a new NDA system may have been qualified in accordance with the requirements of the WAC, may have specific operating procedures that implement the CH-WAC, and then may have data validation procedures that are used for all NDA systems that still implement the WAC. In this example, the guidance in Option 2 should be followed for the qualification of the NDA system. The data generated in accordance with the CH-WAC is acceptable. However, the data generated per the CH-WAC cannot be validated in accordance with data validation procedures (i.e., batch data reports) that implement the requirements in the WAC. If a site cannot hold the data and validate it after the May 17, 2002 implementation date, then the validation process may be initiated and an NCR written on the Batch Data Report which can be released after May 17, 2002 due to the implementation of the CH-WAC.

It is recommended that sites contact the CBFO for further guidance on this option, due to its potential complexity.
Currently the CBFO is aware of only two generator sites that may be planning to utilize these options. They are:

- RFETS - Multi-Purpose Crate Counter (MPCC)
- Hanford - Gamma Energy Assay System Unit B (GEA B)

In order to process the radicassay data on the non-certified NDA systems, the generator/shipping site must have that NDA system audited by November 22, 2002 (within approximately 6 months of the CH-WAC implementation date of May 17, 2002). All non-certified NDA systems audited after November 22, 2002 will have to meet all of the requirements of the CH-WAC.

**CH-WAC Text and Clarification:** The following pages of documentation provide clarification to various sections of text within the CH-WAC based on questions and comments received from sites, discussion held with regulators, and information provided by various CBFO support organizations. If additional guidance or clarification is required beyond that in this guidance, the CBFO will address the applicable issue on a case-by-case basis and provide the information.

**Subsection 3.1 Summary of WIPP Authorization Basis**

1. **Text of interest (3rd paragraph):** "The WWIS is an electronic database equipped with edit/limit checks to ensure that the data representing the waste payload containers are in compliance with the CH-WAC."

   **Clarification:** The WWIS incorporates the Automated TRUPACT-II Authorized Methods for Payload Control (e-TRAMPAC) software, which is used to evaluate containers and assemblies of CH-TRU waste for compliance with each of the TRAMPAC requirements, including those summarized in this CH-WAC. The use of the WWIS e-TRAMPAC modules is required for TRAMPAC compliance determinations.

**Subsection 3.3.1 Radionuclide Composition**

2. **Text of interest (2nd paragraph):** "In addition, all radionuclides other than the ten WIPP-tracked radionuclides (i.e., 235U, 236Pu, 237Np, 238Pu, 241Pu, 242Pu, 233U, 234U, 238U, 90Sr, and 137Cs) that contribute to 95% of the radioactive hazard for the payload container shall be reported on the TRUPACT-II bill of lading or manifest in accordance with 49 CFR §172.203 and 49 CFR §173.433. The activities and masses of these other radioisotopes shall also be reported to the WWIS along with their associated TMU, expressed in terms of one standard deviation for each waste container."

   **Clarification:** All isotopes comprising 95% of the radioactive hazard, whether they are one of the ten WIPP-tracked radionuclides or not, are reported in the WWIS. Trace amounts of nuclides need not be reported as long as 95% of the radioactive hazard is accounted for. Isotopes that are included in the list of the ten WIPP-tracked isotopes must be reported to WWIS as indicated in the 1st paragraph in Section 3.3 of the CH-WAC to establish the fact that a site has met the requirements for the 10 WIPP-tracked isotopes. Isotopes not on the WIPP-tracked list that do and not needed to be identified to meet the 95% radioactive hazard reporting criterion do not need to be recorded in the batch report, WWIS, or the shipping papers. There are two exceptions to this general guidance:

   1. When an isotope, such as 235U (which is not on of the 10 WIPP-tracked radionuclides and may not contribute to 95% of the radiological hazard), is used to establish the isotopic ratio of another isotope(s) that is one of the WIPP tracked radionuclides, such as 233U and/or 238U, then, at a minimum, the activity/mass of that radionuclide (i.e., 238U in this example) must be reported in the Batch Data Report.

   2. For isotopes, such as 237Np, that contribute to the FGE mass (determination made by the site as to when such isotopes are deemed to contribute), but are not required to be tracked as one of the 10 WIPP-tracked radionuclides or do not contribute to 95% of the radiological
hazard, then, at a minimum, the activity/mass of that radionuclide (i.e., $^{237}$Np in this example) must be reported in the Batch Data Report.

Site are permitted to report as much detail beyond the minimum required data with regard to the isotopic composition of the radionuclides to the WWIS as they desire.

Subsection 3.3.3 TRU Alpha Activity Concentration

3. **Text of interest:** "The TRU alpha activity concentration shall be reported to the WWIS; however, there are no reporting requirements for its associated TMU."

**Clarification:** This statement is not in conflict with Section A.5.2 of Appendix A which states that the TRU alpha activity concentration and its associated TMU shall be documented for each container and reported in either the radioassay batch data report or other QA record or database. Whereas Subsection 3.3.3 applies to WWIS reporting requirements, Section A.5.2 pertains specifically to internal site reporting requirements. TMU data is retained by the site as a lifetime QA record (see Section 1.5.2.4 of the QAPD).

Subsection 3.3.4 $^{239}$Pu Equivalent Activity

4. **Text of interest:** PE-Ci quantities shall be calculated for each payload container (see Appendix B) and reported to WIPP using the WWIS.

**Clarification:** The unit used for reporting $^{239}$Pu equivalent activity to the WWIS is PE-Ci (plutonium equivalent curies).

Subsection 3.3.6 Decay Heat

5. **Text of interest:** All

**Clarification:** The total decay heat from all containers in a TRUPACT-II shall be less than 40 W as specified in Appendix 6.2 of the TRUPACT-II Authorized Methods for Payload Control (Revision 19).

6. **Text of interest:** "The sum of the decay heat for each payload container plus its TMU shall be less than or equal to the limits of the assigned shipping category specified in table 5.5-1 of appendix 5.5 of the TRAMPAC.

**Clarification:** As defined in Table 5-2 of Section 5.0 of the TRAMPAC, payload containers of Waste Material Type II.1 and Waste Type III that meet the criteria for the application of dose-dependent G values (watt*year >0.012) shall be assigned a shipping category that uses a dose-dependent G value. This assignment revises the four-digit G value notation used in the numeric shipping category otherwise assigned to the payload container. The evaluation of payload containers and programmed reassignment of shipping category will be completed by WWIS (i.e., use of the dose-dependent G value for qualifying container is not optional). Sites may reassign shipping categories, as applicable, prior to entering data into the WWIS.

Subsection 3.5.5 Headspace Gas Concentrations

7. **Text of interest:** "Test category payload containers shall be tested to quantify the hydrogen/methane, VOC, and total gas generation rates (as appropriate) for purposes of determining if all applicable limits are met."

**Clarification:** As described in Section 5.0 of the TRAMPAC, qualification of payload containers under the test category is by one of two options: (1) measurement of the headspace gas or (2) full-drum testing to quantify the gas generation rate of the payload container.
Subsection A.1  Introduction

8. **Text of interest**: Existing radioassay data collected prior to the implementation of a quality assurance program pursuant to 40 CFR §194.22(a)(1) may be qualified in accordance with an alternate methodology that is approved by CBFO and employs one or more of the following methods:

   a. peer review in accordance with NUREG-1297 (reference A1)
   b. corroborating data
   c. confirmatory testing (i.e., testing made on a representative sub-population of payload containers within a waste stream), or
   d. demonstrating the equivalent of an alternate QA program (as described in reference A2, section 5.4).

   **Clarification**: The listed methods are pursuant to 40 CFR §194.22(b) and require CBFO and EPA approval prior to implementation.

Subsection A.2.1  Methods for Confirmation of Isotopic Ratio AK

9. **Text of interest** (4th paragraph): If *valid* (emphasis added) AK does not exist, then the data generated on a WIPP-certified system can only be used to detect or calculate $^{238}$U, $^{235}$U, and $^{233}$U or to confirm their absence.

   **Clarification**: The term "valid" in the context of this paragraph means sufficient and defensible. It is understood by the CBFO that these terms are still imprecise and are up to interpretation from any auditors. The CBFO is evaluating this concern and trying to determine how to provide more precise guidance to the sites.

Subsection A.2.2.3  Discrepancy Resolution

10. **Text of interest** (1st sentence): If there is a discrepancy between AK information related to isotopic ratios or composition, the site will evaluate the sources of the discrepancy to determine if the discrepant information is credible.

   **Clarification**: If there is a discrepancy within the AK information that is related to either isotopic ratios or isotopic composition, the site will evaluate the sources of the discrepancy to determine if the discrepant information is credible. In effect, the sites should continue to process discrepancies as they are presently doing.

Subsection A.3  Data Quality Objectives

11. **Text of interest** (Table A-3): The confidence for meeting the TRU α-activity concentration DQO is listed in the third column as N/A.

   **Clarification**: When looking at 2-sided confidence intervals, the 1 sigma and 2 sigma confidence intervals of a normally distributed measurement are ~68% and ~95%, respectfully. When looking at 1-sided confidence intervals, the 1 sigma and 2 sigma confidence intervals of a normally distributed measurement are ~84% and ~97.5%, respectfully. Because the DQO only cares *specifies* that the measurement plus error (not plus or minus the error) is below the limit, a 1-sided distribution is specified in Table A-3.

12. **Text of interest** (1st paragraph under Lower Limit of Detection): The lower limit of detection (LLD) for each radioassay system must be determined. Instruments performing TRU/low-level waste discrimination measurements must have an LLD of 100 nCi/g or less.

   **Clarification**: The requirement for a total LLD of 100 nCi/g or less only applies to the determination of TRU alpha activity. The requirement for individual isotopes is simply to determine the LLD value.
based on the definition provided and use it accordingly. For purposes of WIPP related reports, only measured activities greater than the LLD are considered to be "detected" and reported as directly measured.

13. Text of interest (1st paragraph under Calibration Procedures and Frequencies): During calibration or re-calibration, system correction factors shall be established and algorithms adjusted such that the value of %R is set equal to 100%; i.e., the system is calibrated to 100%R.

Clarification: The objective of calibrating an NDA instrument is to obtain 100%R; i.e., to correctly determine with absolute accuracy the activity/mass of the radioactive material in the drum. However, it is understood that this is rarely possible, but rather is considered a goal. Typically, when calibrating NDA instruments, a calibration curve is fitted to a number of data points obtained with calibration sources. This curve will not usually pass through all the points, but will be as close as feasible for the particular curve shape used. While the calibration obtained will not allow 100%R for all regions of the curve, it will generally be within a few percent (though it could be larger, if the calibration is defined to include the determination of various matrix correction factors). This degree of accuracy is generally quite acceptable for NDA measurements of waste. Any deviation of the calibration curve from 100%R will be reflected in the assigned calibration uncertainty, which is incorporated in the TMU of the system.

14. Text of interest (2nd paragraph under Calibration Procedures and Frequencies): Calibrations(s) shall be performed in accordance with consensus standards, when such standards exist.

Clarification: The requirement to use consensus standards (e.g., ANSI or ASTM standards documents) for calibration applies only to those radioassay systems for which consensus standards exist and that are not already WIPP certified (as of May 16, 2002). However, a site's calibration procedures must be revised to reflect this requirement. Radioassay systems previously certified by WIPP are not required to be recalibrated specifically to be re-calibrated in accordance with consensus standard. However, if during the course of operations it is determined that re-calibration is required, the radioassay system will then be subject to this new requirement.

15. Text of interest (2nd paragraph under Calibration Procedures and Frequencies): Primary calibration standards shall be obtained from suppliers maintaining a nationally accredited measurement program.

Clarification: A primary calibration standard (i.e., a source) is one designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity. It should be noted that the QAPD currently requires NIST-traceable calibration standards; however, the requirement to be NIST-traceable is in the process of being changed due to a lack of a regulatory driver to reflect the regulatory requirement that primary calibration standards shall be traceable to nationally recognized standards (see ASME NQA-1-1989, Supplement 12S-1). Thus, NIST-traceability still remains an option but is no longer the sole option for obtaining primary calibration standards.

If a site has generated their own NIST-traceable calibration standard and it has been confirmed to have the necessary pedigree in accordance with the site's and CBFO's QA programs, then that standard is considered acceptable.

16. Text of interest (1st paragraph under Calibration Confirmation): The replicate measurements shall be performed using nationally recognized standards, or certified standards derived from nationally recognized standards that span the range of use.

Clarification: The wording "that span the range of use" may be interpreted as follows: A minimum of two source strengths is required—one from the lower one third of the range and one from the top third of the range or beyond, so long as the site technically justifies that the number of sources and the source strengths used are acceptable to qualify the NDA system. An example would be an
instrument that had an operating range from 0.3g to 200g WG Pu. Then one source with a mass between 0.3 and 70 g and one greater than 134 would be required for the matrix checks. Obviously, a source very close to the LLD of the instrument would be expected to have a large %RSD, and might not be satisfactory for this test. Likewise, a source that greatly exceeded the upper limit of the range might not provide satisfactory results for accuracy. Additional sources could be used at the discretion of the NDA facility. For NDA systems that have operational ranges in excess of 200g Pu, such as for a SWB counter (325 g Pu operational limit), it is not required to have a source strength in excess of 200g, so long as the site technically justifies that the source strength used is acceptable to qualify the NDA system at the higher mass loadings. It should be noted that this description of source strengths sufficient for "calibration confirmation" does not apply to the number or sizes of sources needed for calibration or recalibration of instruments; those requirements are addressed in the appropriate consensus standards.

17. Text of interest (1st paragraph under Calibration Confirmation): Calibration confirmation replicate measurements shall be performed on containers of the same nominal size as those in which actual waste is assayed and according to approved waste assay procedures.

Clarification: While this requirement allows some flexibility in the actual size and shape of the waste container being measured, it does not allow replicate measurements made on 55-gallon drums to be used for calibration confirmation of, for example 30-gallon, 85-gallon or 100-gallon drums. The intent was to allow any nominal 55-gallon drum to be represented by a single 55-gallon drum without having to confirm container outer diameters and heights or container volume.

18. Text of interest (1st paragraph under Calibration Confirmation): Accuracy is reported as percent recovery (%R).

Clarification: Refer to the Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program (DOE/CBFO-01-1005) for the equation to calculate %R.

19. Text of interest (1st paragraph under Calibration Confirmation): Precision is reported as percent relative standard deviation (%RSD).

Clarification: Refer to the Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program (DOE/CBFO-01-1005) for the equation to calculate %RSD. It should be noted that the equation for calculating %RSD in the PDP plan is different from the equation for calculating %RSD in Revision 7 of the WAC.

20. Text of interest (1st paragraph under Calibration Confirmation): The applicable range for accuracy shall not exceed ±30% on a non-interfering matrix.

Clarification: The phrase "shall not exceed ±30%" means the measured value shall not exceed ±30% of the true value (70%R ≤ Source Activity ≤ 130%R) for a non-interfering matrix.

21. Text of interest (Table A-3.2 under Calibration Confirmation): The footnote.

Clarification: The footnote pertains to the numerical values listed in the row labeled "Max %RSD."

Subsection A.4.2 NDA QC Requirements

22. Text of interest (1st paragraph under Instrument Performance Measurements): Performance checks shall include efficiency checks (when applicable), matrix correction checks and, for spectrometric instruments, peak position and resolution checks.

Clarification: Instrument performance measurements involving matrix correction checks The term "matrix correction checks" as used in this sentence necessitates the use of surrogate waste matrix
containers including appropriate radioactive standards. Since some sites have indicated that surrogate matrix containers and/or standards may not be available in a time frame to meet the implementation deadline of May 17, 2002, the CBFO has approved the site's use of PDP surrogate waste matrices and standards for meeting this requirement. Any damage incurred by either the PDP surrogate waste matrix containers or radioactive standards during the performance of these measurements must be repaired at the site's expense and within a time frame not impactive to future PDP cycles.

23. Text of interest (1st paragraph under Instrument Performance Measurements): Performance checks shall include efficiency checks (when applicable), matrix correction checks and, for spectrometric instruments, peak position and resolution checks.

Clarification: This sentence The generic term "performance checks" as used in this sentence is generic and applies to both the daily performance checks (efficiency, peak position, and resolution) and weekly performance checks (matrix correction). Matrix correction checks are specific to weekly performance measurements.

24. Text of interest (2nd paragraph under Instrument Performance Measurements): To verify calibration, radioactivity standards must be selected such that, over a six month period, the operating range of the assay system is tested in each applicable surrogate waste matrix.

Clarification: The phrase "to verify calibration" does not refer to the subsection titled "Calibration Verification" contained in Section A.3. Rather, the phrase "to verify calibration" means, "to verify instrument performance."

25. Text of interest (2nd paragraph under Instrument Performance Measurements): To verify calibration, radioactivity standards must be selected such that, over a six month period, the operating range of the assay system (emphasis added) is tested in each applicable surrogate waste matrix.

Clarification: The phrase "the operating range of the assay system" refers to the operating range for which the assay system was WIPP-certified. If over a six month period, however, the actual waste assayed spans a reduced portion of the full operating range of the assay system, then only the reduced portion of the full operating range of the assay system needs to be tested during the six month time period for each applicable surrogate waste matrix.

26. Text of interest (2nd paragraph under Instrument Performance Measurements): To verify calibration, radioactivity standards must be selected such that, over a six month period, the operating range of the assay system is tested in each applicable surrogate waste matrix.

Clarification: The word "applicable" refers only to those surrogate waste matrices that correspond to the actual waste matrices assayed by the system over the six month time period – not the full range of matrices for which the assay system was WIPP-certified.

27. Text of interest (1st paragraph under Data Checks): Background (for calorimetry: baseline or base power) and performance measurements shall be reviewed and evaluated at least weekly to determine continued acceptability of the assay system and to monitor performance trends. If daily performance checks result in data that are outside the acceptable range, the required responses in Table A-4.2 shall be followed.

Clarification: Only daily performance measurements are required to be checked using the criteria in Table A-4.2. The CH-WAC does not require either background measurements or weekly performance measurements to be tested using the criteria in Table A-4.2; however, NDA facilities must specify in site procedures the process or alternate criteria they use to determine if the weekly measurements are acceptable. These usually are based on some multiple of the expected fluctuations in the measured quantity; i.e., fluctuations in the daily background or weekly matrix check measurements, but this is not a WIPP requirement. It is understood that it may take sometime to
develop a baseline, or for some of the matrices that may only be tested once per 6-month period, that
the process or criteria may default to expert review of the data. With regard to background
measurements, the CBFOs expectation is that the sites evaluate the daily background measurements
at least on a weekly basis to determine continued acceptability of the radioassay system. It should be
noted that the 2nd paragraph of Section A.4.2 of the CH-WAC requires daily background
measurements. If a site evaluates these measurements daily, then by default they meet the
requirement to evaluate the background measurements at least weekly. Furthermore, the
background measurements are not required to be monitored for performance trends because that
would indicate that the background measurements were being varied to determine impact on the
NDA system measurements on a daily basis - this is not something the CBFO is advocating or
requiring. It is not the intent of the CH-WAC to have statistical control limits applied to background
measurements. However, CBFO does expect that the sites understand the impact of the background
radiation on the radioassay system and that when background levels are to the point that
"continued acceptability of the radioassay system" is suspect or is known to be degraded, that
corrective measures are put in place or radioassay measurements are suspended until the
background radiation levels drop to an acceptable level.

28. Text of interest (Table A-4.2 under Data Checks): In the case where the data falls within the warning
range, the required response is as follows: The performance check standard shall be rerun no more
than two times. If the rerun performance check(s) result in data within ±2σ, then the additional
performance checks shall be documented and work may continue. If the system does not fall within
±2σ after two rerun performance checks, then the required response for the Action Range shall be
followed.

Clarification: In Table A-4.2, it is intended that the action taken for the "Warning Range" is as follows:
If the first performance check rerun is less than 2σ, then proceed with waste assay measurements;
there is no requirement to perform another performance measurement. If the first performance check
is greater than 3σ, then go to the response required for the "Action Range." If the first performance
check is between 2σ and 3σ, then make one more performance measurement. If that measurement is
less than 2σ, then proceed with waste assay measurements; otherwise go to the response for the
"Action Range."

29. Text of interest (Table A-4.2 under Data Checks): In the second column of Table A-4.2, the absolute
value of the data (| Data |) is used in defining the acceptability range.

Clarification: In the context of Table A-4.2, data is defined as follows: Data = μ(mean) –
μ(measured), where μ(mean) is the expected value for the performance measurement (usually the
mean value of a number of previous measurements from which the value of σ is obtained), and
μ(measured) is the value of the performance measurement being "checked."

Subsection A.5.2 Data Reporting

30. Text of interest (3rd bullet of 2nd paragraph): Background and performance data or control charts for
the relevant time period.

Clarification: The instruction to include background and performance data or control charts for the
relevant time period also pertains to the weekly matrix check, as follows: The guidance here is to
include in each testing batch data package the matrix check result from the most recently acquired
measurement obtained before or during the dates the waste assay data is acquired. In addition, the
allowable limits for that data, as specified in facility documents, must be reported with the actual
result. For example, if the weekly matrix measurement is always obtained on a Monday, then each
data package obtained on that Monday or later in the week would have that Monday matrix check
result and acceptable limits. If a testing batch is collected for a period longer than a week, it should
include any additional matrix checks obtained during that period, with acceptable limits specified. (It is
noted that because the matrix-check cycle length could be as long as six months, the matrix check
result included in a particular testing batch data report may not be for the same type of matrices as
the waste containers in that particular package.)

31. Text of interest (5th bullet of 2nd paragraph): Activities and/or masses of individual radioisotopes
present and their associated TMUs (curies and/or grams).

Clarification: It is recognized that the methods used by NDA facilities to report results to the site
project office may vary somewhat at different sites. The guidance here is for sites to decide the
details of how facilities report the NDA measurement results to the project office, within the following
guidelines. The NDA facility may report either activity or masses or both to the project office.
However, the project office must report both mass and activity in the WWIS, as specified in the
section 3.3.1 of the WAC and in the guidance provided above for that section. That section also
specifies, under certain circumstances, that the results entered into the WWIS must be reported as
<LLD or zero for some isotopes. If this determination is made at the NDA facility, the results reported
in the testing batch data package can be stated as <LLD or zero for particular isotopes, as
appropriate, instead of a numerical value (presumably less than the instruments LLD) and TMU.
Thus, the data related to individual isotopes reported in the testing batch data package, may be
stated in terms of activity, mass, <LLD, or zero, or combinations thereof, as specified in site
procedures.

Similarly, the information listed under the heading “Other radiological properties...” can be calculated
by the NDA facility and included in the testing batch data package, or it can be calculated and
recorded elsewhere prior to entry in the WWIS, using the activities/mass data provided in the batch
data report.

Appendix D Payload Container Integrity Checklist

32. Text of interest (Item #9): Examine the payload container regions near vents, top lid fittings, bottom
fittings, welds, seams and intersections of one or more metal sheets or plates.

Clarification: The term “vents” refers to “filter vents.”

33. Text of interest (Item #7): Is the payload container properly closed?

Clarification: Item #7 is incorrectly stated. It should be stated as follows: Is the payload container
improperly closed?